NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

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

Final scope

1. Introduction

The technologies included in this NICE HealthTech evaluation are adjunctive artificial intelligence (AI) technologies used in echocardiography to support the diagnosis of heart failure. The technologies are proposed to be assessed for early use. Early use assessments consider HealthTech products that could address a national NHS unmet need. It rapidly assesses products early in the lifecycle (but that have appropriate regulatory approval for use in the UK) or that have limited use in the NHS and need further evidence to support wider use. Technologies considered for early use can be conditionally recommended for use while further evidence is generated during the evidence generation period. This enables early access to promising new technologies for patients. Conditional recommendations are for a fixed period of time, and the technologies will be reassessed for routine use using the evidence generated. This document describes the context and the scope of the assessment. The methods and process for the assessment follow the NICE HealthTech programme manual.

2. The condition

Heart failure occurs when the heart is unable to pump blood around the body as well as it should. This may be because it does not contract strongly enough, it does not fill correctly, or there is a problem with the valves of the heart. Symptoms of heart failure include breathlessness (dyspnoea), coughing and wheezing, exercise intolerance, tiredness, feeling dizzy or lightheaded, and having swollen feet and ankles (NHS, 2025). Heart failure may develop gradually as people get older, or more suddenly following other conditions, such as myocardial infarction (a “heart attack”). It can severely limit a person’s day-to-day quality of life and activities and can lead to disability and early death.

Heart failure is common, with about a million people being affected in the UK and is becoming more prevalent as the population ages. In 2010, around 390,000 people were estimated to have heart failure in England; by 2024 this had increased to about 670,000 people (British Heart Foundation, 2025). There are around 200,000 new diagnoses of heart failure made each year, and in the year 2023/2024 there were at least 66,000 admissions to hospital directly related to heart failure. Of these, 87% involved the use of echocardiography in the diagnostic work up (National Cardiac Audit Programmes, 2025).

3. Current practice

3.1 Current guidelines on heart failure

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)

A full list of related NICE guidance and other guidelines and policy documents relevant to the NHS can be found in Appendix A of this document.

3.2 Presentation and referral

Heart failure most commonly presents acutely, with symptoms consistent with sudden cardiac decompensation (the heart not pumping enough blood for the body). This is usually secondary to acute causes such as acute coronary syndrome, arrhythmias, infection or sepsis, and uncontrolled hypertension. Acute heart failure usually presents in the emergency department (ED) in secondary care and requires immediate diagnostic work up and critical management. Up to 80% of heart failure diagnoses in England are made in hospital, despite 40% of people having symptoms that should have triggered an earlier assessment (British Heart Foundation, 2025). Heart failure may also develop more gradually due to cardiovascular and metabolic comorbidities such as hypertension and diabetes, where it may be suspected by a primary healthcare professional such as a general practitioner (GP). For both acute and chronic onset of heart failure, NICE guidelines (NG106 and CG187) recommend a blood test is done to test for levels of N-terminal pro-B-type natriuretic peptide (NT-proBNP), which is the preferred biomarker for the condition, although it is recognised in practice this does not always take place, and when it does take place, this is sometimes not prior to an echocardiogram. The thresholds for NT-proBNP are different depending on the suddenness of onset of symptoms due to reasons relating to pre-test probability, clinical context, and biological and kinetic considerations. However, in both acute and chronic heart failure, when the thresholds are exceeded, confirmatory diagnosis with echocardiography is required. Echocardiography will also determine the type and severity of heart failure and may help determine possible causes.

3.3 Echocardiography

Transthoracic echocardiography (TTE) is the primary diagnostic tool used for heart failure. Cardiac magnetic resonance imaging (MRI) may also be used for some complex cases or in the rare instances when echocardiography is inconclusive or contraindicated but it is not readily available in all centres. Echocardiography is usually performed in the NHS by a specialist cardiac physiologist, although the settings and type of technology used may vary depending on the referral pathway, with people in ED settings more likely to be diagnosed with point-of-care echocardiography devices (such as handheld or trolley systems) compared with those referred for elective diagnoses where static technologies will usually be used.

Diagnosis with echocardiography determines whether the heart failure is left or right sided, or biventricular. Additionally, heart failure may be categorised according to the ejection fraction (proportion of blood being pumped out of the left ventricle) into classes such as heart failure with preserved ejection fraction (HFpEF), heart failure with reduced ejection fraction (HFrEF), or the intermediate class of heart failure with mildly reduce ejection fraction (HFmrEF), which gives insight into the cause of the disorder and may help guide future treatment. Information from the echocardiograph is used in combination with clinical measurements such as the New York Heart Association (NYHA) scale to determine the overall severity of the heart failure, its impact on the person with heart failure, treatment pathways, and prognosis. Following on from diagnosis, some patients may require ongoing monitoring of their heart failure, for example if symptoms worsen, new signs develop, or there's a need to assess response to therapy or device performance (NICE NG106).

Cardiac physiologists are dedicated specialists, and their role cannot be done by sonographers from other specialities. Most TTEs are scheduled for around 45 minutes per person being assessed. The cardiac physiologist positions the person being assessed to acquire standard parasternal, apical, subcostal, and suprasternal views, and uses the probe to measure chamber dimensions, wall thickness, doppler velocities, and ejection. Data are collected as static or looped records known as Digital Imaging and Communications in Medicine (DICOM) files and annotated for review. DICOM images are uploaded and stored on the Picture Archiving and Communication System (PACS), and the entire imaging workflow is managed using the Radiology Information System (RIS). Once imaging is complete, the physiologist writes a fact-based report that directly addresses the referral question, flags any acute or life-threatening findings to on-call clinicians, and forwards the study to the referring team. Formal diagnosis is usually made by the consultant cardiologist or clinical referrer, who integrates the echocardiographic metrics with the referred individual's overall clinical context (British Society for Echocardiography, 2024).

4. Unmet need

There is a lengthy waiting list for echocardiography in England, with the total number having increased steadily since 2021, reaching 235,476 people in June 2025 (NHS England, 2025). Quality targets state that 90% of people referred should be investigated with echocardiography, but only around half of hospitals achieve this (National Cardiac Failure Audit, 2022). Whilst all people indicated for echocardiography for suspected heart failure should be seen within 6 weeks, data suggests only around a third of referral times meet this standard (NHS England, 2024).

Issues with staff shortages (recruitment and retention) and backlogs, partly caused by the COVID-19 pandemic, have negatively impacted access to echocardiography (British Society of Echocardiography, 2021). Delayed access may have harmful consequences for the downstream management of people with heart failure. Data from one study showed later diagnosis of heart failure was linked to higher mortality and morbidity rates as well as increased healthcare resource usage (REVOLUTION HF study, 2025). Late diagnosis of heart failure delays access to key therapies, including newer treatments such as sodium–glucose co-transporter-2 (SGLT2) inhibitors, which have been shown to be effective when used early in the course of heart failure (Lewinski, 2023).

The backlog in waiting lists for echocardiography has also put a large pressure on the echocardiography workforce, with warnings there are "unprecedented challenges as [specialist services] struggle to retain, recruit and train staff" (British Society of Echocardiography, 2023). Staff absenteeism and turnover may be made worse by musculoskeletal pain related to the awkward posture cardiac physiologists need to take during echocardiographic procedures (Solanki, 2015).

In summary, 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.

5. The technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and publicly available information. NICE has not carried out an independent evaluation of these descriptions.

AI technologies for echocardiography are software designed to aid interpretation and quantification of acquired echocardiography images, reduce operator dependency and variability, and enhance measurement accuracy and diagnostic consistency. This will potentially support clinicians in the early detection and ongoing management of heart failure. All the technologies in this assessment are designed to be adjunctive, not automative - they are intended to aid the operator, not replace them.

To work with NHS systems, the AI software must be compatible with and function on DICOM files and integrate with PACS and RIS. As a minimum, all adjunctive AI technologies offer automatic measurement of anatomical structures and physiological processes such as the pumping action of the heart. Some technologies also offer additional functionality, such as flagging and prioritising potential abnormalities, auto-generating reports, automatically entering images onto PACS, or providing feedback and consistency checks to improve operator performance.

Sections 5.1 to 5.4 and Table 1 describe the 4 included technologies. 3 of the included technologies were potentially available to the NHS at the time of writing this scope, with the fourth expecting to receive a CE mark in 2026.

5.1 EchoConfidence (MyCardium)

EchoConfidence (MyCardium AI) is a CE-marked, Class IIb AI-powered diagnostic aid to be used with echocardiography, indicated to support the assessment and monitoring of heart failure. The company states

EchoConfidence makes multiple validated measurements, including left and right ventricular volumes, ejection fraction, global longitudinal strain, diastolic parameters, atrial volumes, wall thicknesses, valve areas and doppler flows. These metrics are presented with normative reference ranges to help clinicians detect changes in cardiac function and make informed decisions about heart-failure diagnosis, therapy response and longitudinal follow-up.

All image data and AI analyses generated from EchoConfidence are run on local premises within the hospital's existing DICOM, PACS and RIS infrastructure, ensuring that no individuals' images leave the facility or feed back into the model. According to the company, this maintains full data sovereignty and aligns with General Data Protection Regulation (GDPR). Images are analysed post-examination on standard personal computer hardware or tablets, so the system does not allow for reinforcement training. The company states EchoConfidence integrates with any ultrasound system or tablet-based device already in use.

5.2 EchoGo Heart Failure (Ultromics)

EchoGo Heart Failure (Ultromics) is a diagnostic aid that is indicated for detecting heart failure with preserved ejection fraction (HFpEF). It is expected to receive a CE mark (Class IIa) in June 2026. According to the company, it highlights patterns of diastolic dysfunction that correlate with HFpEF, enabling clinicians to make difficult diagnoses. EchoGo automates measurements including left ventricular volumes, ejection fraction and global longitudinal strain.

The company states that all DICOM images captured from the echocardiograph are uploaded into the Microsoft Azure cloud, where encrypted processing complies with International Standards Organization (ISO) 27001 and GDPR standards. The results, including editable contours, quantified metrics and flagged findings, are returned within 20 to 30 minutes to the site's PACS and electronic health records (EHR), allowing sonographers and cardiologists to review, refine and integrate AI-generated reports without any onsite hardware or software installations. As analysis is done on post-examination DICOM files, the system does not allow for reinforcement training.

5.3 Ligence Heart (Ligence UAB)

Ligence Heart (Ligence, UAB) is a CE-marked (Class IIa) AI-powered echocardiography software designed to assist clinicians in the post-processing and interpretation of 2D TTE. It automatically detects, measures, and reports cardiac structural and functional parameters. The system is intended for adult patients in stable, non-critical conditions with sinus rhythm, and is contraindicated in cases involving significant anatomical distortion, arrhythmias, or congenital heart disease. The company claims Ligence Heart integrates with standard NHS imaging infrastructure, supporting DICOM formats and RIS feeds, and can be deployed either locally or via cloud servers. Its outputs are compatible with PACS and EHR systems, and reports must be reviewed and approved by certified clinicians.

The company claims Ligence Heart offers measurable workflow benefits, such as reduced procedure time and improved consistency in measurements. The technology does not guide image acquisition or use reinforcement learning.

5.4 Us2.v2 (US2.ai)

Us2.v2 is a CE-marked (Class IIb) AI-powered echocardiography copilot system designed to accelerate and standardise the detection of most forms of heart failure, independent of ejection fraction. The company states it fully automates multiple measurements including linear dimensions, volumes, systolic and diastolic function from B-mode, M-mode, and doppler modalities. The system also generates a complete, editable report with annotations and comparisons to international reference guidelines.

The company states all processing can run on premises, in the cloud or a hybrid environment, integrating with existing PACS via the server or other AI marketplaces. Images are automatically pulled from and results pushed back into the institution's DICOM and PACS, while deployment options include dedicated hardware, virtual machines or cloud instances. The turnaround time is claimed to average under 2 minutes per study. As analysis is done on post-examination DICOM files, the system does not currently allow for reinforcement training.

5.5 The place of technologies in the care pathway

The AI diagnostic aids would be used following the echocardiographic procedure during the diagnosis or monitoring of heart failure, with the AI analyses being performed on DICOM files. This might be in a dedicated echocardiographic suite for elective examinations, or at the point-of-care with portable echocardiographic equipment for emergency scenarios.

The use of these adjunctive AI technologies depends on the capture of high-quality images and cineloops. The AI technologies may not be appropriate in people in whom a suitable image cannot be captured, for instance people with class 3 obesity. The use of an AI technology may also not be suitable for people with cardiac conditions the AI technology has not been trained on. These may be technology specific, but may include people with congenital heart abnormalities, people who have experienced previous cardiac surgery or have implanted devices, or people with myocardial tumours. Heart failure is rare in children and adolescents (under the age of 18), the care pathway and clinical decision-making differ from adults, and these technologies are not designed for, and do not have regulatory approval, in these groups. Therefore, this evaluation is focussed on adults (aged over 18 years) only.

5.6 Innovative aspects

Using automation to aid cardiac physiologists in the diagnosis and characterisation of heart failure could potentially release time during appointments, 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.

6. Comparator

The comparator is the standard of care which is TTE used in the diagnosis of heart failure without AI. Whilst TTE is also commonly considered to be the reference standard in heart failure, a true gold standard for establishing diagnostic accuracy may include cardiac MRI, haemodynamic assessment, and expert adjudication, especially when determining the cause (phenotype) of left-sided heart failure.

7. Patient issues and preferences

The use of AI technologies in the diagnosis of illness in healthcare is a relatively new development and some people may have concerns about data privacy and security when AI is used to analyse their heart images, as well as transparency about how the data is used (Mooghali, 2024). Research has shown that people are generally less concerned about the implementation of automated measurements (e.g. chamber sizes, ejection fractions) that can be considered as objective "data chores" that simply speed up and standardise the scan compared with when AI offers a definitive diagnosis without a human in the loop (Chan, 2023). Such 'black-box' judgments trigger questions around who is accountable, how the decision was reached, and whether it has been tested on people 'like me'.

On the other hand, these concerns about AI may be balanced against anxieties about long waiting lists for echocardiography and the implications for delayed treatment and prognosis. Heart failure can follow an unpredictable course, with symptoms that can improve or suddenly worsen. This may cause considerable anxiety or depression in those affected (Marie Curie, 2022).

8. Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

Equality issues with the use of AI technologies in echocardiography may primarily arise due to a mismatch between the groups used to train the AI and groups that are present in NHS clinical practice. Heart failure is predominantly considered to be a disorder affecting older people and this group are most likely to benefit from the technology. But most models have been built on large, adult cohorts (likely to be predominantly white people) from North American and European centres. As such there may be potential issues with diagnostic accuracy or related outcomes in certain subgroups, for instance concerning:

- Age, as training data may under-represent very young or very old people, leading to inaccurate norms.
- Disability (e.g. people with amputated limbs or people with scoliosis), as acoustic windows may differ and AI may misread doppler signals.
- Pregnancy, as haemodynamic changes in pregnancy may alter echo metrics; and unvalidated models could misclassify these.
- Race and ethnicity, as ethnic differences in cardiac size and function could skew datasets to yield systematic errors.
- Sex, as there are differences in myocardial thickness and mixed-sex models may underperform in one sex.

9. Decision problem

The key decision questions for this assessment are:

- Does offering adjunctive AI technologies for use in echocardiography to aid the diagnosis or monitoring of heart failure have the potential to be a clinically and cost-effective use of NHS resources?

- What are the key gaps in the evidence base?

Table 2: Decision problem for the use of AI technologies in echocardiography in heart failure

Type of assessment	Early use

Population	Adults with suspected heart failure or who require ongoing monitoring for diagnosed heart failure. If the evidence allows, the following subgroups may be considered: • People with acute onset of symptoms presenting as an emergency. • People with chronic symptoms initially referred from primary care.
Interventions	AI technologies (adjunctive) for use in echocardiography to aid the diagnosis or monitoring of heart failure including: • EchoConfidence (MyCardium) • EchoGo Heart Failure (Ultromics) • Ligence (Ligence UAB) • Us2.v2 (Us2.ai)
Comparator	Echocardiography used in the diagnosis or monitoring of heart failure without adjunctive AI technologies
Setting	Secondary care, echocardiography suite Secondary care, emergency or ward setting
Outcomes (may include but are not limited to)	<u>Diagnostic and intermediate outcomes:</u> • Diagnostic accuracy outcomes including sensitivity, specificity, likelihood ratios, positive predictive value (PPV) and negative predictive value (NPV). • Diagnostic yield outcomes including false positive (FP) and false negative (FN) rates • Classification and stratification of heart failure by type and severity • Time to diagnosis • Time to initiation of treatment • Biomarker responses (e.g. changes to NT-proBNP) <u>Clinical outcomes:</u> • All-cause mortality • Cardiovascular mortality • Heart-failure hospitalisations • Composite of cardiovascular death or hospitalisation due to heart failure • NYHA class shifts • 6-minute walk test <u>Patient-reported outcomes:</u> • Kansas City Cardiomyopathy Questionnaire (KCCQ) score improvements • Minnesota Living with Heart Failure Questionnaire (MLHFQ) score improvements

	• Generic health-related quality of life (e.g. EQ-5D-3L, SF-36) • Service user acceptability, views, experience and satisfaction • Carer acceptability, views, experience and satisfaction <u>Costs and resource use:</u> • Cost of technology • Cost of treatment and management • Cost of training • Cost of down-stream diagnostic tests (e.g. cardiac MRI) • Staff time at different specialisms and levels of pay • Staff cost at different specialisms and levels of pay • Health service resource use in different settings • Cost of health service resource use in different settings

10. Other issues for consideration

10.1 Health economic modelling

This assessment covers the use of AI technologies as an adjunct to current echocardiographic methods for diagnosing heart failure. Whilst diagnostic accuracy may be a factor, as standard echocardiography is usually considered to be the reference test in the NHS, it is unlikely that the technologies will be able to demonstrate superiority in diagnostic accuracy. Rather, improvements to healthcare may be delivered through enhanced throughput leading to earlier diagnosis and resulting improved clinical care, and the conceptual model could reflect this.

Heart failure is a complicated clinical syndrome with several possible underlying causes. For instance, different patterns of ejection fraction imply different causes and may require different management strategies. The ability of each AI technology to discriminate these forms of heart failure could be considered in the model. Additionally, some AI technologies may be able to detect and diagnose other heart conditions, such as amyloidosis. The additional utility from this may not be directly applied in the model but could be noted in the overall considerations.

10.2 Setting, training and operator issues

Echocardiography is currently done almost exclusively in secondary care, either in bespoke cardiology units for elective referrals, or in emergency or bedside settings using a point-of-care device. Examinations are usually done by a skilled and qualified cardiac physiologist. In the future, the use of AI technologies in echocardiography may have the potential to allow for echocardiography to be used in community hub settings. Evidence on use in this setting, both clinically and in terms of healthcare resource use, should be considered in the assessment.

The impact of AI technologies on training and the potential for deskilling should be considered in the assessment.

10.3 Potential implementation issues

The scope of this assessment includes adjunctive AI technologies to be integrated into the pathway alongside echocardiography devices already used in the NHS. The AI technologies should integrate as seamlessly as possible with PACS and RIS and be user friendly so as not to cause barriers to use. The assessment should collate information from the technology providers on how the AI technologies integrate into current NHS infrastructure without causing disruption or place an extra burden on operators (Royal College of Radiologists 2021).

Data security is of paramount importance when deploying AI diagnostic algorithms in echocardiography, as these models often require access to both raw and processed patient data, introducing new challenges around confidentiality, integrity, and governance. Consideration should be made to issues such as data ownership and custodianship, risks of re-identification of depersonalised data, unauthorised access and system vulnerabilities, and patient consent and data sharing. Integral to these concerns will be where the data is stored and operated on, such as being localised or cloud based, and the security measures employed.

Procurement and pricing structures may differ between the technologies, with different pricing options such as one-off payment or subscription models. Any additional, bespoke company software may also be a potential barrier to implementation and may increase the risk of vendor lock-in. Additionally, the availability (and potential cost) of software updates should be considered.

NICE team

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Appendix A: Related Guidance

NICE Clinical Guidelines

Acute heart failure: diagnosis and management (2014) NICE guideline CG187. Last updated November 2021

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

Heart valve disease presenting in adults: investigation and management (2021) NICE guideline NG208

Acute coronary syndromes (2020) NICE guideline NG185

NICE Diagnostic Assessments

Heart failure algorithms for remote monitoring in people with cardiac implantable electronic devices (2024) NICE diagnostics guidance 61

NICE Quality Standards

Acute heart failure (2015) NICE quality standard 103

Chronic heart failure in adults (2011) NICE quality standard 9. Last updated January 2023

NICE Indicators

Heart failure: confirmation of diagnosis (2019) NICE indicator 192

Diabetes: admission rates (heart failure) (2016) NICE indicator 43. Last updated March 2022

Heart failure: mortality within 12 months of admission (2013) NICE indicator 8. Last updated November 2020

Heart failure: referral for cardiac rehabilitation (2012) NICE indicator 102. Last updated November 2020

NICE guidance in development

Chronic heart failure in adults: diagnosis and management. NICE guideline. Publication expected September 2025

Venoarterial extracorporeal membrane oxygenation (VA ECMO) for acute heart failure in adults. NICE interventional procedures guidance. Publication expected October 2025

Pulmonary artery pressure technologies for remote monitoring of chronic heart failure. NICE diagnostics guidance. Publication expected January 2026

British Society of Echocardiography

Protocols and guidelines published in Echo Research and Practice available at https://www.bsecho.org/Public/Public/Education/Guidelines.aspx (published between 2017 and 2019)

British Society of Echocardiography minimum dataset for performing TTE (Robinson, 2020)

Other relevant national policy documents

Department of Health (2016) NHS outcomes framework 2016 to 2017

NHS (2024) Evidence Brief: Echocardiography

GIRFT (2021) Cardiology: GIRFT programme national speciality report

Public Health England (2019) Health matters: preventing cardiovascular disease

Centre for Workforce Intelligence (2017) Securing the future workforce supply: Sonography workforce review

NHS England (2017) Heart failure with preserved ejection fraction: pathway support tool

NHS England (2023) Enhancing GP direct access to diagnostic tests for patients with suspected chronic obstructive pulmonary disease, asthma, or heart failure

NHS England (2023) Guidance note: virtual ward care for people with heart failure

NHS England (2023) Addressing palliative and end of life care needs for people living with heart failure: a revised framework for integrated care systems

NHS England (2024) Case study: improving access to diagnostic echocardiography

NHS England (2022) Transforming heart failure diagnosis pathway to improve the patient journey