

HealthTech Programme

Artificial intelligence (AI)-assisted echocardiography analysis and reporting to support the diagnosis and monitoring of heart failure: Early Value Assessment

The following documents are made available to stakeholders:

1. External assessment report (EAR) updated in response to stakeholder comments.
2. External assessment report overview (ARO)
3. Patient group and professional group submissions
 - 3a. Cardiomyopathy UK
 - 3b. British Society for Echocardiography
4. Addendum to External Assessment Report (EAR)
5. Stakeholder comments on the EAR and responses prepared by Centre for Healthcare Evaluation, Device Assessment and Research (CEDAR) the External Assessment Group (EAG)

HTE10067 Artificial intelligence assisted echocardiography to support the diagnosis and monitoring of heart failure

External assessment report

Produced by: CEDAR

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Number of attached appendices: 6

Purpose of the early value assessment report

The purpose of this external assessment report (EAR) by an external assessment group (EAG) for early value assessment is to review the evidence currently available for technologies within the decision problem and advise what further evidence should be collected to help inform future decisions on whether the technologies should be widely adopted in the NHS. NICE has commissioned this work and provided the template for the report. The report forms part of the papers considered by the Committee when it is making decisions about the early value assessment.

Declared interests of the authors

Description of any declared interests with related companies, and the matter under consideration. See [NICE's Policy on managing interests for board members and employees](#).

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Responsibility for report

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Confidential information

Summary table of all confidential information and its source in report.

| Brief description | AIC/CIC | Page numbers | Source |
|----------------------------------|---------|---------------|-------------|
| Technology version | CIC | 16, 17 | Company RFE |
| Ongoing studies for technologies | AIC | 109, 112, 113 | Company RFE |

Changes made post-stakeholder comments

The table below summarises all changes made to the EAR following receipt of stakeholder comments.

| Brief description of change | Section | Page numbers |
|---|--------------------------|-----------------|
| Amendment of confidentiality status of EchoConfidence trial results. | Throughout EAR. | Throughout EAR. |
| Changes to description of external validation data available for EchoConfidence. | Executive summary, 5.3.2 | 13, 67 |
| Changes to description of Us2.ai technology. | 2 | 15 |
| Amendment of DTAC status for EchoConfidence. Amendment of descriptions of intended use for Us2.ai and Lgence Heart. | 2 (Table 1) | 17, 18 |
| Amendment of description of point-of-care TTE. | 3.2 | 21 |
| Clarification on AI-aided image acquisition being out of scope and amendments to appointment duration in Figure 1. | 3.2 | 22 |
| Changing reference 'Huang et al. 2024' to 'Huang et al. 2024a' to differentiate from publication referenced in EAR addendum (Huang et al. 2024b). | Throughout EAR. | Throughout EAR. |
| Reordering of evidence sections for technologies to ease interpretation. | 5.2.2 | 54-56 |
| Addition of reference to ongoing trials relevant to community settings. | 5.2.9, 8.1 | 66, 110 |
| Changes to colour coding assigned to Us2.ai | 8.2 | 115 |

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Abbreviations

| Term | Definition |
|------------|---|
| ACEi | Angiotensin Converting Enzyme Inhibitors |
| ACHD | Adult Congenital Heart Disease |
| AED | Accident and Emergency Department |
| AF | Atrial Fibrillation |
| AI | Artificial Intelligence |
| AIC | Academic In Confidence |
| AMI | Acute Myocardial Infraction |
| ARBs | Angiotensin Receptor Blockers |
| ARNIs | Angiotensin Receptor-neprilysin Inhibitors |
| ATTRact | Asian Network for Translational Research and Cardiovascular Trials |
| AUROC/AUC | Area Under (Receiver Operating Characteristic) Curve |
| BB | Beta blockers |
| CEDAR | Centre for Healthcare Evaluation Device Assessment and Research |
| CE | Clinical Expert |
| CI | Confidence Interval |
| CKD | Chronic Kidney Disease |
| CMRI | Cardiac Magnetic Resonance Imaging |
| COPD | Chronic Obstructive Pulmonary Disease |
| CoV | Coefficient of Variability |
| CPRD | Clinical Practice Research Datalink |
| DHSC | Department of Health and Social Care |
| DTAC | Digital Technology Assessment Criteria |
| EAG | External Assessment Group |
| EAR | External Assessment Report |
| ECG | Electrocardiogram |
| ED | Emergency Department |
| E/e' Ratio | Early Diagnostic Mitral Inflow Velocity to early diastolic mitral annulus velocity ratio. |
| EF | Ejection Fraction |
| EIA | Equalities Impact Assessment |
| E'lateral | Early Diastolic Velocity of the Mitral Annulus |
| EQ-5D | EuroQol 5 dimension 5 level questionnaire |
| EU MDR | European Union Medical Device Regulation |
| EVA | Early Value Assessment |

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|-----------|--|
| FDA | Food and Drug Administration |
| GDMT | Guideline-direct Medical Therapy |
| GLS | Global Longitudinal Strain |
| GP | General Practitioner |
| GPwSI | General Practitioner with Special Interest |
| HCP | Healthcare Professional |
| HER2 | Human Epidermal Growth Factor Receptor 2 |
| HF | Heart Failure |
| HFA-PEFF | Heart Failure Association Pre-test assessment, Echocardiography and Natriuretic Peptide, Functional Testing Final Etiology |
| HFmrEF | Heart Failure with Mildly Reduced Ejection Fraction |
| HFpEF | Heart Failure with Preserved Ejection Fraction |
| HFrEF | Heart Failure with Reduced Ejection Fraction |
| HES | Hospital Episode Statistics |
| HMC-QU-MI | Hamad Medical Corporation Heart Hospital and Qatar University and Tampere University Myocardial Infraction dataset. |
| HR | Hazard ratio |
| ICC | Intraclass Correlation Coefficient |
| IEC | Individual Equivalence Coefficient |
| ICER | Incremental Cost-effectiveness Ratio |
| IQR | Interquartile range |
| IT | Information Technology |
| KCCQ-12 | Kansas City Cardiomyopathy Questionnaire |
| LoA | Limits of Agreement |
| LOS | Length Of Stay |
| LV | Left Ventricle |
| LVEDV | Left Ventricular End Diastolic Volume |
| LVEF | Left Ventricular Ejection Fraction |
| LVESV | Left Ventricular End Systolic Volume |
| MAD | Mean Absolute Deviation |
| MAUDE | Manufacturer and User Facility Device Experience |
| MDC | Minimal Detectable Change |
| MHRA | Medicines & Healthcare products Regulatory Agency |
| MI | Myocardial Infraction |
| MRAs | Mineralocorticoid Receptor Antagonists |

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| | |
|--------------|--|
| NHFA | National Heart Failure Audit |
| NICE | National Institute for Health and Care Excellence |
| NICOR | National Institute for Cardiovascular Outcomes Research |
| NPV | Negative Product Value |
| NR | Not Reported |
| NT-proBNP | N-Terminal Pro-B-Type Natriuretic Peptide |
| ONS | Office for National Statistics |
| POC | Point of Care |
| PPV | Positive Predictive Value |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analyses |
| PROMIS-HFpEF | Prevalence of Microvascular Dysfunction-HF and preserved ejection fraction (study) |
| PSSRU | Personal Social Services Research Unit |
| QALY | Quality-adjusted Life Year |
| QUORUM | Quality of Reporting of Meta-analyses |
| RCT | Randomised Controlled Trial |
| RFE | Request for Evidence |
| RMSE | Root Means Square Error |
| ROC | Receiver Operating Characteristic |
| RRT | Renal Replacement Therapy |
| SCM | Specialist Committee Member |
| SD | Standard Deviation |
| SGLT2i | Sodium-glucose Transport 2 Inhibitors |
| SMR | Standardised Mortality Rate |
| TTE | Transthoracic Echocardiography |
| VAS | Visual Analogue Scale |
| VAT | Value Added Tax |
| WTP | Willingness to Pay |

Executive summary

Background

The topic of this Early Value Assessment (EVA) is artificial intelligence (AI) assisted echocardiography to support the diagnosis and monitoring of heart failure. There are 4 technologies in the scope of this EVA: EchoGo Heart Failure (Ultromics Ltd), Us2.ai (EKO Pte Ltd), Ligence Heart (Ligence, UAB) and EchoConfidence (MyCardium AI Ltd).

The decision problem is described in detail in the published [scope](#) and the EAG approach to the assessment is described in the published [protocol](#).

Clinical evidence

There were 17 studies identified as the clinical evidence base: 3 for EchoGo Heart Failure, 9 for Us2.ai, 2 for Ligence Heart and 3 for EchoConfidence. For EchoGo Heart Failure, all studies were retrospective case-control studies. For Us2.ai, there were 9 studies. Four of these were prospective comparative studies, 2 were retrospective comparative studies (Tromp et al. 2022a, Myhre et al. 2024a), 2 were retrospective validation studies and one study was a randomised controlled crossover trial. For Ligence Heart, there were 2 comparative studies, one of which was a prospective, the other was retrospective. For EchoConfidence, there were 3 comparative studies, one of which was prospective. Two of these studies were interim analyses of ongoing studies. Human operators, or manual measurements, were the comparator in all comparative and validation studies.

The EAG considers there to be some evidence of moderate quality to support the use of EchoGo Heart Failure. There was evidence that the AI technology had good performance in aiding detection of HFpEF, in comparison to two validated multiparametric manual clinical scoring tools. Us2.ai had the largest volume of evidence, relative to other technologies in scope, and was the only technology to have an associated RCT (reported in a non-peer reviewed pre-print) which demonstrated some time savings in TTE procedures following the implementation of AI-assistance. However, this evidence was of limited

generalisability to the NHS. One study based in the NHS demonstrated the potential utility of Us2.ai in automating measurements alongside handheld TTE acquisition. Evidence of Us2.ai's diagnostic accuracy in comparison to humans was largely observed to be good, as was the technology's performance in discrimination of cases of HF from controls without HF. However, the outcome measures and comparisons reported across the evidence base were heterogeneous, which makes it difficult to synthesize consistent overall findings. Evidence for Ligence Heart was limited and of moderate quality. Outcome measures reported for Ligence Heart were limited to correlation and agreement with human measurements, with some evidence on high yield of measurements from TTE images. Correlation was observed to be strong with human comparators, but agreement was variable. Evidence for EchoConfidence was very limited and of uncertain quality. No published evidence was identified for this technology and all data included in the clinical evidence review was provided by the company. However, this evidence was from NHS settings and provided some limited evidence of potential system benefits through decreasing TTE analysis time. Diagnostic test accuracy results were mixed, with good specificity for both HFrEF and HFpEF, with a moderate false negative rate for HFrEF. Correlation with human measurements was observed to moderate.

Overall, the clinical evidence is mixed. There is potential for these AI technologies to successfully assist with automation of measurements and report creation following TTE acquisition, and diagnostic test accuracy outcomes are generally reported to be good in comparison to measurements and reports made by humans. However, there is some evidence to suggest that agreement and correlation is low between AI and human measurements for some parameters. There was considerable variation across the evidence base with respect to the measurements which were compared and the comparator (e.g. different HCPs in different settings and clinical pathways). Few of the included studies were conducted in a UK/NHS setting, reducing the generalisability of the results. Clinical evidence is discussed in detail in Section [5.2](#), with quality assessment reported in Section [5.1](#).

The EAG noted there was not enough evidence to determine whether the EchoGo Heart Failure, Us2.ai and Ligence Heart technologies had been adequately validated in UK populations (or populations similar to that of the UK), to ensure their suitability for use in the target population. This may pose clinical risk, which is discussed in Section [5.3.2](#). There is evidence that EchoConfidence has been externally validated in a UK population.

There are significant evidence gaps which are outlined in Section [8.2](#). In summary, these are: impact on procedure time, impact on clinical outcomes (e.g. time to diagnosis and initiation of treatment), validity in UK cohorts and adverse events.

Economic evidence

The EAG did not identify any relevant economic studies related to the technologies in this assessment. An exploratory economic analysis was performed using an early Markov model over a one-year time horizon, to capture the impact of echocardiography waiting time with AI technology compared to standard care. However, the model is limited by the lack of data on current waiting time and uncertainty on evidence related to time saved with AI in terms of settings, time parameters measured, and person performing echocardiography in these studies. Therefore, the analysis undertaken should be considered as exploratory, and results should be interpreted with caution. As there is no evidence on time to diagnosis with AI-assistance, the EAG estimated the impact on waiting time using evidence on time saved and a number of assumptions. The analysis included two AI technologies: EchoConfidence and Us2.ai, using the available clinical evidence on the procedure time reduction. The model finds that EchoConfidence is potentially less costly and more effective and the proportion of patients meeting the target referral time of 6 weeks may increase by 15%. This is due to the estimated reduction in waiting time of 17%, driven by shorter echocardiography time, and thus resulting in small staff time savings. However, the EAG considers the evidence on time saved is not robust and is low quality due to a lack of detail on the raw data feeding into mean values, and the way in which any time savings from AI-assisted analysis would impact

TTE workflow on a practical level. While it appears EchoConfidence may be a cost-saving strategy, the uncertainty around the model and evidence outweighs the modest cost-saving. For Us2.ai, the results indicate that it may be dominated by standard care, as it is estimated that the modest reduction in echocardiography time would not lead to any change in waiting time. Results are sensitive to the impact of waiting time reduction and the proportion of patients diagnosed in a one stop diagnostic clinic. Currently there are considerable areas of uncertainty including current waiting time, the proportion of patients attending a one stop diagnostic clinic, clinical evidence on time saved, and evidence on waiting time change. These uncertainties mean that the validity of the economic findings is limited.

Evidence gaps are identified and outlined in Section [8.2](#). In summary, these are: long-term impact on time to diagnosis, impact of downstream diagnostic costs. In addition, there are evidence gaps related to baseline model inputs including waiting time and utilities of HF.

Key points for decision makers

- There are significant gaps in the evidence base which mean the benefits of introducing AI-assisted echocardiography into the heart failure diagnosis and monitoring pathway are currently unclear.
- There is potential for AI-assisted echocardiography to facilitate faster echocardiography analysis and reporting, but data on this are limited.
- Evidence should be generated on impact on procedure time and the subsequent impact on health-related outcomes, such as time to diagnosis and time to initiation of treatment.
- The AI technologies should be externally validated in cohorts representative of UK populations, to evidence their suitability for use in the NHS.
- Shifting echocardiography out of secondary care to primary or community care settings to improve patient access may be aided by AI technologies, but there is a paucity of evidence to support this.

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1. Decision problem

The topic of this Early Value Assessment (EVA) is artificial intelligence (AI) assisted echocardiography to support the diagnosis and monitoring of heart failure. The decision problem is described in detail in the published [scope](#).

The EAG made no further changes or comments on the scope.

2. Technologies

There are 4 technologies in the scope of this EVA: EchoGo Heart Failure (Ultromics Ltd), Us2.ai (EKO Pte Ltd), Ligence Heart (Ligence, UAB) and EchoConfidence (MyCardium AI Ltd).

EchoGo Heart Failure (Ultromics Ltd) is an automated machine learning-based decision support system intended to aid clinicians in detecting heart failure with preserved ejection fraction (HFpEF). This technology automates echocardiographic measurements including left ventricular volumes, ejection fraction and global longitudinal strain. **Us2.ai (EKO Pte Ltd)** is an AI software that can be used to automate measurements, analysis and reporting of transthoracic echocardiography (TTE) images, to support decision making of healthcare professionals for various cardiac conditions, including heart failure.

Ligence Heart (Ligence, UAB) is an AI software used to automate echocardiographic measurements and the generation of echocardiographic reports, to be reviewed and approved by human operators. **EchoConfidence (MyCardium AI Ltd)** is an AI software that assists the user in reviewing acquired images, automating measurements and automating report generation.

Details on technology versions, use cases and regulatory status can be found in [Table 1](#). This summary is based on information provided by NICE, information submitted by the companies, and publicly available information. Please see the published [scope](#) for further details on the properties of these technologies. The EAG comments column contains any clarifications sought from the companies on versions and generalisability of evidence.

Table 1: Description of technologies.

| Technology (manufacturer) | Version history | Use cases | Regulatory status | EAG comments |
|--------------------------------------|--|--|---|---|
| EchoGo Heart Failure (Ultromics Ltd) | <p>EchoGo Heart Failure v1.0</p> <ul style="list-style-type: none"> Launched Nov 2022 <p>EchoGo Heart Failure v2.0</p> <ul style="list-style-type: none"> Launched Sept 2024 Update to v1.0 to include EchoGo score and “explainability features” | <p><u>Intended use:</u> to provide adjunctive information on a patient's cardiovascular condition (diagnostic aid for HFpEF).</p> <p><u>Indications for use:</u> diagnostic aid for adult populations over 25 years of age undergoing routine functional cardiovascular assessment using diagnostic echocardiography or those suspected of heart failure.</p> <p><u>Exclusions:</u> NR</p> | <p>Class IIa (EU MDR 2017/745) expected June 2026 (version not specified)</p> <p>DTAC not in place.</p> | <p>The EAG noted in the literature the existence of other ‘EchoGo’ devices. These included Echo Go Pro, Echo Go Core and Echo Go Cardiac Amyloidosis. The company confirmed that these are all separate technologies. This assessment only considers EchoGo Heart Failure (v1.0 and v2.0), in line with the scope and in agreement with NICE.</p> <p>The company stated that v1.0 and v2.0 are separate from a regulatory perspective, but evidence can be considered generalisable between them (supported by company test data showing a 0.1% increase in inconclusive studies, and small increases in sensitivity (~2%) and specificity (~4%) from v1.0 to v.2.0).</p> |
| EchoConfidence (MyCardium AI Ltd) | <p>EchoConfidence v01.01.00</p> <ul style="list-style-type: none"> Launched May 2025  | <p><u>Intended use:</u> for detection and diagnosis of heart failure via screening or clinical echocardiograms, for stratifying heart failure (HFrEF, HFmrEF vs HFpEF), and for monitoring disease progression and response to treatment.</p> <p><u>Indications for use:</u> patients, both healthy or with underlying cardiac disease, requiring review or analysis</p> | <p>Class IIb (EU MDR 2017/45), awarded May 2025 (for v01.01.00)</p>  | <p>The company stated that “evidence is generalisable between versions, but the test datasets (for FDA, CE and precision) are re-run with each version release to ensure that performance is stable/improves”.</p> |

| | | | | |
|---------------------------------|--|--|---|--------------|
| | <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> | <p>of their echocardiographic images acquired for their cardiac anatomy, structure and function.</p> <p><u>Exclusions:</u> patients with a known congenital cardiac abnormality, paediatric patients (age<18). It has no special features to detect or make allowances for myocardial tumours.</p> | <p>[REDACTED]</p> <p>DTAC in place.</p> | |
| Ligence Heart (Ligence, UAB) | <p>Ligence Heart v3.42.0</p> <ul style="list-style-type: none"> Launched Jan 2025 [REDACTED] [REDACTED] [REDACTED] | <p><u>Intended use:</u> to detect, measure, and calculate various specifications of structure and function of the heart and great vessels by analysing echocardiographic images and automatically providing echocardiographic reports.</p> <p><u>Indications for use:</u> patients who are not in a life-threatening state of health, time is not critical for medical decisions and no major therapeutic interventions are required.</p> <p><u>Exclusions:</u> complex or critical congenital heart disease, heart tumours, prosthetic valves, post-operative heart valves, cardiac geometry changing cardiothoracic surgeries, implantable intracardiac devices, heart arrhythmias (atrial flutter, atrial fibrillations), aorta dissection.</p> | <p>Class IIa (EU MDR 2017/45), awarded June 2022 (for v3.42.0).</p> <p>[REDACTED]</p> <p>DTAC not in place.</p> | <p>None.</p> |

| | | | | |
|----------------------|---|---|--|--|
| Us2.ai (EKO Pte Ltd) | Us2.ai v1 <ul style="list-style-type: none"> Launched June 2022 | <p><u>Intended use:</u> to process acquired transthoracic cardiac ultrasound images, to analyse and make measurements on images in order to provide automated estimation of cardiac structural and functional parameters.</p> | <p>Class IIb EU MDR 2017/45, date awarded unknown (for both v1 and v2)</p> <p>DTAC in place.</p> | <p>The company stated that v1 and v2 have separate MDR certification, but evidence for v1 may be considered generalisable to v2.</p> <p>There is a 'cardiac amyloid model' which is included as a subset of the v2 software.</p> |
| | Us2.ai v2 <ul style="list-style-type: none"> Launched June 2025 Additional measurements | <p><u>Indications for use:</u> in adult patients as decision support for the detection of specific cardiac conditions such as heart failure, pulmonary hypertension, cardiac amyloidosis, hypertrophic cardiomyopathy and valve disease (aortic stenosis, mitral regurgitation).</p> <p><u>Exclusions:</u> NR</p> | | |

Abbreviations: AI: artificial intelligence; DICOM: digital imaging and communications in medicine; DTAC: digital technology assessment criteria; EU MDR: European Union Medical Device Regulation; HF: heart failure; HFmEF: heart failure with mid-range ejection fraction; HFpEF: heart failure with preserved ejection fraction; HFrEF: heart failure with reduced ejection fraction; LV: left ventricle; NR: not reported.

3. Clinical context

This early value assessment (EVA) will focus on the use of artificial intelligence (AI) assisted echocardiography to support the diagnosis and monitoring of heart failure (HF). This section describes the clinical context of this assessment, including the condition, the echocardiography procedure and relevant clinical pathways.

3.1 Heart failure (HF)

Heart failure (HF) is a condition where the heart is unable to pump blood around the body properly. This can be due to structural or functional abnormalities. While not usually curable, some symptoms of HF can be managed. Common symptoms of HF include breathlessness (dyspnoea), chronic exhaustion, and swollen legs and ankles. HF can be chronic (due to cardiovascular comorbidities such as hypertension) or acute (e.g., secondary to acute coronary syndrome). It usually affects older populations but can also occur in younger individuals.

HF is common, with over a million people being affected in the UK. It is becoming more prevalent as the population ages. There are approximately 200,000 new HF diagnoses every year in the UK, with over 800,000 people on their GP's HF register ([British Heart Foundation, 2025](#)). Of those diagnosed with HF, an estimated 87% involved the use of echocardiography in the diagnostic work up ([National Heart Failure Audit Data \(NHFA\) 2025](#)).

Heart failure is categorised according to the left ventricular ejection fraction (LVEF) measurements, which may be acquired through echocardiography. The categories are: 'heart failure with preserved ejection fraction' (HFpEF, LVEF of $\geq 50\%$), 'heart failure with reduced ejection fraction' (HFrEF, LVEF is $\leq 40\%$), or the intermediate class of 'heart failure with mildly reduced ejection fraction' (HFmrEF, LVEF between 41-49%).

3.2 Echocardiography

Transthoracic echocardiography (TTE) is used to aid diagnosis of HF, in combination with presence of clinical symptoms, elevated biomarker levels (N-terminal pro-B-type natriuretic peptide (NT-proBNP)) and other cardiac imaging modalities. TTE facilitates detection of abnormalities and defects in the heart's chambers and valves and provides measurements of blood flow and the heart's pumping ability. Where an echocardiogram detects abnormal ejection heart fraction, abnormalities in the heart's walls' motions, or hypertrophy, this can be indicative of HF.

Cardiac magnetic resonance imaging (CMRI) may also be used for some complex cases or in the rare instances when TTE is inconclusive or contraindicated, but it is not readily available in all centres. TTE is usually performed in the NHS by a specialist cardiac physiologist or cardiologist, although the settings and type of technology used may vary depending on the referral pathway.

Potential place for AI-assisted echocardiography technologies in the care pathway

Transthoracic echocardiography (TTE) is typically conducted in the secondary care setting, in dedicated clinics or suites with static equipment. While not the focus of this assessment, clinical experts highlighted the concept of “one-stop clinics” for people with suspected heart failure, where multiple diagnostic investigations (including TTE) are combined into a single visit, with the goal of quicker time to diagnosis and initiation of treatment. Point-of-care echocardiography (e.g. handheld TTE) may be used in urgent situations such as presentation to the emergency department. The EAG has focused on evidence from secondary care, in line with the scope, but has included evidence from primary care and community settings in the UK where available. A typical elective TTE appointment in the outpatient setting is depicted in **Figure 1**, with an indication of where the AI technologies may be used. The EAG have developed this figure based on discussions in the scoping workshop, information from the published [scope](#) and responses from

clinical experts ([Appendix A](#)). The AI technologies may assist with automation of measurements, automation of report generation and classification of HF. AI-assisted TTE image acquisition is not in scope for this assessment.

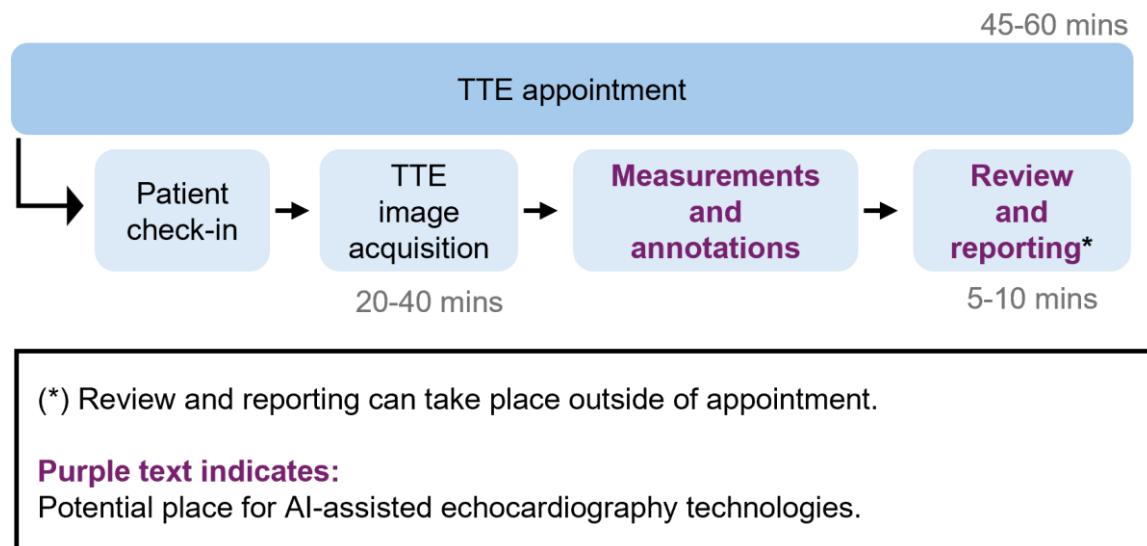


Figure 1: Echocardiography procedure.

Abbreviations: TTE: transthoracic echocardiogram.

3.3 Clinical pathways

Initial clinical assessments for patients presenting with symptoms indicative of suspected heart failure (HF) include blood tests for detection of biochemical markers (NT-proBNP) followed by a transthoracic echocardiogram (TTE). A summary of NICE guidelines relevant TTE and the suspected acute and chronic HF clinical pathway is presented in [Table 2](#).

The differentiation between acute and chronic HF is the onset of symptoms, the referral route and recommended time for receiving TTE. However, the TTE procedure itself does not differ between those suspected of acute and those suspected of chronic HF.

Table 2: NICE guidance relevant to heart failure.

| Guideline | Topic | Relevant guidance |
|------------------------------------|--|--|
| CG187 (NICE, 2014) | Diagnosis and management of (possible) acute heart | In people presenting with new suspected acute heart failure with raised natriuretic peptide levels, transthoracic Doppler 2D echocardiography to |

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| | failure in individuals aged 18 and over | establish the presence or absence of cardiac abnormalities. In people presenting with new suspected acute heart failure, consider performing transthoracic Doppler 2D echocardiography within 48 hours of admission to guide early specialist management. |
| NG106 (NICE, 2018) | Diagnosis and management of chronic heart failure in individuals aged 18 and over. | Because very high levels of NT-proBNP carry a poor prognosis, refer people with suspected heart failure and an NT-proBNP level more than 2,000 nanogram per litre (236 picomole per litre) urgently, to have specialist assessment and transthoracic echocardiography within 2 weeks. Refer people with suspected heart failure and an NT-proBNP level between 400 and 2,000 nanogram per litre (47 to 236 pmol per litre) to have specialist assessment and transthoracic echocardiography within 6 weeks. |

Abbreviations: CG: Clinical Guidance; NG: National Guidance; NICE: National Institute of Health and Care Excellence; NT-proBNP: N-terminal pro-B-type natriuretic peptide; 2D: two-dimensional.

3.4 Equality issues

Equality issues and considerations for this early value assessment are described in the [equalities impact assessment](#) (EIA) alongside the scope. No additional equality issues have been identified during the assessment.

4. Clinical evidence

4.1 Search strategies and study selection

The EAG conducted literature searches to identify evidence relevant to the decision problem of this assessment. Inclusion and exclusion criteria for this assessment is outlined in the published [protocol](#). Details of the EAG searches are provided in [Appendix B](#).

The titles and abstracts of the identified studies were screened by one reviewer and 20% of excluded records were checked by a second reviewer against the pre-specified inclusion and exclusion criteria. Full texts of the included records were obtained and screened by one reviewer and a random 20% of exclusions were checked by a second reviewer.

In line with the published [protocol](#), studies with full-text publications were prioritised for inclusion in this assessment. Conference proceedings were

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included if they reported data that could be used as inputs in the economic model (Section [6.2](#)). Other studies only reported in conference proceedings are summarised in [Appendix C](#). Results were not extracted from these conference proceedings due to the lack of detail available to facilitate assessment of study quality and the time constraints of this assessment.

Studies where outcomes were not considered relevant to the diagnosis or monitoring of HF were excluded e.g. studies investigating AI-automation of aortic measurements or AI-aided assessment of aortic stenosis.

Community care settings were not included by NICE in the scope of this assessment. However, during the scoping phase, specialist committee members (SCMs) and clinical experts highlighted the potential for these technologies to facilitate the shifting of echocardiography from secondary care to community settings. In the published [protocol](#), the EAG stated that relevant evidence from community care settings may be considered for inclusion, if feasible in the given timescale. In agreement with NICE, the EAG decided to include studies from a community setting that were based in the UK, where results were expected to be generalisable to the population of interest in this assessment. Evidence from community care settings outside of the UK was excluded. Evidence from community care settings did not inform the economic modelling, as this is outside of the scope.

4.2 Included and excluded studies

A PRISMA diagram depicting the study selection process is in [Appendix B](#).

A total of 17 key studies were included in this assessment. 14 studies had full-text publications available. Where multiple publications were identified for the same study, only the most recent and comprehensive publication was used for data extraction and is used as the primary study reference throughout this report. Additional publications identified as related to the key studies are listed in [Appendix C](#). The remaining 3 studies were provided by the company (all for EchoConfidence), of which 2 were interim analyses of ongoing studies. These were provided by the company as part of their 'request for evidence' (RFE) submissions submitted to NICE.

Six studies focused on training, testing and validation of the AI technologies, reporting outcomes on diagnostic test accuracy (e.g., sensitivity and specificity) and performance in aiding detection of HF (e.g., classification, discrimination of cases), with manual measurements as the comparator. Nine studies drew comparisons between AI-assisted TTE with manual TTE (including cart-based and handheld equipment). One study compared novice operated AI-assisted handheld TTE with expert sonographer operated standard cart-based TTE. The remaining study was a randomised controlled trial (RCT) which investigated the impact of introducing AI-assisted technology (Us2.ai) on examination time, image quality and staff experience. This study also compared AI performance against human operators.

Studies comparing AI-assisted TTE with manual TTE included outcomes such as interchangeability, correlation and agreement of AI measurements with human measurements. Where the diagnostic accuracy or performance of AI technologies was being evaluated or validated, this was usually in comparison to diagnoses made by humans, which is in line with current clinical practice in the NHS. However, the type of healthcare professional (HCP) conducting the 'manual' TTE acquisition, analysis and reporting in the comparator group across the studies varied, and included cardiologists, sonographers, nurses, analysts, and technologists. For EchoGo Heart Failure, the studies also compared the performance of the AI model in detecting HFpEF with existing manual multiparametric clinical scoring tools.

Table 3 summarises the 17 included studies. A rating of **GREEN** indicates an element that meets the scope fully, **AMBER** meets the scope partially, and **RED** does not meet the scope. The EAG noted there was inconsistency in the description of HCPs involved in the studies, so descriptors of comparators have been extracted verbatim from the publications for transparency.

Studies reported only in conference proceedings which met all aspects of the scope are reported in Appendix C.

7 ongoing studies have been identified as relevant to this assessment, 5 of which were identified through the company submissions (reported in Section 8.1).

Table 3: Description of studies selected by the EAG as the evidence base.

| Study name, design and location | Participants and setting | Intervention(s) and comparator | Outcomes |
|--|--|---|--|
| EchoGo Heart Failure | | | |
| <u>Study:</u> Akerman 2025a <u>Design:</u> Retrospective case-control study (external validation) <u>Location:</u> Beth Israel Deaconess Medical Center, MA, USA <u>Publication status:</u> Published | <u>Participants:</u> <ul style="list-style-type: none"> - Cases with HFpEF: n=240 - Controls: n=256 <u>Demographics:</u> <p>Cases</p> <ul style="list-style-type: none"> • Mean age: 74.2 ± 12.1 years • F/M: 54.2% female • Ethnicity: <ul style="list-style-type: none"> - 68.3% White - 18.3% Black - 5.8% Asian - 7.1% Other <p>Controls</p> <ul style="list-style-type: none"> • Mean age: 75.0 ± 13.0 years • F/M: 55.1% female • Ethnicity: <ul style="list-style-type: none"> - 78.1% White - 6.6% Black - 5.5% Asian - 9.0% Other <u>Setting:</u> Academic tertiary medical centre (secondary care) GREEN | <u>Intervention:</u> EchoGo Heart Failure v2.0 <u>Comparator:</u> Manual clinical scoring tools (HF2PEF, HFA-PEFF) AMBER | 1) Diagnostic performance of AI HFpEF model vs H2FPEF <ul style="list-style-type: none"> • Discrimination (AUROC) • Calibration • Classification and re-classification • Sensitivity • Specificity • Re-classification • Clinical utility 2) Diagnostic performance of AI HFpEF model HFA-PEFF scores 3) Patient outcomes <ul style="list-style-type: none"> • Mortality • HF hospitalisation GREEN |

| | | | |
|--|--|--|--|
| <p><u>Study:</u> Akerman 2023a</p> <p><u>Design:</u> Retrospective case-control study (training, validation and external testing)</p> <p><u>Location:</u> UK and USA</p> <p><u>Publication status:</u> Published</p> | <p><u>Participants:</u></p> <p>Training and validation:</p> <ul style="list-style-type: none"> • Cases with HF: n=2,971 • Controls: n=3,785 <p>Independent testing:</p> <ul style="list-style-type: none"> • Cases with HF: n=646 • Controls: n=638 <p><u>Demographics:</u></p> <p>Training</p> <p><u>Controls:</u></p> <ul style="list-style-type: none"> • Mean age: 55.8 ± 15.7 years • F/M: 52.2% female • Ethnicity: <ul style="list-style-type: none"> - 90.0% White, non-Hispanic - 3.0% African American - 1.7% Other <p><u>Cases:</u></p> <ul style="list-style-type: none"> • Mean age: 73.2 ± 11.5 years • F/M: 50.5% female • Ethnicity: <ul style="list-style-type: none"> - 89.1% White, non-Hispanic - 1.9% African American - 1.7% Other <p>Validation</p> <p><u>Controls:</u></p> <ul style="list-style-type: none"> • Mean age: 57.5 ± 15.8 years • F/M: 52.4% female • Ethnicity: <ul style="list-style-type: none"> - 3.2% African American - 91.8% White, non-Hispanic - 0.8% Other | <p><u>Intervention:</u> EchoGo Heart Failure v1.0</p> <p><u>Comparator:</u> Manual clinical scoring tools (HF2PEF, HFA-PEFF)</p> <p>AMBER</p> | <p>1) Discrimination (training and validation)</p> <ul style="list-style-type: none"> • AUROC <p>2) Sensitivity and specificity (independent testing)</p> <ul style="list-style-type: none"> • Sensitivity • Specificity • PPV • NPV <p>3) Reclassification</p> <p>4) Mortality</p> <p>GREEN</p> |
|--|--|--|--|

| Study name, design and location | Participants and setting | Intervention(s) and comparator | Outcomes |
|---------------------------------|--|--------------------------------|----------|
| | <p>Cases: Mean age: 73.7 ± 11.5 years F/M: 53.7% female <ul style="list-style-type: none"> • 87.3% White, non-Hispanic • 1.4% African American • 1.8% Other Independent testing Controls: <ul style="list-style-type: none"> • Mean age: 64.6 ± 17.4 years • F/M: 51.1% female • Ethnicity <ul style="list-style-type: none"> - 60.0% White, non-Hispanic - 19.9% African American - 20.1% Other Cases: <ul style="list-style-type: none"> • Mean age: 72.4 ± 13.3 years • F/M: 52.2% female • Ethnicity: <ul style="list-style-type: none"> - 61.8% White, non-Hispanic - 19.2% African American - 19.0% Other Setting: 7 hospitals, 1 community outreach centre (mixed secondary and primary care) GREEN </p> | | |

| Study name, design and location | Participants and setting | Intervention(s) and comparator | Outcomes |
|---|--|--|---|
| <p><u>Study:</u> Cassianni 2024</p> <p><u>Design:</u> Retrospective case-control study (external validation)</p> <p><u>Location:</u> NR</p> <p><u>Publication status:</u> Published</p> | <p><u>Participants (same as Akerman 2023a independent testing cohort):</u></p> <ul style="list-style-type: none"> Cases with HF: n=646 Controls: n=638 <p><u>Demographics:</u></p> <p>Controls:</p> <ul style="list-style-type: none"> Mean age: 64.6 ± 17.4 years F/M: 51.1% female <ul style="list-style-type: none"> 60.0% White, non-Hispanic 19.9% African American 20.1% Other <p>Cases:</p> <ul style="list-style-type: none"> Mean age: 72.4 ± 13.3 years F/M: 52.2% female <ul style="list-style-type: none"> 61.8% White, non-Hispanic 19.2% African American 19.0% Other <p><u>Setting:</u> 7 hospitals, 1 community outreach centre (mixed secondary and primary care)</p> <p>AMBER</p> | <p><u>Intervention:</u> EchoGo Heart Failure v2.0</p> <p><u>Comparator:</u> Manual clinical scoring tools (HF2PEF, HFA-PEFF)</p> <p>AMBER</p> | <ol style="list-style-type: none"> HF hospitalisation and deaths according to predicted group Association between AI output and risk for HF hospitalisation Association between AI output and cardiac mortality Application of AI model to nondiagnostic H2FPEF outputs HF hospitalisation risk according to H2FPEF classification (positive and negative) HF hospitalisation risk according to H2FPEF category (indeterminate) <p>GREEN</p> |

Us2.ai

| Study name, design and location | Participants and setting | Intervention(s) and comparator | Outcomes |
|--|--|---|--|
| <p><u>Study:</u> Campbell 2025</p> <p><u>Design:</u> Prospective comparative study (diagnostic accuracy)</p> <p><u>Location:</u> Glasgow, UK</p> <p><u>Publication status:</u> Published</p> | <p><u>Participants:</u> 867 patients with suspected HF</p> <p><u>Demographics:</u></p> <ul style="list-style-type: none"> Median age: 77 years (69-83) F/M: 51% female Ethnicity: <ul style="list-style-type: none"> 98% White <p><u>Setting:</u> Outpatient sites (secondary care)</p> <p>GREEN</p> | <p><u>Intervention:</u> Us2.ai</p> <p><u>Comparator:</u> Expert accredited sonographers</p> <p>GREEN</p> | <p>1) Diagnostic test accuracy</p> <ul style="list-style-type: none"> (true positive + true negative) / (true positive + true negative + false positive +false negative) Sensitivity Specificity NPV PPV AUROC <p>2) A) Interchangeability of LVEF measurements between AI-automated TTE and human cart-based TTE</p> <p>B) Interchangeability of HFpEF measurements between AI-automated handheld/cart-based TTE and human reporting of cart-based TTE</p> <ul style="list-style-type: none"> IEC <p>3) Interchangeability of LVEF measurements between AI-automated cart-based TTE and human reporting of cart-based TTE</p> <ul style="list-style-type: none"> IEC <p>4) Agreement between AI and human analysis</p> <ul style="list-style-type: none"> IEC Pearson correlation coefficient analysis <p>GREEN</p> |

| Study name, design and location | Participants and setting | Intervention(s) and comparator | Outcomes |
|--|--|---|---|
| <u>Study</u> : Hirata 2024 <u>Design</u> : Prospective comparative study <u>Location</u> : Japan <u>Publication status</u> : Published | <u>Participants</u> : 23 patients who underwent echocardiography <u>Demographics</u> : <ul style="list-style-type: none"> Mean age: 57±17 years F/M: 70% female Ethnicity: NR <u>Setting</u> : NR AMBER | <u>Intervention</u> : Us2.ai <u>Comparator</u> : Experienced, certified echocardiography technologist GREEN | 1) Agreement between human and AI-automated measurements <ul style="list-style-type: none"> ICC 2) Time required for AI and manual measurements and reporting <ul style="list-style-type: none"> Mean time in seconds ±SD GREEN |
| <u>Study</u> : Huang 2024a <u>Design</u> : Prospective comparative study <u>Location</u> : National Heart Centre, Singapore <u>Publication status</u> : Published | <u>Participants</u> : 100 patients with ≥1 HF symptom <u>Demographics</u> : <ul style="list-style-type: none"> Average (presumed mean) age: 61.2±15.0 years F/M: 44% female Ethnicity: NR <u>Setting</u> : Cardiac imaging laboratory (secondary care) GREEN | <u>Intervention</u> : Novice-operated Us2.ai-assisted handheld TTE <u>Comparator</u> : Expert-operated standard cart-based TTE AMBER | 1) Accuracy of AI-enhanced novice-performed POC echocardiogram and AI-interpreted LVEF to detect a reduced LVEF<50% <ul style="list-style-type: none"> AUC Sensitivity Specificity PPV NPV 2) Yield and learning curve of novice performing POC cardiac ultrasound <ul style="list-style-type: none"> Yield: exams with AI-measurable LVEF compared to cart-based cardiologist reported LVEFs Learning curve: mean exam time, learning rate. GREEN |

| Study name, design and location | Participants and setting | Intervention(s) and comparator | Outcomes |
|--|---|---|--|
| <u>Study:</u> Lafitte 2025 <u>Design:</u> Prospective comparative study <u>Location:</u> Bordeaux University Hospital, France <u>Publication status:</u> Published | <u>Participants:</u> 894 echocardiographic examinations <u>Demographics:</u> <ul style="list-style-type: none"> Mean age: 64.8 ± 16.3 years F/M: 43% female Ethnicity: NR <u>Setting:</u> Echocardiography department (secondary care) AMBER | <u>Intervention:</u> Us2.ai <u>Comparator:</u> Human operators with three different expertise levels: nurses, residents and experts. GREEN | 1) Agreement between automatic AI measurements and manual measurements <ul style="list-style-type: none"> Pearson correlation coefficients ICC Bland-Altman analyses (LoA) 3) GREEN |
| <u>Study:</u> Myhre 2024a <u>Design:</u> Retrospective comparative study <u>Location:</u> Cardiology echo lab of the University Hospital of Parma, Italy <u>Publication status:</u> Published | <u>Participants:</u> 109 patients who underwent 2D and 3D transthoracic echocardiography <u>Demographics:</u> <ul style="list-style-type: none"> Mean age: 56 ± 15 years F/M: 71% female Ethnicity: NR <u>Setting:</u> Tertiary care centre, cardiology echocardiography laboratory (secondary care) AMBER | <u>Intervention:</u> Us2.ai <u>Comparator:</u> Experienced human operators with echocardiography certification AMBER | 1) Agreement, correlation and reliability between human operators and AI for LVEDV, LVESV, LVEF, GLS measures <ul style="list-style-type: none"> Bias and level of agreement (LOA) Pearson's correlation Average k 4) GREEN |

| Study name, design and location | Participants and setting | Intervention(s) and comparator | Outcomes |
|---|--|---|--|
| <p><u>Study:</u> Myhre 2024b</p> <p><u>Design:</u> Retrospective comparative study (external validation in 3 cohorts)</p> <p><u>Location:</u> 1) Taiwan; 2) Sweden, Finland, USA, Singapore; 3) Qatar</p> <p><u>Publication status:</u> Published</p> | <p><u>Participants:</u></p> <ol style="list-style-type: none"> 1) Participants with and without HF (n=4,228) 2) PROMIS-HFpEF study data (n=183), 3) HMC-QU-MI study of patients with suspected AMI (n=162) <p><u>Demographics:</u></p> <ol style="list-style-type: none"> 1) <ul style="list-style-type: none"> • Mean age: 55 ± 15 years • F/M: 33% female • Ethnicity: <ul style="list-style-type: none"> - 100% Asian 2) <ul style="list-style-type: none"> • Mean age: 74 ± 9 years • F/M: 44% female • Ethnicity: <ul style="list-style-type: none"> - 88% White - 8% Asian - 4% African American 3) NR <p><u>Setting:</u> 1) community, 2) secondary care, 3) secondary care</p> <p>GREEN</p> | <p><u>Intervention:</u> Us2ai</p> <p><u>Comparator:</u></p> <ol style="list-style-type: none"> 1) Sonographers or cardiologists 2) Experienced research sonographers 3) NR <p>GREEN</p> | <p>1) Agreement between AI and manual measurements</p> <p>2) Ability to identify HF</p> <p>3) Yield</p> <p>GREEN</p> |

| Study name, design and location | Participants and setting | Intervention(s) and comparator | Outcomes |
|---|--|---|---|
| <u>Study:</u> Sakamoto 2025 <u>Design:</u> Randomised controlled trial (single-blinded crossover) <u>Location:</u> Jutendo University Hospital (Tokyo, Japan) <u>Publication status:</u> Pre-print | <u>Participants:</u> 585 participants with known or unknown cardiac diseases <u>Demographics:</u> Non-AI days <ul style="list-style-type: none"> Mean age: $64y \pm 16$ years F/M: 54% female Ethnicity: NR AI-days <ul style="list-style-type: none"> Mean age: $65y \pm 15$ years F/M: 60% female Ethnicity: NR <u>Setting:</u> echocardiography laboratory (secondary care) | <u>Intervention:</u> Us2.ai <u>Comparator:</u> Certified sonographers (average experience in echocardiography 9.0 ± 4.4 years); expert echocardiologists reviewed and finalised reports. | 1) Examination efficiency <ul style="list-style-type: none"> Examination time per patient Number of examinations per day 2) Sonographer fatigue <ul style="list-style-type: none"> Self-reported questionnaire 3) Number of analysed echocardiographer parameters 4) Image quality on days using AI vs days without AI 5) AI performance <ul style="list-style-type: none"> Rate of AI analysis Concordance between AI measurements and measurements finalised by humans AMBER |
| <u>Study:</u> Tromp 2022a <u>Design:</u> Retrospective case-control study (external validation) <u>Location:</u> Brigham and Women's Hospital Cardiac Imaging Core Laboratory (Boston, MA, USA) <u>Publication status:</u> Published | <u>Participants:</u> n=600 (602 echocardiographic studies) <ul style="list-style-type: none"> Control (without HF): n=179 Cases with HFrEF: n=421 <u>Demographics:</u> <ul style="list-style-type: none"> Mean age: 57 ± 16 years F/M: 69% female Ethnicity: NR <u>Setting:</u> imaging laboratory (secondary care) | <u>Intervention:</u> Us2.ai <u>Comparator:</u> human expert measurements | 1) Interchangeability <ul style="list-style-type: none"> IEC 2) Agreement between automated and human measurements <ul style="list-style-type: none"> ICC MAD wCV RMSE LoA 3) Yield GREEN |

| Study name, design and location | Participants and setting | Intervention(s) and comparator | Outcomes |
|---|---|---|--|
| <p><u>Study:</u> Tromp 2022b</p> <p><u>Design:</u> retrospective comparative study (training, internal testing and external validation)</p> <p><u>Location:</u> China, Hong Kong, India, Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Taiwan, and Thailand, Canada, USA</p> <p><u>Publication status:</u> Published</p> | <p><u>Participants:</u></p> <ul style="list-style-type: none"> • ATTRaCT: n=1,076 participants • HEART: n=621 participants • Taiwan cohort: n=9,289 participants <p><u>Demographics:</u> ATTRaCT: NR</p> <p>HEART cohort:</p> <ul style="list-style-type: none"> • Mean age: 66y \pm12 years • F/M: 43% female • Ethnicity: <ul style="list-style-type: none"> - 91% Caucasian - 2% Aboriginal - 1% African American - 5% Asian - 1% other <p>Taiwan cohort</p> <ul style="list-style-type: none"> • Mean age: 66 \pm15 years • F/M: 48% female • Ethnicity: <ul style="list-style-type: none"> - 100% Asian <p><u>Setting:</u> NR</p> <p>AMBER</p> | <p><u>Intervention:</u> Us2ai</p> <p><u>Comparator:</u> Expert sonographers</p> <p>GREEN</p> | <p>1) Difference between automated versus manual measurements</p> <p>2) Ability to identify patients with LVEF<40%, e' lateral wave velocity <10cm/s, E/e' ratio \geq13</p> <p>GREEN</p> |

Ligence Heart

| Study name, design and location | Participants and setting | Intervention(s) and comparator | Outcomes |
|--|--|---|---|
| <u>Study:</u> Karužas 2025 <u>Design:</u> Prospective comparative study <u>Location:</u> Hospital of Lithuanian University of Health Sciences, Lithuania <u>Publication status:</u> Published | <u>Participants:</u> 302 adult patients in sinus rhythm at the time of examination and experiencing dyspnea <u>Demographics:</u> <ul style="list-style-type: none"> Mean age: 60.07 ± 16.14 years F/M: 58.3% female Ethnicity <ul style="list-style-type: none"> 100% Caucasian <u>Setting:</u> University hospital clinic (secondary care) AMBER | <u>Intervention:</u> Ligence Heart software version 3.32.0 <u>Comparator:</u> Single expert cardiologist GREEN | 1) Yield 2) Difference between AI and manual values 3) Range of variation between automated and manual measurements 4) Agreement between manual and AI measurements 5) Accuracy of grading GREEN |

| Study name, design and location | Participants and setting | Intervention(s) and comparator | Outcomes |
|--|---|---|--|
| <p><u>Study:</u> Mołek-Dziadosz 2025</p> <p><u>Design:</u> Retrospective comparative study</p> <p><u>Location:</u> St. John Paul II Hospital, Kraków, Poland</p> <p><u>Publication status:</u> Published</p> | <p><u>Participants:</u> n=118 adult patients with clinical indications for CMR</p> <p><u>Demographics:</u></p> <ul style="list-style-type: none"> Median age: 54 years (37-67) F/M: 32% female Ethnicity: NR <p><u>Setting:</u> Department of Coronary Artery Disease and Heart Failure (secondary care)</p> <p>AMBER</p> | <p><u>Intervention:</u> Ligece Heart version 3.42.0</p> <p><u>Comparator:</u> 2 independent human experts</p> <p>AMBER</p> | <ol style="list-style-type: none"> Variability between multi-loop AI analysis and expert 1, and expert 2 <ul style="list-style-type: none"> Pearson's R Concordance index Cohen K Variability between single-loop AI analysis and expert 1, and expert 2 <ul style="list-style-type: none"> Pearson's R Concordance index Systematic bias of multi-loop AI analysis relative to expert 1 and expert 2 <ul style="list-style-type: none"> LoA Systematic bias of single-loop AI analysis relative to expert 1 and expert 2 <ul style="list-style-type: none"> LoA Mean absolute LVEF difference between modalities <ul style="list-style-type: none"> LVEF MAD between single-loop AI analysis vs expert 1 LVEF MAD between single-loop AI analysis vs expert 2 LVEF MAD between single-loop AI analysis vs multi-loop analysis Patient outcomes <ul style="list-style-type: none"> Number of deaths during follow-up period Survival analysis <p>GREEN</p> |

EchoConfidence

| Study name, design and location | Participants and setting | Intervention(s) and comparator | Outcomes |
|---|--|---|--|
| <p><u>Study:</u> Almeida 2025 (FEATHER, unpublished)</p> <p><u>Design:</u> Retrospective comparative study</p> <p><u>Location:</u> UK</p> <p><u>Publication status:</u> Unpublished</p> | <p><u>Participants:</u> 300 consecutive patients referred to for HF investigation, of which n=299 (99.7%) echocardiograms used</p> <p><u>Demographics:</u></p> <ul style="list-style-type: none"> • <u>Mean age:</u> 73.1 ± 12.2 years • F/M: 44% male • <u>Ethnicity</u> <ul style="list-style-type: none"> - 30.4% White - 14.4% Asian - 12% Black - 43.1% Other <p><u>Setting:</u> Community sites</p> <p>GREEN</p> | <p><u>Intervention:</u> EchoConfidence v1.3</p> <p><u>Comparator:</u> BSE-accredited sonographers</p> <p>GREEN</p> | <p>1) Sensitivity of AI to diagnose HFrEF, HFmrEF, HFpEF (human 1, then human 2 as reference)</p> <p>2) Specificity of AI to diagnose HFrEF, HFmrEF, HFpEF human 1, then human 2 as reference)</p> <p>3) Diagnostic accuracy of AI to diagnose HFrEF, HFmrEF, HFpEF (human 1, then human 2 as reference)</p> <p>4) NPV, PPV, FP rate, FN rate, LR+, LR-</p> <p>5) Time taken for analysis</p> <p>6) Comparison of survival curves</p> <p>7) Categorisation performance by human 1, human 2 and AI, and discordance rate</p> <p>GREEN</p> |

| Study name, design and location | Participants and setting | Intervention(s) and comparator | Outcomes |
|--|--|---|---|
| <u>Study:</u> RECARDIO-TOX <u>Design:</u> Prospective comparative study <u>Publication status:</u> Unpublished | <u>Participants:</u> 60 patients with cancer undergoing cardiotoxicity surveillance echocardiography <u>Demographics</u> <ul style="list-style-type: none"> Mean age: 52±12years F/M: 83% female Ethnicity: <ul style="list-style-type: none"> 53% White 22% Asian 18% Black 7% Other <u>Setting:</u> Barts Heart Centre (secondary care) AMBER | <u>Intervention:</u> EchoConfidence <u>Comparator:</u> Professionally accredited expert readers (median 7 years' post accredited clinical experience) GREEN | <ol style="list-style-type: none"> Test re-test (paired studies) variability in LVEF and GLS, between average of experts' and AI's measurements <ul style="list-style-type: none"> MAD Correlation, r value Secondary outcome – Evaluation of other precision metrics <ul style="list-style-type: none"> MDC WSCoV LOA Bland-Altman method Inter-observer precision Comparison of 3DE LVEF measurements to 2DE LVEF measurements, both expert and AI <ul style="list-style-type: none"> MAD MDC GREEN |
| <u>Study:</u> ACE-HEART <u>Design:</u> Retrospective comparative study <u>Location:</u> NR <u>Publication status:</u> Unpublished | <u>Participants:</u> 10 patients undergoing long-term anti-HER2 therapy (interim analysis from a total of n=191 patients) <u>Demographics:</u> NR <u>Setting:</u> NR AMBER | <u>Intervention:</u> EchoConfidence v1.2 <u>Comparator:</u> expert human reader GREEN | <ol style="list-style-type: none"> Variability of LVEF and GLS measurements <ul style="list-style-type: none"> CoV Correlation between AI and unblinded human reader <ul style="list-style-type: none"> Pearson's r GREEN |

Abbreviations: AI: artificial intelligence; AMI: acute myocardial infarction; ATTRaCT: Asian Network for Translational Research and Cardiovascular Trials; AUROC/AUC: area under the receiver operating characteristic curve; CoV: coefficient of variability; E/e' ratio: early diastolic mitral inflow velocity to early diastolic mitral annulus velocity ratio; e' lateral: early diastolic velocity of the mitral annulus; F/M: female/male; GLS: global longitudinal strain; HEART: (Alberta) Heart Failure Etiology and Analysis Research Team;

HER2: human epidermal growth factor receptor 2; HF: heart failure; H2PEF: score for Heart Failure With Preserved Ejection Fraction; HFA-PEFF: heart Failure Association Pre-test assessment, Echocardiography and natriuretic peptide, Functional testing, Final etiology; HFmrEF: heart failure with mildly reduced ejection fraction; HFpEF: heart failure with preserved ejection fraction; HFrEF: heart failure with reduced ejection fraction; HMC-QU-MI: Hamad Medical Corporation Heart Hospital and Qatar University and Tampere University Myocardial Infarction (dataset); ICC: intraclass correlation coefficient; IEC: individual equivalence coefficient; LoA: limits of agreement; LR+/LR-: positive and negative likelihood ratio; LVEF: left ventricular ejection fraction; MAD: mean absolute deviation; MDC: minimal detectable change; NA: not applicable; NPV: negative predictive value; NR: not reported; POC: point-of-care; PPV: positive predictive value; PROMIS-HFpEF: prevalence of microvascular dysfunction-HF and preserved ejection fraction (study); RMSE: root mean square error; SD: standard deviation; TTE: transthoracic echocardiogram; wCV/WSCoV: within-subject coefficient of variation.

5. Clinical evidence review

5.1 Quality appraisal of studies

This section outlines key risks of bias identified for each study, as well as consistent limitations identified across the evidence base ([Table 4](#)). As outlined in the [protocol](#), the EAG did not use formal critical appraisal checklists to assess the quality of evidence. This is in accordance with the methods described in the [NICE EVA interim statement](#). Therefore, this section does not constitute a comprehensive summary of the quality of each study.

There were 17 studies identified as the clinical evidence base: 3 for EchoGo Heart Failure, 9 for Us2.ai, 2 for Ligence Heart and 3 for EchoConfidence.

EchoGo Heart Failure

The 3 studies included for EchoGo Heart Failure were all retrospective case-control studies focusing on the training and validation of the AI model. The study by Akerman et al. (2023a) was split into two stages. In the first stage, study authors developed EchoGo Heart Failure v1.0, by training the AI model on a mixture of cases (n=2,971) and controls (n=3,785) from UK and USA-based datasets to detect HFpEF using a single apical 4-chamber transthoracic echocardiogram (TTE) video clip. In the second stage, the AI model was validated in a USA-based multisite dataset, consisting of 646 cases and 638 controls. Its performance was also compared against existing clinical scoring tools intended to aid detection of HFpEF. The EAG notes the clinical scores used as a comparator were retrospectively calculated and were not required for the original clinical diagnoses. While the control group was randomly sampled, the cases group were significantly older, meaning complete matching was not possible.

The study by Akerman et al. (2025a) compared the diagnostic performance of the updated version of EchoGo Heart Failure (v2.0) against the same existing clinical scoring tools (n=240 cases and n=256 controls from a single centre in the USA). The same limitations described for the previous study with respect to retrospective calculation of the clinical scores also apply to this study.

Cases and controls were matched on age and sex. Study authors noted that analysts calculating the clinical scores were not blinded to the case/control status of that individual.

The study by Cassianni et al. (2024) reported on the validation of EchoGo Heart Failure v2.0, using the same cases and controls test data used for external validation by Akerman et al. (2023a). The study compared HF classifications made by the AI technology to those made by existing clinical scoring tools. This study also reported incident HF-related hospitalisation and HF-related mortality post-echocardiography.

Us2.ai

In the prospective comparative study by Campbell et al. (2025), participants (n=867) received 2 echocardiograms on the same day at the same clinic visit: one with a handheld portable device and one using conventional cart-based equipment. Both echocardiograms were then analysed using Us2.ai software. Diagnostic accuracy and interchangeability of AI measurements on handheld echocardiograms were compared with human analysis of cart-based echocardiography. This study was based in the UK (Glasgow) and was co-developed with people with lived experience of HF. The handheld scan was performed prior to the cart-based scan for all participants, introducing potential bias as the acquisition of the first scan may have influenced HCP performance when acquiring the second scan. Assessment of the primary endpoint (detection of LVEF $\leq 40\%$) was only possible in 51% participants.

The prospective comparative study by Hirata et al. (2024) was a single-centre study based in Japan where a single operator conducted echocardiographic examinations on 23 consecutive patients. Images were assessed by both a human expert and AI. Measurement time and report creation time were compared between AI and manual methods. The small sample size, single centre and single operator design of this study limits generalisability of the results to a wider population.

The prospective comparative study by Huang et al. (2024a) was a single-centre study based in Singapore, in which participants (n=100) underwent

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echocardiography by AI-assisted novices and trained echocardiographers (the images of which were reported by a cardiologist). Study authors compared diagnostic accuracy of AI-assisted novice echocardiography to standard echocardiography. 94% of participants had sinus rhythm, meaning the AI software was not tested in more complex cases. The study authors could not conclude if suboptimal image quality (present in 4% of images) was attributable to the AI software or to the operator.

Tromp et al. (2022a) reported a retrospective comparative study based in a single centre in the USA. In this study, 2 expert sonographers evaluated images (n=602, which had already been evaluated once), giving rise to three human measurements. Automated measurements were then compared to the human measurements, with respect to agreement, correlation and yield. Only high-quality images were analysed due to limitations in the AI software in analysing low quality images, and the cohort did not include those with HFpEF or atrial fibrillation. The EAG noted a breakdown of the ethnicity of participants was not reported.

The study by Lafitte et al. (2025) was a single centre prospective comparative study based in France. AI-assistance was implemented in 2 echocardiography examination rooms. 894 echocardiographic examinations were conducted during the study period, and both human measurements and AI measurements were made. 31 paired measurements were identified, where both AI and humans performed the same measurement, and were assessed for concordance and correlation. The short data collection period (2 months) means the results may not have captured the full range of clinical scenarios. The study authors note that the study was conducted in a controlled setting, without the pressures of 'real world' practice, meaning results may not be generalisable to a wider range of settings.

Myhre et al. (2024a) reported on a retrospective single centre study in Italy, where analysis was conducted on 109 participants who underwent 2D and 3D transthoracic echocardiography. LV end-diastolic and end-systolic volumes (LVEDV, LVESV) and ejection fraction (LVEF) were measured by two human operators the Us2.ai software, and the 3D Heart Model. Study participants

largely had LV volumes and EF measurements within the normal range, limiting generalisability to the diverse range of cases present in real practice.

In the retrospective validation study by Myhre et al. (2024b) Study authors developed and trained a deep learning algorithm (Us2.ai) for left ventricular (LV) strain measurements in an internal dataset. Then, global longitudinal strain (GLS) was validated externally against human measurements in 3 cohorts, with data from Taiwan, Sweden, Finland, the USA, Singapore and Qatar. The study authors noted that a lack of a 'gold standard' approach in manually calculating strain measurements may limit generalisability of the results.

In the retrospective validation study by Tromp et al. (2022b), study authors developed an AI-assisted (Us2.ai) workflow for making measurements and classifications of echocardiographic images. A training dataset of 1145 images was used, followed by an internal test set of 406 images. Validation was then conducted against manual measurements from 3 datasets from Canada, Taiwan and the USA. Only images of 'sufficient' quality were able to be analysed and annotated by the AI software, as the model was trained on expert annotations by trained human operators.

The study by Sakamoto et al. (2025) was a single centre prospective crossover randomised controlled trial (RCT) based in Japan, reported in a non-peer reviewed pre-print publication. Echocardiograms (n=585) were conducted with AI in one arm (across 19 days) and without AI in the other arm (across 19 days) to evaluate the impact on efficiency of examinations. The study had a relatively short duration of 2.5 months, meaning the full range of potential clinical scenarios may not have been captured, and operators being aware of using AI in the intervention arm may have introduced performance bias (although this would have been unavoidable).

Ligence Heart

Mołek-Dziadosz et al. (2025) conducted a retrospective comparative study, investigating the performance of Ligence Heart in measuring LVEF in a single centre in Poland (n=118). The EAG notes the main comparator in this study

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was cardiac magnetic resonance (CMR). However, the study also drew comparisons between AI-assisted echocardiography and manual echocardiography. Only outcomes relating to AI-assisted echocardiography versus manual measurements were extracted and reported by the EAG in this assessment. In this study, participants were only included if they had clinical indications for CMR, which limits generalisability to wider populations suspected of HF.

Karuzas et al. (2025) reported a retrospective comparative study set in a single centre in Lithuania (n=302), comparing the performance of Ligence Heart against human operators in assessing left ventricular diastolic function. The study authors noted an under-representation of patients with more severe degrees of diastolic dysfunction.

EchoConfidence

All studies for EchoConfidence were supplied by the company (n=3). No published peer-reviewed evidence was identified by the EAG relating to this technology. Two studies were interim analyses of ongoing trials.

The FEATHER study (Almeida et al.: unpublished data 2025) was a retrospective comparative study where the diagnostic performance of EchoConfidence was compared to human operators, using data from the UK (n=300). Participants were consecutively included in the study, representing an 'all-comers' population. There is a lack of information around the reported AI analysis time, making it difficult to interpret results.

RECORDIO-TOX was a prospective single centre study based in the UK (n=60), where EchoConfidence was evaluated against human operators, in the context of monitoring those with potential post-cancer therapy cardiotoxicity (which can lead to HF). The study authors noted that the controlled setting of this study is unlikely to be representative of real-world settings.

ACE-HEART was a retrospective multi-centre comparative study in which EchoConfidence was compared against human operators, with respect to

performance in monitoring post-cancer therapy cardiac dysfunction. This report lacked detail on the study design, participants, setting and results to facilitate adequate quality assessment.

The EAG notes that both the RECARDIO-TOX and ACE-HEART studies are set in niche populations (post cancer surveillance) and so findings may not be generalisable to the wider population in the scope of this assessment.

Table 4: Key limitations of the evidence base.

| Key limitations | EAG comments |
|--|--|
| Retrospective study designs | 11 studies were retrospective, which means they are subject to inherent bias such as the reliance on completeness of medical records, potential for selection bias and variation in practice where echocardiograms were acquired across multiple sites. |
| Lack of UK-based data | 13 studies were set outside of the UK or used non-UK participant data. This limits the generalisability of the findings due to potential differences in clinical practice and population demographics. |
| Controlled settings not reflective of real-world populations and practice | 7 studies noted the exclusion of 'complex' cases in the study cohorts, either actively through case selection or passively through short study periods. This may introduce spectrum bias and limit the generalisability of findings to real-world settings. Additionally, some prospective studies were conducted in 'controlled' environments which meant the conditions were not reflective of real workflow e.g. time pressure. |
| Exclusion of poor-quality images | 5 studies stated that poor-quality images were either excluded prospectively as it was known the AI software cannot analyse them adequately, or poor-quality images were excluded from retrospective analyses as the AI software was unable to read and take measurements. This may impact upon the suitability of AI tools in real practice, where image quality may vary. |
| Single centre (and occasionally single operator) studies | 9 studies were based in a single centre or used data from a single site. Furthermore, one study had one operator conducting echocardiograms. This does not allow for inter-centre or inter-operator variability and could limit generalisability of findings. |
| Lack of clarity on technology versions used | 11 studies did not specify the generation or version of technology being investigated. The EAG sought clarification on versions where possible and has included this information in the report. |
| Lack of downstream health-related outcomes recorded | There was a paucity of health-related outcomes reported in relation to the implementation of any of the AI technologies in scope. This means it is difficult to determine any clinical benefit to patients through introducing these technologies into the care pathway. There is some evidence to suggest the AI technologies could support shifting echocardiography |

| | |
|--|---|
| | to community/mobile care settings to improve access and decrease time to diagnosis, but this evidence is limited. |
|--|---|

Abbreviations: AI: artificial intelligence; EAG: external assessment group; HF: heart failure; UK: United Kingdom.

5.2 Results from the evidence base

The evidence base consisted of 17 key studies across the 4 technologies in scope:

- EchoGo: n=3 studies
- Us2.ai: n=9 studies
- Ligence Heart: n=2 studies
- EchoConfidence: n=3 studies

[Table 5](#) summarises the outcomes which are reported across the studies, split by technology.

Table 5: Summary of outcomes reported, split by technology.

| | | EchoGo Heart Failure | | | Us2.ai | | | | | | | | Ligence Heart | | EchoConfidence | | | |
|------------------|--|----------------------|---------------|---------------|---------------|-------------|-------------|--------------|-------------|-------------|---------------|-------------|---------------|---------------------|----------------|------------------------|--------------|-----------|
| Outcome grouping | Outcome | Akerman 2025a | Akerman 2023a | Cassiani 2024 | Campbell 2025 | Hirata 2024 | Huang 2024a | Lafitte 2025 | Myhre 2024a | Myhre 2024b | Sakamoto 2025 | Tromp 2022a | Tromp 2022b | Molek-Dziadosz 2025 | Karužas 2025 | Almeida 2025 (FEATHER) | RECARDIO-TOX | ACE-HEART |
| Diagnostic | Diagnostic test accuracy | ✓ | ✓ | | ✓ | | ✓ | | | | | | | | | ✓ | | |
| | Detection and classification of HF | ✓ | ✓ | | ✓ | | ✓ | | | ✓ | | | | ✓ | | | | |
| Validation | Interchangeability | | | | ✓ | | | | | | | | ✓ | | | | | |
| | Correlation | | | | | | | | | | | | | ✓ | ✓ | ✓ | ✓ | ✓ |
| | Agreement | | | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | | | |
| Clinical | Clinical endpoints following AI analysis | ✓ | ✓ | ✓ | | | | | | | | | | | | ✓ | | |
| Procedural | Yield | | | | | | ✓ | | | ✓ | | | ✓ | | ✓ | | | |
| | Impact on procedure time | | | | | ✓ | | | | | ✓ | | | | | ✓ | | |

Abbreviations: AI: artificial intelligence; HF: heart failure.

Table 6 summarises the key outcomes reported across the evidence base and how results should be interpreted.

Table 6: Included outcome measures and descriptions.

| Measure | Definitions and Interpretation |
|--|--|
| Individual equivalence coefficient (IEC) | <p>Compares the disagreement between deep learning and human readers relative to the disagreement among human readers.</p> <p><u>Interpretation:</u></p> <p>A mean IEC of -0.25 means the variability between AI and human measurements was 25% lower than the variability among humans.</p> <p>A mean IEC of 0.25 means that the variability between AI and human measurements were 25% higher than the variability among humans.</p> |
| Intraclass correlation coefficient (ICC) | <p>Used to determine if measurements or ratings are consistent with each other.</p> <p><u>Interpretation:</u></p> <p><0.5: poor reliability</p> <p>0.5-0.75: moderate reliability</p> <p>0.75-0.9: good reliability</p> <p>>0.9: excellent reliability</p> |
| κ value (Cohen's kappa coefficient) | <p>Used to measure inter-rater reliability.</p> <p><u>Interpretation:</u></p> <p>A value of +1 indicates perfect agreement,</p> <p>A value of 0 indicates agreement by chance,</p> <p>Values <0 indicate agreement is worse than chance.</p> |
| Limit of agreement (LoA) | <p>Results are reported as lower LoA, upper LoA.</p> <p><u>Interpretation:</u></p> <p>A narrow range (between upper and lower LoA) indicates better agreement.</p> <p>A wide range suggests the two methods may not be interchangeable.</p> |
| Mean absolute deviation (MAD) | <p>The mean (average) of the absolute values of the deviations (errors) between actual and forecast data.</p> <p><u>Interpretation:</u></p> <p>The larger the MAD, the greater variability there is in the data</p> |
| Negative predictive value (NPV) | <p>$(\text{true negative}) / (\text{true negative} + \text{false negative})$</p> <p>Probability that following a negative test result, the individual will truly not have the condition.</p> |
| Pearson's r | <p>Indicates the linear correlation between two sets of data.</p> <p><u>Interpretation:</u></p> <p>The closer the value is to -1 or +1, the stronger the relationship.</p> |
| Positive predictive value (PPV) | <p>$(\text{true positive}) / (\text{true positive} + \text{false positive})$</p> <p>Probability that following a positive test result, the individual will truly have the condition.</p> |

| | |
|---|--|
| Receiver operating characteristic (ROC) curve, area under the curve (AUC)/ or discrimination | Measures how well an AI model can differentiate patients with the condition from those without the outcome. <u>Interpretation:</u> A higher AUC indicates better performance (where 1 is a perfect fit) A random model would have an AUC of 0.5. |
| Root mean standard error (RMSE) | Measure of how spread out the residuals (difference between actual and predicted value) are from the regression line (line of best fit which shows the relationship between two variables in a dataset). <u>Interpretation:</u> The lower the RMSE, the better the agreement among the different measurements. |
| Sensitivity (true positive rate) | (true positives)/(true positives+true negatives) Interpretation: a sensitivity rate of 90% means 90% of individuals who have the condition will test positive. |
| Specificity (true negative rate) | (true negative)/(true negative+false positive) Interpretation: a specificity rate of 90% means 90% of individuals who do not have the condition will test negative. |
| Within subject coefficient of variation (wCV or WSCoV) | Within-patient variability of individual measurements relative to the within-patient mean. <u>Interpretation:</u> Low wCV indicates high reproducibility, meaning measurements on the same person are similar. High wCV suggests greater day-to-day or test-retest variability within that individual. |
| Yield (%) | Proportion of echocardiogram exams/studies where AI could successfully measure the relevant variable, such as the proportion of exams with an AI-measurable LVEF or GLS. <u>Interpretation:</u> If an AI technology could successfully produce a read on LVEF or GLS measurement for 96 of 100 studies, the yield was 96%. |

Abbreviations: AI: artificial intelligence; AUC: area under the curve; GLS: global longitudinal strain; ICC: intraclass correlation coefficient; IEC: individual equivalence coefficient; LoA: level of agreement; LVEF: left ventricular ejection fraction; MAD: mean absolute deviation; NPV: negative predictive value; PPV: positive predictive value; RMSE: root mean standard error; ROC: Receiver Operating Characteristic; wCV/WSCoV: within subject coefficient of variation.

5.2.1 Diagnostic test accuracy

Diagnostic test accuracy was assessed using sensitivity, specificity, negative predictive value (NPV) and positive predictive value (PPV), ([Table 6](#)). These outcomes are reported across 5 studies, for 3 of the technologies:

- EchoGo Heart Failure: n=2 studies
- Us2.ai: n=2 studies
- EchoConfidence: n=1 study

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Evidence for EchoGo Heart Failure

[Akerman et al. \(2025a\)](#) compared EchoGo Heart Failure V2 to two existing multiparametric clinical scoring tools (H2FPEF and HFA-PEFF), reporting sensitivity, specificity, NPV and PPV in detection of HFpEF in a case-control study. Cases were retrospectively identified as those recorded as having grade II-III diastolic dysfunction. Results show that, when considering all available data, EchoGo Heart Failure v2.0 had improved sensitivity and specificity in comparison to the H2FPEF and HFA-PEFF scores, but there was no difference in NPV or PPV in comparison to H2FPEF and lower NPV and PPV in comparison to HFA-PEFF. [Akerman et al. \(2023a\)](#) reported the same diagnostic test accuracy outcomes for the validation of EchoGo Heart Failure v1.0 in detecting HFpEF cases. Sensitivity and specificity were observed to exceed average reported data in the literature (sensitivity of 74% and specificity of 65%), used by study authors as a priori benchmark, with corresponding NPV and PPV values ([Table 7](#)).

Table 7: Diagnostic test accuracy results for EchoGo Heart Failure.

| Model/score | Sensitivity | Specificity | NPV | PPV |
|----------------------------------|------------------------------|------------------------------|-----------------------------|-----------------------------|
| EchoGo Heart Failure v2.0 | 77.4% (95% CI 74.6–79.6%) | 50.2% (95% CI 48.6–52.1%) | 81.6% (95% CI 73.6%–87.6%) | 67.3% (95% CI 59.6%–71.7%) |
| H2FPEF | 53.9% (95% CI 50.2–58.2%) | 12.8% (95% CI 11.8–13.9%) | 90.3% (95% CI 75.0–100.0%) | 73.6% (95% CI 64.9–79.3%) |
| HFA-PEFF | 63.2% (95% CI 58.3–68.0%) | 29.0% (95% CI 26.9–31.0%) | 98.5% (95% CI 94.7–100.0%) | 86.3% (95% CI 79.3–91.1%) |
| EchoGo Heart Failure v1.0 | (87.8%; 95% CI: 84.5%-90.9%) | (81.9%; 95% CI: 78.2%-85.6%) | 86.5% (95% CI: 83.0%-90.0%) | 83.6% (95% CI: 80.2%-87.0%) |

Abbreviations: CI: confidence interval; H2FPEF: Heavy, Hypertensive, Atrial Fibrillation, Pulmonary Hypertension, Elderly, Filling Pressure); HFA-PEFF: Heart Failure Association Pre-test assessment, Echocardiographic and Natriuretic Peptide Score, Functional Testing in Case of Uncertainty, and Final Etiology; NPV: negative predictive value; PPV: positive predictive value.

Evidence for Us2.ai

[Huang et al. \(2024a\)](#) and [Campbell et al. \(2025\)](#) report on the diagnostic accuracy of the Us2.ai technology in conjunction with handheld TTE ([Table 8](#)). In the study by Huang et al. (2024a) comparisons were drawn between AI-

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assisted novice-performed handheld TTE and standard sonographer-performed cart-based TTE as the reference standard. In the study by Campbell et al. (2025), comparisons were drawn between AI-assisted sonographer-performed handheld TTE and manual sonographer-performed cart-based TTE as the reference standard. The results are mixed, with higher specificity and NPV values, and lower sensitivity and PPV values observed for the AI technology, particularly in the study by Campbell et al. (2025).

Table 8: Diagnostic test accuracy results for Us2.ai-assisted handheld TTE.

| Study | Sensitivity | Specificity | NPV | PPV |
|----------------------|-------------|-------------|-----|-----|
| Huang et al. 2024a | 85% | 91% | 94% | 79% |
| Campbell et al. 2025 | 61% | 95% | 97% | 50% |

Abbreviations: NPV: negative predictive value; PPV: positive predictive value.

Evidence for EchoConfidence

The FEATHER study interim analysis reported on diagnostic test accuracy of EchoConfidence for detection of HFrEF and HFpEF with human measurements as the reference standard. Results were mixed, with a moderately high FN rate reported for HFrEF ([Table 9](#)).

Table 9: Diagnostic test accuracy outcomes (FEATHER).

| Condition | FP Rate | FN Rate | NPV | PPV | Specificity |
|-----------|---------|---------|-------|-------|---------------------------|
| HFrEF | 2.83% | 41.2% | 90.8% | 83.3% | 91.1% (95% CI 88.6-93.5%) |
| HFpEF | 7.23% | 15.3% | 95.8% | 75.8% | 95.2% (95% CI 93.2-97.2%) |

Abbreviations: CI: confidence interval; FP: false positive; FN: false negative; HFpEF: heart failure with preserved ejection fraction; HFrEF: heart failure with reduced ejection fraction; NPV: negative predictive value; PPV: positive predictive value.

Using human measurements as the reference standard, specificity of EchoConfidence in detecting HF of any subtype was 83.1% (95% CI 78.8-87.4%). Specificity to detect HFmrEF was 90.0% (95% CI 87.2-92.8%).

5.2.2 Detection and classification of HF

This section refers to outcomes measuring a technology's ability to detect echocardiographic findings which are indicative of HF, including differentiation between types of HF (e.g. HFrEF and HFpEF). This can be evaluated using the area under the curve (AUC) of the receiver operating characteristic (ROC) curve, ([Table 6](#)). This outcome is reported across 6 studies, across 2 technologies:

- EchoGo Heart Failure: n=2 studies
- Us2.ai: n=4 studies

Evidence for EchoGo Heart Failure

Akerman et al. (2025a) compared the ability to detect HFpEF of EchoGo Heart Failure v2.0 with that of an existing clinical scoring tool (H2FPEF). There was no significant difference between the two, with a mean difference in AUROC of 0.01 (95% CI -0.043-0.064, p=0.710); EchoGo Heart Failure v2.0 AUROC of 0.798 (95.0% CI: 0.756-0.799 vs H2FPEF AUROC of 0.788 (95.0% CI: 0.745-0.789).

Akerman et al. (2023a) assessed EchoGo Heart Failure v1.0's ability to aid detection of HFpEF in a cohort of 2,971 patients with diagnosed HF (training set) and 646 patients with diagnosed HF (validation set). The AUROC was 0.97 (95% CI: 0.96-0.97) in the training set and 0.95 (95% CI: 0.93-0.96) in the validation set. This indicates good performance in aiding detection of HFpEF.

Evidence for Us2.ai

[Myhre et al. \(2024b\)](#) assessed Us2.ai's ability to discriminate between patients with HF from those without, as well as between HFrEF and non-HF patients, and between HFpEF and non-HF patients, using automated

measurement of GLS. Validation was performed in two cohorts, where the AUC related to the ability to identify region wall-motion abnormalities.

In the first cohort the following AUC values were reported:

- AUC=0.89 (95%CI 0.87–0.89, identifying HF from non-HF)
- AUC=0.98 (95%CI 0.97–0.98, identifying HFrEF from non-HF)
- AUC=0.82 (95%CI 0.80–0.82, identifying HFpEF from non-HF)

In the second cohort the average AUC was 0.80 (CIs not reported).

[Tromp et al. \(2022b\)](#) assessed Us2.ai's ability to automate 3 common echocardiographic measures which may be indicative of HFpEF: e' lateral wave velocity <10cm/s, LVEF <40% and E/e' ratio ≥13, using the AUC of ROC. Internal validation was conducted using one dataset (ATTRaCT) and external validation was conducted in 3 cohorts (HEART, Taiwan cohort, EchoNet Dynamic).

The results suggest good performance in both internal and external datasets, with high AUC values reported across all cohorts ([Table 10](#)).

Table 10: AUC values from study by Tromp et al. (2022b).

| Cohort | LVEF <40% | e' lateral wave velocity <10cm/s | E/e' ratio |
|-----------------|-----------------------------|----------------------------------|----------------------|
| ATTRaCT | AUC 0.96 (95% CI 0.92–0.99) | AUC 0.95 (0.88–0.99) | AUC 0.96 (0.92–0.99) |
| HEART | AUC 0.91 (95% CI 0.88–0.94) | AUC 0.88 (0.84–0.92) | AUC 0.91 (0.88–0.94) |
| EchoNet Dynamic | AUC 0.92 (0.91–0.94) | NR | NR |
| Taiwan | AUC 0.90 (0.89–0.90) | AUC 0.94 (0.93–0.95) | AUC 0.91 (0.89–0.93) |

Abbreviations: AUC: area under curve; CI: confidence interval.

Huang et al. (2024a) reported the AUC for novice-operated handheld TTE assisted by Us2.ai in detecting LVEF <50% as 0.880 (95% CI 0.802-0.958).

Campbell et al. (2025) reported the AUROC for handheld TTE assisted by Us2.ai in detecting LVEF ≤40% as 0.96 (95% CI 0.94-0.98). These results

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suggest that the Us2.ai technology has good performance detecting left ventricular dysfunction that is indicative of HF.

5.2.3 Interchangeability between human and AI measurements

Interchangeability between human and AI measurements refers to the extent to which the AI model's measurements match measurements made by human healthcare professionals (HCPs). It is measured using the individual equivalence coefficient (IEC, see [Table 6](#)). This outcome is reported across 2 studies, both of which relate to the Us2.ai technology.

Evidence for Us2.ai

Campbell et al. (2025) report the IEC between Us2.ai-automated analysis and human analysis. The IEC between handheld transthoracic echocardiogram (TTE) Us2.ai analysis with two human sonographers' analysis of cart-based TTE was -0.40 (95% CI -0.60 to -0.16). IEC between cart-based TTE Us2.ai-automated analysis with two human sonographers' analysis of cart-based was -0.39 (95% CI -0.60 to -0.12). IEC between Us2.ai-automated analysis of handheld TTE with two human sonographers' analysis of handheld TTE was -0.34 (95% CI -0.53 to -0.11). The negative IEC values reported suggest less variability between AI-automated analysis and human analysis relative to the variability between two measurements made by humans. Tromp et al. (2022a) reported mean IEC between AI-assisted TTE and manual TTE across several parameters, from -0.04 (left ventricular posterior wall diameter) to -0.81 (left ventricular diastolic volume). All are below 0, indicating low levels of variability between AI-automated analysis and human analysis, relative to variability between human measurements.

5.2.4 Correlation between human and AI measurements

Correlation between human and AI measurements is a measure of how closely the two measurements align. It differs from agreement, reported in the subsequent section, as it is a simple measure of the linear relationship between two measurements, and has no bearing on whether they are consistent with each other.

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This outcome is reported across 4 studies:

- Us2.ai: n=1 study
- Ligence Heart: n=1 study
- EchoConfidence: n=2 studies

Evidence for Us2.ai

Tromp et al. (2022b) retrospectively assessed the correlation between automated and manual measurements for 3 clinically relevant parameters in aiding HF diagnosis, using Pearson's r correlation coefficient: left ventricular ejection fraction (LVEF), early diastolic velocity of the mitral annulus (e' lateral), and E/e' ratio which is used to estimate the left ventricular (LV) filling pressure. Each clinical parameter was assessed for correlation using an internal dataset (ATTRaCT) and then assessed using 3 external datasets from Canada (HEART), the USA (EchoNet Dynamic) and Taiwan. Overall, the results suggest moderate correlation between automated and manual measurements across all 4 datasets ([Table 11](#)).

Table 11: Correlation results from Tromp et al. (2022b).

| Cohort | LVEF | e' lateral | E/e' ratio |
|-----------------|------------------------|-------------------------|--------------------|
| ATTRaCT | $r = 0.89$ (MAE: 5.5%) | $r=0.92$ (MAE 0.7cm/s) | $r=0.90$ (MAE 1.7) |
| HEART | $r=0.75$ (MAE 8.6%) | $r= 0.79$ (MAE 1.2cm/s) | $r=0.75$ (MAE 2.2) |
| EchoNet Dynamic | $r=0.76$ (MAE 6.5%) | NR | NR |
| Taiwan cohort | $r=0.75$ (MAE 10.2%) | $r=0.87$ (MAE 1.6cm/s) | $r=0.79$ (MAE 1.8) |

Abbreviations: LVEF: left ventricular ejection fraction; MAE: mean absolute error.

Evidence for Ligence Heart

[Karužas et al. \(2025\)](#) reported mixed results with respect to correlation between AI and manual measurements. Strong correlation was observed in some parameters (left atrium volume index: $r=0.92$, E velocity: $r=0.93$, E/A

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ratio $r=0.94$). Correlation for other parameters ranged from 0.55 (for maximum tricuspid regurgitant velocity) to 0.89 (for E/Le' ratio (mitral velocity).

[Mołek-Dziadosz et al. \(2025\)](#) compared single-loop AI analysis and multi-loop AI analysis with human expert measurements. Multi-loop AI analysis was observed to have strong correlation with the two human experts ($r = 0.88$ and $r = 0.9$, respectively). Single-loop AI analysis also demonstrated strong agreement with both human experts ($r = 0.89$ and $r = 0.92$, respectively).

Evidence for EchoConfidence

The results presented here are interim results for the RECARDIO-TOX and ACE-HEART studies. In the RECARDIO-TOX study, the authors report moderate correlation coefficients between AI and human measurements for LVEF and GLS:

- LVEF: $r=0.74$
- GLS: $r=0.72$

In the ACE-HEART study, EchoConfidence (v.1.1) measurements were assessed for correlation with a blinded human expert, and with the participants' original clinical reports, for both LVEF and GLS. Moderate correlation was observed across all comparisons, with a lower correlation observed between blinded expert and AI measurements for GLS ([Table 12](#)).

Table 12: Correlation results between EchoConfidence and human measurements.

| Comparison | LVEF (Pearson's r) | GLS (Pearson's r) |
|---------------------------------------|---------------------|-------------------------|
| Blinded expert versus AI | 0.739 (0.630-0.819) | $r=0.584$ (0.429-0.706) |
| Blinded expert versus clinical report | 0.773 (0.676-0.844) | $r=0.615$ (0.440-0.745) |
| AI versus clinical report: | 0.779 (0.687-0.846) | $r=0.689$ (0.544-0.794) |

Abbreviations: AI: artificial intelligence; GLS: global longitudinal strain; LVEF: left ventricular ejection fraction.

5.2.5 Agreement between human and AI measurements

Agreement refers to the concordance between measurements produced by humans (HCPs) versus those produced by AI. It can be measured using the intraclass correlation coefficient (ICC), the level of agreement (LoA), the mean absolute difference (MAD) ([Table 6](#)) and the mean difference (MD). This outcome is reported across 9 studies, for 2 of the technologies:

- Us2.ai: n=7 studies
- Ligence Heart: n=2 studies

Evidence for Us2.ai

In post-hoc analyses, Campbell et al. (2025) reported the agreement between human and AI measurements using the MD between AI-automated and human measurements of LVEF. For AI-automated LVEF vs human core laboratory analyses for handheld scans, MD was 5.2% (95% CI 4.2 - 6.2; p<0.0001). For AI-automated LVEF and human core laboratory analyses for cart scans, MD was 4.2% (95% CI 3.4 - 5.0); (p<0.0001). Both MD values were smaller than the difference between human clinical assessment and human core laboratory measurements of cart-scans (6.5%, 95% CI 5.7, 7.3; p<0.0001).

[Hirata et al. \(2024\)](#) used the ICC to assess the agreement between AI and human measurements. The ICC values ranged from 0.48 (95% CI 0.09-0.75) for deceleration time (DecT) to 1.00 (95% CI 0.99-1.00) for aortic valve maximum velocity (AoV V_{MAX}). This indicates variability in levels of agreement across the tested parameters.

[Lafitte et al. \(2025\)](#) report the ICC values for AI measurements versus human measurements, which ranged from 0.35 (95% CI 0.26-0.43) for DecT, to 0.97 (95% CI 0.95-0.98) for mitral valve E wave velocity (MV-E). This indicates a wide range of agreement between AI and human measurements. The authors

also report a global MD of -4% (SD 15%) between AI and human measurements.

[Myhre et al. \(2024a\)](#) assessed the ICC between AI-automated measurements and the mean of human operator measurements. The ICC between AI-automated and mean operator measurements for left ventricular end-diastolic volumes (LVEDV) (0.941 (95% CI 0.913–0.959)) was higher than that between two human operators (0.847 (95% CI 0.777–0.896)), and similar to that of two measurements by the same reader (0.944 (95% CI 0.918–0.962)). For left ventricular end-systolic volumes (LVESV) measurements, ICC was highest for that of two measurements by the same reader (0.947 (95% CI 0.922–0.964)), and lowest for AI-automated versus mean operator measurements (0.600 (95% CI 0.415–0.726)). For LVEF, the ICC between AI-automated and mean operator measurements (0.818 (95% CI 0.734–0.875)) was similar to the ICC between two operators (0.812 (95% CI 0.725–0.871)). This suggests that the AI model showed high agreement with human measurements, except for LVESV measurements where agreement was slightly lower. Myhre et al. (2024b) reported the agreement between automated and manual measurements of GLS using RMSE (2.6), suggesting good agreement between both methods.

Tromp et al. (2022a) reported that the ICC between automated and human measurements was higher than amongst human experts, although this was an exploratory analysis. Both within subject coefficient variance (wCV) and RMSE were, however, higher for automated versus human measurements. The LoA ranged from 0.05 ± 0.39 for tricuspid regurgitation maximum velocity (TR V_{MAX}) to 11.12 ± 88.10 for DecT, demonstrating mixed results with respect to agreement calculated for different parameters.

Sakamoto et al. (2025) report that the ICC between AI and sonographers were all >0.8 across 301 measured parameters (all p-values <0.001) which suggests good concordance between initial measurements made by AI and final report values.

Evidence for Ligence Heart

Mołek-Dziadosz et al. (2025) reported moderate concordance of multi-loop AI analysis with human experts for categorization of LVEF into subgroups, Cohen κ values 0.74 and 0.76 for two human experts respectively. Karuzas et al. (2025) reported mixed results with respect to lower and upper LoA across various echocardiographic parameters, indicating some variation in level of agreement with manual measurements. Lower and upper LoA values were noticeably wide for DecT (-62.28 to 73.27).

5.2.6 Clinical outcomes

Clinical outcomes are reported in 4 studies, 3 of which relate to the EchoGo Heart Failure technology. The remaining study relates to EchoConfidence. These studies investigated clinical endpoints being met by those assessed with AI, to determine the usefulness of the AI technologies in the HF clinical pathway. Outcomes included HF-related hospitalisations and mortality.

Evidence for EchoGo Heart Failure

Akerman et al. (2025a) reported on the prognostic association between AI-assisted analysis and a composite endpoint of HF hospitalisations or death. In the study cohort, at a median follow-up of 25.0 (IQR: 15.0-35.0) months, there were 45 HF hospitalisations (10.3%) and 61 deaths (14.2%). The authors stated that a diagnostic positive result indicated by EchoGo Heart Failure was associated with a two-fold risk of the composite endpoint. However, a similar increase in risk was also observed for 'positive' results from the manual clinical scoring tool comparators. [Cassianni et al. \(2024\)](#) also reported on the risk of HF hospitalisation and death in the study cohort of 1284 patients followed for a median of 3.4 (IQR: 1.7-6.5) years (n=252 and n=540, respectively). Again, the increased risk in the adverse clinical endpoints were associated 'positive' outputs from EchoGo Heart Failure and both clinical scoring tool comparators. Akerman et al. (2023a) observed that during follow-up (median: 2.3 years), 444 (34.6%) patients died. Mortality was observed to be higher in patients classified as HFpEF by AI [HR: 1.9 (95% CI: 1.5-2.4) in comparison to those classified without having HFpEF by AI.

The results reported from these studies suggest EchoGo Heart Failure may be useful in aiding detection of HF, but its benefit over other methods (such as existing manual clinical scoring tools) is unclear, with respect to clinical outcomes such as HF-related hospitalisation and HF-related death.

Evidence for EchoConfidence

Interim results from the FEATHER study report freedom from death or HF hospitalization, and compared differences in survival curves for those with HF diagnoses (HF, HFrEF, HFmrEF or HFpEF) to those without HF diagnoses, as classified by the AI model and 2 human comparators ([Table 13](#)).

Table 13: Differences in survival curves between HF cases and non-cases (FEATHER).

| Comparison | Human 1 | Human 2 | EchoConfidence |
|----------------------------------|---------|---------|----------------|
| HF and no HF | p=0.225 | p<0.05 | p=0.078 |
| HFrEF and no HF | p<0.05 | p<0.01 | p<0.001 |
| HFmrEF or HFrEF and no HF | p<0.05 | p<0.01 | p<0.01 |
| HFpEF and no HF | p=0.737 | p=0.143 | p=0.846 |

Abbreviations: HF: heart failure; HFpEF: heart failure with preserved ejection fraction; HFmrEF: heart failure with mildly reduced ejection fraction; HFrEF: heart failure with reduced ejection fraction.

There is limited information reported beyond p values, so it is not possible to interpret and draw conclusions from this data.

5.2.7 Yield of measurements

The yield of AI models, with respect to generating or automating measurements, is reported across 4 studies, of which 3 studies are for Us2.ai (Huang et al. 2024a, Myhre et al. 2024b, Tromp et al. 2022a) and one study for Ligence Heart (Karužas et al. 2025).

Evidence for Us2.ai

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In the study by Huang et al. (2024a), yield was defined as the proportion of images acquired by novices using Us2.ai-assisted handheld TTE where an LVEF measurement was successfully generated, using the number of standard cart-based TTEs with cardiologist-reported LVEFs as the denominator. Yield was reported to be 96%.

Myhre et al. (2024b) defined yield as the proportion of GLS measurements generated by Us2.ai-assisted TTE, in comparison to the original manual methods of measurement in 3 retrospective datasets. Yield was 89% in the Taiwan cohort, 96% in the PROMIS-HFpEF cohort, and 98% in the HMC-QU-MI cohort.

In the study by Tromp et al. (2022a), average yield proportion using Us2.ai was 0.88 (range 0.69-0.97) across 23 echocardiographic parameters, in comparison to the average measurements yielded by 3 humans.

Evidence for Ligence Heart

Karužas et al. (2025) reported that Ligence Heart achieved a perfect yield (1.0) for all Doppler parameters relevant to diastolic function. Yield of left atrial area measurements ranged from 0.82–0.95.

5.2.8 Impact on procedure time

Impact on reporting, scanning or analysis time is reported across 3 studies, 2 for Us2.ai and 1 study for EchoConfidence.

Evidence for Us2.ai

In the study by Hirata et al. (2024), it was reported that using Us2.ai-assistance achieved time savings in making echocardiographic measurements (mean manual measurement time of 325 ± 94 seconds versus mean AI measurement time of 159 ± 66 seconds, $p<0.01$). Report creation time was also reportedly shorter when using AI (mean manual report creation time of 429 ± 128 s versus mean AI report creation time of 71 ± 39 s, $p<0.01$). The mean time for measurement and report creation per case reduced by 524s (70%) with AI assistance. This was a small single-centre, single-operator study with just 23 participants, based in Japan.

In the study by Sakamoto et al. (2025), examination time per patient was reported to be shorter with AI assistance (Us2.ai) (13.0 ± 3.5 minutes versus 14.3 ± 4.2 minutes without AI, $p<0.001$). Number of examinations per day was also reported to be greater with AI assistance (16.7 ± 2.5) versus without AI (14.1 ± 2.5 , $p=0.003$). This study is reported in a pre-print publication, and so it must be noted that these findings have not been subject to peer review. Only the mean values were reported so it was not possible for the EAG to assess the data in detail. Reports of significant differences should be interpreted with caution.

Evidence for EchoConfidence

In the FEATHER study (Almeida et al.: unpublished data 2025), it was reported that EchoConfidence reduced mean time for analysis of echocardiographic parameters (3.2 ± 0.4 seconds) versus 2 humans (553 ± 44 seconds and 587 ± 64 seconds). Only the mean values were reported so it was not possible for the EAG to assess the data in detail.

5.2.9 Impact on echocardiography setting and operators

Clinical experts highlighted the potential for the AI technologies to support a shift of echocardiography out of secondary care, into primary or community settings. As outlined in Section 4.1, studies from a community setting were only included by the EAG if conducted in the UK (as community settings were not formally included in the published scope). The EAG has summarised any evidence of AI-assisted echocardiography in community care, or evidence relating to a change in setting or operator as a result of implementation of AI-assisted echocardiography.

Of the 17 key studies identified by the EAG, 1 included data from a UK community care setting (Almeida et al.: unpublished data 2025, EchoConfidence). However, this was an interim analysis. The company states further data will be reported in December 2025 (see Section 8.1). Results from this study relating to the technology's performance have been discussed in previous sections. The interim results reported indicate there may be potential for EchoConfidence to be safely implemented in community care, but

evidence to demonstrate its impact on procedure time and the type of operator is limited.

Two studies reported data which may be considered relevant to the use of echocardiography in community settings, but the studies themselves were in secondary care settings. The use of AI-assisted (Us2.ai) handheld echocardiography, as opposed to cart-based standard echocardiography, is reported in the study by Campbell et al. (2025). Huang et al. (2024a) compared the diagnostic accuracy of AI-assisted (Us2.ai) echocardiography performed by 'novice' operators, compared to standard expert-led echocardiography. Results from these studies have been discussed in previous sections. Evidence from studies demonstrate there is potential for the AI technologies to be successfully integrated with handheld TTE. The feasibility of using AI to assist to automate measurements on handheld systems and automating measurements to assist novice operators may demonstrate potential for these technologies to be used in community settings.

No studies reported in conference proceedings identified by the EAG were set in community settings in the UK ([Appendix C](#)). Ongoing trials that were identified as relevant to supporting the shifting of TTE to community settings are discussed in Section [8.1](#).

5.3 Adverse events and clinical risk

5.3.1 Adverse events

A search of the MAUDE database and MHRA (field safety notices/device safety information) did not identify any adverse events or safety concerns relating to any of the included technologies. Adverse events were not reported in any of the studies included in the clinical evidence review. This may reflect the largely retrospective nature of the evidence base.

5.3.2 Clinical risk

Artificial intelligence (AI) models such as those used by the technologies in the scope of this assessment typically undergo the following stages of development:

- 1) Training: teaching the model how to perform its intended function by using a training population
- 2) Internal validation: testing if the model works as intended on the same type of population it was trained on
- 3) External validation: testing if the model works as intended on a different type of population to that it was trained on

During the scoping phase of this assessment, SCMs and clinical experts highlighted that if AI models have not been validated on a UK population, or a cohort similar to that of the UK population, this may limit its suitability for use in UK settings (i.e. the ‘target’ population in this assessment) and pose a clinical risk. Therefore, the demographics (age, sex, ethnicity, key comorbidities) of external validation cohorts (either from published studies or from information submitted by companies to NICE) have been extracted by the EAG and presented alongside the demographics of HF admissions in the UK ([National Heart Failure Audit, 2025](#)) ([Table 14](#)). While there is an argument to suggest models may be suitable for use in the target population if the internal validation “test” population during a train-test split was similar to that target population, the likelihood of that occurring is very low. Therefore, the EAG have focused on comparison between the external validation populations to the target population in question. The EAG notes that EchoConfidence was validated on a UK population as part of its CE marking process. Inconsistency between the format of demographic data reported between studies/datasets and the reference data used from the UK NHFA audit makes it difficult to draw conclusions about the suitability of the remaining AI technologies for use in the UK population. The EAG believes there is a lack of evidence to determine whether EchoGo Heart Failure,

US2.ai or Ligence Heart have been adequately externally validated in a UK population, or a population with demographics close to that of UK population.

Table 14: Comparison between demographics of external validation cohorts and UK HF cohort.

| Technology (source) | Age | Sex | Ethnicity | Demographics |
|---|---|---|--|---|
| EchoGo Heart Failure v1.0 (Akerman 2023a) | <u>Controls</u> Mean age: 64.6±17.4 years <u>Cases</u> Mean age: 72.4±13.3 years | <u>Controls</u> 51.1% female <u>Cases</u> 52.2% female | <u>Controls</u> <ul style="list-style-type: none"> 19.9% African American 60.0% White, non-Hispanic 20.1% Other <u>Cases</u> <ul style="list-style-type: none"> 19.2% African American 61.8% White, non-Hispanic 19.0% Other | <u>Controls</u> <ul style="list-style-type: none"> 35.8% hypertension 12.5% AF 7.9% CAD 11.6% DM <u>Cases</u> <ul style="list-style-type: none"> 78.8% hypertension 35.0% AF 33.6% CAD 39.6% DM |
| EchoGo Heart Failure v2.0 (Akerman 2025a) | <u>Controls</u> Mean age: 75.0 ± 13.0 years <u>Cases</u> Mean age: 74.2 ± 12.1 years | <u>Controls</u> 55.1% female <u>Cases</u> 54.2% female | <u>Controls</u> <ul style="list-style-type: none"> 78.1% White 6.6% African American 5.5% Asian 9.0% other <u>Cases</u> <ul style="list-style-type: none"> 68.3% White 18.3% African American 15.8% Asian 7.1% other | <u>Controls</u> <ul style="list-style-type: none"> 87.1% hypertension 45.0% AF 41.7% diabetes 34.2% CAD 17.5% COPD <u>Cases</u> <ul style="list-style-type: none"> 69.5% hypertension 18.85 AF 21.5% diabetes 19.5% CAD 5.9% COPD |

| | | | | |
|--|---|---|---|---|
| Us2.ai Tromp (2022b) | <u>HEART Cohort</u> Mean age: 66 ± 12 years <u>Taiwan Cohort</u> Mean age: 66 ± 15 years | <u>HEART Cohort</u> 43% female <u>Taiwan Cohort</u> 48% female | <u>HEART Cohort</u> <ul style="list-style-type: none"> • 2% Aboriginal • 1% African American • 91% Caucasian • 5% Asian • 1% Other <u>Taiwan Cohort</u> <ul style="list-style-type: none"> • 100% Asian | <u>HEART Cohort</u> <ul style="list-style-type: none"> • 32% diabetes • 34% CAD • 31% AF • 14% COPD <u>Taiwan Cohort</u> <ul style="list-style-type: none"> • 30% diabetes • 30% CAD • 16% AF • 8% COPD |
| Ligence Heart | No validation data identified. | No validation data identified. | No validation data identified. | No validation data identified. |
| EchoConfidence (provided by company in RFE) | Age split: <ul style="list-style-type: none"> • 5% 18-40 years • 42% 41-60 years • 53% 61-90 years | 50% female | <ul style="list-style-type: none"> • 47% White • 13% Black • 12% Hispanic/Asian • 28% Other | NR |
| NICOR NHFA HF admissions data | <u>Mean age: 77.5 years</u> | <u>44% female</u> | <u>All data/excluding missing data:</u> <ul style="list-style-type: none"> • 52%/86% White/White British • 4%/6% Asian/Asian British • 2%/3% Black • 3%/5% Other/Mixed • 39% Unknown | <u>HFrEF</u> <ul style="list-style-type: none"> • Hypertension: 55.16% • AF 39.13% • IHD 38.48% • Diabetes 35.73% • Valve disease 27.65% • COPD 15.05% • Asthma 10.44% <u>Non-HFrEF</u> |

| | | | | |
|--|--|--|--|---|
| | | | | <ul style="list-style-type: none"> • <i>Hypertension</i>: 69.94% • <i>AF</i> 51.57% • <i>IHD</i> 31.94% • <i>Diabetes</i> 37.41% • <i>Valve disease</i> 35.82% • <i>COPD</i> 19.24% • <i>Asthma</i> 11.55% |
|--|--|--|--|---|

Abbreviations: AF: atrial fibrillation; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disorder; DM: diabetes mellitus; HF: heart failure; HFrEF: Heart Failure with Reduced Ejection Fraction; NHFA: National Heart Failure Audit; NICOR: NR: not reported; RFE: request for evidence.

Additional clinical risks identified by clinical experts, SCMs and professional organisations are:

- Potential over-reliance on AI measurements and automation resulting in inaccurate results
- Some AI technologies use just one image to assess ejection fraction, which could result in other pathology being missed (that would have otherwise been detected on additional images)
- Where AI is being used to detect one cardiac diagnosis (e.g. HFpEF), this raises the possibility of a missed diagnosis due to other cardiac pathologies

5.4 Clinical evidence summary and interpretation

In this section, key findings from the evidence are summarised narratively for each technology. It was not appropriate to undertake meta-analysis of outcomes reported across the evidence base for any of the technologies in this EVA due to the clinical and methodological heterogeneity observed between studies. Evidence gaps are discussed in Section 8.

EchoGo Heart Failure

The EAG considers there to be limited evidence of moderate quality to support the use of EchoGo Heart Failure in the diagnosis and monitoring of heart failure (HF). The 3 studies identified for this technology were concerned with comparing the performance of EchoGo Heart Failure (v1.0 and v2.0) in aiding detection of HFpEF using a single TTE video clip. There was evidence that the AI technology had good performance in comparison to two validated multiparametric manual clinical scoring tools, with respect to sensitivity and specificity. However, there was no observed difference in NPV or PPV in comparison to H2FPEF and lower NPV and PPV in comparison to HFA-PEFF. Additionally, there was no significant difference in AUROC between EchoGo Heart Failure v2.0 and existing clinical scoring tools with respect to classifying HFpEF. The impact of implementing EchoGo Heart Failure on clinical outcomes and health-related quality of life downstream of receiving AI-

assisted TTE as part of the HF diagnosis or monitoring pathway is unclear. There is limited evidence to suggest that those receiving a ‘positive’ output from AI-assisted TTE are at an increased risk of developing adverse events linked with HF, such as hospitalisation or death. However, an increase in risk was also observed following ‘positive’ results from the manual clinical scoring tools. Overall, there is a lack of evidence demonstrating clinical benefit to patients following TTE assisted by EchoGo Heart Failure. There is also a lack of evidence to suggest system benefits such as increased echocardiography capacity or shifting care from secondary to community care settings.

Us2.ai

The EAG considers there to be good evidence of moderate quality for Us2.ai. This technology had the largest volume of evidence, relative to other technologies in scope, and was the only technology to have an associated RCT (reported in a non-peer reviewed pre-print) and published evidence relating to potential system benefits such as time saved during TTE appointments.

Evidence of Us2.ai’s diagnostic accuracy and performance in comparison to humans was largely observed to be good. However, the outcome measures and comparisons reported across the evidence base were heterogeneous, which makes it difficult to synthesize consistent overall findings. There was evidence from a UK setting to suggest that AI-assisted handheld TTE had high specificity and NPV values in comparison to cart-based standard TTE, but specificity and PPV values were observed to be lower. The technology’s ability to discriminate cases of HF from controls without HF was observed to be good, with high AUC values observed for both HFrEF and HFpEF. Good AUC values were also observed with respect to Us2.ai’s ability to detect echocardiographic parameter measurements indicative of HF. Good levels of agreement between AI-automated LVEF measurements and human-generated LVEF measurements were also observed, but other parameters showed lower levels of agreement.

There was some evidence of potential increases in appointment efficiency and throughput by shortening the TTE procedure time (through AI-automation of measurements and report creation), but this was of limited generalisability to the NHS and of low quality. It should also be noted that findings have not been subjected to peer-review.

There was very limited evidence to suggest that Us2.ai may be effective in assisting handheld TTE analysis performed by novices (in comparison to standard expert-performed TTE) and performed by trained sonographers (in comparison to standard TTE without AI assistance. Again, this was of limited generalisability to the NHS.

Ligence Heart

Evidence for Ligence Heart was limited and of moderate quality, with 2 studies identified as relevant to the decision problem. Mixed results were reported with respect to correlation between AI and manual measurements, but agreement was reported to be high for some measurements such as E velocity and E/A ratio. Agreement varied for other measurements. There was a general lack of evidence of downstream impacts on health-related outcomes and quality of life as a result of introducing Ligence Heart to the clinical pathway.

EchoConfidence

Evidence for EchoConfidence was very limited and of uncertain quality. No published evidence was identified for this technology and all data included as part of the clinical evidence review was provided by the company (3 studies). Two studies were reports of interim analyses of ongoing studies. The evidence included had limited relevance to the general acute or chronic HF diagnostic or monitoring pathway, with 2 of the 3 studies focusing on cancer therapy-induced cardiotoxicity (which may lead to HF). One study was based in the UK and did report time savings following introduction of EchoConfidence into the TTE procedure, in comparison to manual TTE. However, there was a lack of detail to assess the significance of these results.

The EAG consulted with clinical experts, many of whom suggested that the main benefits to be expected from introducing AI-assisted echocardiography technologies would be a reduction in examination times and report generation, leading to increased capacity for examinations and the subsequent alleviation of long waiting lists ([Appendix A](#)). However, in the current evidence base, there was little evidence to demonstrate these potential improvements in the heart failure patient pathway. Where studies did report on the impact on examination time or report creation (n=3), all had notable risks of potential bias as described in Section [5.1](#) and [5.2.8](#) (Sakamoto et al. 2025, Hirata et al. 2024, Almeida et al.: unpublished data 2025 (FEATHER)). Additionally, one clinical expert commented that AI-assisted echocardiography could facilitate acquisition of echocardiograms in community or ‘mobile’ settings or by ‘trained’ novice operators. There is a small amount of indirect evidence to support this, discussed in Section [5.2.9](#).

Across all the technologies, there is potential that with further evidence generation, the unmet need described in the decision problem may be addressed. However, there are currently considerable gaps to be addressed which are discussed in Section [8.2](#).

6. Economic evidence

6.1 Existing economic evidence

The search strategy outlined in Section 4.1 was sufficiently broad to identify any relevant economic studies. Any additional studies provided by the companies were considered if they were relevant to the scope. The EAG did not identify any relevant economic studies.

Relevant economic models

The EAG conducted a search on the NICE clinical guidelines to identify any economic modelling on HF. A total of three economic models from two NICE guidelines were identified: (i) Chronic heart failure in adults: diagnosis and management (NG106) [2018](#) and [2025](#) and (ii) Acute heart failure: diagnosis

and management (CG187). The EAG found that the NICE NG106 2018 model and CG187 model were relevant to the scope.

The [2018 NICE guidance NG106](#) economic analysis was performed to identify the natriuretic peptide testing (NT-proBNP) cut-off where it would be the most cost-effective for referral from primary care for echocardiography and specialist clinical assessment. The model population was patients presenting with HF symptoms in primary care and tested for their NT-proBNP levels. The model consisted of a decision tree attached to Markov models. In the decision tree, patients were separated into 5 groups based on the diagnostic accuracy outcomes and NT-proBNP test results: (i) true positive, NT-proBNP $>400\text{pg/ml}$, (ii) true positive, NT-proBNP $<400\text{pg/ml}$, (iii) false negative, NT-proBNP $<400\text{pg/ml}$, (iv) false positive (NT-proBNP $>400\text{pg/ml}$ and NT-proBNP level $<400\text{pg/ml}$, and (v) true negative. A Markov model for each patient group was attached at the end of the decision tree, to estimate the costs and outcomes over a lifetime time horizon. The waiting time for echocardiography and clinical assessment following the NT-proBNP testing was modelled in the Markov model. A 2-week cycle length was used to allow for the estimation of costs and outcomes during the wait. While there were variations in health states included in each Markov model, they shared some common health states: “waiting for echocardiography and specialist clinical assessment” and “HF (treated)”. Additionally, hospitalisation during the waiting period was considered and patients were assumed to be diagnosed and treated during their hospital stay. For true negative cases, the Markov model incorporated a health state to simulate the wait for further testing, and the true conditions considered were chronic obstructive pulmonary disease, myocardial ischemia and obesity.

In [NICE guidance CG187](#), the economic analysis considered patients presenting to emergency department (ED) with acute dyspnoea and suspected acute heart failure, over 4 years’ time horizon. A decision tree combined with 11 Markov models was constructed to simulate 11 patient subgroups by condition (HF with or without left ventricular systolic dysfunction or no HF), diagnostic accuracy outcomes and subsequent treatment. A model

cycle length of 3 months was used, and the health states included were “suspected acute HF”, “chronic HF”, “readmission”, “usual health” and “dead”.

These NICE models were used to inform the EAG early economic model. In addition, a conceptual economic model provided by a company was considered in the early model development. As these AI technologies would be used as an adjunct to standard TTE and a specialist clinical assessment is required for HF diagnosis, it is unlikely that there would be any differences in diagnostic outcomes between technologies. It was therefore not necessary to consider false negative and false positive outcomes in this assessment.

6.2 Early economic model

An economic model was developed by the EAG, by making adaptations using the NICE models for this assessment. The model was used to assess the potential cost-effectiveness of AI-assisted echocardiography in HF diagnosis or monitoring, compared to standard care using standard TTE. A one-year time horizon was chosen as it would be sufficiently long to capture the impact of waiting time resulting from the reduced echocardiography time using AI technologies. While earlier diagnosis would improve downstream outcomes, this was not modelled in the EAG model given the significant uncertainties on the current waiting time. The perspective of NHS and Personal Social Services was undertaken. Costs were expressed in 2023/2024 prices and where applicable, costs were inflated using NHS Cost Inflation Index (NHSCI). The primary outcome in the economic analysis was quality-adjusted life years (QALYs), measured using utility values for each intervention. No discounting was applied.

6.2.1 Model structure

A Markov model with 2-week cycle length was developed in Microsoft Excel. This enabled the EAG to explore the impact of reduced waiting time driven by AI technologies by accounting for costs and outcomes of events (such as hospitalisation) during the wait. Following the assumption in NICE NG106, both sensitivity and specificity of standard TTE and specialist clinical assessment were 100%, suggesting that the model should consider only true

positive and true negative outcomes. Patients with undiagnosed HF or diagnosed HF waiting for monitoring (true positive) are assumed to progress to treatment with a reduced waiting time with AI technology. Patients without HF (true negative), may require subsequent investigations, however the EAG have assumed that a change in waiting time would not have a significant effect due to the complexity of pathways and the paucity of available evidence. Therefore, only true positive cases were considered in the EAG model.

Based on inputs from clinical experts on the clinical pathway, the EAG early model is illustrated in [Figure 2](#), where 4 health states were included:

- (i) Symptomatic on waiting list, where patients are waiting for echocardiography and clinical assessment or one stop diagnostic clinic,
- (ii) acute episode,
- (iii) treated HF and
- (iv) dead.

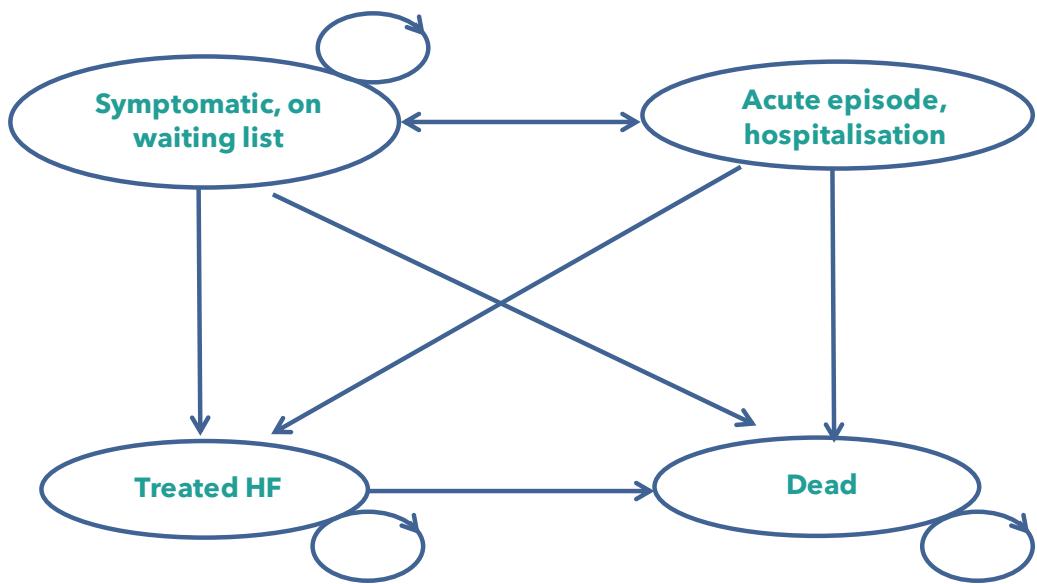


Figure 2: Schematic representation of the EAG early economic model.

During the scoping workshop, the EAG noted that some patients would require further magnetic resonance imaging (MRI) investigation after an echocardiogram. However, the proportion of patients needing additional tests and the associated waiting time based on clinical experts' feedback were highly variable. The EAG believe the availability of MRI facility in each site may contribute to this high variability. Additionally, the relevant evidence is lacking to indicate any differences in patients needing additional MRI between technologies in scope, and thus this was not considered in the EAG model.

As only true positive cases were accounted for in the model, all patients who entered the model would have diagnosed or undiagnosed HF. They would enter through "symptomatic on waiting list" or "acute episode" health states.

"Symptomatic on waiting list" state: Patients with HF symptoms on the waiting list for echocardiography and specialist clinical assessment or one stop diagnostic clinic may develop acute symptoms and require hospitalisation. These patients would move to the "acute episode" state.

"Acute episode" state: These patients would be hospitalised as they developed acute onset of symptoms. Some of these patients may not have a diagnosis prior to discharge and are subsequently placed on the waiting list.

These patients would transition to “Symptomatic on waiting list”. In addition, some patients on the waiting list may develop acute symptoms and become hospitalised.

“Treated HF” state: Patients would transition to the “treated HF” state when a diagnosis was confirmed, either during a hospital admission or at a clinic appointment. In this state, patients would receive treatment.

“Dead” state: This is an absorbing state, where patients from other health states may move to this state and remain in this state.

Costs and utilities were attached to each health state, to derive the total costs and QALYs over 1 year for each intervention. Compared to standard care, incremental costs and QALYs were calculated, alongside the estimated percentage of patients that met the target referral time (6 weeks).

6.2.2 Model assumptions

- Standard TTE plus specialist clinical assessment is 100% accurate, as described in Section [6.2.3](#) (NICE NG106 2018).
- The accuracy is assumed to be unaltered when using AI-assisted echocardiography, followed by a specialist clinical assessment.
- Patients remain in the “treated HF” state following diagnosis until they die or until the end of the 1-year time horizon. It is assumed that the treatment is sufficient to manage their condition and prevent any acute episodes resulting in hospital admission. In reality, some patients would require inpatient admission if they experience symptoms worsening. For model simplicity, transition from “treated HF” to “acute episode” is not explicitly captured due to the short time horizon.
- The model assumes a proportion of patients would attend a one stop diagnostic clinic, where they receive echocardiography and specialist clinical review in one appointment. The cost of a one stop diagnostic clinic is assumed to be the same as the combined costs of an

echocardiography appointment and a separate outpatient specialist clinic visit.

- For model simplicity, all patients who developed acute symptoms would enter through an ED and subsequently be hospitalised. In reality, patients could be admitted through a number of different routes including GP, community HF teams or other clinics.

6.2.3 Clinical parameters

Patient characteristics: The UK National Institute for Cardiovascular Outcomes Research (NICOR) reports nationwide data on adults admitted to hospitals in England and Wales with a primary diagnosis of HF. In the most recent [National Heart Failure Audit Data \(NHFA\) 2025](#) annual report (data up to 2023/24) approximately 49% of patients admitted had HFrEF, the average age at first presentation was 77.5 years, and 56.1% of patients were male.

Proportion of acute episodes: An observational study using the Clinical Practice Research Datalink (CPRD) between 2010 and 2013, found 79.2% had HF symptoms first recorded during a hospital admission ([Bottle et al., 2017](#)). This was used to represent those first entering the model through “acute episode” state.

Proportion of inpatients that were discharged without a HF diagnosis: The model assumes that a proportion of inpatients are discharged without a HF diagnosis. This proportion was obtained from clinical experts’ feedback and the [2018 National Confidential Enquiry into Patient Outcome and Death \(NCEPOD\) report](#). The NCEPOD report found that 44.2% patients received echocardiography during their hospital stay. The estimated proportion ranged between 10% to 55.8%, thus giving an average of 32.9%. However, the NICE guideline recommends that all inpatients should be diagnosed before discharged, and thus a sensitivity analysis was conducted to explore this variation.

Sensitivity and specificity of echocardiography plus specialist clinical assessment for diagnosis of HF: These values were extracted from NG106

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and were based upon a committee assumption. To be consistent with this guidance, the same assumption - that standard TTE plus specialist clinical assessment is 100% accurate - has been applied.

Mortality for HF: Standardised mortality ratio (SMR) was calculated from a published 1-year survival rate ([Taylor et al., 2019](#)). This retrospective, population-based cohort study used Clinical Practice Research Datalink (CPRD) data from 2000–2017, including over 55,000 patients with newly diagnosed heart failure. An observed 1-year survival of 75.9% corresponded to a 24.1% mortality rate. Using the expected sex weighted 1-year mortality at the average diagnosis age (77.5 years) from Office for National Statistics (ONS) 2021-23 life tables, the SMR was calculated as observed / expected mortality, giving an SMR of 7.37. This was applied to patients with treated HF in the model.

In the most recent data summary, NICOR presented in-hospital mortality for acute HF admissions was 10.4%, and was applied to patients who were admitted due to acute symptoms in the model.

Hospitalisation: This rate is used to model the movement from “symptomatic” state to “acute episode” state. Heart-failure-related hospitalisation rates were extracted from the PULSE study ([Linden, Gollop & Famer, 2023](#)). The study included 383,896 adults in England diagnosed with heart failure between 2015 and 2019. Using Hospital Episode Statistics (HES) data, admissions with HF listed as the primary diagnosis were counted as HF-related hospitalisations. Rates were expressed as events per 1,000 person-years, crude rates for all HF patients, and age and sex adjusted rates for specific subtypes (HFrEF and HFpEF) were used to calculate the weighted two-week hospitalisation probabilities used in this model.

Length of Stay (LOS): The NICOR NHFA presents median LOS in the most recent annual summary reports, however, older reports (e.g., [2020](#), [2021](#) and [2023](#)) graphically presented mean LOS for patients who had been admitted to hospital. In each report, mean LOS was less than 14 days, therefore, the model assumed that the inpatient stay for a patient with acute HF would last

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for one cycle, meaning they would transition to another health state after one cycle (2 weeks).

Baseline time to diagnosis and proportion of diagnosed: The dataset from NHS England Diagnostics Waiting Times and Activity was explored to deduce the total time waited for standard TTE, with the distribution to allow modelling at 2-week intervals. However, the dataset reported the number of people waiting at different time points, but not the overall length of their wait. The EAG contacted the NHS England Diagnostics Waiting Times and Activity team to explore if there was any relevant data available. It was noted that the total time waited by patients for echocardiography was not routinely collected. Potentially, the Hospital Episode Statistics (HES) data may capture this information under outpatient appointments and day case, but echocardiography is not coded routinely on the outpatient dataset. Given the short timeframe of this assessment, it was not possible for the EAG to explore this further.

Baseline time to diagnosis was calculated from clinical experts' estimates of waiting time and the NHS diagnostic waiting time & activity data ([NHS England, July 2025](#)). Wait list activity data indicated that 10.6% of patients referred wait 13 weeks or more to receive echocardiography, therefore approximately 89.4% of patients wait under 13 weeks in the model.

According to estimates from clinical experts, in settings without a one-stop diagnostic clinic, the average waiting time for an echocardiogram from point of referral ranges from 6 to 12 weeks. Assuming that waiting times follow a normal distribution, that no patients receive an echocardiogram before 6 weeks, and that 10.6% of patients wait more than 13 weeks, a normal distribution curve was modelled to estimate the proportion of patients who received an echocardiogram in two-week intervals.

Clinical experts estimated that the average interval between echocardiogram and subsequent clinical assessment is 1 to 4 weeks. It was therefore assumed that 50% of patients receive clinical assessment in the first 2 weeks post-echocardiography and 50% receive clinical assessment in week 3 and 4

post-echocardiography. Finally, a combined wait time was then derived by aggregating these wait times, yielding the proportion of the HF population diagnosed at two-week intervals. Details of the calculation are outlined in [Appendix D](#).

Based on estimates from clinical experts, one stop diagnostic clinics have a wait time from referral to diagnosis of between 2-10 weeks. In the model, a mean waiting time of 6 weeks was assumed, with patient waiting times represented by a normal distribution. This distribution was applied to estimate the proportion of the HF population diagnosed at two-week intervals. The calculation is described in [Appendix D](#).

It has been reported that 51.9% of patients with HF are diagnosed in a one stop diagnosis clinic (Kwok et al., 2025). The weighted proportion of patients diagnosed in each two-week interval has been calculated based on the proportion of patients diagnosed in settings with or without a one stop diagnostic clinic ([Table 16](#)).

Effect of reduced echocardiography time with AI technologies on the waiting times: Two technologies presented evidence on procedural time saved using AI-assisted echocardiography – EchoConfidence and Us2.ai. EchoConfidence provided evidence comparing the time taken for human or AI analysis of an echocardiogram from an interim analysis (Almeida et al.: unpublished data 2025 (FEATHER)). Us2.ai provided two relevant studies evidencing time reduction for AI-assisted echocardiography: the first was a pre-print randomised crossover trial used in the base case analysis, the second a pilot study used to inform the sensitivity analysis. A number of limitations with these studies should be considered. First, the setting and type of operators in each study. Both Us2.ai studies were conducted in Japan, therefore both setting and operators are unlikely to be comparable to the NHS. While the FEATHER study was based in community settings in the UK, the results were derived from an interim analysis with very limited information (Almeida et al.: unpublished data 2025). This limits its comparability with the NHS secondary care practice. Second, as these AI technologies impact different stages of the procedure, the time measurements reported in these

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studies are unclear. For Us2.ai, Sakomoto et al. (2025) reported an examination time per patient of 14.3 mins without AI, whereas the combined measurement and report creation time was 12.5 mins without AI in Hirata et al. (2024). The EAG could not ascertain whether the examination time measured in Sakomoto et al. (2025) was for a full echocardiography procedure, as the time reported was much lower than the average procedure time in the NHS (45 mins), obtained from clinical experts. Similarly, in the FEATHER study (Almeida et al.: unpublished data 2025) an analysis was conducted on the time taken for EchoConfidence to automate steps which make up part of an echocardiographic assessment. Due to the lack of detail in the FEATHER study, it is not clear how these steps fit into the overall TTE procedure, and how the time savings reported would impact TTE workflow on a practical level. It was not possible to determine if the procedure was comparable to the NHS. While the EAG consider that the evidence is not robust and of low quality, these study results are used in the EAG model to explore the plausible cost effectiveness of these AI technologies, therefore the EAG advise that the economic analysis should be considered as exploratory. Details of these studies and their limitations are summarised in [Table 15](#).

Table 15: Studies reporting time saved with AI and their limitations.

| Study | Setting | Sample size | Comparator (operator type) | Parameter measured | EAG comments |
|--|-----------------------|-------------|----------------------------|--|---|
| EchoConfidence: FEATHER unpublished study, Almeida et al. (unpublished, 2025) | UK community settings | 300 | Sonographer | Analysis time (27 steps in each TTE procedure) | It is unclear how the analysis time measured fits into the overall TTE procedure, and if the operator used is comparable to NHS practice in secondary care. This data is unpublished and has not been subject to peer review. |
| Us2.ai: Sakomoto et al. (2025) | Japan | 585 | Sonographer | Examination time | The EAG considers the setting is unlikely to be comparable to NHS practice. In addition, it is unclear if the staff qualifications and experience are similar to the NHS staff delivering echocardiography, and what the examination entails. This is non-peer reviewed data. |
| Us2.ai: Hirata et al. (2024) | Japan | 23 | Not reported | Measurement process and report creation | The EAG considers the setting is unlikely to be comparable to NHS practice. The EAG also notes the small sample size and single centre design, which limits the generalisability of the findings. |

Abbreviations: EAG: external assessment group; TTE: transthoracic echocardiography

As there is no direct evidence on time to diagnosis with AI, the EAG estimated the change in waiting time using the evidence on reduced time with AI-assisted echocardiography. The patient load in standard care was calculated based on the number of procedures per full day and the average wait for echocardiography, by assuming 5 working days per week. This yielded a patient load of 575. A shorter procedure time was used to calculate a new number of procedures per day. The average wait time using AI-assisted echocardiography was then calculated by dividing the patient load of 575 by the new number of procedures per full day. Subsequently, the percentage reduction in average wait time was applied to generate a new distribution of echocardiography wait time. The model also assumed the same reduction for the one stop diagnostic clinic wait time. The reduction in average wait time with EchoConfidence was estimated to be 17%, and 0% for Us2.ai (base case). Assuming the wait for specialist clinical assessment would remain unchanged, the proportion of the HF population diagnosed for each technology was populated. The calculation is described in [Appendix E](#).

Table 16: Main clinical parameters.

| Variable | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s |
|--|------------|---------------------|--|
| Patient characteristics | | | |
| Average age of heart failure patients at first presentation | 77.5 years | NICOR, 2025 | |
| Diagnosis parameters | | | |
| Sensitivity of standard TTE plus clinical assessment | 1.00 | NICE NG 106 (2018) | Committee assumption |
| Specificity of standard TTE plus clinical assessment | 1.00 | NICE NG 106 (2018) | Committee assumption |
| Proportion of acute episodes | 79.2% | Bottle et al., 2017 | |

| Proportion of HF subtypes | | | |
|---|-------------------|---------------------|--|
| HFrEF | 0.49 | NICOR, 2025 | |
| non-HFrEF (includes HFpEF and HFmrEF) | 0.51 | NICOR, 2025 | Patients with clinical symptoms and signs of HF who have preserved heart pump function (HFpEF) or intermediate levels (HFmrEF) were collectively designated as 'non-HFrEF' |
| Mortality | | | |
| 1-year survival rates after a diagnosis of HF | 75.9% | Taylor et al., 2019 | The assumed mortality rate of 24.1% was used based on the observed survival rate of 75.9% |
| SMR - 1-year following diagnosis | 7.37 | EAG calculation | Based on published 1-year mortality rate following diagnosis (Taylor et al., 2019) |
| In-hospital mortality | 10.4% | NICOR, 2025 | |
| 2-week hospitalisation probabilities | | | |
| Hospitalisation probability for HFpEF | 0.16% | EAG calculation | Annual rate (Linden et al, 2023) was converted to a two-week probability |
| Hospitalisation probability for HFrEF | 0.39% | EAG calculation | Annual rate (Linden et al, 2023) was converted to a two-week probability |
| Weighted hospitalisation probability | 0.27% | EAG calculation | Weighted using the proportion of HFpEF and HFrEF |
| LOS | Less than 14 days | NICOR | |
| Baseline time to diagnosis, proportion of diagnosed | | | |
| Waiting time from referral to echocardiography | 6-12 weeks | Clinical experts | |
| Waiting time from echocardiography to specialist clinical assessment | 1-4 weeks | Clinical experts | |
| Waiting time from referral to one stop diagnostic clinic | 2-10 weeks | Clinical experts | |

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| | | | |
|---|-------------------|--|---|
| Proportion of patients who have been waiting for > 13 weeks | 10.6% | NHS Diagnostic Waiting Times and Activity, July 2025 | Assumed that these patients would be waiting at week 14 and receive an echocardiography at week 16. |
| Proportion of one stop diagnostic clinic | 51.9% | Kwok et al., 2025 | |
| Weighted cumulative proportion of patients diagnosed, all settings | | | |
| ≤4 weeks | 3.4% | EAG calculation | Based on the proportion of patients diagnosed in settings with and without a one-stop diagnostic clinic calculated from clinical experts' estimates and NHS diagnostic waiting time & activity data (2025) Weighted using the proportion of one stop diagnostic clinic (Kwok et al., 2025) |
| ≤6 weeks | 26.0% | | |
| ≤8 weeks | 48.5% | | |
| ≤10 weeks | 52.9% | | |
| ≤12 weeks | 58.3% | | |
| ≤14 weeks | 71.7% | | |
| ≤16 weeks | 87.8% | | |
| ≤18 weeks | 97.5% | | |
| ≤20 weeks | 100.0% | | |
| Impact on time to diagnosis with AI assisted echocardiography | | | |
| Standard echocardiography appointment | 45 mins (0.75 hr) | Clinical experts | |
| Number of standard echocardiography performed (per day) | 10 | EAG calculation | Based on a 7.5 hour working day and the time taken for an appointment |
| Patient load | 575 | EAG calculation | Based on mean 11.5 used to derive the normal distribution of patients receiving echocardiography and assuming 5 days per week (11.5 weeks x 5 working days per week x 10 procedures per day = 575) |
| Average wait time | 11.5 weeks | EAG calculation | |
| Echocardiography appointment: EchoConfidence | 36 mins (0.59 hr) | EAG calculation, Almeida et al.: unpublished data 2025 | Based on time reduction of 9.45 mins (Human 9.5mins average vs AI 0.05mins) |

| | | | |
|---|---|---|---|
| Number of echocardiography performed (per day): EchoConfidence | 12 | EAG calculation | |
| Average wait time: EchoConfidence | 9.58 weeks | EAG calculation | Based on the patient load and new number of procedures per day (575 patients / (12 procedures per day x 5 working days per week)) |
| Reduction in average wait time: EchoConfidence | 17% | EAG calculation | Calculated using the AI wait time and current wait time |
| Echocardiography appointment: Us2.ai | Base case: 44 mins (0.73 hr) Sensitivity analysis: 36 mins (0.60 hr) | EAG calculation, Sakamoto et al., 2025, Hirata et al., 2025 | Based on time reduction of 1.3 mins in base case (human 14.3mins vs AI 13.0mins), and 8.7 mins in sensitivity analysis (human 12.6mins vs AI 3.8mins) |
| Number of echocardiography performed (per day): Us2.ai | Base case: 10 Sensitivity analysis: 12 | EAG calculation | |
| Average wait time: Us2.ai | Base case: 11.5 weeks Sensitivity analysis: 9.58 weeks | EAG calculation | Based on the patient load and new number of procedures per day |
| Reduction in average wait time: Us2.ai | Base case: 0% Sensitivity analysis: 17% | EAG calculation | Calculated using the AI wait time and current wait time |

Abbreviations: TTE: transthoracic echocardiography; EAG: external assessment group; HFrEF: heart failure with reduced ejection fraction; HFpEF: heart failure with preserved ejection fraction; HFmrEF: heart failure with mildly reduced ejection fraction; LOS: length of stay; NICOR: National Institute for Cardiovascular Outcomes Research; SMR: standardised mortality ratio.

6.2.4 Resource use and cost parameters

Technology costs: The costs and other resource use requirements for each technology are described in [Table 17](#).

For implementation, costs included were the set-up fee and hardware (server). As hardware requirements for integrating the technology vary

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depending on the IT system at each site, the additional hardware costs for each technology were included in the EAG base case but removed for sensitivity analysis. The implementation (set up and hardware) and training costs were split over a 3-year period. The cost per scan for implementation and training were derived from an assumed number of scans per year.

The annual scans per site were estimated using the median monthly scans per site from the NHS England Diagnostic Waiting Times and Activity July 2025 dataset, to represent typical usage. Given the time limitation, only the July 2025 dataset was used in the calculation. This was then used to derive the costs per scan, where the license fee, system implementation, training, information technology (IT) support and staff time were included. The actual costs will vary according to the actual number of scans, and this should be considered for implementation locally.

Per-scan costs were varied by volume in the sensitivity analysis. The annual scans per site for Guy's and St Thomas' NHS Trust (21,000 scans per year) was used to represent high volume usage ([Freitas et al., 2023](#)). For low volume usage, the first quartile of monthly scans per site from the NHS England Diagnostic Waiting Times and Activity July 2025 dataset was used to derive the annual scans per site (5,000 scans per year).

These AI technologies are delivered by the same staff delivering standard echocardiography and thus costed at a band 7 cardiac physiologist. Staff time for AI-assisted echocardiography is derived by subtracting the time reduction reported in clinical papers from the standard echocardiography time of 45 minutes. The calculation is described in Section [6.2.3](#).

The cost of reversing a decision is estimated using any up-front costs to purchase the equipment and setting up the service, training costs and any costs associated with the pricing model that could not be recouped.

EchoConfidence

The software is priced at £4 per use, excluding VAT. Set up fees apply, however if the site requires additional hardware, this may be provided by the

vendor at a cost. The hardware cost is currently unknown, and thus not included in the EAG model. Staff training consists of 2 days on site and additional remote training as required. This is costed as an additional package and included in the EAG model. Any IT support for hardware (if provided by the company) and software is provided at an additional fee. During the integration process, a minimal IT staff time is required, but the information provided was not sufficient to be included in the EAG calculation. The company noted that there is additional training available to minimise the need for ongoing support. The cost of reversing the decision would primarily be the set-up fee, any additional hardware and staff training.

EchoGo Heart Failure

This is offered as a package of £25 to £50 per use, excluding VAT. This includes software use, IT support, any cloud support, integration and staff training. The company provided an indicative cost breakdown, but did not provide additional information on the type of contract that would be used and therefore the EAG cannot comment on the costs of reversing the decision. The company also noted that the technology would require minimal training and no additional equipment.

Ligence Heart

Two software pricing models are available: (i) unlimited license model offered for 1 or 3 years, including support, with pricing based on the number of workstations, and (ii) tier-based model (pay per case) based on the number of scans and users. The company charges only for software use, however a server can be provided at an additional cost depending on the contract. A one-hour training per person is provided at no additional cost. The service provided by the company includes server delivery (if server purchased), software installation and ongoing support. The company also noted that any installation costs are included in the pricing models.

The company costs were provided in Euro's, and this was converted at the rate of €1 to £0.87 (obtained from xe.com, 15 October 2025). In the EAG cost calculation, the tier-based pricing model was applied using the estimated

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annual scan volumes from the NHS England Diagnostic Waiting Times and Activity dataset.

The cost of reversing the decision would be the server fee and any unused scans from the committed pricing model.

Us2.ai

The software pricing model is based on the scan volumes. The installation can be done as cloud implementation or on-site installation, at an additional cost. There is rental server available from the company for piloting the software or transitioning to full adoption. The price of the server varies with the specification. The rental server costs are currently unknown. In the EAG calculation, an on-site installation of a basic server is applied. Routine support, clinical and IT support are provided at no additional fee. However, it is unclear if this includes staff training, therefore training costs are not included in the EAG calculation.

The cost of reversing the decision would be the server fee and any unused scans from the committed pricing model.

Table 17: Technology cost parameters.

| | EchoConfidence | EchoGo Heart Failure | Ligence Heart | Us2.ai |
|--|--|--|--|--|
| License | Available as cost per use. | Cost per use with software use, IT support, integration fee and training included. | Two pricing models are available: unlimited (by number of users) and tier-based (by number of scans) | Pricing is based on volume per year. Consolidating sites or multiple years usage could be negotiated. |
| System implementation | Included consultancy with IT department for integration, site visits, creation of the instance of the software and user access controls. | Included in the per-use costs. | Includes complete installation of the software and integration to the hospital IT system. | Available as “on premises” and cloud integration. |
| Supporting hardware and other infrastructure if provided by the company | Not included, cost currently unknown if provided by vendor. The requirement depends on the complexity of integration required and if adaptations required. | No additional hardware is required. | Server to be provided by vendor at an additional cost, subjected to the contract. This will depend on the integration. | Server and cloud are provided at an additional cost. Rental server is offered by vendor for pilot. Costs are not provided by the vendor. |
| Training | 2 days on site and then remote as required. | No significant training is required. Included in the per-use costs. | 1 hour per person. | Clinical support is available. No information on training and the associated costs. |
| IT support and/or maintenance | Hardware and software support is offered at an additional cost. Trainings are provided by the company to ensure that any support requests are minimal. | Included in the per-use costs. | Support is available. | Support is available. |
| Per patient costs excluding VAT, no discounting applied (annual scans: 10,000 per site) | | | | |
| License/software per scan | £4 | 70% of per-scan costs = £26.25 per scan | £2.61 | £8.00 |

| | | | | |
|---|---|--|--|---|
| System set up per scan | £4,500 spread over 3 years = £0.15 per scan | 20% of per-scan costs = £7.50 per scan | Server £2,611 spread over 3 years = £0.09 per scan | Basic server £6,000 spread over 3 years = £0.20 per scan |
| Training costs per scan | £750 per day for 2 days over 3 years = £0.05 per scan | 10% of per-scan costs = £3.75 per scan | 0 | No information provided by vendor |
| IT support costs per scan | 10% of the per scan cost for hardware, 5% for software Assuming 10% scans needed IT supports per year, 15% of per scan costs for each support (£0.6 per support) and spread across the annual scans = £0.06 per scan | Included in the license per scan | 0 | 0 |
| Staff time per scan | 35.6 mins (Almeida et al.: unpublished data 2025) | No data available | No data available | 43.7 mins (Sakomoto et al., 2025) |
| Staff time costs per scan using band 7 cardiac physiologist | £39.11 | NA | NA | £48.07 |
| Total costs per scan, not including HCP costs | £4.26 | £37.50 (average derived from the range provided by vendor, £25-50) | £2.70 | £8.20 |
| Total costs per scan (low volume, 5,000 per site per year) | £4.46 | No additional information provided | £2.79 | £8.40 |
| Total costs per scan (high volume, 21,000 per site per year) | £4.16 | No additional information provided | £2.22 | £6.50 EAG assumes a 20% reduction in license cost per scan for high volume usage |

| | | | | |
|--|-------|------------------------------------|-------|-------|
| Total costs per scan, excluding hardware | £4.26 | No additional information provided | £2.61 | £8.00 |
|--|-------|------------------------------------|-------|-------|

Abbreviations: VAT: value added tax.

Standard TTE costs: AI technologies are used as an adjunct to standard TTE, therefore the cost of standard echocardiography was not included in either arm of the model. Staff time is included for both arms, as this is the key element that may change with the introduction of AI technologies. Staff time required to deliver each technology was costed using a band 7 cardiac physiologist.

Heart failure hospitalisation and emergency department (ED) costs: These costs were taken from the 2025 economic modelling in NICE guidance NG 106.

Follow-up costs post-HF diagnosis: In the model, all patients would be reviewed in an outpatient cardiology specialist clinic for a formal diagnosis, and therefore it was not necessary to include the costs of this first appointment. Follow up costs were valued using the resource requirement for heart failure obtained from the NICE guidance NG106. These estimates were validated through consultation with clinical experts, ensuring that the resource use assumptions reflected current UK clinical practice. The costs of specialist nurse visits were costed using a band 6 nurse, following the approach taken in NICE guidance NG106.

Heart failure treatment costs: Weighted drug treatment costs were calculated based on the proportion of patients receiving each treatment ([NICOR, 2025](#)), and converted from a 3-monthly cost, as in NG106, to a 2-weekly cost. NICOR data indicated that 91% of patients with HFrEF were prescribed beta blockers (BB), 68% were prescribed mineralocorticoid receptor antagonists (MRAs), and 85% were prescribed either angiotensin-converting enzyme inhibitors (ACEi), angiotensin receptor blockers (ARBs) or angiotensin receptor-neprilysin inhibitors (ARNIs). The weighted cost does not include ARNIs which are recommended as a replacement for ACEi's in the case that the patient remains symptomatic ([NG106, 2025](#)).

Table 18: Key cost parameters.

| Parameter | Value | Source | Comment |
|-----------|-------|--------|---------|
|-----------|-------|--------|---------|

| | | | |
|--|---------------|---------------------------|--|
| HF hospitalisations | £2,885.47 | NHS cost collection 23/24 | Heart failure or shock (EB03A-E with CC score 0-14+) – weighted average of non-elective long and short stay |
| ED attendance for HF | £652.87 | NHS cost collection 23/24 | Heart failure or shock (EB03A-E with CC score 0-14+) - weighted average of heart failure day case. |
| Follow-up costs for HF | | | |
| Specialist visit (cardiology) - Follow up appointment | £164.25 | NHS cost collection 23/24 | Weighted average of consultant led, and non-consultant led non-admitted face-to-face attendance, follow up appointment (WF01A) |
| GP appointment (10 minutes) | £45.00 | PSSRU 2024 | Including qualification costs and direct care staff costs |
| Band 6 Nurse appointment (30 minutes) | £31.00 | PSSRU 2024 | Including qualification costs. Calculated based on £62.00 per working hour |
| Number of HCP appointments in year 1: | HFrEF; HFpEF: | NICE NG106 (2018) | Resource use for patients with HFrEF and HFpEF was obtained from NG106 and validated by clinical experts |
| - GP | 2; 1 | | |
| - Outpatient cardiology visits | 2; 1 | | |
| - Specialist HF nurse visits | 10; 1 | | |
| Two-week weighted average drug therapy cost (BB, MRA, and ACEi/ARB) | £2.42 | EAG calculation | Three-monthly weighted costs obtained from NG106, proportion receiving each treatment obtained from NICOR, 2024 |

Abbreviations: ED; emergency department; GP; general practitioner; PSSRU; Personal Social Services Research Unit; HFrEF: heart failure with reduced ejection fraction; HFpEF: heart failure with preserved ejection fraction; BB; beta blocker; MRA; mineralocorticoid receptor antagonist; ACEi; angiotensin-converting enzyme inhibitor; ARB: angiotensin receptor blockers.

6.2.5 Health state utilities

Patients were assigned to different utility values for each health state in the model. Utility values were obtained from [TA773](#) and NG106. The utility value of 0.58 (untreated and treated HF patients) was obtained from NG106 (2018). This value was derived from EQ-5D data in the REFER study ([Taylor et al.](#)).

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[2017](#), unpublished data), which NICE used as the basis for its model cohort in NG106. The REFER population consisted of predominantly older patients (mean age 77, 50.6% male) with mostly HFpEF (86.5%). In contrast, the NG106 ([2025](#)) economic analysis reported a higher utility of 0.78 for treated HFrEF patients. However, because this estimate applies only to that subgroup, the original utility value of 0.58 was retained for treated HF in the EAG model, and assumed a 10% disutility for untreated HF.

The HF-related hospitalisation utility decrement, extracted from TA773 and also reported in NG106, represents the temporary reduction in health-related quality of life experienced by a patient during and immediately after a hospital admission for HF.

Table 19: Utility values.

| Variable | Value | Source | Comment |
|--|-------|--------------------------|---|
| Treated HF | 0.58 | NICE NG106 (2018) | Unpublished data from the REFER trial (Taylor et al., 2017) |
| Untreated HF disutility | 0.058 | EAG assumption | |
| HF-related hospitalisation disutility | 0.019 | NICE TA773; NG106 (2025) | |

Abbreviations: EAG: external assessment group; HF: heart failure.

6.2.6 Key assumptions

- The wait time for standard TTE and one stop diagnostic clinic was assumed to follow a normal distribution.
- To model the effect of reduced echocardiography time with AI technologies on waiting time, it was assumed that the reduced procedure time would proportionately increase the number of patients per day, and that the calculated reduction in average wait time would shift the entire wait time distribution forward by the same magnitude.
- The number of patients referred to echocardiography was assumed to be constant. In reality, when waiting time becomes shorter, a number of

factors may lead to an increase of referrals, such as a change in the referral pattern.

- It was assumed that the waiting time for a specialist clinical assessment following echocardiography would remain unchanged. However, if the specialist clinic is already running at full capacity and there is no additional capacity available, this would limit the number of patients receiving an earlier diagnosis despite having an earlier echocardiography.

6.2.7 Model validation

For model validation, the economic model was reviewed by a second health economist independently. The validation process included checks on the calculations used to derive model inputs, the movement between health states and the computations generating total costs, QALYs and other outcomes. All model inputs were verified against their primary data sources, and the inputs were varied to check if the results were consistent with a priori expectations.

6.2.8 Presentation of results

Given the significant uncertainty with various model inputs and the number of assumptions required, the cost effectiveness analysis undertaken by the EAG should be considered as exploratory. In the base case analysis, only AI technologies with evidence related to their impact on procedure time were included: EchoConfidence and Us2.ai. These AI technologies were compared to standard care using standard TTE, and an ICER was calculated for each comparison.

One-way sensitivity analyses have been carried out as it is more appropriate to identify the key drivers and to explore the impact of a wide range of plausible inputs where there is either variation across sites, or in practice. A probabilistic sensitivity analysis to quantify the level of confidence with the ICER would provide little value on determining key drivers of the economic model to guide further evidence generation, and thus this was not undertaken.

A range of one-way and scenario sensitivity analyses were performed including:

Table 20: One-way sensitivity analyses and the value used

| One-way sensitivity analyses | Low value | High value |
|---|--|--|
| Waiting time reduction of EchoConfidence driven by the reduced echocardiography time: $\pm 50\%$ from base case | 8% | 25% |
| Reduced echocardiography time with Us2.ai using alternative paper (Hirata et al., 2024) | NA | 8.7mins |
| Longer echocardiography waiting times | NA | 36 weeks |
| Proportion of acute episode: -20% from base case | 63% | NA |
| Technology costs, excluding hardware | EchoConfidence: £4.26 Us2.ai: £8.00 | NA |
| Technology costs: high volume, low volume | EchoConfidence: £4.16 Us2.ai: £6.50 | EchoConfidence: £4.46 Us2.ai: £8.40 |
| All patients receive an echocardiogram during hospital stay | 0% | NA |
| Band 8a cardiac physiologist in echocardiography delivery | NA | EchoConfidence: £43.85 Us2.ai: £53.90 |
| Proportion diagnosed in one stop diagnostic clinic | 20% | 40% |

Abbreviations: NA: not applicable.

Scenario analyses were chosen based on the uncertainty in the model and the key drivers indicated by the one-way sensitivity analyses results:

1. Analysis comparing EchoConfidence and standard care:
 - combining longer waiting times of 36 weeks and a lower proportion diagnosed in a one stop diagnostic clinic (20%)
 - combining a lower waiting time reduction with EchoConfidence (8%) and a lower proportion diagnosed in a one stop diagnostic clinic (20%)
2. Analysis comparing Us2.ai and standard care:
 - combining time reduction reported by Hirata et al., 2024 and a lower proportion diagnosed in a one stop diagnostic clinic (20%)

6.3 Results from the economic modelling

Base case and sensitivity analyses results are reported in [Table 21](#) and [Table 22](#). Both incremental costs and incremental QALYs were calculated as the differences between the AI technology and standard care.

EchoConfidence

From the base case results, it appears that EchoConfidence is potentially more effective and less costly than standard care, and therefore a cost-saving strategy. The proportion that met the target referral time of 6 weeks post-referral may increase by 15% with EchoConfidence from 26% to 40%. However, there is a lot of uncertainty surrounding the model and the very limited clinical evidence used in this analysis, this limits the validity of the results.

The cost-saving results are primarily attributable to the reduction in staff time per scan cost of £10, which is able to offset EchoConfidence's cost per use. As the base case assumes a 17% reduction in waiting time driven by the shorter procedure time with EchoConfidence, some patients would receive earlier diagnosis and treatment, resulting in modest QALYs gained.

Results from the one-way sensitivity analyses suggest that the economic findings are sensitive to the proportion diagnosed in a one stop diagnostic clinic and the impact of waiting time reduction with EchoConfidence. When the proportion of patients diagnosed in a one stop diagnostic clinic is reduced to 20%, only 16% of patients would meet the target referral time with EchoConfidence, yielding an increase of 6% compared to standard care. Similarly, when the EchoConfidence impact of waiting time reduction is lowered to 8%, the increase of those meeting the target referral time reduces from 15% in the base case to 7%. Additionally, in the scenario combining a lower proportion diagnosed in a one stop diagnostic clinic (20%) and a lower reduction in waiting time (8%), this results in a small increase of 3% in those meeting the target referral time (EchoConfidence 13%, standard care 10%). The model appears to be relatively insensitive to the longer waiting time of 36 weeks based on the one-way sensitivity analyses results. This is likely due to

the high proportion diagnosed in a one stop diagnostic clinic used in the base case. However, in a combined scenario (20% diagnosed in a one stop diagnostic clinic, 36-week waiting time), the increase in those that met the target referral time reduces from 15% in the base case to 6%.

While the results appear to suggest that EchoConfidence is potentially a cost-saving strategy, the considerable uncertainty surrounding the current waiting time and how the shorter procedure time with EchoConfidence would impact the echocardiography workflow. In turn, the change in waiting time would outweigh the modest cost savings with EchoConfidence. Therefore, the results should be interpreted with caution.

Table 21: Base case and sensitivity analyses results: EchoConfidence (EC) vs standard care

| | Total costs, EC | Total costs, Std Care | Total QALYs, EC | Total QALYs, Std Care | Incremental costs (£) | Incremental QALYs | ICER | Proportion meeting the target referral time, EC | Proportion meeting the target referral time, Std Care | Difference between EC and standard care |
|---|-----------------|-----------------------|-----------------|-----------------------|-----------------------|-------------------|-------------|---|---|---|
| Base case | £3,230 | £3,233 | 0.4742 | 0.4736 | -£3.14 | 0.0005 | Cost saving | 40.5% | 26.0% | 14.5% |
| % waiting time reduction: 8% | £3,229 | £3,233 | 0.4739 | 0.4736 | -£4.59 | 0.0003 | Cost saving | 33.3% | 26.0% | 7.3% |
| % waiting time reduction: 25% | £3,231 | £3,233 | 0.4744 | 0.4736 | -£1.94 | 0.0008 | Cost saving | 45.2% | 26.0% | 19.2% |
| Echocardiography waiting time: 6 to 36 weeks | £3,230 | £3,233 | 0.4741 | 0.4736 | -£3.20 | 0.0005 | Cost saving | 40.5% | 26.0% | 14.5% |
| % diagnosed in hospital: -20% from base case (63%) | £2,681 | £2,684 | 0.4835 | 0.4828 | -£2.45 | 0.0007 | Cost saving | 40.5% | 26.0% | 14.5% |
| Technology costs, no hardware costs | £3,230 | £3,233 | 0.4742 | 0.4736 | -£3.14 | 0.0005 | Cost saving | 40.5% | 26.0% | 14.5% |
| Technology costs, low volume | £3,230 | £3,233 | 0.4742 | 0.4736 | -£2.94 | 0.0005 | Cost saving | 40.5% | 26.0% | 14.5% |
| Technology costs, high volume | £3,230 | £3,233 | 0.4742 | 0.4736 | -£3.24 | 0.0005 | Cost saving | 40.5 | 26.0% | 14.5% |
| All inpatients receive echo | £3,242 | £3,246 | 0.4763 | 0.4760 | -£4.81 | 0.0003 | Cost saving | 40.5% | 26.0% | 14.5% |
| Band 8a cardiac physiologist | £3,230 | £3,234 | 0.4742 | 0.4736 | -£4.33 | 0.0005 | Cost saving | 40.5% | 26.0% | 14.5% |
| % one stop diagnostic clinic: 20% | £3,224 | £3,226 | 0.4729 | 0.4722 | -£2.36 | 0.0007 | Cost saving | 15.7% | 10.0% | 5.7% |
| % one stop diagnostic clinic: 60% | £3,231 | £3,234 | 0.4744 | 0.4738 | -£3.20 | 0.0005 | Cost saving | 46.8% | 30.0% | 16.8% |
| Combining 36-week waiting time and 20% one stop diagnostic clinic | £3,220 | £3,222 | 0.4721 | 0.4713 | -£1.97 | 0.0008 | Cost saving | 15.8% | 10.0% | 5.7% |
| Combining 8% waiting time reduction and 20% one stop diagnostic clinic | £3,222 | £3,226 | 0.4725 | 0.4722 | -£4.22 | 0.0003 | Cost saving | 12.8% | 10.0% | 2.8% |

Abbreviations: EC: EchoConfidence; ICER: Incremental cost-effectiveness ratio; QALY: Quality adjusted life year.

Us2.ai

Base case results show that Us2.ai may be more costly than standard care, but with no change in QALYs, suggesting that standard care dominates. This is because of the small procedure time reduction with Us2.ai (mean difference 1.30 mins), reported by Sakomoto et al. (2025). Similarly, the clinical evidence on the time saved is unlikely to be generalisable to the NHS setting, as well as the uncertainty with other key model inputs. These have implications on the validity of the economic results.

Given no change in the waiting time with Us2.ai is modelled, overall results from one-way sensitivity analyses remain consistent with the base case results. However, when a shorter procedure time (36 mins) using the findings from a pilot study by Hirata et al. (2024), it shows that Us2.ai is more costly and more effective (cost difference £1.40, QALY difference 0.0005), giving an ICER of £2,547 per QALY, below the NICE willingness to pay (WTP) threshold of £20,000 per QALY. This results in a 15% increase in those meeting the target referral time. In a combined scenario (20% diagnosed in a one stop diagnostic clinic, 36 mins echocardiography), the ICER increases to £3,090 per QALY and the increase in those meeting the target referral time reduces to 6%. This suggests that the results are sensitive to the proportion diagnosed in a one stop diagnostic clinic.

Table 22: Base case and sensitivity analyses: Us2.ai vs standard care

| | Total costs, Us2.ai | Total costs, Std Care | Total QALYs, Us2.ai | Total QALYs, Std Care | Incremental costs (£) | Incremental QALYs | ICER | Proportion meeting the target referral time, Us2.ai | Proportion meeting the target referral time, Std Care | Difference between Us2.ai and standard care |
|--|---------------------|-----------------------|---------------------|-----------------------|-----------------------|-------------------|-----------|---|---|---|
| Base case | £3,240 | £3,233 | 0.4736 | 0.4736 | £6.49 | 0.0000 | Dominated | 26.0% | 26.0% | 0.0 |
| Echocardiography time reduction, Hirata et al., 2024 | £3,235 | £3,233 | 0.4742 | 0.4736 | £1.40 | 0.0005 | 2,547 | 40.5% | 26.0% | 14.5% |
| Echocardiography waiting time: 6 to 36 weeks | £3,239 | £3,233 | 0.4736 | 0.4736 | £6.49 | 0.0000 | Dominated | 26.0% | 26.0% | 0.0 |
| % diagnosed in hospital: -20% from base case (63%) | £2,690 | £2,684 | 0.4828 | 0.4828 | £6.50 | 0.0000 | Dominated | 26.0% | 26.0% | 0.0 |
| Technology costs, no hardware costs | £3,240 | £3,233 | 0.4736 | 0.4736 | £6.30 | 0.0000 | Dominated | 26.0% | 26.0% | 0.0 |
| Technology costs, low volume | £3,240 | £3,233 | 0.4736 | 0.4736 | £6.68 | 0.0000 | Dominated | 26.0% | 26.0% | 0.0 |
| Technology costs, high volume | £3,238 | £3,233 | 0.4736 | 0.4736 | £4.85 | 0.0000 | Dominated | 26.0% | 26.0% | 0.0 |
| All inpatients receive echo | £3,253 | £3,246 | 0.4760 | 0.4760 | £6.72 | 0.0000 | Dominated | 26.0% | 26.0% | 0.0 |
| Band 8a cardiac physiologist | £3,240 | £3,234 | 0.4736 | 0.4736 | £6.32 | 0.0000 | Dominated | 26.0 | 26.0% | 0.0 |
| % one stop diagnostic clinic: 20% | £3,232 | £3,226 | 0.4722 | 0.4722 | £6.46 | 0.0000 | Dominated | 10.0% | 10.0% | 0.0 |
| % one stop diagnostic clinic: 60% | £3,241 | £3,234 | 0.4738 | 0.4738 | £6.49 | 0.0000 | Dominated | 30.0% | 30.0% | 0.0 |
| Combining time reduction reported by Hirata et al., 2024 and 20% one stop diagnostic clinic | £3,228 | £3,226 | 0.4729 | 0.4722 | £2.16 | 0.0007 | 3,090 | 15.7% | 10.0% | 5.7% |

Abbreviations: ICER: Incremental cost-effectiveness ratio; QALY: Quality adjusted life year.

6.4 Summary and interpretation of the economic evidence

An exploratory cost-effectiveness analysis using an early economic model was conducted. Based on the limited clinical evidence, the cost-effectiveness results suggest that EchoConfidence has the potential to be a cost-saving intervention for NHS use. With similar limitations in evidence, Us2.ai may be dominated by standard care, indicating it may be more costly and less effective than standard care. However, the evidence used to model the impact on waiting time with AI technologies is very limited and it is unclear if the settings, operators and measurement taken are comparable to that of NHS practice. Additionally, there is significant variation and uncertainty around the current waiting time, which makes it challenging to model the current practice reliably. As indicated by the sensitivity analyses results, one of the key drivers is the proportion of patients diagnosed in a one stop diagnostic clinic. These clinics are likely to have a shorter waiting time, but the proportion of patients on this pathway is unclear. This proportion can be very different at different sites, and result in different impacts. Additionally, the current wait time is likely to be underestimated, leading to an overestimation of AI technology impact in the model. Given these uncertainties, the results should be interpreted with caution.

Waiting time is inherently dynamic and influenced by a number of factors including staff shortage, increase demand for services and funding constraints. Given this complexity, the use of a dynamic model such as discrete event simulation could be a more appropriate approach in capturing the patient flow and system capacity. However, this approach is more data-intensive and the current evidence is not adequate to support this modelling approach. During this modelling exercise, the EAG identified key data gaps:

- waiting time distribution for echocardiography,
- proportion of inpatients entering the outpatient echocardiography waiting list

- proportion of further investigations
- proportion of patients diagnosed in a one stop diagnostic clinic

In order to create an exploratory model, the EAG were required to use multiple assumptions. Some of this uncertainty that could be addressed by additional data collection.

While the clinical evidence shows a reduction in echocardiography time with EchoConfidence, it is unclear whether its introduction would change the workflow in practice. The EAG have noted different views on the potential changes driven by AI technology on the echocardiography workflow. Given the lack of any supporting data, an assumption was made to model the impact of waiting time with AI in the EAG model based on reduced measurement and reporting time. Waiting time is a key model driver, and the only input parameter that changes between the comparator and intervention. It is crucial to assess this impact in future studies.

The introduction of AI may lead to reduced waiting times, resulting in earlier diagnosis and treatment. This helps to slow down disease progression and potentially prevent subsequent acute episodes requiring hospitalisation. A one-year time horizon was applied in the EAG model, therefore long-term impacts were not captured. Results showed that there was a modest QALY gained with EchoConfidence due to earlier diagnosis and fewer hospitalisations. However, the model is limited by a lack of utility data that differentiates between untreated and treated HF, limiting the estimation of QALY differences between these two patient groups. The EAG had to assume an arbitrary 10% disutility for untreated HF.

While the costs per use for some AI technologies are small, these costs can become substantial when used at high volume. There are initial implementation costs such as set-up fee and hardware costs, but the costs are not large when spread across a few years. These costs vary depending on the complexity of integrating the AI technology into NHS IT systems. Therefore, the cost of reversing a decision may vary depending on local implementation and usage.

7. Integration into the NHS

Key considerations identified by the EAG related to integration of AI-assisted echocardiography into the NHS are summarised in this section. This is informed by evidence from studies identified that were set in the UK, responses to questions posed by the EAG to SCMs and clinical experts ([Appendix A](#)) and submissions received by NICE from the companies and professional organisations during this assessment.

Clinical pathway

These AI technologies are designed to work in conjunction with existing NHS processes, including compatibility with current software and image processing methods. Changes to the clinical pathway may be required to introduce the technologies into the NHS, but this is dependent on when and how they are implemented. These changes are mainly related to procedure time and resources and are discussed below. Two SCMs commented on the ability of AI technologies to potentially make echocardiography more accessible for patients, by facilitating a shift from TTEs being performed in secondary care to primary or community care. There was limited evidence identified to support this. Additionally, there was a consensus that, should the technologies be clinically effective, this would shorten time to diagnosis and initiation of treatment. There was a lack of health-related outcomes reported in the evidence base.

Impact on procedure time and resources

The views from SCMs and clinical experts on the anticipated impact on procedure time and requirement of resources were mixed. The general consensus from SCMs was that AI-assisted echocardiography technologies may increase efficiency of procedures, shortening TTE appointment times and increasing overall capacity. However, one clinical expert commented that they would expect that introduction of these AI-assisted technologies would reduce TTE throughput due to additional time being needed for AI analysis and additional time needed in a typical clinic day to allow for human quality assurance checks of AI-generated reports. There was some evidence of

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limited quality to support the concept of a reduction in procedure time following implementation of AI-assisted TTE.

Time required for audit and measurement of outputs was also cited by clinical experts as a potential increase in resources required following implementation of these technologies.

IT integration and ongoing technical support

SCMs and clinical experts consistently raised IT integration and infrastructure in the NHS as a key consideration for implementation of these AI technologies. One clinical expert commented on IT infrastructure in the NHS potentially not being advanced enough to support the AI technologies. One SCM stated that IT integration may be an issue that can be overcome.

Data governance and privacy

Information received from a professional organisation indicated that data governance and privacy should be considered if the AI technologies are to be implemented in the NHS. It was stated that transparency over data sharing, storage and ownership should be clear to patients and NHS organisations.

Staff training

SCMs and clinical experts stated that additional practical training for healthcare professionals who conduct TTE would be required to successfully implement the AI technologies. This is supported by information submitted by the companies for this assessment. It is expected that training may need to include AI literacy and an understanding of the technologies' limitations, risk of errors/bias and how outputs should be monitored.

8. Evidence gap analysis

8.1 Ongoing studies

The EAG identified 7 ongoing studies which were relevant to the decision problem ([Table 23](#)). The TARTAN-HF and SYMPHONY-HF studies are both RCTs investigating a targeted screening strategy to detect undiagnosed heart

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failure in high-risk patients, where Us2.ai-assisted echocardiography is part of the interventional arm. The TARTAN-HF study is specific to a population with diabetes. The AI software is not the focus of these studies, but the EAG has included them to demonstrate the potential utility of Us2.ai in wider clinical contexts. Additionally, these two ongoing studies involve the use of AI-assisted handheld TTE, which may provide evidence to support the use of Us2.ai in community or primary care settings. The company provided 3 AIC studies for Us2.ai, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Ligence provided 2 ongoing studies (1 AIC). [REDACTED]

[REDACTED], and the other is evaluating Ligence Heart for assessing left ventricular systolic and diastolic parameters.

The key study (Almeida et al.: unpublished data 2025 (FEATHER)) for EchoConfidence included in the clinical evidence review is an interim analysis, and further data is expected to be reported in December 2025 (n=1200). The company describe this as a “double-blind evaluation of AI for heart failure diagnosis and stratification on unselected consecutive patients referred for evaluation to community cardiology services”.

These studies may add further evidence of the accuracy and validity of the AI technologies, in comparison to human measurements. However, none of the studies appear to address the key evidence gaps identified by the EAG, which are outlined in Section 8.2. Additionally, none of the conference proceedings identified appear to report outcomes that would address the key evidence gaps ([Appendix C](#)).

Table 23: Summary of relevant ongoing studies.

| Study details, status | Population | Device, Comparator | Outcomes relevant to scope |
|---|--|--|--|
| Us2.ai (n=5 studies) | | | |
| <p>Study name: TARTAN-HF – Targeted Assessment In High Risk patient With dIAbetes to identify Undiagnosed Heart Failure</p> <p>Study number: NCT05705869</p> <p>Study design: prospective, multicentre, unblinded, RCT</p> <p>Location: NHS Greater Glasgow and Clyde, NHS Lanarkshire, UK</p> <p>Status: Recruiting</p> <p>Estimated study completion date: 12.2032</p> <p>Aim: to assess a targeted screening strategy to detect undiagnosed heart failure in high-risk patients with diabetes</p> | <p>Population: patients with diabetes at high risk of HF</p> <p>Estimated enrolment: n=1,000</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • ≥40 years of age • Provide informed consent • An established diagnosis of diabetes (type 1 or type 2) • At least one additional risk factor for heart failure (coronary artery disease, persistent or permanent AF, previous ischemic or embolic stroke, peripheral arterial disease, CKD, regular loop diuretic use, COPD) <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Inability to give informed consent • Previous documented diagnosis of HF • Currently receiving scheduled RRT | <p>Device: Us2.ai</p> <p>Intervention: NT-proBNP and other biomarker testing, as well as KCCQ-12, ED-5D questionnaires, followed by AI-assisted echocardiography.</p> <p>Comparator: Routine care</p> | <p>Primary outcome(s):</p> <ol style="list-style-type: none"> 1. Diagnosis of HFmrEF within six months 2. Diagnosis of HFpEF within six months 3. Diagnosis of asymptomatic LV dysfunction (LVEF≤40%) within six months <p>Secondary outcome(s):</p> <ol style="list-style-type: none"> 1. Time to first HF hospitalisation at 1, 2, 5 years 2. All-cause mortality at 1, 2, 5 years 3. Time to first occurrence of any components of the following clinical composite 1) heart failure hospitalisation 2) all-cause mortality 4. Accuracy of handheld TTE with AI-automated reporting compared to full cart-based TTE and manual reporting for the measurement of LVEF 5. ICER over a 5-year time-horizon |

| | | | |
|---|---|---|---|
| | <ul style="list-style-type: none"> • Anyone not suitable to participate in the trial, in investigators' opinion | | |
| <p>Study name: Screening for early Heart Failure Diagnosis and Management in Primary Care or at HOme Using Natriuretic Peptides and echocardiographY "SYMPHONY-HF" (SYMPHONY-HF)</p> <p>Study number: NCT05919342</p> <p>Location: Scotland, Denmark, Canada, USA, Sweden</p> <p>Study design: prospective, multicentre, unblinded RCT</p> <p>Status: Recruiting</p> <p>Estimated study completion date: 21.12.2032</p> <p>Aim: to assess a targeted screening strategy to detect undiagnosed HF in high-risk patients</p> | <p>Population: Patients at high risk of HF</p> <p>Estimated enrolment: n=3,904</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • > 40 years of age • Can provide informed consent • Has 2 or more of the following risk factors for heart failure: Coronary artery disease, established diagnoses of diabetes, persistent or permanent AF, previous ischemic or embolic stroke, peripheral arterial disease, CKD, regular loop diuretic use, COPD <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Inability to give informed consent • Previous documented diagnosis of HF • Current RTT • Anyone not suitable to participate in the trial, in investigators' opinion | <p>Device: Us2.ai</p> <p>Intervention: NT-proBNP blood sample measurement. Then patients with elevated Roche NT-proBNP will undergo a clinical exam, ECG and AI-assisted echocardiography.</p> <p>Comparator: Routine care</p> | <p>Primary outcome(s): 1 – diagnosis of HF within 6 months</p> <p>Secondary outcome(s): 1 – Diagnosis of HFrEF within 6 months 2 – People diagnosed with HFrEF receiving GDMT within 6 months</p> <p>Other outcome(s): 1 – Diagnosis of HFmrEF or HFpEF within 6 months 2 – People with HFmrEF or HFpEF receiving SGLT2i therapy within 6 months 3 – Diagnosis of asymptomatic LVEF ($\leq 40\%$) within 6 months 4 – Time to first HF hospitalisation at 1,2 and 5 years 5 – All-cause mortality at 1,2 and 5 years 6 – ICER over a 5-year time horizon 7 – number of patients in the NT-proBNP / echo group with echo features of potential amyloid as assessed by the Us2.ai algorithm report conclusion of 'amyloid to be considered'</p> |



| | | | |
|--|--------------------------------------|--|--|
| <p>Study design: NR</p> <p>Status: NR</p> <ul style="list-style-type: none"> - publication expected 2025 Q4 <p>Estimated study completion date: NR</p> <p>Aim: to evaluate an investigational automated 2D TTE software (Ligence Heart) for assessing LV systolic and diastolic parameters in routine clinical cases.</p> | <p>Exclusion criteria: NR</p> | | |
|--|--------------------------------------|--|--|

Abbreviations: AF: atrial fibrillation; AI: artificial intelligence; CKD: chronic kidney disease; COPD: chronic obstructive pulmonary disease; ECG: electrocardiogram; EF: ejection fraction; EQ-5D: EuroQol 5 dimension 5 level questionnaire; GDMT: guideline-direct medical therapy; GLS: global longitudinal strain; HF: heart failure; HFmrEF: heart failure with mildly reduced ejection fraction; HFpEF: heart failure with preserved ejection fraction; HFrEF: heart failure with reduced ejection fraction; ICC: intraclass correlation coefficient; ICER: incremental cost-effectiveness ratio; KCCQ-12: Kansas City Cardiomyopathy Questionnaire; LV: left ventricle; LVEF: left ventricular ejection fraction; NHS: national Health Service; NR: not reported; NT-proBNP: N-terminal pro-B-type natriuretic peptide; Q4: fourth quarter; RCT: randomised controlled trial; RMSE: root mean square error; RRT: renal replacement therapy; SGLT2i: sodium-glucose transport 2 inhibitors; TTE: transthoracic echocardiogram.

8.2 Evidence gap analysis

[Table 24](#) summarises the evidence gaps relating to groups of outcomes in the scope of this assessment for each technology. **GREEN** indicates there is good evidence available, **AMBER** indicates there is partial evidence available, **RED** indicates there is no evidence available.

Table 24: Evidence gap analysis

| Outcomes | EchoGo Heart Failure | Us2.ai | Ligence Heart | EchoConfidence |
|---|----------------------|--------|---------------|----------------|
| Diagnostic test accuracy | AMBER | AMBER | RED | AMBER |
| Diagnostic performance (HF detection/classification) | GREEN | GREEN | RED | RED |
| Validation against manual measurements | AMBER | GREEN | AMBER | AMBER |
| Clinical and patient-reported outcomes | RED | RED | RED | RED |
| Procedural outcomes (including changes to procedure time) | RED | AMBER | RED | AMBER |
| Costs and resource use | RED | RED | RED | RED |
| Changes to staff or setting for delivering echocardiography | RED | RED | RED | RED |
| Costs of AI license | AMBER | GREEN | GREEN | GREEN |
| Implementation | RED | AMBER | AMBER | GREEN |
| Training and support | AMBER | AMBER | GREEN | GREEN |
| Cost of downstream diagnostic test | RED | RED | RED | RED |
| Adverse events | RED | RED | RED | RED |

Abbreviations: HF: heart failure.

Economic modelling inputs

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Across all the technologies, there are gaps relating to the economic modelling including:

- Downstream treatment costs
- Utilities associated with untreated HF
- Utilities associated with treated HF

8.3 Key areas for evidence generation

Across the evidence base, the main outcomes reported are measures of diagnostic accuracy and clinical validation. Key gaps identified by the EAG as priorities for evidence generation are summarised in [Table 25](#).

Table 25: Areas for evidence generation.

| Evidence gap | Recommended outcomes to be collected |
|---|--|
| Impact on procedure time | <ul style="list-style-type: none">• Time required for automation of echocardiographic measurements• Time taken for automation of echocardiography report• Overall procedure time |
| Impact on clinical outcomes | <ul style="list-style-type: none">• Time to receive HF diagnosis• Time to initiation of treatment for HF• Patient-reported health-related quality of life |
| Validity in cohorts representative of UK population | <ul style="list-style-type: none">• Diagnostic test accuracy• Interchangeability, agreement and correlation with human measurements• Diagnostic performance (in detecting and classifying HF) |
| Acceptability of AI tool | <ul style="list-style-type: none">• Ease of use• Confidence in accuracy of automation• Feasibility of implementation in different settings (primary and secondary care) with staff of varying skill levels |
| Adverse events | <ul style="list-style-type: none">• Inaccurate measurements, leading to incorrect diagnoses• Rate of AI failure to analyse images |

Abbreviations: HF: heart failure; UK: United Kingdom

Where evidence is generated for the technologies, sufficient detail should be collected and reported in relation to:

- The demographics of included participants
- The type of setting (primary/community or secondary care)
- The staff involved in echocardiogram acquisition, analysis and reporting and their level of expertise
- The specific generation or version of technology being investigated

Where possible, studies should be prospective in design, to minimise the impact of selection bias and potential confounding. However, retrospective designs where previously acquired TTE images are analysed by AI could be beneficial in eliminating any potential clinical risk to patients. Ideally, operators participating in retrospective studies such as these should be blinded to the original diagnostic results (including measurement values) associated with the TTE images.

9. References

[Acute heart failure: Diagnosis and management](#) (2014) NICE guideline CG187

Akerman A (2023b). Automated Echocardiographic Detection of Heart Failure with Preserved Ejection Fraction using Artificial Intelligence (American Society of Echocardiography 34th Annual Scientific Sessions). *Journal of the American Society of Echocardiography*, 36(7), e1-e110

Akerman A (2024). AI-based Echocardiographic Assessment Is Associated With HF Hospitalization and Cardiac Mortality in HFpEF. *ASM 2024, HFSA Annual Scientific Meeting*

Akerman A (2025b). Three rules to find them all: clinical risk scores in heart failure with preserved ejection fraction. *European Journal of Heart Failure*, 27, 3-542. (Abstract)

Akerman A P, Al-Roub N, Angell-James C et al. (2023c). Comparison of an Artificial Intelligence Heart Failure Detection Model and Clinical Prediction Models in Patients With Heart Failure With Preserved Ejection Fraction (HFPEF). *Circulation*, 148. (American Heart Association's 2023 Scientific Sessions and the American Heart Association's 2023 Resuscitation Science Symposium. Philadelphia, PA United States.)

Akerman A P, Al-Roub N, Angell-James C et al. (2025a). External validation of artificial intelligence for detection of heart failure with preserved ejection fraction. *Nature communications*, 16(1), 2915. Erratum in: *Nature Communications*. 2025 Apr 17;16(1):3662

Akerman A, P Porumb, M, Scott C et al. (2023a). Automated Echocardiographic Detection of Heart Failure With Preserved Ejection Fraction Using Artificial Intelligence. *Journal of the American College of Cardiology. Advances*, 2(6), 100452

Akerman A, Porumb M, Beqiri A et al. (2023d). COMPARISON OF CLINICAL ALGORITHMS AND ARTIFICIAL INTELLIGENCE APPLIED TO AN ECHOCARDIOGRAM TO CATEGORIZE RISK OF HEART FAILURE WITH PRESERVED EJECTION FRACTION (HFPEF). *Journal of the American College of Cardiology*, 81(8), 360. (ACC.23. New Orleans United States.)

Akerman, A P, Hawkes W, Slivnick J et al. (2025c). INTEGRATING ARTIFICIAL INTELLIGENCE PIPELINES INTO THE DIAGNOSIS OF CARDIOMYOPATHIES. Journal of the American College of Cardiology, 85(12), 2850. (American College of Cardiology, (ACC) Meeting 2025. Chicago United States.)

[Artificial intelligence assisted echocardiography to support the diagnosis and monitoring of heart failure, Final scope](#) (2025). NICE project document GID-HTE10067

[Artificial intelligence assisted echocardiography to support the diagnosis and monitoring of heart failure, Final protocol](#) (2025). NICE project document GID-HTE10067

Bottle A, Kim D, Aylin P et al. (2018). Routes to diagnosis of heart failure: Observational study using linked data in England. Heart, 104(7), 600–605

British Heart Foundation. (2025). UK Cardiovascular Disease Factsheet. [Heart statistics publications - BHF](#)

Campbell R T (2023). OPERA-AI: Artificial Intelligence Reporting of Handheld Echocardiography in Suspected Heart Failure. (ESC Congress 2023, Amsterdam and Online)

Campbell R T, Petrie M C, Docherty K et al. (2025). Artificial intelligence fully automated analysis of handheld echocardiography in real-world patients with suspected heart failure. European Journal of Heart Failure (online, ahead of print)

Cassianni C E, Huntley G D, Akerman A P et al. (2023). An Artificial Intelligence Based Model for Heart Failure With Preserved Ejection Fraction Predicts Cardiac Mortality. Circulation, 148. (American Heart Association's 2023 Scientific Sessions and the American Heart Association's 2023 Resuscitation Science Symposium. Philadelphia, PA United States.)

Cassianni C, Huntley G D, Castrichini M et al. (2024). Automated Echocardiographic Detection of Heart Failure With Preserved Ejection Fraction Using Artificial Intelligence Is Associated With Cardiac Mortality and Heart Failure Hospitalization. Journal of the American Society of Echocardiography. 37(9), 914-916

[Chronic heart failure in adults: diagnosis and management](#) (2018) NICE guideline NG106

External assessment report: HTE10067 Artificial Intelligence assisted Echocardiography to support diagnosis of heart failure: Early Value Assessment
Date: December 2025

clinicaltrials.gov. Anonymous. (2022). Targeted Assessment in High-Risk paTients With dIAbetes to ideNtify Undiagnosed Heart Failure (TARTAN-HF).

<https://clinicaltrials.gov/study/NCT05705869>

clinicaltrials.gov. Anonymous. (2023). Screening for earlY Heart Failure Diagnosis and Management in Primary Care or at HOme Using Natriuretic Peptides and echocardiographY. <https://clinicaltrials.gov/study/NCT05919342>

Dohse C A, Kansal M M, Twing A et al. (2024). APPLICATION OF MACHINE LEARNING TECHNOLOGY TO AUTOMATE PROXIMAL AORTA DIMENSION BY ECHOCARDIOGRAPHY. *Journal of the American College of Cardiology*, 83(13), 1550. (American College of Cardiology 73rd Annual Scientific Session & Expo. Atlanta United States.)

Dowsing B, Menacho K, Culotta V et al. (2025). Improved measurement precision for cancer cardiotoxicity screening using fully automated analysis. *European Heart Journal - Cardiovascular Imaging*, 26(Supplement_1)

[Early value assessment interim statement](#) (2022). NICE process and methods.
PMG39

[Empagliflozin for treating chronic heart failure with reduced ejection fraction](#) (2022)
NICE technology appraisal guidance 773

Freitas D, Alner S, Demetrescu C et al. (2023). Time to be more efficient: Reducing wasted transthoracic echocardiography (TTE) diagnostic appointment slots at Guy's and St Thomas' NHS Trust. *BMJ Open Quality*, 12(3), e002317

Hamid N (2024). Association of a Novel, Non-invasive AI Model to Automate Echocardiographic Detection of Heart Failure with Preserved Ejection Fraction (HFpEF) with Invasive Hemodynamics. Available at:
<https://www.ultromics.com/proof/tht-2024-association-of-a-novel-non-invasive-ai-model-to-automate-echocardiographic-detection-of-hfpef-with-invasive-hemodynamics>

Hirata Y, Nomura Y, Saito Y et al. (2024). Reducing echocardiographic examination time through routine use of fully automated software: a comparative study of measurement and report creation time. *Journal of Echocardiography*, 22(3), 162-170

Huang W, Koh T, Tromp J et al. (2024a). Point-of-care AI-enhanced novice echocardiography for screening heart failure (PANES-HF). *Scientific reports*, 14(1), 13503

Huang W, Lee A, Tromp J et al (2023). POINT-OF-CARE AI-ASSISTED NOVICE ECHOCARDIOGRAPHY FOR SCREENING OF HEART FAILURE (PANES-HF). *Journal of the American College of Cardiology*, 81(8), 2145. (ACC.23. New Orleans United States.)

Ioannou A, Patel R K, Razvi Y et al. (2023). Automated analysis of echocardiograms at diagnosis is able to predict prognosis in ATTR cardiomyopathy. *European Heart Journal Cardiovascular Imaging*, 24, i617 (European Association of Cardiovascular Imaging Congress, EACVI 2023. Barcelona Spain.)

Karnik A, Nelson L, Freed B H et al. (2025). DEEP LEARNING FOR DETECTION OF PRECLINICAL HEART FAILURE IN THE MULTI-ETHNIC STUDY OF ATHEROSCLEROSIS. *Journal of the American College of Cardiology*, 85(12), 2579. (American College of Cardiology, (ACC) Meeting 2025. Chicago United States.)

Karnik A, Shrivastav R, Tilkens B et al. (2024). Prospective Clinical Validation of a Deep Learning-Based Automated Pipeline for Assessment of Right Ventricular Size and Function. (Abstract P5-21 from ASE 2024 Scientific Sessions Original Science Abstracts.). *Journal of the American Society of Echocardiography*, 37(7), e1-e121

Karnik, A., Jankowski, M., & Narang, A (2024). Unmasking HFpEF With Artificial Intelligence: A Disruptive Opportunity for Disease Detection. *Journal of Cardiac Failure*, 30(11), 1533-1534.

<https://doi.org/https://dx.doi.org/10.1016/j.cardfail.2024.02.010>

Karuzas A, Miskikas L, Kiziela A et al. (2025). Deep Learning-Driven Automated Assessment of Left Ventricular Diastolic Function in Echocardiography. *Echocardiography* (Mount Kisco, N.Y.), 42(9), e70290

Kwok C S, Piper S E, Deaton C et al. (2025). Heart failure services from the hospital perspective in the UK: A cross-sectional survey. *British Journal of Cardiology*, 32, 14–18

External assessment report: HTE10067 Artificial Intelligence assisted Echocardiography to support diagnosis of heart failure: Early Value Assessment

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Lafitte S, Lafitte L, Jonveau M et al. (2025). Integrating artificial intelligence into an echocardiography department: Feasibility and comparative study of automated versus human measurements in a high-volume clinical setting. *Archives of Cardiovascular Diseases*, 118(8), 477 EP - 488

Linden S, Gollop N D, Farmer R (2023). Resource utilisation and outcomes of people with heart failure in England: A descriptive analysis of linked primary and secondary care data – the PULSE study. *Open Heart*, 10(2), e002467

Molek-Dziadosz P, Wozniak A, Furman-Niedziejko A et al. (2025). Left ventricular ejection fraction assessment: artificial intelligence compared with echocardiography expert and cardiac magnetic resonance measurements. *Polish Archives of Internal Medicine*, 135(9)

Myhre P L, Gaibazzi N, Tuttolomondo D et al. (2024a). Concordance of left ventricular volumes and function measurements between two human readers, a fully automated AI algorithm, and the 3D heart model. *Frontiers in Cardiovascular Medicine*, 11, 1400333

Myhre P L, Hung C L, Frost M J et al. (2024b). External validation of a deep learning algorithm for automated echocardiographic strain measurements. *European Heart Journal. Digital health*, 5(1), 60-68

Myhre P, Hung C L, Frost M et al. (2023). External validation of a deep learning algorithm for automated echocardiographic strain measurements. *European Heart Journal Cardiovascular Imaging*, 24, i693 EP - i694. (European Association of Cardiovascular Imaging Congress, EACVI 2023. Barcelona Spain.)

National Confidential Enquiry into Patient Outcome and Death. (2018). Acute heart failure: Failure to function – a review of the care received by patients who died in hospital following an admission with acute heart failure. NCEPOD.

<https://www.ncepod.org.uk/2018report2/AHF%20full%20report.pdf>

National Institute for Cardiovascular Outcomes Research. (2020). National Heart Failure Audit (NHFA) 2020 summary report (2018/19 data). Derby: NICOR.
<https://www.nicor.org.uk/national-cardiac-audit-programme/previous-reports/heart-failure-3/2020-2/national-heart-failure-audit-2020-final?layout=file>

National Institute for Cardiovascular Outcomes Research. (2021). National Heart Failure Audit (NHFA) 2021 summary report (2019/20 data). Derby: NICOR.
External assessment report: HTE10067 Artificial Intelligence assisted Echocardiography to support diagnosis of heart failure: Early Value Assessment
Date: December 2025

<https://www.nicor.org.uk/national-cardiac-audit-programme/previous-reports/heart-failure-3/2020-2/national-heart-failure-audit-2020-final?layout=file>

National Institute for Cardiovascular Outcomes Research. (2023). National Heart Failure Audit (NHFA) 2023 summary report (2021/22 data). Derby: NICOR.

<https://www.nicor.org.uk/national-cardiac-audit-programme/previous-reports/heart-failure-3/2023-4/10633-nicor-annual-summary-reports-nhfa-v5-ac?layout=file>

National Institute for Cardiovascular Outcomes Research. (2025). National Heart Failure Audit (NHFA) 2025 annual summary report. Derby: NICOR.

<https://www.nicor.org.uk/interactive-reports/national-heart-failure-audit-nhfa>

NHS England. (2025). Diagnostic waiting times and activity for July 2025 [Online report]. <https://www.england.nhs.uk/statistics/statistical-work-areas/diagnostics-waiting-times-and-activity/monthly-diagnostics-waiting-times-and-activity/>

NHS England. National Cost Collection for the NHS (2023/24) Available at <https://www.england.nhs.uk/costing-in-the-nhs/national-cost-collection/>

Palmer C, Patel K, Frost M et al. (2024). FULLY AUTOMATED ARTIFICIAL INTELLIGENCE ASSESSMENT OF THE LEFT VENTRICLE BY CONTRAST ECHOCARDIOGRAPHY. Journal of the American College of Cardiology, 83(13), 1424. (American College of Cardiology 73rd Annual Scientific Session & Expo. Atlanta United States.)

Personal Social Services Research Unit (PSSRU) Unit Costs of Health and Social Care 2024 Available at <https://www.pssru.ac.uk/unitcostsreport/>

Sakamoto A, Kagiyama N, Sato E et al. (2024). Artificial Intelligence-based automated ECHOcardiographic measurements and the workflow of sonographers (AI-ECHO): Randomized Crossover Trial. (Abstract 4171745 from Late-Breaking Science Abstracts and Featured Science Abstracts From the American Heart Association's Scientific Sessions 2024 and L. Circulation, 150(25), e712-e763)

Sakamoto A, Kagiyama N, Sato E et al. (2025). Artificial Intelligence-based Automated Echocardiographic Analysis and the Workflow of Sonographers: A randomized crossover trial. medRxiv, 2025.2008.2020.25334115

Shrivastav R, Tilkens B, Karnik A et al. (2024). Comparison of Human vs. Artificial Intelligence (AI) based US2.AI Software Derived Measurement of Left Ventricular

External assessment report: HTE10067 Artificial Intelligence assisted Echocardiography to support diagnosis of heart failure: Early Value Assessment

Date: December 2025

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Diastology Variables. (Abstract P3-23 from ASE 2024 Scientific Sessions Original Science Abstracts.). *Journal of the American Society of Echocardiography*, 37(7), e1-e121

Subramanian V, Chandra A, Segar M et al. (2024). Performance of an automated echocardiographic artificial intelligence model to detect subclinical heart failure with preserved ejection fraction (HFpEF) in community-dwelling older adults. *European Heart Journal*, 45. (European Society of Cardiology Congress, ESC 2024. London United Kingdom.)

Sveric K, Platzek I, Haussig S et al. (2025). Validation of a fully automated AI system for accurate left ventricular ejection fraction measurement in echocardiography. *European Heart Journal - Cardiovascular Imaging*, 26, jeaе333.003

Taylor C J, Ordóñez-Mena J M, Roalfe A K et al. (2019). Trends in survival after a diagnosis of heart failure in the United Kingdom 2000–2017: Population based cohort study. *BMJ*, 364, l223

Taylor C J, Roalfe A K, Illes R et al. (2017). Primary care REFerral for EchocaRdiogram (REFER) in heart failure: a diagnostic accuracy study. *The British Journal of General Practice: the Journal of the Royal College of General Practitioners*, 67(655), e94–e102

Teramoto K, Hung C L, Frost M et al. (2022). External Validation of Deep Learning-Based Echocardiography Algorithms to Automate View Selection and Annotation of the Echocardiogram. *Circulation*, 146. (American Heart Association's 2022 Scientific Sessions and the American Heart Association's 2022 Resuscitation Science Symposium. Chicago, IL United States.)

Tromp J, Bauer D N, Claggett B L et al. (2022c). A prospective validation of a deep learning-based automated workflow for the interpretation of the echocardiogram. *European Heart Journal Cardiovascular Imaging*, 23, i4 EP - i5. (Annual Meeting of the European Association of Echocardiography, EUROECHO 2021. Online.)

Tromp J, Bauer D, Claggett B L et al. (2022a). A formal validation of a deep learning-based automated workflow for the interpretation of the echocardiogram. *Nature Communications*, 13(1), 6776

Tromp J, Seekings P J, Hung C L et al. (2022b). Automated interpretation of systolic and diastolic function on the echocardiogram: a multicohort study. *The Lancet. Digital Health*, 4(1), e46-e54

Tsourdinis G E, Xia E, Hussain K et al. (2024a). MACHINE LEARNING BASED ASSESSMENT OF AORTIC VALVE PARAMETERS ON TRANSTHORACIC ECHOCARDIOGRAPHY AND COMPARISON TO PREVIOUS LITERATURE. *Journal of the American College of Cardiology*, 83(13)

Tsourdinis G E, Xia E, Hussain K et al. (2024b). FULLY AUTOMATED MACHINE LEARNING BASED ECHOCARDIOGRAPHIC ASSESSMENT OF LEFT VENTRICULAR EJECTION FRACTION. *Journal of the American College of Cardiology*, 83(13), 1523. (American College of Cardiology 73rd Annual Scientific Session & Expo. Atlanta United States.)

Upton R, Akerman A P, Porumb M et al. (2024). Clinical Utility Of An AI-Based Model For Detection Of Heart Failure With Preserved Ejection Fraction Using Decision Curve Analysis. *Journal of Cardiac Failure*, 30(1), 130. (Heart Failure Society of America's (HFSA) Annual Scientific Meeting 2023. Cleveland United States.)

Venneri, L (2024). FLAT-ATTR: A fully automated machine learning algorithm to track disease progression in ATTR-CM. (EuroEcho-Imaging Congress 2024)

Walser A, Flammer A, Schwotzer R et al. (2025). Moderate accuracy but high precision of artificial intelligence for automated echocardiographic measurements in ATTR cardiomyopathy. *Swiss Medical Weekly*, 155, 111S EP - 112S. (Swiss Society of Cardiology and Swiss Society of Cardiac Surgery Annual Meeting 2025. Zurich Switzerland.)

Yaku H., Komtebedde J, Silvestry F E et al. (2024). DEEP LEARNING-BASED AUTOMATED MEASUREMENTS OF ECHOCARDIOGRAPHIC ESTIMATORS OF INVASIVE PULMONARY CAPILLARY WEDGE PRESSURE PERFORM EquALLY TO CORE LAB MEASUREMENTS: RESULTS FROM REDUCE LAP-HF II. *Journal of the American College of Cardiology*, 83(13), 316. (American College of Cardiology 73rd Annual Scientific Session & Expo. Atlanta United States.)

Yaros K, Segar M, Subramanian V et al. (2024). Diagnostic and prognostic evaluation of an echocardiography-based artificial intelligence algorithm for detecting

HFpEF: a case-control analysis. European Heart Journal, 45. (European Society of Cardiology Congress, ESC 2024. London United Kingdom.)

10. Appendices

Appendix A: Summary of responses from SCMs and clinical experts

Appendix B: Search strategies and PRISMA diagram

Appendix C: Associated publications and conference proceedings

Appendix D: Baseline time to diagnosis and proportion of diagnosed

Appendix E: Effect of reduced echocardiography time with AI technologies on the waiting times

Appendix F: Studies excluded at full text

Appendix A: Summary of responses from SCMs and clinical experts

| Echocardiography procedure | | |
|---|---|---|
| <i>Q1: What stages make up an echocardiography appointment? E.g. image acquisition, taking measurements, annotations/reporting etc.</i> | | |
| SCM responses | Consultant cardiologist | Confirming patient identity, confirming indication for echo, explaining to patient regarding procedure, positioning patient, optimising device settings, image acquisition, taking measurements, reporting, if clinician performing echo- explaining result to patient |
| | Consultant cardiologist | The patient comes into the room, give verbal consent for the procedure, undresses and puts on a hospital gown, lies on the examination couch in the left lateral position, the sonographer attaches a 3 lead ECG to the patient and places an echo probe in multiple places on their chest wall to acquire the images needed for a full echocardiogram. Measurements may be made on the machine in real-time or in post-processing once the patient has left the consultation. Once the patient has dressed and left the room, the sonographer transfers the images from the echo machine to a computer where they then review the images, add necessary measurements and complete a report. |
| | Consultant cardiologist | Referral for an echo. Triaging the request. Scheduling the request. Information to patient. Reminder for patient. Scanning the patients. Measurements during scanning then post procedure more complex measurements (3D etc). Reporting. Filing the report on electronic record and sending to referrer / GP |
| | GPwSI in cardiology | Patient check-in, image acquisition, measurements, annotations, summary reporting |
| CE responses | Cardiac clinical scientist and cardiac physiologist | Checking the referral and relevant clinical details. Gaining patient blood pressure, height and weight. Patient identification, explanation and preparation. Set up of machine with patient details. Image acquisition, measurements, reporting, uploading / posting reports. Where patients are unwell / significant pathology is identified, a review maybe necessary, this would include doing a blood pressure, 12 lead electrocardiogram, being reviewed by a Medic (which often requires long waits as it is typically the on-call Medic who could be anywhere in the hospital dealing with multiple patients at any one time – on averaged waiting times can around 1-2 hrs). This review will then need documenting which is typically done on the echocardiogram report. |
| <i>Q2: Are these tasks all conducted 'live' during an appointment, or would some be conducted post-appointment?</i> | | |

| | | |
|---|---|---|
| SCM responses | Consultant cardiologist | Reporting usually performed (particularly by physiologists after appointment) |
| | Consultant cardiologist | Some measurements and the writing of the report are performed after the appointment is complete and the patient has left. |
| | Consultant cardiologist | Normally all acquisition measuring reporting and filing done within the 45 minute slot |
| | GPwSI in cardiology | Mostly live; some review and clinical reporting done after. |
| CE responses | Cardiac clinical scientist and cardiac physiologist | The majority are conducted 'live'. Some echocardiographers prefer to do measurements post scanning but within the allotted 45-60mins appointment time. We do not suffer the same reporting delays that X-ray, CT, CMR have. |
| <p><i>Q3: Roughly how long do these tasks/stages take? Please give approximate times, using minutes.</i></p> | | |
| SCM responses | Consultant cardiologist | Confirming identity, indications, explaining procedure, positioning patient, optimising device settings) – 10 minutes. Image acquisition 25 minutes, taking measurements, 10 minutes, report 5 minutes |
| | Consultant cardiologist | Depending on the complexity of the echocardiogram, the appointment takes 45mins to 1 hour. Scanning the patient takes between 20-40 minutes. |
| | Consultant cardiologist | Scanning reporting and filing results around 45 minutes. Triaging and scheduling maybe 15 mins |
| | GPwSI in cardiology | Total 30–45 min: acquisition 20–30 min, reporting 5–10 min. |
| CE responses | Cardiac clinical scientist and cardiac physiologist | 45-60 minutes. |
| <p><i>Q4:</i></p> <p><i>A. Which healthcare professionals (and associated banding) are involved in echocardiography appointments?</i></p> <p><i>B. Are the same healthcare professionals involved in post appointment analysis and reporting?</i></p> | | |
| SCM responses | Consultant cardiologist | A. Receptionist, physiologist, cardiology registrar, consultant B. physiologist, cardiology registrar (if performing echo), consultant (if performing echo) |
| | Consultant cardiologist | Both doctors and sonographers are involved in the appointments, both in scanning and post appointment analysis and reporting. |
| | Consultant cardiologist | Scheduling band 3 or 4 Scanning and reporting physiologist (band 6 7 or 8) |
| | GPwSI in cardiology | Cardiac physiologist (Band 6–7), senior physiologist (Band 7–8a) Usually same physiologist; senior cardiologist may over-read. |

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| | | |
|---|---|---|
| CE responses | Cardiac clinical scientist and cardiac physiologist | A. echocardiographers - band 7/ band 8a. Assistant technical officers – band 2 or 3. B. Only accredited echocardiographers – band 7/band 8a. |
| Q5: What is the average number of appointments in a single clinic/session? Please specify how long a clinic or session is. | | |
| SCM responses | Consultant cardiologist | 4-5 appointments |
| | Consultant cardiologist | This is very variable between hospitals. A clinic session is usually half a day, so 4 hours, and the sonographer would be expected to perform between 5-6 scans in this time. |
| | Consultant cardiologist | Each simple echo is normally 45 minutes. Some more complex ones (eg ACHD) may be an hour. So 10-14 a day depending on length of the day |
| | GPwSI in cardiology | 6-8 studies in a 4-hour session; 12-16 per full day |
| CE responses | Cardiac clinical scientist and cardiac physiologist | Morning clinic: 8am – 12pm. 6 patients. This is for outpatients and inpatients. Afternoon clinic: 12.30pm-4pm. 4 patients. |
| The intervention: AI-assisted echocardiography | | |
| Q6: How would the AI technologies in scope alter the workflow of an echocardiography appointment? | | |
| SCM responses | Consultant cardiologist | <ul style="list-style-type: none"> - AI can aid image acquisition by trained healthcare professionals (GP, specialist nurses, cardiologist) in the community to acquire point of care images and the report without 15 minutes so prognostic life saving HF therapies can be started promptly - AI can also reduce the time required for image acquisition and reporting by physiologists - AI echocardiography can also help speed up image acquisition for patients requiring repeat focussed echo's (post GDMT optimisation to decide about device therapy, cardio oncology patients receiving chemo) |
| | Consultant cardiologist | Automated measurements and reporting using AI may shorten the appointment time. |
| | Consultant cardiologist | Most of the technologies would automate some of the measurements and reporting, potentially shortening the time needed to do an echo. There is also the possibility of point of care or community echo, potentially with abbreviated protocols and alternative workforce |
| | GPwSI in cardiology | AI gives view recognition, auto-measurements, draft reports → faster, more consistent workflow. |

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| CE responses | Cardiac clinical scientist and cardiac physiologist | <p>It would be used within the reporting phase of the echocardiogram workflow. Consideration would be needed as to how this is implemented some of the AI technologies take up to 20-30 mins for analysis. Currently this would mean that the appointment time of 45-60mins would need extending. Alternatively, clinics would be shortening to account for checking the AI generated report at a later point in the day. Either way this would reduce the echocardiography through put.</p> |
| <p><i>Q7: Are there different generations of the AI technologies? If yes, would you consider evidence to be generalisable across different generations?</i></p> | | |
| SCM responses | Consultant cardiologist | <ul style="list-style-type: none"> - Yes 1st generation devices only report EF - 2nd generation devices have Doppler and 3rd generation devices have GLS, amyloidosis reporting |
| | Consultant cardiologist | <p>There are different types of AI software and evidence is not generalisable between them. For example, automated measurements can be checked by the sonographer and altered if incorrect, whereas other algorithms may not be so explainable and therefore need more robust evidence to be put in practice. Each generation requires its own validation, risk assessment, and governance frameworks.</p> |
| | Consultant cardiologist | <p>I think each generation needs to be judged on its individual evidence</p> |
| | GPwSI in cardiology | <p>Yes, newer generations are more capable; evidence partly generalisable.</p> |
| CE responses | Cardiac clinical scientist and cardiac physiologist | <p>Unsure.</p> |
| <p><i>Q8: How do these AI technologies differ from existing software that work to automate measurements in echocardiography?</i></p> | | |
| SCM responses | Consultant cardiologist | <p>AI technologies require less number of images to be acquired to still generate a full report, can also guide the image acquirer in real time regarding probe position to aid image acquisition. Certain AI echo providers are also validated for HFpEF and amyloidosis</p> |
| | Consultant cardiologist | <p>Traditional software performed narrow specific tasks such as boundary detection of doppler measurements. AI algorithms, particularly those using deep learning, can perform broader tasks such as automated view classification, segmentation of cardiac structures, measurement prediction. The crucial difference is that AI models need validation on external datasets to ensure good performance.</p> |
| | Consultant cardiologist | <p>Existing software is really very limited and is more of an aid to measure for example volumes, but still needs clinical input to adjust as necessary</p> |
| | GPwSI in cardiology | <p>New AI automates full workflow, not just single measurements.</p> |

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| CE responses | Cardiac clinical scientist and cardiac physiologist | <p>Ultrometrics and US2.ai use details within the image to diagnosis heart failure with preserved ejection particularly for the diagnosis of cardiac amyloidosis. How of the condition is detected is unknown due to the AI algorithm that is used.</p> <p>For the other AI technologies, it is my understanding that they automate the measurements that echocardiographers would normally do. These would still need checking to ensure accuracy and prevent misdiagnosis. Additionally, it is known that in poor image quality, AI analysis takes longer and is less reliable.</p> |
| Implementation | | |
| <i>Q9: Would there be extra training or resources required to successfully implement these technologies into the care pathway?</i> | | |
| SCM responses | Consultant cardiologist | Yes training of physiologists to use AI echo, training of non-physiologists for image acquisition, IT integration via Cloud or PACS for transfer or storage of images |
| | Consultant cardiologist | Doctors and sonographers would need training in understanding how AI generates results, including its assumptions and limitations, and be able to recognise errors and bias. They would need an understanding of how models are trained, validated and updated as well as how they should be monitored and audited. |
| | Consultant cardiologist | Yes |
| | GPwSI in cardiology | Brief training, SOP updates, IT integration, governance checks |
| CE responses | Cardiac clinical scientist and cardiac physiologist | <p>Additional training will be required for all echocardiographers to ensure they are aware of the basics of AI and data literacy. This will improve confidence in using AI which will support its clinical adoption.</p> <p>There also needs to be training to ensure echocardiographers maintain critical analysis skills to prevent over reliance on AI. This will reduce inaccurate results being provided.</p> <p>Consideration to IT infrastructure will be needed to ensure the technology can be used equitably across the UK. It also needs to be timely and seamless, as we know NHS IT systems are notoriously slow and fragmented. If this continues, there is a high risk that the AI technology will be brought, implemented but not used.</p> |
| <i>Q10: Do you foresee any issues with implementing these technologies into the care pathway?</i> | | |
| SCM responses | Consultant cardiologist | IT integration but this is achievable |
| | Consultant cardiologist | Increased resources would need to be deployed to ensure staff are adequately trained and that there are |

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| | | robust systems in place to audit and monitor the AI technologies. |
| | Consultant cardiologist | Reassurance for clinical staff that it is robust technology |
| | GPwSI in cardiology | interoperability, over-reliance, accountability, cost, data security. |
| CE responses | Cardiac clinical scientist and cardiac physiologist | <p>The technologies being considered here will ultimately not improve the detection of patients with heart failure with reduced ejection fraction as none are designed to assess this. There is It will also not reduce the echocardiography appointment time. In some instances, the use of AI will increase the echocardiography pathway time. For instance, one of the companies requires 20-30mins for results. Therefore, at some point during that working day, time will be needed to review the results and action the outcome which will reduce patient activity.</p> <p>Additionally, for some of the technologies, only one image is required for the assessment of heart failure with preserved ejection fraction. However, if only one image is acquired there is a high risk that heart failure with reduced ejection fraction or other significant pathology will be missed. If the echocardiography workflow is reduced to 10mins to acquire one image. It will ultimately lead to a patient requiring multiple echocardiograms (a focused one and a complete one). This will lead to increased waiting times for all echocardiography services. It is also unclear whether patients would be happy for multiple trips for the same test.</p> <p>IT infrastructure and funding to implement AI technologies maybe an issue. A national approach and commitment to funding to upgrade IT and implement AI across all healthcare settings will be important. Otherwise, it could lead to worsening of healthcare in poorer regions.</p> |
| Outcomes | | |
| <p>Q11: Which outcomes would you expect these technologies to improve or impact? <i>Please consider both patient and system impacts.</i></p> | | |
| SCM responses | Consultant cardiologist | <p>The patient impact will be the biggest as if AI image acquisition and reporting can be performed in community/ GP surgeries/ A&E (7 days a week 24 hours), Critical Care settings (7 days, 24 hours) so prognostic therapies are not delayed , this will prevent patient adverse outcomes such as rehospitalisation, death or poor quality of life</p> <p>System impact – quicker reporting will allow greater number of patients to be accommodated into echo lists, physiologists to have more time for complex echo's (stress echo, 3D echo, TOEs), reduced waiting lists, health economic benefits by preventing hospitalisations and mortality, and leading to improved quality of life</p> |

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| | Consultant cardiologist | There is a chance that if the AI performs well, the diagnostic accuracy of echo would be improved. The time taken for a scan and report may be reduced, saving money for trusts and reducing pressure on staff. |
| | Consultant cardiologist | More efficient patient flows. More patients scanned and in more suitable situations (primary care, A and E, CDHs, one stop clinics, surveillance scans) |
| | GPwSI in cardiology | Faster diagnosis, fewer repeats, improved throughput and consistency. |
| CE responses | Cardiac clinical scientist and cardiac physiologist | <p>The AI technologies which focus on heart failure with preserved ejection and the detection of amyloidosis will be valuable. These patients are often difficult to diagnose and on average have multiple echocardiograms and wait 2 years for a diagnosis. Anything to improve this will improve access to echocardiography services and provide patients with a diagnosis and access to treatment quicker.</p> <p>The issues surrounding the detection of heart failure with reduced ejection fraction are more challenging and I don't feel that the current AI technologies will help as the challenges more involve accessing the echocardiography service and delays in medics/heart failure nurses picking up the report, actioning an appointment and the patient then being seen in the heart failure clinic.</p> <p>There are now "one stop" clinics for patients with a BNP >2000 which reduces this wait however the funding to support this means often only one echocardiographer is able to support this service. There is also a need for more heart failure nurses to improve access to heart failure clinics.</p> |
| Patient Pathway (chronic heart failure) | | |
| <p><i>Q12: Could you describe the patient pathway from echocardiography referral to getting a diagnosis of chronic heart failure?</i></p> | | |
| SCM responses | Consultant cardiologist | <p>Assessing patient's symptoms and signs for heart failure in primary care by a clinician. Performing NTproBNP, baseline blood tests and ECG. Based on the above referring for echocardiogram to HF specialist clinic. Patient assessment by HF specialist. Performance of echocardiogram with report. Interpretation of echo report and patient assessment by HF specialist to confirm or refute diagnosis of heart failure</p> |
| | Consultant cardiologist | <p>Once the patient has had their echocardiogram, the report is made available to the referring doctor who then contacts the patient with the next management steps. Depending on the results this may be referral to a cardiologist in outpatient clinic or even hospital admission if there is acute decompensation.</p> |

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| | Consultant cardiologist | Clinical suspicion, then measurement of NTproBNP (blood test). If raised NTproBNP referral to one stop clinic for echo and clinical review within 2 or 6 weeks depending on how high the bnp is. Though very few areas meet these timelines. |
| | GPwSI in cardiology | Referral → NT-proBNP → echocardiogram → specialist review → diagnosis → treatment start. |
| CE responses | Cardiac clinical scientist and cardiac physiologist | <p>Echocardiogram referral – triage to within 4 or 6 weeks depending on BNP – If no relevant details referral rejected until details provided – echocardiogram – report – report posted out to referral team and uploaded onto patient electronic notes (these systems typically do not alert the referring team that the echo report is available to review and often relies on paper copy being received in the post) – if new finding of heart failure with reduced ejection fraction, email to heart failure team to inform them (done at time of echocardiogram).</p> <p>Currently we are not allowed to provide results to patients so the patient would remain unaware.</p> |
| <p><i>Q13: Are you aware of any sources that report waiting times for echocardiography? If no, please use your own knowledge to provide a “ballpark number” or a range for the following waiting times:</i></p> <ol style="list-style-type: none"> <i>The wait time for an echocardiogram from initial referral.</i> <i>The wait time for a formal diagnosis following echocardiography.</i> <i>If a one-stop diagnostic clinic for heart failure is available in your organisation, how long do patients wait for an appointment in this clinic, from referral?</i> | | |
| SCM responses | Consultant cardiologist | <p>The wait time from initial referral in community for suspected heart failure varies in different parts of the country from few months to up to 8-9 months</p> <p>My organisation 2-6 weeks</p> <p>Wait time after echocardiography can be a further 1 month after diagnostic clinic appointment</p> <p>One-stop diagnostic clinic available selectively in my organisation (my clinic where I perform echo and a few other slots)</p> |
| | Consultant cardiologist | <p>a. This is variable across trusts and I am currently moving between several trusts. My primary workplace aims to complete the echo within 8 weeks of the referral. The wait time for formal diagnosis is entirely dependent on the referring doctor and their individual practices.</p> <p>b. From my own perspective, I check my own results every 1-2 days when working, so the maximum wait time would be 2 weeks if I happened to be at the beginning of a period of annual leave. If there was an abnormal report which needed immediate action all trusts I have worked at have a pathway which allows the sonographer to escalate the report to an on-call doctor.</p> <p>c. I am unaware of such a pathway.</p> |

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| | Consultant cardiologist | Waiting time for a routine echo in my region varies from 6 to around 35 weeks. For one stop clinics average wait is around 8 – 10 weeks |
| | GPwSI in cardiology | 13a) Echo wait 6–12 wks. b) Diagnosis 1–4 wks. c) One-stop clinic 4 wks. |
| CE responses | Cardiac clinical scientist and cardiac physiologist | NHS England diagnostic waiting times and activity report Approximate waiting times from my experience: a. 10-12 weeks b. Diagnosis is available immediately (or within a week if a review of the echo is need at an MDT). The time to diagnosis will depend on the referring team pick up with results. This can be up to 6 -12 months after the echocardiogram and depends on the backlog of the referring team. c. In our one stop clinic, patients with a BNP >2000 are typically waiting 6-10weeks. Patients with a BNP 400-2000 are waiting >10 weeks. |
| <p><i>Q14: A. Can you estimate the proportion of patients requiring cardiac MRI investigation for heart failure diagnosis?</i></p> <p><i>B. How long do patients wait for a cardiac MRI from initial referral?</i></p> | | |
| | | |
| SCM responses | Consultant cardiologist | 80% 3 -8 months (average 5-6 months) My organisation 2-3 months |
| | Consultant cardiologist | Unknown |
| | Consultant cardiologist | Probably 30-40% will get an MRI at the point of diagnosis, but ongoing monitoring is normally done by echo. In my trust waits are less than echo (around 6 weeks) |
| | GPwSI in cardiology | a) MRI needed ~10-15%. b) MRI wait 10–12 wks. |
| CE responses | Cardiac clinical scientist and cardiac physiologist | A. estimated at less than <1%. If echocardiography is limited, a contrast left ventricular opacification test using echocardiography would be the next test. B. Estimated at 6 months. |
| <p><i>Q15: Can you estimate the proportion of patients who would have acute onset of symptoms while waiting for an echocardiography appointment?</i></p> | | |
| | | |
| SCM responses | Consultant cardiologist | 30-35% (AED attendance, hospitalisation and mortality), 50-60% have acute worsening of symptoms leading to worsening quality of life, time off work etc. |
| | Consultant cardiologist | Unknown, but if there is more than an 8 week wait for an echo, then I estimate that 5% patients with heart failure might experience an acute decompensation prior to echo. |

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| | Consultant cardiologist | Difficult to know, but given the fact most heart failure patients are diagnosed as an inpatient probably quite high (hard to know in that group how many had had an echo ordered) |
| | GPwSI in cardiology | About 5–15% deteriorate while waiting |
| CE responses | Cardiac clinical scientist and cardiac physiologist | <1%. In my experience patients either are symptomatic or remain asymptomatic whilst waiting for an echocardiogram. There are very few instances where I need to get patients reviewed / admitted at the point of the echocardiography due to acute onset of symptoms whilst waiting for an appointment. |
| <p><i>Q16: Could you comment on whether the description of appointments applicable to each patient group, outlined in the 2018 NICE Guideline for Chronic Heart Failure (NG106), is representative of current practice?</i></p> <p><i>See Figure 1 at the foot of this table.</i></p> | | |
| SCM responses | Consultant cardiologist | - |
| | Consultant cardiologist | This seems correct except for the nurse appointments. This number in the first years seems higher than what I have experienced in practice although this is likely variable from trust to trust. |
| | Consultant cardiologist | It is a reasonable guide but there are more treatments for hfpef now so they probably need more appointments. For HFREF we now push for more rapid uptitration so may not need 10 HF nurse appts. Lot of variability depending on pt and their comorbidities |
| | GPwSI in cardiology | NICE NG106 still broadly accurate; timing targets often missed. |
| CE responses | Cardiac clinical scientist and cardiac physiologist | <p>I would say neither is representative of current practice</p> <p>HF-REF: patients would be seen by heart failure nurse; this may include 1-3 appointments to titrate medications. Once stable patient would be discharge back to GP with no further follow-up. There may be instances where younger patients are reviewed in cardiology clinics, but this is not reflective of all patients.</p> <p>I am not aware of patients having that many appointments.</p> <p>HR-PEF: These patients typically have an echocardiogram and are then referred back to the GP for management with diuretics and co-morbidities management. They wouldn't have the appointments are listed in the guidance.</p> |
| Patient Pathway (acute heart failure) | | |
| <p><i>Q17: Please read the below description (in italics) and comment on whether you think this is an accurate representation of the acute heart failure pathway. If not, please elaborate:</i></p> <p><i>"All patients with acute onset of symptoms would be hospitalised. During their inpatient stay, they receive echocardiography and MRI (if needed), then receive a diagnosis and start treatment."</i></p> | | |

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| SCM responses | Consultant cardiologist | Depending on the expertise of centres (such as ours about 60% of acute heart failure can be managed in an ambulatory setting or virtual ward (at home) |
| | Consultant cardiologist | This is an accurate representation of the acute heart failure pathway. |
| | Consultant cardiologist | I think this depends on the setting. If the patients get admitted under a cardiology team this is probably correct. If managed in A and E / acute medical unit or care of the elderly beds then the treatment is perhaps more variable |
| | GPwSI in cardiology | Mostly accurate, but MRI rarely acute; some managed ambulatory. |
| CE responses | Cardiac clinical scientist and cardiac physiologist | I think that is accurate of the majority of patients. Although whether patients are hospitalised is down to the patient, so you could have patients that are treated at home and attend urgent outpatient appointments. |
| <p><i>Q18: A. Would some of these hospitalised patients be discharged without having received an echocardiogram during their hospital stay, and be put onto the waiting list for an outpatient echocardiography?</i></p> <p><i>B. If yes, roughly what proportion?</i></p> | | |
| SCM responses | Consultant cardiologist | About 60% patients are discharged from A&E or hospital without having an echocardiogram AHF full report.pdf |
| | Consultant cardiologist | At my current trust this does not occur. However I have heard of this happening in other trusts although I am unsure of the proportion of patients this affects. |
| | Consultant cardiologist | Yes , but again very variable depending on the hospital / ward / team Overall across the country maybe 30% but that is a guess |
| | GPwSI in cardiology | a) Yes. b) Around 10–20%. |
| CE responses | Cardiac clinical scientist and cardiac physiologist | Yes, this could happen if it was deemed that the patient was well to go home but would be very rare. Proportion wise would be <1%. |
| <p><i>Q19: What is the entry point to the care pathway for acute heart failure patients? e.g. emergency department, urgent referral from GP, other.</i></p> | | |
| SCM responses | Consultant cardiologist | Entry points A&E, GP, community HF teams, from other clinics |
| | Consultant cardiologist | Emergency department, GP, other specialties, ambulatory care units |
| | Consultant cardiologist | The entry point is nearly always A and E. If they see the GP first they are still normally directed to A and E |
| | GPwSI in cardiology | Usually via ED or urgent GP referral. |
| CE responses | Cardiac clinical scientist and cardiac physiologist | Urgent referral from GP, IP requests. |

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| Q20: Do you have any other comments or information that you think would be helpful for our assessment? | | |
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| SCM responses | Consultant cardiologist | As also discussed previously the NICE EVA Topic is regarding AI assisted echocardiography to aid the diagnosis of HF. The above questions largely focus on the performance of echocardiography without enough emphasis regarding the diagnostic pathway of HF which is performed by HF specialists and the main issues which are due to delays in diagnosis of HF due to the lack of availability of echocardiography promptly in primary care and community settings in order for prompt initiation of life-saving HF treatments. There are also similar delays in echocardiography in the hospital setting particularly if the patient presents on Friday with acute HF and echocardiogram and prognostic therapies can be delayed for 4-5 days. The failings due to delays in hospital setting have been highlighted in the NCEPOD report AHF full report.pdf |
| | Consultant cardiologist | - |
| | Consultant cardiologist | - |
| | GPwSI in cardiology | No |
| CE responses | Cardiac clinical scientist and cardiac physiologist | N/A |

Abbreviations: A&E: accident and emergency; ACHD: adult congenital heart disease; AED: accident and emergency department; AI: artificial intelligence; CE: clinical expert; CMR: cardiac magnetic resonance; CT: computerised tomography; ECG: electrocardiogram; ED: emergency department; EF: ejection fraction; GDMT: guideline-directed medical therapy; GLS: global longitudinal strain; GP: general practitioner; GPwSI: general practitioner with special interest; HF: heart failure; HFpEF (HR-PEF): heart failure with preserved ejection fraction; HFrEF (HF-REF): heart failure with reduced ejection fraction; MDT: multidisciplinary team; MRI: magnetic resonance imaging; N/A: not applicable; NT-proBNP: N-terminal pro-B-type natriuretic peptide; SCM: specialist committee member; TOE: trans-oesophageal echocardiogram.

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Appendix B: Search strategies and PRISMA diagram

The EAG performed a search for clinical evidence as directed by the scope. The following bibliographic databases were searched on 22nd and 23rd September 2025 from inception using a combination of free-text terms and controlled vocabulary: MEDLINE via Ovid, Embase via Ovid, Cochrane Library (CDSR and CENTRAL), and International HTA database (INAHTA). Two clinical trial registries were searched for ongoing and unpublished trials: ClinicalTrials.gov and the International Clinical Trials Registry Platform (ICTRP), and the pre-print server medRxiv was searched for pre-prints. The EAG also searched the companies' websites for literature. The Medicines and Healthcare products Regulatory Agency's (MHRA) alerts, recalls and safety information and the FDA MAUDE database were searched for adverse events.

885 records were identified through the EAG database searches. 107 records were identified via searching company websites. Following de-duplication, 776 records were then sifted at title and abstract stage, where 356 records were excluded. 420 records were sifted at full-text stage. Records supplied by the companies were deduplicated against the results of the EAG database and company website searches, resulting in 32 additional records. 17 key studies were included (reported across 27 publications), 7 ongoing trials were included and 21 additional studies reported only in conference proceedings were included in an appendix ([Appendix C](#)) ([Figure 3](#)).

All records excluded at the full text screening stage are listed in [Appendix F](#) with reasons for exclusion.

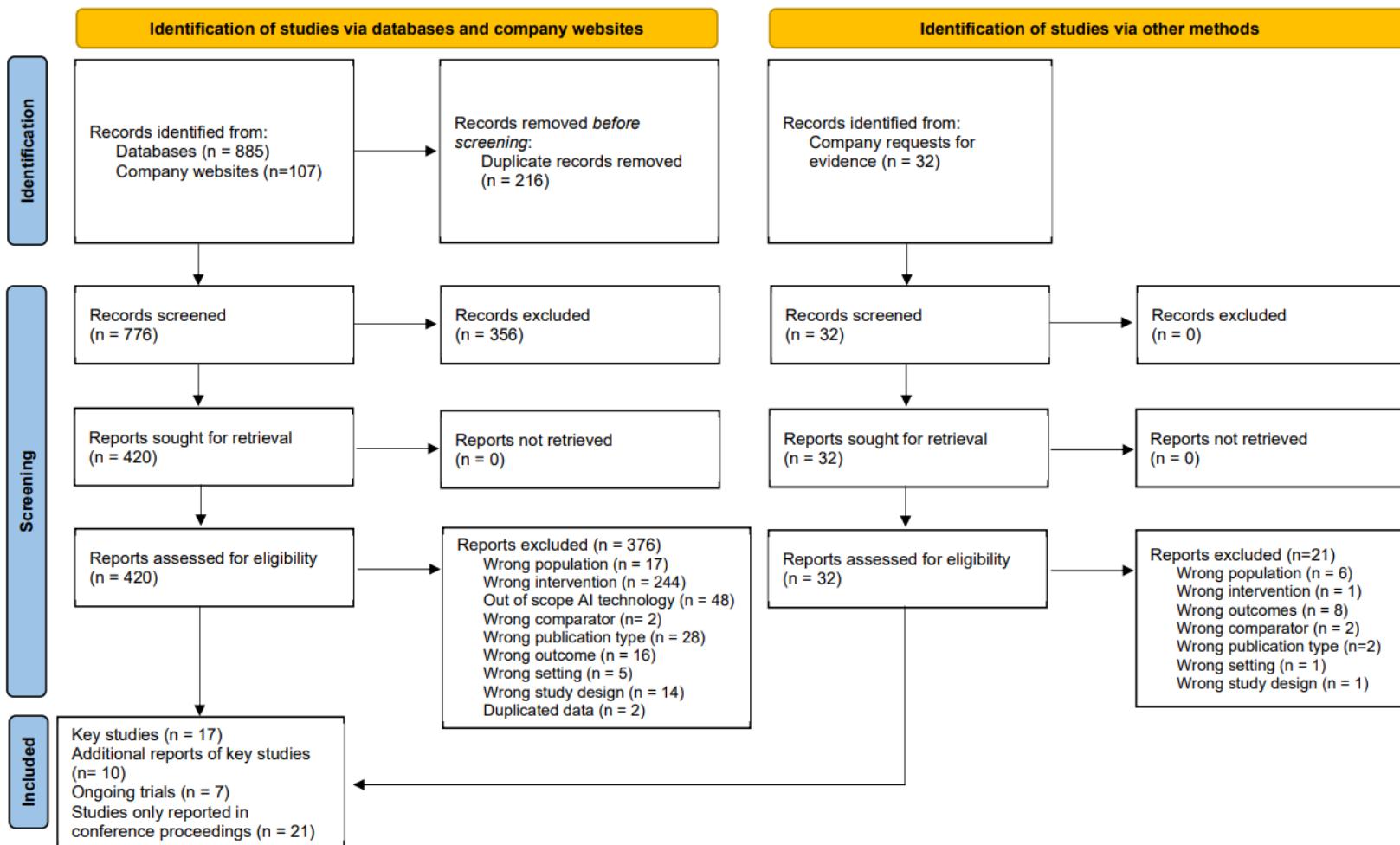


Figure 3: PRISMA Study Selection Flow Diagram.

Database and company website searches.

| Search date | Database / company website | Searcher | Number of hits |
|--|---|----------|----------------|
| 22/09/25 | Medline ALL (Ovid) | MK | 161 |
| 22/09/25 | Embase (Ovid) | MK | 614 |
| 23/09/25 | Cochrane Library CDSR Cochrane Library CENTRAL | MK/SW | 0 35 |
| 23/09/25 | International HTA database (INAHTA) | MK | 1 |
| 23/09/25 | ClinicalTrials.gov | MK | 32 |
| 23/09/25 | International Clinical Trials Registry Platform (ICTRP) | MK | 11 |
| 23/09/25 | medRxiv | MK | 31 |
| Total from databases before deduplication | | | 885 |
| 27/08/25 | Ultromics (The Proof) | AR | 45 |
| 28/08/25 | Us2.ai (Publications) | AR | 45 |
| 28/08/25 | EchoConfidence (Publication List) | AR | 8 |
| 28/08/25 | Ligence (Research highlights) | AR | 9 |
| Total from websites before deduplication | | | 107 |
| Total from databases and websites before deduplication | | | 992 |
| Total from databases and websites after deduplication | | | 776 |

Adverse event searches.

| Device | Query | Hits |
|--|-----------------------------|-----------------------------------|
| MHRA 23/10/25 (no filters) | | |
| EchoConfidence (MyCardium) | EchoConfidence MyCardium | 0 0 |
| EchoGo Heart Failure (Ultromics) | EchoGo Ultromics | 0 0 |
| Ligence (Ligence UAB) | Ligence | 0 |
| Us2.v2 (Us2.ai) | Us2.v2 Us2.ai | 25 (0 relevant) 4 (0 relevant) |
| FDA MAUDE 23/10/25 (simple search, all years) | | |
| EchoConfidence (MyCardium) | EchoConfidence MyCardium | 0 0 |
| EchoGo Heart Failure (Ultromics) | EchoGo Ultromics | 0 0 |
| Ligence (Ligence UAB) | Ligence | 0 |
| Us2.v2 (Us2.ai) | Us2.v2 | 0 |

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| | | |
|--|--------|---|
| | Us2.ai | 0 |
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Search strategies

Ovid MEDLINE(R) ALL <1946 to September 19, 2025>

| # | Query | Hits |
|------|--|---------|
| 1 | EchoGo*.mp. | 10 |
| 2 | Ultromics*.mp. | 5 |
| 3 | ligence*.mp. | 6 |
| 4 | "Us2.ai*".mp. | 9 |
| 5 | "Us2.v2*".mp. | 0 |
| 6 | "eko.ai*".mp. | 0 |
| 7 | "A*STAR Biomedical Research Council".mp. | 3 |
| 8 | ("A*STAR" and "Exploit Technologies").mp. | 1 |
| 9 | EchoConfidence*.mp. | 0 |
| 10 | MyCardium*.mp. | 12 |
| 11 | or/1-10 | 40 |
| 12 | exp Heart Failure/ | 161668 |
| 13 | ((heart or cardiac) adj2 (failure or insufficiency or decompensation)).tw. | 258642 |
| 14 | (HFref or HFmrEF or HFpEF).tw. | 10384 |
| 15 | or/12-14 | 297576 |
| 16 I | ((echocardi* or "echo cardi*" or "transthoracic cardi*" or ((heart or cardi*) adj2 (ultraso* or sonogra*))) adj10 (AI or "artificial intelligence*" or "deep learning" or "machine learning" or "neural network*" or CNN or DNN or "augmented intelligence" or "automated recognition")).tw. | 905 |
| 17 | 15 and 16 | 132 |
| 18 | 11 or 17 | 170 |
| 19 | limit 18 to english language | 165 |
| 20 | exp animals/ not humans.sh. | 5376628 |
| 21 | 19 not 20 | 161 |

Embase <1974 to 2025 September 18>

| # | Query | Hits |
|---|----------------|------|
| 1 | EchoGo*.mp. | 29 |
| 2 | Ultromics*.mp. | 21 |
| 3 | ligence*.mp. | 25 |
| 4 | "Us2.ai*".mp. | 29 |
| 5 | "Us2.v2*".mp. | 1 |

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| | | |
|----|--|--------|
| 6 | "eko.ai*".mp. | 7 |
| 7 | "A*STAR Biomedical Research Council".mp. | 5 |
| 8 | ("A*STAR" and "Exploit Technologies").mp. | 1 |
| 9 | EchoConfidence*.mp. | 0 |
| 10 | MyCardium*.mp. | 32 |
| 11 | or/1-10 | 126 |
| 12 | exp heart failure/ | 766637 |
| 13 | ((heart or cardiac) adj2 (failure or insufficiency or decompensation)).tw. | 442290 |
| 14 | (HFrefEF or HFmrEF or HFpEF).tw. | 24027 |
| 15 | or/12-14 | 836026 |
| 16 | ((echocardi* or "echo cardi*" or "transthoracic cardi*" or ((heart or cardi*) adj2 (ultraso* or sonogra*))) adj10 (AI or "artificial intelligence*" or "deep learning" or "machine learning" or "neural network*" or CNN or DNN or "augmented intelligence" or "automated recognition")).tw. | 1664 |
| 17 | 15 and 16 | 520 |
| 18 | 11 or 17 | 630 |
| 19 | limit 18 to english language | 614 |

Cochrane Library (23/09/2025)

| ID | Search | Hits |
|-----|--|-------|
| #1 | (EchoGo*) | 5 |
| #2 | (Ultromics*) | 4 |
| #3 | (ligence*) | 2 |
| #4 | ("Us2.ai") | 4 |
| #5 | ("Us2.v2") | 0 |
| #6 | ("eko.ai") | 0 |
| #7 | ("A*STAR Biomedical Research Council") | 0 |
| #8 | ("A*STAR" and "Exploit Technologies") | 0 |
| #9 | (EchoConfidence*) | 0 |
| #10 | (MyCardium*) | 1 |
| #11 | #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 | 12 |
| #12 | MeSH descriptor: [Heart Failure] explode all trees | 15009 |
| #13 | ((heart or cardiac) NEAR/1 (failure or insufficiency or decompensation)):ti,ab,kw | 40910 |
| #14 | (HFrefEF or HFmrEF or HFpEF):ti,ab,kw | 2803 |
| #15 | #12 OR #13 OR #14 | 40981 |
| #16 | ((echocardi* or (echo NEXT cardi*) or (transthoracic NEXT cardi*) or ((heart or cardi*) NEAR/1 (ultraso* or sonogra*))) NEAR/9 (AI or (artificial NEXT intelligence*) or "deep learning" or "machine | 67 |

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| | | |
|-----|---|---------|
| | learning" or (neural NEXT network*) or CNN or DNN or "augmented intelligence" or "automated recognition")):ti,ab,kw | |
| #17 | #15 AND #16 | 27 |
| #18 | #11 OR #17 | 35 |
| | <i>CDSR</i> <i>CENTRAL</i> | 0 35 |

INAHTA (23/09/2025)

| Line | Query | Hits |
|------|---|------|
| 18 | #17 OR #11 | 1 |
| 17 | #16 AND #15 | 0 |
| 16 | (echocardi* OR "echo cardi*" OR "transthoracic cardi*" OR ((heart OR cardi*) AND (ultraso* OR sonogra*))) AND (AI OR "artificial intelligence*" OR "deep learning" OR "machine learning" OR "neural network*" OR CNN OR DNN OR "augmented intelligence" OR "automated recognition") | 0 |
| 15 | #14 OR #13 OR #12 | 492 |
| 14 | (HFrEF OR HFmrEF OR HFpEF) | 1 |
| 13 | ((heart OR cardiac) AND (failure OR insufficiency OR decompensation)) | 444 |
| 12 | "Heart Failure"[mhe] | 272 |
| 11 | #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1 | 1 |
| 10 | (MyCardium*) | 0 |
| 9 | (EchoConfidence*) | 0 |
| 8 | ("A*STAR" and "Exploit Technologies") | 0 |
| 7 | ("A*STAR Biomedical Research Council") | 0 |
| 6 | ("eko.ai") | 0 |
| 5 | ("Us2.v2") | 0 |
| 4 | ("Us2.ai") | 0 |
| 3 | (ligence*) | 0 |
| 2 | (Ultromics*) | 0 |
| 1 | (EchoGo*) | 1 |

Clinicaltrials.gov (23/09/2025)

| Query | Hits | Total hits |
|------------------------------------|------|------------|
| EchoGo (Intervention/treatment) | 3 | 3 |
| Ultromics (Intervention/treatment) | 2 | 3 |
| Ligence (Intervention/treatment) | 0 | 3 |
| Us2.ai (Intervention/treatment) | 2 | 5 |
| Us2.v2 (Intervention/treatment) | 0 | 5 |
| eko.ai (Intervention/treatment) | 0 | 5 |

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| | | |
|---|----|----|
| EchoConfidence (Intervention/treatment) | 0 | 5 |
| MyCardium (Intervention/treatment) | 0 | 5 |
| Heart Failure (Condition/disease) | 22 | 26 |
| Artificial Intelligence (Other terms) | | |
| Echocardiography (Intervention/treatment) | | |
| Heart Failure (Condition/disease) | 4 | 26 |
| Deep learning (Other terms) | | |
| Echocardiography (Intervention/treatment) | | |
| Heart Failure (Condition/disease) | 7 | 32 |
| Machine Learning (Other terms) | | |
| Echocardiography (Intervention/treatment) | | |
| Heart Failure (Condition/disease) | 1 | 32 |
| Neural Network (Other terms) | | |
| Echocardiography (Intervention/treatment) | | |
| Heart Failure (Condition/disease) | 6 | 32 |
| augmented intelligence (Other terms) | | |
| Echocardiography (Intervention/treatment) | | |
| Heart Failure (Condition/disease) | 0 | 32 |
| automated recognition (Other terms) | | |
| Echocardiography (Intervention/treatment) | | |

ICTRP (23/09/2025)

| Query | Hits |
|--|--------------------|
| EchoGo OR Ultromics OR ligence OR Us2.ai OR Us2.v2 OR eko.ai OR EchoConfidence OR MyCardium | 2 |
| heart failure (in the Condition) AND AI or "artificial intelligence" or "deep learning" or "machine learning" or "neural network" or CNN or DNN or "augmented intelligence" or "automated recognition" (in the Intervention) | 9 |
| Total deduplicated | 11 (no duplicates) |

MedRxiv (23/09/2025)

| Query (in Full Text or Abstract or Title, words: all) | Hits | Total hits |
|---|------|------------|
| EchoGo | 2 | 2 |
| Ultromics | 18 | 19 |
| Ligence | 2 | 21 |
| Us2.ai | 10 | 31 |
| Us2.v2 | 0 | 31 |
| eko.ai | 0 | 31 |
| EchoConfidence | 0 | 31 |
| MyCardium | 0 | 31 |

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Appendix C: Associated publications and conference proceedings

The table below lists publications identified as relevant by the EAG which are associated with key included studies. Where multiple publications were identified for the same study, only the most recent and comprehensive publication was used for data extraction and is used as the primary study reference throughout this report.

| # | Reference | Associated key study |
|----|-----------------------|--|
| 1 | Akerman et al. 2024 | Akerman et al. 2023a |
| 2 | Akerman et al. 2023d | Akerman et al. 2023a |
| 3 | Akerman et al. 2023b | Akerman et al. 2023a |
| 4 | Campbell et al. 2023 | Campbell et al. 2025 |
| 5 | Cassianni et al. 2023 | Cassianni et al. 2024 |
| 6 | Dowsing et al. 2025 | Associated with study provided AIC for EchoConfidence (no usable data) |
| 7 | Huang et al. 2023 | Huang et al. 2024a |
| 8 | Sakamoto et al. 2024 | Sakamoto et al. 2025 |
| 9 | Tromp et al. 2022c | Tromp et al. 2022a |
| 10 | Upton et al. 2024 | Akerman et al. 2023a |

The table below summarises conference proceedings identified as relevant to the decision problem by the EAG. Results were not extracted from conference proceedings due to the lack of detail available to facilitate assessment of study quality and the time constraints of this assessment. The EAG reviewed the conference abstracts for relevance to the evidence gaps identified (Section 8).

| Author, year | Study Design | Population | Intervention | Comparator | Primary outcome measure(s) | Setting (country) |
|-----------------------------|----------------------------|---|--|--------------------------------|---|---|
| EchoGo Heart Failure | | | | | | |
| Akerman 2023c | Retrospective case-control | Patients with ICD-10 codes for HF (I50.X), LVEF \geq 50%, and grade II or III diastolic dysfunction | EchoGo Heart Failure | Clinical H2FPEF score | Sensitivity, specificity | Beth Israel Deaconess Medical Center, Harvard Medical School, USA |
| Akerman 2025b | Clinical validation | Patients undergoing clinically indicated echocardiograms | EchoGo Heart Failure | H2FPEF and HFA-PEFF scores | Discrimination, calibration, classification, and clinical utility | NR |
| Akerman 2025c | Clinical validation | Patients with cardiac amyloidosis and HFpEF | EchoGo Amyloidosis and Echo Go Heart Failure | Models separately and combined | Output and differentiation | NR |

| Author, year | Study Design | Population | Intervention | Comparator | Primary outcome measure(s) | Setting (country) |
|------------------|---------------------|--|----------------------------|---|--|--|
| Hamid 2024 | Clinical validation | Patients with New York Heart Association Class I, II, III or ambulatory IV heart failure with LVEF 40% and elevated PCWP during supine ergometry (2'25 mmHg) | EchoGo Heart Failure v2.0 | PCWP at rest and exercise, 6MWT and KCCQ. | Association with hemodynamic, functional, and patient-reported outcomes | NR |
| Karnik 2024 | Clinical validation | HFpEF | EchoGo Heart Failure | Routine echocardiographic analysis using tools such as HF2PEF score | Ability to detect HFpEF from echocardiogram alone without any additional clinical information | NR |
| Karnik 2025 | Clinical validation | Patients with preclinical HF and abnormal cardiac mechanics | EchoGo HF | 6MWT distance and KCCQ scores | HFpEF probabilities and associated risk factors | NR |
| Subramanian 2024 | Clinical validation | Subclinical HFpEF | EchoGo (version not named) | Previously validated H2FpEF score | HFpEF phenotype and the presence of subclinical HFpEF, VO ₂ peak, exercise Stress E/e', left ventricular strain, and left atrial strain | UT Southwestern Medical Center, Texas, USA |
| Yaros 2024 | Clinical validation | HFpEF | EchoGo (version not named) | Clinical history, normal ejection fraction (>45%), and evidence of elevated filling | Diagnostic and prognostic performance – | NR |

| Author, year | Study Design | Population | Intervention | Comparator | Primary outcome measure(s) | Setting (country) |
|---------------|----------------------------------|--|--------------|--|--|---|
| | | | | pressure by resting (PCWP > 15 mm Hg) or exercise invasive hemodynamics (PCWP > 25 mm Hg) or echocardiogram (E/e' >14) | sensitivity, accuracy and specificity | |
| Us2.ai | | | | | | |
| Dohse 2024 | Clinical validation | Patients with aortic root dilation | Us2.ai | Board certified cardiologist | Manual measurements of LVOT, SoV, SJ | University of Illinois, Chicago (USA) |
| Ioannou 2023 | Clinical validation | Transthyretin amyloidosis cardiomyopathy patients | Us2.ai | Manual analysis | Parameters and prognosis prediction | NR |
| Karnik 2024 | Clinical validation | Patients who underwent routine, clinical echocardiograms | Us2.ai | Board-certified cardiologists | Precision, accuracy, and agreement between the automated and manual measurements | Northwestern Memorial Hospital, Chicago, IL (USA) |
| Myhre 2023 | Model development and validation | Patients undergoing echocardiographic strain imaging | Us2.ai | Manual strain analysis and measurements | Interpretation of echocardiographic strain imaging | Taiwan and USA |

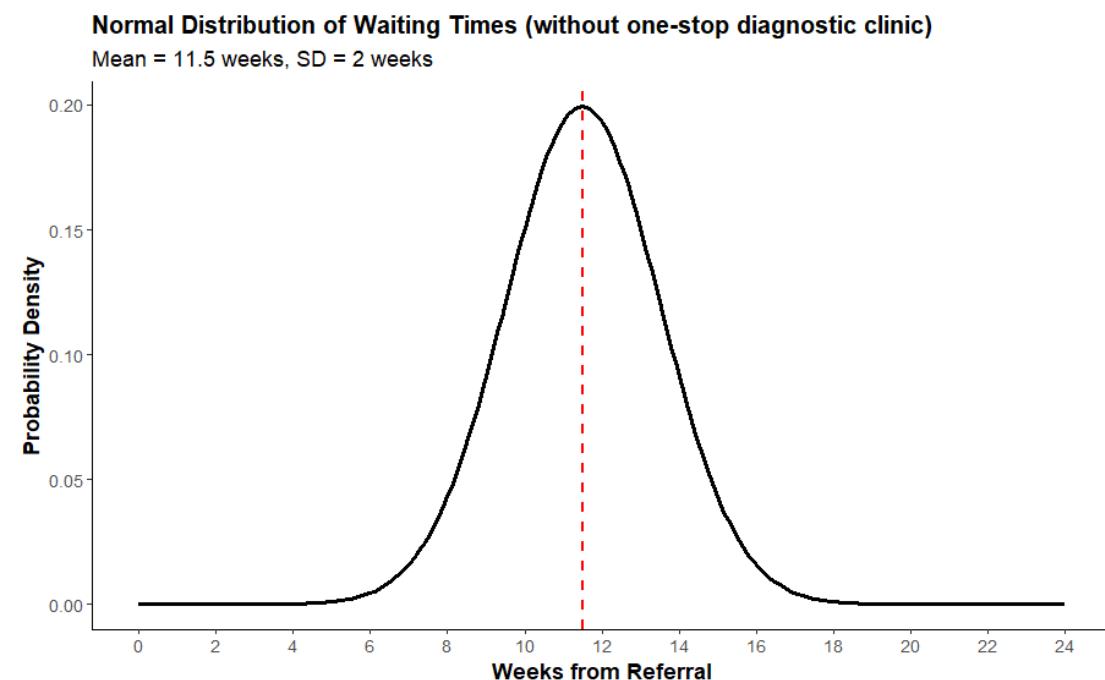
| Author, year | Study Design | Population | Intervention | Comparator | Primary outcome measure(s) | Setting (country) |
|------------------|---------------------------------|---|--------------|--|---|----------------------------------|
| Palmer 2024 | Clinical validation | Patients undergoing contrast echocardiography to assess LV volumes | US.2.ai | Human reader | LVEDV, LVESV, and LVEF | |
| Shrivastav 2024 | Clinical validation | Patients undergoing measurement of left ventricular diastology | US.2.ai | Gold standard measurements made by board-certified cardiologists | Diastolic function | NR |
| Teramoto 2022 | Clinical validation | PROMIS-HFpEF study cohort (not specified) | Us.ai | Conventional echocardiographic measurements | Association of automated and manual parameters with N-terminal pro-B-type natriuretic peptide | Multinational (not specified) |
| Tsourdinis 2024a | Clinical validation | Patients undergoing transthoracic echocardiography (from 26 TTE studies selected) | Us2.ai | Board-certified cardiologists | Feasibility of Us2.ai for assessment of aortic valve parameters was re-demonstrated | NR |
| Tsourdinis 2024b | Clinical validation | Patients with left ventricular ejection fraction (from 25 studies selected) | Us2.ai | Board-certified cardiologists | Correlation between AI and human reads of LVEF assessment | NR |
| Venneri 2024 | Prospective longitudinal cohort | Patients with transthyretin cardiac amyloidosis | Us2.ai | N/A | Association between changes in echocardiographic parameters and mortality | National Amyloidosis Centre (UK) |

| Author, year | Study Design | Population | Intervention | Comparator | Primary outcome measure(s) | Setting (country) |
|----------------------|-----------------------------------|---|--|---------------------------------------|---|-------------------|
| Walser 2025 | Retrospective longitudinal cohort | Patients with cardiac transthyretin amyloidosis, who underwent serial echocardiograms | Us2.ai | Expert cardiologist | Automated measurements agreement and precision | NR |
| Yaku 2024 | Clinical validation | Patients with HF and LVEF $\geq 40\%$ | Us2.ai | Core labs | Association between test characteristics of core lab vs. deep learning-based measurements | USA |
| Ligence Heart | | | | | | |
| Sveric 2025 | Clinical validation | Patients with symptomatic aortic valve stenosis, with mitral valve regurgitation, or with tricuspid valve regurgitation | A fully automated artificial intelligence system for left ventricular mass measurement in Echo (not named) | Experienced cardiologist measurements | Pearson's correlation coefficient, regression analysis, and mean absolute error to assess agreement between AI and human measurements | NR |

Appendix D: Baseline time to diagnosis and proportion of patients diagnosed in standard care

Inputs from clinical experts and NHS Diagnostic waiting time and activity data were used to model a normal distribution curve (Figure 1) based on 10.6% of patients waiting more than 13 weeks for an echocardiogram, and the assumptions that no patients received an echocardiogram prior to 6 weeks and that patients who waited more than 13 weeks received an echocardiogram by week 16. A mean waiting time and standard deviation that met these assumptions was established through trial and error. From the normal distribution curve, the proportion of patients receiving an echocardiogram in two-week intervals was extracted (Table 1, Section A.2).

Figure 1. Normal Distribution Curve of Baseline Waiting Time to Echocardiogram (in settings without a one-stop diagnostic clinic)



Once the time waited for echocardiography was established, the additional wait time between the echocardiography and clinical assessment (Section A.3) was aggregated to give the proportion of patients in each two-week

waiting time interval in settings without a one-stop diagnostic clinic (Section A.4).

For settings with a one-stop diagnostic clinic, there was no data available on waiting list activity, therefore estimates from clinical experts was used. From the estimates provided, which ranged from 2 to 10 weeks from referral to diagnosis (because the echocardiography and clinical assessment occurred on the same day), the mean wait time was calculated to be 6 weeks. Using this information a normal distribution curve was modelled (Figure 2) to provide the proportions of patients diagnosed in each two-week interval in settings with a one-stop diagnostic clinic (Section B.2).

Finally, weighting based on the proportion of patients who attend a one-stop diagnostic clinic was applied to the proportion of HF patients diagnosed in two-week intervals (Section C.2). The cumulative proportion diagnosed was used in the model.

Figure 2. Normal Distribution Curve of Baseline Waiting Time to Diagnosis (in settings with a one-stop diagnostic clinic)

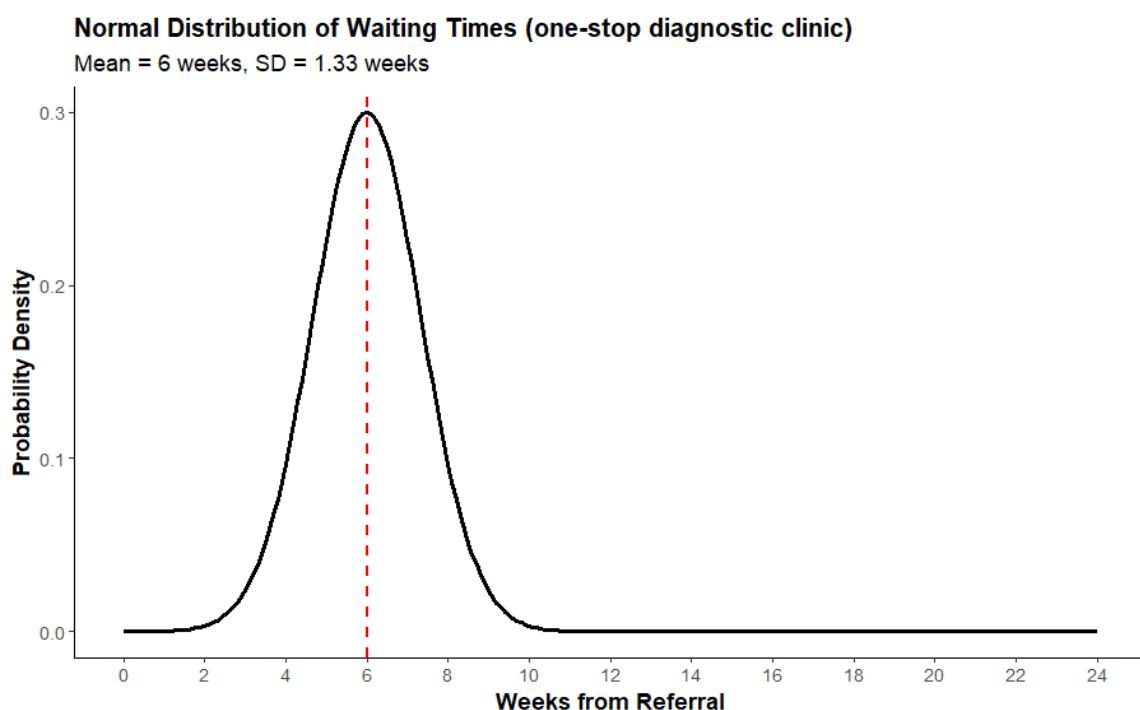


Table 1. Proportion of HF patients diagnosed in standard care

| Section | | | |
|------------|---|-------------------------------------|--|
| A.1 | Settings without one stop diagnostic clinic | Value | Source |
| | Waiting time from referral to echo | 6-12 weeks | Clinical expert, excluding outliers 36 weeks |
| | Waiting time from echo to clinical assessment | 1-4 weeks | Clinical expert |
| | Total wait from referral to clinical assessment | 7-16 weeks | Calculation |
| | % patient have been waiting for 13+ weeks in those waiting for echocardiography | 10.6 | NHS diagnostic waiting time & activity, Jul 2025 |
| A.2 | Time from referral to echocardiography (week) | % received an echocardiogram | cumulative % |
| | 0 | 0% | 0% |
| | 2 | 0% | 0% |
| | 4 | 0.01% | 0% |
| | 6 | 0.29% | 0% |
| | 8 | 3.71% | 4% |
| | 10 | 18.65% | 23% |
| | 12 | 37.21% | 60% |
| | 14 | 29.57% | 89% |
| | 16 | 10.56% | 100% |
| A.3 | Time from echocardiography to clinical assessment (week) | % seen a clinician | cumulative % |
| | 0 | 0% | 0% |
| | 2 | 50% | 50% |
| | 4 | 50% | 100% |
| A.4 | Total time from referral to clinical assessment (week) | % diagnosed | cumulative % |
| | 0 | 0% | 0% |
| | 2 | 0% | 0% |
| | 4 | 0% | 0% |
| | 6 | 0% | 0% |
| | 8 | 0% | 0% |
| | 10 | 2% | 2% |
| | 12 | 11% | 13% |
| | 14 | 28% | 41% |
| | 16 | 33% | 75% |
| | 18 | 20% | 95% |
| | 20 | 5% | 100% |
| B.1 | Settings with one stop diagnostic clinic | Value | Source |
| | <i>Waiting time from referral to clinical assessment</i> | 2-10 weeks | Clinical expert |
| B.2 | Time from referral to clinical assessment (week) | % diagnosed | cumulative % |
| | 0 | 0% | 0% |
| | 2 | 0% | 0% |
| | 4 | 7% | 7% |
| | 6 | 43% | 50% |
| | 8 | 43% | 93% |
| | 10 | 7% | 100% |

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| C.1 | All settings, weighted | Value | Source |
|-----|--|--------------------|---------------------|
| | % one stop diagnostic clinic | 51.90 | Kwok, 2025 |
| C.2 | Weighted total time from referral to clinical assessment (week) | % diagnosed | cumulative % |
| | 0 | 0% | 0.0% |
| | 2 | 0% | 0% |
| | 4 | 3%. | 3% |
| | 6 | 23% | 26% |
| | 8 | 23% | 49% |
| | 10 | 4% | 53% |
| | 12 | 5% | 58% |
| | 14 | 13% | 72% |
| | 16 | 16% | 88% |
| | 18 | 10% | 98% |
| | 20 | 3% | 100% |

Note. Due to rounding, figures may not add up to totals.

Appendix E: Effect of reduced echocardiography time with AI technologies on the waiting times

Based on the time reduction derived from clinical studies, new echocardiography durations, time saved (in %) and therefore new number of procedures performed per day were calculated. The percentage reduction in average wait time was applied to generate a new distribution of echocardiography wait time. The model also assumed the same reduction for the one stop diagnostic clinic wait time. The reduction in average wait time with EchoConfidence was estimated to be 17%, and 0% for Us2.ai (base case). Using EchoConfidence as an example, the new distribution is illustrated as follows:

Table 2. Proportion of HF patients diagnosed (EchoConfidence)

| Settings without one stop diagnostic clinic | Value | Source |
|---|-------------------------------------|--|
| Average waiting time | 11.50 weeks | Mean used to generate distribution in base case |
| Number of procedures per day | 10 | Clinical experts |
| Time per procedure | 0.75 hr | Clinical experts |
| Patient load | 575 | Calculation |
| New time per procedure | 0.59 hr | Calculation, Almeida et al.: unpublished data 2025 |
| New number of procedures per day | 12 | Calculation |
| New average waiting time | 9.58 weeks | Calculation |
| % time reduction | 17% | Calculation |
| Time from referral to echocardiography (week) | % received an echocardiogram | cumulative % |
| 0 | 0% | 0% |
| 2 | 0% | 0% |
| 4 | 0% | 0% |
| 6 | 4% | 4% |
| 8 | 18% | 22% |
| 10 | 37% | 59% |
| 12 | 30% | 89% |
| 14 | 10% | 99% |
| 16 | 1% | 100% |
| Time from echocardiography to clinical assessment (week) | % seen a clinician | cumulative % |
| 0 | 0% | 0% |
| 2 | 50% | 50% |
| 4 | 50% | 100% |
| Total time from referral to clinical assessment (week) | % diagnosed | cumulative % |
| 0 | 0% | 0% |
| 2 | 0% | 0% |
| 4 | 0% | 0% |

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| | | |
|--|--------------------|---------------------|
| 6 | 0% | 0% |
| 8 | 2% | 2% |
| 10 | 11% | 13% |
| 12 | 28% | 41% |
| 14 | 34% | 74% |
| 16 | 20% | 94% |
| 18 | 5% | 99% |
| 20 | 1% | 100% |
| Settings with one stop diagnostic clinic | Value | Source |
| Time from referral to clinical assessment (week) | % diagnosed | cumulative % |
| 0 | 0% | 0% |
| 2 | 1% | 1% |
| 4 | 22% | 23% |
| 6 | 55% | 78% |
| 8 | 21% | 99% |
| 10 | 1% | 100% |
| All settings, weighted | Value | Source |
| <i>% one stop diagnostic clinic</i> | 51.90 | Kwok 2025 |
| Weighted total time from referral to clinical assessment (week) | % diagnosed | cumulative % |
| 0 | 0% | 0% |
| 2 | 0% | 0% |
| 4 | 11% | 12% |
| 6 | 29% | 41% |
| 8 | 12% | 52% |
| 10 | 6% | 58% |
| 12 | 13% | 71% |
| 14 | 16% | 88% |
| 16 | 10% | 97% |
| 18 | 3% | 100% |
| 20 | 0% | 100% |

Note. Due to rounding, figures may not add up to totals.

Appendix F: Studies excluded at full text

| # | Reference | Exclusion reason |
|-----|---|------------------------|
| 1. | Abraham, N., Sanagala, T., Stoilova, M., & Karagodin, I. (2025). Artificial Intelligence in Echocardiography—Revolution or Replacement? <i>Journal of the American Society of Echocardiography</i> , 38(8), 733. https://doi.org/https://doi.org/10.1016/j.echo.2025.04.012 | Wrong publication type |
| 2. | Abramikas, Z., Jasiukeviciute, I., Balciunaite, G., Glaveckaite, S., Palionis, D., & Valeviciene, N. (2025). Artificial Intelligence Performance in Cardiac Magnetic Resonance Strain Analysis for Aortic Stenosis: Validation with Echocardiography and Healthy Controls. <i>Medicina (Kaunas, Lithuania)</i> , 61(6). https://doi.org/https://dx.doi.org/10.3390/medicina61060950 | Wrong intervention |
| 3. | Abramikas, Z., Kazukauskiene, I., Sablauskas, K., Cesnaitė, G., Vrublevska, G., Pugaciauskaitė, K., Balciūnaitė, G., & Glaveckaitė, S. (2025). Agreement between automated echocardiography and expert cardiologist for aortic valve hemodynamic parameters in severe aortic stenosis patients. <i>European Heart Journal - Cardiovascular Imaging</i> , 26, jeae333.033. https://doi.org/10.1093/ehjci/jeae333.033 | Wrong intervention |
| 4. | Adedinsewo, D. A., Morales-Lara, A. C., Afolabi, B. B., Kushimo, O. A., Mbakwem, A. C., Ibiyemi, K. F., Ogunmodede, J. A., Raji, H. O., Ringim, S. H., Habib, A. A., Hamza, S. M., Ogah, O. S., Obajimi, G., Saanu, O. O., Jagun, O. E., Inofomoh, F. O., Adeolu, T., Karaye, K. M., Gaya, S. A., . . . Carter, R. E. (2024). Artificial intelligence guided screening for cardiomyopathies in an obstetric population: a pragmatic randomized clinical trial. <i>Nature Medicine</i> , 30(10), 2897 EP - 2906. https://doi.org/https://dx.doi.org/10.1038/s41591-024-03243-9 | Wrong intervention |
| 5. | Adedinsewo, D., Carter, R. E., Attia, Z., Johnson, P., Kashou, A. H., Dugan, J. L., Albus, M., Sheeke, J. M., Bellolio, F., Friedman, P. A., Lopez-Jimenez, F., & Noseworthy, P. A. (2020). Artificial Intelligence-Enabled ECG Algorithm to Identify Patients With Left Ventricular Systolic Dysfunction Presenting to the Emergency Department With Dyspnea. <i>Circulation. Arrhythmia and electrophysiology</i> , 13(8), e008437. https://doi.org/https://dx.doi.org/10.1161/CIRCEP.120.008437 (Comment in: <i>Circ Arrhythm Electrophysiol</i> . 2020 Aug;13(8):e009111. doi: 10.1161/CIRCEP.120.009111 | Wrong intervention |
| 6. | Adhyapak, S. M., & Menon, P. G. (2024). Detecting Incipient Heart Failure in Asymptomatic Patients with Normal Ejection Fraction and comparisons with patients with heart failure and preserved ejection fraction using TimeSformer for classifying Echocardiography videos. <i>medRxiv</i> . https://doi.org/https://dx.doi.org/10.1101/2024.10.22.24315954 | OOS AI technology |
| 7. | Adhyapak, S., & Menon, P. (2024). Classification of Echocardiography Videos Using TimeSformer for Detecting Incipient Heart Failure in Asymptomatic Patients with Normal Ejection Fraction and Patients with Heart Failure. <i>Circulation</i> , 150. https://doi.org/https://dx.doi.org/10.1161/circ.150.suppl_1.4120990 (American Heart Association's 2024 Scientific Sessions and the American Heart Association's 2024 Resuscitation Science Symposium. Chicago, IL United States.) | OOS AI technology |
| 8. | Agency for Care Effectiveness. (2025). EchoGo Heart Failure to aid in the diagnosis of heart failure with preserved ejection fraction. https://www.ace-hta.gov.sg/healthcare-professionals/ace-horizon-scanning/echogo-heart-failure-to-aid-in-the-diagnosis-of-heart-failure-with-preserved-ejection-fraction | Wrong publication type |
| 9. | Aghezzaf, S., Coisne, A., Hamzi, K., Toupin, S., Bouleti, C., Fauvel, C., Brette, J. B., Montaigne, D., Rossanaly Vasram, R., Trimaille, A., Lemesle, G., Schurtz, G., Dillinger, J. G., Henry, P., & Pezel, T. (2023). Machine learning score focused only on echocardiographic data to predict in-hospital outcomes in ICCU patients. A study from the ADDICT ICCU cohort. <i>European Heart Journal</i> , 44. https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehad655.015 (European Society of Cardiology Congress, ESC 2023. Amsterdam Netherlands.) | Wrong intervention |
| 10. | Aghezzaf, S., Coisne, A., Hamzi, K., Toupin, S., Bouleti, C., Fauvel, C., Brette, J. B., Montaigne, D., Vasram, R. R., Trimaille, A., Lemesle, G., Schurtz, G., Dillinger, J. G., Henry, P., & Pezel, T. (2024). Machine learning score using only echocardiographic data for prediction of in-hospital outcomes in ICCU patients. <i>Archives of Cardiovascular Diseases</i> , 117(1), S66. https://doi.org/https://dx.doi.org/10.1016/j.acvd.2023.10.117 (JESFC 2024. Paris France.) | Wrong intervention |

| | | |
|-----|---|---------------------------------|
| 11. | Ahluwalia, M., Almadani, A., Agu, E., & Kpodonu, J. (2023). HYPERTROPHIC CARDIOMYOPATHY DETECTION IN DIVERSE POPULATIONS USING DEEP LEARNING. <i>Journal of the American College of Cardiology</i> , 81(8), 417. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2823%2900861-6 (ACC.23. New Orleans United States.) | OOS AI technology |
| 12. | Akerman, A. (2025). Echocardiography and Artificial Intelligence in the Cardiac Amyloidosis Referral Pathway. | Wrong intervention |
| 13. | Akerman, A., Bernard, L., Deschamps, T., Foster, B., Hawkes, W., Mirhadi, E., Piotrowska, H., Sarwar, R., Tetlow, L., Woodward, G., & Becher, H. (2022). Automated contouring of non-contrast echocardiograms result in similar estimates of left ventricular function to manually contoured contrast-enhanced images in chemotherapy patients. <i>European Heart Journal - Cardiovascular Imaging</i> , 23, jeab289.013. https://doi.org/10.1093/ehjci/jeab289.013 | Wrong population |
| 14. | Akerman, A., Bernard, L., Deschamps, T., Foster, B., Hawkes, W., Mirhadi, E., Piotrowska, H., Sarwar, R., Tetlow, L., Woodward, G., & Becher, H. (2022). FULLY AUTOMATED CONTOURING OF CONTRAST ENHANCED ECHOCARDIOGRAMS IN CANCER THERAPY-RELATED CARDIAC DYSFUNCTION IS FEASIBLE AND PRECISE. <i>Journal of the American College of Cardiology</i> , 79(9), 1942. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2822%2902933-3 (ACC.22. Washington, DC United States.) | Wrong intervention |
| 15. | Al-Alusi, M., Kopparapu, K., Singh, P., Achille, P. D., Lau, E. S. W., Reeder, C., Khurshid, S., Ellinor, P., Ho, J., Picard, M. H., Batra, P., & Lubitz, S. (2023). RV SIZE MEASURED BY DEEP LEARNING PREDICTS ATRIAL FIBRILLATION, HEART FAILURE AND MORTALITY. <i>Journal of the American College of Cardiology</i> , 81(8), 2275. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2823%2902719-5 (ACC.23. New Orleans United States.) | Wrong intervention |
| 16. | Alenezi, F. (2025). AI-Automated Detection of Hypertrophic Cardiomyopathy by Echocardiography: Training and External Validation. <i>ASE2025</i> , | Wrong population |
| 17. | Ali, M. R., Lam, C. S. P., Stromberg, A., Hand, S. P. P., Booth, S., Zaccardi, F., McCann, G. P., Khunti, K., & Lawson, C. A. (2025). Heart failure symptoms predict hospitalization and mortality at diagnosis, 6 and 12 month follow-ups. <i>medRxiv</i> , 2024.2006.2012.24308679. https://doi.org/10.1101/2024.06.12.24308679 | Wrong intervention |
| 18. | Alishetti, S., Pan, W., Beecy, A. N., Liu, Z., Gong, A., Huang, Z., Clerkin, K. J., Goldsmith, R. L., Majure, D. T., Kelsey, C., vanMaanan, D., Ruhl, J., Tesfuzigta, N., Lancet, E., Kumaraiah, D., Sayer, G., Estrin, D., Weinberger, K., Kuleshov, V., ... Uriel, N. (2025). Predicting Cardiopulmonary Exercise Testing Performance in Patients Undergoing Transthoracic Echocardiography - An AI Based, Multimodal Model. <i>medRxiv</i> . https://doi.org/https://dx.doi.org/10.1101/2025.07.05.25330921 | Wrong intervention |
| 19. | Alotaibi, A., Contreras, R., Thakker, N., Mahapatro, A., Adla Jala, S. R., Mohanty, E., Devulapally, P., Mirchandani, M., Marsool Marsool, M. D., Jain, S. M., Joukar, F., Alizadehhasl, A., Hosseini Jebelli, S. F., Amini-Salehi, E., & Ameen, D. (2025). Bibliometric analysis of artificial intelligence applications in cardiovascular imaging: trends, impact, and emerging research areas. <i>Annals of medicine and surgery</i> (2012), 87(4), 1947-1968. https://doi.org/https://dx.doi.org/10.1097/MS9.0000000000003080 | Wrong study design |
| 20. | Al-Zahir, M., Punjabi, K., Artico, J., Shiwani, H., Davies, R., Moon, J., Kellman, P., Xue, H., & Pierce, I. (2024). Deployed Inline AI for Ventricular Analysis - a Review and Classification of Errors During the First 1500 Clinical Cases. <i>Journal of Cardiovascular Magnetic Resonance</i> , 26, 100145. https://doi.org/https://dx.doi.org/10.1016/j.jcmr.2024.100145 (CMR 2024 Global CMR Conference. QEII Centre, London United Kingdom.) | Wrong intervention |
| 21. | Alzahrani, T., Choi, B., Krepp, J., & Lewis, J. F. (2019). Predicting clinical outcomes of inpatients with heart failure based on echocardiogram reports using natural language processing and deep learning models. <i>Circulation</i> , 140. https://doi.org/https://dx.doi.org/10.1161/circ.140.suppl_1.15630 (American Heart Association Scientific Sessions, AHA 2019. Philadelphia, PA United States.) | Wrong intervention |
| 22. | Andersson, P., Lindqvist, P., & Venkateshvaran, A. (2025). Utilizing echocardiographic findings and machine learning to predict elevated left ventricular filling pressures in patients with preserved ejection fraction. <i>European Heart Journal Cardiovascular Imaging</i> , 26, i705 EP - i706. https://doi.org/https://dx.doi.org/10.1093/ehjci/jeae333.455 (24th annual congress of the European Association of Cardiovascular Imaging. Berlin Germany.) | Wrong intervention |
| 23. | Andjelkovic, K., Kalimanovska Ostric, D., & Andjelkovic, I. (2014). Prediction of heart failure in adults with congenital heart disease. <i>European Journal of Heart Failure</i> , 16, 87. https://doi.org/https://dx.doi.org/10.1002/ejhf.93_4 (Heart Failure Congress 2014 and the 1st World Congress on Acute Heart Failure. Athens Greece.) | Wrong intervention |
| 24. | Anonymous. (2024). Identifying Undiagnosed HFpEF Among Patients With Type 2 Diabetes Using Ultromics AI HFpEF Algorithm A1 - clinicaltrials.gov. https://clinicaltrials.gov/study/NCT06593314 | Duplicated ongoing trial record |

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| 25. | Arends, B., Vessies, M., Van Amsterdam, W., Teske, A., Van Der Harst, P., Van Osch, D., & Van Es, R. (2024). Preventing unnecessary echocardiograms in de novo patients referred to the cardiology outpatient clinic using electrocardiogram-based deep learning. <i>European Heart Journal</i> , 45. https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehae666.3486 (European Society of Cardiology Congress, ESC 2024. London United Kingdom.) | Wrong intervention |
| 26. | Arnaout, R. (2021). Can Machine Learning Help Simplify the Measurement of Diastolic Function in Echocardiography? <i>JACC: Cardiovascular Imaging</i> , 14(11), 2105 EP - 2106. https://doi.org/https://dx.doi.org/10.1016/j.jcmg.2021.06.007 | Wrong publication type |
| 27. | Arnold, J. H., Desai, K. V., Słostad, B., Bhayani, S., Ouwerkerk, W., Hummel, Y. M., Lam, C. S. P., Ezekowitz, J. A., Frost, M., Jiang, Z., Equilbec, C., Twing, A., Pellikka, P. A., Frazin, L. J., Kansal, M. M., & Krishna, H. (2024). ARTIFICIAL INTELLIGENCE-ASSISTED CLASSIFICATION OF AORTIC STENOSIS SEVERITY. <i>Journal of the American College of Cardiology</i> , 83(13), 2450. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2824%2904440-1 (American College of Cardiology 73rd Annual Scientific Session & Expo. Atlanta United States.) | Wrong outcome |
| 28. | Arnold, J. H., Smith, D., Bhayani, S., Frost, M., Tiu, D., Hsu, S., Sweeney, J., Sandhu, S., Alluri, V., Pellikka, P. A., Darbar, D., Bavishi, A., Kansal, M., & Krishna, H. (2025). Uncharted Waters: Examining Prevalence and Prognosis of Low-Gradient Aortic Stenosis in Women and Minority Populations ASE2025, https://us2.ai/aortic-stenosis-severity-classification-with-an-ai-solution/ | Wrong outcome |
| 29. | Arora, R. S., Quach, N., Fong, R., Kong, S., Kasinpila, P., Castro, M., Guha, A., Suarez, E. E., Jovinge, S., Lee, S., Boeve, T., Langlotz, C. P., Amsalem, M., Haddad, F., Shudo, Y., Woo, Y. J. Y., Teuteberg, J., & Hiesinger, W. (2020). Multi-center Validation of a Novel Echocardiography Artificial Intelligence System to Predict Post-operative Right Ventricular Failure in LVAD Patients. <i>Circulation</i> , 142. https://doi.org/https://dx.doi.org/10.1161/circ.142.suppl_3.15341 (American Heart Association Scientific Sessions, AHA 2020. Virtual.) | Wrong intervention |
| 30. | Artico, J., Laymouna, R., Fox, P., Shiwanji, H., Kurdi, H., Abioudin, A., Pierce, I., Davies, R., Xue, H., Kellman, P., Westwood, M., Manisty, C., Treibel, T., & Moon, J. (2023). CMR SERVICE IMPROVEMENT VIA DEPLOYED SERVICELEVEL RAPID CMR PROTOCOLS WITH INTEGRATED AI. <i>Heart</i> , 109, A5 EP - A6. https://doi.org/https://dx.doi.org/10.1136/heartjnl-2022-BSCMR.6 (17th British Society of Cardiovascular Magnetic Resonance Annual Congress, BSCMR 2022. Liverpool United Kingdom.) | Wrong intervention |
| 31. | Asch, F. M., Descamps, T., Sarwar, R., Karagodin, I., Singulane, C. C., Xie, M., Tucay, E. S., Tude Rodrigues, A. C., Vasquez-Ortiz, Z. Y., Monaghan, M. J., Ordonez Salazar, B. A., Soulat-Dufour, L., Alizadehast, A., Mostafavi, A., Moreo, A., Citro, R., Narang, A., Wu, C., Addetia, K., Lang, R. M. (2022). Human versus Artificial Intelligence-Based Echocardiographic Analysis as a Predictor of Outcomes: An Analysis from the World Alliance Societies of Echocardiography COVID Study. <i>Journal of the American Society of Echocardiography</i> , 35(12), 1226 EP - 1237.e1227. https://doi.org/https://dx.doi.org/10.1016/j.echo.2022.07.004 | Wrong intervention |
| 32. | Attia, Z. I., Kapa, S., Lopez-Jimenez, F., McKie, P., Ladewig, D., Setam, G., Pellikka, P., Munger, T., Asirvatham, S., Dronca, S., Scott, C., Carter, R., & Friedman, P. (2018). Application of artificial intelligence to the standard 12 lead ECG to identify people with left ventricular dysfunction. <i>Journal of the American College of Cardiology</i> , 71(11). https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2818%2930847-7 (67th Annual Scientific Session of the American College of Cardiology and i2 Summit: Innovation in Intervention, ACC.18. Orlando, FL United States.) | Wrong intervention |
| 33. | Attia, Z. I., Kapa, S., Noseworthy, P. A., Lopez-Jimenez, F., & Friedman, P. A. (2020). Artificial Intelligence ECG to Detect Left Ventricular Dysfunction in COVID-19: A Case Series. <i>Mayo Clinic Proceedings</i> , 95(11), 2464 EP - 2466. https://doi.org/https://dx.doi.org/10.1016/j.mayocp.2020.09.020 | Wrong intervention |
| 34. | Babur Guler, G., Er, Y. A., Guler, A., Uysal, H., Kalkan, A. K., Tanyel, T., Erturk, M., & Oksuz, I. (2025). Transfer learning for echocardiographic detection of heart failure with preserved ejection fraction: preliminary results of TALE-HFpEF Study. <i>European Heart Journal Cardiovascular Imaging</i> , 26, i12 EP - i13. https://doi.org/https://dx.doi.org/10.1093/ehjci/jeae333.009 (24th annual congress of the European Association of Cardiovascular Imaging. Berlin Germany.) | OOS AI technology |
| 35. | Balinisteanu, A., Duchenne, J., Puvrez, A., Wouters, L., Bezy, S., Youssef, A., Minten, L., Bekhuis, Y., Van Langenhoven, L., Papangelopoulou, K., Cieplucha, A., Cattapan, I., Tostes, P., Bogaert, J., Vinereanu, D., Thomas, J. D., Badano, L. P., & Voigt, J.-U. (2025). Vendor differences in 2D-speckle tracking global longitudinal strain: an update on a 10-year standardization effort. <i>European heart journal. Cardiovascular Imaging</i> , 26(8), 1360-1373. https://doi.org/https://dx.doi.org/10.1093/ehjci/jeaf155 (Comment in: <i>Eur Heart J Cardiovasc Imaging</i> . 2025 Jul 31;26(8):1374-1375. doi: 10.1093/ehjci/jeaf171. | Wrong comparator |
| 36. | Baloescu, C., Chen, A., Varasteh, A., Toporek, G., McNamara, R. L., Raju, B., & Moore, C. (2023). Two- Versus 8-Zone Lung Ultrasound in Heart Failure: Analysis of a Large Data Set Using a Deep Learning Algorithm. <i>Journal of ultrasound in medicine : official journal of the American Institute of Ultrasound in Medicine</i> , 42(10), 2349-2356. https://doi.org/https://dx.doi.org/10.1002/jum.16262 | Wrong intervention |

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| 37. | Bandyopadhyay, S., Chiu, I. M., Liu, S., Ansari, R., Perino, A., Bhatia, N. K., Ouyang, D., Ashley, E., Perez, M., Zou, J., Narayan, S. M., & Rogers, A. J. (2025). PO-05-047 DEEP LEARNING-RECONSTRUCTED 12 LEAD ECG SIGNALS FOR CONTINUOUS AMBULATORY MONITORING OF DROPS IN LEFT VENTRICULAR EJECTION FRACTION. Heart Rhythm, 22(4), S583. https://doi.org/https://dx.doi.org/10.1016/j.hrthm.2025.03.1445 (Heart Rhythm 2025. San Diego United States.) | Wrong intervention |
| 38. | Barbieri, A., Laus, V., Bursi, F., Bonatti, S., Malaguti, M., Paolini, M., & Boriani, G. (2025). Prevalence of low-flow state by automated machine-learning 3D echocardiography in patients with moderate-to-severe aortic stenosis and normal ejection-fraction. International Journal of Cardiovascular Imaging, 41(6), 1141 EP - 1150. https://doi.org/https://dx.doi.org/10.1007/s10554-025-03398-7 | Wrong intervention |
| 39. | Barison, A., Timoteo, A. T., El Messaoudi, S., Borodzicz-Jazdzyk, S., Moscatelli, S., Mandoli, G. E., Luong, C., Levelt, E., Ramkisoensing, A. A., Raisi-Estabragh, Z., Antonopoulos, A., Moharem-Elgammal, S., Liga, R., Pontone, G., & Neglia, D. (2025). Cardiovascular imaging in 2024: review of current research and innovations. European heart journal. Imaging methods and practice, 3(1), qyaf066. https://doi.org/https://dx.doi.org/10.1093/ehjimp/qyaf066 | Wrong publication type |
| 40. | Becerra-Becerra, R., Balderrabano-Saucedo, N. A., Cano-Hernandez, K., Tamayo-Espinosa, T., Arevalo-Salas, L. A., & Erdmenger-Orellana, J. R. (2014). Usefulness of three-dimensional echocardiography in the evaluation of intraventricular dyssynchrony in children with refractory heart failure secondary to dilated cardiomyopathy and its correlation with QRS morphology and duration. Cardiology in the Young, 24, S16. https://doi.org/https://dx.doi.org/10.1017/S1047951114000559 (48th Annual Meeting of the Association for European Paediatric and Congenital Cardiology, AEPC with Joint Sessions with the Japanese Society of Pediatric Cardiology and Cardiac Surgery and Asia-Pacific Pediatric Cardiac Society. Helsinki Finland.) | Wrong intervention |
| 41. | Becher, H. (2021). Mazankowski - Echo Go Discovery Protocol Retrospective LVEF/GLS Comparison. NCT04877899. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT04877899 | Wrong intervention |
| 42. | Beecy, A., Bratt, A., Brouwer, L., Alakbarli, J., Sherifi, I., Devereux, R., Weinsaft, J., & Kim, J. (2019). DEVELOPMENT OF A NOVEL DEEP LEARNING MODEL FOR RIGHT VENTRICULAR QUANTIFICATION ON ECHOCARDIOGRAPHY: A MULTIMODALITY VALIDATION STUDY. Journal of the American College of Cardiology, 73(9), 1437. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2819%2932043-1 (68th Annual Scientific Session of the American College of Cardiology: ACC.19. New Orleans United States.) | Wrong intervention |
| 43. | Begiashvili, B., Fernandez Candel, C. J., & Perez Paredes, M. (2025). Acoustic Index: A Novel Ai-Driven Parameter for Cardiac Disease Risk Stratification Using Echocardiography. SSRN. https://www.ssrn.com/index.cfm/en/ | Wrong study design |
| 44. | Beqiri, A., Parker, A., Mumith, A., Hassanali, N., Upton, R., Woodward, G., Dockerill, C., Woodward, W., Alsharqi, M., & McCourt, A. (2020). Fully Automated Quantification of Contrast and Non-Contrast Echocardiograms Eliminates Inter-Operator Variability. Journal of the American Society of Echocardiography, 33(6), B15. | Wrong intervention |
| 45. | Bhayani, S., Arnold, J. H., Frost, M., Tiu, D., Hsu, S., Sweeney, J., Sandhu, S., Alluri, V., Pellikka, P., Darbar, D., Bavishi, A., Kansal, M., & Krishna, H. (2025). Convolutional Neural Network-Derived Left Atrial Reservoir Strain, Left Ventricular Global Longitudinal Strain, & Diastolic Function Predict Heart Failure Hospitalization and Time to Aortic Valve Replacement in Patients with Aortic Stenosis ASE2025, https://us2.ai/aortic-stenosis-severity-classification-with-an-ai-solution/ | Wrong outcome |
| 46. | Bian, P., Zhang, X., Liu, R., Li, H., Zhang, Q., & Dai, B. (2021). Deep-Learning-Based Color Doppler Ultrasound Image Feature in the Diagnosis of Elderly Patients with Chronic Heart Failure Complicated with Sarcopenia. Journal of healthcare engineering, 2021, 2603842. https://doi.org/10.1155/2021/2603842 | Wrong intervention |
| 47. | Binder, C., Sahashi, Y., Ieki, H., Vukadinovic, M., Yuan, V., Rawlani, M., Cheng, P., Ouyang, D., & Siegel, R. J. (2025). Automated Aortic Regurgitation Detection and Quantification: A Deep Learning Approach Using Multi-View Echocardiography. medRxiv, 2025.2003.2018.25323918. https://doi.org/10.1101/2025.03.18.25323918 | OOS AI technology |
| 48. | Bismee, N. N., Scalia, I. G., Abbas, M. T., Farina, J. M., Pereyra Pietri, M., Awad, K., Ali, N. B., Javadi, N., Esfahani, S. A., Sheashaa, H., Ibrahim, O. H., Abdelfattah, F. E., Fortuin, F. D., Lester, S. J., Sweeney, J. P., Ayoub, C., & Arsanjani, R. (2025). Prognostication Following Transcatheter Edge-to-Edge Mitral Valve Repair Using Combined Echocardiography-Derived Velocity Time Integral Ratio and Artificial Intelligence Applied to Electrocardiogram. Journal of Personalized Medicine, 15(8), 371. https://doi.org/https://dx.doi.org/10.3390/jpm15080371 | Wrong intervention |

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| 49. | Borde, D. P., Apsingekar, P., Kharche, M., & Joshi, S. (2025). Handheld Echocardiography with Artificial Intelligence for Comprehensive Left Ventricular Diastolic Dysfunction Evaluation in Preoperative Patients ASE2025, https://us2.ai/ai-handheld-echo-for-preoperative-assessment/ | Wrong population |
| 50. | Bose, B., Butt, S. A., Arshad, H. B., Nicolas, C. C., Gullapelli, R., Nwana, N., Javed, Z., Shahid, I., Pournazari, P., Patel, K., Chamsi Pasha, M. A., Little, S. H., Faza, N. S., Jones, S., Cainzos, M. A., Al-Kindi, S., Saad, J. M., Zoghbi, W., Nagueh, S. F., & Nasir, K. (2024). Building a Novel Artificial Intelligence-Driven Echocardiographic Data Pipeline: Findings From a Large Learning Health System. <i>Journal of the American Society of Echocardiography</i> , 37(9), 916 EP - 918. https://doi.org/https://dx.doi.org/10.1016/j.echo.2024.05.018 | Wrong intervention |
| 51. | Bransby, K. M., Beqiri, A., Cho Kim, W.-J., Oliveira, J., Chartsias, A., & Gomez, A. (2024). Backmix: Mitigating shortcut learning in echocardiography with minimal supervision. <i>International Conference on Medical Image Computing and Computer-Assisted Intervention</i> . | Wrong outcome |
| 52. | Bransby, K. M., Kim, W.-J. C., Oliveira, J., Thorley, A., Beqiri, A., Gomez, A., & Chartsias, A. (2024). Multi-Site Class-Incremental Learning with Weighted Experts in Echocardiography. <i>International Workshop on Advances in Simplifying Medical Ultrasound</i> . | Wrong outcome |
| 53. | Brigham and Women's Hospital. (2024). Manual Versus AI-Assisted Clinical Trial Screening Using Large-Language Models. NCT06588452. ClinicalTrials.gov . https://clinicaltrials.gov/ct2/show/NCT06588452 | Wrong intervention |
| 54. | Brito, B. O. F., Attia, Z. I., Martins, L. N. A., Perel, P., Nunes, M. C. P., Sabino, E. C., Cardoso, C. S., Ferreira, A. M., Gomes, P. R., Ribeiro, A. L. P., & Lopez-Jimenez, F. (2021). Left ventricular systolic dysfunction predicted by artificial intelligence using the electrocardiogram in Chagas disease patients-The SaMi-Trop cohort. <i>PLoS Neglected Tropical Diseases</i> , 15(12), e0009974. https://doi.org/https://dx.doi.org/10.1371/journal.pntd.0009974 | Wrong intervention |
| 55. | Burke, D. A., Corrigan, N., Herlihy, M., Nasaj, O., Dickson, J., Delaney, D., & Westrup, J. (2022). Real world evaluation of artificial intelligence echocardiography image guidance and acquisition with novice scanners in multiple clinical settings. <i>European Heart Journal Cardiovascular Imaging</i> , 23, i20. https://doi.org/https://dx.doi.org/10.1093/ehjci/jeab289.011 (Annual Meeting of the European Association of Echocardiography, EUROECHO 2021. Online.) | OOS AI technology |
| 56. | Cai, A., Dan, Z., Zhou, Y., Feng, Y., & Nie, Z. (2023). Prognostic implications of machine learning-derived echocardiographic phenotypes in community hypertensive patients. <i>Clinical and Experimental Hypertension</i> , 45(1), 2236334. https://doi.org/https://dx.doi.org/10.1080/10641963.2023.2236334 | Wrong intervention |
| 57. | Cai, C., Imai, T., Hasumi, E., & Fujii, K. (2024). One-shot screening: Utilization of a two-dimensional convolutional neural network for automatic detection of left ventricular hypertrophy using electrocardiograms. <i>Computer Methods and Programs in Biomedicine</i> , 247, 108097. https://doi.org/https://dx.doi.org/10.1016/j.cmpb.2024.108097 | Wrong intervention |
| 58. | Canadian Cardiovascular Congress 2019. (2019). <i>Canadian Journal of Cardiology</i> , 35(10), A1 EP - A18. | Wrong publication type |
| 59. | Cannesson, M., Tanabe, M., Suffoletto, M. S., McNamara, D. M., Madan, S., Lacomis, J. M., & Gorcsan, I. J. (2007). A Novel Two-Dimensional Echocardiographic Image Analysis System Using Artificial Intelligence-Learned Pattern Recognition for Rapid Automated Ejection Fraction. <i>Journal of the American College of Cardiology</i> , 49(2), 217 EP - 226. https://doi.org/https://dx.doi.org/10.1016/j.jacc.2006.08.045 | Wrong intervention |
| 60. | Celestin, B. E., Bagherzadeh, S. P., Santana, E., Frost, M., Mathias, I., Sweatt, A. J., Zamanian, R., Hummel, Y., Sandros, M., Gomez Rendon, G., Salerno, M., & Haddad, F. (2024). Echocardiography in Pulmonary Arterial Hypertension Using Deep Learning Segmentation Algorithms. <i>The Journal of Heart and Lung Transplantation</i> , 43(4). https://doi.org/10.1016/j.healun.2024.02.1312 | Wrong population |
| 61. | Celestin, B., Bagherzadeh, S. P., Santana, E., Frost, M., Iversen, M., Hermansson, F. N., Sweatt, A., Zamanian, R. T., Hummel, Y. M., Rendon, G. G., Yen, J., Sandros, M., Salerno, M., & Haddad, F. (2025). Artificial Intelligence-Based Echocardiography in Pulmonary Arterial Hypertension. <i>Chest</i> . https://doi.org/10.1016/j.chest.2025.06.052 | Wrong population |
| 62. | Celestin, B., Bagherzadeh, S., Santana, E., Frost, M., Iversen, M., Sweatt, A., Zamanian, R., Hummel, Y., Sandros, M., Gomez Rendon, G., Salerno, M., & Haddad, F. (2024). Fully Automated versus Core Laboratory Analysis of Tricuspid Regurgitation Maximal Velocity in Patients with Pulmonary Hypertension. <i>The Journal of Heart and Lung Transplantation</i> , 43(4), S410-S411. https://doi.org/10.1016/j.healun.2024.02.1313 | Wrong population |

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| 63. | Cerna, A. E. U., Wehner, G., Hartzel, D. N., Haggerty, C., & Fornwalt, B. (2017). Data driven phenotyping of patients with heart failure using a deep-learning cluster representation of echocardiographic and electronic health record data. <i>Circulation</i> , 136 | Wrong intervention |
| 64. | Chan, J. S. K., Tse, G., Zhao, H., Luo, X. X., Jin, C. N., Kam, K., Fan, Y. T., & Lee, A. P. W. (2020). Echocardiography update for primary care physicians: a review. <i>Hong Kong medical journal = Xianggang yi xue za zhi</i> , 26(1), 44-55. https://doi.org/https://dx.doi.org/10.12809/hkmj198080 | Wrong publication type |
| 65. | Chandramouli, C., Tay, W. T., Tan, S. Y., Wong, J. S. Y., Yeo, C. P., Goh, G. B. B., Tan, H. C., Kwek, J. L., Lam, C. S. P., & Bee, Y. M. (2024). Screening for stage B heart failure in Type 2 diabetes: natriuretic peptide screening alone misses echocardiographic abnormalities. <i>European Heart Journal</i> , 45. https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehae666.947 (European Society of Cardiology Congress, ESC 2024. London United Kingdom.) | Wrong outcome |
| 66. | Chang, K., Sachar, R., Latz, M., Allen, T., Blair, J., Kim, G., Grinstein, J., Lang, R., & Woodward, G. (2024). Right Ventricular Hemodynamics in Patients Screened for HFpEF with a Novel Artificial Intelligence Screening Tool. <i>Circulation</i> , 150. https://doi.org/https://dx.doi.org/10.1161/circ.150.suppl_1.4147650 (American Heart Association's 2024 Scientific Sessions and the American Heart Association's 2024 Resuscitation Science Symposium. Chicago, IL United States.) | Wrong intervention |
| 67. | Chartsias, A., Gao, S., Mumith, A., Oliveira, J., Bhatia, K., Kainz, B., & Beqiri, A. (2021). Contrastive learning for view classification of echocardiograms. <i>International Workshop on Advances in Simplifying Medical Ultrasound</i> , | Wrong outcome |
| 68. | Cheema, B. S., Walter, J., Narang, A., & Thomas, J. D. (2021). Artificial Intelligence-Enabled POCUS in the COVID-19 ICU: A New Spin on Cardiac Ultrasound. <i>JACC: Case Reports</i> , 3(2), 258 EP - 263. https://doi.org/https://dx.doi.org/10.1016/j.jaccas.2020.12.013 | Wrong intervention |
| 69. | Chen, J., & Gao, Y. (2021). The Role of Deep Learning-Based Echocardiography in the Diagnosis and Evaluation of the Effects of Routine Anti-Heart-Failure Western Medicines in Elderly Patients with Acute Left Heart Failure. <i>Journal of healthcare engineering</i> , 2021, 4845792. https://doi.org/https://dx.doi.org/10.1155/2021/4845792 | Wrong intervention |
| 70. | Chen, L., Han, Z., Wang, J., & Yang, C. (2022). The emerging roles of machine learning in cardiovascular diseases: a narrative review. <i>Annals of Translational Medicine</i> , 10(10), 611. https://doi.org/https://dx.doi.org/10.21037/atm-22-1853 | Wrong publication type |
| 71. | Chen, W., Wu, J., Zhang, Z., Gao, Z., Chen, X., Zhang, Y., Lin, Z., Tang, Z., Yu, W., Fan, S., Zhang, H., & Xia, B. (2024). Artificial intelligence-assisted echocardiographic monitoring in pediatric patients on extracorporeal membrane oxygenation. <i>Frontiers in Cardiovascular Medicine</i> , 11, 1418741. https://doi.org/https://dx.doi.org/10.3389/fcvm.2024.1418741 | Wrong intervention |
| 72. | Chen, X., Owen, C. A., Huang, E. C., Maggard, B. D., Latif, R. K., Clifford, S. P., Li, J., & Huang, J. (2021). Artificial Intelligence in Echocardiography for Anesthesiologists. <i>Journal of Cardiothoracic and Vascular Anesthesia</i> , 35(1), 251 EP - 261. https://doi.org/https://dx.doi.org/10.1053/j.jvca.2020.08.048 | Wrong study design |
| 73. | Chen, Y., Hua, W., Yang, W., Shi, Z., & Fang, Y. (2022). Reliability and feasibility of automated function imaging for quantification in patients with left ventricular dilation: comparison with cardiac magnetic resonance. <i>International Journal of Cardiovascular Imaging</i> , 38(6), 1267 EP - 1276. https://doi.org/https://dx.doi.org/10.1007/s10554-021-02510-x | OOS AI technology |
| 74. | Cheriyam, J. (2024). Utilising AI Analysis of Sounds To prEdict heaRt failurE decOmpensation. NCT06555757. <i>ClinicalTrials.gov</i> . https://clinicaltrials.gov/study/NCT06555757 | Wrong intervention |
| 75. | Chiou, Y.-A., Hung, C.-L., & Lin, S.-F. (2021). AI-Assisted Echocardiographic Prescreening of Heart Failure With Preserved Ejection Fraction on the Basis of Intrabeat Dynamics. <i>JACC: Cardiovascular imaging</i> , 14(11), 2091-2104. https://doi.org/https://dx.doi.org/10.1016/j.jcmg.2021.05.005 (Comment in: <i>JACC Cardiovasc Imaging</i> . 2021 Nov;14(11):2105-2106. doi: 10.1016/j.jcmg.2021.06.007 | Wrong intervention |
| 76. | Choi, H. M., Cho, Y., Kim, J., Park, J. B., Yoon, Y. E., Cho, G. Y., & Hwang, I. C. (2024). ECG-DERIVED GLOBAL LONGITUDINAL STRAIN USING ARTIFICIAL INTELLIGENCE: A COMPARATIVE STUDY WITH TRANSTHORACIC ECHOCARDIOGRAPHY. <i>Journal of the American College of Cardiology</i> , 83(13), 2360. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2824%2904350-X (American College of Cardiology 73rd Annual Scientific Session & Expo. Atlanta United States.) | Wrong intervention |

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| 77. | Choi, H.-M., Kim, J., Park, J., Park, J.-B., Kim, H.-K., Choi, H. J., Yoon, Y. E., Cho, G.-Y., Cho, Y., & Hwang, I.-C. (2024). AI derived ECG global longitudinal strain compared to echocardiographic measurements. <i>Scientific reports</i> , 14(1), 26458. https://doi.org/https://dx.doi.org/10.1038/s41598-024-78268-8 | Wrong intervention |
| 78. | Chou, C.-C., Liu, Z.-Y., Chang, P.-C., Liu, H.-T., Wo, H.-T., Lee, W.-C., Wang, C.-C., Chen, J.-S., Kuo, C.-F., & Wen, M.-S. (2024). Comparing Artificial Intelligence-Enabled Electrocardiogram Models in Identifying Left Atrium Enlargement and Long-term Cardiovascular Risk. <i>The Canadian journal of cardiology</i> , 40(4), 585-594. https://doi.org/https://dx.doi.org/10.1016/j.cjca.2023.12.025 (Comment in: <i>Can J Cardiol</i> . 2024 Apr;40(4):595-597. doi: 10.1016/j.cjca.2023.11.015. | Wrong intervention |
| 79. | Cikes, M., Sanchez Martinez, S., Claggett, B., Solomon, S. D., & Bijnens, B. (2019). Machine-learning integration of complex echocardiographic patterns and clinical parameters from cohorts and trials. <i>European Heart Journal</i> , 40, 2549. https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehz745.0147 (European Society of Cardiology Congress, ESC 2019, Paris France.) | Wrong intervention |
| 80. | Cohen, I., Fiman, M., Loutati, R., Fisher, L., Amshalom, A., Schwammenthal, E., Klempfner, R. V., Raanani, E., Zimlichman, E., & Maor, E. (2025). ARTIFICIAL INTELLIGENCE DIAGNOSIS OF PAROXYSMAL ATRIAL FIBRILLATION USING TRANSTHORACIC ECHOCARDIOGRAPHY DURING SINUS RHYTHM. <i>Journal of the American College of Cardiology</i> , 85(12), 2735. https://doi.org/https://dx.doi.org/10.1016/S0735-1097(2825%2903219-X (American College of Cardiology, (ACC) Meeting 2025. Chicago United States.) | OOS AI technology |
| 81. | Cohen-Shelly, M., Attia, Z. I., Friedman, P. A., Ito, S., Essayagh, B. A., Ko, W. Y., Murphree, D. H., Michelena, H. I., Enriquez-Sarano, M., Carter, R. E., Johnson, P. W., Noseworthy, P. A., Lopez-Jimenez, F., & Oh, J. K. (2021). Electrocardiogram screening for aortic valve stenosis using artificial intelligence. <i>European Heart Journal</i> , 42(30), 2885 EP - 2896. https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehab153 | Wrong intervention |
| 82. | Comella, A., Gard, E., Patel, H., Mariani, J., Kaye, D., & Nanayakkara, S. (2023). Invasive Haemodynamic Profiles in Patients With Heart Failure With Preserved Ejection Fraction. <i>Heart Lung and Circulation</i> , 32, S165. https://doi.org/https://dx.doi.org/10.1016/j.hlc.2023.06.096 (71st Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand. Adelaide Australia.) | Wrong intervention |
| 83. | Cotella, J. I., Slivnick, J. A., Sanderson, E., Singulane, C., O'Driscoll, J., Asch, F. M., Addetia, K., Woodward, G., & Lang, R. M. (2023). Artificial intelligence based left ventricular ejection fraction and global longitudinal strain in cardiac amyloidosis. <i>Echocardiography</i> (Mount Kisco, N.Y.), 40(3), 188-195. https://doi.org/https://dx.doi.org/10.1111/echo.15516 | Wrong intervention |
| 84. | Cotella, J., Randazzo, M., Maurer, M. S., Helmke, S., Scherrer-Crosbie, M., Soltani, M., Goyal, A., Zareba, K., Cheng, R., Kirkpatrick, J. N., Yugeswaran, V., Kitano, T., Takeuchi, M., Fernandes, F., Hotta, V. T., Campos Vieira, M. L., Elissamburu, P., Ronderos, R., Prado, A., ... Lang, R. M. (2024). Limitations of apical sparing pattern in cardiac amyloidosis: a multicentre echocardiographic study. <i>Eur Heart J Cardiovasc Imaging</i> , 25(6), 754-761. https://doi.org/10.1093/ehjci/jeae021 | Wrong outcome |
| 85. | Crockett, D., Kelly, C., Brundage, J., Jones, J., & Ockerse, P. (2022). A Stress Test of Artificial Intelligence: Can Deep Learning Models Trained From Formal Echocardiography Accurately Interpret Point-of-Care Ultrasound? <i>Journal of ultrasound in medicine : official journal of the American Institute of Ultrasound in Medicine</i> , 41(12), 3003-3012. https://doi.org/https://dx.doi.org/10.1002/jum.16007 | OOS AI technology |
| 86. | Cunningham, J. W., Singh, P., Reeder, C., Claggett, B., Marti-Castellote, P. M., Lau, E. S., Khurshid, S., Batra, P., Lubitz, S. A., Maddah, M., Philippakis, A., Desai, A. S., Ellinor, P. T., Vardeny, O., Solomon, S. D., & Ho, J. E. (2023). Natural Language Processing for Adjudication of Heart Failure Hospitalizations in a Multi-Center Clinical Trial. <i>medRxiv</i> , 2023.2008.2017.23294234. https://doi.org/10.1101/2023.08.17.23294234 | Wrong intervention |
| 87. | Dadon, Z., Steinmetz, Y., Levi, N., Orlev, A., Belman, D., Butnaru, A., Carasso, S., Glikson, M., Alpert, E. A., & Gottlieb, S. (2023). Artificial Intelligence-Powered Left Ventricular Ejection Fraction Analysis Using the LVivoEF Tool for COVID-19 Patients. <i>Journal of clinical medicine</i> , 12(24). https://doi.org/https://dx.doi.org/10.3390/jcm12247571 | OOS AI technology |
| 88. | de Siqueira, V. S., Borges, M. M., Furtado, R. G., Dourado, C. N., & da Costa, R. M. (2021). Artificial intelligence applied to support medical decisions for the automatic analysis of echocardiogram images: A systematic review. <i>Artificial Intelligence in Medicine</i> , 120, 102165. https://doi.org/https://dx.doi.org/10.1016/j.artmed.2021.102165 | Wrong outcome |
| 89. | Debertin, J. G., Schaff, H. V., Sawma, T., Aslahishahri, M., Dearani, J. A., Friedman, P. A., Geske, J. B., Ommen, S. R., Attia, Z. I., Lee, E., Oh, J. K., & Sontis, K. C. (2025). Artificial intelligence-enhanced electrocardiogram diastolic function grade predicts post-septal myectomy mortality in hypertrophic cardiomyopathy. <i>The Journal of thoracic and cardiovascular surgery</i> . https://doi.org/https://dx.doi.org/10.1016/j.jtcvs.2025.05.015 | Wrong intervention |
| 90. | Decoedt, P., Sierra-Sosa, D., Anghel, L., Cuminetti, G., De Keyzer, E., & Morissens, M. (2024). Transfer Learning Video Classification of Preserved, Mid-Range, and Reduced Left Ventricular Ejection Fraction in Echocardiography. <i>Diagnostics</i> , 14(13), 1439. https://doi.org/https://dx.doi.org/10.3390/diagnostics14131439 | OOS AI technology |

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| 91. | Demissei, B. G., Sawant, V. S., Cellamare, M., Zhang, C., Verma, B., Chitturi, K., Hashim, H. D., Ozturk, S. T., Cermak, V., Case, B., Asch, F. M., Sadeghpour, A., & Waksman, R. (2025). ARTIFICIAL INTELLIGENCE ASSISTED MYOCARDIAL DEFORMATION ASSESSMENT IN ANGINA WITH NONOBSTRUCTIVE CORONARY ARTERY DISEASE (ANOCA). <i>Journal of the American College of Cardiology</i> , 85(12), 1961. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2825%2902445-3 (American College of Cardiology, (ACC) Meeting 2025. Chicago United States.) | Wrong outcome |
| 92. | Dhingra, L. S., Aminorroaya, A., Sangha, V., Khunte, A., Oikonomou, E. K., Mortazavi, B. J., McNamara, R., Herrin, J., Wilson, F. P., Krumholz, H. M., & Khera, R. (2023). Study Protocol for the Pilot Evaluation for SMartphone-adaptable Artificial Intelligence for PRediction and DeTection of Left Ventricular Systolic Dysfunction (The SMART-LV Pilot Study Protocol). <i>medRxiv</i> . https://doi.org/https://dx.doi.org/10.1101/2023.01.30.23285120 | Wrong intervention |
| 93. | Dhingra, L. S., Aminorroaya, A., Sangha, V., Pedroso, A. F., Asselbergs, F. W., Brant, L. C. C., Barreto, S. M., Ribeiro, A. L. P., Krumholz, H. M., Oikonomou, E. K., & Khera, R. (2025). Heart failure risk stratification using artificial intelligence applied to electrocardiogram images: a multinational study. <i>European Heart Journal</i> , 46(11), 1044 EP - 1053. https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehae914 | Wrong intervention |
| 94. | Dhingra, L., Aminorroaya, A., Camargos, A. P., Khunte, A., Sangha, V., Brant, L., Barreto, S., Ribeiro, A. L., Krumholz, H., Oikonomou, E., & Khera, R. (2024). Artificial Intelligence Enabled Prediction of Future Structural Heart Disease and Cardiovascular Risk from Single-lead Electrocardiograms. <i>Circulation</i> , 150. https://doi.org/https://dx.doi.org/10.1161/circ.150.suppl_1.4142809 (American Heart Association's 2024 Scientific Sessions and the American Heart Association's 2024 Resuscitation Science Symposium. Chicago, IL United States.) | Wrong intervention |
| 95. | Dindane, Z., Sveric, K., Winkler, A., Botan, R., Mierke, J., Svitil, J., Heidrich, F. M., Ulbrich, S., & Linke, A. (2022). The automatic identification of left ventricular chambers and quantification of ejection fraction using a novel artificial intelligence-based system - a validation against cardiac magnetic resonance. <i>European Heart Journal</i> , 43, 325. https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehac544.325 (43rd European Society of Cardiology Congress, ESC 2022. Barcelona Spain.) | Wrong intervention |
| 96. | DISCORD-HFpEF study (EchoConfidence) | Wrong comparator |
| 97. | Dorr, M. (2023). Machine learning approach based on echocardiographic data to improve prediction of cardiovascular events in hypertrophic cardiomyopathy. <i>Archives of Cardiovascular Diseases Supplements</i> , 15(3), 266. https://doi.org/https://dx.doi.org/10.1016/j.acvdsp.2023.04.047 (Printemps de la cardiologie 2023. Marseille France.) | Wrong intervention |
| 98. | Drks, & Universitätsmedizin Rostock, Y. (2024). Overcoming the limitations of cardiac MRI: AI-based strategies for acceleration. In <i>Overcoming the limitations of cardiac MRI: AI-based strategies for acceleration</i> . | Wrong intervention |
| 99. | Duan, C., Montgomery, M. K., Chen, X., Ullas, S., Stansfield, J., McElhanon, K., & Hirenallur-Shanthappa, D. (2022). Fully automated mouse echocardiography analysis using deep convolutional neural networks. <i>American journal of physiology. Heart and circulatory physiology</i> , 323(4), H628-H639. https://doi.org/https://dx.doi.org/10.1152/ajpheart.00208.2022 | Wrong intervention |
| 100. | Ducharme, A. (2023). Multidisciplinary Approach for High-risk Patients Leading to Early Diagnosis of Canadians With Heart Failure. <i>NCT05860608</i> . <i>ClinicalTrials.gov</i> . https://clinicaltrials.gov/study/NCT05860608 | Wrong intervention |
| 101. | Duchateau, N., & Bernardino, G. (2024). AI-Based Strain Estimation in Echocardiography Using Open and Collaborative Data: The More Experts the Better? <i>JACC: Cardiovascular Imaging</i> , 17(8), 877 EP - 879. https://doi.org/https://dx.doi.org/10.1016/j.jcmg.2024.05.020 | Wrong publication type |
| 102. | ERS International Congress 2022 Abstracts. (2022). <i>European Respiratory Journal</i> , 60. (European Respiratory Society International Congress, ERS 2022. Barcelona Spain. A1 - Anonymous.) | Wrong publication type |

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| 103. | ESC Congress 2020. (2020). European Heart Journal, 41. (European Society of Cardiology Congress, ESC 2020. Virtual. A1 - Anonymous.) | Wrong publication type |
| 104. | ESC Congress 2021. (2021). European Heart Journal, 42. (European Society of Cardiology Congress, ESC 2021. Virtual. A1 - Anonymous.) | Wrong publication type |
| 105. | ESC Congress 2023. (2023). European Heart Journal, 44. (European Society of Cardiology Congress, ESC 2023. Amsterdam Netherlands. A1 - Anonymous.) | Wrong publication type |
| 106. | ESC Congress 2024. (2024). European Heart Journal, 45. European Society of Cardiology Congress, ESC 2024. London United Kingdom. A1 - Anonymous.) | Wrong publication type |
| 107. | Esquitin, K. (2019). Artificial Intelligence in Echocardiography: a Pilot Study of Bay Labs Technology in Image Acquisition, Education, and Analysis. NCT03936413. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT03936413 | OOS AI technology |
| 108. | EuroEcho-Imaging 2024. (2025). European Heart Journal Cardiovascular Imaging, 26. (24th annual congress of the European Association of Cardiovascular Imaging. Berlin Germany. A1 - Anonymous.) | Wrong publication type |
| 109. | Fahmy, A. S. (2019). A deep learning based model for predicting heart failure in hypertrophic cardiomyopathy patients with left ventricular outflow tract obstruction. Circulation, 140. https://doi.org/https://dx.doi.org/10.1161/circ.140.suppl_1.14553 (American Heart Association Scientific Sessions, AHA 2019. Philadelphia, PA United States.) | Wrong intervention |
| 110. | Fernandez-Ruiz, I. (2023). AI outperforms sonographers at diagnosing cardiac function on echocardiography. Nature Reviews Cardiology, 20(6), 371. https://doi.org/https://dx.doi.org/10.1038/s41569-023-00878-y | OOS AI technology |
| 111. | Ferreira, A. L. C., Feitoza, L. P. G. d. C., Benitez, M. E., Aziri, B., Begic, E., de Souza, L. V. F., Bulhoes, E., Monteiro, S. O. N., Defante, M. L. R., Vieira, R. A. M. S., & Guida, C. (2025). Diagnostic accuracy of artificial-intelligence-based electrocardiogram algorithm to estimate heart failure with reduced ejection fraction: A systematic review and meta-analysis. Current problems in cardiology, 50(4), 103004. https://doi.org/https://dx.doi.org/10.1016/j.cpcardiol.2025.103004 | Wrong intervention |
| 112. | Ferreira, D. L., Lau, C., Salaymang, Z., & Arnaout, R. (2025). Self-supervised learning for label-free segmentation in cardiac ultrasound. Nature Communications, 16(1), 4070. https://doi.org/https://dx.doi.org/10.1038/s41467-025-59451-5 | Wrong intervention |
| 113. | Firima, E., Gonzalez, L., Manthabiseng, M., Bane, M., Lukau, B., Leigh, B., Kaufmann, B. A., Weisser, M., Amstutz, A., Tromp, J., Labhardt, N. D., & Burkard, T. (2024). Implementing focused echocardiography and AI-supported analysis in a population-based survey in Lesotho: implications for community-based cardiovascular disease care models. Hypertension Research, 47(3), 708 EP - 713. https://doi.org/https://dx.doi.org/10.1038/s41440-023-01559-6 | Wrong setting |
| 114. | Fisher, L., Fiman, M., Segal, E., Rubin, N., Cohen, I., Amshalom, A., Schwammenthal, E., Klempfner, R. V., Zimlichman, E., Raanani, E., & Maor, E. (2025). ONE VIEW TO RULE THEM ALL? APPLYING ARTIFICIAL INTELLIGENCE TO ASSESS VALVULAR DISEASE AND VENTRICULAR FUNCTION USING A SINGLE APICAL 4-CHAMBER ECHOCARDIOGRAPHIC VIEW. Journal of the American College of Cardiology, 85(12), 2756. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2825%2903240-1 (American College of Cardiology, (ACC) Meeting 2025. Chicago United States.) | OOS AI technology |
| 115. | Fletcher, A. J., Lapidaire, W., & Leeson, P. (2021). Machine Learning Augmented Echocardiography for Diastolic Function Assessment. Frontiers in Cardiovascular Medicine, 8, 711611. https://doi.org/https://dx.doi.org/10.3389/fcvm.2021.711611 | Wrong study design |

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| 116. | Foo, D. (2023). Learning Curve of Novice in Artificial Intelligence-enhance Point-of-Care Echocardiogram. | Wrong setting |
| 117. | Foo, D. (2025). Decentralized community-based rapid cardiac ultrasound triage for early heart failure detection using a hub-and-spoke model: findings from Heart2Miss initiative. | Wrong setting |
| 118. | Fraix, A., Huttin, O., Pace, N., Girerd, N., Filippetti, L., Donal, E., Lairez, O., Damy, T., & Selton-Suty, C. (2023). Echocardiography machine learning based to improve detection of transthyretin cardiac amyloidosis: The R3M Algorithm. <i>Archives of Cardiovascular Diseases Supplements</i> , 15(3), 248 EP - 249. https://doi.org/https://dx.doi.org/10.1016/j.acvdsp.2023.04.012 (Printemps de la cardiologie 2023. Marseille France.) | Wrong intervention |
| 119. | Fujiki, G., Kodera, S., Setoguchi, N., Tanabe, K., Miyaji, K., Kushida, S., Saji, M., Nanasato, M., Maki, H., Fujita, H., Kato, N., Watanabe, H., Suzuki, M., Takahashi, M., Sawada, N., Ando, J., Sato, M., Sawano, S., Katsushika, S., . . . Komuro, I. (2025). Deep Learning-Based Identification of Echocardiographic Abnormalities From Electrocardiograms. <i>JACC Asia</i> , 5(1), 88-98. https://doi.org/https://dx.doi.org/10.1016/j.jacasi.2024.10.012 | Wrong intervention |
| 120. | Gahungu, N., Trueick, R., Bhat, S., Sengupta, P. P., & Dwivedi, G. (2020). Current Challenges and Recent Updates in Artificial Intelligence and Echocardiography. <i>Current Cardiovascular Imaging Reports</i> , 13(2), 5. https://doi.org/https://dx.doi.org/10.1007/s12410-020-9529-x | Wrong study design |
| 121. | Gao, S., Porumb, M., Mumith, A., Parker, A., Walker, S., Jones, G., Chartsias, A., Oliveira, J., Hawkes, W., Sarwar, R., Leeson, P., Woodward, G., & Beqiri, A. (2022). Fully automated quantification of LV regional wall motion from echocardiograms to detect myocardial infarction. <i>European Heart Journal - Cardiovascular Imaging</i> , 23, jeab289.009. https://doi.org/10.1093/ehjci/jeab289.009 | Wrong population |
| 122. | Gearhart, A., Goto, S., Deo, R. C., & Powell, A. J. (2022). An Automated View Classification Model for Pediatric Echocardiography Using Artificial Intelligence. <i>Journal of the American Society of Echocardiography</i> , 35(12), 1238 EP - 1246. https://doi.org/https://dx.doi.org/10.1016/j.echo.2022.08.009 | Wrong intervention |
| 123. | Girerd, N., & Kobayashi, M. (2023). The new era of evidence-based echocardiographic algorithms using artificial intelligence. <i>International Journal of Cardiology</i> , 380, 35 EP - 36. https://doi.org/https://dx.doi.org/10.1016/j.ijcard.2023.03.029 | Wrong publication type |
| 124. | Gladding, P. A., James, N., & Hewitt, W. (2020). Multiscale Predictive Modelling in Heart Failure: Machine Learning Applied to Big Data, Imaging and Multiomics. <i>Heart Lung and Circulation</i> , 29, S24 EP - S25. https://doi.org/https://dx.doi.org/10.1016/j.hlc.2020.05.062 (Cardiac Society of Australia and New Zealand Annual Scientific Meeting (New Zealand) 2020. Dunedin New Zealand.) | Wrong intervention |
| 125. | Gladding, P. A., Loader, S., Smith, K., Zarate, E., Green, S., Villas-Boas, S., Shepherd, P., Kakadiya, P., Hewitt, W., Thorstensen, E., Keven, C., Coe, M., Nakisa, B., Vuong, T., Rastgoo, M. N., Jullig, M., Starc, V., & Schlegel, T. T. (2021). Multiomics, virtual reality and artificial intelligence in heart failure. <i>Future cardiology</i> , 17(8), 1335-1347. https://doi.org/https://dx.doi.org/10.2217/fca-2020-0225 | OOS AI technology |
| 126. | Gladding, P., Gleeson, S., Liao, Y., Dugo, C., Cave, A., Zhou, L., Christiansen, J., Scott, T., Dawson, L., Gavin, A., & Schlegel, T. (2017). Ecg-derived spatial QRS-T angle is associated with icd implantation, mortality and heart failure admissions in patients with LV systolic dysfunction. <i>Heart Lung and Circulation</i> , 26, S164. https://doi.org/https://dx.doi.org/10.1016/j.hlc.2017.06.276 (65th Cardiac Society of Australia and New Zealand Annual Scientific Meeting and the International Society for Heart Research Australasian Section Annual Scientific Meeting. Perth, WA Australia.) | Wrong intervention |
| 127. | Glavaski, M., Ilic, A., & Velicki, L. (2024). Gene-Specific Discriminative Echocardiogram Findings in Hypertrophic Cardiomyopathy Determined Using Artificial Intelligence: A Pilot Study. <i>Cardiogenetics</i> , 14(1), 1 EP - 25. https://doi.org/https://dx.doi.org/10.3390/cardigenetics1401001 | OOS AI technology |
| 128. | Gleeson, S., Liao, Y. W., Dugo, C., Cave, A., Zhou, L., Ayar, Z., Christiansen, J., Scott, T., Dawson, L., Gavin, A., Schlegel, T., & Gladding, P. (2016). Machine learning applied to advanced ECG and echocardiographic metadata, in patients with left ventricular dysfunction. <i>Heart Lung and Circulation</i> , 25, S10 EP - S11. https://doi.org/https://dx.doi.org/10.1016/j.hlc.2016.05.025 (Cardiac Society of Australia and New Zealand Annual Scientific Meeting and the International Society for Heart Research Australasian Section Annual Scientific Meeting 2016. Rotorua New Zealand.) | Wrong intervention |

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| 129. | Gleeson, S., Liao, Y.-W., Dugo, C., Cave, A., Zhou, L., Ayar, Z., Christiansen, J., Scott, T., Dawson, L., Gavin, A., Schlegel, T. T., & Gladding, P. (2017). ECG-derived spatial QRS-T angle is associated with ICD implantation, mortality and heart failure admissions in patients with LV systolic dysfunction. <i>PLoS one</i> , 12(3), e0171069. https://doi.org/https://dx.doi.org/10.1371/journal.pone.0171069 | Wrong intervention |
| 130. | Golany, T., Radinsky, K., Kofman, N., Litovchik, I., Young, R., Monayer, A., Love, I., Tziporin, F., Minha, I., Yehuda, Y., Ziv-Baran, T., Fuchs, S., & Minha, S. (2022). Physicians and Machine-Learning Algorithm Performance in Predicting Left-Ventricular Systolic Dysfunction from a Standard 12-Lead-Electrocardiogram. <i>Journal of Clinical Medicine</i> , 11(22), 6767. https://doi.org/https://dx.doi.org/10.3390/jcm11226767 | Wrong intervention |
| 131. | Greason, C. M., Paraschiv, C., Tobah, Y. B., Kane, G. C., Bird, J. G., & Young, K. A. (2025). Feasibility and Quality of Focused Cardiac Ultrasound (FoCUS) by Novice Scanners in an Obstetric Population. <i>Obstetrics and Gynecology</i> , 145(6), 7S EP - 8S. https://doi.org/https://dx.doi.org/10.1097/AOG.00000000000005916.024 (73rd Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists. Minneapolis, MN United States.) | OOS AI technology |
| 132. | Grinstein, J., Kruse, E., Sayer, G., Fedson, S., Kim, G. H., Sarswat, N., Adatya, S., Ota, T., Jeevanandam, V., Mor-Avi, V., Lang, R. M., & Uriel, N. (2016). Novel echocardiographic parameters of aortic insufficiency in continuous-flow left ventricular assist devices and clinical outcome. <i>The Journal of heart and lung transplantation : the official publication of the International Society for Heart Transplantation</i> , 35(8), 976-985. https://doi.org/https://dx.doi.org/10.1016/j.healun.2016.05.009 (Comment in: <i>J Heart Lung Transplant</i> . 2016 Aug;35(8):973-5. doi: 10.1016/j.healun.2016.06.006 | Wrong intervention |
| 133. | Gulati, S., Lerman, R. D., Natale, A., Kolski, B., Tyler, J., DuBois, D., & Acquista, A. J. (2024). PO-02-067 DIRECT-FROM-ECG SCREENING FOR HEART FAILURE WITH REDUCED AND PRESERVED EJECTION FRACTION. <i>Heart Rhythm</i> , 21(5), S287. https://doi.org/https://dx.doi.org/10.1016/j.hrthm.2024.03.799 (Heart Rhythm 2024. Boston United States.) | Wrong intervention |
| 134. | Gulati, S., Natale, A., Skipitaris, N. T., Kolski, B., Tyler, J., DuBois, D., & Acquista, A. J. (2024). PO-02-066 DIRECT-FROM-ECG EJECTION FRACTION SEVERITY FOR MANAGING HEART FAILURE IN PATIENTS WITH MULTIPLE COMORBIDITIES. <i>Heart Rhythm</i> , 21(5), S286 EP - S287. https://doi.org/https://dx.doi.org/10.1016/j.hrthm.2024.03.798 (Heart Rhythm 2024. Boston United States.) | Wrong intervention |
| 135. | Guler, G. B., Er, Y. A., Guler, A., Uysal, H., Kalkan, A. K., Tanyel, T., Erturk, M., & Oksuz, I. (2024). Transfer learning for echocardiographic detection of heart failure with preserved ejection fraction: preliminary results of TALE-HFpEF Study. <i>Anatolian Journal of Cardiology</i> , 28, S127 EP - S128. https://doi.org/https://dx.doi.org/10.14744/AnatolJCardiol.2024.102024 (40th National Cardiology Congress. Antalya Turkey.) | Wrong intervention |
| 136. | Guo, C., Gao, B., Han, X., Zhang, T., Tao, T., Xia, J., & Liu, H. (2025). Interpretable artificial intelligence model for predicting heart failure severity after acute myocardial infarction. <i>BMC cardiovascular disorders</i> , 25(1), 362. https://doi.org/https://dx.doi.org/10.1186/s12872-025-04818-1 | Wrong intervention |
| 137. | Hamamoto, R., Suvarna, K., Yamada, M., Kobayashi, K., Shinkai, N., Miyake, M., Takahashi, M., Jinnai, S., Shimoyama, R., Sakai, A., Takasawa, K., Bolatkan, A., Shozu, K., Dozen, A., Machino, H., Takahashi, S., Asada, K., Komatsu, M., Sese, J., & Kaneko, S. (2020). Application of artificial intelligence technology in oncology: Towards the establishment of precision medicine. <i>Cancers</i> , 12(12), 1 EP - 32. https://doi.org/https://dx.doi.org/10.3390/cancers12123532 | Wrong outcome |
| 138. | Hanif, W., Goldberg, Y., Taub, C. C., Vorchheimer, D. A., Slipczuk, L., Ho, E., Rodriguez, C., Farooq, M., Garcia, M. J., & Zhang, L. (2021). Automated measurement of global longitudinal strain by speckle-tracking echocardiography in cardio-oncology patients using artificial intelligence. <i>Circulation</i> , 144. https://doi.org/https://dx.doi.org/10.1161/circ.144.suppl-1.11383 (American Hearts Association's 2021 Scientific Sessions. Boston, MA United States.) | Wrong intervention |
| 139. | Hathaway, Q. A., Yanamala, N., Budoff, M. J., Sengupta, P. P., & Zeb, I. (2021). Deep Neural Survival Networks for Cardiovascular Risk Prediction: The Multi-Ethnic Study of Atherosclerosis (MESA). <i>medRxiv</i> , 2021.2004.2012.21255286. https://doi.org/10.1101/2021.04.12.21255286 | Wrong intervention |
| 140. | Hawkes, W. (2020). Quantification of left ventricular regional wall motion: novel imaging features to predict coronary artery disease. (2020 ASE 31st Annual Scientific Sessions). <i>Journal of the American Society of Echocardiography</i> , 33(6), B1-B109. https://doi.org/https://dx.doi.org/10.1016/j.echo.2020.04.015 | Wrong intervention |
| 141. | Hawkes, W. (2021). AI enabled global longitudinal strain quantification in hospitalized COVID-19 patients with myocardial injury. | Wrong intervention |

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|------|---|--------------------|
| 142. | Hawkes, W. (2022). Automated Analysis Of Segmental Longitudinal Strain In Ischemic Heart Disease(ASE 33, Annual Scientific Sessions Scientific Research Abstracts. Journal of the American Society of Echocardiography, 35(7), 789. https://doi.org/10.1016/j.echo.2022.05.013 | Wrong intervention |
| 143. | Hawkes, W., Beqiri, A., Mumith, A., Parker, A., Upton, R., McCourt, A., Woodward, W., Dockerill, C., Heitner, S., & Yadava, M. (2020). Fully Automated Strain Analysis at Rest and Peak Stress During Standard and Contrast Enhanced Stress Echocardiography. Journal of the American Society of Echocardiography, 33(6), B6-B7. | Wrong population |
| 144. | Hawkes, W., Deschamps, T., Parker, A., Woodward, G., & Sarwar, R. (2023). Artificial intelligence-driven segmental longitudinal strain quantification of patients with myocardial infarction. Echo Research and Practice, 10. https://doi.org/https://dx.doi.org/10.1186/s44156-023-00030-z (British Society of Echocardiography Annual Meeting, BSEcho 2022. London United Kingdom.) | Wrong intervention |
| 145. | Hawkes, W., Slivnick, J., Akerman, A., Woodward, G., Hamza, I., Desai, V., Scott, C., Cotella, J. I., Maurer, M. S., Scherrer-Crosbie, M., Goyal, A., Zareba, K. M., Cheng, R. K.-H., Kitano, T., Takeuchi, M., Elissamburu, P., Prado, A., Pursnani, A., Patel, A. R., . . . Pellikka, P. A. (2025). CLINICAL UTILITY OF SCREENING FOR TRANSTHYRETIN CARDIAC AMYLOIDOSIS IN HEART FAILURE WITH PRESERVED EJECTION FRACTION. Journal of the American College of Cardiology, 85(12), 2465. https://doi.org/https://doi.org/10.1016/S0735-1097(25)02949-3 | Wrong intervention |
| 146. | Hawkins, N. (2023). Multidisciplinary Approach for High Risk Patients Leading to Early Diagnosis of Canadians. NCT05859048. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT05859048 | Wrong intervention |
| 147. | Hedman, A. K., Hage, C., Sharma, A., Brosnan, M. J., Buckbinder, L., Gan, L.-M., Shah, S. J., Linde, C. M., Donal, E., Daubert, J.-C., Malarstig, A., Ziemek, D., & Lund, L. (2020). Identification of novel pheno-groups in heart failure with preserved ejection fraction using machine learning. Heart (British Cardiac Society), 106(5), 342-349. https://doi.org/https://dx.doi.org/10.1136/heartjnl-2019-315481 (Comment in: Heart. 2020 Mar;106(5):318-320. doi: 10.1136/heartjnl-2019-316030) | Wrong intervention |
| 148. | Hewitt, W., Curtis, L., Spyker, A., Howitt, L., Walsh, H., & Gladding, P. (2019). Artificial intelligence in echocardiography for standard clinical metrics. European Heart Journal, 40, 1216. https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehz748.0673 (European Society of Cardiology Congress, ESC 2019. Paris France.) | Wrong intervention |
| 149. | Hewitt, W., Curtis, L., Spyker, A., Walsh, H., Howitt, L., & Gladding, P. (2019). Artificial Intelligence in Echocardiography for Standard Clinical Metrics. Heart Lung and Circulation, 28, S12. https://doi.org/https://dx.doi.org/10.1016/j.hlc.2019.05.034 (ANZSCTS Annual Scientific Meeting 2018. Australia.) | Wrong intervention |
| 150. | Hirata, Y., & Kusunose, K. (2025). AI in Echocardiography: State-of-the-art Automated Measurement Techniques and Clinical Applications. Jmaj, 8(1), 141-150. https://doi.org/10.31662/jmaj.2024-0180 | Wrong study design |
| 151. | Hollitt, K. J., Milanese, S., Joseph, M., & Perry, R. (2025). Can automation and artificial intelligence reduce echocardiography scan time and ultrasound system interaction? Echo Research and Practice, 12(1), 11. https://doi.org/https://dx.doi.org/10.1186/s44156-025-00077-0 | Wrong intervention |
| 152. | Holste, G., Oikonomou, E. K., Tokodi, M., Kovacs, A., Wang, Z., & Khera, R. (2025). Complete AI-Enabled Echocardiography Interpretation with Multitask Deep Learning. JAMA. https://doi.org/https://dx.doi.org/10.1001/jama.2025.8731 | OOS AI technology |
| 153. | Hong, G., Ouyang, D., Vrudhula, A., & Yuan, N. (2024). Artificial Intelligence- Enhanced Echocardiogram Assessment Helps Distinguish Cardiomyopathy from Beat-to-Beat Variation in Atrial Fibrillation. Circulation, 150. https://doi.org/https://dx.doi.org/10.1161/circ.150.suppl_1.4118387 (American Heart Association's 2024 Scientific Sessions and the American Heart Association's 2024 Resuscitation Science Symposium. Chicago, IL United States.) | OOS AI technology |
| 154. | Hôpital Broca APHP. (2024). Precision and RElevance of Cardiac ultraSound Using Artificial Intelligence for Left Ventricle Ejection Fraction Assessment in the Elderly. (PRECISE AI). NCT06478901. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT06478901 | OOS AI technology |

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|------|--|------------------------|
| 155. | Hourmozdi, J., Easton, N., Benigeri, S., Thomas, J. D., Narang, A., Ouyang, D., Duffy, G., Upton, R., Hawkes, W., Akerman, A., Okwuosa, I., Kline, A., Kho, A. N., Luo, Y., Shah, S. J., & Ahmad, F. S. (2024). Evaluating the performance and potential bias of predictive models for detection of transthyretin cardiac amyloidosis. medRxiv. https://doi.org/https://dx.doi.org/10.1101/2024.10.09.24315202 | Wrong intervention |
| 156. | Hourmozdi, J., Easton, N., Benigeri, S., Thomas, J. D., Narang, A., Ouyang, D., Duffy, G., Upton, R., Hawkes, W., Akerman, A., Okwuosa, I., Kline, A., Kho, A. N., Luo, Y., Shah, S. J., & Ahmad, F. S. (2025). Evaluating the Performance and Potential Bias of Predictive Models for Detection of Transthyretin Cardiac Amyloidosis. JACC Advances, 4(8), 101901. https://doi.org/https://dx.doi.org/10.1016/j.jacadv.2025.101901 (Update of: medRxiv. 2025 Jun 24:2024.10.09.24315202. doi: 10.1101/2024.10.09.24315202. | Wrong intervention |
| 157. | Hsia, B. C., Lai, A., Singh, S., Samtani, R., Bienstock, S., Liao, S., Stern, E., LaRocca, G., Sanz, J., Lerakis, S., Croft, L., Carrasco, S., Rosenmann, D., DeMaria, A., Stone, G. W., & Goldman, M. E. (2023). Validation of American Society of Echocardiography Guideline-Recommended Parameters of Right Ventricular Dysfunction Using Artificial Intelligence Compared With Cardiac Magnetic Resonance Imaging. Journal of the American Society of Echocardiography, 36(9), 967 EP - 977. https://doi.org/https://dx.doi.org/10.1016/j.echo.2023.05.015 | OOS AI technology |
| 158. | Hu, B., Xiao, J., Tian, H., Jiang, N., & Zhou, Q. (2019). Automated Diagnosis of Ischemic Cardiomyopathy Using Feature-Categorized Vision Method: An Echocardiography Study with Computed Neural Network. Journal of the American Society of Echocardiography, 32(6), B67. https://doi.org/https://dx.doi.org/10.1016/j.echo.2019.04.414 (34th IEEE/ACM International Conference on Automated Software Engineering (ASE 2019). San Diego United States.) | Wrong intervention |
| 159. | Huang, F. (2023). Validation of Point-of-care Handheld Echocardiography to Assess Diastolic Function in Primary Care Diabetic Patients. | Wrong setting |
| 160. | Huang, W., Ong, W. C., Wong, M. K. F., Ng, E. Y. K., Koh, T., Chandramouli, C., Ng, C. T., Hummel, Y., Huang, F., Lam, C. S. P., & Tromp, J. (2024). Applying the UTAUT2 framework to patients' attitudes toward healthcare task shifting with artificial intelligence. BMC Health Serv Res, 24(1), 455. https://doi.org/10.1186/s12913-024-10861-z | Wrong outcome |
| 161. | Huang, Y. C., Hsu, Y. C., Liu, Z. Y., Lin, C. H., Tsai, R., Chen, J. S., Chang, P. C., Liu, H. T., Lee, W. C., Wo, H. T., Chou, C. C., Wang, C. C., Wen, M. S., & Kuo, C. F. (2023). Artificial intelligence-enabled electrocardiographic screening for left ventricular systolic dysfunction and mortality risk prediction. Frontiers in Cardiovascular Medicine, 10, 1070641. https://doi.org/https://dx.doi.org/10.3389/fcvm.2023.1070641 | Wrong intervention |
| 162. | Huerta, N., Rao, S. J., Isath, A., Wang, Z., Glicksberg, B. S., & Krittawong, C. (2024). The premise, promise, and perils of artificial intelligence in critical care cardiology. Progress in cardiovascular diseases, 86, 2-12. https://doi.org/https://dx.doi.org/10.1016/j.pcad.2024.06.006 | Wrong intervention |
| 163. | Hull University Teaching Hospitals NHS Trust. (2019). Machine Learning in Quantitative Stress Echocardiography. NCT04193475. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT04193475 | Wrong intervention |
| 164. | Hung, C.-L. (2025). Artificial Intelligence-based Automatic Echocardiographic Quantification in Advanced Heart Failure (AIED Study). NCT07010952. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT07010952 | Wrong intervention |
| 165. | Indolfi, C., Agostoni, P., Barilla, F., Barison, A., Benenati, S., Bilo, G., Boriani, G., Brunetti, N. D., Calabro, P., Carugo, S., Casella, M., Ciccarelli, M., Ciccone, M. M., Ferrari, G. M. D., Greco, G., Esposito, G., Locati, E. T., Mariani, A., Merlo, M., ... Curcio, A. (2025). Expert consensus document on artificial intelligence of the Italian Society of Cardiology. Journal of Cardiovascular Medicine, 26(5), 200 EP - 215. https://doi.org/https://dx.doi.org/10.2459/JCM.00000000000001716 | Wrong publication type |
| 166. | Ioannou, A. (2024). CA-AI Echo - Diagnosis of cardiac amyloidosis on echocardiography using artificial intelligence: a multicentre international development and validation study. | Wrong intervention |
| 167. | Ishizu, T. (2022). Deep Learning Brings New Era in Echocardiography. Circulation Journal, 86(1), 96 EP - 97. https://doi.org/https://dx.doi.org/10.1253/circj.CJ-21-0663 | Wrong publication type |

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|------|---|------------------------|
| 168. | Isrctn. (2021). PROTEUS: evaluating the use of artificial intelligence to support stress echocardiography testing for heart disease. https://trialsearch.who.int/Trial2.aspx?TrialID=ISRCTN15113915 . https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02329967/full | Wrong intervention |
| 169. | Istituto Auxologico Italiano. (2023). Valutazione Delle Pressioni di Riempimento Del Ventricolo Sinistro Attraverso l'Impiego di un Software di Intelligenza Artificiale Applicato Alla Stima Dello Strain Atriale Sinistro Con Ecocardiografia Speckletracking: Studio di Validazione Mediante Cateterismo Cardiaco. NCT05768698. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT05768698 | Wrong intervention |
| 170. | Ito, S., Cohen-Shelly, M., Attia, Z. I., Lee, E., Friedman, P. A., Nkomo, V. T., Michelena, H. I., Noseworthy, P. A., Lopez-Jimenez, F., & Oh, J. K. (2023). Correlation between artificial intelligence-enabled electrocardiogram and echocardiographic features in aortic stenosis. <i>European heart journal. Digital health</i> , 4(3), 196-206. https://doi.org/https://dx.doi.org/10.1093/ehjdh/ztad009 | Wrong intervention |
| 171. | Ito, S., Shelly, M., Attia, Z. I., Lee, E., Friedman, P. A., Nkomo, V. T., Michelena, H. I., Noseworthy, P., Lopez-Jimenez, F., & Oh, J. K. (2023). STRUCTURAL, FUNCTIONAL, AND HEMODYNAMIC CORRELATES OF ARTIFICIAL INTELLIGENCE-ENABLED ELECTROCARDIOGRAM IN AS. <i>Journal of the American College of Cardiology</i> , 81(8), 1942. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2823%2902386-0 (ACC.23. New Orleans United States.) | Wrong intervention |
| 172. | Jacobs, P., & Khoche, S. (2024). Artificial Intelligence and Echocardiography: A Genuinely Interesting Conundrum. <i>Journal of Cardiothoracic and Vascular Anesthesia</i> , 38(5), 1065 EP - 1067. https://doi.org/https://dx.doi.org/10.1053/j.jvca.2024.01.014 | Wrong publication type |
| 173. | James, J. K., Huntley, G., Arystan, A. Z., Cassianni, C., Scott, C. G., Davison, H., Akerman, A., Hawkes, W., Oliveria, J., Chartsias, A., Gomez, A., Upton, R., & Pellikka, P. A. (2025). Application of an Artificial Intelligence Model to Detect Heart Failure With Preserved Ejection Fraction to Handheld Ultrasound Imaging. <i>Journal of the American Society of Echocardiography</i> , 38(7), 633 EP - 635. https://doi.org/https://dx.doi.org/10.1016/j.echo.2025.03.016 | Wrong comparator |
| 174. | Jang, Y., Choi, H., Yoon, Y. E., Jeon, J., Kim, H., Kim, J., Jeong, D., Ha, S., Hong, Y., Lee, S.-A., Park, J., Choi, W., Choi, H.-M., Hwang, I.-C., Cho, G.-Y., & Chang, H.-J. (2024). An Artificial Intelligence-Based Automated Echocardiographic Analysis: Enhancing Efficiency and Prognostic Evaluation in Patients With Revascularized STEMI. <i>Korean circulation journal</i> , 54(11), 743-756. https://doi.org/https://dx.doi.org/10.4070/kcj.2024.0060 | Wrong intervention |
| 175. | Jani, V., Vungarala, S., Yoo, E., Hsu, S., Hahn, V., Kass, D., & Sharma, K. (2024). Clinical Phenomapping Of Obese Heart Failure With Preserved Ejection Fraction. <i>Journal of Cardiac Failure</i> , 30(1), 121. https://doi.org/https://dx.doi.org/10.1016/j.cardfail.2023.10.010 (Heart Failure Society of America's (HFSA) Annual Scientific Meeting 2023. Cleveland United States.) | Wrong intervention |
| 176. | Jeong, J. H., Kwon, J. M., Lee, H. S., Choi, Y. Y., Kim, Y. G., Shim, J., Kim, Y. H., & Choi, J. I. (2024). PO-03-013 NOVEL DEEP LEARNING ALGORITHM FOR PREDICTION OF HEART FAILURE WITH REDUCED EJECTION FRACTION IN PATIENTS WITH ATRIAL FIBRILLATION WITH RAPID VENTRICULAR RESPONSE. <i>Heart Rhythm</i> , 21(5), S411. https://doi.org/https://dx.doi.org/10.1016/j.hrthm.2024.03.1109 (Heart Rhythm 2024. Boston United States.) | Wrong intervention |
| 177. | Jiang, J., Liu, B., Li, Y. W., & Hothi, S. S. (2023). Clinical service evaluation of the feasibility and reproducibility of novel artificial intelligence based-echocardiographic quantification of global longitudinal strain and left ventricular ejection fraction in trastuzumab-treated patients. <i>Frontiers in Cardiovascular Medicine</i> , 10, 1250311. https://doi.org/https://dx.doi.org/10.3389/fcvm.2023.1250311 | Wrong intervention |
| 178. | Jiang, J., Wah Li, Y., & Hothi, S. S. (2023). Clinical service evaluation of the utility of artificial intelligence based-echocardiographic quantification of left ventricular global longitudinal strain and ejection fraction in trastuzumab-treated oncology patients. <i>Echo Research and Practice</i> , 10. https://doi.org/https://dx.doi.org/10.1186/s44156-023-00030-z (British Society of Echocardiography Annual Meeting, BSEcho 2022. London United Kingdom.) | Wrong intervention |
| 179. | Jiang, R., Yeung, D., Behnami, D., Jue, J., Tsang, M., Gin, K., Luong, C., Nair, P., Girgis, H., Abolmaesumi, P., & Tsang, T. (2019). MACHINE LEARNING TO FACILITATE ASSESSMENT OF DIASTOLIC FUNCTION BY ECHOCARDIOGRAPHY. <i>Canadian Journal of Cardiology</i> , 35(10), S4 EP - S5. https://doi.org/https://dx.doi.org/10.1016/j.cjca.2019.07.060 (Canadian Cardiovascular Congress 2019. Montreal Canada.) | Wrong intervention |
| 180. | Jing, L., Doddamani, S., Hartzel, D. N., Ulloa Cerna, A. E., Sauers, N. M., Good, C. W., Patel, A. A., Haggerty, C. M., & Fornwalt, B. K. (2018). Predicting mortality and hospitalization in 11,327 patients with heart failure using machine learning. <i>Circulation</i> , 138. | Wrong intervention |

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|------|---|--------------------|
| 181. | Jonna, S., Raavi, L., Isha, S., McDill, B., Agrawal, S., Jenkins, A., Hanson, A., Murthy, H., Dabaja, M. K., Goswami, R., & Sanghavi, D. (2024). EXPLORING AI-ENABLED ELECTROCARDIOGRAM PREDICTION TO DETECT CARDIOVASCULAR EFFECTS OF CAR-T THERAPY. <i>Critical Care Medicine</i> , 52(1), S41. https://doi.org/https://dx.doi.org/10.1097/01.ccm.0000998720.92827.10 (2024 Critical Care Congress. Phoenix, AZ United States.) | Wrong intervention |
| 182. | Joy, G., Artico, J., Kurdi, H., Seraphim, A., Lau, C., Thornton, G. D., Oliveira, M. F., Adam, R. D., Aziminia, N., Menacho, K., Chacko, L., Brown, J. T., Patel, R. K., Shiwani, H., Bhuva, A., Augusto, J. B., Andiapan, M., McKnight, A., Noursadeghi, M., . . . Moon, J. C. (2021). Prospective Case-Control Study of Cardiovascular Abnormalities 6 Months Following Mild COVID-19 in Healthcare Workers. <i>JACC Cardiovasc Imaging</i> , 14(11), 2155-2166. https://doi.org/10.1016/j.jcmg.2021.04.011 | Wrong intervention |
| 183. | Joy, G., Knott, K., Pierce, I., Augusto, J., Seraphim, A., Shiwani, H., Treibel, T., Manisty, C. H., Kellman, P., Moon, J., & Davies, R. (2024). AI Left Ventricular Segmentation Outperforms Humans for Prediction of All-cause Mortality in Known or Suspected Coronary Disease. <i>Journal of Cardiovascular Magnetic Resonance</i> , 26, 100128. https://doi.org/https://dx.doi.org/10.1016/j.jcmr.2024.100128 (CMR 2024 Global CMR Conference. QEII Centre, London United Kingdom.) | Wrong intervention |
| 184. | Jung, I. H. (2025). AI-based Prediction of Cardiac Function Using Echocardiography and Body Composition Data (ECHO-FIT Study). NCT06811519. ClinicalTrials.gov . https://clinicaltrials.gov/study/NCT06811519 | Wrong intervention |
| 185. | Kampaktsis, P. N., Bohoran, T. A., Lebbehn, M., McLaughlin, L., Leb, J., Liu, Z., Moustakidis, S., Siouras, A., Singh, A., Hahn, R. T., McCann, G. P., & Giannakidis, A. (2024). An attention-based deep learning method for right ventricular quantification using 2D echocardiography: Feasibility and accuracy. <i>Echocardiography</i> , 41(1), e15719. https://doi.org/https://dx.doi.org/10.1111/echo.15719 | Wrong intervention |
| 186. | Kampaktsis, P. N., Moustakidis, S., Siasos, G., Vavuranakis, M., & Lebbehn, M. (2024). Towards deep learning methods for quantification of the right ventricle using 2D echocardiography. <i>Future Cardiology</i> , 20(7), 339 EP - 341. https://doi.org/https://dx.doi.org/10.1080/14796678.2024.2347125 | Wrong intervention |
| 187. | Kane, C., Borgeson, J., Greason, C., Anisuzzaman, D. M., Malins, J., Tsaban, G., Anand, V., Lopezlimenez, F., Kane, G. C., Thaden, J., Pistraru, S., Attia, Z. I., & Bird, J. G. (2025). FEASIBILITY AND ACCURACY OF AI-GUIDED CARDIOVASCULAR FOCUSED ULTRASOUND BY SCANNERS WITHOUT CLINICAL OR IMAGING EXPERIENCE TO DETECT STAGE B HEART FAILURE. <i>Journal of the American College of Cardiology</i> , 85(12), 2466. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2825%2902950-X (American College of Cardiology, (ACC) Meeting 2025. Chicago United States.) | OOS AI technology |
| 188. | Karabayir, I., Davis, R., Tootooni, M. S., Chinthalal, L., Soliman, E., Jefferies, J., Baykaner, T., Shah, S., Bertoni, A., Kitzman, D., Herrington, D., & Akbilgic, O. (2024). ECG-AI to Assist with the Classification of Low Ejection Fraction and Heart Failure with Preserved Ejection Fraction. <i>Circulation</i> , 150. https://doi.org/https://dx.doi.org/10.1161/circ.150.suppl_1.4143513 (American Heart Association's 2024 Scientific Sessions and the American Heart Association's 2024 Resuscitation Science Symposium. Chicago, IL United States.) | Wrong intervention |
| 189. | Karagodin, I., Carvalho Singulane, C., Woodward, G. M., Xie, M., Tucay, E. S., Tude Rodrigues, A. C., Vasquez-Ortiz, Z. Y., Alizadehasl, A., Monaghan, M. J., Ordonez Salazar, B. A., Soulat-Dufour, L., Mostafavi, A., Moreo, A., Citro, R., Narang, A., Wu, C., Descamps, T., Addetia, K., Lang, R. M., & Asch, F. M. (2021). Echocardiographic Correlates of In-Hospital Death in Patients with Acute COVID-19 Infection: The World Alliance Societies of Echocardiography (WASE-COVID) Study. <i>Journal of the American Society of Echocardiography</i> : official publication of the American Society of Echocardiography, 34(8), 819-830. https://doi.org/https://dx.doi.org/10.1016/j.echo.2021.05.010 (Comment in: <i>J Am Soc Echocardiogr</i> . 2021 Dec;34(12):1323.) | Wrong population |
| 190. | Karakus, G., Degirmencioglu, A., & Nanda, N. C. (2022). Artificial intelligence in echocardiography: Review and limitations including epistemological concerns. <i>Echocardiography</i> , 39(8), 1044 EP - 1053. https://doi.org/https://dx.doi.org/10.1111/echo.15417 | Wrong study design |
| 191. | Karuzas, A., Balciunas, J., Fukson, M., Verikas, D., Matuliauskas, D., Platukis, T., Vaiciulienė, D., Jurgaityte, J., Kupstyte-Kristapone, N., Dirsiene, R., Jarusevicius, G., Sakalyte, G., Plisiene, J., & Lesauskaite, V. (2022). Artificial intelligence for automated evaluation of aortic measurements in 2D echocardiography: Feasibility, accuracy, and reproducibility. <i>Echocardiography</i> (Mount Kisco, N.Y.), 39(11), 1439-1445. https://doi.org/https://dx.doi.org/10.1111/echo.15475 | Wrong population |
| 192. | Karuzas, A., Miskikas, L., Sablauskas, K., Kazukauskiene, I., Verikas, D., Naskauskas, K., Sakalyte, G., Jarusevicius, G., Plisiene, J., & Lesauskaite, V. (2025). Deep learning-driven automated assessment of left ventricular diastolic function in echocardiography. <i>European Heart Journal Cardiovascular Imaging</i> , 26, i14. https://doi.org/https://dx.doi.org/10.1093/ehjci/jeae333.010 (24th annual congress of the European Association of Cardiovascular Imaging. Berlin Germany.) | Wrong intervention |

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| 193. | Karuzas, A., Sablauskas, K., Skrodenis, L., Verikas, D., Rumbinaite, E., Zaliaduonyte-Peksiene, D., Zuteliene, K., Vaskelyte, J. J., Jurkevicius, R., & Plisiene, J. (2019). P1465Artificial intelligence in echocardiography - Steps to automatic cardiac measurements in routine practice. European Heart Journal, 40, ehz748.0230. https://doi.org/10.1093/eurheartj/ehz748.0230 | Wrong intervention |
| 194. | Karuzas, A., Sablauskas, K., Verikas, D., Skrodenis, L., Teleisyte, E., Matuliauskas, D., Balciunas, J., Kiziela, A., Rumbinaite, E., Lapinskas, T., Ereminiene, E., Mizariene, V., Vaskelyte, J. J., Jurkevicius, R., & Plisiene, J. (2020). Accurate prediction of left ventricular diastolic dysfunction in 2D echocardiography using ensemble of deep convolutional neural networks. European Heart Journal, 41, ehaa946.3436. https://doi.org/10.1093/ehjci/ehaa946.3436 | Wrong intervention |
| 195. | Karuzas, A., Sablauskas, K., Verikas, D., Teleisyte, E., Skrodenis, L., Matuliauskas, D., Balciunas, J., Mileris, J., Rumbinaite, E., Zaliaduonyte-Peksiene, D., Vaskelyte, J. J., Jurkevicius, R., & Plisiene, J. (2020). 544 Deep learning in segmentation and function evaluation of right ventricle in 2D echocardiography. European Heart Journal - Cardiovascular Imaging, 21, jez319.278. https://doi.org/10.1093/ehjci/jez319.278 | Wrong intervention |
| 196. | Karuzas, A., Sablauskas, K., Zvirblyte, R., Skrodenis, L., Teleisyte, E., Verikas, D., Balciunas, J., Matuliauskas, D., Kiziela, A., Rumbinaite, E., Vaskelyte, J. J., Ereminiene, E., Jurkevicius, R., & Plisiene, J. (2021). Automated evaluation of the right-sided heart function and geometry using deep learning. European Heart Journal - Cardiovascular Imaging, 22, jea356.427. https://doi.org/10.1093/ehjci/jea356.427 | Wrong intervention |
| 197. | Kashou, A. H., Medina-Inojosa, J. R., Noseworthy, P. A., Rodeheffer, R. J., Lopez-Jimenez, F., Attia, I. Z., Kapa, S., Scott, C. G., Lee, A. T., Friedman, P. A., & McKie, P. M. (2021). Artificial Intelligence-Augmented Electrocardiogram Detection of Left Ventricular Systolic Dysfunction in the General Population. Mayo Clinic Proceedings, 96(10), 2576-2586. https://doi.org/https://dx.doi.org/10.1016/j.mayocp.2021.02.029 | Wrong intervention |
| 198. | Katz, D. H., Deo, R. C., Aguilar, F. G., Selvaraj, S., Martinez, E. E., Beussink-Nelson, L., Kim, K.-Y. A., Peng, J., Irvin, M. R., Tiwari, H., Rao, D. C., Arnett, D. K., & Shah, S. J. (2017). Phenomapping for the Identification of Hypertensive Patients with the Myocardial Substrate for Heart Failure with Preserved Ejection Fraction. Journal of cardiovascular translational research, 10(3), 275-284. https://doi.org/https://dx.doi.org/10.1007/s12265-017-9739-z | Wrong intervention |
| 199. | Kazkauskiene, I., Sablauskas, K., Ciampi, Q., Cortigiani, L., Wierzbowska-Drabik, K., Kasprzak, J. D., Lowenstein, J., Karuzas, A., Prota, C., Gaibazzi, N., Lepone, A., Marconi, S., Kiziela, A., Arbucci, R., Picano, E., & Stress Echo study, g. (2025). Effect of image quality on automated evaluation of the left-sided heart volumes. European Heart Journal - Cardiovascular Imaging, 26, jea333.020. https://doi.org/10.1093/ehjci/jea333.020 | Wrong intervention |
| 200. | Kent, S. C. Y. (2025). Artificial Intelligence Versus Sonographer Echocardiogram Analysis and Reporting in Patients With Heart Failure. NCT07021599. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT07021599 | Wrong intervention |
| 201. | Kim, S. T., Lim, K., Roh, G. H., Kim, S., Lee, S. Y., Kim, G. B., Bae, E. J., Chae, J. H., Kim, K., & Song, M. K. (2025). Artificial intelligence based electrocardiogram analysis for prediction of cardiovascular prognosis in dystrophinopathy patients. Europace, 27, i1425. https://doi.org/https://dx.doi.org/10.1093/europace/euaf085.828 (European Heart Rhythm Association Congress, EHRA 2025. Vienna Austria.) | Wrong intervention |
| 202. | Kinaszczuk, A., Morales-Lara, A. C., Garzon-Siatoya, W. T., El-Attar, S., Clapp, A. D., Olutola, I. A., Moerer, R., Johnson, P., Wieczorek, M. A., Attia, Z. I., Lopez-Jimenez, F., Friedman, P. A., Carter, R. E., Noseworthy, P. A., & Adedinsewo, D. (2025). Artificial Intelligence Tools for Preconception Cardiomyopathy Screening Among Women of Reproductive Age. Annals of family medicine, 23(3), 246 EP - 254. https://doi.org/https://dx.doi.org/10.1370/afm.230627 | Wrong intervention |
| 203. | Kobayashi, M., Huttin, O., Ferreira, J. P., Duarte, K., Gonzalez, A., Heymans, S., Verdonschot, J. A. J., Brunner-La Rocca, H.-P., Pellicori, P., Clark, A. L., Petutschnigg, J., Edelmann, F., Cleland, J. G., Rossignol, P., Zannad, F., & Girerd, N. (2023). A machine learning-derived echocardiographic algorithm identifies people at risk of heart failure with distinct cardiac structure, function, and response to spironolactone: Findings from the HOMAGE trial. European journal of heart failure, 25(8), 1284-1289. https://doi.org/https://dx.doi.org/10.1002/ejhf.2859 (Comment in: Eur J Heart Fail. 2023 Aug;25(8):1290-1292. doi: 10.1002/ejhf.2938) | OOS AI technology |
| 204. | Kobayashi, M., Huttin, O., Magnusson, M., Ferreira, J. P., Bozec, E., Huby, A.-C., Preud'homme, G., Duarte, K., Lamiral, Z., Dalleau, K., Bresso, E., Smail-Tabbone, M., Devignes, M.-D., Nilsson, P. M., Leosdottir, M., Boivin, J.-M., Zannad, F., Rossignol, P., & Girerd, N. (2022). Machine Learning-Derived Echocardiographic Phenotypes Predict Heart Failure Incidence in Asymptomatic Individuals. JACC: Cardiovascular imaging, 15(2), 193-208. https://doi.org/https://dx.doi.org/10.1016/j.jcmg.2021.07.004 (Comment in: JACC Cardiovasc Imaging. 2022 Feb;15(2):209-211. doi: 10.1016/j.jcmg.2021.09.011) | OOS AI technology |
| 205. | Kokubo, T., Kodera, S., Sawano, S., Katsushika, S., Nakamoto, M., Takeuchi, H., Kimura, N., Shinohara, H., Matsuoka, R., Nakanishi, K., Nakao, T., Higashikuni, Y., Takeda, N., Fujii, K., Daimon, M., Akazawa, H., Morita, H., Matsuyama, Y., & Komuro, I. (2022). Automatic Detection of Left Ventricular Dilatation and Hypertrophy from Electrocardiograms Using Deep Learning. International heart journal, 63(5), 939-947. https://doi.org/https://dx.doi.org/10.1536/ihj.22-132 | Wrong intervention |

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|------|--|------------------------|
| 206. | Koops, J. (2021). Machine Learning in an Elderly Man with Heart Failure. <i>International medical case reports journal</i> , 14, 497-502. https://doi.org/https://dx.doi.org/10.2147/IMCRJ.S322827 | Wrong study design |
| 207. | Kotlo, S., Chiou, T., Akingbade, O., Kanelidis, A., Campagna, R., Kim, G., Beaser, A., & Slivnick, J. (2024). Clinical and Echocardiographic Markers for the Prediction of Incident Atrial Arrhythmias in Hypertrophic Cardiomyopathy. <i>Circulation</i> , 150. https://doi.org/https://dx.doi.org/10.1161/circ.150.suppl_1.4134896 (American Heart Association's 2024 Scientific Sessions and the American Heart Association's 2024 Resuscitation Science Symposium. Chicago, IL United States.) | Wrong outcome |
| 208. | Kowlgi, G., Dai, Q., Greason, G., Woelber, T., Wight, J., Noseworthy, P. A., Friedman, P. A., Asirvatham, S. J., & Attia, I. Z. (2023). Detection of left ventricular contractile dysfunction in patients with premature ventricular contractions using electrocardiogram trained using a deep learning model. <i>European Heart Journal</i> , 44. https://doi.org/https://dx.doi.org/10.1093/eurheartj/eahd655.2938 (European Society of Cardiology Congress, ESC 2023. Amsterdam Netherlands.) | Wrong intervention |
| 209. | Krishna, H., Desai, K., Slostad, B., Bhayani, S., Arnold, J. H., Ouwerkerk, W., Hummel, Y., Lam, C. S. P., Ezekowitz, J., Frost, M., Jiang, Z., Equilbec, C., Twing, A., Pellikka, P. A., Frazin, L., & Kansal, M. (2023). Fully Automated Artificial Intelligence Assessment of Aortic Stenosis by Echocardiography. <i>Journal of the American Society of Echocardiography: official publication of the American Society of Echocardiography</i> , 36(7), 769-777. https://doi.org/https://dx.doi.org/10.1016/j.echo.2023.03.008 | Wrong population |
| 210. | Krishna, H., Ouwerkerk, W., Arnold, J. H., Bhayani, S., Frost, M., Jiang, Z., Equilbec, C., Lam, C. S., Pellikka, P. A., Shah, S., Darbar, D., & Kansal, M. (2025). Aortic Stenosis Severity Classification: A Diagnostic Quandary with an Artificial Intelligence Solution. ASE2025, | Wrong population |
| 211. | Krittawong, C., Tunhasiriwet, A., Zhang, H., Wang, Z., Aydar, M., & Kitai, T. (2017). Deep Learning With Unsupervised Feature in Echocardiographic Imaging. <i>Journal of the American College of Cardiology</i> , 69(16), 2100 EP - 2101. https://doi.org/https://dx.doi.org/10.1016/j.jacc.2016.12.047 | Wrong publication type |
| 212. | Kumar, D., Balraj, K., Seth, S., Vashista, S., Ramteke, M., & Rathore, A. S. (2024). An improved machine learning-based prediction framework for early detection of events in heart failure patients using mHealth. <i>Health and Technology</i> , 14(3), 495 EP - 512. https://doi.org/https://dx.doi.org/10.1007/s12553-024-00832-z | Wrong intervention |
| 213. | Kusunose, K., Haga, A., Abe, T., Fukuda, D., Yamada, H., & Sata, M. (2019). Assessment of left ventricular ejection fraction from echocardiographic images using deep learning algorithm. <i>Circulation</i> , 140. https://doi.org/https://dx.doi.org/10.1161/circ.140.suppl_1.10409 (American Heart Association Scientific Sessions, AHA 2019. Philadelphia, PA United States.) | Wrong intervention |
| 214. | Kusunose, K., Haga, A., Yamaguchi, N., Abe, T., Fukuda, D., Yamada, H., Harada, M., & Sata, M. (2020). Deep Learning for Assessment of Left Ventricular Ejection Fraction from Echocardiographic Images. <i>Journal of the American Society of Echocardiography</i> , 33(5), 632 EP - 635.e631. https://doi.org/https://dx.doi.org/10.1016/j.echo.2020.01.009 | Wrong intervention |
| 215. | Kwon, J.-M., Kim, K.-H., Jeon, K.-H., & Park, J. (2019). Deep learning for predicting in-hospital mortality among heart disease patients based on echocardiography. <i>Echocardiography</i> (Mount Kisco, N.Y.), 36(2), 213-218. https://doi.org/https://dx.doi.org/10.1111/echo.14220 | Wrong intervention |
| 216. | Lang, C. C., Oo, M. M., Gao, C., Cole, C., Hummel, Y., Guignard-Duff, M., Mordi, I., Jefferson, E., Hare, J., Palmer, C., Voors, A. A., de Boer, R. A., Tromp, J., & Lam, C. S. (2023). Abstract 12519: Biomarker Characterisation of Heart Failure Subtypes: A Population-Based Bioresource Linked Study. <i>Circulation</i> , 148(Suppl_1). https://doi.org/https://dx.doi.org/10.1161/circ.148.suppl_1.12519 | Wrong intervention |
| 217. | Larson, N. B., Weston, S., Michelena, H. I., Bielinski, S. J., Jiang, R., Joo, J., Manemann, S. M., Chamberlain, A. M., & Roger, V. L. (2021). Deep phenotyping of heart failure with machine learning: An echocardiographic community study. <i>Circulation</i> , 144. https://doi.org/https://dx.doi.org/10.1161/circ.144.suppl_1.10515 (American Hearts Association's 2021 Scientific Sessions. Boston, MA United States.) | Wrong intervention |
| 218. | Lau, E. S., Di Achille, P., Kopparapu, K., Andrews, C. T., Singh, P., Reeder, C., Al-Alusi, M., Khurshid, S., Haimovich, J. S., Ellinor, P. T., Picard, M. H., Batra, P., Lubitz, S. A., & Ho, J. E. (2023). Deep Learning-Enabled Assessment of Left Heart Structure and Function Predicts Cardiovascular Outcomes. <i>Journal of the American College of Cardiology</i> , 82(20), 1936-1948. https://doi.org/https://dx.doi.org/10.1016/j.jacc.2023.09.800 (Comment in: <i>J Am Coll Cardiol</i> . 2023 Nov 14;82(20):1949-1952. doi: 10.1016/j.jacc.2023.09.799.) | OOS AI technology |
| 219. | Lee, E., Ito, S., Kane, G. C., Lopez-Jimenez, F., Friedman, P. A., Attia, Z. I., & Oh, J. K. (2023). AN ARTIFICIAL INTELLIGENCE-ENABLED ECG ALGORITHM FOR LEFT VENTRICULAR DIASTOLIC FUNCTION ASSESSMENT. <i>Journal of the American College of Cardiology</i> , 81(8), 4023. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2823%2904467-4 (ACC.23. New Orleans United States.) | Wrong intervention |

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| 220. | Lee, E., Ito, S., Miranda, W. R., Lopez-Jimenez, F., Kane, G. C., Asirvatham, S. J., Noseworthy, P. A., Friedman, P. A., Carter, R. E., Borlaug, B. A., Attia, Z. I., & Oh, J. K. (2024). Artificial intelligence-enabled ECG for left ventricular diastolic function and filling pressure. <i>NPJ digital medicine</i> , 7(1), 4. https://doi.org/https://dx.doi.org/10.1038/s41746-023-00993-7 | Wrong intervention |
| 221. | Lee, E., Miranda, W., Lopez-Jimenez, F., Yu, H. T., Friedman, P., Attia, Z., & Oh, J. K. (2023). Prognostic Value of Artificial Intelligence-Enabled ECG for Increased Left Ventricular Filling Pressure. <i>Circulation</i> , 148. https://doi.org/https://dx.doi.org/10.1161/circ.148.suppl_1.14666 (American Heart Association's 2023 Scientific Sessions and the American Heart Association's 2023 Resuscitation Science Symposium. Philadelphia, PA United States.) | Wrong intervention |
| 222. | Leeson, P., & Fletcher, A. J. (2019). Combining Artificial Intelligence with Human Insight to Automate Echocardiography. <i>Circulation: Cardiovascular Imaging</i> , 12(9), e009727. https://doi.org/https://dx.doi.org/10.1161/CIRCIMAGING.119.009727 | Wrong publication type |
| 223. | Li, C., Dou, G., Ding, Y., Xin, R., Wang, J., Guo, J., Chen, Y., & Yang, J. (2022). Machine Learning Model-Based Simple Clinical Information to Predict Decreased Left Atrial Appendage Flow Velocity. <i>Journal of Personalized Medicine</i> , 12(3). https://doi.org/https://dx.doi.org/10.3390/jpm12030437 | Wrong intervention |
| 224. | Li, M., Zeng, D., Zhou, Y., Chen, J., Cao, S., Song, H., Hu, B., Yuan, W., Chen, J., Yang, Y., Wang, H., Fei, H., Shi, Y., & Zhou, Q. (2023). A novel risk stratification model for STEMI after primary PCI: global longitudinal strain and deep neural network assisted myocardial contrast echocardiography quantitative analysis. <i>Frontiers in Cardiovascular Medicine</i> , 10, 1140025. https://doi.org/https://dx.doi.org/10.3389/fcvm.2023.1140025 | Wrong intervention |
| 225. | Li, Y., Hong, K., Shi, X., Pang, W., Xiao, Y., Zhao, P., Xu, D., Song, C., Zhou, X., & Zhou, Y. (2025). A deep learning based approach for automatic cardiac events identification. <i>Biomedical Signal Processing and Control</i> , 100, 107164. https://doi.org/https://dx.doi.org/10.1016/j.bspc.2024.107164 | Wrong intervention |
| 226. | Li, Y., Weber, J., Dang, O., Cheng, J., & Cao, J. J. (2024). DEEP LEARNING ASSESSMENT OF PULMONARY ARTERY PRESSURE WITH CMR FLOW IMAGING. <i>Journal of the American College of Cardiology</i> , 83(13), 1376. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2824%2903366-7 (ACC.24. Atlanta United States.) | Wrong intervention |
| 227. | Liastuti, L. D., Budi Siswanto, B., Sukmawan, R., Jatmiko, W., Nursakina, Y., Putri, R. Y. I., Jati, G., & Nur, A. A. (2022). Detecting Left Heart Failure in Echocardiography through Machine Learning: A Systematic Review. <i>Reviews in cardiovascular medicine</i> , 23(12), 402. https://doi.org/https://dx.doi.org/10.31083/j.rcm2312402 | Wrong intervention |
| 228. | Liastuti, L. D., Siswanto, B. B., Sukmawan, R., Jatmiko, W., Alwi, I., Wiweko, B., Kekalih, A., Nursakina, Y., Putri, R. Y. I., Jati, G., Ramadhan, M. M. L., Govardi, E., & Nur, A. A. (2022). Learning Intelligent for Effective Sonography (LIFES) Model for Rapid Diagnosis of Heart Failure in Echocardiography. <i>Acta medica Indonesiana</i> , 54(3), 428-437. | OOS AI technology |
| 229. | Liu, C.-M., Hsieh, M.-E., Hu, Y.-F., Wei, T.-Y., Wu, I. C., Chen, P.-F., Lin, Y.-J., Higa, S., Yagi, N., Chen, S.-A., & Tseng, V. S. (2022). Artificial Intelligence-Enabled Model for Early Detection of Left Ventricular Hypertrophy and Mortality Prediction in Young to Middle-Aged Adults. <i>Circulation. Cardiovascular quality and outcomes</i> , 15(8), e008360. https://doi.org/https://dx.doi.org/10.1161/CIRCOUTCOMES.121.008360 | Wrong intervention |
| 230. | Liu, N., Lau, Y. H., Sim, D., Sim, L. L., Ong, M., Tan, R. S., & Zhong, L. (2016). Prediction of mortality for heart failure patients using intelligent machine learning method. <i>European Journal of Heart Failure</i> , 18, 119 EP - 120. https://doi.org/https://dx.doi.org/10.1002/ejhf.539 (Heart Failure 2016 and the 3rd World Congress on Acute Heart Failure. Florence Italy.) | Wrong intervention |
| 231. | Liu, Y., Xie, S., Lin, Z., & Zhao, C. (2025). Enhancing predictions of subclinical cardiac dysfunction in SLE patients through integrative machine learning analysis. <i>Lupus Science and Medicine</i> , 12(2), e001616. https://doi.org/https://dx.doi.org/10.1136/lupus-2025-001616 | Wrong intervention |
| 232. | Liu, Z., Huang, Y., Li, H., Li, W., Zhang, F., Ouyang, W., Wang, S., Luo, Z., Wang, J., Chen, Y., Xia, R., Li, Y., & Pan, X. (2023). A generalized deep learning model for heart failure diagnosis using dynamic and static ultrasound. <i>Journal of translational internal medicine</i> , 11(2), 138-144. https://doi.org/https://dx.doi.org/10.2478/jtim-2023-0088 | OOS AI technology |
| 233. | Lobodzinski, S. (2024). Revolutionizing cardiac care: Exploring the impact of AI-ECG FDA breakthrough device designation on clinical practice. <i>Journal of Electrocardiology</i> , 84, 14 EP - 15. https://doi.org/https://dx.doi.org/10.1016/j.jelectrocard.2024.05.029 (The International Society for Computerized Electrocardiology (ISCE). Chateau Elan, Braselton United States.) | Wrong intervention |

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| 234. | Loncaric, F., Marti Castellote, P. M., Sanchez-Martinez, S., Fabijanovic, D., Nunno, L., Mimbrero, M., Sanchis, L., Doltra, A., Montserrat, S., Cikes, M., Crispí, F., Piella, G., Sitges, M., & Bijnens, B. (2021). Automated Pattern Recognition in Whole-Cardiac Cycle Echocardiographic Data: Capturing Functional Phenotypes with Machine Learning. <i>Journal of the American Society of Echocardiography</i> , 34(11), 1170 EP - 1183. https://doi.org/https://dx.doi.org/10.1016/j.echo.2021.06.014 | Wrong intervention |
| 235. | Lu, M. (2020). Multimodality Imaging (Cardiovascular Magnetic Resonance Imaging, Echocardiography, and Nuclear Medicine Imaging) in the Screening, Diagnosis and Risk Stratification of Heart Failure With Preserved Ejection Fraction- a Multicenter Study. NCT04602338. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT04602338 | Wrong intervention |
| 236. | Luong, C. L., Behnami, D., Liao, Z., Yeung, D. F., Tsang, M. Y. C., Van Woudenberg, N., Gin, K., Sayre, E. C., Jue, J., Nair, P., Hawley, D., Abolmaesumi, P., & Tsang, T. S. M. (2023). Machine learning derived echocardiographic image quality in patients with left ventricular systolic dysfunction: insights on the echo views of greatest image quality. <i>International Journal of Cardiovascular Imaging</i> , 39(7), 1313 EP - 1321. https://doi.org/https://dx.doi.org/10.1007/s10554-023-02802-4 | Wrong intervention |
| 237. | Lyell, D., Coiera, E., Chen, J., Shah, P., & Magrabi, F. (2021). How machine learning is embedded to support clinician decision making: An analysis of FDA-approved medical devices. <i>BMJ Health and Care Informatics</i> , 28(1), e100301. https://doi.org/https://dx.doi.org/10.1136/bmjhci-2020-100301 | Wrong intervention |
| 238. | Mahdavi, M., Thomas, N., Flood, C., Stewart-Lord, A., Baillie, L., Grisan, E., Callaghan, P., Panayotova, R., Hothi, S. S., Griffith, V., Jayadev, S., & Frings, D. (2024). Evaluating artificial intelligence-driven stress echocardiography analysis system (EASE study): A mixed method study. <i>BMJ open</i> , 14(10), e079617. https://doi.org/https://dx.doi.org/10.1136/bmjopen-2023-079617 | Wrong intervention |
| 239. | Majchrowska, S., Hildeman, A., Mokhtari, R., Diethe, T., & Teare, P. (2025). Exploring interpretable echo analysis using self-supervised parcels. <i>Computers in biology and medicine</i> , 192, 110322. https://doi.org/https://dx.doi.org/10.1016/j.combiomed.2025.110322 | OOS AI technology |
| 240. | Makimoto, H. (2024). Bridging the gap: AI in echocardiography for early detection of LVH in underserved areas. <i>Hypertension Research</i> , 47(5), 1434 EP - 1435. https://doi.org/https://dx.doi.org/10.1038/s41440-024-01608-8 | Wrong publication type |
| 241. | Malins, J. G., Anisuzzaman, D. M., Jackson, J. I., Lee, E., Naser, J. A., Bird, J. G., Friedman, P. A., Ngo, C. C., Oh, J. K., Tsaban, G., Pellikka, P. A., Thaden, J. J., Lopez-Jimenez, F., Attia, Z. I., Pistaru, S. V., & Kane, G. C. (2024). A deep learning model for classifying left ventricular enlargement for both transthoracic echocardiograms and handheld cardiac ultrasound. <i>European heart journal. Imaging methods and practice</i> , 3(3), qyaf049. https://doi.org/https://dx.doi.org/10.1093/eihjimp/qyaf049 (Erratum in: <i>Eur Heart J Imaging Methods Pract</i> . 2025 Aug 14;3(2):qyaf104. doi: 10.1093/eihjimp/qyaf104. | Wrong intervention |
| 242. | Manisty, C., Shun-Shin, M., Miyoshi, T., Shiwani, H., Gallagher, C., Dufour, L. S., Slivnick, J., Patel, H., Mor-Avi, V., Ng, T., Topriceanu, C.-C., Addetia, K., Almeida, G., Moon, J. C., Francis, D. P., Unsworth, B., Asch, F., & Lang, R. M. (2025). PC1-34 Interventricular Septal Wall Thickness - Moving Towards Personalized Normal Reference Ranges for Diagnosis of Hypertrophic Cardiomyopathy. <i>Journal of the American Society of Echocardiography</i> , 38(9), e18-e19. https://doi.org/10.1016/j.echo.2025.06.013 | Wrong outcome |
| 243. | Martin, J. A., Hill, T., Saric, M., Vainrib, A. F., Bamira, D., Bernard, S., Ro, R., Zhang, H., Austrian, J. S., Aphinyanaphongs, Y., Koesmahargyo, V., Williams, M. R., Chinitz, L. A., & Jankelson, L. (2024). Evaluating Patient-Oriented Echocardiogram Reports Augmented by Artificial Intelligence. <i>JACC: Cardiovascular Imaging</i> , 17(11), 1381 EP - 1383. https://doi.org/https://dx.doi.org/10.1016/j.jcmg.2024.05.021 | Wrong publication type |
| 244. | Marwick, T. (2022). Use of Artificial Intelligence-Guided Echocardiography to assist cardiovascular Patient management. NCT05558605. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT05558605 | OOS AI technology |
| 245. | Mazankowski Alberta Heart Institute, & Ultromics Ltd. (2021). Mazankowski Alberta Heart Institute (MAHI) EchoGo Discovery 1 Protocol. NCT04877899. ClinicalTrials.gov. https://clinicaltrials.gov/show/NCT04877899 | Wrong intervention |
| 246. | McElhinney, D. (2024). Pediatric Ventricle Function Assessment Study. NCT06739057. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT06739057 | Wrong intervention |

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| 247. | Melichova, D., Nyberg, J., Nguyen, T. M., Salte, I. M., Brunvand, H., Haugaa, K. H., Edvardsen, T., Dalen, H., Lovstakken, L., Ostvik, A., & Grenne, B. (2025). Clinical validation of a novel fully automated measurement method for echocardiographic mechanical dispersion using deep learning. <i>European Heart Journal Cardiovascular Imaging</i> , 26, i40. https://doi.org/https://dx.doi.org/10.1093/ehjci/jeae333.024 (24th annual congress of the European Association of Cardiovascular Imaging. Berlin Germany.) | Wrong intervention |
| 248. | Melichova, D., Nyberg, J., Nguyen, T. M., Salte, I. M., Brunvand, H., Haugaa, K., Edvardsen, T., Dalen, H., Lovstakken, L., Ostvik, A., & Grenne, B. (2024). Fully automated measurements of echocardiographic mechanical dispersion using deep learning: enhanced prediction of ventricular arrhythmias in a large heart failure cohort. <i>European Heart Journal</i> , 45. https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehae666.004 (European Society of Cardiology Congress, ESC 2024. London United Kingdom.) | Wrong intervention |
| 249. | Mesin, L., Policastro, P., Re, A., Sanson, C., Albani, S., Petersen, C., Sciarrone, P., Taddei, C., & Giannoni, A. (2022). AUTOMATED REAL TIME ECHOCARDIOGRAPHIC TOOL FOR EDGE TRACKING OF INFERIOR VENA CAVA AND NON-INVASIVE ESTIMATION OF RIGHT ATRIAL PRESSURE. <i>European Heart Journal, Supplement</i> , 24, K75. https://doi.org/https://dx.doi.org/10.1093/eurheartj/suac121.212 (83rd SIC National Congress. Virtual.) | Wrong intervention |
| 250. | Mika, S., Gola, W., Gil-Mika, M., Wilk, M., & Misiollek, H. (2024). Ultrasonographic Applications of Novel Technologies and Artificial Intelligence in Critically Ill Patients. <i>Journal of personalized medicine</i> , 14(3). https://doi.org/https://dx.doi.org/10.3390/jpm14030286 | Wrong study design |
| 251. | Moradi, S., Oghli, M. G., Alizadehhasl, A., & Shabanzadeh, A. (2019). Deep learning approach for left atrium segmentation. <i>Iranian Journal of Radiology</i> , 16, S7. https://doi.org/https://dx.doi.org/10.5812/IRANJRADIOL.99142 (1st National Conference on Artificial Intelligence in Medical Imaging, AIMIN 2019. Tehran Iran, Islamic Republic of.) | Wrong intervention |
| 252. | Morbach, C., Gelbrich, G., Schreckenberg, M., Hedemann, M., Pelin, D., Scholz, N., Miljukov, O., Wagner, A., Theisen, F., Hitschrich, N., Wiebel, H., Stapf, D., Karch, O., Frantz, S., Heuschmann, P. U., & Stork, S. (2024). Population data-based federated machine learning improves automated echocardiographic quantification of cardiac structure and function: the Automatisierte Vermessung der Echokardiographie project. <i>European heart journal. Digital health</i> , 5(1), 77-88. https://doi.org/https://dx.doi.org/10.1093/ehjdh/ztad069 | OOS AI technology |
| 253. | Muraki, R., Teramoto, A., Sugimoto, K., Sugimoto, K., Yamada, A., & Watanabe, E. (2022). Automated detection scheme for acute myocardial infarction using convolutional neural network and long short-term memory. <i>PLoS one</i> , 17(2), e0264002. https://doi.org/https://dx.doi.org/10.1371/journal.pone.0264002 | Wrong intervention |
| 254. | Murta, I. O., Ruiz, E. E. S., Pazin-Filho, A., Schmidt, A., Almeida-Filho, O. C., Simoes, M. V., Marin-Neto, J. A., & Maciel, B. C. (2006). Automated grading of left ventricular segmental wall motion by an artificial neural network using color kinesis images. <i>Brazilian Journal of Medical and Biological Research</i> , 39(1), 1 EP - 7. https://doi.org/https://dx.doi.org/10.1590/s0100-879x2006000100001 | Wrong intervention |
| 255. | Myhre, P. L., Grenne, B., Asch, F. M., Delgado, V., Khera, R., Lafitte, S., Lang, R. M., Pellikka, P. A., Sengupta, P. P., Vemulapalli, S., & Lam, C. S. P. (2025). Artificial intelligence-enhanced echocardiography in cardiovascular disease management. <i>Nature Reviews Cardiology</i> . https://doi.org/https://dx.doi.org/10.1038/s41569-025-01197-0 | Wrong study design |
| 256. | Myhre, P. L., Tromp, J., Ouwerkerk, W., Ting, D. S. W., Docherty, K. F., Gibson, C. M., & Lam, C. S. P. (2024). Digital tools in heart failure: addressing unmet needs. <i>Lancet Digit Health</i> , 6(10), e755-e766. https://doi.org/10.1016/S2589-7500(24)00158-4 | Wrong publication type |
| 257. | Naghavi, M., Atlas, K., Zhang, C., Reeves, A., Jaalouk, E., Henschke, C., Yankelevitz, D., Roy, S., & Budoff, M. (2024). AI-enabled Cardiac Chambers Volumetry in Non-Contrast Cardiac CT scans (AICAC) Detects HFrEF vs. HFpEF. <i>Circulation</i> , 150. https://doi.org/https://dx.doi.org/10.1161/circ.150.suppl_1.4144057 (American Heart Association's 2024 Scientific Sessions and the American Heart Association's 2024 Resuscitation Science Symposium. Chicago, IL United States.) | Wrong intervention |
| 258. | National Taiwan University Hospital. (2024). The Development of the Simulation Curriculum and Artificial Intelligence-incorporated Assessment Tools for Transesophageal Echocardiography in Patients With Cardiac Arrest. <i>NCT06567912</i> . <i>ClinicalTrials.gov</i> . https://clinicaltrials.gov/study/NCT06567912 | Wrong intervention |
| 259. | Nguyen, M. B., Dragulescu, A., Chaturvedi, R., Fan, C. P. S., Villemain, O., Friedberg, M. K., & Mertens, L. L. (2021). Supervised machine learning for relating echocardiographic parameters to invasive pressure measurements in pediatric diastolic function assessment. <i>Circulation</i> , 144. https://doi.org/https://dx.doi.org/10.1161/circ.144.suppl-1.10386 (American Heart Association's 2021 Scientific Sessions. Boston, MA United States.) | Wrong intervention |

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| 260. | Nguyen, M. B., Dragulescu, A., Chaturvedi, R., Fan, C. P. S., Villemain, O., Friedberg, M. K., & Mertens, L. L. (2022). Understanding Complex Interactions in Pediatric Diastolic Function Assessment. <i>Journal of the American Society of Echocardiography</i> , 35(8), 868 EP - 877.e865. https://doi.org/https://dx.doi.org/10.1016/j.echo.2022.03.017 | Wrong intervention |
| 261. | NHS Greater Glasgow and Clyde. (2021). Optimising a Digital Diagnostic Pathway for Heart Failure in the Community. NCT04724200. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT04724200 | Wrong intervention |
| 262. | O'Driscoll, J. (2021). Fully Automated Left Ventricular Ejection Fraction And Global Longitudinal Strain Predicts Obstructive Coronary Artery Disease In Patients Undergoing Stress Echocardiography: A Multi-Centre Study. | Wrong intervention |
| 263. | O'Driscoll, J. M., Hawkes, W., Beqiri, A., Mumith, A., Parker, A., Upton, R., McCourt, A., Woodward, W., Dockerill, C., Sabharwal, N., Kardos, A., Augustine, D. X., Balkhausen, K., Chandrasekaran, B., Firoozan, S., Marciniak, A., Heitner, S., Yadava, M., Kaul, S., . . . Leeson, P. (2022). Left ventricular assessment with artificial intelligence increases the diagnostic accuracy of stress echocardiography. <i>European heart journal open</i> , 2(5), oeac059. https://doi.org/https://dx.doi.org/10.1093/ehjopen/oeac059 | Wrong intervention |
| 264. | O'Driscoll, J. M., Tuttolomondo, D., & Gaibazzi, N. (2023). Artificial intelligence calculated global longitudinal strain and left ventricular ejection fraction predicts cardiac events and all-cause mortality in patients with chest pain. <i>Echocardiography</i> (Mount Kisco, N.Y.), 40(12), 1356-1364. https://doi.org/https://dx.doi.org/10.1111/echo.15714 | Wrong intervention |
| 265. | Oikonomou, E. K., Holste, G., Yuan, N., Coppi, A., McNamara, R. L., Haynes, N., Vora, A. N., Velazquez, E. J., Li, F., Menon, V., Kapadia, S. R., Gill, T. M., Nadkarni, G. N., Krumholz, H. M., Wang, Z., Ouyang, D., & Khera, R. (2023). A Multimodality Video-Based AI Biomarker For Aortic Stenosis Development And Progression. <i>medRxiv</i> . https://doi.org/https://dx.doi.org/10.1101/2023.09.28.23296234 | Wrong intervention |
| 266. | Oo, M. M., Gao, C., Cole, C., Hummel, Y., Guignard-Duff, M., Jefferson, E., Hare, J., Voors, A. A., de Boer, R. A., Lam, C. S. P., Mordi, I. R., Tromp, J., & Lang, C. C. (2024). Artificial intelligence-assisted automated heart failure detection and classification from electronic health records. <i>ESC heart failure</i> , 11(5), 2769-2777. https://doi.org/https://dx.doi.org/10.1002/ehf2.14828 | Wrong intervention |
| 267. | Ortiz, J., Ghefter, C. G., Silva, C. E., & Sabbatini, R. M. (1995). One-year mortality prognosis in heart failure: a neural network approach based on echocardiographic data. <i>Journal of the American College of Cardiology</i> , 26(7), 1586-1593. https://doi.org/https://dx.doi.org/10.1016/0735-1097(95)00385-1 | Wrong intervention |
| 268. | Ouyang, D. (2021). Blinded Randomized Controlled Trial of Artificial Intelligence Guided Assessment of Cardiac Function. NCT05140642. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT05140642 | OOS AI technology |
| 269. | Ouyang, D. (2023). Safety and Efficacy Study of AI Wall Thickness Measurement (EchoNet-LVH-RCT). NCT05791227. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT05791227 | OOS AI technology |
| 270. | Ouyang, D., Ghorbani, A., Chen, J. H., Harrington, R. A., Zou, J., Ashley, E. A., & Liang, D. (2019). Machine learning prediction of left ventricular chamber size and ejection fraction. <i>Circulation</i> , 140. https://doi.org/https://dx.doi.org/10.1161/circ.140.suppl_1.16339 (American Heart Association Scientific Sessions, AHA 2019. Philadelphia, PA United States.) | Wrong intervention |
| 271. | Pandey, A. (2024). Identifying Undiagnosed HFpEF Among Patients With Type 2 Diabetes Using Ultromics AI HFpEF Algorithm. NCT06593314. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT06593314 | Wrong outcome |
| 272. | Pandey, A., Kagiyama, N., Yanamala, N., Segar, M. W., Cho, J. S., Tokodi, M., & Sengupta, P. P. (2021). Deep-Learning Models for the Echocardiographic Assessment of Diastolic Dysfunction. <i>JACC. Cardiovascular imaging</i> , 14(10), 1887-1900. https://doi.org/https://dx.doi.org/10.1016/j.jcmg.2021.04.010 | Wrong intervention |
| 273. | Pantelidis, P., Dilaveris, P., Ruiperez-Campillo, S., Goliopoulou, A., Giannakodimos, A., Theofilis, P., De Lucia, R., Katsarou, O., Zisimos, K., Kalogerias, K., Oikonomou, E., & Siasos, G. (2025). Hearts, Data, and Artificial Intelligence Wizardry: From Imitation to Innovation in Cardiovascular Care. <i>Biomedicines</i> , 13(5). https://doi.org/https://dx.doi.org/10.3390/biomedicines13051019 | Wrong intervention |

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| 274. | Paraschiv, C., Greason, C., Tobah, Y. S. B., Kane, C., Borgeson, J., Adedinsewo, D., Anisuzzaman, D. M., Malins, J., Tsaban, G., Lopez-Jimenez, F., Attia, Z. I., Thaden, J., Pislaru, S., Kane, G. C., Bird, J. G., & Young, K. (2025). FEASIBILITY OF ARTIFICIAL INTELLIGENCE-ENHANCED FOCUSED CARDIAC ULTRASOUND (FOCUS) TO ASSESS LEFT VENTRICULAR SYSTOLIC FUNCTION IN AN OBSTETRIC POPULATION. <i>Journal of the American College of Cardiology</i> , 85(12), 2656. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2825%2903140-7 (American College of Cardiology, (ACC) Meeting 2025. Chicago United States.) | OOS AI technology |
| 275. | Park, J., Jeon, J., Yoon, Y. E., Jang, Y., Kim, J., Jeong, D., Lee, J., Hong, Y., Ha, S., Reza, A., Park, H.-B., Lee, S.-A., Choi, H., Choi, H.-M., Hwang, I.-C., Cho, G.-Y., & Chang, H.-J. (2024). Artificial intelligence-enhanced automation of left ventricular diastolic assessment: a pilot study for feasibility, diagnostic validation, and outcome prediction. <i>Cardiovascular diagnosis and therapy</i> , 14(3), 352–366. https://doi.org/https://dx.doi.org/10.21037/cdt-24-25 | Wrong intervention |
| 276. | Park, J., Kim, J., Jeon, J., Yoon, Y. E., Jang, Y., Jeong, H., Hong, Y., Lee, S. A., Choi, H. M., Hwang, I. C., Cho, G. Y., & Chang, H. J. (2024). Artificial Intelligence-Enhanced Comprehensive Assessment of the Aortic Valve Stenosis Continuum in Echocardiography. <i>medRxiv</i> . https://doi.org/https://dx.doi.org/10.1101/2024.07.08.24310123 | Wrong intervention |
| 277. | Park, J., Kim, J., Jeon, J., Yoon, Y. E., Jang, Y., Jeong, H., Hong, Y., Lee, S.-A., Choi, H.-M., Hwang, I.-C., Cho, G.-Y., & Chang, H.-J. (2025). Artificial intelligence-enhanced comprehensive assessment of the aortic valve stenosis continuum in echocardiography. <i>EBioMedicine</i> , 112, 105560. https://doi.org/https://dx.doi.org/10.1016/j.ebiom.2025.105560 | Wrong intervention |
| 278. | Park, J., Kim, J., Jeon, J., Yoon, Y. E., Jang, Y., Jeong, H., Lee, S. A., Choi, H. M., Hwang, I. C., Cho, G. Y., & Chang, H. J. (2025). Single View Echocardiographic Analysis for LVOT Obstruction Prediction in Hypertrophic Cardiomyopathy: A Deep Learning Approach. <i>medRxiv</i> . https://doi.org/https://dx.doi.org/10.1101/2025.03.10.25323713 | Wrong intervention |
| 279. | Park, J., Sarijaloo, F. B., Canha, C., Zhong, X., & Wokhlu, A. (2021). A HIGH-PERFORMANCE MACHINE LEARNING MODEL TO PREDICT 90-DAY ACUTE HEART FAILURE READMISSION AND DEATH IN HEART FAILURE WITH PRESERVED EJECTION FRACTION. <i>Journal of the American College of Cardiology</i> , 77(18), 783. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2821%2902142-2 (ACC.21. Virtual, Online.) | Wrong intervention |
| 280. | Park, J., Yoon, Y. E., Jang, Y., Jung, T., Jeon, J., Lee, S. A., Choi, H. M., Hwang, I. C., Chun, E. J., Cho, G. Y., & Chang, H. J. (2025). Novel Deep Learning Framework for Simultaneous Assessment of Left Ventricular Mass and Longitudinal Strain: Clinical Feasibility and Validation in Patients with Hypertrophic Cardiomyopathy. <i>medRxiv</i> . https://doi.org/https://dx.doi.org/10.1101/2025.01.17.25320694 | Wrong intervention |
| 281. | Park, J., Yoon, Y. E., Jang, Y., Jung, T., Jeon, J., Lee, S.-A., Choi, H.-M., Hwang, I.-C., Chun, E. J., Cho, G.-Y., & Chang, H.-J. (2025). Novel deep learning framework for simultaneous assessment of left ventricular mass and longitudinal strain: clinical feasibility and validation in patients with hypertrophic cardiomyopathy. <i>Journal of echocardiography</i> . https://doi.org/https://dx.doi.org/10.1007/s12574-025-00694-y | Wrong intervention |
| 282. | Pelin, D. D., Calvarons, A., Hitschrich, N., Franitzka, K., Degel, M., Schummers, G., Schreckenberg, M., Le Maire, M., Krieger, L., Fette, G., Karch, O., Frantz, S., Stoerk, S., & Morbach, C. (2025). Automated TTE view selection is accurate and reduces analysis time - results from the PAVE project. <i>European Heart Journal Cardiovascular Imaging</i> , 26, i38. https://doi.org/https://dx.doi.org/10.1093/ehjci/jeae333.022 (24th annual congress of the European Association of Cardiovascular Imaging. Berlin Germany.) | OOS AI technology |
| 283. | Pellikka, P. A., Strom, J. B., Pajares-Hurtado, G. M., Keane, M. G., Khazan, B., Qamruddin, S., Tutor, A., Gul, F., Peterson, E., Thamman, R., Watson, S., Mandale, D., Scott, C. G., Naqvi, T., Woodward, G. M., & Hawkes, W. (2022). Automated analysis of limited echocardiograms: Feasibility and relationship to outcomes in COVID-19. <i>Frontiers in Cardiovascular Medicine</i> , 9, 937068. https://doi.org/https://dx.doi.org/10.3389/fcvm.2022.937068 | Wrong intervention |
| 284. | Pellikka, P. (2024). Echocardiographic screening for cardiac amyloidosis using artificial intelligence: A multi-site study for algorithm training and external validation. <i>ESC Congress 2024</i> , | Wrong intervention |
| 285. | Picano, E., Ciampi, Q., Cortigiani, L., Arruda-Olson, A. M., Borguezan-Daros, C., de Castro E Silva Pretto, J. L., Cocchia, R., Bossone, E., Merli, E., Kane, G. C., Varga, A., Agoston, G., Scali, M. C., Morrone, D., Simova, I., Samardjieva, M., Boshchenko, A., Ryabova, T., Vrublevsky, A., . . . Cardiovascular Imaging, S. (2021). Stress Echo 2030: The Novel ABCDE-(FGLPR) Protocol to Define the Future of Imaging. <i>Journal of clinical medicine</i> , 10(16). https://doi.org/https://dx.doi.org/10.3390/jcm10163641 | Wrong publication type |
| 286. | Piccirilli, M., Tokodi, M., Hu, L., Ashraf, M., Casalang-Verzosa, G., & Sengupta, P. (2019). A SEMI-SUPERVISED MACHINE LEARNING PIPELINE FOR CARDIAC RISK STRATIFICATION USING ECHOCARDIOGRAPHIC VARIABLES. <i>Journal of the American College of Cardiology</i> , 73(9), 1441. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2819%2932047-9 (68th Annual Scientific Session of the American College of Cardiology: ACC.19. New Orleans United States.) | Wrong intervention |

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| 287. | Pieszko, K. (2024). Multimodal, Multicentre Registry of Clinical and Imaging Data to Develop Predictive Models Based on Artificial Intelligence to Support the Diagnostic and Therapeutic Process for Patients with Atrial Fibrillation Undergoing Catheter Ablation and Cardioversion. NCT06584266. https://clinicaltrials.gov/study/NCT06584266 | Wrong intervention |
| 288. | Playford, D., Bordin, E., Mohamad, R., Stewart, S., & Strange, G. (2020). Enhanced Diagnosis of Severe Aortic Stenosis Using Artificial Intelligence: A Proof-of-Concept Study of 530,871 Echocardiograms. <i>JACC: Cardiovascular Imaging</i> , 13(4), 1087 EP - 1090. https://doi.org/https://dx.doi.org/10.1016/j.jcmg.2019.10.013 | Wrong intervention |
| 289. | Playford, D., Bordin, E., Talbot, L., Mohamad, R., Anderson, B., & Strange, G. (2018). Moderated poster analysis of aortic stenosis using artificial intelligence. <i>Journal of the American Society of Echocardiography</i> , 31(6), B101. https://doi.org/https://dx.doi.org/10.1016/j.echo.2018.04.010 (29th Annual Scientific Sessions of the American Society of Echocardiography, ASE 2018. Nashville, TN United States.) | Wrong intervention |
| 290. | Porumb, M., Mumith, A., Gao, S., Parker, A., Beqiri, A., Upton, R., Woodward, W., Dockerill, C., McCourt, A., & Woodward, G. (2020). Coronary Artery Disease Prediction from Resting Echocardiograms using Novel Imaging Biomarkers. <i>Journal of the American Society of Echocardiography</i> , 33(6), B15-B16. | Wrong population |
| 291. | Poulos, C., Gebben, D., Peay, H., Saha, A., Vaezy, S., Pierce, A., Pina, I., Farb, A., Moultrie, R., Babalola, O., & Tarver, M. E. (2023). PCR199 Benefit-Risk Preferences of Patients for the Use of Artificial Intelligence and Ultrasound Imaging in Different Settings in Echocardiography. <i>Value in Health</i> , 26(6), S349. https://doi.org/https://dx.doi.org/10.1016/j.jval.2023.03.2378 (ISPOR 2023: Impacting Innovation, Value, and Healthcare Decision Making. Boston United States.) | Wrong intervention |
| 292. | Randazzo, M. C. J. I. M. M. H. S. S.-C. M. S. M. G. A. (2024). Novel Echocardiography Approach for Detecting Transthyretin Cardiac Amyloidosis (ASE 2024 Scientific Sessions Original Science Abstracts). <i>Journal of the American Society of Echocardiography</i> , 37(7), e1-e121. https://doi.org/10.1016/j.echo.2024.04.008 | Wrong outcome |
| 293. | Randazzo, M. J., Slivnick, J. A., Lim, S. C., Maurer, M. S., Helmke, S., Scherrer-Crosbie, M., Soltani, M., Goyal, A., Zareba, K. M., Cheng, R., Nakamatsu, N., Kitano, T., Takeuchi, M., Hotta8, V. T., Vieira, M. L. C., Eliassamburu, P., Ronderos, R. E., Prado, A., Koutroumpakis, E., . . . Lang, R. M. (2025). Independent External Validation of Deep Learning-based Echocardiographic Detection of Cardiac Amyloidosis using a Global Multiethnic Population ASE2025. | Wrong outcome |
| 294. | Rawlani, M., Ieki, H., Binder, C., Yuan, V., Chiu, I. M., Bhatt, A., Ebinger, J. E., Sahashi, Y., Ambrosy, A. P., Cheng, P., Kwan, A. C., Cheng, S., & Ouyang, D. (2025). Artificial Intelligence Prediction of Age from Echocardiography as a Marker for Cardiovascular Disease. <i>medRxiv : the preprint server for health sciences</i> . https://doi.org/https://dx.doi.org/10.1101/2025.03.25.25324627 | Wrong intervention |
| 295. | Reddy, C. D., Lopez, L., Ouyang, D., Zou, J. Y., & He, B. (2023). Video-Based Deep Learning for Automated Assessment of Left Ventricular Ejection Fraction in Pediatric Patients. <i>Journal of the American Society of Echocardiography</i> , 36(5), 482 EP - 489. https://doi.org/https://dx.doi.org/10.1016/j.echo.2023.01.015 | OOS AI technology |
| 296. | Reynaud, H., Meng, Q., Dombrowski, M., Ghosh, A., Day, T., Gomez, A., Leeson, P., & Kainz, B. (2024). Echonet-synthetic: Privacy-preserving video generation for safe medical data sharing. <i>International Conference on Medical Image Computing and Computer-Assisted Intervention</i> , | Wrong intervention |
| 297. | Reynaud, H., Vlontzos, A., Hou, B., Beqiri, A., Leeson, P., & Kainz, B. (2021). Ultrasound video transformers for cardiac ejection fraction estimation. <i>International Conference on Medical Image Computing and Computer-Assisted Intervention</i> , | OOS AI technology |
| 298. | Riley, A. F. (2025). Point-of-Care Screening Echocardiography to Improve Cardiac Diagnostic Access Among American Indians ASE 2025, https://us2.ai/improving-heart-health-in-american-indian-communities-with-ai-echo/ | Wrong setting |
| 299. | Rogstadkjernet, M., Zha, S. Z., Klaeboe, L. G., Larsen, C. K., Aalen, J. M., Scheirlynck, E., Droogmans, S., Cosyns, B., Smiseth, O. A., Haugaa, K. H., Edvardsen, T., Samset, E., & Brekke, P. H. (2021). Automated echocardiographic left ventricular strain measurements using deep learning. <i>European Heart Journal Cardiovascular Imaging</i> , 22, i204. https://doi.org/https://dx.doi.org/10.1093/ehjci/jeaa356.178 (EACVI - Best of Imaging 2020. Online.) | Wrong intervention |
| 300. | Rogstadkjernet, M., Zha, S. Z., Klaeboe, L. G., Larsen, C. K., Aalen, J. M., Scheirlynck, E., Singstad, B.-J., Droogmans, S., Cosyns, B., Smiseth, O. A., Haugaa, K. H., Edvardsen, T., Samset, E., & Brekke, P. H. (2024). A deep learning based method for left ventricular strain measurements: repeatability and accuracy compared to experienced echocardiographers. <i>BMC medical imaging</i> , 24(1), 305. https://doi.org/https://dx.doi.org/10.1186/s12880-024-01470-7 | Wrong intervention |

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| 301. | Rosner, A. (2020). Prediction of Heart-failure and Mortality by Echocardiographic Parameters and Machine Learning in Individuals With Left Bundle Branch Block. NCT04293471. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT04293471 | Wrong intervention |
| 302. | Sachar, R., Latz, M., Blair, J., Allan, T., Kim, G., Grinstein, J., Lang, R., Belkin, M., & Woodward, G. (2024). Invasive Hemodynamic Validation of a Novel Echocardiographic Artificial Intelligence Screening Tool for HFrEF. <i>Circulation</i> , 150. https://doi.org/https://dx.doi.org/10.1161/circ.150.suppl_1.4144947 (American Heart Association's 2024 Scientific Sessions and the American Heart Association's 2024 Resuscitation Science Symposium. Chicago, IL United States.) | Wrong intervention |
| 303. | Sadeghi, A., Oliveira, L., Gessert, N., Liu, J., Wehle, S., De Craene, M., Prabhu, D., Eslami, P., Waechter, I., Mor-Avi, V., Singh, A., & Lang, R. M. (2022). DEEP LEARNING-BASED CLASSIFICATION OF DIASTOLIC FUNCTION USING 2D ECHOCARDIOGRAPHIC IMAGES. <i>Journal of the American College of Cardiology</i> , 79(9), 1183. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2822%2902174-X (ACC 22. Washington, DC United States.) | Wrong intervention |
| 304. | Sadeghpour, A., Jiang, Z., Hummel, Y. M., Frost, M., Lam, C. S. P., Shah, S. J., Lund, L. H., Stone, G. W., Swaminathan, M., Weissman, N. J., & Asch, F. M. (2025). An Automated Machine Learning-Based Quantitative Multiparametric Approach for Mitral Regurgitation Severity Grading. <i>JACC: Cardiovascular Imaging</i> , 18(1), 1-12. https://doi.org/https://doi.org/10.1016/j.jcmg.2024.06.011 | Wrong population |
| 305. | Saeed, I., Hashmi, M. U., Khalid, M., Ramzan, H., Ibrahim, M., Baig, M. F., Mansoor, S. A., Asad, Z., Abbas, J., & Pillai, S. (2025). The Role of Artificial Intelligence in Heart Failure Diagnostics, Risk Prediction, and Therapeutic Strategies: A Comprehensive Review. <i>Cureus</i> , 17(7), e87130. https://doi.org/https://dx.doi.org/10.7759/cureus.87130 | Wrong study design |
| 306. | Saha, S., Rahman, A., & Kiotsekoglou, A. (2024). Beyond standard echocardiography: Strain imaging as the AI-powered key to comprehensive cardiac function evaluation. <i>Echocardiography</i> , 41(3), e15794. https://doi.org/https://dx.doi.org/10.1111/echo.15794 | Wrong publication type |
| 307. | Sahashi, Y., Ieki, H., Yuan, V., Christensen, M., Vukadinovic, M., Binder-Rodriguez, C., Rhee, J., Zou, J. Y., He, B., Cheng, P., & Ouyang, D. (2025). Artificial intelligence automation of echocardiographic measurements. <i>medRxiv</i> , 2025.2003.2018.25324215. https://doi.org/10.1101/2025.03.18.25324215 | OOS AI technology |
| 308. | Sahashi, Y., Vukadinovic, M., Duffy, G., Li, D., Cheng, S., Berman, D. S., Ouyang, D., & Kwan, A. C. (2024). Using Deep learning to Predict Cardiovascular Magnetic Resonance Findings from Echocardiography Videos. <i>medRxiv</i> , 2024.2004.2016.24305936. https://doi.org/10.1101/2024.04.16.24305936 | Wrong intervention |
| 309. | Sakamoto, T., Ito, S., Endo, A., Yoshitomi, H., & Tanabe, K. (2020). Classification of HFrEF based on echocardiography using machine learning to predict future HFrecEF events. <i>European Heart Journal</i> , 41, 923. https://doi.org/https://dx.doi.org/10.1093/ehjci/ehaa946.0923 (European Society of Cardiology Congress, ESC 2020. Virtual.) | Wrong intervention |
| 310. | Salehi, M., Alabed, S., Sharkey, M., Maiter, A., Dwivedi, K., Yardibi, T., Selej, M., Hameed, A., Charalampopoulos, A., Kiely, D. G., & Swift, A. J. (2025). Artificial intelligence-based echocardiography assessment to detect pulmonary hypertension. <i>ERJ open research</i> , 11(3). https://doi.org/https://dx.doi.org/10.1183/23120541.00592-2024 | Wrong population |
| 311. | Salte, I. M., Oestvik, A., Smistad, E., Melichova, D., Nguyen, T. M., Brunvand, H., Edvardsen, T., Loevstakken, L., & Grenne, B. (2020). Deep learning/artificial intelligence for automatic measurement of global longitudinal strain by echocardiography. <i>European Heart Journal Cardiovascular Imaging</i> , 21, i297. https://doi.org/https://dx.doi.org/10.1093/ehjci/jez319.279 (Annual Meeting of the European Association of Echocardiography, EUROECHO 2019. Vienna Australia.) | Wrong intervention |
| 312. | Salte, I. M., Ostvik, A., Smistad, E., Melichova, D., Nguyen, T. M., Karlsen, S., Brunvand, H., Haugaa, K. H., Edvardsen, T., Loevstakken, L., & Grenne, B. (2021). Artificial Intelligence for Automatic Measurement of Left Ventricular Strain in Echocardiography. <i>JACC: Cardiovascular Imaging</i> , 14(10), 1918 EP - 1928. https://doi.org/https://dx.doi.org/10.1016/j.jcmg.2021.04.018 | Wrong intervention |
| 313. | Samad, M. D., Jing, L., Ulloa Cerna, A. E., Hartzel, D. N., Williams, B. A., Good, C. W., Doddamani, S., Haggerty, C. M., & Fornwalt, B. K. (2018). Machine learning significantly improves accuracy to predict survival over the Seattle heart failure model. <i>Circulation</i> , 138. | Wrong intervention |
| 314. | Sanjeevi, G., Gopalakrishnan, U., Parthinarupothi, R. K., & Madathil, T. (2024). Deep learning supported echocardiogram analysis: A comprehensive review. <i>Artificial Intelligence in Medicine</i> , 151, 102866. https://doi.org/https://dx.doi.org/10.1016/j.artmed.2024.102866 | Wrong outcome |

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| 315. | Sankaranarayanan, R., Hartshorne-Evans, N., McLean, L., Jones, J., Salla, M., Chakrabarti, B., Hadcroft, J., Pritchard, C., Smith, A., & Lam, C. S. P. (2025). Early Detection of Cardiorespiratory Diseases at Everton BEAT-Breathlessness Community Hub: How Football Can Help Save Lives. <i>JACC Heart Fail</i> , 13(4), 663-665. https://doi.org/10.1016/j.jchf.2025.01.008 | Wrong publication type |
| 316. | Scanlon, L., Loke, C., Chan, N., Mallouhi, M., Vollbon, W., Stewart, P., Atherton, J., Lin, A., & Prasad, S. (2025). Comprehensive Echocardiographic Data Enhances Machine Learning Prediction of Heart Failure Readmission Following Myocardial Infarction. <i>Heart Lung and Circulation</i> , 34, S283 EP - S284. https://doi.org/https://dx.doi.org/10.1016/j.hlc.2025.06.297 (73rd Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand. Brisbane Australia.) | OOS AI technology |
| 317. | Schlesinger, R., Alexandrino, F., Bird, J., Kane, G., Deshmukh, A., Pellikka, P., Oh, J., Noseworthy, P., Lopez-Jimenez, F., Friedman, P., Pislaru, S., & Tsaban, G. (2025). A new paradigm for structural heart disease detection: cost savings of screening with AI-ECG and POCUS. <i>European Heart Journal Cardiovascular Imaging</i> , 26, i27 EP - i28. https://doi.org/https://dx.doi.org/10.1093/ehjci/jeae333.017 (24th annual congress of the European Association of Cardiovascular Imaging. Berlin Germany.) | Wrong intervention |
| 318. | Schuuring, M. J., Isgum, I., Cosyns, B., Chamuleau, S. A. J., & Bouma, B. J. (2021). Routine Echocardiography and Artificial Intelligence Solutions. <i>Frontiers in Cardiovascular Medicine</i> , 8, 648877. https://doi.org/https://dx.doi.org/10.3389/fcvm.2021.648877 | Wrong study design |
| 319. | SCIENTIST study (EchoConfidence) | Wrong outcome |
| 320. | Shad, R., Quach, N., Fong, R., Kasinpila, P., Bowles, C., Castro, M., Guha, A., Suarez, E. E., Jovinge, S., Lee, S., Boeve, T., Amsallem, M., Tang, X., Haddad, F., Shudo, Y., Woo, Y. J., Teuteberg, J., Cunningham, J. P., Langlotz, C. P., & Hiesinger, W. (2021). Predicting post-operative right ventricular failure using video-based deep learning. <i>Nature Communications</i> , 12(1), 5192. https://doi.org/https://dx.doi.org/10.1038/s41467-021-25503-9 | Wrong intervention |
| 321. | Shah, S. J. (2019). 20th Annual Feigenbaum Lecture: Echocardiography for Precision Medicine-Digital Biopsy to Deconstruct Biology. <i>Journal of the American Society of Echocardiography</i> : official publication of the American Society of Echocardiography, 32(11), 1379-1395.e1372. https://doi.org/https://dx.doi.org/10.1016/j.echo.2019.08.002 | Wrong publication type |
| 322. | Shimizu, M., Manno, T., Tsunoda, T., Miyazaki, H., Misu, Y., Ryo, T., Yamaguchi, M., Yamakami, Y., Kato, N., Shimada, H., Isshiki, A., Kimura, S., Fujii, H., Suzuki, M., Nishizaki, M., & Sasano, T. (2022). Machine Learning of Pressure-Strain Curve Analysis on Ultrasound Echocardiography Can Predict Cardiac Prognosis in Patients With Congestive Heart Failure. <i>Circulation</i> , 146. https://doi.org/https://dx.doi.org/10.1161/circ.146.suppl_1.9414 (American Heart Association's 2022 Scientific Sessions and the American Heart Association's 2022 Resuscitation Science Symposium. Chicago, IL United States.) | Wrong intervention |
| 323. | Sibilia, B., Toupin, S., Dillinger, J. G., Brette, J. B., Ramonatxo, A., Schurtz, G., Hamzi, K., Trimaille, A., Bouali, N., Piliero, N., Logeart, D., Andrieu, S., Picard, F., Henry, P., & Pezel, T. (2023). Machine learning to predict in-hospital outcomes in patients with acute heart failure. <i>European Heart Journal</i> , 44. https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehad655.1102 (European Society of Cardiology Congress, ESC 2023. Amsterdam Netherlands.) | OOS AI technology |
| 324. | Simonsen, J. O., Modin, D., Skaarup, K., Djernaes, K., Lassen, M. C. H., Johansen, N. D., Marott, J. L., Jensen, M. T., Jensen, G. B., Schnohr, P., Martinez, S. S., Claggett, B. L., Mogelvang, R., & Biering-Sorensen, T. (2025). Utilizing echocardiography and unsupervised machine learning for heart failure risk identification. <i>International journal of cardiology</i> , 418, 132636. https://doi.org/https://dx.doi.org/10.1016/j.ijcard.2024.132636 | Wrong intervention |
| 325. | Singh, A., Yamat, M., Guile, B., Mor-Avi, V., & Lang, R. M. (2022). Performance of artificial intelligence system for prescriptive acquisition guidance of transthoracic echocardiography by novice users combined with automated quantification of ejection fraction. <i>European Heart Journal Cardiovascular Imaging</i> , 23, i1. https://doi.org/https://dx.doi.org/10.1093/ehjci/jeab289 (Annual Meeting of the European Association of Echocardiography, EUROECHO 2021. Online.) | Wrong intervention |
| 326. | Slivnick, J. (2023). Novel Deep Learning Model For The Detection Of Cardiac Amyloidosis, A Pilot Reader Study (ASE 34th Annual Scientific Sessions Scientific Research Abstracts). <i>Journal of the American Society of Echocardiography</i> , 36(7), 802. https://doi.org/https://doi.org/10.1016/j.echo.2023.05.005 | Wrong intervention |
| 327. | Slivnick, J. (2025). Multimodal Artificial Intelligence for Cardiac Amyloidosis Diagnosis: Integrating Echocardiography with Clinical and Laboratory Data for Improved Detection ESC Congress 2025, https://us2.ai/multimodal-ai-for-cardiac-amyloidosis-diagnosis/ | Wrong comparator |

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| 328. | Slivnick, J. A., Hawkes, W., Oliveira, J., Woodward, G., Akerman, A., Gomez, A., Hamza, I., Desai, V. K., Barrett-O'Keefe, Z., Grogan, M., Dispenzieri, A., Scott, C. G., Davison, H. N., Cotella, J., Maurer, M., Helmke, S., Scherrer-Crosbie, M., Soltani, M., Goyal, A., . . . Pellikka, P. A. (2025). Cardiac amyloidosis detection from a single echocardiographic video clip: a novel artificial intelligence-based screening tool. <i>European Heart Journal</i> . https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehaf387 | Wrong intervention |
| 329. | Slivnick, J. A., Oliveira, J., Beqiri, A., Patel, A. R., Yogeswaran, V., Cheng, R. K., Kirkpatrick, J. N., Kitano, T., Takeuchi, M., & Addetia, K. (2022). Can Deep Learning Diagnostic Networks Be Used to Better Understand Morphologic Diagnostic Patterns in Cardiac Amyloidosis? | Wrong outcome |
| 330. | Soh, C. H., Wright, L., Baumann, A., Seidel, B., Yu, C., Nolan, M., Mylius, T., & Marwick, T. H. (2024). Use of artificial intelligence-guided echocardiography to detect cardiac dysfunction and heart valve disease in rural and remote areas: Rationale and design of the AGILE-echo trial. <i>American heart journal</i> , 277, 11-19. https://doi.org/https://dx.doi.org/10.1016/j.ahj.2024.08.004 | OOS AI technology |
| 331. | Soh, C., Wright, L., Seidel, B., Baumann, A., Yu, C., Mylius, T., & Marwick, T. (2024). An Artificial Intelligence-Guided Echocardiography in Primary Care Patients from Rural and Remote Communities: The AGILE-Echo Study. <i>Heart Lung and Circulation</i> , 33, S161. https://doi.org/https://dx.doi.org/10.1016/j.hlc.2024.06.083 (72nd Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand. Perth Convention and Exhibition Centre, Perth Australia.) | Wrong intervention |
| 332. | Sooriyakanthan, M., Jayadeva, P. S., Saha, S., Fan, C. P. S., Yu, C., Marwick, T. H., Rivera-Theurel, F., Sen, J., Abdel-Qadir, H., Aragam, K., Amir, E., & Thavendiranathan, P. (2025). Whole-Heart Changes During Cancer Therapy and Their Potential Relevance in Women With Breast Cancer. <i>Journal of the American Society of Echocardiography</i> . https://doi.org/https://dx.doi.org/10.1016/j.echo.2025.07.012 | Wrong population |
| 333. | Spielvogel, C. P., Haberl, D., Kluge, K., Mascherbauer, K., Hennenberg, J., Yu, J., Ning, J., Traub-Weidinger, T., Calabretta, R., Mascherbauer, J., Kammerlander, A., Hengstenberg, C., Hacker, M., & Nitsche, C. (2024). Detection and risk stratification of cardiac amyloidosis patients by integration of imaging and non-imaging data using a machine learning approach. <i>European Heart Journal</i> , 45. https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehae666.3459 (European Society of Cardiology Congress, ESC 2024. London United Kingdom.) | Wrong intervention |
| 334. | Stein, N., Sandhu, R. K., Albert, C. M., Cheng, S., Chugh, S. S., Ouyang, D., & Yuan, N. (2023). DEEP LEARNING EVALUATION OF ECHOCARDIOGRAMS TO IDENTIFY OCCULT ATRIAL FIBRILLATION. <i>Heart Rhythm</i> , 20(5), S164. https://doi.org/https://dx.doi.org/10.1016/j.hrthm.2023.03.532 (Heart Rhythm 2023. New Orleans United States.) | Wrong intervention |
| 335. | Stern, L. (2024). Artificial Intelligence Guided Echocardiographic Screening of Rare Diseases (EchoNet-Screening). NCT06664866 ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT06664866 | OOS AI technology |
| 336. | Stern, L. K., Marker, I. R., Duffy, G., Joung, S., Kwan, A. C., Ebinger, J. E., Rader, F., Cheng, S., Patel, J. K., & Ouyang, D. (2023). Preliminary Assessment of Artificial Intelligence Guided Echocardiographic Screening of Cardiac Amyloidosis. <i>Circulation</i> , 148. https://doi.org/https://dx.doi.org/10.1161/circ.148.suppl_1.17060 (American Heart Association's 2023 Scientific Sessions and the American Heart Association's 2023 Resuscitation Science Symposium. Philadelphia, PA United States.) | OOS AI technology |
| 337. | Strange, G. A., Feneley, M. P., Prior, D., Muller, D., Venkataraman, P., Situ, Y., Stewart, S., & Playford, D. (2024). Detection of severe aortic stenosis by clinicians versus artificial intelligence: A retrospective clinical cohort study. <i>American Heart Journal Plus: Cardiology Research and Practice</i> , 48, 100485. https://doi.org/https://dx.doi.org/10.1016/j.ahjo.2024.100485 | Wrong intervention |
| 338. | Strom, J., Playford, D., Stewart, S., & Strange, G. (2023). An artificial intelligence algorithm for detection of severe aortic stenosis: a clinical cohort study. <i>European Heart Journal</i> , 44. https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehad655.1680 (European Society of Cardiology Congress, ESC 2023. Amsterdam Netherlands.) | Wrong intervention |
| 339. | Subramanian, V. (2024). Performance of an Automated Echocardiographic Artificial Intelligence Model. To detect subclinical Heart Failure with preserved Ejection Fraction (HFpEF) in Community-dwelling older adults. | Duplicated abstract |
| 340. | Sveric, K., Platzek, I., Haussig, S., & Linke, A. (2025). Validation of a fully automated AI system for accurate left ventricular mass measurement in echocardiography. <i>European Heart Journal - Cardiovascular Imaging</i> , 26(Supplement_1). https://doi.org/10.1093/ehjci/jeae333.039 | Wrong population |

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| 341. | Syryca, F., Grasser, C., Trenkwalder, T., & Nicol, P. (2025). Automated generation of echocardiography reports using artificial intelligence: a novel approach to streamlining cardiovascular diagnostics. <i>International Journal of Cardiovascular Imaging</i> , 41(5), 967 EP - 977. https://doi.org/https://dx.doi.org/10.1007/s10554-025-03382-1 | Wrong intervention |
| 342. | Szijarto, A., Merkely, B., Kovacs, A., & Tokodi, M. (2025). Deep learning-enabled echocardiographic assessment of biventricular ejection fractions: the dual-task QUEST-EF model. <i>European Heart Journal Cardiovascular Imaging</i> , 26(8), 1402 EP - 1405. https://doi.org/https://dx.doi.org/10.1093/ehjci/jeaf147 | OOS AI technology |
| 343. | Tian, Y., & Liu, H. (2025). Advances and challenges in echocardiographic diagnosis and management of cardiac amyloidosis. <i>The international journal of cardiovascular imaging</i> , 41(6), 1021-1037. https://doi.org/https://dx.doi.org/10.1007/s10554-025-03362-5 | Wrong outcome |
| 344. | Tokodi, M., & Kovacs, A. (2023). A New Hope for Deep Learning-Based Echocardiogram Interpretation: The DROIDs You Were Looking For. <i>Journal of the American College of Cardiology</i> , 82(20), 1949 EP - 1952. https://doi.org/https://dx.doi.org/10.1016/j.jacc.2023.09.799 | Wrong publication type |
| 345. | Tokodi, M., Magyar, B., Soos, A., Takeuchi, M., Tolvaj, M., Lakatos, B. K., Kitano, T., Nabeshima, Y., Fabian, A., Szigeti, M. B., Horvath, A., Merkely, B., & Kovacs, A. (2023). Deep Learning-Based Prediction of Right Ventricular Ejection Fraction Using 2D Echocardiograms. <i>JACC: Cardiovascular Imaging</i> , 16(8), 1005 EP - 1018. https://doi.org/https://dx.doi.org/10.1016/j.jcmg.2023.02.017 | Wrong intervention |
| 346. | Tokodi, M., Magyar, B., Soos, A., Tolvaj, M., Lakatos, B. K., Fabian, A., Szigeti, M. B., Merkely, B., Horvath, A., & Kovacs, A. (2022). DEEP LEARNING-BASED PREDICTION OF RIGHT VENTRICULAR EJECTION FRACTION USING 2D ECHOCARDIOGRAMS. <i>Journal of the American College of Cardiology</i> , 79(9), 2045. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2822%2903036-4 (ACC 22. Washington, DC United States.) | OOS AI technology |
| 347. | Tokodi, M., Shah, R., Jamthikar, A., Craig, N., Hamirani, Y., Casaclang-Verzosa, G., Hahn, R. T., Dweck, M. R., Pibarot, P., Yanamala, N., & Sengupta, P. P. (2024). Deep Learning Model of Diastolic Dysfunction Risk Stratifies the Progression of Early-Stage Aortic Stenosis. <i>medRxiv</i> . https://doi.org/https://dx.doi.org/10.1101/2024.05.30.24308192 | Wrong intervention |
| 348. | Tokodi, M., Shah, R., Jamthikar, A., Craig, N., Hamirani, Y., Casaclang-Verzosa, G., Hahn, R. T., Dweck, M. R., Pibarot, P., Yanamala, N., & Sengupta, P. P. (2025). Deep Learning Model of Diastolic Dysfunction Risk Stratifies the Progression of Early-Stage Aortic Stenosis. <i>JACC: Cardiovascular Imaging</i> , 18(2), 150 EP - 165. https://doi.org/https://dx.doi.org/10.1016/j.jcmg.2024.07.017 | Wrong intervention |
| 349. | Tokodi, M., Shrestha, S., Bianco, C., Kagiyama, N., Casaclang-Verzosa, G., Narula, J., & Sengupta, P. P. (2020). Interpatient Similarities in Cardiac Function: A Platform for Personalized Cardiovascular Medicine. <i>JACC: Cardiovascular Imaging</i> , 13(5), 1119 EP - 1132. https://doi.org/https://dx.doi.org/10.1016/j.jcmg.2019.12.018 | Wrong intervention |
| 350. | Tokodi, M., Szijarto, A., Righetti, F., Mancinelli, A., Cotella, J. I., Asch, F. M., Addetia, K., Merkely, B., Bagyura, Z. S., Surkova, E., Muraru, D., Takeuchi, M., Lang, R. M., Badano, L. P., & Kovacs, A. (2025). Deep learning for the single-view echocardiographic assessment of biventricular ejection fractions: the dual-task EF2Net model. <i>European Heart Journal Cardiovascular Imaging</i> , 26, i32 EP - i33. https://doi.org/https://dx.doi.org/10.1093/ehjci/jeae333.019 (24th annual congress of the European Association of Cardiovascular Imaging. Berlin Germany.) | OOS AI technology |
| 351. | Tolu-Akinnawo, O. Z., Ezekwueme, F., Omolayo, O., Batheja, S., & Awoyemi, T. (2025). Advancements in Artificial Intelligence in Noninvasive Cardiac Imaging: A Comprehensive Review. <i>Clinical Cardiology</i> , 48(1), e70087. https://doi.org/https://dx.doi.org/10.1002/clc.70087 | Wrong study design |
| 352. | Troebs, S., Hauptmann, T., Velmeden, D., Soehne, J., Schuch, A., Mueller, F., Heidorn, M., Gobel, S., Schulz, A., Munzel, T., Prochaska, J., Kramer, S., & Wild, P. (2021). Convolutional neural networks are noninferior to expert assessment for the evaluation of left ventricular systolic function and mass in chronic heart failure-results from the myovasc study. <i>Circulation</i> , 144. https://doi.org/https://dx.doi.org/10.1161/circ.144.suppl_1.12753 (American Hearts Association's 2021 Scientific Sessions. Boston, MA United States.) | Wrong intervention |
| 353. | Tromp, J., Claggett, B., Frost, M., Iversen, M., Prasad, N., Petrie, M., Ezekowitz, J., & Solomon, S. (2022). Deep Learning-Based Automated Workflow for the Interpretation of the Echocardiogram for the Presence of LV Dysfunction and Probability of Pulmonary Hypertension. <i>American Journal of Respiratory and Critical Care Medicine</i> , 205(1). https://doi.org/https://dx.doi.org/10.1164/ajrccm-conference.2022.205.1_MeetingAbstracts.A4919 (International Conference of the American Thoracic Society, ATS 2022. San Francisco, CA United States.) | Wrong population |

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| 354. | Tromp, J., Sarra, C., Nidhal, B., Mejdi, B. M., Zouari, F., Hummel, Y., Mzoughi, K., Kraiem, S., Fehri, W., Gamra, H., Lam, C. S. P., Mebazaa, A., & Addad, F. (2024). Nurse-led home-based detection of cardiac dysfunction by ultrasound: results of the CUMIN pilot study. <i>European Heart Journal - Digital Health</i> , 5(2), 163-169. https://doi.org/10.1093/ehjdh/ztad079 | Wrong setting |
| 355. | Ulloa Cerna, A. E., Jing, L., Good, C. W., vanMaanen, D. P., Raghunath, S., Suever, J. D., Nevius, C. D., Wehner, G. J., Hartzel, D. N., Leader, J. B., Alsaid, A., Patel, A. A., Kirchner, H. L., Pfeifer, J. M., Carry, B. J., Pattichis, M. S., Haggerty, C. M., & Fornwalt, B. K. (2021). Deep-learning-assisted analysis of echocardiographic videos improves predictions of all-cause mortality. <i>Nature biomedical engineering</i> , 5(6), 546-554. https://doi.org/https://dx.doi.org/10.1038/s41551-020-00667-9 | Wrong intervention |
| 356. | Ulloa, A., Jing, L., Carry, B., Good, C., VanMaanen, D., Hartzel, D., Leader, J., Haggerty, C. M., & Fornwalt, B. (2020). A Multi-view Echocardiography Video Deep Learning Model Outperforms the Seattle Heart Failure Model in Predicting Mortality. <i>Circulation</i> , 142. https://doi.org/https://dx.doi.org/10.1161/circ.142.suppl_3.312 (American Heart Association Scientific Sessions, AHA 2020. Virtual.) | Wrong intervention |
| 357. | Ultromics Ltd. (2021a). PROTEUS: A PROspective Randomised Controlled Trial Evaluating the Use of Artificial Intelligence in Stress Echocardiology. NCT05028179. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT05028179 | Wrong intervention |
| 358. | Ultromics Ltd. (2021b). PROTEUS: evaluating the Use of Artificial Intelligence to Support Stress Echocardiography Testing for Heart Disease. NCT05028179. ClinicalTrials.gov. https://clinicaltrials.gov/show/NCT05028179 | Wrong intervention |
| 359. | University College London. (2024). Virtual Twins and Tools for Personalised Clinical Care- the Heart Failure With Reduced Ejection Fraction Sub-study. NCT06534151. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT06534151 | Wrong intervention |
| 360. | University of Notre Dame Australia. (2024). Practice Nurses to Augment the Clinical Evaluation and care of people at high-risk of Heart Failure (PANACEA-HF) Trial. ACTRN12624001242516. https://anzctr.org.au/ACTRN12624001242516.aspx | Wrong intervention |
| 361. | Upton, R. (2024). A Prospective Randomised Controlled Trial Evaluating The Use Of Artificial Intelligence in Stress Echocardiography. ESC Congress 2024, | Wrong intervention |
| 362. | Upton, R., Cassianni, C., Huntley, G., Castrichini, M., Porumb, M., Scott, C., Hawkes, W., Woodward, G., Borlaug, B., Akerman, A., & Pellikka, P. (2025). AI-based Echocardiographic Assessment Is Associated With HF Hospitalization And Cardiac Mortality In HFpEF. <i>Journal of Cardiac Failure</i> , 31(1), 187 EP - 188. https://doi.org/https://dx.doi.org/10.1016/j.cardfail.2024.10.026 (Heart Failure Society of America's (HFS) Annual Scientific Meeting 2024. Atlanta United States.) | Wrong intervention |
| 363. | Upton, R., Mumith, A., Beqiri, A., Parker, A., Hawkes, W., Gao, S., Porumb, M., Sarwar, R., Marques, P., Markham, D., Kenworthy, J., O'Driscoll, J. M., Hassanali, N., Groves, K., Dockerill, C., Woodward, W., Alsharqi, M., McCourt, A., Wilkes, E. H., . . . Leeson, P. (2022). Automated Echocardiographic Detection of Severe Coronary Artery Disease Using Artificial Intelligence. <i>JACC. Cardiovascular imaging</i> , 15(5), 715-727. https://doi.org/https://dx.doi.org/10.1016/j.jcmg.2021.10.013 (Comment in: <i>JACC Cardiovasc Imaging</i> . 2022 May;15(5):728-730. doi: 10.1016/j.jcmg.2021.11.010) | Wrong intervention |
| 364. | Valsaraj, A., Kalmady, S. V., Sharma, V., Frost, M., Sun, W., Sepehrvand, N., Ong, M., Equilbec, C., Dyck, J. R. B., Anderson, T., Becher, H., Weeks, S., Tromp, J., Hung, C.-L., Ezekowitz, J. A., & Kaul, P. (2023). Development and validation of echocardiography-based machine-learning models to predict mortality. <i>EBioMedicine</i> , 90, 104479. https://doi.org/https://dx.doi.org/10.1016/j.ebiom.2023.104479 | Wrong intervention |
| 365. | van der Boon, R. M. A., & Karper, J. C. (2025). Transforming echocardiography with artificial intelligence. <i>Neth Heart J</i> , 33(10), 319-321. https://doi.org/10.1007/s12471-025-01987-8 | Wrong study design |
| 366. | Vasile, C. M., & Iriart, X. (2023). Embracing AI: The Imperative Tool for Echo Labs to Stay Ahead of the Curve. <i>Diagnostics</i> , 13(19), 3137. https://doi.org/https://dx.doi.org/10.3390/diagnostics13193137 | Wrong publication type |

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|------|---|--------------------|
| 367. | Vasile, C. M., Bouteiller, X. P., Avesani, M., Velly, C., Chan, C., Jalal, Z., Thambo, J. B., & Iriart, X. (2023). Exploring the Potential of Artificial Intelligence in Pediatric Echocardiography-Preliminary Results from the First Pediatric Study Using AI Software Developed for Adults. <i>Journal of Clinical Medicine</i> , 12(9), 3209. https://doi.org/https://dx.doi.org/10.3390/jcm12093209 | Wrong population |
| 368. | Vasile, C., Bouteiller, X., Avesani, M., Velly, C., Chan, C., Thambo, J. B., & Iriart, X. (2023). Exploring the potential of artificial intelligence in pediatric echocardiography. Preliminary results from the first pediatric study using AI software developed for adults. <i>Archives of Cardiovascular Diseases Supplements</i> , 15(4), 290 EP - 291. https://doi.org/https://dx.doi.org/10.1016/j.acvdsp.2023.07.038 (FCPC 2023. Marseille France.) | Wrong population |
| 369. | Vemulapalli, S., Kong, F., Alenezi, F., Giczevska, A., Kang, L., Chiswell, K., Henao, R., & Wang, A. (2022). Machine Learning Computer Vision for Point of Care Decision Support of Echocardiographic Identification of Hypertrophic Cardiomyopathy. <i>Circulation</i> , 146. https://doi.org/https://dx.doi.org/10.1161/circ.146.suppl_1.14817 (American Heart Association's 2022 Scientific Sessions and the American Heart Association's 2022 Resuscitation Science Symposium. Chicago, IL United States.) | Wrong intervention |
| 370. | Venema, C. S., Van Bergeijk, K. H., Plekkenpol, L. H., Tromp, J., Ouwerkerk, W., Hummel, Y. M., Krikken, J. A., Van Der Werf, H. W., Van Den Heuvel, A. F. M., Douglas, Y. L., Lipsic, E., Voors, A. A., & Wykrzykowska, J. J. (2024). Discordance between symptomatic response and changes in cardiac structure and function one year after transcatheter aortic valve implantation. <i>European Heart Journal</i> , 45(Supplement_1). https://doi.org/10.1093/eurheartj/ehae666.2464 | Wrong outcome |
| 371. | Verlyck, M., Zhao, D., Ferdian, E., Creamer, S., Quill, G., Poppe, K., Doughty, R., Babarenda Gamage, T., & Nash, M. (2025). A Multimodal Deep Learning Model for Non-Invasive Detection of Elevated Left Ventricular End-Diastolic Pressure. <i>Heart Lung and Circulation</i> , 34, S53 EP - S54. https://doi.org/https://dx.doi.org/10.1016/j.hlc.2025.04.063 (The Cardiac Society of Australia and New Zealand Annual Scientific Meeting (New Zealand) 2025. Rotorua.) | Wrong intervention |
| 372. | Viola, F., Bustamante, M., Bolger, A., Engvall, J., & Ebbers, T. (2024). Diastolic function assessment with four-dimensional flow cardiovascular magnetic resonance using automatic deep learning E/A ratio analysis. <i>Journal of cardiovascular magnetic resonance : official journal of the Society for Cardiovascular Magnetic Resonance</i> , 26(1), 101042. https://doi.org/https://dx.doi.org/10.1016/j.jcmr.2024.101042 | Wrong intervention |
| 373. | Viola, F., Bustamante, M., Engvall, J., Bolger, A., & Ebbers, T. (2024). Diastolic Function Assessment with 4D Flow CMR Using Automatic Deep Learning EA Ratio Analysis. <i>Journal of Cardiovascular Magnetic Resonance</i> , 26, 100607. https://doi.org/https://dx.doi.org/10.1016/j.jcmr.2024.100607 (CMR 2024 Global CMR Conference. QEII Centre, London United Kingdom.) | Wrong intervention |
| 374. | Vrudhula, A., Duffy, G., Vukadinovic, M., Liang, D., Cheng, S., & Ouyang, D. (2024). High Throughput Deep Learning Detection of Mitral Regurgitation. <i>medRxiv</i> , 2024.2002.2008.24302547. https://doi.org/10.1101/2024.02.08.24302547 | Wrong intervention |
| 375. | Vrudhula, A., Vukadinovic, M., Haeffle, C., Kwan, A. C., Berman, D., Liang, D., Siegel, R., Cheng, S., & Ouyang, D. (2024). Deep Learning Phenotyping of Tricuspid Regurgitation for Automated High Throughput Assessment of Transthoracic Echocardiography. <i>medRxiv</i> , 2024.2006.2022.24309332. https://doi.org/10.1101/2024.06.22.24309332 | Wrong intervention |
| 376. | Walsh, J. L., Aluaroudi, W. A., Lamaa, N., Abou Hassan, O. K., Jalkh, K., Elhajj, I. H., Sakr, G., & Isma'eel, H. (2020). A speckle-tracking strain-based artificial neural network model to differentiate cardiomyopathy type. <i>Scandinavian cardiovascular journal : SCJ</i> , 54(2), 92-99. https://doi.org/10.1080/14017431.2019.1678764 | OOS AI technology |
| 377. | Wang, T. K. M., Cremer, P. C., Chan, N., Piotrowska, H., Woodward, G., & Jaber, W. A. (2022). Utility of an Automated Artificial Intelligence Echocardiography Software in Risk Stratification of Hospitalized COVID-19 Patients. <i>Life (Basel, Switzerland)</i> , 12(9). https://doi.org/https://dx.doi.org/10.3390/life12091413 | Wrong outcome |
| 378. | Wang, T. K. M., Cremer, P., Chan, N., Piotrowska, H., Woodward, G., & Jaber, W. (2021). UTILITY OF AN AUTOMATED ARTIFICIAL INTELLIGENCE ECHOCARDIOGRAPHY SOFTWARE IN RISK STRATIFICATION OF HOSPITALIZED COVID-19 PATIENTS. <i>Journal of the American College of Cardiology</i> , 77(18), 3089. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2821%2904444-2 (ACC.21. Virtual, Online.) | Wrong outcome |
| 379. | Wass, S. Y., Carneiro, H., Lobo, T., Amutuhaire, W., Tashtish, N., Okyere, R., Al-Kindi, S., & Hoit, B. (2023). Artificial Intelligence-Derived Left Ventricular Global Longitudinal Strain is Associated More Strongly With AllCause Mortality Than is Speckle Tracking EchocardiographyDerived Strain in a Cohort of Cardio-Oncology Patients. <i>Circulation</i> , 148. https://doi.org/https://dx.doi.org/10.1161/circ.148.suppl_1.15592 (American Heart Association's 2023 Scientific Sessions and the American Heart Association's 2023 Resuscitation Science Symposium. Philadelphia, PA United States.) | Wrong population |

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|------|--|------------------------|
| 380. | Wongwantanee, S. (2024). Assessing the Efficacy of Artificial Intelligence in Left Ventricular Function Screening Using Parasternal Long Axis View Cardiac Ultrasound Video Clips. NCT06330103. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT06330103 | Wrong intervention |
| 381. | Woodward, G., Bajre, M., Bhattacharyya, S., Breen, M., Chiocchia, V., Dawes, H., Dehbi, H.-M., Descamps, T., Frangou, E., Fazakarley, C.-A., Harris, V., Hawkes, W., Hewer, O., Johnson, C. L., Krasner, S., Laidlaw, L., Lau, J., Marwick, T., Petersen, S. E., . . . Leeson, P. (2023). PROTEUS Study: A Prospective Randomized Controlled Trial Evaluating the Use of Artificial Intelligence in Stress Echocardiography. <i>American heart journal</i> , 263, 123-132. https://doi.org/https://dx.doi.org/10.1016/j.ahj.2023.05.003 | Wrong intervention |
| 382. | Wright, L., Soh, C., Baumann, A., Seidel, B., Yu, C., Nolan, M., Mylius, T., & Marwick, T. (2025). Evaluation of Implementation of Artificial Intelligence (AI)-Assisted Echocardiography in Clinical Practice. <i>Heart Lung and Circulation</i> , 34, S178. https://doi.org/https://dx.doi.org/10.1016/j.hlc.2025.06.143 (73rd Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand. Brisbane Australia.) | Wrong intervention |
| 383. | Yamaguchi, N., Kosaka, Y., Haga, A., Sata, M., & Kusunose, K. (2023). Artificial intelligence-assisted interpretation of systolic function by echocardiogram. <i>Open heart</i> , 10(2). https://doi.org/https://dx.doi.org/10.1136/openhrt-2023-002287 | Wrong intervention |
| 384. | Yamaguchi, N., Kusunose, K., Haga, A., Morita, S., Hirata, Y., Torii, Y., Nishio, S., Ookushi, Y., Takahashi, T., Yamada, N., Yamada, H., & Sata, M. (2020). Assessment of left ventricular ejection fraction from echocardiographic images using machine learning algorithm. <i>European Heart Journal Cardiovascular Imaging</i> , 21, i292. https://doi.org/https://dx.doi.org/10.1093/eihci/jez319.274 (Annual Meeting of the European Association of Echocardiography, EUROECHO 2019. Vienna Australia.) | Wrong intervention |
| 385. | Yang, C., Chen, Z. H., Gorantla, L., Joshi, S. A., Longhi, N. J., Yang, J., Armenian, S., Bhat, A., Border, W., Buddhe, S., Leger, K. J., Leisenring, W. M., Meacham, L. R., Nathan, P., Sachdeva, R., Sadak, K., Chow, E., Boyle, P. M., & Edwards, L. A. (2022). Machine Learning-Assisted Echocardiographic Identification of Children at High Risk for Treatment-Related Cardiomyopathy: A Proof-of-Concept Study. <i>Circulation</i> , 146. https://doi.org/https://dx.doi.org/10.1161/circ.146.suppl_1.10580 (American Heart Association's 2022 Scientific Sessions and the American Heart Association's 2022 Resuscitation Science Symposium. Chicago, IL United States.) | Wrong population |
| 386. | Yao, X., Rushlow, D. R., Inselman, J. W., McCoy, R. G., Thacher, T. D., Behnken, E. M., Bernard, M. E., Rosas, S. L., Akfaly, A., Misra, A., Molling, P. E., Krien, J. S., Foss, R. M., Barry, B. A., Siontis, K. C., Kapa, S., Pellikka, P. A., Lopez-Jimenez, F., Attia, Z. I., . . . Noseworthy, P. A. (2021). Artificial intelligence-enabled electrocardiograms for identification of patients with low ejection fraction: a pragmatic, randomized clinical trial. <i>Nature Medicine</i> , 27(5), 815-819. https://doi.org/https://dx.doi.org/10.1038/s41591-021-01335-4 (Comment in: <i>Med</i> . 2021 Jul 9;2(7):791-793. doi: 10.1016/j.medj.2021.06.003) | Wrong intervention |
| 387. | Yasheng, Z., Zhao, R., Zhu, Y., Zhang, Z., Lv, Q., Xie, M., & Zhang, L. (2025). Machine learning in echocardiography-based prediction model of cardiovascular diseases. <i>Chinese Medical Journal</i> , 138(2), 228 EP - 230. https://doi.org/https://dx.doi.org/10.1097/CM9.00000000000003350 | Wrong publication type |
| 388. | Yuan, V., Ieki, H., Binder, C., Sahashi, Y., Cheng, P. C., & Ouyang, D. (2025). Detection of Left Ventricular Outflow Obstruction from Standard B-Mode Echocardiogram Videos using Deep Learning. <i>medRxiv</i> . https://doi.org/https://dx.doi.org/10.1101/2025.03.02.25323199 | Wrong intervention |
| 389. | Yuan, V., Sahashi, Y., Ieki, H., Vukadinovic, M., Binder, C., Pieszko, K., Ambrosy, A. P., Cheng, P. P., Cheng, S., & Ouyang, D. (2025). Automated Deep Learning Pipeline for Characterizing Left Ventricular Diastolic Function. <i>medRxiv</i> : the preprint server for health sciences. https://doi.org/https://dx.doi.org/10.1101/2025.04.29.25326683 | OOS AI technology |
| 390. | Yurk, D., Barrios, J. P., Labrecque Langlais, E., Avram, R., Aras, M. A., Abu-Mostafa, Y., Padmanabhan, A., & Tison, G. H. (2024). Automated Assessment of Right Atrial Pressure From Ultrasound Videos Using Machine Learning. <i>JACC. Advances</i> , 3(9), 101192. https://doi.org/https://dx.doi.org/10.1016/j.jacadv.2024.101192 | Wrong intervention |
| 391. | Zha, S., Rogstadkjernet, M., Scheirlynck, E. S., Aalen, J. M., Larsen, C. K., Cosijns, B., Droogmans, S., Smiseth, O. A., Samset, E., Edvardsen, T., & Brekke, P. H. (2022). A deep learning approach for automatic echocardiographic right ventricular strain measurements using a limited dataset. <i>European Heart Journal</i> , 43, 62. https://doi.org/https://dx.doi.org/10.1093/eurheartj/ehac544.062 (43rd European Society of Cardiology Congress, ESC 2022. Barcelona Spain.) | OOS AI technology |
| 392. | Zhang, L., Liu, B., Li, S., Wang, J., Mu, Y., Zhou, X., & Sheng, L. (2024). Deep learning-based measurement of echocardiographic data and its application in the diagnosis of sudden cardiac death. <i>Biotechnology and Genetic Engineering Reviews</i> , 40(4), 4466 EP - 4478. https://doi.org/https://dx.doi.org/10.1080/02648725.2023.2213041 | Wrong intervention |

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|------|---|--------------------|
| 393. | Zhang, Y., Liu, B., Bunting, K. V., Brind, D., Thorley, A., Karwath, A., Lu, W., Zhou, D., Wang, X., Mobley, A. R., Tica, O., Gkoutos, G. V., Kotecha, D., & Duan, J. (2024). Development of automated neural network prediction for echocardiographic left ventricular ejection fraction. <i>Frontiers in medicine</i> , 11, 1354070. https://doi.org/https://dx.doi.org/10.3389/fmed.2024.1354070 | Wrong intervention |
| 394. | Zhao, C., Yu, F., Jiang, Z., Huang, F., Dougherty, S. D., Ma, H. L. B., & Lee, A. P.-W. (2025). VALIDATION OF A DEEP LEARNING-BASED ALGORITHM IN QUANTIFYING TRICUSPID VALVE REGURGITATION. <i>Journal of the American College of Cardiology</i> , 85(12), 2066. https://doi.org/https://doi.org/10.1016/S0735-1097(25)02550-1 | Wrong population |
| 395. | Zheng, C., Rainer, K., Akerman, A., Al-Roub, N., Angell-James, C., Bosque, L. E., Hawkes, W. P., Leeson, P., Woodward, G., Pellikka, P. A., Upton, R., & Strom, J. B. (2025). IMPACT OF TECHNICAL CHANGES IN ARTIFICIAL INTELLIGENCE BASED DETECTION OF HEART FAILURE WITH PRESERVED EJECTION FRACTION AND MODEL PERFORMANCE AND PROGNOSTICATION. <i>Journal of the American College of Cardiology</i> , 85(12), 1971. https://doi.org/https://dx.doi.org/10.1016/S0735-1097%2825%2902455-6 (American College of Cardiology, (ACC) Meeting 2025. Chicago United States.) | Wrong intervention |
| 396. | Zhou, M., Deng, Y., Liu, Y., Su, X., & Zeng, X. (2023). Echocardiography-based machine learning algorithm for distinguishing ischemic cardiomyopathy from dilated cardiomyopathy. <i>BMC cardiovascular disorders</i> , 23(1), 476. https://doi.org/https://dx.doi.org/10.1186/s12872-023-03520-4 | Wrong intervention |
| 397. | Zhu, Y., Liu, M., Zhang, Z., Zhao, Y., Yang, X., Xie, M., & Zhang, L. (2022). Artificial Intelligence-Enhanced Echocardiography for Systolic Function Assessment. <i>Journal of Clinical Medicine</i> , 11(10), 2893. https://doi.org/https://dx.doi.org/10.3390/jcm11102893 | Wrong study design |

Early-use assessment

HTE10067 Artificial Intelligence assisted echocardiography to support diagnosis of heart failure

Assessment report overview

This overview summarises key information from the assessment and sets out points for discussion in the committee meeting. It should be read together with the [final scope](#), external assessment report and the addendum. A list of abbreviations used in this overview is in [appendix A](#).

1. The technologies

This assessment included 4 technologies (EchoConfidence, EchoGo Heart Failure, Ligence Heart and Us2.ai) that use artificial intelligence (AI) software to aid the interpretation and quantification of echocardiography images, reduce operator dependency and variability, and enhance measurement accuracy and diagnostic consistency (see table 1). All the technologies included in this assessment are designed to aid the operator (adjunctive), not replace them (automative). See section 5 of the [final scope](#) and table 1 in the external assessment report (EAR) for further details about the included technologies.

Table 1 Interventions

| Technology (company) | Regulatory status and DTAC | Intended use | Target population |
|----------------------------|----------------------------|--|--|
| EchoConfidence (MyCardium) | Class IIb DTAC in place | Software as a Medical Device that displays images from a transthoracic Echocardiogram, and assists the user in reviewing the images, making measurements and writing a report. | Adults with or without underlying cardiac disease, requiring review or analysis of their echocardiographic images. |

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| | | For detection and diagnosis of heart failure via screening or clinical echocardiograms, for stratifying heart failure (HFrEF, HFmrEF vs HFpEF), and for monitoring disease progression and response to treatment. | |
| EchoGo Heart Failure (Ultromics) | Class IIa (expected June 2026) DTAC not in place | Detecting heart failure with preserved ejection fraction (HFpEF). Diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography. To provide adjunctive information on a patient's cardiovascular condition for detecting heart failure with preserved ejection fraction (HFpEF). | Adults over 25 years of age having routine functional cardiovascular assessment using diagnostic echocardiography or people suspected of heart failure |
| Ligence Heart (Ligence UAB) | Class IIa DTAC not in place | Analysis of echocardiography images acquired from patients in accordance with the latest guidelines for echocardiography examination. Used to detect, measure, and calculate various specifications of structure and function of the heart and great vessels by analysing echocardiographic images and automatically providing echocardiographic reports. | Adults, 18 years and over who are not in a life-threatening state of health, time is not critical for medical decisions and no major therapeutic interventions are required. |
| US2.ai (EKO Pte Ltd) | Class IIb DTAC in place | To process acquired transthoracic cardiac ultrasound images, to analyse and make measurements on images in order to provide automated estimation of several cardiac structural and functional parameters. To accelerate and standardise the detection of most forms of heart failure, independent of ejection fraction. Detect, measure, and calculate various specifications of structure and function of the heart and great | Adults as decision support for the detection of specific cardiac conditions such as heart failure, pulmonary hypertension, cardiac amyloidosis, hypertrophic cardiomyopathy and valve disease (aortic stenosis, mitral regurgitation). |

| | | | |
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| | | vessels by analysing echocardiographic images. | |
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2. The condition

Heart failure occurs when the heart cannot pump blood effectively due to structural or functional abnormalities. It is not usually curable, but symptoms such as breathlessness, fatigue, and ankle swelling can be managed ([NHS, 2025](#)). Heart failure may develop gradually (chronic, often linked to hypertension or diabetes) or suddenly (acute, for example after myocardial infarction, arrhythmia, infection, or uncontrolled hypertension). Acute heart failure requires urgent care and often presents in emergency departments.

Heart failure significantly impacts quality of life and can lead to disability and early death. Around 80% of heart failure diagnoses in England occur in hospital, despite 40% of patients having symptoms that could have prompted earlier assessment ([British Heart Foundation, 2025](#)).

Heart failure is classified by left ventricular ejection fraction (LVEF) measured with echocardiography. Preserved ejection fraction (HFpEF) is defined as an LVEF of 50% or more, reduced ejection fraction (HFrEF) is defined as LVEF of 40% or less, whilst mildly reduced heart failure (HFmrEF) is an intermediate category with an LVEF of 41 to 49%.

Heart failure is common, affecting over 1 million people in the UK, with 200,000 new diagnoses annually and 800,000 on GP registers ([British Heart Foundation, 2025](#)). Echocardiography is used in 87% of diagnoses ([NHFA, 2025](#)).

3. Current practice

In the NHS, the diagnosis and management of heart failure follows 2 NICE guidelines:

- Chronic heart failure in adults: diagnosis and management ([NG106](#))
- Acute heart failure: diagnosis and management ([CG187](#))

Assessment report overview – HTE10067 Artificial Intelligence assisted echocardiography to support diagnosis of heart failure

December 2025

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Initial clinical assessments for patients presenting with symptoms indicative of suspected heart failure include blood tests for detection of biochemical markers followed by a transthoracic echocardiogram (TTE). For both acute and chronic onset of heart failure, NICE guidelines ([NG106](#) and [CG187](#)) recommend testing to measure levels of N-terminal pro-B-type natriuretic peptide (NT-proBNP). When the thresholds are exceeded, confirmatory diagnosis with echocardiography is required.

TTE is the primary diagnostic tool used for heart failure. It is usually performed in secondary care in the NHS by a specialist cardiac physiologist. TTE facilitates detection of abnormalities and defects in the heart's chambers and valves and provides measurements of blood flow and the heart's pumping ability. Where an echocardiogram detects abnormal ejection heart fraction, abnormalities in the heart's walls' motions, or hypertrophy, this can be indicative of heart failure. Diagnosis with echocardiography determines whether heart failure is left or right sided, or biventricular. The TTE process typically takes between 45 and 60 minutes (see Figure 1).

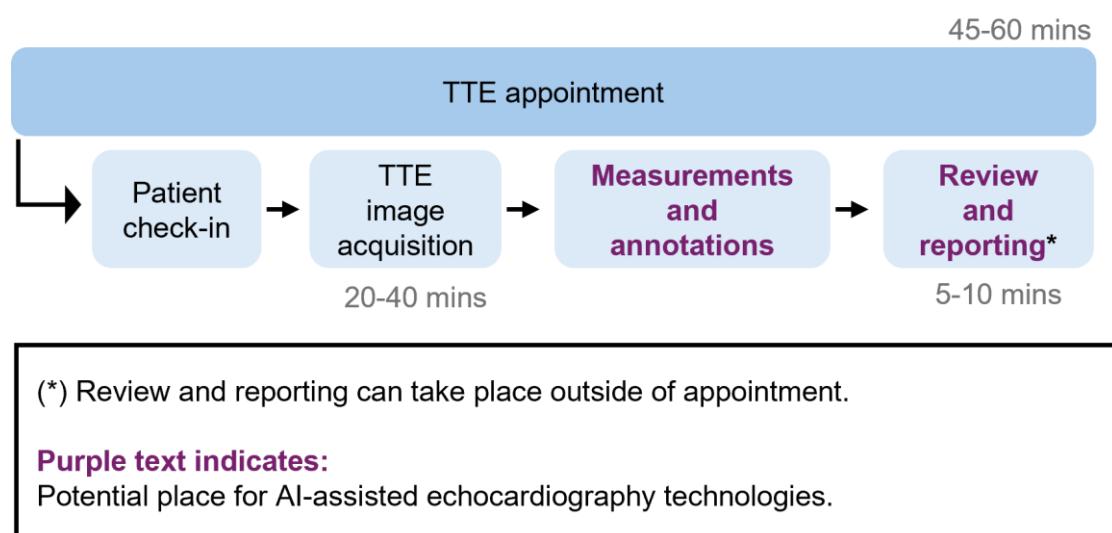


Figure 1: Echocardiography procedure (taken from EAR)

Cardiac magnetic resonance imaging (MRI) may also be used for some complex cases, to determine the nature of heart failure (HFrEF, HFmEF or HFmEF), for instances when echocardiography is inconclusive or the

procedure is contraindicated, or to determine the underlying cause. However, the availability and access to cardiac MRI may vary by locality.

4. Unmet need

There are long waiting lists for echocardiography caused by several factors, including the time the procedures take, the setting of the procedures (requiring referral), and an insufficient skilled workforce. This may lead to suboptimal outcomes for people with heart failure and increased use of healthcare resources.

There is a significant backlog for echocardiography in England, with waiting lists rising to 235,476 people in June 2025 ([NHS England, 2025](#)). NICE quality standards require 90% of referrals to be investigated with echocardiography, but only half of hospitals meet this target ([National Heart Failure Audit, 2025](#)). Although suspected heart failure cases should be seen within 6 weeks, only about two thirds meet this standard ([NHS England, 2024](#)).

Staff shortages and COVID-19-related backlogs have worsened access ([British Society of Echocardiography, 2021](#)). Delays can lead to poorer outcomes as reported in the [REVOLUTION HF study \(2025\)](#), which linked late diagnosis to higher mortality, morbidity, and resource use. It may also delay access to effective treatments such as SGLT2 inhibitors ([Lewinski, 2023](#)). Workforce pressures remain severe, with warnings of “unprecedented challenges” in recruitment and retention ([British Society of Echocardiography, 2021](#)).

AI technologies could help by automating measurements, interpretation, and report generation after TTE, potentially reducing procedure time and easing waiting lists.

5. Innovative aspects

Using automation to aid cardiac physiologists in measurement, interpretation, and report generation after TTE could potentially release time during appointments. It could improve throughput and workflow, reduce examination times and waiting lists, standardise diagnosis and characterisation of heart failure, track people with heart failure over time, and through this ultimately improve care and promote efficient use of NHS resources.

Further details, including descriptions of the interventions, comparator, care pathway and outcomes, are in the [final scope](#).

6. Clinical effectiveness

The external assessment group (EAG) did a literature search to identify relevant published clinical evidence. The search and selection methods are in section 4.1 and appendix B of the external assessment report (EAR).

6.1 Overview of key studies

The EAG identified 19 key studies across the 4 technologies. This included 11 studies for Us2.ai (2 provided by the company following comments on the EAR. See section 2 in the addendum), 3 studies for EchoGo Heart Failure, 3 studies for EchoConfidence and 2 studies for Ligence Heart. Full text publications were available for 14 of the studies, 3 were provided by the company for EchoConfidence and 2 of these were interim analyses of ongoing studies.

The EAG appraised the studies for quality, risk of bias, and generalisability to the NHS. Overall, the studies on the technologies had several limitations. Most studies were retrospective, introducing risks such as selection bias and incomplete records. Fourteen studies used non-UK data, potentially limiting generalisability to NHS practice. Seven studies excluded complex cases or were conducted in controlled environments, which may not reflect real-world workflows. Additionally, poor-quality images were often excluded, raising concerns about applicability in routine care. The EAG noted that 10 studies

were set in single-centres, and some relied on a single operator, possibly not reflecting the variability that would be expected in real world settings. Thirteen of the studies did not specify technology versions, although the EAG sought clarification where possible. Importantly, there was a lack of evidence reported on downstream health outcomes, making it difficult to directly assess patient benefit.

A summary of the studies identified is reported in Table 3 of the EAR and a description of study limitations by technology is reported in Section 5.1 (Table 4) of the EAR. The outcomes reported by each study are summarised in Table 5 of the EAR. A description on the definitions of diagnostic and agreement measurements is reported in Table 6 of the EAR. The addendum includes full details of the 2 additional Us2.ai studies, provided following stakeholder comments on the EAR.

6.2 Results of key studies

6.2.1 Diagnostic accuracy

Diagnostic test accuracy was assessed using sensitivity, specificity, negative predictive value (NPV) and positive predictive value (PPV). These outcomes are reported across 5 studies, for 3 of the technologies (EchoConfidence, EchoGo Heart Failure and Us2.ai).

For EchoConfidence, with human interpretation of the measurements as the reference standard, the FEATHER interim analysis found EchoConfidence had high specificity for detecting heart failure subtypes but a notable false-negative rate for HFrEF (41%). Specificity was 91% for HFrEF and 95% for HFpEF, with predictive values generally high (see table 9 in the EAR). Overall specificity for any heart failure subtype was 83%. EchoGo Heart Failure was compared with existing literature benchmarks (EchoGo Heart Failure V1.0) or multiparametric clinical scoring tools (EchoGo Heart Failure V2.0) in 2 diagnostic case control studies (Akerman et al. 2025a and 2023a). V1.0 had a reported sensitivity of 88% and specificity of 82%, whereas V2 had higher sensitivity and specificity than the tools, but predictive values were

similar or lower (see table 7 in the EAR). Two studies assessed Us2.ai with handheld TTE (Huang et al. 2024a and Campbell et al. 2025). AI-assisted scans reported higher specificity and NPV, but lower sensitivity and PPV compared with manual cart-based TTE.

The EAG reported no diagnostic accuracy data was available for Ligence.

6.2.2 Detection and classification of heart failure

Six studies (4 for Us2.ai and 2 for EchoGo Heart Failure) reported the area under the curve for the receiver operator characteristics curve (AUC) for detecting echocardiographic findings indicative of heart failure. AUC measures overall diagnostic accuracy by summarising sensitivity and specificity across all probability thresholds.

EchoGo Heart Failure was assessed in 2 studies (Akerman et al. 2025a and 2023a). One study on EchoGo Heart Failure V1 reported an AUC of 0.97 in the training set compared with 0.95 in a validation set, indicating good accuracy. One study reported EchoGo Heart Failure v2.0 performed similarly to multiparametric clinical scoring tools (AUROC 0.798 compared with 0.788 respectively).

Four studies evaluated Us2.ai for detecting heart failure and automation of related echocardiographic measures (Myhre et al. 2024b, Tromp et al. 2022b, Huang et al. 2024a and Campbell et al. 2025). Myhre et al. (2024b) reported strong discrimination between people with heart failure from those without (AUC=0.89), as well as between HFrEF and non-HF (AUC=0.98), and between HFpEF and non-HF (AUC=0.82), using global longitudinal strain (GLS). Tromp et al. (2022b) reported high AUCs (0.88 to 0.96) for key parameters across internal and external cohorts. Huang et al. (2024a) and Campbell et al. (2025) reported AUCs of 0.88 and 0.96 for handheld TTE detecting reduced LVEF. Overall, the EAG considered Us2.ai demonstrated consistently good diagnostic accuracy for identifying left ventricular dysfunction and other heart failure indicators.

No data on these metrics were reported for EchoConfidence or Ligence.

6.2.3 Other clinical effectiveness metrics reported in the key studies

The key studies also reported evidence for a number of other clinical effectiveness measures. These included: interchangeability between human and AI measurements; correlation between human and AI measurements; agreement between human and AI measurements; yield of measurement. Full details of this evidence is in sections 5.2.3 to 5.2.7 of the EAR. The 2 studies included in section 2 of the addendum reported evidence on coverage of echocardiographic parameters and concordance with clinical records (Oo et al. 2024) and acceptability of AI in TTE and relationship between variables and behavioural intention (Huang et al. 2024b).

6.2.4 Clinical Outcomes

Four studies investigated how clinical endpoints were met when echocardiography was assessed with AI, to determine the usefulness of the AI technologies in the heart failure clinical pathway. Outcomes included heart failure-related hospitalisations and mortality. The EAG stated that data comparing clinical outcomes was limited.

Three studies using EchoGo Heart Failure (Akerman et al. 2025a, Akerman et al. 2023a and Cassianni et al. 2024), found that a positive diagnosis of HFpEF was associated with higher risk of heart failure hospitalisation and death, similar to manual clinical scoring tools. Akerman et al. (2023a) reported that AI-classified HFpEF was linked to increased mortality (hazard ratio [HR] 1.9) when compared with those classified as not having HFpEF by AI. Overall, the EAG concluded EchoGo Heart Failure may help detect heart failure, but its advantage over existing methods for predicting outcomes remains unclear.

For EchoConfidence, interim data from the FEATHER study compared survival curves for heart failure diagnoses classified by AI and 2 human comparators. Significant differences were observed for HFrEF and HFmrEF compared with no heart failure across all methods, but not for HFpEF for human or AI diagnosis. However, limited detail beyond p values means conclusions cannot be drawn.

No clinical outcome data was identified for Ligence or Us2ai. Further details on clinical outcomes is in section 5.2.6 of the EAR.

6.2.5 Impact on procedure time

The impact of AI technologies on reporting, scanning or analysis time was reported in 3 studies for 2 technologies (EchoConfidence and Us2.ai).

One interim study reporting on EchoConfidence found AI reduced the mean time for analysis of echocardiographic parameters to a mean of 3.2 seconds (SD 0.4) compared with a mean of 553 seconds (SD 44) and 587 seconds (SD 64) for 2 human readers.

For US2ai, the study by Hirata et al. (2024) reported that the use of AI assistance reduced time for echocardiographic measurements from 325 seconds (SD 94) to 159 seconds (SD 66) ($p<0.01$). Report creation time also decreased from 429 seconds (SD 128) to 71 seconds (SD 39) ($p<0.01$). Overall, measurement and report creation time per case was reduced by 524 seconds (70%). This was a small, single-centre study with one operator and 23 participants in Japan.

The study by Sakamoto et al. (2025) found examination time per patient was shorter with AI, at 13.0 minutes (SD 3.5) compared with 14.3 minutes, (SD 4.2) ($p<0.001$) without AI. The number of examinations per day was higher with AI (16.7, SD 2.5) than without AI (14.1, SD 2.5) ($p=0.003$). This study is reported in a pre-print and has not been peer reviewed. The EAG commented that as only mean values were reported, the data could not be assessed in detail, and reports of significant differences should be interpreted with caution.

6.2.6 Adverse events

The EAG did a search of the MAUDE database and MHRA safety notices and did not identify any adverse events or safety concerns for the included technologies. No adverse events were reported in any of the clinical studies reviewed.

6.2.7 Clinical risk

Development of AI models for echocardiography typically involves training, internal validation and external validation. A lack of external validation on UK or similar populations may limit suitability of the technologies and pose clinical risks, or impact equality considerations. The EAG noted that EchoConfidence was validated in a UK population as part of its CE marking process. It also indicated that demographic inconsistencies make conclusions about the other technologies difficult. A comparison between demographics of external validation cohorts and UK heart failure cohorts is reported in Table 14 of the EAR.

6.2.8 Meta-analysis

The EAG considered it was not appropriate to undertake meta-analyses of outcomes reported across the evidence base for any of the technologies due to the clinical and methodological heterogeneity observed between studies.

6.2.9 Ongoing studies

The EAG identified 7 ongoing studies, listed in Table 23 of the EAR. For Us2.ai, the ongoing evidence generation included 2 RCTs (TARTAN-HF and SYMPHONY-HF) investigating the use of AI-assisted echocardiography as part of screening strategies, plus 3 company-led validation or pattern-recognition studies. Licence is being evaluated by 2 studies, with [REDACTED] and 1 assessing systolic and diastolic parameters. The key study for EchoConfidence is the FEATHER study (Almeida et al. unpublished data 2025 (n=1200), with interim data included in the EAR and further data expected in December 2025. The company state this is a double-blind evaluation of AI for heart failure diagnosis and stratification on unselected consecutive patients referred for evaluation to community cardiology services.

Overall, the EAG considered these studies may strengthen the evidence base on accuracy and validity of the AI technologies but will not address key gaps

such as impact of AI on clinical outcomes or system benefits. Further details of ongoing studies are in section 8.1 and table 23 of the EAR.

6.3 Potential use of AI technologies to support echocardiography in community settings

Echocardiography is currently done almost exclusively in secondary care, in bespoke cardiology units for elective referrals, or emergency or bedside settings using a point-of-care device. Examinations are usually done by a qualified cardiac physiologist. Clinical experts highlighted the potential for the AI technologies to support a shift of echocardiography out of secondary care, into primary or community settings. As this was not part of the decision problem in the final scope, the EAG only included studies from a community care setting if they were based in the UK. Only the interim report from the FEATHER study (Almeida et al. unpublished data 2025) included data from a UK community care setting (see section 6.2.9). The EAG stated that the interim results indicate there may be potential for EchoConfidence to be safely implemented in community care, but evidence to demonstrate its impact on procedure time and the type of operator is limited. Further details of studies and ongoing trials that the EAG considered may be relevant to the use of echocardiography in community settings are included in sections 5.2.9 and 8.1 of the EAR.

7. Health economic evidence

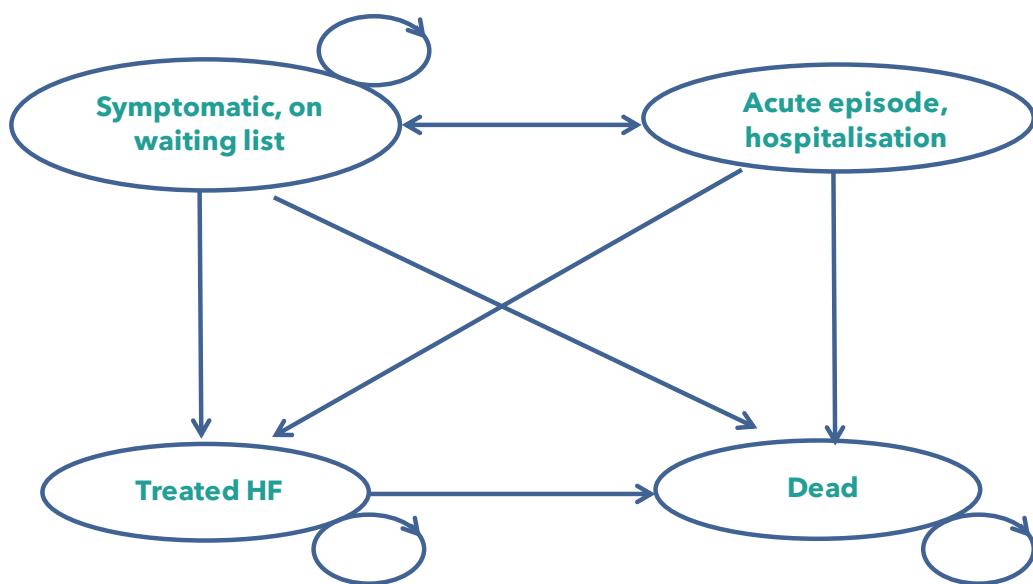
The external assessment group (EAG) did a review of the literature to identify suitable health economic models. A total of 3 economic models from 2 NICE guidelines were identified, these were (i) Chronic heart failure in adults: diagnosis and management (NG106) [2018](#) and [2025](#) and (ii) Acute heart failure: diagnosis and management ([CG187](#)). The EAG found that the NICE NG106 2018 model and CG187 model were relevant to the scope. These NICE models were used to inform the EAG conceptual economic model. Further details of these models are presented in section 6.1 of the external assessment report (EAR).

7.1 Health economic model

The EAG adapted the existing NICE models to assess the potential cost-effectiveness of AI-assisted transthoracic echocardiography (TTE) for heart failure diagnosis compared with standard TTE. The Markov model used a 1-year time horizon to capture the impact of reduced waiting times from shorter TTE durations. Downstream benefits of earlier diagnosis were not modelled because of the uncertainty around current waiting times. The standard NICE reference case was adopted, with QALYs based on utility values as the benefits outcome. As the time horizon was 1-year, no discounting was applied.

The model had a 2-week cycle and maintained the assumptions made in NICE NG106, that the sensitivity and specificity for standard TTE and specialist assessment were set at 100%, so only true positive and true negative outcomes were considered. The EAG stated that because the AI technologies would be used as an adjunct to standard TTE and a specialist clinical assessment is required for heart failure diagnosis, it is unlikely that there would be any differences in diagnostic outcomes between technologies. So it was not necessary to consider false negative and false positive outcomes in this assessment. True positive patients were assumed to start treatment sooner with AI due to shorter waiting times. True negatives were assumed to be unaffected and so were excluded in the model. The model included 4 health states: (i) symptomatic on waiting list, (ii) acute episode, (iii) treated heart failure, and (iv) dead. These are shown in Figure 2. Further details on the model structure are presented in section 6.2.1 of the EAR.

Figure 2: Schematic representation of the EAG early economic model (from EAR)



7.1.1 Key model assumptions

- Standard TTE plus specialist clinical assessment is 100% accurate, as described in Section 6.2.3 (NICE NG106 2018).
- Accuracy is assumed to be unaltered when using AI-assisted echocardiography, followed by a specialist clinical assessment.
- Patients remain in the “treated heart failure” state following diagnosis until they die or until the end of the 1-year time horizon. It is assumed that the treatment is sufficient to manage their condition and prevent any acute episodes resulting in hospital admission.
- Model assumes a proportion of patients would attend a one stop diagnostic clinic, where they receive echocardiography and specialist clinical review in one appointment. The cost of a one stop diagnostic clinic is assumed to be the same as the combined costs of an echocardiography appointment and a separate outpatient specialist clinic visit.
- For model simplicity, all patients who developed acute symptoms would enter through an ED and subsequently be hospitalised.
- The wait time for standard TTE and one stop diagnostic clinic was assumed to follow a normal distribution.

- It was assumed that the reduced procedure time would proportionately increase the number of patients per day, and that the calculated reduction in average wait time would shift the entire wait time distribution forward by the same magnitude.
- Number of patients referred to echocardiography was assumed to be constant.
- Waiting time for a specialist clinical assessment following echocardiography would remain unchanged. However, if the specialist clinic is already running at full capacity and there is no additional capacity available, this would limit the number of patients receiving an earlier diagnosis despite having an earlier echocardiography.

7.1.2 Description of population, health states, and transitions

As only true positive cases were accounted for in the model, all patients who entered the model would have diagnosed or undiagnosed heart failure. They entered the model through “symptomatic on waiting list” or “acute episode” health states.

Symptomatic, on waiting list

Patients with symptoms of heart failure in primary care who are on the waiting list for echocardiography and specialist clinical assessment or one stop diagnostic, start on the “Symptomatic on waiting list” state. The National Heart Failure Audit ([NHFA, 2025](#)) from the National Institute for Cardiovascular Outcomes Research (NICOR) reports that 49% of patients admitted with heart failure had HFrEF. The average age at first presentation was 77.5 years, and 56.1% were male.

Based on data from [Bottle et al., 2017](#) EAG assumed 21% entered the model on the waiting list with the remaining 79% entering the model in the acute episode state.

People on the waiting list can transition to 3 states. They could be diagnosed with heart failure in secondary care using TTE with or without AI. This was the only part of the model affected by the AI technologies, through the reduction in

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waiting times, discussed in Section 7.1.2. People could also have an acute episode. Hospitalisation rates used in the model were based on real world data from the PULSE study ([Linden et al., 2023](#)). Rates were expressed per 1,000 person-years and adjusted for age and sex by heart failure subtypes (HFrEF and HFpEF) to calculate weighted 2-week hospitalisation probabilities in the model. People could also die whilst on the waiting list, with mortality rates being based on a published 1-year survival rate of 75.9% ([Taylor et al., 2019](#)), giving a 24.1% annual mortality rate whilst awaiting diagnosis.

Acute episode, hospitalisation

The “Acute episode, hospitalisation” state represents people who are hospitalised as they develop acute onset of symptoms of heart failure; these patients are therefore analogous to patients with acute heart failure, covered by NICE [CG187](#), and most patients in the model start in this state. Length of hospital stay was based on the NICOR NHFA reports. As this was found to be consistently under 14 days, the model assumed an inpatient stay lasts one cycle (2 weeks) before transition to another health state. An in-hospital mortality rate of 10.4% was applied to patients admitted with acute symptoms, derived from NICOR data.

The EAG assumed that people admitted for acute episodes of heart failure and who survived could transition to the waiting list, as they are discharged without a heart failure diagnosis. This was based on clinical expert input and a report by National Confidential Enquiry into Patient Outcome and Death ([NCEPOD](#), 2018). Estimates ranged from 10% to 55.8%, giving an average of 32.9%. Because NICE guidance recommends all inpatients should be diagnosed before discharge, a sensitivity analysis was done to explore this variation. The remaining people were assumed to transition to the “treated heart failure” state.

Treated Heart Failure

Once diagnosed, either from the waiting list or directly from hospital, the EAG assumed people remain in the “treated heart failure” state until they die or until

the end of the 1-year time horizon. It is assumed that the treatment is sufficient to manage their condition and prevent any acute episodes resulting in hospital admission. The EAG stated that, in reality, some patients would require inpatient admission if they experienced severe symptoms. However, for model simplicity, this transition is not explicitly captured due to the short time horizon.

A standardised mortality ratio of 7.37 was applied to patients with treated heart failure in the model according to age and sex from the office for national statistics life tables.

7.1.3 Waiting list times (time to diagnosis)

Symptomatic people on the waiting list transition to being diagnosed and treated accordingly, with the time this takes being related to simulated waiting list times. People could access TTE from this state through standard referrals, where the TTE is performed first followed by a further wait for clinical assessment. The EAG also assumed a proportion of people would attend a one stop diagnostic clinic, where they receive echocardiography and specialist clinical review in one appointment.

Baseline time to diagnosis and proportion diagnosed

Total wait time for echocardiography is not routinely collected so the EAG based waiting time estimates on NHS diagnostic activity data (July 2025) and clinical expert input. National data show that around 10.6% of patients wait 13 weeks or more for echocardiography, while most (approximately 89.4%) wait less than 13 weeks. Experts advised that, in settings without a one-stop diagnostic clinic, the typical waiting time from referral to echocardiogram is between 6 and 12 weeks. To model this, a normal distribution was assumed, where no patients received echocardiography before 6 weeks, and 10.6% waited beyond 13 weeks. This distribution was used to estimate the proportion of patients diagnosed at 2-week intervals.

Clinical experts also estimated that the interval between echocardiography and subsequent clinical assessment is usually 1 to 4 weeks. The EAG

assumed that half of patients are assessed within the first 2 weeks after echocardiography and the remainder in weeks 3 and 4. These intervals were combined to calculate overall waiting times and the proportion of patients diagnosed at 2-week intervals. Clinical experts estimated one stop diagnostic clinics have a wait time from referral to diagnosis of between 2 to 10 weeks. In the model, a mean waiting time of 6 weeks was assumed, with patient waiting times represented by a normal distribution. This distribution was applied to estimate the proportion of the heart failure population diagnosed at 2-week intervals.

Effect of AI technologies on wait times

Two technologies (EchoConfidence and Us2.ai) reported evidence on time savings with AI-assisted echocardiography, these are reported in section 6.2.5. The EAG considered these studies have important limitations. Both Us2.ai studies were conducted in Japan, so the setting and operators may not reflect NHS practice. The FEATHER study was UK-based but reported interim results with very limited detail. It included consecutive patients referred to community outpatient cardiology clinics and so has limited generalisability to standard NHS practice. Time measurements were also unclear because the studies reported the technology's impact at different stages of the procedure. For example, Sakamoto et al. (2025) reported an examination time of 14.3 minutes without AI, while Hirata et al. (2024) reported combined measurement and report creation time of 12.5 minutes without AI. The EAG were uncertain whether these times represent a full echocardiography procedure, as they are much shorter than the NHS average of 45 minutes (clinical expert estimate, see Figure 1). Similarly, FEATHER reported time savings for specific automated steps, but it is unclear how these fit into the overall TTE workflow or whether they would translate into practical efficiency gains. The EAG considers this evidence low quality and not robust, so the analysis should be regarded as exploratory. Details of these studies and their limitations are summarised in Table 15 of the EAR.

The EAG estimated changes in waiting time using evidence on reduced procedure time with AI-assisted echocardiography. First, the current number
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of patients that received an echocardiogram within the average wait time under standard care was calculated. This was estimated using the current number of procedures completed in a full day and the average waiting time for echocardiography, assuming a 5-day working week. This gave an estimated total of 575 patients under standard care.

A shorter procedure time with AI was then applied to calculate the new number of procedures per day. The average wait time with AI-assisted echocardiography was estimated by dividing the same number of patients calculated for standard care (575) by this new daily capacity. The percentage reduction in average wait time was then applied to generate a revised distribution of echocardiography waiting times. The same reduction was assumed for one-stop diagnostic clinic waiting times.

In the base case, the estimated reduction in average wait time was 17% for both EchoConfidence and Us2.ai (see section 6.2.3 in the EAR and section 4 in the addendum). The model assumed that waiting time for specialist clinical assessment remained unchanged. These estimates were used to calculate the proportion of the heart failure population diagnosed for each technology. Full details of the calculation are provided in Appendix E of the EAR.

7.1.4 Costs

Standard of care and state costs

Costs in the model were based on published sources and expert input. Staff time was included for both arms, costed using a band 7 cardiac physiologist. Hospitalisation and emergency department costs were taken from NICE guidance [NG106](#) (2025 economic modelling). Follow-up costs after heart failure diagnosis were based on NG106 resource requirements and validated by clinical experts; specialist nurse visits were costed using a band 6 nurse. Drug treatment costs were weighted by prescribing patterns reported in NICOR (2025) and aligned with NG106 recommendations. These costs are listed in Table 18 of the EAR. The EAG excluded standard TTE costs because AI technologies are used as an adjunct to standard echocardiography. A

breakdown of technology costs included in the model are reported in Table 17 of the EAR.

EchoConfidence

The EchoConfidence software is priced at £4 per use, with additional set-up and training costs. Hardware may be supplied by the vendor at extra cost, but these costs were not included in the EAG model because they are currently unknown. Staff training includes 2 days on site plus remote sessions and is costed as an additional package. Information technology (IT) support for integration and ongoing maintenance may incur extra fees, but limited information was available to include these in the model. Reversing implementation would mainly involve set-up, hardware, and training costs.

EchoGo Heart Failure

The EchoGo Heart Failure technology is offered as a package priced at £25 to £50 per use (excluding VAT), covering software, IT and cloud support, integration, and staff training. The company did not provide contract details, so reversal costs cannot be assessed. Minimal training is required, and no additional equipment is needed.

Ligence Heart

Ligence have 2 pricing models available: an unlimited licence (1 or 3 years) based on workstations, or a tiered pay-per-use model. For its cost calculation the EAG used the tier-based pricing model, using the estimated annual scan volumes from the NHS England Diagnostic Waiting Times and Activity dataset. This resulted in a cost per scan of £2.61. Costs cover software, installation, and support. A server may be provided at extra cost, and one-hour training per person is included at no additional cost. Reversal costs would include any server fees and unused scans.

US2ai

The company offers a tier-based (pay per scan) package based on the number of scans. Using the estimated annual scan volumes from the NHS

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England Diagnostic Waiting Times and Activity dataset resulted in a cost per scan of £7.50. Installation can be cloud-based or on-site, with optional rental servers for piloting or transition; server costs vary. In its cost calculation, the EAG included an on-site installation of a basic server. The costs include software use, clinical and IT support, training, installation and routine support updates. Reversal costs would include any server fees and unused scans (see section 3 of the addendum).

7.1.5 Health state utilities

Patients were assigned utility values for each health state in the model, based on NICE [TA773](#) and [NG106](#). The utility of 0.58 for both untreated and treated heart failure was derived from EQ-5D data in the REFER study (Taylor et al., 2017, unpublished). The EAG noted the REFER population mainly included older patients (mean age 77, 50.6% male) with HFpEF (86.5%). The EAG retained a utility value of 0.58 for treated heart failure and applied a 10% disutility for untreated heart failure (EAG assumption). A temporary (1 cycle) utility decrement for heart failure-related hospitalisation of 0.019 was also included, based on TA773 and NG106, to reflect reduced quality of life during and immediately after admission.

7.1.6 Presentation of results

The EAG stated that the cost-effectiveness analysis should be considered exploratory due to significant uncertainty in input variables and multiple assumptions. The base case included only AI technologies with evidence of impact on procedure time (EchoConfidence and Us2.ai), compared with standard TTE. Probabilistic sensitivity analysis was not performed because the EAG stated it would add little value for guiding evidence generation. One-way deterministic sensitivity analyses were undertaken to identify key drivers and explore plausible ranges. The values used are listed in Table 20 of the EAR.

7.2 Model results

7.2.1 EchoConfidence

The base case results suggest EchoConfidence may be cost-saving compared with standard care (cost difference of -£3.14), mainly due to reduced staff time per scan offsetting its per-use cost. The model assumes a 17% reduction in waiting time, which could increase the proportion meeting the 6-week referral target from 26% to 40% and deliver modest QALY gains (QALY difference of 0.0005).

However, the EAG considered these findings are highly uncertain because of limited clinical evidence and assumptions about workflow impact. One-way sensitivity analyses show results are most sensitive to the proportion diagnosed in one-stop diagnostic clinics and the effect of waiting time reduction (Table 21 of EAR). Combined scenarios with lower clinic use and smaller time savings substantially reduce the benefit, but the technology remained cost saving in all scenarios. Overall, while the EAG concluded that EchoConfidence appears potentially cost-saving, it stated that results should be interpreted with caution given the uncertainty.

7.2.2 US2.ai

The base case results suggest Us2.ai may be more costly and more effective than standard care (cost difference of £0.92, QALY difference of 0.0005), with an ICER of £1,674 per QALY gained (see section 4 and table 4 in the addendum). This results in a 14.5% increase in those meeting the target referral time. Results from one-way sensitivity analyses suggest that the economic findings are sensitive to a number of inputs including the impact of waiting time reduction with Us2.ai, the proportion diagnosed in a one stop diagnostic clinic, the proportion of inpatients receiving TTE, and the staff delivering TTE. Overall, the EAG noted that while the results suggest that Us2.ai is potentially cost-effective, the findings should be interpreted with caution given the significant uncertainty surrounding the current waiting time and the impact of Us2.ai on TTE workflow. Full details of the cost effectiveness results for Us2.ai are in section 4 of the addendum.

8. Equality considerations

The [final scope](#) and the [scoping equality impact assessment](#) describe equality considerations for this assessment. The external assessment group (EAG) did not identify additional equality issues.

9. Key points, limitations and considerations

9.1 Diagnostic accuracy and clinical evidence

9.1.1 Key points

- AI-assisted echocardiography technologies generally show good diagnostic accuracy for detecting heart failure and related parameters compared with human measurements, particularly for core measures like LVEF and classification of heart failure.
- In studies that assessed diagnostic accuracy only, the AI technologies are assessed as standalone.
- In studies that assessed implementation beyond diagnostic accuracy, AI technologies are positioned as adjunctive, and so lower risk as per the scope.
- All 4 technologies have some evidence to support their use, with US2ai having the most extensive evidence base.
- There was a general lack of evidence on the impact of AI used to assist echocardiography in terms of clinical or procedural outcomes. There was limited evidence on procedure time.
- One interim study reported data from a UK community care setting, indicating there may be potential for EchoConfidence to be safely implemented in community care, but evidence to demonstrate its impact on procedure time and the type of operator is limited.

9.1.2 Limitations

- The study designs lacked robustness. Many studies were retrospective, single-centre, and sometimes single-operator, introducing bias and reducing generalisability. Only 1 RCT (on US2.ai) was identified.
- There is a lack of UK-based and real-world data. Most studies were conducted outside the UK or in controlled settings, limiting generalisability to NHS practice. Complex cases and poor-quality images were often excluded, which does not reflect real-world conditions.
- There was a lack of clinical outcomes. Few studies reported health-related outcomes such as time to diagnosis, treatment initiation, or patient quality of life. Most evidence focused on measurement accuracy rather than clinical impact.

9.1.3 Considerations for committee

- Most studies were on aspects of diagnostic accuracy, with limited evidence on procedure time. Does the evidence show that the technologies have plausible potential to address the specified unmet need?
- Four technologies were assessed. What does the identified evidence tell us about the relative diagnostic performance of these technologies and their suitability for use in the NHS?
- What are the key potential benefits of AI echocardiography technologies? Are they clinical or system benefits?
- Are there any clinical or system risks with using AI echocardiography to aid the operator that can be managed?
- What are the key evidence gaps for these technologies?

- Are AI technologies for echocardiography likely to be used in primary or community care settings in the future?

9.2 Health economic evidence

9.2.1 Key points

- The key driver of cost-effectiveness was the potential of AI to reduce procedure times, streamline appointments and increase throughput, reduce waiting list times for diagnosis, improve access to treatment, and thereby improve clinical outcomes.
- Data on procedural time was key to the economic model but the robustness and generalisability of the studies informing these data were uncertain.
- Although 1 study reported an increase in the number of examinations per day this was not based in the UK and so it is uncertain whether any time savings would translate into meaningful increases in throughput in NHS clinical practice.
- Reduced staff time per scan appears to drive the cost effectiveness in the 1-year time horizon, with only a modest QALY gain in the short term
- The conceptual model indicates that EchoConfidence and Us2.ai have the potential to be cost-saving or cost effective. However, the evidence is uncertain and results should be interpreted with caution.

9.2.2 Limitations

- The model had a time horizon of 1 year due to the lack of longer term evidence. The key benefits of the effect of the AI technologies on heart failure treatment may not be realised for several years. Longer-term benefits are a key evidence gap.

- There was a lack of information to inform current NHS echocardiographic waiting times or to extrapolate how AI derived efficiencies might improve these.
- The costs of the AI technologies are complex and the implications of their adoption at a local level is poorly understood.
- Cardiac MRI, which is sometimes used downstream of TTE in the classification of heart failure, was not modelled as the EAG could not find data on its use or the impact or regional variability.

9.2.3 Considerations for committee

- Does the conceptual model represent the care pathway and capture all the relevant parameters. Is it fit for purpose? If not, why not and would this impact the evidence gaps evidence generation needs to address?
- Have all the key potential economic benefits of the technologies been identified?
- To what extent would relatively small procedure time savings be likely to translate into higher patient throughput in NHS clinical practice?
- What evidence gaps need to be addressed to reduce uncertainties concerning the cost-effectiveness of the AI technologies?

Appendix A Abbreviations

| | |
|-----------|---|
| A | Artificial intelligence |
| EAG | External assessment group |
| EAR | External assessment report |
| GLS | Global longitudinal strain |
| HF | Heart failure |
| HFmEF | Heart failure with mildly reduced ejection fraction |
| HFpEF | Heart failure with preserved ejection fraction |
| HFrEF | Heart failure with reduced ejection fraction |
| ICC | Intraclass correlation coefficient |
| LVEF | Left ventricular ejection fraction |
| MAD | Mean absolute difference |
| MD | Mean difference |
| NPV | Negative predictive value |
| NT-proBNP | N-terminal pro b-type natriuretic peptide |
| PPV | Positive predictive value |
| QALY | Quality adjusted life year |
| RCT | Randomised controlled trial [delete if not needed] |
| SD | Standard deviation |
| TTE | Transthoracic echocardiography |

HealthTech Programme

HTE10067: Artificial intelligence assisted echocardiography to support diagnosis of heart failure (provisional title)

Patient organisation submission

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on patient experience of using the technology in the context of current clinical practice that is not typically available from the published literature.

To help you give your views, please use this questionnaire. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
- Your response should not be longer than 10 pages.

Information about your organisation

| | |
|-----------------------|-------------------|
| Organisation name | Cardiomyopathy UK |
| Contact person's name | [REDACTED] |
| Role or job title | [REDACTED] |
| Email | [REDACTED] |
| Telephone | [REDACTED] |

Brief description of the organisation, such as:

- **Who funds it?**
- **How many members does it have?**
- **What region your organisation represents**

Cardiomyopathy UK is the national charity for people affected by all forms of cardiomyopathy. The charity provides a range of support and information services, provides clinical education opportunities, raises awareness of the condition among the general public, supports research

and advocates for improved access to quality treatment.

The charity's database contains 22,000 individuals and there are around 100 active volunteers who facilitate support groups, provide peers support, advocate for improvements in health services, undertake fundraising activities and take on a range of other roles.

The charity's trustees, the majority of whom have personal experience of the condition are ultimately responsible for the charity and are supported by a professional team of 19 staff.

The charity is funded by community fundraising, donations and legacies (78%) charitable trusts and foundations (8%) the pharmaceutical industry (14%) Total income from the year January - December 2024 was £1,054,678

Cardiomyopathy is a leading cause of heart failure.

Declarations

Do you have any conflicts of interest? Please let us know if you have a question on the [NICE policy on declaring and managing interests](#).

No

How did you gather information about the experiences of patients and carers to include in your submission?

Cardiomyopathy UK conducted a national survey of the cardiomyopathy community, called the MyInsight survey, in summer 2024.

Cardiomyopathy UK commissioned the Picker Institute to provide expertise on the survey development and design. Picker is a leading international health and social care charity, which carries out research to understand individuals' needs and their experiences of care. A total of 1323 people responded to the survey.

Intelligence is gathered on an ongoing basis about our community's experiences by our helpline nurses and peer support team.

| | |
|--|---|
| Are you willing for this submission to be shared on our website? | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| We may invite you to a scoping meeting and/or committee meeting where this technology is to be discussed. Would a member of your organisation be willing to join such a meeting (this may be in person or virtually)? | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |

| | |
|---|---|
| Does the organisation have any direct or indirect links with, or funding from, the tobacco industry? | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> |
|---|---|

Impact of the symptoms, condition or disease on patients and / or family and carers

1. What is it like to live with the condition? What do carers experience when caring for someone with the condition?

The MyInsight survey of the cardiomyopathy community in 2024 found the following:

- 62% of all people with cardiomyopathy reported that their exercise had been negatively impacted in the last two years.
- This is in comparison to 80% of people with amyloidosis cardiomyopathy stated that exercise had been negatively impacted by amyloidosis cardiomyopathy.
- 34% of all people with cardiomyopathy reported that their mobility had been negatively impacted in the last two years.
- By contrast, 55% of people with amyloidosis cardiomyopathy stated that their mobility had been negatively impacted by amyloidosis cardiomyopathy.
- 51% of all people with cardiomyopathy reported that their self-confidence had been negatively impacted in the last two years.
- 50% of people with amyloidosis cardiomyopathy stated that their self-confidence had been negatively impacted by amyloidosis cardiomyopathy.
- 49% of all people with cardiomyopathy reported that their mental health had been negatively impacted in the last two years.
- 40% of people with amyloidosis cardiomyopathy stated that their mental health had been negatively impacted by amyloidosis cardiomyopathy.

Survey respondents from our 2022 national survey indicated that the most impactful physical symptoms of the condition were breathlessness, exhaustion and the inability to carry out day to day tasks. Respondent told us;

"I would say that the grinding daily fatigue is the hardest of all the symptoms to cope with as it takes away much of the enjoyment of life"

"I'm existing, not living, I've lost much of my mobility and have to rely on a walking stick, can't walk more than about 3 feet without having to stop due to the pain and breathlessness and sheer exhaustion, have had to have a wet room fitted as can't use a bath, can't lay down at all so have to sleep on my recliner sofa sitting bolt upright... I barely leave the house anymore except for appointments mainly. I want a life back"

Our national survey also looked at the impact of cardiomyopathy on emotional wellbeing of someone with the condition. Comments included:

"I find it hard sometimes to not do what I used to do and my close family find it hard too. I try to be philosophical and appreciate what I can do though. It's difficult when out and about and I can't walk as far as others or go upstairs easily - some disabilities are hidden"

"I live alone and I get very scared about my condition and how to cope with it. Also I feel anxious a lot of the time as I never know what will happen next in my body"

When we asked the loved ones of people with cardiomyopathy about their experience, they told us that they were also struggling emotionally with the impact of cardiomyopathy. 60% of respondents said that they found it hard to cope and 28% believed that counselling could help their emotional wellbeing.

Experiences and availability of current health technologies

2. How do the existing health technologies play a role in managing the condition, and what are their advantages and disadvantages? What new technologies do you know of that you could tell NICE about?

Echocardiography is crucial to the diagnosis of cardiomyopathy – the aetiology behind the heart failure. Moreover, its use is also important in the screening of all first-degree relatives of patients with cardiomyopathy.

Echocardiography is also essential to the prescribing and up-titration of the drug mavacamten, for people with hypertrophic obstructive cardiomyopathy.

Given its centrality to the diagnosis of cardiomyopathy – and one of the few dedicated cardiomyopathy medications – the only main disadvantage to echo is the waiting times. Patients have often had cardiomyopathy symptoms for some time before it is recognised that they may have a heart condition (rather than asthma, anxiety etc). Delays on echos means that these patients have to wait still longer before a diagnosis can be confirmed.

Similarly waiting for echos as part of ongoing care can cause distress to patients, as in the example below from our 2024 national patient survey:

“Not seen cardiologist since leaving hospital. Had cardiac arrest out of hospital. CRTD fitted. Only had phone call and could not ask things as so rushed (I appreciate waiting lists crazy). Was not listened to when said still very breathless. Having to wait over a year for a repeat echocardiogram to check things. This is causing distress...”

Improved access to echocardiography would therefore help to allay (or confirm) patient concerns and worries. Our patient community would also like the reassurance of more regular access to echocardiography – and in some cases the lack of this is causing behaviour change, to alleviate risk. Many don't have regular echos and worry about whether any changes to their condition would be picked up on. Moreover, patients have seen a deterioration in access to echo in recent years. Very concerningly, this is not necessarily clinically-led, as in the example below.

"The care I had initially was excellent but since Covid the annual tests ECG/Holter/Blood/Echo tests that I'm supposed to have in advance of talking to my consultant have become impossible to get. The consultant orders them but the scheduling person decides that they are not necessary. So I've only had an echo and an ECG in the past two years despite arguing with the appointment booking people. My cardiologist said it's because they are under orders to reduce tests for financial reasons and the finance team have higher priority than him.

"I would like more regular echocardiograms. I haven't had one for about 6-7 years. I know NHS is underfunded and overstretched after covid. I am also afraid of chest infections, hospitalisations and I don't like to go out. If I do, I wear a mask which I think is sensible."

"Getting an echocardiogram in advance of my annual appointment can be a challenge."

In general there is a strong feeling from our patient community that echo is in very short supply and that they either don't get echos, or have to push for what ought to be happening systematically.

"I have to push through my GP the local cardiology department for my regular echocardiograms and follow up consultations, they do not respond to me and do not programme them automatically."

"Routine ICD checkups have always been good. But feel other tests and checkups are too infrequent. I've not had an echocardiogram in over 4 years."

"My cardiologist wants me to move to biennial echocardiograms despite being recommended annual, she relented to this year's echocardiogram in the end, but it felt like an afford."

About the health technology being assessed

3. What are the potential benefits of the health technology/technologies being assessed compared with what currently exists?

Improvement in patient access to echo would be a very positive outcome from this technology appraisal. We would hope that use of AI results in additional system capacity.

Speeding up diagnosis doesn't just have positive impacts for that particular patient but for other potential patients too – the issue of delayed diagnosis of the proband has implications of later diagnosis in their family members, where it turns out to be an inherited cardiomyopathy.

Any use of this technology in community hubs would potentially give patients an opportunity for care closer to home (not having to travel to the hospital centre for their echo) - which is important to many, especially those who are more unwell and less mobile.

4. What are the potential disadvantages of the health technology/technologies being assessed compared with what is currently available?

It is essential that AI echoes must be safe both in terms of giving reliable results and in relation to privacy and patient data. Safety is particularly at issue if use of the technology widens access to HCPs who are not trained in its use. Misdiagnosis/false negatives must be avoided at all costs, given the repercussions and impacts this would have for patients.

5. Do you foresee people having any specific concerns regarding the integration of artificial intelligence technologies into heart failure diagnostic pathways?

We have heard from different sources about issues with patients having to have two echoes due to poor reporting and/or poor data integration between hospitals e.g. having an echo in a CDC or local hospital and this having to be repeated in the cardiology department.

“My local hospital did not send Barts the results of 2022 and 2023 Echos. I had to request Barts for an Echo this year.”

Having to repeat echoes is a significant waste of NHS resource, but also impacts patients whose time and energy is wasted in attending unnecessary echo appointments. This is dispiriting and frustrating for patients – and results in a poorer experience of care. The new technology will not be a panacea to resolving all echo problems – and indeed will be most impactful if these wider issues are resolved.

Equality issues

6. Are there any groups of people who might benefit more or less from the technology than others?

Where this technology is used is a key issue – and how the results of these scans are transferred to hospital centres, if done in local hospitals/CDCs. Ideally we want for people to have their care as close to home as possible – if the AI echo increases capacity for this, this would be a positive outcome. However, should AI echo only be rolled out in hospital centres attention needs to be given as to whether this could be disadvantageous to rural/coastal populations.

Those with Hypertrophic Obstructive Cardiomyopathy stand to gain in particular, if improved echo capacity results from this technology, resulting in more people being able to access mavacamten.

Cardiac amyloidosis is often under diagnosed, not least because it is difficult to diagnose (heterogeneity of symptoms at presentation according to the ESC). Improved echo access could make a significant difference in improving diagnosis of ATTR-CM heart failure. Diagnosing the aetiology behind the heart failure is crucial given the new drugs coming on line for ATTR-CM.

7. Are there any groups of people that might need further consideration in using the technologies (for example, because they have higher levels of ill health, poorer outcomes, problems accessing or using treatments or procedures)?

While heart failure in general may be more prevalent in older people, cardiomyopathy can affect people of any age – and indeed is a leading cause of heart failure in working age people. Modelling and safety considerations must consider younger people with cardiomyopathy.

8. Are there any potential equality or health inequality issues that should be taken into account when considering this condition and the technology?

Enter text.

Additional information

9. Please include any additional information you believe would be helpful in assessing the value of the technologies.

Enter text.

Key messages

In up to 5 bullet points, please summarise the key messages of your submission. bullet points.

- Echo capacity causes delays in diagnosis which is a significant cause of patient stress/distress.
- Improving capacity would have a positive impact on patients – both in diagnosis and ongoing care and treatment.
- Patient safety must be central to considerations – including that of younger people with heart failure caused by cardiomyopathy.
- Improvements in data integration/reporting are needed to ensure the AI echo reaches its potential – and to improve patient experience (avoiding duplication/two visits).

Thank you for your time. Please return your completed submission to medtech@nice.org.uk

If you haven't already, please register as a stakeholder by completing the [stakeholder registration form](#) and returning it to medtech@nice.org.uk

Did you know NICE meetings are held in public? You can [register on the NICE website](#) to attend a meeting up to 20 working days before it takes place. Registration will usually close 10 days before the meeting takes place.

HealthTech Programme

HTE10067: Artificial intelligence assisted echocardiography to support diagnosis of heart failure (provisional title)

Professional organisation submission

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To help you give your views, please use this questionnaire. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

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- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
- Your response should not be longer than 10 pages.

About the organisation

| | |
|--------------------------|-------------------------------------|
| Organisation name | British Society of Echocardiography |
|--------------------------|-------------------------------------|

| | |
|--|--|
| Contact person's name | [REDACTED] |
| Role or job title | [REDACTED] |
| Are you (please highlight Yes or No): | <p>An employee or representative of a healthcare professional organisation that represents clinicians? Yes or No</p> <p>A specialist in the treatment of people with this condition? Yes or No</p> <p>A specialist in the clinical evidence base for this condition or technology? Yes or No</p> <p>Other (please specify): I represent the group of clinical experts in this field. The information in this submission has been compiled by clinical experts.</p> |
| Please provide a brief description of the organisation (including where funding comes from) | <p>The British Society of Echocardiography is a highly engaged member organisation which represents clinical echocardiography professionals working at all levels and in all areas of the field. Our aim is to provide our members with the necessary education and professional support to deliver the highest standard of care in echocardiography.</p> <p>We are funded through membership, accreditation and event fees. We receive some sponsorship from industry in support of events and our industry partners. This accounts for 9% of our income.</p> |
| Has the organisation received any funding from any company with a technology related to the evaluation in the last 12 months? If so, please state the name of company, amount, and purpose of funding | Mycardium – exhibition stand at annual conference £3,300 |
| Does the organisation have any direct or indirect links with, or funding from, the tobacco industry? | No |

Current care pathway and unmet need

| | |
|---|--|
| <p>1. Please describe the current standard of care that is used in the NHS. Please note any clinical guidelines used in the NHS which are relevant to the care pathway. What setting would this technology be used in (primary care, general hospitals, specialist centres for example).</p> | <ul style="list-style-type: none">• Chronic heart failure in adults: diagnosis and management (NG106)• Acute heart failure: diagnosis and management (CG187) <p>Patients can present in a number of ways outside the above guidelines:</p> <ol style="list-style-type: none">1. No BNP but symptoms of heart failure / breathlessness.2. Normal BNP with symptoms of a potential cardiac disease. <p>This technology would be used within transthoracic echocardiography (TTE) services (hospital/CDC's) by trained echocardiographers. It would provide a useful diagnostic adjunct to both out- and in-patient TTE services. For the most part, this will be elective, outpatient TTE activity.</p> <p>All echocardiography equipment is portable and as such, TTE can be undertaken in outpatient departments but also at the bedside in acute and emergency wards and clinics. However, for the later, the portable nature of TTE significantly impacts productivity and reduces capacity as additional time is needed to locate the patient, set up equipment at the bedside, and return to the department for the transfer of images and report generation. It is ideal to have a service where inpatients can attend the TTE department as this supports increased inpatient TTE activity and improves ergonomics for echocardiographers.</p> <p>The BSE has published guidelines on the tirage of patients with suspected heart failure, a collaboration with other UK cardiac societies. This was published in 2024 and is currently being converted for dissemination as a GIRFT best practice guideline.</p> <p>https://www.bsecho.org/Public/News/Articles/2024/2024-07/202407-PUE004-PUE005-PUE006.aspx?WebsiteKey=cbc9ffd7-4ee6-4741-9280-d435d6a887f4</p> |
| <p>2. Does this procedure or technology have the potential to replace current standard care or would it</p> | <p>The technology does not have the potential to replace current standard care and would be used as an addition to existing standard of care - The EU AI act (2024) states the decision-making process remains with healthcare and AI is only a supportive tool.</p> |

| | |
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| <p>be used as an addition to existing standard care?</p> <p>Where would the technologies or procedure fit in the care pathway?</p> | <p>We envisage that the technology may prove useful in identifying heart failure with preserved ejection fraction (HFpEF) and reduced ejection fraction. It is unlikely to be useful for the diagnosis of heart failure with reduced ejection fraction (HFrEF), the majority of heart failure patients as echocardiographers are skilled to enable the detection of this and the issue of prolonged delays is not due to this.</p> <p>There are a number of considerations for this use of this technology:</p> <ol style="list-style-type: none"> 1. Workflow 1: Where ONLY AI analysis is preformed and a diagnosis of concern is shown, a comprehensive TTE will still be required to rule out the possibility of other cardiac pathology being present. 2. Workflow 2: Where ONLY AI analysis is preformed and this shows no concerning diagnosis, only HFpEF can potentially be excluded. This raises the possibility of a missed diagnosis due to other cardiac pathologies and as some of the AI systems only use a proportion of the comprehensive TTE dataset, a comprehensive TTE will still be required. This may lead to multiple TTE appointments. This would worsen the “probe to treatment” time and the TTE waiting list as a whole. <p>The approaches outlined in workflow 1 and 2 above would mean:</p> <ol style="list-style-type: none"> a. A potential expedition of care and treatment for patients who do have heart failure b. Duplication of TTE tests / appointments. c. Marginal or no impact on ‘probe to treatment time’. It should be noted that several of the AI tools require 20-30mins for AI analysis and report generation. By comparison a standard TTE takes 45 mins. Where both are needed due to clinical findings, the time taken (‘probe to treatment time’), and thus the waiting list is worsened. <ol style="list-style-type: none"> 2. Workflow 3: Where the AI analysis is performed side by side with a comprehensive TTE, we can see some potential benefits. Depending on their sophistication, some AI tools may have the ability to detect pre-clinical, pre-diagnostic imaging levels of disease (e.g. cardiac amyloidosis). The two combined will allow for the highest degree of clinical accuracy. <p>The length of time the AI systems take to generate reports and how this affects current standard of care needs to be considered.</p> |
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| | <p>It is not currently safe to rely on AI generation of reports ALONE. Additional considerations surround the skills required for the echocardiographer to be able to integrate AI and traditional interpretation models. The degree of interrogation and discernability required to ensure the AI generated reports are accurate needs to be explored. Appropriate training and knowledge demonstration of this will need to be in place.</p> <p>Infrastructure in embedding AI into clinical practice is essential. There needs to be appropriate governance in place and accountability for the AI generated report. It is important that whilst the AI technology may be able to detect ejection fraction, there are other conditions that may present with heart failure symptoms and elevated BNP but an alternative diagnosis is the cause which AI EF tools may miss. For example, heart valve disease; pulmonary hypertension; cardiac infiltrative disease. Having a governance structure in place to ensure that the healthcare professional undertaking the test is appropriately trained and has pathways for escalation and review of imaging.</p> |
| <p>3. Is there an unmet need for patients with the condition or disease, or healthcare professionals managing the condition or disease?</p> | <p>Yes, it would be beneficial for patients where they were unable to undergo a comprehensive TTE, in the first instance. This is not achievable in all areas of service delivery across England, or the UK more widely. However, integration of the AI tools ALONE will not provide a safe platform for treatment delivery in the absence of a comprehensive TTE. Therefore, the AI tools should only be performed in combination with a comprehensive TTE to aid earlier detection.</p> <p>Additionally, there is an unmet need for the prompt identification of phenotypes of HFpEF. One example of this is cardiac amyloidosis which is challenging to assess on TTE and patients typically have several echocardiograms across the disease prodrome with a ~2-year delay in diagnosis. AI technology that can support early diagnosis would be invaluable, improving patient care and facilitating early treatment.</p> <p>As highlighted above there is an unmet need related to the training of echocardiographers in the utility of AI tools and their usefulness as part of the diagnostic pathway.</p> <p>No perceived unmet need for HFrEF as these patients can be assessed using routine TTE without issues as highlighted above. Several of the AI tools under evaluation here are for NOT for HFrEF and thus the majority of patients presented with heart failure will not benefit from these AI tools.</p> |

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| | Further education is required both in relation to the referral of patient and the triage of patient requests. Patients are often referred with insufficient information meaning there is a potential for patients to be triaged inappropriately, or the request to be rejected entirely. In contrast some patients are referred inappropriately when the patient does not meet criteria for heart failure or related diagnostics. The need for training on triage and indications is paramount. |
|--|---|

The technology

| | |
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| 4. What are the potential benefits for patients and healthcare professionals from this technology (consider the potential clinical benefits, cost benefits, benefits to quality of life, and any wider benefits)? | <p>Patient benefits:</p> <p>Improved and earlier diagnosis of HFpEF and its underlying aetiology. Earlier access to treatment which can improve patient quality of life, morbidity, and mortality. For systemic disease such as cardiac amyloidosis this will result in fewer diagnostic tests with a reduction in unnecessary repeated TTE's.</p> <p>Healthcare professional benefits:</p> <p>This technology will help with diagnosis as a result of AI-suggested possible pathologies. Even those that would not routinely be picked up on a comprehensive TTE due to stage/prodrome i.e. early amyloid can be difficult to identify. AI tools may reduce repeated TTE's and improve waiting list times. Consideration of what skills echocardiographers will use AI technologies safely is paramount given the known limitations in terms of bias within the datasets and when / when not to use the AI technologies. This may lead to disparities in care.</p> <p>Wider healthcare community:</p> <p>The technology may support heart failure patients receiving more timely care, potentially at the earlier stages of heart failure leading to less hospital admissions and shorter length of stays. This would have a significant cost saving implication and an improvement in global longevity.</p> |
| 5. Are there any groups of patients who would particularly benefit from this procedure/technology? | <p>Patients with HFpEF. The AI technologies have the potential to improve the detection of amyloidosis which is challenging to assess and often patients have prolonged diagnosis times.</p> <p>Some of the technologies listed are not available for use in patients with atrial fibrillation which can be present in up to 50% of patients with heart failure. What impact will this have on patients with atrial fibrillation and how will this impact the TTE workflow.</p> |

| | |
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| Are there any groups in which the technology would be less effective or would be less likely to benefit? | <p>Consideration is needed on how the AI technologies cope with limited acoustic TTE views. Historically AI tools are trained on “good” TTE images. Yet this is not common in clinical practice. Thus, there is a potential that vast amounts of funding will be spent on AI systems to support clinical TTE workflow that will return limited benefit.</p> <p>Consideration needs to be given to the training sets from which the AI technologies derived data, as some of these may be based on patient demographics which may not be representative of the UK population (i.e US datasets).</p> <p>Echocardiographers will need data literature skills to understand when AI generated results are appropriate and safe to use to prevent misdiagnosis and suboptimal patient care.</p> <p>Echocardiographers will need time to review AI generated results alongside the TTE to ensure safe patient care.</p> |
| 6. How would healthcare resource use differ between the technology and current standard care? | <p>With the implementation of AI tools, IT resource would need to be upgraded to ensure that the AI tools can be accessed quickly and easily available on all workstations. Reporting templates may need to be compatible with existing traditional electronic health records. There would need to be a significant financial contribution. Additional digital storage space would be required. It will be time inefficient to log into multiple cloud based systems to use different AI tools. Where possible, AI vendors should be encouraged to use a local departmental system (Edge AI) or install software on the echo carts themselves.</p> |
| 7. Describe any system changes that would be needed if the NHS were to adopt the technology. Are there any potential barriers to the adoption of the technology or any changes that may be needed to enable implementation of the technology in the NHS? | <p>All of the technologies use DICOM format for analysis however there are variations in DICOM format which may mean some echocardiography storage systems will not be able to integrate the technology. This will cause disparities in care across the UK.</p> <p>Cost is a significant barrier: NHS Trusts may not be able to afford the technology or due to Trust IT systems may not be able to integrate the technology.</p> <p>Would patients be happy sharing their medical information / imaging with third party providers and who would be responsible for the governance around this, the hospital or the AI tool vendor?</p> |

| | |
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| <p>8. Are there any side effects or adverse effects associated with the technology?</p> | <p>Technology bias: Where the AI systems are not developed on representative UK heart failure populations. In addition, there may be misdiagnoses as a result of rare disease types with limited representation within AI datasets.</p> <p>Over-reliance on technology: Emerging evidence indicates that exposure to AI systems may negatively influence the behaviours of healthcare professionals, potentially contributing to a decline in care standards (DOI: 10.63163/jpehss.v3i2.277)</p> <p>Privacy and data security: Patients will need to be informed that AI will be used and that their data maybe transferred to AI companies for analysis. How, when and where this is done for this pathway will need to be considered as it could mean that only a small number of patients will consent to using it.</p> <p>Lack of transparency: Some of the technologies use unsupervised learning which means that the patient / healthcare professional has no idea on how the AI system has derived the answer. This can degrade trust and cause uncertainty in how to diagnosis and treat patients. Consideration of how this can impact trust is needed.</p> <p>Ethical and legal: The EU AI act (2024) clearly states the decision-making process lies with the healthcare professional. Yet it remains unclear where the accountability lies if a mistake is made. This needs clarification as some argue whether healthcare professionals can truly be held responsible for technologies that are not explainable.</p> |
| <p>9. Do you foresee patients having any specific concerns regarding the integration of artificial intelligence technologies into heart failure diagnostic pathways?</p> | <p>The BSE has undertaken patient and public engagement on this area. Their concerns are as follows:</p> <ul style="list-style-type: none"> • AI should not replace healthcare staff • Will all patients at all hospitals have access to the technology • Who takes responsibility for the results • Are staff trained how to use it • How will data remain confidential • What is the environmental impact of the technology. <p>The BSE AI position statement will be submitted for peer review publication in October 2025.</p> |

Equality considerations

| | |
|--|---|
| 10. Are there any <u>equality issues</u> that should be considered for this assessment? | <ul style="list-style-type: none">• All echocardiographers will need upskilling to be able to use the technology. If not, it will not be used in the manner intended. There is concern that in certain locations, access to this technology may not be as readily available due to insufficient financial support.• AI systems will need to ensure equity for all patient demographics to ensure it is safe. |
| 11. Could the technologies reduce or increase <u>health inequalities</u>? How? | <p>The technologies have the potential to reduce health inequalities but only if:</p> <ol style="list-style-type: none">1. The technology can be rolled out equitable across all healthcare settings.2. Echocardiographers are trained in data literacy skills.3. How the AI technologies will integrate into the TTE workflow without an increased need of duplicate scans / appointments.4. The technology is inclusive of the heart failure population that is seen in the UK.5. Issues around accountability can be ironed out at a national level. <p>If the above issues cannot be resolved, we envisage that health inequalities will be increased. This will occur through:</p> <ol style="list-style-type: none">1. Duplication of TTE appointments which will increase the TTE waiting time2. Wrong or no firm diagnosis being given by the AI tool3. No access to AI tools shown to support the diagnosis and aetiology of HFrEF |

Key messages

| | |
|---|---|
| In up to 5 bullet points, please summarise the key messages of your submission | <ul style="list-style-type: none">• AI tools to support and not replace a comprehensive TTE, otherwise potential to worsen current TTE waiting times.• Ethical and legal issues need resolving prior to AI tool being implemented• Echocardiographers need data literacy skills to ensure patient safety• Equitable access of AI technologies across all healthcare settings• AI tools need to be representative of UK patient demographics and results generation needs to be transparent. |
|---|---|

Thank you for completing the submission.

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Your privacy

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**HTE10067 Artificial intelligence assisted echocardiography
to support the diagnosis and monitoring of heart failure
Addendum 1 to External assessment report.**

Produced by: CEDAR

Correspondence to: CEDAR (Centre for Healthcare Evaluation, Device Assessment, and Research), Cardiff and Vale University Health Board, Cardiff Medicentre, CF14 4UJ

Date completed: 10/12/2025

Contains confidential information: No

1. Introduction

The External Assessment Group (EAG) has prepared this addendum in response to comments received from stakeholders on the external assessment report (EAR). Where possible, minor changes have been made in the main report, with more comprehensive changes included in this addendum.

Key issues addressed in this addendum:

| Query from stakeholder | EAG Response |
|--|---|
| One company raised concerns that some evidence for their technology has been omitted from the EAR. | Evidence from 2 additional studies has been reviewed and summarised in this addendum. |
| One company raised concerns that the technology costs used in economic modelling were not the most up to date. | The EAG has updated the technology costs used in the economic modelling. |
| One company provided clarification on appropriate procedure time inputs to be used in the base case economic analysis. | The EAG has updated the inputs representing procedure time in the base case analysis. |

2. Results from additional clinical evidence

An additional 2 studies have been included in this addendum. Both are for the Us2.ai technology. The study by Oo et al. (2024) is a retrospective analysis of NHS Electronic Health Record (EHR) data which investigated the utility of AI-assisted echocardiography in combination with biomarker analysis from routinely stored plasma samples in identifying and classifying heart failure (HF). The study by Huang et al. (2024b) is a prospective comparative study on the acceptability of the introduction of AI-assistance to transthoracic echocardiography (TTE). Participants underwent both TTE by a skilled sonographer and then AI-assisted TTE by a novice operator. A survey was then provided to participants to gain an understanding of

their acceptance of “task shifting” in healthcare through implementation of AI. The EAG notes this is a separate analysis of the same cohort reported on in a key study included in the main EAR (Huang et al. 2024a).

Study characteristics and results are summarised in Table 1. In line with the EAG protocol, only results for outcomes relevant to the scope have been extracted. The quality of these studies has not been formally assessed, in line with the methods described in the EAG protocol and applied in the main EAR. Key findings and limitations have been summarised narratively.

Table 1: Summary of additional clinical studies.

| Study details | Participants | Relevant outcomes and results |
|---|---|--|
| <u>Reference:</u> Oo et al. 2024 <u>Design:</u> Retrospective observational study <u>Intervention:</u> Us2.ai <u>Comparator:</u> manual validation/review of clinical records <u>Setting (location):</u> N/A - EHR study (Scotland, UK) | <u>Participants (n=578):</u> <ul style="list-style-type: none"> • HFrEF (n=156) • HFpEF (n=236) • Controls (n=186) <u>Demographics:</u> <p>HFrEF cases</p> <ul style="list-style-type: none"> • Mean age: 74 ± 10 years • F/M: 37% female • Ethnicity: NR <p>HFpEF cases</p> <ul style="list-style-type: none"> • Mean age: 77.5 ± 13 years • F/M: 61% female • Ethnicity: NR <p>Matched controls:</p> <ul style="list-style-type: none"> • Mean age: 59.5 ± 18 years • F/M: 61% female • Ethnicity: NR | <p>1) Coverage of echocardiographic parameters Across all parameters, coverage by Us2.ai-assisted analysis ranged from 46% to 93%. Of parameters required for diagnosis of HFpEF as per ESC guidelines, coverage was as follows for EHR (manual) data versus Us2.ai-assisted analysis data:</p> <ul style="list-style-type: none"> • LV mass: 51.04% versus 92.56% • Relative wall thickness: 77.85% versus 92.56% • LA volume: 0.00% versus 58.65% • E/e' ratio at rest: 0.00% versus 45.50% • TR velocity at rest: 74.57% versus 67.99% • PASP: 3.11% versus 54.00% <p>2) Concordance with clinical records (manual validation used as reference standard) (n=150) Diagnostic accuracy of Us2.ai-assisted analysis for HFrEF and HFpEF respectively, was: <ul style="list-style-type: none"> • PPV: 86% and 80%; Sensitivity: 100% and 100%; Specificity: 94% and 90% (Kappa value: 0.891 and 0.842) 100% "concordance rate" was noted in the control group.</p> |
| <u>Reference:</u> Huang et al. 2024b <u>Design:</u> Prospective comparative study <u>Intervention:</u> Novice-operated Us2.ai-assisted handheld TTE <u>Comparator:</u> Expert-operated standard cart-based TTE <u>Setting (location):</u> National Heart Centre (Singapore) | <u>Participants:</u> n=100 patients with ≥ 1 HF symptom <u>Demographics:</u> <ul style="list-style-type: none"> • Mean age: 61 ± 15 years • F/M: 44% female • Ethnicity: <ul style="list-style-type: none"> - 75% Chinese - 8% Malay - 13% Indian - 4% Other | <p>1) Survey results on acceptance of novice-operated Us2.ai-assisted handheld TTE Where 1 represents 'strongly disagree' and 5 represents 'strongly agree', scores ranged from 3.59 ± 0.88 (for perceiving the process as fun) to 4.14 ± 0.58 (for trusting healthcare staff).</p> <p>2) Relationship between variables and behavioural intention (acceptance of novice-operated Us2.ai-assisted handheld TTE)</p> <ul style="list-style-type: none"> • All hypothesized variables (performance expectancy, effort expectancy, social influence, facilitating conditions and hedonic motivation) showed significant relationship to behavioural intention. • Facilitating conditions, hedonic motivation and performance expectancy showed the strongest relationship to behavioural intention. • Patient factors such as age ($p=0.181$), education level ($p=0.218$) and gender ($p=0.776$) did not significantly affect behavioural intention. |

Abbreviations: E/e': ratio between early mitral inflow velocity and mitral annular early diastolic velocity; EHR: Electronic Health Record; ESC: European Society of Cardiology; HF: heart failure; HFpEF: heart failure with preserved ejection fraction; HFrEF: heart failure with reduced ejection fraction; LV: left ventricular; LA: left atrial; N/A: not applicable; NR: not reported; PASP: pulmonary arterial systolic pressure; PPV: positive predictive value; TR: tricuspid regurgitation; TTE: transthoracic echocardiography; UK: United Kingdom.

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Date: December 2025

The study by Oo et al. (2024) suggests that Us2.ai-assisted analysis provides good coverage of echocardiographic parameters that may be used to diagnose HF. The EAG considers results from the study by Oo et al. (2024) to be generalisable to the NHS as it used EHR data from Scotland. A key limitation is the retrospective nature of the study, which may introduce selection bias due to the unavailability of data for some individuals. This means the sample included may not be representative of the full range of clinical scenarios present in real-world practice. The method of selecting the sample (n=150) used to investigate concordance between AI-assisted analysis and manual analysis was not reported. Additionally, manual diagnoses recorded in EHR records were not independently verified. Therefore, the comparative diagnostic accuracy results reported are of uncertain quality.

The study by Huang et al. (2024b) provides some evidence of acceptability of the use of AI in echocardiography to service users. However, this study is specifically looking at the acceptability of novice-operated AI-assisted echocardiography versus standard cart-based echocardiography, so provides limited insight into the acceptability of AI technology alone. This study is considered to be of limited generalisability to the NHS due to its location in Singapore, where demographics do not reflect that of the UK population. Study authors also noted the high uptake of digital technologies in the general population of Singapore, and that digital literacy was not controlled for in the study, which introduces a potential confounding factor to results. The EAG acknowledge that this study demonstrates the use of Us2.ai in assisting novice operators to perform TTE, which may support the potential use case for Us2.ai technology to aid TTE being performed in primary or community care settings.

3. Updated technology costs

The costs for Us2.ai have been updated to the most current NHS pricing model and additional information provided by the company. The company offers a tier-based (pay per scan) package based on the number of scans. The costs include software use, clinical and IT support, trainings, installation and routine support updates.

In the EAG economic analyses, evidence of time savings from Sakomoto et al. (2025) was used in the base case, whereas the findings in Hirata et al. (2024) were used in the sensitivity analysis. The company has clarified that the time measured in Sakomoto et al. (2025) was on image acquisition only. The EAG consider the time savings on measurement and reporting creation in Hirata et al. (2024) is more appropriate to be used in the base case, in line with Us2.ai intended use in the company RFI. The staff time cost for Us2.ai has been updated using data from Hirata et al. (2024).

Table 2 describes the updated costs and resource use for Us2.ai.

Table 2: Updated costs and resource use for Us2.ai

| | Us2.ai | Changes made? |
|--|--|----------------------|
| License | Pricing is based on volume per year. Consolidating sites or multiple years usage could be negotiated. | No |
| System implementation | Available as “on premises” and cloud integration. | No |
| Supporting hardware and other infrastructure if provided by the company | Server and cloud are provided at an additional cost. Rental server is offered by vendor for pilot. Costs are not provided by the vendor. | No |
| Training | Clinical support and both initial and refresher trainings are available at no additional cost. | Yes |
| IT support and/or maintenance | Support is available at no additional cost, including routine software updates. | Yes |
| Per patient costs excluding VAT, no discounting applied (annual scans: 10,000 per site) | | |
| License/software per scan | £7.50 | Yes |

| | | |
|---|--|-----|
| System set up per scan | Basic server £6,000 spread over 3 years = £0.20 per scan | No |
| Training costs per scan | 0 | Yes |
| IT support costs per scan | 0 | No |
| Staff time per scan | 36.3 mins (Hirata et al., 2024) | Yes |
| Staff time costs per scan using band 7 cardiac physiologist | £39.89 | Yes |
| Total costs per scan, not including HCP costs | £7.70 | Yes |
| Total costs per scan (low volume, 5,000 per site per year) | £7.90 | Yes |
| Total costs per scan (high volume, 21,000 per site per year) | £6.80 | Yes |
| Total costs per scan, excluding hardware | £7.50 | Yes |

Abbreviations: VAT: value added tax

4. Results of updated economic model

The economic base case analysis for Us2.ai has been updated using the costs in Table 2. Based on the reported time savings of 8.7 mins in Hirata et al. (2024), this results in a 17% reduction in waiting time. However, the generalisability and robustness of the time savings evidence is limited, given the non-NHS settings in terms of workflow and operator type, and the low study quality (small sample size and single centre design).

A series of one-way sensitivity analyses are undertaken (Table 3).

Table 3: One-way sensitivity analyses and the value used for Us2.ai

| One-way sensitivity analyses | Low value | High value |
|---|-----------|------------|
| Waiting time reduction of Us2.ai driven by the reduced echocardiography time: $\pm 50\%$ from base case | 8% | 25% |
| Longer echocardiography waiting times | NA | 36 weeks |

| | | |
|--|---------------|----------------|
| Proportion of acute episode: -20% from base case | 63% | NA |
| Technology costs, excluding hardware | Us2.ai: £7.50 | NA |
| Technology costs: high volume, low volume | Us2.ai: £6.80 | Us2.ai: £7.90 |
| All patients receive an echocardiogram during hospital stay | 0% | NA |
| Band 8a cardiac physiologist in echocardiography delivery | NA | Us2.ai: £44.73 |
| Proportion diagnosed in one stop diagnostic clinic | 20% | 40% |

Following the changes in time input for Us2.ai in base case, the scenario analyses are updated as follows:

- combining longer waiting times of 36 weeks and a lower proportion diagnosed in a one stop diagnostic clinic (20%)
- combining a lower waiting time reduction with Us2.ai (8%) and a lower proportion diagnosed in a one stop diagnostic clinic (20%)

Base case results show that Us2.ai may be more costly and more effective than standard care (cost difference £0.92, QALY difference 0.0005), giving an ICER of £1,674 per QALY, below the NICE willingness to pay (WTP) threshold of £20,000 per QALY (Table 4). This yields a potential increase of 15% in those meeting the target referral time, from 26% to 41%. The cost savings from shorter Us2.ai procedure time are not sufficient to fully offset the earlier treatment costs incurred when more patients receive an earlier diagnosis. This earlier treatment results in an increase in QALY gained.

Results from one-way sensitivity analyses suggest that the economic findings are sensitive to a number of inputs including the impact of waiting time reduction with Us2.ai, the proportion diagnosed in a one stop diagnostic clinic, the proportion of inpatients receiving TTE, and the staff delivering TTE.

When the impact of waiting time reduction for Us2.ai is lowered to 8%, a cost-saving finding results. Us2.ai incurs lower costs and generates higher QALYs than standard care, however the QALY gain is less than seen in the base case. This is because more patients remain in the “symptomatic” state for

longer than in the base case. They therefore experience lower utility for a longer period but without additional costs. Additionally, the increase in those meeting the target referral time reduces from 15% in the base case to 7%.

In the sensitivity analysis where all inpatients receive TTE during their hospital stay, none of those in the “acute episode” state move back to the “symptomatic, waiting list” state. This means there are fewer patients who can benefit from the earlier diagnosis with AI-assisted TTE. This results in lower incremental costs and incremental QALYs compared to base case, and is cost-saving compared to standard care.

When the proportion of patients diagnosed in a one stop diagnostic clinic is reduced to 20%, only 16% of patients would meet the target referral time with Us2.ai, yielding an increase of 6% compared to standard care. Additionally, in the scenario combining a lower proportion diagnosed in a one stop diagnostic clinic (20%) and a lower reduction in waiting time (8%), this results in a small increase of 3% in those meeting the target referral.

Similar to EchoConfidence findings, Us2.ai results appear to be relatively insensitive to the longer waiting time of 36 weeks, primarily due to the high proportion of patients diagnosed in a one stop diagnostic clinic. In the scenario where 20% of patients are diagnosed in a one stop diagnostic clinic and the waiting time is extended to 36 weeks, the increase in those that met the target referral time reduces from 15% in the base case to 6%.

The overall result appears to suggest that Us2.ai is potentially a cost-effective strategy, yielding an ICER below the NICE WTP threshold. These findings should be interpreted with caution given the significant uncertainty surrounding the current waiting time and the impact of Us2.ai on TTE workflow.

Table 4: Base case and sensitivity analyses: Us2.ai vs standard care

| | Total costs, Us2.ai | Total costs, Std Care | Total QALYs, Us2.ai | Total QALYs, Std Care | Incremental costs (£) | Incremental QALYs | ICER | Proportion meeting the target referral time, Us2.ai | Proportion meeting the target referral time, Std Care | Difference between Us2.ai and std care |
|---|---------------------|-----------------------|---------------------|-----------------------|-----------------------|-------------------|-------------|---|---|--|
| Base case | £3,234 | £3,233 | 0.4742 | 0.4736 | £0.92 | 0.0005 | 1,674 | 40.5% | 26.0% | 14.5% |
| % waiting time reduction: 8% | £3,233 | £3,233 | 0.4739 | 0.4736 | -£0.54 | 0.0003 | Cost saving | 33.3% | 26.0% | 7.3% |
| % waiting time reduction: 25% | £3,235 | £3,233 | 0.4744 | 0.4736 | £2.12 | 0.0008 | 2,684 | 45.2% | 26.0% | 19.2% |
| Echocardiography waiting time: 6 to 36 weeks | £3,234 | £3,233 | 0.4741 | 0.4736 | £0.86 | 0.0005 | 1,597 | 40.5% | 26.0% | 14.5% |
| % diagnosed in hospital: -20% from base case (63%) | £2,685 | £2,684 | 0.4835 | 0.4828 | £1.61 | 0.0007 | 2,338 | 40.5% | 26.0% | 14.5% |
| Technology costs, no hardware costs | £3,234 | £3,233 | 0.4742 | 0.4736 | £0.73 | 0.0005 | 1,324 | 40.5% | 26.0% | 14.5% |
| Technology costs, low volume | £3,234 | £3,233 | 0.4742 | 0.4736 | £1.11 | 0.0005 | 2,023 | 40.5% | 26.0% | 14.5% |
| Technology costs, high volume | £3,233 | £3,233 | 0.4742 | 0.4736 | £0.05 | 0.0005 | 93 | 40.5% | 26.0% | 14.5% |
| All inpatients receive TTE | £3,246 | £3,246 | 0.4763 | 0.4760 | -£0.61 | 0.0003 | Cost saving | 40.5% | 26.0% | 14.5% |
| Band 8a cardiac physiologist | £3,234 | £3,234 | 0.4742 | 0.4736 | -£0.18 | 0.0005 | Cost saving | 40.5% | 26.0% | 14.5% |
| % one stop diagnostic clinic: 20% | £3,228 | £3,226 | 0.4729 | 0.4722 | £1.68 | 0.0007 | 2,404 | 15.7% | 10.0% | 5.7% |
| % one stop diagnostic clinic: 60% | £3,235 | £3,234 | 0.4744 | 0.4738 | £0.86 | 0.0005 | 1,596 | 46.8% | 30.0% | 16.8% |
| Combining 36-week waiting time and 20% one stop diagnostic clinic | £3,224 | £3,222 | 0.4721 | 0.4713 | £2.06 | 0.0008 | 2,669 | 15.8% | 10.0% | 5.7% |
| Combining 8% waiting time reduction and 20% one stop diagnostic clinic | £3,226 | £3,226 | 0.4725 | 0.4722 | -£0.19 | 0.0003 | Cost saving | 12.8% | 10.0% | 2.8% |

Abbreviations: ICER: Incremental cost-effectiveness ratio; QALY: Quality adjusted life year.

5. Impact on conclusions of main report

The EAG does not consider the 2 additional clinical studies to have any significant impact on the conclusions of the main report, particularly as neither report data which inform the economic modelling. However, the EAG recognises the value in the addition of evidence from a UK NHS setting (Oo et al. 2024) and evidence of patient acceptability of AI-assisted echocardiography (Huang et al. 2024b), both of which were noted to be lacking in the main EAR.

The results of the updated economic model suggest that Us2.ai may be a cost-effective strategy. However, the evidence on time savings is of low quality and it is unlikely to be generalisable to the NHS setting. Further, uncertainties on waiting time change and other model inputs are considerable, and thus this limits the validity of the economic findings.

6. References

Hirata Y, Nomura Y, Saijo Y et al. (2024). Reducing echocardiographic examination time through routine use of fully automated software: a comparative study of measurement and report creation time. *Journal of Echocardiography*, 22(3), 162-170

Huang W, Ong W C, Wong M K F et al. (2024b). Applying the UTAUT2 framework to patients' attitudes toward healthcare task shifting with artificial intelligence. *BMC Health Serv Res*, 24(1), 455.

Oo M M, Gao C, Cole C et al. (2024). Artificial intelligence-assisted automated heart failure detection and classification from electronic health records. *ESC heart failure*, 11(5), 2769-2777.

Sakamoto A, Kagiyama N, Sato E et al. (2025). Artificial Intelligence-based Automated Echocardiographic Analysis and the Workflow of Sonographers: A randomized crossover trial. *medRxiv*, 2025.2008.2020.25334115

Health Tech Programme

Artificial Intelligence assisted Echocardiography to support diagnosis of heart failure: Early Value Assessment

External Assessment Report - Comments collated table:

Any confidential sections of the information provided should be underlined and highlighted. Please underline all confidential information, and separately highlight information that is '**commercial in confidence**' in blue and all that is '**academic in confidence**' in yellow

| Comment no. | Stakeholder | Page no. | Section no. | Comment | EAG Response |
|-------------|-------------|----------|-------------|---|--|
| 1 | MyCardium | General | | We had been asked whether we would be happy for the academic in confidence evidence trials to be made public, and we had agreed in writing to Simon Webster on 20 th November that we would be happy for this to be done. | Thank you for this clarification, we have removed the AIC highlighting that was in place for these trials throughout the EAR. |
| 2 | MyCardium | 14 | Table 1 | EchoConfidence has a DTAC in place | Thank you for informing us of this. This has been amended in Table 1. |
| 3 | MyCardium | 67 | 5.3 | Given the 'high bar' (better than human) set by the EchoConfidence team for their regulatory validation with regards to the measurements offered to clinicians, the comment at Section 5.3 ' <i>Potential over-reliance on AI measurements and automation resulting in inaccurate results</i> ' as an additional clinical risk seems an oversimplification as 'over reliance' on the AI generated specified measurements would appear to reduce the risk of inaccurate results. | This reflects input received from clinical experts, SCMs and professional organisations. No changes made. |
| 4 | MyCardium | 63 | 5.3 | <i>'The EAG believes there is a lack of evidence to determine whether any of the technologies have been adequately externally validated in a UK population, or a population with demographics close to that of UK population'.</i> For EchoConfidence, both the CE validation dataset and the heart failure diagnostic dataset for the | Thank you for this comment. The report has been amended in Section 5.3 and the executive summary as necessary to reflect this. |

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| | | | | FEATHER study were performed in NHS populations, with demographics reflecting the UK population (including for ethnicity, age, sex). The CE validation study was performed in a hospital setting, and the FEATHER study in community clinics. | |
| 5 | Us2.ai | ~pp. 12–20, 60–75 | Sections 1, 4–5 (overall description of technologies and clinical evidence) | Scope and positioning of Us2.ai – comprehensive echo platform, not just an HF “flag” Us2.ai is a CE-marked, FDA-cleared, vendor-neutral platform that automates the <i>entire</i> adult TTE study: view recognition, guideline-aligned measurements (LV/RV size and function, diastolic function, valves, strain, pulmonary hypertension, cardiomyopathies) and structured, editable report text.[1,6,19] The current EAR narrative largely frames Us2.ai as a disease-specific HF detection / triage tool, with most discussion centred on LVEF and HF pathways alone. This under-represents: (i) the comprehensive BSE-level dataset generated per study;[6] (ii) the end-to-end workflow impact (measurement + reporting time);[1,19] and (iii) the fact that HF is one key use case within a much broader, CE-marked scope. We respectfully request that the final report explicitly describes Us2.ai as a full echocardiography measurement, analysis and reporting platform already in clinical use, with HF diagnosis and management as an important subset of the overall functionality. | Thank you for this comment. The EAR has been updated. The technology is described as relevant to the scope of this assessment. AI-assisted TTE image acquisition is not in scope. |
| 6 | Us2.ai | ~pp. 80–87 | Section 6.2.3; Table 17; text on technology costs and staff time | Economic model – 1.3-minute time saving and “dominated” result In the Us2.ai base case, the model uses a 1.30-minute “procedure time” reduction and assumes no change in waiting times, leading to a “dominated” conclusion.[13,18] We would be grateful if NICE could confirm that this 1.3-minute estimate is | Thank you for the clarification on the time measured in Sakomoto et al. Given that only scan component (i.e. image acquisition) was measured in Sakomoto et al, the EAG agree that findings on measurement and reporting by Hirata et al would be more appropriate to be used as the base case. This is in line with the |

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| | | | (pp. 84–85, 88–90) | <p>derived solely from an examination-time difference (scan component only), and does <i>not</i> include measurement and report-creation time. This appears to be based on a Sakamoto-style “AI day vs non-AI day” comparison for one part of the workflow.[7,13] By contrast, Hirata et al. report ~70% reduction in combined measurement + reporting time (~524 seconds ≈ 8.7 minutes per comprehensive exam) when fully automated software is used in routine practice, with the greatest gains in high-complexity HF-type studies.[1] State-of-the-art reviews summarise similar reductions in acquisition, measurement and post-processing time across AI echo platforms, including Us2.ai.[19] We therefore request that: (i) the EAR explicitly states that 1.3 minutes represents only part of the workflow; and (ii) additional scenario analyses are presented using full workflow-time evidence (e.g. Hirata 2024) for examination + measurement + reporting, with corresponding effects on list capacity and waiting times modelled where appropriate.[1,7,19]</p> | <p>intended use of Us2.ai in the company RFI, where the technology is used to process acquired images, to analyse and provide measurements.</p> <p>The EAG has produced an addendum to the report to present the economic results for Us2.ai using the time savings in Hirata et al. (2024).</p> |
| 7 | Us2.ai | pp. 84–86, 101 | Section 6.2.3–6.2.4; Table 21–22 (Us2.ai vs standard care base case and sensitivity analyses) | <p>Waiting times, one-stop clinics and consistency with EchoConfidence assumptions For EchoConfidence, the model assumes a ~17% reduction in waiting time based on procedure-time savings, leading to cost savings and a higher proportion meeting the 6-week HF referral standard.[13] For Us2.ai, the base case assumes <i>no</i> waiting-time change, despite workflow evidence showing substantial reductions in measurement and reporting time and sensitivity analyses already demonstrating improved waiting-time performance when Hirata-style time savings are applied.[1,17] In Table 22, when Hirata et al. time reductions are used, Us2.ai becomes more effective and only slightly more costly (£1.40 incremental cost; ICER</p> | See EAG response to comment 6. |

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| | | | | ~£2,547 per QALY) with a 14.5% absolute increase in patients meeting the target referral time.[17] For consistency across technologies, we respectfully request that: (i) parallel waiting-time scenarios are presented for Us2.ai using published full-workflow savings (Hirata 2024 and state-of-the-art data);[1,19] and (ii) the report clearly explains how differences in waiting-time assumptions between EchoConfidence and Us2.ai drive divergent cost-effectiveness conclusions. | |
| 8 | Us2.ai | pp. 84–90 | Section 6.2.3–6.2.4; Table 17 (Technology cost parameters) | <p>Pricing model and cost inputs for Us2.ai (Table 17) – clarification requested The current text and Table 17 summarise Us2.ai as having volume-based pricing with additional installation/server costs and “routine support, clinical and IT support... at no additional fee”, but note that training costs are unclear.[4,6] To avoid misinterpretation, we ask that the EAR explicitly reflects our <i>current</i> NHS list pricing and support model:</p> <ul style="list-style-type: none"> • 1,000–10,000 exams per year: £7.50 per exam • 10,001–20,000 exams per year: £6.70 per exam • 20,001–50,000 exams per year: £5.90 per exam <p>Additional discounts for multi year commitment. Crucially, for NHS customers this per-scan subscription fully includes all clinical and technical support, all initial and refresher training, implementation/configuration support and routine software updates. There are no additional Us2.ai support contracts, per-ticket support fees or separate training/maintenance charges beyond the per-exam subscription. We therefore request that Table 17 and the accompanying narrative are updated so that: (i) Us2.ai is shown as a tiered per-exam subscription with training, support and upgrades included; and (ii) no extra Us2.ai-specific support/training cost lines are added on top of the per-scan subscription in the economic model. This will</p> | <p>Thank you for the new pricing structure. The EAG economic analyses have been updated with the new pricing. To align with the new base case, the costs of Us2.ai have been updated, including staff time. The EAG has produced an addendum to summarise the updated costs and resource use for Us2.ai.</p> <p>Thank you for the additional information on training and IT support. The new information has been added in the addendum. As no additional training and support costs are not included for Us2.ai in the EAG economic analyses, no changes made on the calculation related to these costs.</p> |

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| | | | | ensure commissioners see cost-effectiveness results aligned with the actual commercial offer they would encounter in the NHS. | |
| 9 | Us2.ai | pp. 88–91 | Section 6.2.3–6.2.4; Table 17 & Table 20 (resource use, staff time, sensitivity analyses) | <p>Staff time per scan and training / IT support entries for Us2.ai (Tables 17 and 20) Table 17 and related sensitivity analyses appear to use Us2.ai staff-time figures that are very close to baseline (non-AI) practice, with only a 1.3-minute reduction applied, and explicitly list “training” and “IT support” as separate recurrent resource components for Us2.ai.[6,13,18] This does not reflect the workflow with Us2.ai fully implemented, where the main time savings arise from automated measurements and report generation, not just the scan acquisition step.[1,19] Hirata et al. report ~70% reduction in combined measurement + reporting time (~8.7 minutes per comprehensive exam).[1] The JMA state-of-the-art review summarises multi-vendor data showing 30–77% reductions in acquisition, measurement and post-processing time with AI-enabled echo platforms.[19] We therefore ask that: (i) “staff time per scan” for Us2.ai in Table 17 / Table 20 is reviewed so that it represents the <i>post-implementation</i> Us2.ai workflow (e.g. using Hirata-style reductions), not baseline + 1.3 minutes; and (ii) manufacturer-provided training and ongoing clinical/technical support are not treated as separate recurring per-scan staff-time costs for Us2.ai, as these services are fully included within the subscription. Any one-off implementation effort should be handled consistently across all technologies.</p> | <p>See EAG response to comment 8 on staff time, training and IT support.</p> <p>The EAG explored the impact of Us2.ai combined time savings of 10 mins, which were derived from a 1.3-mins reduction in image acquisition, and an 8.7-mins reduction in measurement and reporting. This did not result in any further reduction in waiting time impact, as the additional 1.3 mins was not sufficient to allow one extra procedure to be added in a full clinic day. Further, this assessment aims to evaluate the plausible cost-effectiveness of each technology in scope, and thus the overall AI-echocardiography time reduction findings in the JMA review are not appropriate for use. No changes made.</p> |
| 10 | Us2.ai | ~pp. 40–45, 60–75 | Sections 4–5 (HF pathways, | HF screening, novice/community use and UK relevance The EAR notes that evidence for community and handheld HF echo is limited and of uncertain | Community settings are out of scope for this assessment. However, to address stakeholder appetite for exploring this potential use case, the EAG made a pragmatic decision in |

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| | | | system impact, community handheld echo) | <p>relevance, but does not fully reflect the published data on AI-supported novice and community use with Us2.ai.[2,3] • PANES-HF (Huang et al., Sci Rep 2024) – prospective handheld echo performed by a novice operator with AI analysis in symptomatic patients with suspected HF, showing high diagnostic accuracy for LVEF <50% (AUC ~0.88, good sensitivity/specificity) with exam times ~13 minutes and high proportions of interpretable studies.[2] • Lesotho survey (Firima et al., Hypertens Res 2024) – nurses and nurse-assistants with no prior echo experience performed focused handheld exams after a 2-day course; ~83% of uploaded image files were evaluable by AI and >80% of those were confirmed by cardiologists, with ~88% evaluable + confirmed overall.[3] These studies directly address concerns about operator skill-mix and support the feasibility of HF screening and community echo using AI-assisted workflows. We request more explicit acknowledgement of PANES-HF and the Lesotho data in sections discussing system benefits, community use and workforce extension, as they are aligned with NHS priorities on access and care closer to home.[2,3]</p> | <p>agreement with NICE to include studies from community settings based in the UK (see section 4.1). Therefore, the study by Firima et al. (2024) has been excluded as it is not UK-based (see Appendix F, study number 113).</p> <p>The PANES-HF study by Huang et al. (2024) has been included in the EAR. The diagnostic accuracy results quoted here are reported in Section 5.2.2. The exam time duration quoted here is in relation to the learning curve of novice operators, and there are no data reported on procedure time with AI versus without AI. Therefore, no changes have been made to the EAR.</p> |
| 11 | Us2.ai | ~pp. 45–55 | Sections 4–5 (HF epidemiology, diagnostic pathways, UK relevance) | <p>AI-driven HF detection from integrated data – Scottish EHR/echo work Oo et al. (ESC Heart Fail 2024) used linked EHR data, echocardiography (DICOM) and biomarkers in the Tayside/Fife population (~20% of Scotland) to develop deep-learning models that automatically detect and classify HF subtypes (HFrEF, HFmrEF, HFpEF).[4] The echo component relied on AI-interpreted images, illustrating how AI-assisted echo can be embedded in national-scale HF registries and surveillance systems. We propose that this study is explicitly cited in the sections on UK relevance and integration with HF data systems, as it</p> | <p>Thank you for highlighting this publication. This was incorrectly excluded by the EAG as 'wrong intervention'.</p> <p>The EAG has produced an addendum to the report to summarise the relevant results from this study.</p> |

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| | | | | shows that AI echo is already being used in Scottish HF classification and supports the concept of registry-based case finding and follow-up.[4] | |
| 12 | Us2.ai | ~pp. 55–65 | Sections 4–5, 8 (HF pathways, community echo, ongoing research) | <p>OPERA and SYMPHONY-HF – NHS-linked HF pathway redesign and trials The current EAR gives limited weight to OPERA and does not fully describe SYMPHONY-HF. We suggest both are made more prominent as NHS-linked exemplars of HF pathway redesign using AI-assisted echo.</p> <ul style="list-style-type: none"> • OPERA (Optimised Pathway for Early Identification of Heart Failure in the Community) – NHS programme led by NHS Greater Glasgow & Clyde and NHS Golden Jubilee with academic and industry partners.[8–16] Public reports indicate that, during the NHS Louisa Jordan pilot, waiting lists for HF diagnostics (including echo) were reduced from >12 months to ~6 weeks via a “one-stop” clinic model (ECG, echo, natriuretic peptides, other tests in a single visit).[8–11,15,16] OPERA is repeatedly cited in HF policy and innovation reports as an exemplar of digital and AI-enabled HF pathways reducing waiting times and improving resource use.[8–11] • SYMPHONY-HF (NCT05919342) – large, multinational, prospective randomised trial coordinated by NHS Greater Glasgow & Clyde, evaluating a screening strategy combining NT-proBNP with point-of-care, AI-enabled echo in primary care and home settings versus standard care.[18] We request that OPERA is treated as a central case study for HF pathway redesign and that SYMPHONY-HF is explicitly referenced as ongoing NHS-linked evidence generation in community and primary-care settings.[8–11,17,18] We would welcome guidance on which OPERA/SYMPHONY endpoints (e.g. time to diagnosis, 6-week target attainment, one-stop clinic utilisation, HF admissions, cost per detected case) | Both studies cited here are already included in the EAR. Relevant published evidence has already been included for the OPERA study (key study: Campbell et al., 2025). The EAG has added to section 8 to highlight the use of point-of-care AI-assisted handheld TTE in the SYMPHONY-HF trial to highlight its relevance to use in community and primary care settings in the UK. No further changes have been made to the EAR. |

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| | | | | NICE would find most useful for future model updates.[8–11,17,18] | |
| 13 | Us2.ai | ~pp. 55–65 | Sections 4–5 (acceptability, equity, implementation considerations) | <p>Patient acceptance, trust and task-shifting (UTAUT2)</p> <p>The UTAUT2 study by Huang et al. (BMC Health Serv Res 2024) assessed patients' attitudes to AI-supported healthcare task-shifting, including AI-guided echocardiography.[5] It found significant positive associations between performance expectancy, effort expectancy, facilitating conditions, social influence and hedonic motivation and patients' intention to accept AI-enabled task-shifting, with no evidence that age, gender or education had a negative moderating effect.[5] These findings suggest that, when AI-enabled echo pathways are implemented with appropriate communication and infrastructure, patients are broadly willing to accept AI-augmented diagnostics and task-shifting to non-physician staff – a key enabler for scaling HF diagnostics while maintaining quality. We suggest this evidence is explicitly referenced in the sections on acceptability and equity, and we would welcome guidance on what additional UK-specific patient-experience data (e.g. PROMs/PREMs or surveys in Us2.ai-enabled HF clinics, OPERA, SYMPHONY-HF) NICE would find most informative.[5,8–11,18]</p> | Thank you for highlighting this publication which was incorrectly excluded as having 'wrong outcomes'. The EAG has produced an addendum to summarise this study. |
| 14 | Us2.ai | ~pp. 95–102, 110–120 | Section 6.2.5; Table 22 (Us2.ai base case and sensitivity analyses); Section 8; | <p>Evidence maturity, uncertainties (Table 24) and comparative positioning</p> <p>The EAR notes that Us2.ai has more clinical studies than other technologies, but the conclusion sections and Table 24 do not fully reflect the breadth and maturity of the evidence base. In the public domain, Us2.ai uniquely has: a randomised clinical workflow study ("AI day vs non-AI day" throughput);[7] a dedicated workflow/time study showing</p> | <p>The EAG has referred to the size of the evidence base and presence of an RCT, which is unique to Us2.ai (see Executive Summary, Section 5.4).</p> <p>The colour coding for 'diagnostic performance' and 'validation against human measurements' has been upgraded to green to reflect the</p> |

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| | | | Table 24 (key uncertainties & implementation) | <p>~70% reduction in combined measurement + reporting time;[1] prospective novice/handheld HF screening data (PANES-HF);[2] nurse-led community implementation in Lesotho;[3] UK-linked HF subtype classification with AI-interpreted echo + EHR data (Oo et al.);[4] large studies in other diseases (valve disease, PH, amyloidosis) and high-volume labs;[2,4,19] and formal patient-acceptance data using UTAUT2.[5] We would welcome: (i) an explicit statement in the conclusions that Us2.ai currently has the largest and most diverse evidence base among the assessed technologies; and (ii) adjustments to Table 24 so that diagnostic and clinical validation for Us2.ai are rated to reflect this (e.g. “evidence largely sufficient; further data desirable” rather than implying major gaps), with implementation/support also marked green given the mature deployment history and included training/support model.[1–5,7–11,19]</p> | volume of evidence available, relative to other technologies. No other changes made. |
| 15 | Us2.ai | General (cross-cutting) | Sections 6–8 (modelling structure, comparators, scenarios, future research) | <p>Methodological clarifications and future research priorities To align future submissions with NICE expectations, we would welcome clarification on:</p> <ul style="list-style-type: none"> • Comparators and baseline workflows: Which specific echo workflows are assumed in the reference case (consultant-reported vs physiologist-reported vs mixed; existing semi-automated tools), and whether NICE would like separate scenarios for BSE-accredited hospital labs, community HF clinics and GP-led POCUS services. • Time and cost modelling: Whether NICE supports scenario analyses using published full-workflow time-savings (Hirata 2024; state-of-the-art review) instead of a single 1.3-minute estimate; and preferred approaches to modelling downstream effects such as increased slots per list, reduced backlogs and feasibility of one-stop HF clinics (as in OPERA).[1,7–11,19] • Outcome measures beyond EF: The level of detail | No response required from EAG. |

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| | | | | <p>NICE would like on measurement-level accuracy and reproducibility across the full TTE dataset (e.g. per-parameter bias/LOA, composite metrics, disease-specific performance), given HF guidelines rely on multiple parameters.[1–4,6,19] • Generalisability and case studies: Whether NICE wishes to see explicit modelling for named NHS configurations (e.g. OPERA-style clinics, district general hospitals, community HF pathways) and would value joint work with NHS sites to provide granular service-level data (capacity, backlog trajectories, DNA rates).[8–11,17,18] • Future NHS pilots and core datasets: For NHS pilots using Us2.ai (OPERA expansions, SYMPHONY-HF, TARTAN-HF and others), what minimum core dataset (clinical outcomes, resource use, time metrics, costs) and which sub-populations (older adults, deprived/rural groups, multimorbidity) NICE sees as highest priority for reducing decision uncertainty.[8–11,17,18] We would be pleased to work with NICE and NHS partners to design pilots and evaluations that directly address these priorities.</p> | |
| 16 | Us2.ai | pp. 88–92, 101 | Section 6.2.3–6.2.5; Tables 17, 20, 22 | <p>Summary comment – aligning EAR conclusions with the totality of evidence and real-world offer Overall, we greatly welcome NICE's work on AI-assisted echo for HF and appreciate the opportunity to contribute. Our key requests are that the final EAR: (i) recognises Us2.ai as a comprehensive, guideline-aligned TTE platform rather than a narrow HF flagging tool;[1,6,19] (ii) presents scenario analyses using full workflow-time data (Hirata 2024; state-of-the-art review) and consistent waiting-time assumptions across technologies;[1,7,19] (iii) gives appropriate weight to novice/community HF evidence (PANES-HF, Lesotho), UK-linked HF classification work (Oo et al.) and NHS pathway programmes (OPERA,</p> | No response from EAG. Comments have been individually addressed previously. |

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| | | | | SYMPHONY-HF);[2–4,8–11,17,18] (iv) reflects the strong patient-acceptance data (UTAUT2) when discussing equity and acceptability;[5] (v) accurately represents Us2.ai's pricing model as a tiered per-exam subscription with training, implementation and support fully included; and (vi) clearly describes the relative evidence maturity of Us2.ai versus other technologies.[1–5,7–11,17–19] We believe these adjustments will give decision-makers a more accurate view of the clinical, operational and economic value that Us2.ai can offer within NHS HF pathways. | |
| 17 | NHS England | | | No comments | No response. |
| 18 | Ultromics | | | No comments | No response. |
| 19 | Maria Paton (professional expert) | 18 | | Suggest switching point-of-care sentence and one-stop sentence so that one-stop sentence relates to full TTE rather than point-of-care ultrasound. | Thank you for this comment, this has been amended in the EAR. |
| 20 | | 19 | 3.2 | TTE is recommended by the British Society of Echocardiography to be 45minutes for a minimum dataset to 60minutes for a complex TTE. Notice the flow diagram states 30-60minutes | Thank you for this comment, this has been amended in the EAR. |
| 21 | | 90 | Table 17 | Could you please specify if costs are based on bottom/mid/top of banding for staff? | Thank you for the comment. Staff time in Table 17 has been costed based on Personal Social Services Research Unit (PSSRU), which is a standard cost reference in health economics. It provides average hourly staff cost by band, and thus it is not possible to specify the detail as suggested. No changes made. |
| 22 | | throughout | | Would it be possible to discuss the technologies in the same order in every section. I may have missed it, but felt there wasn't a specified reason for changing and feel this might provide more consistency when reading. | Thank you for your comment. In section 5.2.2, the order of discussing the technologies has now been swapped to mirror the order in section 5.2.1. With regard to the other |

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| | | | | | sections, the outcomes reported across the evidence base were not consistently reported for each technology, so it is not possible to provide any more consistency in the order of reporting. Therefore, no other changes have been made to other sections of the EAR. |

References for US2.ai comments

1. Hirata Y, Nomura Y, Saijo Y, et al. Reducing echocardiographic examination time through routine use of fully automated software. *J Echocardiogr*. 2024;22(3):162–170.
2. Huang W, Koh T, Tromp J, et al. Point-of-care artificial intelligence-enhanced novice echocardiography for screening heart failure in an ageing population (PANES-HF). *Sci Rep*. 2024;14(1):13503.
3. Firima E, Tente T, Cheng S, et al. Implementing focused echocardiography and AI-supported analysis in a population-based survey in Lesotho. *Hypertens Res*. 2024;47(3):708–719.
4. Oo YH, Zakeri R, McAllister DA, et al. Automated detection and classification of heart failure subtypes in the Scottish population using artificial intelligence. *ESC Heart Fail*. 2024;11(5):2769–2777.
5. Huang W, Ong W, Wong M, et al. Applying the UTAUT2 framework to patients' attitudes toward healthcare task shifting supported by artificial intelligence. *BMC Health Serv Res*. 2024;24:10861.
6. Wharton G, Steeds R, Allen J, et al. A minimum dataset for a standard adult transthoracic echocardiogram: a guideline protocol from the British Society of Echocardiography. *Echo Res Pract*. 2015;2(1):G9–G24.
7. Tromp J, Bauer D, Claggett BL, et al. A prospective validation of a deep learning-based automated workflow for interpretation of the echocardiogram. *Eur Heart J Cardiovasc Imaging*. 2022;23(Suppl 1):i4–i5.
8. NHS Golden Jubilee. Landmark partnership aims to improve Scotland's health. Case study describing the OPERA heart failure diagnostic pathway and reductions in waiting times.
9. AstraZeneca. Improving diagnosis pathways in heart failure – PROJECT OPERA case study.
10. Heart Failure Policy Network. *Innovation in heart failure: early diagnosis in community settings*. Policy report highlighting OPERA as an exemplar digital HF pathway.
11. West of Scotland Health Innovation. *Early Diagnostic Heart Failure (OPERA)*. Programme description and outcomes summary.
12. Lenus Health. AI analysis integrated by Lenus Health holds potential to speed detection of heart failure.
13. Lenus Health & Us2.ai. Lenus Health and Us2.ai join forces to automate the fight against heart disease.
14. Us2.ai. Heart failure detection faster with Us2.ai, results interchangeable with humans: the OPERA study.
15. University of Glasgow. AI analysis has potential to speed up detection of heart failure.
16. Health Tech News (HTN). Glasgow study highlights the potential for AI to support heart failure diagnosis.
17. ClinicalTrials.gov. NCT04724200 – *Optimised Pathway for Early Identification of Heart Failure in the Community (OPERA)*.

18. **ClinicalTrials.gov.** NCT05919342 – SYMPHONY-HF: Screening for early Heart Failure Diagnosis and Management in Primary Care or at HOme Using Natriuretic Peptides and EchocardiographY.
19. **Hirata Y, Kusunose K.** Artificial intelligence in echocardiography: state-of-the-art automated measurement techniques and clinical applications. *JMA J.* 2025;8(1):141–150.

Section B Economic model - Comments

| Stakeholder | Comment | Description of problem | Description of proposed amendment | Result of amended model or expected impact on the result (if applicable) | EAG response |
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