NICE National Institute for Health and Care Excellence

Health Tech programme

HTE10067: Artificial intelligence (AI)-assisted echocardiography analysis and reporting to support the diagnosis and monitoring of heart failure

Draft Guidance Collated Comments

Theme 1: Comments on draft recommendations

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE response
1	Consultee 2 Pumping Marvellous Foundation	Are the recommendations sound and a suitable basis for guidance to the NHS?	We disagree with the recommendations. We don't think the committee has asked the appropriate question and doesn't fully understand the value of AI ECHO as an addition to the current standard of care. This appraisal should not be about clinical efficacy; this is not disputed. It should be about whether evidence is lacking, where it is, and setting the system up to go and find it and produce data. In its current format, it will not instil confidence in the development of a technology that has the ability to dramatically assist in the improvement of heart failure care. This attitude to AI in Cancer Diagnosis would never happen. AI ECHO is a digital health technology that is a digital support tool, specifically as an early diagnostic support tool. The system is failing. Heart failure realities are – • Drastic delays in diagnosis • Postcode lottery to access • Emergency admissions • Under optimised GDMT • Poor community monitoring • Poor health outcomes surrounding mortality, cost, and reduced QOL due to system friction and delays This all aligns with the NHS Long Term Plan's cardiovascular priorities, ICS prevention agendas, and overall reductions in health inequalities.	Thank you for your comment which NICE has considered. The Committee can only address the question outlined in the decision problem which was presented and discussed at the scoping workshop. Due to the limited evidence base and clinical expert input, the focus was on transthoracic echocardiography (TTE) procedure times as the main benefit of these technologies. The committee did not consider there was sufficient evidence to demonstrate that small time savings would result in more appointments and reduced waiting lists in practice. There was no evidence that the AI technologies would improve the postcode lottery to access. Community monitoring was not

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			We are trying to solve systemic NHS problems by using AI as an adjunct to standard care. AI ECHO is a scalable digital clinical support and early detection infrastructure for heart failure - designed to reduce time to diagnosis, leading to optimised therapy and preventable avoidable admissions. If set appropriately into the appropriate pathway • It reduces time to diagnosis • Increases GDMT • Reduces emergency admissions • Improves patient self-management • Supports primary care confidence • Supports NICE guidance NG106 This is about giving NHS teams the confidence to believe in the NICE Guidance and implement it.	in scope for this assessment. There is also a lack of evidence to demonstrate that the AI technologies would improve health outcomes.
2	Consultee 3 Individual	Are the recommendations sound and a suitable basis for guidance to the NHS?	No - the question to be addressed is not commensurate to the problem regarding diagnostic delays for HF in the NHS. Hence the recommendations are only applicable to analysis and reporting of echocardiograms (Aided by AI) for echocardiograms performed in secondary care for all conditions which require LV ejection fraction reporting as they neither have particular relevance for HF nor applicability in HF pathway based on the narrow remit/scope as HF diagnosis will be made by a HF specialist clinician who incorporates detailed clinical assessment of the patient with interpretation of blood tests results and echo report.	Thank you for your comment which NICE has considered. HealthTech guidance assesses specific technologies within a defined use case (it does not address issues throughout the heart failure pathway as it is not a clinical guideline). The population was discussed at the scoping workshop and outlined in the final scope. The decision problem focused on the secondary care setting and included echocardiography suites and emergency settings. Due to the limited evidence base

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				and clinical expert input, the EAG focused on TTE appointment/procedure times as the main benefit of these technologies. However, the committee did not consider there was sufficient evidence to demonstrate that small time savings would result in more appointments/reduced waiting lists in practice.

Theme 2: Equality considerations

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
3	Consultee 2 Pumping Marvellous Foundation	Are the recommendations sound and a suitable basis for guidance to the NHS?	Equity AI ECHO can reduce inequality • Reducing postcode variation • Supporting deprived populations • Supporting rural access • Improving early identification in underserved communities All the above aligns with CORE20PLUS5	Thank you for your comment which NICE has considered. Equality considerations were included in the final scope of this assessment and any evidence on equality was presented in the external assessment report (EAR). There was no evidence available to the committee which supports these suggested potential benefits of the AI technologies. Section 3.24 of the guidance has been amended to state that '*The committee was aware of equality issues around access to echocardiography services in the UK. But there was no evidence that the AI technologies could help address equality issues for different groups*'.
4	Consultee 2 Pumping Marvellous Foundation	Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination	There is no consideration to the equity of access and how AI Echo may reduce equality. The only area I could find was surrounding the population that the AI was trained on not being diverse. So due to it's exclusion it doesn't have the usual rigour I would expect for a NICE document.	Thank you for your comment which NICE has considered. Please see response to comment number 3.

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		against any group of people on the grounds of race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?		
5	Consultee 3 Individual	Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?	As detailed in the relevant section below, standard echo reporting template is only applicable for white Caucasian population (as acknowledged by BSE). Despite this and the available evidence for AI from acress the work, the seeming "lack of evidence in other ethnicities" has been cited to justify not recommending AI echo. This contrasts with NICE recommendation of HFrEF therapies such as ACEi, ARNI, MRA, SGLT2i despite under-representation of different ethnicities in trials, lack of sufficient representation of British population in these trials. There is evidence that currently delays in std echo disproportionately affect women, ethnic minorities and areas of socio-economic deprivation disproprtionately (https://openheart.bmj.com/content/10/2/e002373 https://www.theguardian.com/society/2025/jun/05/heart-disease-referral-less-likely-women-ethnic-minority-deprived-areas-england#:~:text=Dr%20Sonya%20Babu-Narayan,%20the%20clinical%20director%20at,and%20people%20living%20in%20more%20deprived%20communities).	Thank you for your comment which NICE has considered. Please see the response to comment number 6 regarding diverse population representation in the AI technologies training and validation data sets. This was noted by clinical experts as a key equality issue at both the scoping stage and during the committee meeting. Although this was not the only justification for the committee's recommendation, it was an important consideration. Therefore the committee concluded that more research is needed to understand how the AI technologies are trained and more transparency is needed

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			AI echo could provide a potential solution to this as demonstrated in the Everton project (Sankaranarayanan et al JACC Heart Fail. 2025 Apr;13(4):663-665). The recommendation from this NICE assessment could however limit use of AI and thereby exacerbate the existing inequalities in accessing timely echocardiography and thereby prognostic therapies	around the populations used for validation. The NICE technical team has considered the BMJ Open Heart publication (Rice et al. 2023). The stated aim of this study was to assess gender, ethnicity, and deprivation-based differences in provision of aortic valve replacement (AVR) in England for adults with aortic stenosis. While the study highlights that certain groups are less likely to receive AVR than others it does not appear to link any of its findings to delays in echocardiography. The research letter from JACC Heart Failure (Sankaranarayanan et al. 2025) focuses on the BEAT-HF tool in a community setting. These are both outside the scope of this assessment.
6	Consultee 3 Individual	3.22 3 Committee discussion	Among review of 25 notable randomized clinical trials in heart failure, outcomes by race were reported for <50% of the trials (48%) [Sullivan LT, Randolph T, Merrill P, et al. Representation of black patients in randomized clinical trials of heart failure with reduced ejection fraction. Am Heart J. March 2018;197:43–52.] Souuth Asian and Blck population African-American participants have been underrepresented in pivotal landmark trials that form foundational quad-therapy for HFrEF management in the modern era, often comprising less than 5.5% of the treatment group.	Thank you for your comment which NICE has considered. The EAG noted that it reported on ethnic representation in the studies and validation datasets as this was raised as a potential risk in the scoping period of this assessment. It was highlighted by clinical experts that if an AI algorithm is not exposed to

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			Despite this NICE has recommended ACE Inhibitors, ARNI, BETABLOCKER, sglt2I for the treatment of HFrEF based on efficancy demonstrated in clinical trials which have under-represented these ethnicities. Why does ethnic representation only become an issue for AI echo?	diverse datasets during its development or testing, this introduces a risk that it will not perform adequately in diverse populations.
7	Consultee 3 Individual	3.22 3 Committee discussion	The British Society of Echocardiography Reference Intervals and reporting template for standard echocardiography is largely based on Caucasian populations. However, the guidelines acknowledge that ethnic variations occur and that these standards may not be universally applicable to all and this is also backed up by evidence https://www.sciencedirect.com/science/article/pii/S1936878X15002193#:~:text=The%20URVs%20for%20left%20ventricular,differ%20across%20the%20age%20range. https://www.bsecho.org/common/Uploaded%20files/Education/Posters/BSE%20A1%20New%20Normal%20references%20Mar%2020.pdf If standard echo reporting reference ranges and analyses does not include correwction based on different ethnicities (South Asians, Black population), which should AI echo be judged by a higher yardstick especialkly when it has been studied in different populations across the world (-White Caucasian- UK studies OPERA, Cambell R etall 2025 EJHF, -American studies, -Asians -Huang, W., Koh, T., Tromp, J. et al. Point-of-care AI-enhanced novice echocardiography for screening heart failure (PANES-HF). Sci Rep 14, 13503 (2024). African population -Tromp J, Sarra C, Nidhal B, Mejdi BM, Zouari F, Hummel Y, Mzoughi K, Kraiem S, Fehri W, Gamra H, Lam CSP, Mebazaa A, Addad F. Nurse-led home-based	Thank you for your comment which NICE has considered. Please see response to comment number 6.

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			detection of cardiac dysfunction by ultrasound: results of the CUMIN pilot study. Eur Heart J Digit Health. 2023 Dec 12;5(2):163-169)	

Theme 3: Evidence and generalisability

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
8	Consultee 2 Pumping Marvellous Foundation	Has all of the relevant evidence been taken into account?	Point 1.1 - Not all the eveidence has been taken into account reference US2.ai's platform. The way it is worded implies that the evidence is a totality. It needs to be clearly split to indicate that where there is clinical efficacy this needs to be indicated but there is a deficiency in health economics and patient impact. https://pubmed.ncbi.nlm.nih.gov/40702880/ https://www.gla.ac.uk/news/archiveofnews/2023/august/headline_997199_en.html	Thank you for your comment which NICE has considered. The EAG noted that the study cited here was included in the EAR (Campbell et al. 2025 and Campbell et al. 2023). See section 4.2, table 3 of the EAR.
9	Consultee 2 Pumping Marvellous Foundation	3.8 / 3.10	We do not understand how the committee can come to the conclusion that there was limited generalisability to UK clinical practice in the NHS when it relates to US2.ai, which produced a research study based in Glasgow https://pubmed.ncbi.nlm.nih.gov/40702880/ The cohort in the Glasgow OPERA study comprised of 867 patients. Put this into perspective TA388 for Sacubitril Valsartan had a UK patient cohort of 242 patients. Therefore, the generalisability to the NHS for OPERA is more relevant than TA388, which had 8442 patients across 47 countries and 242 in its UK arm. Sacubitril Valsartan was never questioned; I was on the TA.	Thank you for your comment which NICE has considered. As noted in response to comment 10, the OPERA study was included by the EAG. However, its generalisability to the NHS was limited because in this study AI was not used as an adjunct and it compared AI assisted handheld TTE with manual cart-based TTE. This study did not feed into the economic analysis as the publications identified did not report on procedure time.
10	Consultee 2 Pumping Marvellous Foundation	3.12	Disagree – The OPERA study contained data that was generalisable to the NHS	Thank you for your comment which NICE has considered. The EAG noted that the OPERA study (Campbell et al. 2025 and Campbell et al. 2023) was

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				included. This study did not feed into the economic analysis as the publications identified did not report on procedure time.
11	Consultee 3 Individual	Has all of the relevant evidence been taken into account?	No - as outline below, evidence from UK studies OPERA, Campbell R 2025, EJHF, FEATHER, Everton project etc have not been given due importance	Thank you for your comment which NICE has considered. The EAG included all evidence that met the scope (including OPERA [Campbell et al. 2025], FEATHER). Excluded studies are listed in an appendix to the EAR with justification.
12	Consultee 3 Individual	1.1 What research is needed	The evidence reflect a wide range of populations studied for AI echo across the world. This statement contradicts NICE approval for treatments such as Entresto which was approved by NICE in 2016 even though the PARADIGM HF Trial only recruited 200 patients in the UK	Thank you for your comment which NICE has considered. As noted in the response to comment number 6, it was highlighted by clinical experts that if an AI algorithm is not exposed to diverse datasets during its development or testing, this introduces a risk that it will not perform adequately in diverse populations. The EAG noted that 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. See section 5.3.2 of the EAR.

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13	Consultee 3 Individual	1.1 Why the committee made these recommendations	All the evidence reviewed in the appraisal indicates clinical efficacy of AI assisted echo reporting - I am not clear at all where the uncertain regarding efficacy if (other than the populations studied)	Thank you for your comment which NICE has considered. The committee considered that the evidence on diagnostic performance when used as intended in UK clinical practice was uncertain. The committee also noted that there was no evidence that the appointment time saving would result in more people being seen or reduced waiting times. The EAG stated that it has reported the findings and limitations of the evidence. This is in the EAR.
14	Consultee 3 Individual	3.8 Evidence base	Inaccurate -Campbell et 2025, EJHF Study of 867 consencutive UK patients (>50% obese), patients with poor acoustic windows not excluded and despite this the study showed high diagnostic accuracy of AI echo analysis compared to std echo	Thank you for your comment which NICE has considered. The EAG stated that it recognises this study is based in the UK and included it as a key study in the analysis. Section 3.8 of the guidance has been updated to state that '*There were 2 UK studies, FEATHER study interim analysis for EchoConfidence, and Campbell et al. 2025 for Us2.ai. FEATHER was a retrospective study based in a community care setting. Campbell et al. was a prospective study which*

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				assessed Us2.ai assisted handheld TTE. But in this study the technology was not used as an adjunct and it did not report on TTE procedure times.'
15	Consultee 3 Individual	3.8 Evidence base	OPERA was a UK based study	Thank you for your comment which NICE has considered. Please see response to comment number 14.
16	Consultee 3 Individual	3.8 Evidence base	OPERA Study, Campbell R et al 2025 EJHF and FEATHER - both UK based	Thank you for your comment which NICE has considered. Please see response to comment number 14. The EAG stated that it recognises these studies are based in the UK and included these as key studies in the analysis..
17	Consultee 3 Individual	3.8 Evidence base	the vast majority of heart failure diagnosis is not for complex cases. Complex cases can be limitation for standard echocardiograms performed by physiologists as well (this could even be limitations such as obesity, severe COPD) thereby necessitating the use of cardiac MRI	Thank you for your comment which NICE has considered.
18	Consultee 3 Individual	3.12 Procedure time, waiting times and system impact	Why not? What makes performance and reporting of echocardiogram in the UK so different from the rest of the world? This needs to be backed up by tangible evidence as this has been repeated in severable parts of the document and again is very vague	Thank you for your comment which NICE has considered. The committee was aware of a range of clinical expert views where the general consensus was that echocardiography services and appointment

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				structures vary between countries, and evidence on procedure times or capacity from other countries may not be generalisable. The one prospective UK study (Campbell et al.) didn't report on procedure/waiting times. The FEATHER study did report on procedure time saving but this was in community care. So the UK based studies did not have evidence directly relevant to NHS secondary care settings. The committee's main concern in section 3.13 was whether any potential time saving resulted in shorter waiting times - there was no evidence for this.
19	Consultee 4 EKO Pte Ltd	3.8, 3.23 Generalisability & equality	**Generalisability standards should be applied consistently across technologies** The draft guidance raises generalisability concerns about studies conducted outside the UK. We acknowledge the importance of UK-based evidence and are actively generating it. However, we note that these concerns appear to be applied more stringently to Us2.ai than to other technologies. Us2.ai has: a published UK study (Campbell et al. 2025, 867 patients, Glasgow); active NHS deployment (OPERA, SYMPHONY-HF); multi-ethnic validation across Singapore, USA, Taiwan, Qatar, Scotland and Lesotho; and the only RCT in the evaluation (Sakamoto et al., 585 patients). EchoConfidence's primary evidence comes from the interim FEATHER study at a single UK community site, which is	Thank you for your comment which NICE has considered. As noted in the response to comment 14 the EAG stated that that it recognises the Campbell et al. 2025 study is based in the UK and included it as a key study in the analysis. The committee noted that there was UK cohort validation data for Echoconfidence. The EAG noted that there is a lack of evidence to determine whether EchoGo Heart Failure, US2.ai or Ligence

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			unpublished and not peer-reviewed. On equality (Section 3.23), Us2.ai's multi-ethnic validation data is directly relevant. Training and validation datasets span East Asian, South Asian, African, Middle Eastern and European populations. This breadth is important given the committee's concern about AI technologies trained on datasets that may not reflect NHS diversity. We request that: (i) generalisability caveats are applied consistently across all technologies; (ii) the guidance acknowledges Us2.ai's active NHS deployment and UK-based published evidence; and (iii) the multi-ethnic validation evidence is referenced in the equality considerations section.	Heart have been adequately externally validated in a UK population, or a population with demographics close to that of UK population. The EAG stated that the evidence has been presented accurately to the committee. The consultee states that there is multi-ethnic validation data for this technology but this was not provided so could not be assessed, nor was it raised at various factual accuracy opportunities during the guidance process (including at the committee meeting itself). It is not clear whether this evidence, if it were available, would reflect training in a population mix matching that of the UK.

Theme 4: Primary and community care settings

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
20	Consultee 1 Roche Diagnostics UK and Ireland	3.15 Community and primary care settings	Roche acknowledges that the scope of the decision problem for this guideline was limited to secondary care. We note that the committee papers state that the EAG focused on evidence from secondary care in line with the defined scope, while also incorporating evidence from primary care and community settings in the UK where available. However, Roche would like to emphasise that the implementation of AI technologies in echocardiography is likely to require changes across the entire clinical pathway, rather than within secondary care alone. As such, primary and community care settings are integral to the effective adoption and realisation of the benefits of these technologies and should be considered key components of the evaluation. The OPERA-HF pathway provides a clear example of how heart failure diagnosis can be delivered through an integrated model spanning primary, community, and secondary care, rather than being confined to secondary care settings. This illustrates that implementation of AI-enabled echocardiography is likely to require whole-pathway transformation, with meaningful implications for service delivery beyond secondary care alone, including enabling earlier assessment and more coordinated care between general practice and specialist services. Roche considers that future updates should explicitly assess whole-pathway impacts to fully capture the clinical and system-level value of these technologies.	Thank you for your comment which NICE has considered. The setting outlined in the decision problem for this current assessment was secondary care. Ongoing studies and evidence generation may present opportunities for future assessments in primary care or community care settings, if the heart failure diagnostic pathway changes.

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21	Consultee 2 Pumping Marvellous Foundation	3.14	This is out of scope. The Chair commented during meetings that the only scope was Acute, replay the recordings and check the initial agreed scope. You can't change the scope during appraisal. This is therefore not relevant.	Thank you for your comment which NICE has considered. The scope was not changed during the assessment. The potential use in community and primary care settings was investigated by the EAG and included in the committee discussion as this setting was highlighted by clinical experts as a potential future use, but it did not feature in decision making regarding the recommendation for the scoped population and use case.
22	Consultee 3 Individual	1.1 What research is needed	Use in primary care and community settings is outside the pre-determined scope of the appraisal	Thank you for your comment which NICE has considered. Please see response to comment number 21.
23	Consultee 3 Individual	1.1 What research is needed	settings outside of secondary care are outside the predtermined scope of this appraisal	Thank you for your comment which NICE has considered. Please see response to comment number 21.
24	Consultee 3 Individual	3.10 Diagnostic accuracy	Comments regarding community and primary care setting are outside the predefined scope of this assessment but there is a lot of evidence for this in terms of diagnostic efficacy and pathway benefits. Huang, W., Koh, T., Tromp, J., Chandramouli, C., Ewe, S. H., Ng, C. T., Lee, A. S. Y., Teo, L. L. Y., Hummel, Y., Huang, F., & Lam, C. S. P. (2024). Point-of-care AI-enhanced novice echocardiography for screening heart failure (PANES-HF). Scientific Reports,	Thank you for your comment which NICE has considered. Please see response to comment number 21.

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			14(1), 13503. 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), 708-713. 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. JACC: Heart Failure.	
25	Consultee 3 Individual	3.14 Community and primary care settings	If community use is outsifde the scope of this assessment, why is this statment being made?	Thank you for your comment which NICE has considered. Please see response to comment number 21.

Theme 5: Patient considerations

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
26	Consultee 2 Pumping Marvellous Foundation	3.6	Patients would definitely benefit from an earlier, more efficient diagnosis. In our community of thousands of patients, the time to diagnosis is the most talked about subject. It matters to patients. Getting this diagnosis can mean, in many cases, waiting more than 6 months until treatment is initiated, leaving patients vulnerable to worsening health outcomes and increased risk of spiralling health costs due to risk of unplanned admissions.	Thank you for your comment which NICE has considered. NICE acknowledges that an earlier diagnosis would be beneficial to patients, and committee heard views from experts regarding waiting times for echocardiography services in the NHS. However there was no evidence to demonstrate that the AI technologies would lead to an earlier diagnosis or reduce waiting times.

Theme 6: Current practice

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
27	Consultee 3 Individual	3.2 Current practice	in secondary care, echo is also done frequently by cardiology consultants and registrars	Thank you for your comment which NICE has considered. Section 3.2 of the guidance has been updated to state that '*In the NHS it is usually done in secondary care by a specialist cardiac physiologist, consultant cardiologist or cardiology specialist registrar*.'
28	Consultee 3 Individual	3.2 Current practice	Incomplete and misleading statment - clinical assessment includes detailed eliciting of symptoms, clinical examination followed by NTproBNP and then echo - diagnosis of HF is always made by a HF specialist who assesses all of these and not NTproBNP & echo in isolation. This document equates finding on echocardiography to making a diagnosis of heart failure which is a dangerous oversimplification - for example there can be paramters of diastolic dysfunction on echocardiogram but this does not equate to a diagnosis of HFpEF in the absence of symptoms+/- signs of HF along with raised NTproBNP	Thank you for your comment which NICE has considered. Section 3.2 of the guidance has been updated to state that '*For both acute and chronic onset of heart failure, initial clinical assessment includes a detailed history, clinical examination and a blood test for N-terminal pro-B-type natriuretic peptide (NT-proBNP*).'
29	Consultee 3 Individual	3.2 Current practice	This statment equates finding on echocardiography to making a diagnosis of heart failure which is a dangerous oversimplification - for example there can be paramters of diastolic dysfunction on echocardiogram but this does not equate to a diagnosis of HFpEF in the absence of symptoms+/- signs of HF along with raised NTproBNP. Likewise reduced ejection fraction can be in the context of sepsis, thyrotoxicosis, AF with fast ventricular rates and does not eqaute to a diagnosis of heart failure which is a	Thank you for your comment which NICE has considered. Please see response to comment number 28. Section 3.2 of the guidance has also been updated to state that *'A clinical diagnosis of heart failure is made by a heart failure*

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			clinical diagnosis made by HF specialists who include interpretation of echo along with the clinical context of the patient	*specialist based on interpretation of the TTE in addition to the clinical assessment*.'
30	Consultee 3 Individual	3.2 Current practice	again this is inaccurate as this is equating abnormalities in echo to a diagnosis of HF. Abnormalities in echo such as detailed in this sentence could be seen in AF with fast ventricular rate, thyrootoxicosis, sepsis and other conditions without these abnormalities automatically being equated to a diagnosis of heart failure	Thank you for your comment which NICE has considered. Please see response to comment number 29.
31	Consultee 3 Individual	3.2 Current practice	TTE is the primary diagnostic investigation. Clinical assessment by a HF specialist is the primary diagnostic tool for HF. The statments in this section constantly emphasise the use of echocardiography over and above clinical assessment by a HF specialist to diagnose HF. HF is always a clinical diagnosis and is aided by echocardiography. Both in the acute and chronic settings, HF is frequently diagnosed clinically before NTproBNP or echocardiogram results become available	Thank you for your comment which NICE has considered. Please see response to comment number 29.
32	Consultee 3 Individual	3.2 Current practice	This is inaccurate as has been pointed out before. Determination of left or right sided heart failure is a clinical diagnosis (symptoms of orthopnoea PND, lung crepitations indicates left sided HF , peripheral oedema, raised JVP indicated right sided HF) that does not rely on echocardiography	Thank you for your comment which NICE has considered. Section 3.2 of the guidance has also been updated to remove the text '*Diagnosis with TTE determines whether the heart failure is left or right sided*'.
33	Consultee 3 Individual	3.2 Current practice	heart failure specialist	Thank you for your comment which NICE has considered. Please see response to comment number 29.

Theme 7: Diagnostic accuracy

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
34	Consultee 3 Individual	1.1 What research is needed	what is the comparable diagnostic accuracy and performance when echocardiograms with carying levels of experience are performed in several community diagnostic hubs. There isa huge degree of inter and intra-observer variability when standard echocardiograms are performed by different operators even of good experience and AI echocardiography reduces this variability based on the evidence studied in this appraisal	Thank you for your comment which NICE has considered. The committee considered the potential variability in TTE's performed by different operators. Clinical experts highlighted that in community or primary care, use by healthcare professionals such as GPs, community nurses and pharmacists would affect diagnostic performance. So, they said that the available evidence would not be generalisable to these potential future use cases. See section 3.15 of the guidance.
35	Consultee 3 Individual	3.9 Diagnostic accuracy	i.e, indicating diagnostic efficacy	Thank you for your comment which NICE has considered.
36	Consultee 3 Individual	3.9 Diagnostic accuracy	Is there a need to demonstrate superiority especially as reporting time is reduced (diagnostic efficacy maintained) and time saved - thereby translating into improved HF diagnostic pathway and thereby greater number of patients having echo and thus leading to improved HF patient outcomes and reduced waiting times	Thank you for your comment which NICE has considered. The wording in section 3.10 is not intended to suggest that the AI technologies need to show superiority to standard TTE. The wording reflects the committee's consideration that it understood that it was not possible to show that the AI technologies were superior to standard TTE, only

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				equivalent.
37	Consultee 3 Individual	3.10 Diagnostic accuracy	As mentioned before interpration of echo to aid diagnsis of HF in the UK is similar to that in the rest of the world	Thank you for your comment which NICE has considered.
38	Consultee 3 Individual	3.25 Evidence gaps	diagnostic accuracy is equivalent to standard echo for heart failure as stated in document above	Thank you for your comment which NICE has considered. Please see response to comment number 52.

Theme 8: Procedure and waiting times

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
39	Consultee 2 Pumping Marvellous Foundation	3.19	I think it's important you read these two links as to why the TTE statement in the section is lacking certainty. Please read our BEAT 2 TREAT section https://pumpingmarvellous.org/wp-content/uploads/2025/11/Pumping-Marvellous-BEAT-Playbook-A4.pdf BEAT to TREAT HUB in action in a Scottish Health Board https://www.nhsaaa.net/patients-praise-new-sixty-minute-beat-to-treat-pathway/ Patient commentary on the impact of the BEAT to TREAT pathway incorporating AI ECHO https://www.youtube.com/watch?v=huQM6DOok_w&t=3s	Thank you for your comment which NICE has considered.
40	Consultee 3 Individual	1.1 What research is needed	The OPERA Study reported on the significant benefits through use of AI echo which led to reduction of echo waits from 9 months to 4 weeks.	Thank you for your comment which NICE has considered. The EAG noted that it included the OPERA study in the assessment (Campbell et al. 2025 and Campbell et al. 2023). It also noted that these publications did not include evidence of a reduction in wait for echocardiography. The generalisability of this study to the NHS was limited because AI was not used as an adjunct. The EAG did not identify any other evidence related to this study, and no additional information was provided to the EAG by the company or stakeholders during

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
				the assessment period. See response to comment 50 for further information.
41	Consultee 3 Individual	1.1 Why the committee made these recommendations	Surely this is the most logical extrapolation for use of time saved. What else could the time saved be used for other than seeing and scanning more patients?	Thank you for your comment which NICE has considered. Clinical experts thought that it was unclear whether time savings from studies would translate into routine clinical practice in the NHS, as time savings reported in the studies did not appear to be sufficient to accumulate enough time to enable additional appointments. The committee concluded that it is uncertain whether reported time savings would translate into additional appointments and reduced waiting times. See section 3.13 of the guidance.
42	Consultee 3 Individual	1.1 Why the committee made these recommendations	The OPERA study and the significant benefits to the healtth care system (in terms of reduction in echo waits from 9 months to 4 weeks) and patient benefits are surely applicable to the UK?	Thank you for your comment which NICE has considered. Please see responses to comments 40 and 50.
43	Consultee 3 Individual	1.1 Why the committee made these recommendations	The OPERA study and the significant benefits to the healtth care system (in terms of reduction in echo waits from 9 months to 4 weeks) and patient benefits are surely applicable to the UK?	Thank you for your comment which NICE has considered. Please see responses to comments 40 and 50.
44	Consultee 3 Individual	3.10 Diagnostic accuracy	Yes but currently the prolonged waitfor std echo of several months is leading to patient hard (hospitalisations and deaths) - here we have a potential solution which is	Thank you for your comment which NICE has considered.

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
			equivalent to standrd echo and can also help save time, therebyu allowing more patients to undergo echo	Please see response to comment number 41.
45	Consultee 3 Individual	3.11 Procedure time, waiting times and system impact	70% reduction in measurement and report creation time compared to manual methods Hirata, Y., Nomura, Y., Saijo, Y., Sata, M., & Kusunose, K. (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, 162-170.	Thank you for your comment which NICE has considered. The EAG highlighted that this study was included in the analysis. In the updated base case analysis for Us2.ai, the Hirata et al. 2024 study is used. See section 4 of the addendum. This was considered by the committee. See section 3.20 of the guidance.
46	Consultee 3 Individual	3.12 Procedure time, waiting times and system impact	this conclusion is vague - what else would saved time translate into?	Thank you for your comment which NICE has considered. Please see response to comment number 41. The view of multiple clinical experts was that the time savings reported in the studies would not be sufficient to accumulate enough time to enable additional appointments.
47	Consultee 3 Individual	3.13 Procedure time, waiting times and system impact	some instances need not influence conclusions regarding the vast majority of cases. As mentioned above, in some instances, physiologist standard echocardiograms are also sub-optimal and do not provide ejection fraction, necessitating contrast echo or CMR	Thank you for your comment which NICE has considered. The clinical expert considerations outlined in section 3.14 are not intended to influence the overall conclusions for the majority of cases. However clinical experts

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
				considered that this was a potential issue that could potentially lead to harm and delays. These considerations were a factor in the committee's decision to recommend further research to address evidence gaps on time taken for human review of AI, healthcare professional-reported ease of use and acceptability and any harm caused by using the technologies.
48	Consultee 3 Individual	3.17 Conceptual model structure and assumptions	definitely reduce hospitalisation (not potentially)	Thank you for your comment which NICE has considered. Section 3.18 of the guidance has been amended to state: *'But it noted that if the AI technologies did reduce waiting times, then this could reduce hospitalisation'*.
49	Consultee 3 Individual	3.19 TTE appointment time	UK based OPERA Study (825 patients) Glasgow showed reduction of echo waits from 9 months to 4 weeks	Thank you for your comment which NICE has considered. Please see responses to comments 40 and 50.
50	Consultee 3 Individual (*comment provided after the consultation period as a response to a clarification request*		Please find below all the publications linked to OPERA which showed that echocardiography reporting time reduced from 30 minutes to around 1 minute through use of AI and also that waiting times reduced from 12 months to <6 weeks. https://www.gla.ac.uk/news/archiveofnews/2023/august/headline_997199_en.html	Thank you for your comment which NICE has considered. Please see response to comment number 40. The EAG reviewed the evidence

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
	from the NICE technical team in relation information provided in comment 40).		https://www.woshealthinnovation.scot/latest-updates/opera-heart-failure-innovation-shortlisted-for-top-award/ https://lenushealth.com/news/ai-analysis-integrated-by-lenus-health-holds-potential-to-speed-detection-of-heart-failure/ https://www.parliament.scot/-/media/files/cross-party-groups/heart-and-circulatory-diseases/agenda-for-the-meeting-on-26-september-2023.pdf https://www.gla.ac.uk/news/archiveofnews/2023/august/headline_997199_en.html https://touchcardio.com/heart-failure/conference-hub/ross-campbell-esc-congress-2023-amsterdam-handheld-echocardiography/'	in the links provided and concluded that this data is not reported in enough detail, or in a suitable format, for it to be included in the analysis. This was discussed and agreed with NICE as well as the committee chair. The NICE technical team notes that the evidence provided is not from a peer reviewed article or abstract.

Theme 9: Economic model

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
51	Consultee 2 Pumping Marvellous Foundation	3.17	Most patients do not enter the care pathway through primary care; otherwise, the figure of 79% produced by NICOR's annual Heart Failure audit would be inaccurate. This figure of approx. 80% has been consistent for many years.	Thank you for your comment which NICE has considered. The EAG stated that patients entering the care pathway via primary and secondary care were considered in the EAG economic model, where 79% of patients who had acute episodes would enter the model through hospitalisation.
52	Consultee 3 Individual	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	No - as the NICE document states equivalence of diagnostic efficacy of AI with standard echo in one section based on the wide breadth of evidence and yet goes on to question the same in the conclusion and recommendation. The cost-effectiveness data does not include the impact of reduction in preventable hospitalisations (50% of 80% people diagnosed during emergency hospitalisations) with timely access to echo. The premise of this assessment should be to address the issue of long waits for echo leading do patient harm (hospitalisations and death). Yet the cost-effectiveness from 2 providers and the reduction in reporting time has been seemingly ignored in the recommendation	Thank you for your comment which NICE has considered. The EAG stated that diagnostic accuracy is assumed to be unchanged with the addition of AI in the economic model because it is used as an adjunct and therefore checked by a human operator. The evidence on diagnostic accuracy reported is largely in the context of these technologies being used alone. The EAG noted that it performed exploratory economic modelling using the data available and these findings were presented accurately to the committee.

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
53	Consultee 3 Individual	3.17 Conceptual model structure and assumptions	This is a wrong presumption to make as 79% entering in an acute setting is mainly due to severe delays in having echo in an elective community setting. There how does this assessment look to address delays by comparing to the suboptimal status quo?	Thank you for your comment which NICE has considered. The EAG stated that the model was structured to reflect the available evidence where 79% patients were diagnosed during hospitalisation. Given the limited data, it was impossible to split this figure into patients already on waiting list and those who are not. The EAG sensitivity analysis on the proportion of acute episodes (i.e. varying the 79% figure) showed minimal impact on the cost-effectiveness results. The EAG acknowledges the economic model is limited by the available data on current waiting time and disease progression while waiting. The EAG highlighted that the economic analysis should be considered as exploratory.
54	Consultee 3 Individual	3.17 Conceptual model structure and assumptions	most people should enter the pathway from primary care accoring to the British Society of HF aims of diagnosis people in the community , thereby avoiding delays and emergency diagnosis as well as the government's 10 year plan aim of shifting diagnosis from hospital to communitty	Thank you for your comment which NICE has considered. The EAG stated that the model was populated using the available evidence to reflect the current state. Two entry points (primary and secondary care) were considered in the model. However, the EAG explained

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
				that given the limited data, the EAG model was simplified and populated using the available evidence.
55	Consultee 3 Individual	3.19 TTE appointment time	this is not accurate - the extra 2 patients who undergo echo based on the time saving would have referral waiting times reduced	Thank you for your comment which NICE has considered. The EAG explained that the impact of 2 additional patients undergoing TTE was modelled as a reduction in the waiting time from referral to echocardiography. There was no change modelled in the time between TTE to specialist clinical review. The EAG explained that this was a conservative approach taken to reduce uncertainty in the model, as there was no available evidence for this parameter.
56	Consultee 3 Individual	3.20 Plausibility of cost effectiveness	Cost-effectiveness estimates are not thorough enough as they do not include the cost of hospitalisations due to delays in timely access to diagnostic echo and how this can be addressed through the proposed solution of AI echo. 70-80% diagnosis of HF made during emergency hospitlisation and 50% of these can be avoded through timely access to diagnostic such as echo	Thank you for your comment which NICE has considered. The EAG explained that hospitalisation during the waiting period was incorporated in the model. However, it noted that this estimate was derived from patients receiving heart failure treatment, which may not be reflective of the population in this assessment (patients with suspected heart failure or those

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
				requiring ongoing monitoring). The EAG stated that it acknowledges this limitation, but it is important to note that there is generally a lack of data to support more robust and comprehensive modelling.
57	Consultee 4 EKO Pte Ltd	Has all of the relevant evidence been taken into account?	The committee has considered a substantial body of evidence. However, the weighting given to different studies does not consistently reflect their relevance to Us2.ai's intended use. Specifically, the Hirata et al. (2024) data on measurement and reporting time — which the EAG agreed is more appropriate than the Sakamoto acquisition-time data — should be the primary base case, not a sensitivity analysis. Additionally, Us2.ai's multi-ethnic validation data, active NHS deployment (OPERA, SYMPHONY-HF), and formal patient-acceptance evidence (Huang et al., UTAUT2) deserve greater prominence.	Thank you for your comment which NICE has considered. The EAG highlighted that the addendum states that the findings from Hirata et al. (2024) were more appropriate, and so the data were used in the Us2.ai base case economic analysis. See the revised base case for Us2.ai in section 4 of the addendum. Results using Hirata et al. (2024) were presented and discussed in the committee meeting, not the ones from Sakomoto et al. (2025). NICE notes that multi-ethnic validation data for Us2.ai was not available for the assessment and therefore could not be considered.
58	Consultee 4 EKO Pte Ltd	Are the summaries of clinical and cost effectiveness reasonable interpretations	The economic modelling framework is sound and the Markov model structure is appropriate. However, the base-case inputs for Us2.ai do not reflect the EAG's own updated analysis. When the Hirata data is used — as the EAG recommended — Us2.ai achieves identical cost-effectiveness to EchoConfidence (17% waiting-time	Thank you for your comment which NICE has considered. The EAG noted the limitations of the current evidence base related to time saving, and has

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
		of the evidence?	reduction, ICER £1,674/QALY). The current presentation, which uses acquisition-only time data for Us2.ai while using full workflow data for EchoConfidence, produces an asymmetric comparison that does not reflect either technology's real-world impact.	reported these in the EAR: (i) the unclear, not peer-reviewed analysis-time reduction reported for EchoConfidence, as well as other limitations on settings and operator types, and (ii) results from Hirata et al. (2024) are subjected to limitations including small sample size, generalisability, setting and operator type. The EAG further noted the time reduction for Us2.ai base case analysis was derived from Hirata et al. (2024), which reflects the reduced time on measurement and report creation, rather than image acquisition time only. See the revised base case for Us2.ai in section 4 of the addendum.
59	Consultee 4 EKO Pte Ltd	3.11, 3.19, 3.21 Procedure time & economic base case	**Asymmetric treatment of procedure-time evidence** The 1.3-minute time saving attributed to Us2.ai in the original base case derives from Sakamoto et al., which measured only the image-acquisition (scanning) component of the TTE workflow. The EAG confirmed this in their stakeholder response, stating that "only the scan component (i.e. image acquisition) was measured in Sakamoto et al." The EAG further agreed that "findings on measurement and reporting by Hirata et al. would be more appropriate to be used as the base case." Us2.ai's intended use — as stated in the CE marking and company RFI — is to process acquired images, provide automated measurements across 68+ parameters, and	Thank you for your comment which NICE has considered. Please see response to comment 58. The EAG provided a revised base case for Us2.ai based on the Hirata et al. 2024 study. This is outlined in the addendum (section 4) and was presented to the committee. The 1.3 minute figure reported in the Sakamoto et al. study is not

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
			generate structured reports. The primary time savings therefore arise in the measurement and reporting phase, not in scanning. Hirata et al. demonstrated a 524-second (8.7-minute) reduction in combined measurement and report-creation time, representing a 70% workflow improvement. In the EAG's addendum, when Hirata data is applied, Us2.ai achieves a 17% waiting-time reduction — identical to EchoConfidence — with an ICER of £1,674 per QALY gained, well below the £20,000 threshold. We note that EchoConfidence's base case uses interim FEATHER data from a single UK community site (unpublished, not peer-reviewed), while Hirata is a published peer-reviewed study. The committee acknowledged (Section 3.12) that evidence for both technologies is "limited and not generalisable" — yet only Us2.ai's base case was penalised. **We respectfully request that:** (i) The guidance explicitly states that the 1.3-minute figure captures only image acquisition, not the technology's primary intended use; (ii) The Hirata-based scenario (8.7-minute measurement + reporting saving) is presented as the primary base case for Us2.ai, consistent with the EAG's own recommendation; (iii) The economic results are presented on a like-for-like basis, noting that both technologies achieve comparable cost-effectiveness when equivalent evidence standards are applied.	presented in the guidance document. Section 3.12 states that '*The committee noted that Hirata et al. reported an overall time saving of 524 seconds, similar to that reported for EchoConfidence in FEATHER*'. The cost effectiveness results for Us2.ai presented in section 3.22 are based on the revised base case using the Hirata et al. 2024 time saving.

Theme 10: Further research needed

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
60	Consultee 2 Pumping Marvellous Foundation	Are the recommendations sound and a suitable basis for guidance to the NHS?	If there is a need to generate further evidence surrounding the Health Economics Questions that need asking are • What is the cost per patient? • What admissions can be avoided? • What is the estimated QALY gain? • What is the break-even timeline? • Does it reduce system cost?	Thank you for your comment which NICE has considered. The committee considered what further research was needed and these considerations are presented in section 1.1 of the guidance.
61	Consultee 3 Individual	3.25 Evidence gaps	The issue of verying staff levels is more of a problem for standard echocardiography as real world experience is that junior echocardiographers may acquire images but this requires interpretation by more experienced echocardiographers, thereby delaying the report generation. This is less likely to be an issue for AI echo - where AI echo reporting can reduce this delay in generating report	Thank you for your comment which NICE has considered. The committee considered the reported evidence gaps and lack of real-world evidence. It recommended that further research was needed to understand the diagnostic performance of the AI technologies when used by operators with varying levels of experience outside of secondary care. See section 1.1 in the guidance.

Theme 11: Ongoing studies

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
62	Consultee 1 Roche Diagnostics UK and Ireland	3.26 Ongoing studies	Roche welcomes the committee's recognition of the ongoing studies, including TARTAN-HF and SYMPHONY-HF, evaluating AI-assisted echocardiography as part of screening strategies. We wish to emphasise that these trials are expected to generate important additional evidence which may be relevant to the current uncertainties identified by the committee. Roche therefore considers that the outcomes of these studies should be formally taken into account once available, and that the technologies should be reassessed in light of the new evidence to ensure that recommendations reflect the most up-to-date data base.	Thank you for your comment which NICE has considered. NICE encourages research which addresses the evidence gaps identified by the committee.
63	Consultee 4 EKO Pte Ltd	3.26, 1.1 Ongoing studies & recommendations	**Ongoing NHS research directly addresses identified evidence gaps** We welcome the committee's acknowledgement of ongoing studies (Section 3.26). We wish to highlight that OPERA and SYMPHONY-HF are specifically designed to address the evidence gaps identified in Section 3.25: OPERA (Glasgow): Active NHS deployment generating real-world UK data on procedure time, throughput, implementation experience and diagnostic workflow in secondary care. SYMPHONY-HF: UK NHS multi-site RCT investigating AI-assisted echocardiography in community and primary care settings, directly addressing the committee's questions about different operators, care settings and real-world time savings. TARTAN-HF: RCT on AI-assisted screening strategies for heart failure. Us2.ai is willing to co-design additional data collection with NICE to ensure that ongoing studies address any remaining specific requirements. We respectfully request that the	Thank you for your comment which NICE has considered. NICE encourages research which addresses the evidence gaps identified by the committee. If sufficient evidence becomes available in future, processes would be followed regarding notification to NICE and possible evaluation.

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
			committee considers interim OPERA data for an accelerated reassessment timeline, given that this study is generating exactly the NHS-specific evidence the committee has requested.	

Theme 12: Evidence gaps

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
64	Consultee 3 Individual	3.25 Evidence gaps	Has there been a comparison made to these metrics as reference standard for standard echocardiography as this evidence gap exists for standard echocardiography	Thank you for your comment which NICE has considered. Standard echocardiography is current standard care as recommended in NICE guideline 106 (Chronic heart failure in adults: diagnosis and management), and the comparator in this assessment. The NICE HealthTech programme does not assess evidence levels for comparators/standard care.
65	Consultee 4 EKO Pte Ltd	Are the recommendations sound and a suitable basis for guidance to the NHS?	We support the principle that further NHS-specific evidence will strengthen the case for adoption, and our ongoing studies (OPERA, SYMPHONY-HF, TARTAN-HF) are designed to provide exactly this. However, we have two concerns about the evidence gap framing. First, requiring clinical outcome data (time to diagnosis, treatment initiation, QoL) from a decision-support tool that the committee's own model assumes does not alter diagnostic accuracy sets a disproportionate evidence bar. The appropriate evidence for a workflow efficiency tool is measurement accuracy, time savings, safety and cost — all of which are available. Second, the "more research needed" recommendation should be differentiated to reflect that Us2.ai has materially more evidence than technologies with no procedure-time data, no RCT, and no active NHS deployment.	Thank you for your comment which NICE has considered. The evidence gaps outlined in section 3.26 of the guidance reflect those identified in the EAR. The committee took these into consideration when agreeing what further research was needed. This research needed is presented in section 1.1 of the guidance. Section 3.7 of the guidance states that 'most studies assessed Us2.ai'.
66	Consultee 4 EKO Pte Ltd	3.25, 3.17 Evidence gaps	**Evidence requirements should be proportionate to the AI's mechanism of action**	Thank you for your comment which NICE has considered.

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
		& model assumptions	We welcome the committee's thorough consideration of evidence needs and share the goal of ensuring robust data supports adoption. However, we note an apparent tension between the model's assumptions and the evidence gap list. The committee's own economic model (Section 3.17) establishes that: (a) the AI is used as an adjunct to standard TTE — it does not replace the operator; (b) a specialist clinical assessment is still required to confirm diagnosis; (c) diagnostic accuracy is therefore assumed to be unaltered; and (d) the model explicitly excludes false positive and false negative outcomes, considering only true positives and true negatives, per NICE NG106. This framework correctly identifies that the AI's contribution is limited to one step within an already-established care pathway: accelerating measurement and report generation within the TTE appointment. The upstream pathway (referral, NT-proBNP, specialist review) and downstream pathway (treatment initiation, monitoring, clinical outcomes) remain unchanged. However, Section 3.25 lists evidence gaps including "time to heart failure diagnosis," "time to treatment initiation," and "patient-reported health-related quality of life." These are outcomes of the overall HF care pathway, which NICE has already evaluated in NG106 and CG187. They are driven by NHS capacity, staffing and clinic configuration — not by the measurement tool used within the appointment. **We suggest that the evidence requirements be structured in two tiers:** Tier 1 — AI-specific evidence (appropriate for this assessment): measurement accuracy equivalence, procedure-time savings, safety/failure rate, usability, and cost per use. Evidence exists for all of these for Us2.ai.	Please see response to comment number 65, regarding the research recommended by the committee.

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
			Tier 2 — Pathway-level outcomes (already addressed by existing NICE guidelines): time to diagnosis, treatment initiation, clinical outcomes, QoL. These are consequences of waiting-list reduction and NHS service design, not of the AI tool itself. The economic model already converts Tier 1 inputs into Tier 2 outputs through its Markov structure — this is the appropriate methodology. Requiring prospective clinical-outcome data from a workflow efficiency tool that (by the committee's own assumption) does not alter diagnostic accuracy would create a circular evidence barrier: the tool cannot generate outcome data without NHS adoption, but adoption requires outcome data. We respectfully suggest that the Tier 1 evidence already available, combined with the economic modelling approach, provides a proportionate and appropriate basis for evaluation.	

Theme 13: Technologies

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
67	Consultee 3 Individual	1.1 More research is needed	Why have GE Caption AI LVEF reporting and Kosmos AI EF reporting not been reviewed?	Thank you for your comment which NICE has considered. Proposed technologies to be included in the assessment were discussed at the scoping workshop and presented in the final scope. The assessment included AI technologies that are used following the echocardiographic procedure. Neither the GE Caption AI LVEF or Kosmos AI EF were identified or highlighted by stakeholders as being in scope. The Kosmos AI EF is a handheld ultrasound device with AI and the GE Caption AI running on the VScan handheld probe uses image acquisition AI during Echo. Both these technologies are not within the scope of this assessment.
68	Consultee 4 EKO Pte Ltd	2.1, 3.10 Technology scope	**Us2.ai should be described as a comprehensive TTE platform, not solely an HF tool** The draft guidance and Table 1 correctly note Us2.ai's intended use across heart failure, pulmonary hypertension, cardiac amyloidosis, hypertrophic cardiomyopathy and valve disease. However, the framing throughout the document centres predominantly on HF detection, which understates the technology's value to the NHS. Us2.ai is a CE-marked (Class IIb), vendor-neutral platform	Thank you for your comment which NICE has considered. The decision question for this assessment is 'Does offering adjunctive AI technologies for use in echocardiography to aid the diagnosis or monitoring of heart failure have the potential to

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
			that automates the entire adult TTE study: view recognition, guideline-aligned measurements across 68+ parameters (LV/RV size and function, diastolic function, valves, strain), and structured editable report text. This comprehensive scope means that the time savings and workflow benefits apply to all TTE referrals, not only suspected HF cases. We request that Section 2 describes Us2.ai as “an automated analysis and decision-support tool for comprehensive adult transthoracic echocardiography, with heart failure diagnosis and monitoring as one of several key clinical applications.” This more accurately reflects the CE-marked intended use and the broader NHS value proposition.	be a clinically and cost-effective use of NHS resources? Therefore the framing of the technologies reflects this. The draft guidance does note the various intended use and various target populations (see table 1). The EAG also updated table 1 in the EAR to reflect this. The wording in table 1 of the guidance is taken from the intended use sections of the company’s response to the request for information and the user guide submitted to NICE, as well as the final scope. The purpose of the information in table 1 is to highlight the technology name, regulatory status, intended use and target population.

Theme 14: Technology costs

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
69	Consultee 4 EKO Pte Ltd	3.20 Technology costs	**Pricing comparison should reflect like-for-like inclusions** Section 3.20 states costs of £4.26 for EchoConfidence and £7.70 for Us2.ai. This comparison does not reflect what is included in each price. Us2.ai's NHS subscription pricing is: £7.50 (1–10K exams/year), £6.70 (10–20K), £5.90 (20–50K), with additional multi-year discounts. This subscription includes all training, implementation support, clinical support, IT integration, maintenance and software updates at no additional cost. EchoConfidence's £4.26 excludes set-up costs, a required 2-day on-site training course, IT integration and potential hardware costs. A like-for-like comparison should account for total cost of ownership. We request that: (i) Table 17 is updated with tiered pricing; (ii) a like-for-like comparison is presented noting inclusions and exclusions; and (iii) sensitivity analyses use mid-tier (£6.70) and high-volume (£5.90) pricing, which reflects typical NHS trust volumes.	Thank you for your comment which NICE has considered. The EAG highlighted that table 17 in the EAR outlines the costs components and calculation for each AI technology. All costs included and excluded for each technology are explicitly described and discussed in the EAR Section 6.2.4. For EchoConfidence £4.26 per use, this includes a one-off set-up fee, two-day training, software costs per scan and any ongoing support for hardware and software. Hardware costs were excluded for EchoConfidence as they were unknown but were included in Us2.ai. The EAG explained that this was explored in the sensitivity analysis, which showed robust results when hardware costs were excluded. As software/licensing cost is the main cost component, costs such as hardware are negligible when spread over the technology's lifespan and thus have little impact on the cost-effectiveness results.

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
				The EAG stated that it recognises the inconsistency in the costs components used to derive costs per use for each AI technology, due to the varying level of information provided by the companies. The EAG stated that the sensitivity analyses for high- and low- volume usage based on the actual NHS volume reported in the published literature and NHS England Diagnostic Waiting Times and Activity dataset are sufficiently representative of NHS settings.

Theme 15: Comments relating to the external assessment report

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
70	Consultee 4 EKO Pte Ltd	Table 24 Training & support; Implementation	**Table 24 AMBER ratings for Training & Support and Implementation do not reflect available evidence** Us2.ai is rated AMBER for both Training & Support and Implementation, while EchoConfidence receives GREEN for both. We believe the available evidence supports upgrading Us2.ai to GREEN in both domains. Training & Support: Us2.ai completed formal human factors testing with 23 users per IEC 62366-1. The system is designed for use by qualified sonographers within their existing competence — no formal classroom training is required. All training, implementation support, ongoing clinical and technical support, and software updates are included in the per-exam subscription at no additional cost. By contrast, EchoConfidence (rated GREEN) requires a separate 2-day on-site training course. We would welcome clarification on what additional evidence would be needed to achieve GREEN, given that the training model has been validated through regulatory human factors testing and is already included in the commercial offering. Implementation: Us2.ai is deployed across 12+ countries, has processed over 1 million studies with zero safety-related recalls, and holds ISO 27001/27017/27018 certification. The technology has DTAC in place and uses DICOM-standard integration (PS 3.x). Critically, Us2.ai is actively deployed in the NHS through the OPERA programme (Glasgow) and the SYMPHONY-HF RCT, providing direct evidence of NHS implementability. The CER documents compliance with EN ISO 13485, ISO 14971, IEC 62304, IEC 82304-1, and IEC	Thank you for your comment which NICE has considered. The EAG will not be making amendments to the EAR at this stage in the assessment. The EAG made amendments to the EAR following the fact-check period which provided an opportunity for stakeholders to provide comments on the report content.

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
			80001-1. We respectfully suggest this represents the most mature implementation evidence of any technology in the evaluation. **We request that:** (i) Both domains are upgraded to GREEN for Us2.ai; (ii) The guidance narrative acknowledges that Us2.ai has the most extensive deployment history and evidence base among the evaluated technologies (as noted by the EAG in their Executive Summary); (iii) Consistent criteria are applied across technologies, such that active NHS deployment, regulatory human factors validation, and all-inclusive subscription support are given appropriate weight.	

Theme 16: Evidence in other heart conditions

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
71	Consultee 3 Individual	3.10 Diagnostic accuracy	evidence in valve disease - https://us2.ai/clinical-evidence/ai-echo-for-tricuspid-regurgitation-severity/ 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.JACC. Cardiovascular imaging,18(1), 1–12. https://doi.org/10.1016/j.jcmg.2024.06.011 Xu, B., & Sanchez-Nadales, A. (2025). Artificial Intelligence in Echocardiographic Evaluation of Mitral Regurgitation: Envisioning the Future. JACC. Cardiovascular imaging, 18(1), 13–15. https://doi.org/10.1016/j.jcmg.2024.05.026	Thank you for your comment which NICE has considered. Valve disease was outside the scope of this assessment.
72	Consultee 3 Individual	3.10 Diagnostic accuracy	Evidence in pulmonary hypertension- Celestin, B., Bagherzadeh, S. P., Santana, E., Frost, M., Iversen, M., Hermansson, F. N., Sweatt, A., Zamanian, R. T., Hummel, Y. M., Rendon, Gabriela. Gomez., Yen, J., Sandros, M., Salerno, M., & Haddad, F. (2025). Artificial Intelligence-Based Echocardiography in Pulmonary Arterial Hypertension. CHEST.	Thank you for your comment which NICE has considered. Pulmonary hypertension was outside the scope of this assessment.

Other comments

Comment Number	Consultee number/ organisation name	Section number	Comment [sic]	NICE Response
73	Consultee 2 Pumping Marvellous Foundation	1.1	Specific areas of challenge – 1.1 In our experience, US2.ai will not process images unless the image has been acquired correctly; therefore, reducing the variability of image acquisition by differing levels of scanning operators. Patient cohorts used to train the AI could be correlated to the variability of patients in large randomised controlled trials. Reliability and failure rate compared to sonographer led echocardiograms – see https://pubmed.ncbi.nlm.nih.gov/40702880/ US2.ai is clinically efficacious – the evidence is clear US2.ai was trialled in Glasgow, this cohort is appropriate https://pubmed.ncbi.nlm.nih.gov/40702880/ Appraisal was only scoped for an acute (hospital setting) – no other setting	Thank you for your comment which NICE has considered. The committee recommended further research to understand how the technologies perform in real-world settings when used by operators with varying levels of experience outside of secondary care. The committee concluded that more research is needed to understand how the AI technologies are trained and more transparency is needed around the populations used for validation (see section 3.24 of the guidance). The Campbell et al. 2025 study was included in the EAR. This study does not appear to report reliability and failure rate outcomes. Its generalisability to the NHS was limited because in this study AI was not used as an adjunct and it compared AI assisted handheld TTE with manual cart-based TTE. This study did not feed into the economic analysis as it did not report on procedure time.

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74	Consultee 2 Pumping Marvellous Foundation		Other points not attributable to sections in the draft • Key Stakeholders not included – British Society of Heart Failure • The initial scoping document produced was of poor quality and clinically inaccurate. It does not appear to have gone through the due diligence expected from an organisation such as NICE for such an important appraisal, given the impact on so many patients who are diagnosed with HF yearly (200,000 BHF) • Not all AI technologies were in the scope, e.g. GE Caption AI running on the VScan handheld probe • What does more evidence look like? It needs to be more prescriptive. You are asking organisations to gather extra data. It is poor insight to expect SME technology organisations to have the financial strength to satisfy the same stringent requirements of RTC's.	Thank you for your comment which NICE has considered. NICE can confirm that the British Society of Heart Failure was registered as a stakeholder for this assessment. The final scope for this early use guidance (please note, a different process to that of a technology appraisal) was prepared following the scoping workshop. This workshop facilitated extensive input from a range of stakeholders including clinical experts, who were provided with the draft scope in advance. The NICE technical team sought input from clinical experts during the preparation of the scope. For the comment relating to the additional technologies, please refer to the response to comment 67. The committee is aware of the challenges involved in collecting data, and did not indicate that randomised control trials are the only form of acceptable evidence generation to address the evidence gaps.
75	Consultee 2	Are the	We believe AI ECHO can help the NHS implement existing	Thank you for your comment

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	Pumping Marvellous Foundation	recommendations sound and a suitable basis for guidance to the NHS?	NICE guidance more effectively.	which NICE has considered.
76	Consultee 2 Pumping Marvellous Foundation	Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?	See above *[NICE added text - this refers to comments 1, 3, 9, 10, 21, 26, 39, 51, 60, 73, 74, 75]*	Thank you for your comment which NICE has considered. Please see responses to comments 1, 3, 9, 10, 21, 26, 39, 51, 60, 73, 74 and 75
77	Consultee 4 EKO Pte Ltd	Not specified	Closing Statement Us2.ai is actively engaged with the NHS and committed to generating the evidence the committee has identified as important. OPERA is producing real-world UK data now, and SYMPHONY-HF will provide the community and primary care evidence the committee has specifically requested. We respectfully submit that the evidence currently available — including the only RCT in the evaluation, the most extensive published evidence base, active NHS deployment, multi-ethnic validation, and cost-effectiveness below the NICE threshold — supports a more favourable position than is reflected in the draft guidance. We are happy to discuss any aspect of this response with the committee or EAG, and we remain willing to co-design additional data collection activities to address specific evidence requirements. We would welcome the opportunity to present to the committee ahead of the 11 March meeting.	Thank you for your comment which NICE has considered.