



Wednesday, 23 April 2025

# The Heart of The Matter: AI Meets Cardiology

Evolution Capital initiates on Echo IQ ('EIQ') with a fair valuation of \$0.74 (155% TSR) and a Speculative Buy recommendation. Echo IQ has developed EchoSolv, an AI-powered clinical decision support tool designed to enhance the accuracy, reliability, and early detection of structural heart diseases, initially targeting Aortic Stenosis (AS) and soon expanding into Heart Failure (HF).

## A New Standard in Diagnosing Aortic Stenosis

EchoSolv-AS is already FDA-cleared and has demonstrated near-perfect accuracy in detecting severe AS, outperforming traditional clinical interpretation in both rigorous internal and external validation studies. In one study at Harvard's Beth Israel Deaconess Medical Center, EchoSolv demonstrated an AUC of 0.986, and sensitivity and specificity of 82.2% and 98.1% specificity. Critically, the technology is excellent at identifying high-risk patients who do not meet conventional clinical guidelines but who demonstrate equally high mortality risks. This emphasises EchoSolv's ability to reduce missed diagnoses and significantly enhance clinicians' ability to intervene earlier and improve patient outcomes.

## Tapping a US\$2B+ Market, with Sights Set on Even More

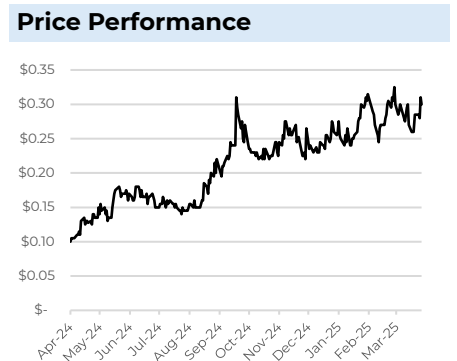
With over 7 million echocardiograms performed annually in the US—a number poised for continued growth amid rising prevalence of heart disease—EchoSolv-AS taps into a substantial and expanding diagnostic market. Echo IQ's subscription-based model specifically targets a US\$2.1 billion total addressable market for Aortic Stenosis diagnosis. Additionally, the anticipated FDA clearance of EchoSolv-HF in late 2025 – addressing the vastly larger, underdiagnosed Heart Failure market worth an estimated US\$70 billion annually – positions Echo IQ to accelerate market penetration. With over 60 hospitals in the integration pipeline on top of the existing 41 partnerships, the company is rapidly capturing these market opportunities.

## Built to Scale: Seamless Integration, Exclusive Data & Strong Tailwinds

EchoSolv's unique integration approach allows it to seamlessly slot into existing clinical workflows, analysing data directly from echocardiogram reports without the need for raw image access or specialised hardware. The company also holds exclusive access to the world's largest echo-linked mortality database (NEDA), creating a significant competitive moat. Backed by existing US reimbursement codes (Code 93799) and a clearly mapped pathway toward a dedicated Category III CPT code expected in mid-2025, EchoSolv is strongly positioned for accelerated commercial adoption and robust revenue growth.

<b>Recommendation</b>	<b>SPEC BUY</b>
<b>Share Price</b>	<b>\$0.29</b>
<b>Fair Valuation</b>	<b>\$0.74</b>

<b>Company Profile</b>	
Market Cap	~\$170M
Enterprise Value	~\$165M
SOI	~588.5M
Free Float	~73%
ADV (3-month)	~\$997.4k
52-Week Range	\$0.10 - \$0.33



**Company Overview**

Echo IQ Limited (ASX: EIQ) is an Australian medical technology company specialising in AI-driven solutions to improve clinical decision-making in cardiology. The company's flagship product, EchoSolv, leverages advanced AI and proprietary algorithms to enhance the diagnosis and assessment of severe structural heart diseases, particularly Aortic Stenosis (AS) and Heart Failure (HF). Validated through rigorous clinical studies, EchoSolv-AS received FDA 510(k) clearance in October 2024 and is now in commercialisation through integration partnerships with leading imaging software providers and large hospital networks across the US.

**Analyst**  
Jacob Hoenig      jh@eveq.com  
*Healthcare Analyst*

Catalyst	Timeline
Initiation of EchoSolv-HF validation study in US	Q2 2025
Expansion of EchoSolv-AS via imaging/PACS providers	Q2 – Q3 2025
Launch of health economics study with BIDMC	Q2 2025
Receipt of category III CPT code for EchoSolv-AS	Mid-2025
FDA 510(k) submission for EchoSolv-HF	H2 2025
510(k) clearance for EchoSolv-HF	H2 2025 – early 2026
Initiation of EchoSolv-PH pilot study	Q4 2025
New patent filings and IP updates (EchoSolv-AS and EchoSolv-HF)	Ongoing in 2025



# Contents

<b>Investment Case.....</b>	<b>3</b>
<b>1. What Is the Market Opportunity? .....</b>	<b>5</b>
Heart Disease: A Big Killer .....	5
Aortic Stenosis.....	5
<b>2. Is EchoSolv the Real Deal?.....</b>	<b>12</b>
Development & Internal Validation .....	12
External Validation.....	15
And Away We Go.....	18
IP Portfolio .....	20
<b>3. One and done? There's more to come. ....</b>	<b>20</b>
Heart Failure.....	20
Pulmonary Hypertension.....	23
<b>4. EchoSolv – Best of The Bunch? .....</b>	<b>23</b>
Direct Competitors – AI-Powered Echocardiography Diagnostics.....	23
Indirect Competitors – AI in Other Imaging Modalities.....	27
Advances In Imaging Technology .....	28
<b>Valuation.....</b>	<b>29</b>
M&A Precedents.....	29
Key Assumptions .....	30
DCF .....	31
<b>Key Risks.....</b>	<b>32</b>
<b>Appendix .....</b>	<b>33</b>
Financial Statements.....	33
Leadership Team.....	34

## Investment Case

Echo IQ's value proposition surrounds enhancing the detection and diagnostic capability of echocardiography – the gold-standard imaging modality for structural heart diseases. With EchoSolv, an advanced artificial intelligence tool developed on the world's largest echocardiographic dataset linked to mortality, the Company aims to provide rapid, accurate, and reliable identification of at-risk patients while reducing late and misdiagnoses, ensuring timely intervention. Already FDA-approved for Aortic Stenosis (AS), EchoSolv is being developed for Heart Failure (HF) as well as Pulmonary Hypertension (PH).

In a saturated market of AI-enhanced diagnostics (over 1,000 tools approved by the FDA, 161 of which relating specifically to cardiology), the critical question of whether Echo IQ can deliver on this value proposition and whether the company can succeed in the long-term can be answered by exploring four key points. These four questions form the backbone of our evaluation.

- 1. What is the market opportunity?**
- 2. Is EchoSolv the real deal?**
- 3. EchoSolv-AS: one and done or more to come?**
- 4. Is EchoSolv the best of the bunch?**

Heart disease is the leading cause of death in the US. Unsurprisingly, the economic burden of heart disease is immense and growing, with estimates pointing toward a total cost of over US\$250 billion per annum. Aortic Stenosis is a significant component of heart disease in the US, particularly among older adults, affecting approximately 5% of individuals aged 65 or older according to the CDC. It involves the pathologic narrowing of the aortic valve orifice. This impedes blood flow from the left ventricle into the aorta, resulting in poor ability to pump blood. If left untreated, AS can lead to heart failure.

Echocardiography is the imaging mechanism used to detect AS. It is a non-invasive ultrasound examination of the heart that provides real-time visualisation of the aortic valve and measurement of the haemodynamic significance of any stenosis. Over 7 million echos are performed in the US per annum, a figure likely to grow significantly with population growth. Echo is great, but not perfect: it often underdiagnoses severe AS (often defined by how small the maximum area of the valve opening when open) and it is prone to human error because measurement collection relies heavily on (i) perfect probe placement for image capture, and (ii) perfect manual measurement of areas, gradients, and so forth.

Cue EchoSolv-AS. Integrating into all clinical workflows, it is a cloud-based AI tool that, in a matter of seconds, identifies at-risk patients using echocardiogram reports. EchoSolv is a mixture density network (MDN) – a type of neural network that outputs the parameters of a probability distribution instead of a single value, allowing it to model uncertainty. In this context, it takes the 140+ parameters included in an echocardiogram report and provides a probabilistic risk prediction. It was trained on over 1 million echocardiogram reports from over 600,000 individuals from Australia's National Echo Database (NEDA). Importantly, measurements used to directly calculate AVA (aortic valve area – the key parameter concerning AS severity) were withheld from model training, forcing the MDN to learn the AS phenotype from indirect markers. The model can also handle missing or sparse data by imputing probable data based on the set of available parameters, making it highly flexible in real-world settings. In multiple external validation studies, EchoSolv-AS has matched or outperformed human interpretation: the largest of which, with the Beth Israel Deaconess Medical Center involving 31,141 individuals, it showed an AUC (area under the operating curve) of 0.986 in detecting severe AS, proving the MDN has near-perfect ability to distinguish between patients with and without severe AS.

Beyond AS, EIQ is developing EchoSolv for HF and PH. Successful development, and validation of these variations is critical to market penetration – hospitals would greatly benefit from a tool applicable to a greater number of indications. For heart failure, approximately 50% of cases are missed or underdiagnosed in clinical practice, and a 2023 study found that 43% of patients hospitalised for HF had no prior adequate clinical management despite showing symptoms documented in primary care records. This diagnostic gap delays treatment, leading to poorer patient outcomes. Now, when you think of the scale – HF affecting 6.7 million Americans today and projected to reach 11.4 million by 2050 – this is a massive issue. EchoSolv-HF has the potential to identify high-risk individuals earlier, potentially lowering cost through earlier intervention and reduced readmissions. EIQ is on track to submit an application for FDA 510(k) clearance in H2 2025.

However, as mentioned, AI in cardiology is not new – 161 AI diagnostic tools have been approved by the FDA. EIQ's competitive landscape can be broken down into three categories: direct competitors enhancing echocardiography with AI; indirect competitors enhancing other heart imaging modalities with AI; and lastly, indirect competitors improving the imaging modality hardware itself. In this fast-paced industry, advances in all three of these categories could hinder growth for Echo IQ as one technology may be preferred in clinical practice over another. Ultrasonics, for example, has developed EchoGo – an FDA-cleared AI tool that analyses raw DICOM images with machine learning. While potentially more comprehensive due to direct image integration and automation of measurement collection, it is slow and faces challenges due to integration requirements. There is limited evidence of its clinical utility. Moreover, UltraSight has developed a tool that provides real-time, on-screen feedback to the sonographer guiding probe placement. It automatically saves the best views and measures parameters, removing manual need.

It is likely that other AI products work synergistically with EchoSolv, improving the clinical experience and outcomes in multiple ways. At the end of the day, EchoSolv needs to prove clinical utility to promote market adoption. We believe that, while EIQ is not without strong competitors, it is strategically differentiated through focus on specific, underdiagnosed structural heart diseases; ease-of-use and universal integration capability; robust real-world validation on large datasets; and establishment of mutually beneficial partnerships with hospitals. Nevertheless, Echo IQ must continue to demonstrate sustained technological superiority, navigate evolving regulatory frameworks, and maintain competitive pricing strategies to ensure successful market penetration.

From a risk perspective, EIQ's trajectory is not without potential hurdles. Replicability is a crucial issue of MDNs. EIQ mitigates this risk through exclusive access to the NEDA database. In addition, long-term commercial viability requires attaining at least the next level of reimbursement for EchoSolv-AS, as well as regulatory approvals for HF and PH indications. Nonetheless, it is our view that EchoSolv is the 'best of the bunch' and there exists little to no direct competition for taking an echo report and providing a risk assessment for AS.

This is reflected in our intrinsic valuation estimate. We believe that 'the proof is in the pudding', so to speak: the diagnostic uplift EchoSolv provides relative to human-only interpretation more than justifies adoption for the hospital, especially considering they incur zero financial burden under either a fee-sharing arrangement or EIQ's subscription model. Driving our valuation is the expectation that EIQ attains more favourable CPT reimbursement codes (enabling a greater proportion of echos to be reimbursed and at a higher rate). At the current share price of \$0.29, EIQ is a compelling investment opportunity seeking exposure to the 'AI in healthcare' thematic.

# 1. What Is the Market Opportunity?

## Heart Disease: A Big Killer

Heart disease encompasses a range of conditions affecting the heart’s structure and function. In the US, heart disease remains the leading cause of death, responsible for 702,880 deaths in 2022 (1 in 5 deaths nationwide). The economic impact is substantial: the CDC reported heart disease-related costs totalled approximately US\$252 billion from 2019 to 2020. This figure takes into account the cost of health care services, medications, and lost productivity due to incapacity and mortality.

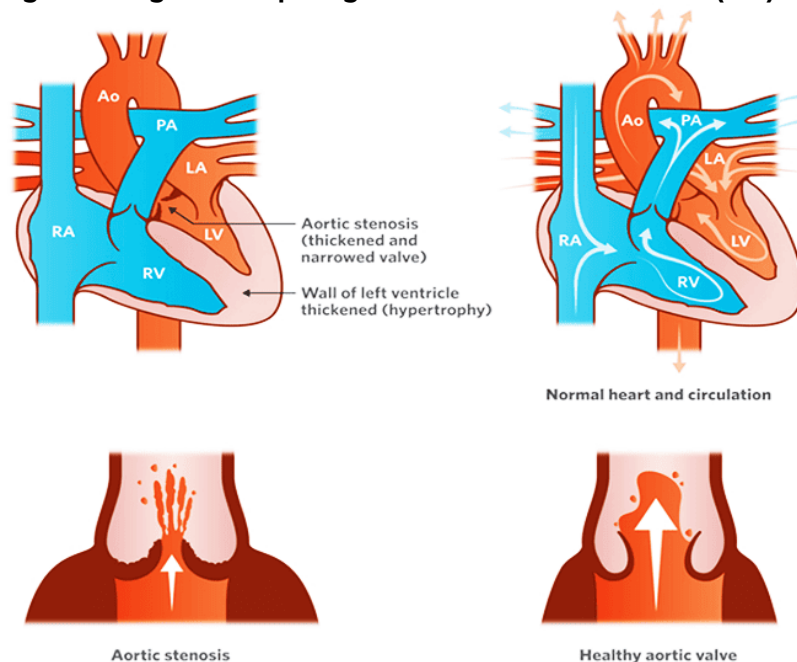
The prevalence of heart disease escalates with age. According to the CDC, the prevalence of diagnosed heart disease among adults in the US in 2022 was 0.9% for ages 18-44; 5.9% for ages 45-64; and 18.2% for those aged 65 or older. Like many developed countries around the world, the US population continues to age. In 2022, there were approximately 57.8 million individuals aged 65 or older, representing 17.3% of the population. According to the US Census Bureau’s 2023 *National Population projections Tables*, this number is expected to increase to 82 million by 2050, a 47% increase, bringing the proportion of those 65 or older to 23%. Putting this in the context of heart disease, an estimated 10.5 million individuals had heart disease in the US in 2022. Should prevalence remain constant, this number increases to a whopping 14.9 million by 2050. This doesn’t even factor in the likely possibility of increased prevalence due to improved diagnostic capabilities brought on by technology such as EchoSolv.

## Aortic Stenosis

### What is it?

Aortic Stenosis, also known as Aortic Valve Stenosis, is one of the most common heart diseases, affecting approximately 5% of individuals aged 65 or older in the US according to the CDC. It involves the pathologic narrowing of the aortic valve orifice (i.e. the aortic valve is unable to completely open), typically occurring due to progressive calcific degeneration of the valve leaflets (though it can also result from congenital abnormalities or rheumatic heart disease). The stenotic valve impedes blood flow from the left ventricle into the aorta leading to increased left ventricular pressures, compensatory hypertrophy, and ultimately, the risk of heart failure if left untreated.

**Figure 1: diagram comparing a heart with aortic stenosis (left) to a healthy heart**



As depicted on the left, the orifice of the aortic valve is narrow, limiting blood flow. Source: Children’s Health Queensland: Aortic Stenosis.

## Prevalence, Incidence & Mortality

AS is a disease where prevalence increases exponentially with age. According to the American Heart Association, >13% of the US population 75 and older have AS. Estimates suggest around 5% of those over 65 have AS, a proportion expected to double by 2050. In total, an estimated 1.5 million Americans are living with AS, of whom roughly 500,000 have severe AS.

AS carries a high mortality rate if untreated. Over the 2008-2017 period, 139,000+ deaths in the US were attributed to AS as the underlying cause. Without Aortic Valve Replacement (the primary surgical intervention), severe symptomatic AS has a grim prognosis – about 50% mortality within 2 years of symptom onset.

On a global stage, AS prevalence and mortality is similarly dire. In 2019, AS was estimated to cause approximately 127,000 deaths worldwide. Many of these deaths occur in settings where access to valve replacement therapy is limited. Global disability metrics underscore the impact: AS led to ~1.8 million disability-adjusted life years (DALYs) lost in 2019.

## TAM

The core addressable patient group for AS diagnostics in the US is the large and growing pool of seniors with valvular disease. As mentioned, there are roughly 500,000 in the US with severe AS, yet only 80,000 to 85,000 aortic valve replacements are performed yearly – indicating a substantial gap of under-diagnosed or untreated patients. In addition, the total 1.5 million US patients with AS (all severities) represent those who could benefit from enhanced severity detection.

~3.2 million people worldwide have severe AS (many of whom are undiagnosed or underdiagnosed). Additionally, an aging global population and improved awareness are expanding the pool of patients being evaluated; the total global heart valve disease population is over 28 million (all valve conditions), with AS being the leading subtype.

Echocardiography is the primary diagnostic modality for AS, and its widespread use defines the addressable market for EchoSolv. In the US, approximately 7.1 million echocardiograms are performed each year. Over 20% of Medicare beneficiaries get at least one echo annually. The US structural heart imaging market (which includes echocardiography for valvular disease) is valued at roughly \$2.6 billion in 2024. Globally, the cardiovascular ultrasound market (echo machines and services) was about \$2.4 billion in 2022 and is projected to reach >US\$4 billion by 2032. Each echocardiogram is an opportunity for AS diagnosis, and deployment of AI-driven interpretation could capture significant value from this volume.

Applying Echo IQ's subscription-based revenue model (and assuming a US\$150 reimbursement per scan), the EchoSolv-AS specific TAM is around US\$1.1 billion at current volumes of echos performed per year. And, as previously mentioned, the number of echos performed per annum is expected to rise.

## Severe AS: What Is the Threshold?

The severity of AS is categorised by haemodynamic criteria. In adults, severe AS is generally defined by one or more of the following parameters (all measured using echocardiography):

- Aortic Valve Area (AVA): the effective opening through which blood flows from the left ventricle into the aorta during systole (the phase of the heartbeat where the heart muscle contracts, forcing blood into the arteries). AS is severe where  $AVA \leq 1.0 \text{ cm}^2$ .



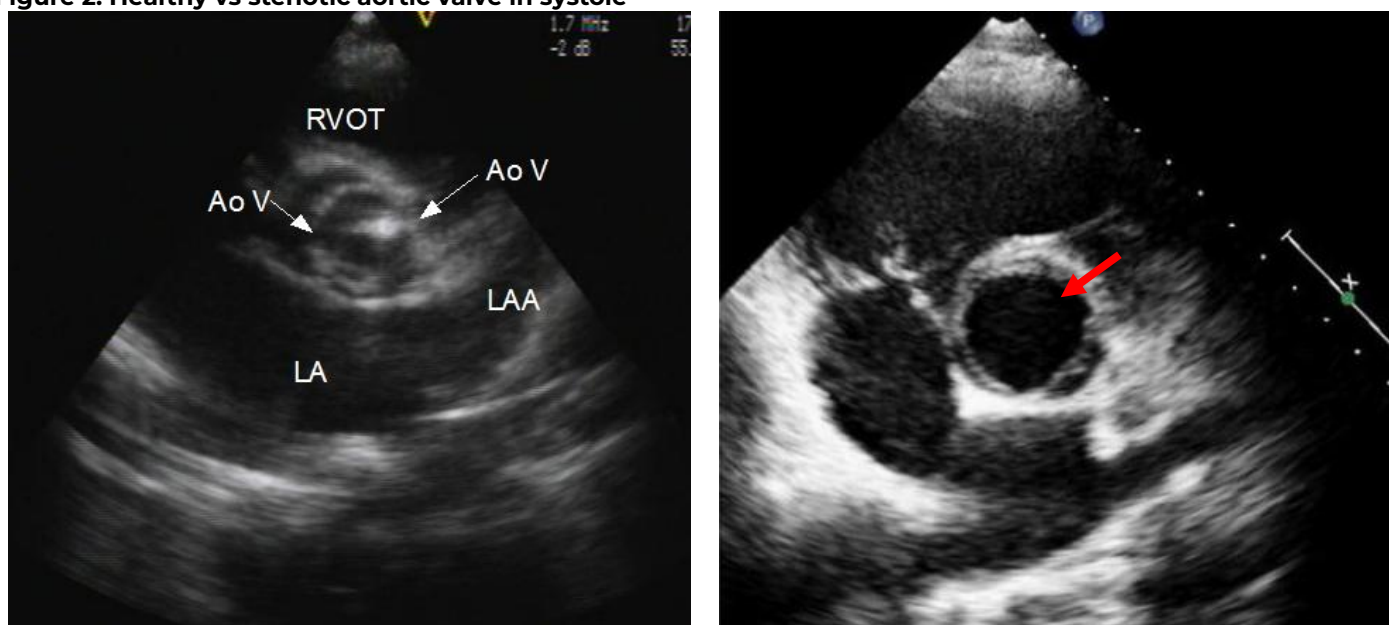
- **Peak Aortic Jet Velocity:** a measure of the highest speed of blood flow across the aortic valve during systole. AS is severe where this parameter is  $\geq 4.0$  m/s. The higher the peak velocity, the narrower the opening through which the blood flows.
- **Mean Transvalvular Pressure Gradient:** the average pressure difference between the left ventricle and the aorta during systole. Calculated using the modified Bernoulli equation, peak aortic jet velocity is converted to pressure gradient. AS is severe where this gradient is  $\geq 40$  mmHg. In simpler terms, the higher the pressure difference, the greater the blockage of blood flow. It quantifies the additional workload on the heart as it attempts to overcome the resistance caused by the narrowed valve.

### Diagnosis: Echocardiography Is the Gold Standard

Transthoracic Echocardiography (TTE) with Doppler haemodynamic assessment is the gold standard in AS diagnosis. It is a non-invasive ultrasound examination of the heart that provides real-time visualisation of the aortic valve and measurement of the haemodynamic significance of the stenosis. No other modality offers this at bedside. To understand the clinical utility of EchoSolv-AS, it's imperative to understand how an echocardiogram works.

- **Visualisation of aortic morphology:** during an echocardiogram, ultrasound waves generate real-time images of the aortic valve, allowing clinicians to clearly identify structural abnormalities, including leaflet thickening, calcification, a bicuspid valve, and impaired mobility. In patients with AS, these valve leaflets often appear notably thickened and calcified, with limited opening during the heart's pumping phase (systole). Severe AS typically shows pronounced calcification and minimal leaflet separation (often less than 8 mm). By visualizing these morphological features, echocardiography provides direct, reliable evidence of valve narrowing, allowing physicians not only to confirm the presence of AS but also to quantify its severity, which is crucial for guiding clinical decision-making and timing therapeutic interventions.

**Figure 2: Healthy vs stenotic aortic valve in systole**



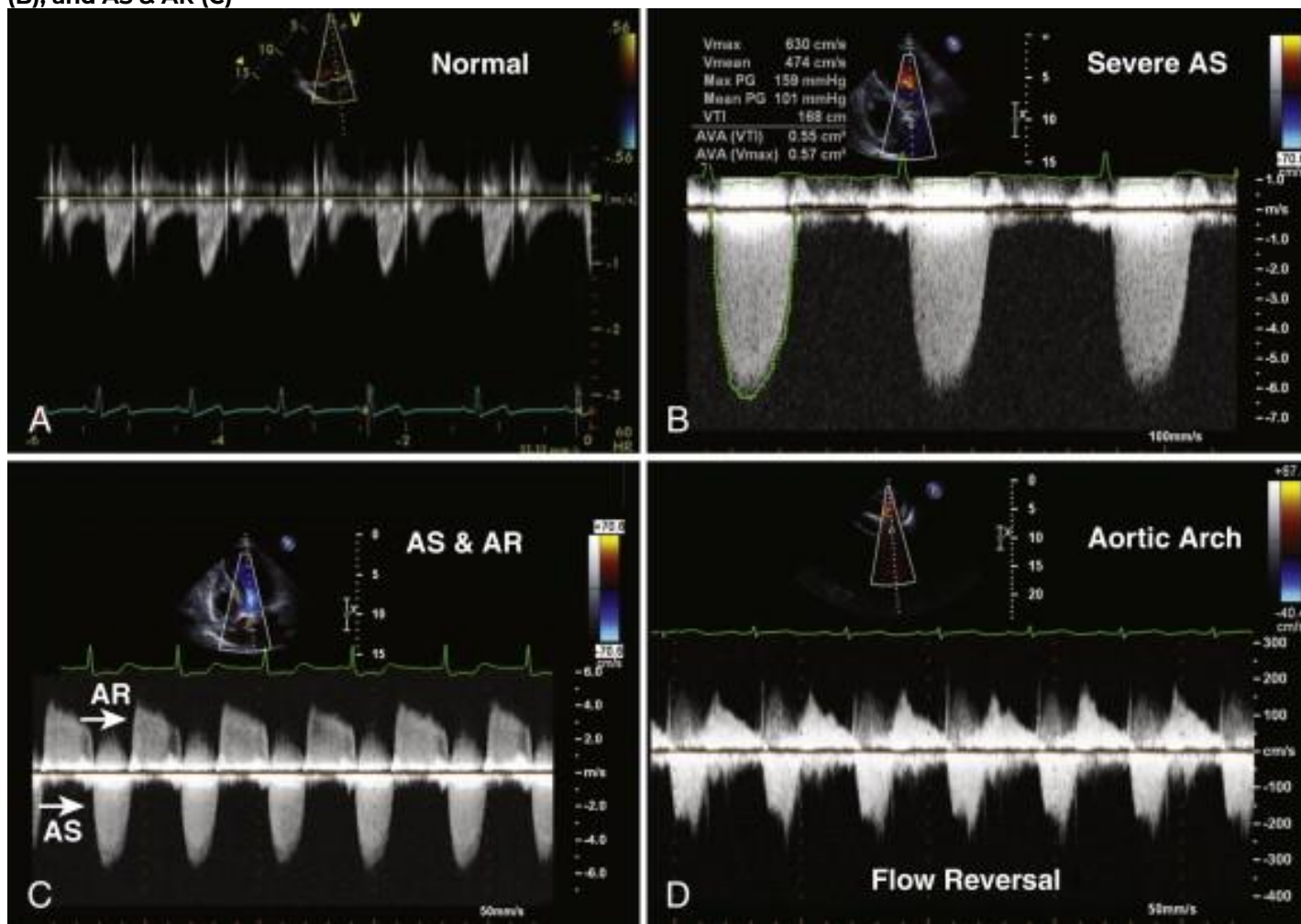
The two parasternal short-axis views illustrate stark morphological differences between a stenotic and a healthy aortic valve as seen on 2D TTE. In the image on the left, the aortic valve demonstrates a markedly abnormal appearance, consistent with a stenotic unicuspid valve. The valve orifice is highly restricted, and leaflet thickening is evident. Instead of the typical three commissures forming a Y-shaped systolic opening, there appears to be a single commissural attachment point, forming an eccentric, slit-like orifice – an appearance suggestive of a congenital

unicuspid valve with significant calcific degeneration. This limited opening during systole contributes to obstructed flow and elevated transvalvular gradients, characteristic of severe aortic stenosis. By contrast, the image on the right depicts a normal tricuspid aortic valve. In systole, the leaflets separate symmetrically to form a wide, circular central orifice (indicated by the red arrow), producing the classical “Y-shaped” opening pattern. There is no visible thickening or calcification of the leaflets, and the commissures are well formed – hallmarks of a competent and unobstructed valve.

- Left ventricular response: when the aortic valve narrows, the left ventricle (LV) must work harder to pump blood through the restricted opening. Chronic pressure overload from AS leads to thickening of the ventricular wall – known as concentric LV hypertrophy (LVH). TTE can detect and quantify this LV wall thickening, which serves as an important indicator of AS and AS severity. TTE also evaluates left ventricular ejection fraction (LVEF) – the percentage of blood leaving the heart each time it squeezes. This is a key indicator of heart function, measuring how effectively the left ventricle is working. In patients with asymptomatic severe AS, an LVEF of 50% is considered the threshold for medical intervention.
- Turbulent jet on colour doppler: TTE uses colour Doppler imaging to visualise blood flow across the aortic valve. In patients with AS, colour Doppler reveals high-velocity, turbulent flow of blood through the narrowed valve during systole. This jet appears as a mosaic of colours, indicating disturbed flow patterns. The presence and characteristics of this jet serve as important qualitative indicators of AS severity. In severe cases, the jet is more prominent, extending into the aorta. This imaging output also helps guide where to place the continuous-wave Doppler beam to measure velocity.
- Continuous-wave (CW) doppler measurements: fundamental component of TTE used to measure the velocity of blood flow across the aortic valve. The ultrasound beam is aligned parallel to blood flow through the aortic valve. Beams continuously transmit signals along this line, allowing for measurement of peak aortic jet velocity (as discussed in the section above). CW doppler also measures AVA and mean transvalvular pressure gradient.



**Figure 3: CW Doppler across the aortic valve in apical five-chamber view for 4 indications - healthy (A), severe AS (B), and AS & AR (C)**



**Image A:** this CW Doppler recording from the apical five-chamber view shows a peak velocity of 1.2 m/s, which is within the normal range. The spectral trace is smooth and symmetric, indicating unobstructed blood flow through the aortic valve. **Image B:** in this image, also from the apical five-chamber view, the CW Doppler shows a peak velocity of 6.3 m/s and a peak gradient of 159 mm Hg, indicative of severe aortic stenosis. The spectral trace is dense and has a "dagger-shaped" appearance, reflecting the high-velocity jet across the narrowed valve.

For peak velocity, normal valves typically have peak velocities around 1–2 m/s, whereas severe aortic stenosis often exceeds 4 m/s. Normal flow produces a smooth, symmetric trace, while severe stenosis results in a dense, dagger-shaped trace due to turbulent, high-velocity flow. The pressure gradient across the valve increases significantly in stenosis, as seen in the severe case above.

TTE with doppler is considered definitive due to the reliability of these outputs. In experienced hands, TTE with doppler measurements of AS correlate well with invasive catheter measurements. Current clinical guidelines uniformly recommend TTE as the first-line test for any patient with suspected AS (e.g. anyone with a systolic murmur or relevant symptoms). TTE has become the definitive standard for evaluating severity as well, to the extent that invasive measures are no longer routinely recommended except in cases of diagnostic ambiguity.

Cardiac catheterisation is the former gold-standard. It involves threading a catheter through a blood vessel to the left ventricle under the guidance of x-ray imaging. A second catheter is positioned in the ascending aorta. The peak and mean transvalvular pressure gradients are directly recorded as the pressure difference between the LV and aorta during systole. The AVA is calculated directly using the Gorlin equation. It's used in cases of low-flow, low-gradient severe AS with preserved LVEF and in cases of poor echo windows.

Looking at accuracy, in one study, Doppler-estimated gradients had correlation coefficients around 0.96 with cath gradients. The calculation of AVA by continuity equation also correlates well with cath-derived AVA (Gorlin formula), though slight systematic differences may exist.

When it comes to measuring accuracy of echocardiography alone, most studies focus on sensitivity and specificity of specific cutoffs for severe AS detection. For example, a 2019 retrospective observational study - *Use of routinely captured echocardiographic data in the diagnosis of severe aortic stenosis* – looked at the accuracy and reliability of TTE-derived measures relative to documented interpretation of severe AS. Among 77,067 patients with complete assessment of the aortic valve, 1.6% were categorized as having severe AS by the TTE reader. Relative to the documented interpretation, AVA as a measure of severe AS had a high sensitivity (94.1%) but a low positive predictive value (37.5%). However, when AVA is concordant with elevated gradients and high peak velocity (i.e. mean gradient  $\geq 40$  mmHg,  $V_{\text{max}} \geq 4.0$  m/s), the positive predictive value of echocardiography is substantially higher.

Aortic peak velocity and mean gradient were specific (>99%), but less sensitive (<70%). A measure incorporating peak velocity, mean gradient and dimensionless index (either by velocity time integral or peak velocity ratio) achieved a balance of sensitivity (92%) and specificity (99%) with little detriment in accuracy relative to peak velocity and mean gradient alone (98.9% vs 99.3%). Using all available data, the proportion of patients whose echocardiogram could be assessed for aortic stenosis was 79.8% as compared with 52.7% by documented interpretation alone.

Conversely, using a very high gradient threshold (e.g. mean gradient >80 mmHg) is 100% specific for severe AS but very insensitive, which illustrates that echo can definitively rule in severe AS when values are extreme.

In practical terms, a normal echocardiogram effectively rules out significant AS almost perfectly – if the valve looks normal and Doppler velocities are normal, the patient does not have moderate or severe AS. At the other end, when multiple echo criteria for severe AS are met (and technical quality is good), the positive predictive value is very high; such patients almost invariably have true severe narrowing at surgery or by cath. The few instances of false positives or negatives usually relate to technical limitations (e.g., poor alignment underestimating a jet, or a mis-measured LVOT diameter causing AVA underestimation). Those limitations can be mitigated by repeat study, TEE, ancillary testing, or advancements in TTE capture aided by tech from the likes of UltraSight and Caption Health (see page 29).

Put simply, TTE is good at diagnosing AS and its severity using a composite of data points. But when key measurements are missing and assessment of severity relies on just AVA, for example, TTE may overdiagnose or underdiagnose. This bolsters the theoretical utility of EchoSolv given its ability to diagnose with key data missing or incorrect.

### **Other Modalities**

Cardiac catheterisation is now reserved as a confirmatory test if echo results are discordant with clinical findings. Advanced modalities like CT and CMR are generally adjuncts – they augment specific aspects (calcification and myocardial fibrosis) but do not replace echo for the primary diagnosis and grading of AS.

### **Other Types of Echo**

Transoesophageal echocardiography (TOE) involves inserting an ultrasound probe into the oesophagus, directly adjacent to the heart. This approach provides higher-resolution images compared to traditional TTE, as the ultrasound beam encounters fewer anatomical obstructions, such as ribs and lung tissue. TOE is particularly valuable for identifying structural abnormalities, such as heart valve defects, blood clots, and cardiac masses. It is frequently used when TTE images are insufficiently

clear, especially in obese patients or those with lung conditions that degrade acoustic windows.

Despite its imaging superiority, TOE is used less frequently than TTE due to its invasiveness and associated discomfort. It typically requires sedation or anaesthesia, resulting in longer procedure times and increased healthcare costs. Consequently, TOE is usually reserved for scenarios where detailed cardiac structure evaluation is critical, such as prior to cardiac surgery, evaluating endocarditis, or investigating unexplained stroke.

Stress echocardiography assesses cardiac function under physical or pharmacological stress to reveal abnormalities not apparent at rest. The test is conducted either by having patients perform physical exercise (typically treadmill or bicycle exercise) or by administering drugs, such as dobutamine, that increase heart rate and cardiac workload. This method is particularly effective for detecting coronary artery disease (CAD), assessing myocardial viability, and evaluating cardiac function in patients experiencing chest pain or shortness of breath.

While stress echocardiography offers valuable diagnostic information regarding functional cardiac performance under stress conditions, its use is more limited compared to TTE due to logistical complexities, higher resource requirements, and the potential for patient discomfort during exercise or adverse drug reactions. Therefore, it is typically utilized when there is suspicion of CAD that may not manifest clearly under resting conditions, or to assess the effectiveness of therapeutic interventions.

### **Treatment: Patient Outcomes Significantly Improve with Early AS Diagnosis & Intervention**

In advanced stages, the only definitive treatments are those that relieve the obstruction – aortic valve replacement (AVR). Historically, the standard-of-care was surgical AVR (SAVR) via open heart surgery. In the past decade, transcatheter AVR (TAVR) has emerged as a less invasive alternative that can be performed using catheter-based delivery. In the case of TAVR, a collapsible bioprosthetic valve is deployed inside the native valve. The TAVR valve crushes the old, calcified leaflets aside and immediately begins functioning. Unlike SAVR, TAVR does not require stopping the heart or opening the chest. It is often done under conscious sedation without intubation.

TAVR was first approved in the US in 2011 for inoperable patients and in 2012 for high-risk surgical candidates. In 2012, only 6,500 TAVR procedures were performed, accounting for 11% of AVRs in that year. In 2018, this number was 57,155, accounting for 58% of AVRs. By contrast, 44,0,117 SAVRs were performed in 2008 compared to a slightly lesser number of 41,455 in 2018. Findings from a 2019 study published in *JAMA – Mortality Due to Aortic Stenosis in the United States, 2008-2017* – showed a decreasing rate of mortality due to AS since 2013. We may therefore derive that increased occurrence of TAVR has resulted in decreased AS mortality, highlighting the significant benefit to treating AS ahead of irreversible disease progression, and therefore also emphasising the importance of early AS diagnosis.

In 2019, the FDA approved TAVR for low-surgical-risk patients, opening the door to a larger patient pool including younger, healthier patients who would have previously received SAVR. In 2022, over 98,000 TAVRs were performed in the US. The key point here is that TAVR has expanded the total number of patients receiving therapy: the American College of Cardiology reported that, within a decade of TAVR's introduction, the overall AVR treatment rate in older adults increased by about 60%.

When it comes to patient outcomes, AVR has changed the prognosis from that of a terminal disease to that of that of the patient's underlying health status. A 2022 publication in the *Journal of Clinical Medicine - One and Five-Year Mortality Risk Prediction in Patients with Moderate and Severe Aortic Stenosis* – found that in a

large analysis of patients with severe AS, 1-year survival was ~74% among AVR recipients compared to ~45% of non-recipients.

What does this mean for EIQ? Today, treatment interventions keep AS patients alive for longer. These treatment options are performed far more often than even half a decade ago and on a broader segment of prospective recipients. Early diagnosis and prognosis assessment of AS leads to better patient outcomes, bolstering the case for incorporation of EchoSolv-AS into the standard-of-care.

## 2. Is EchoSolv the Real Deal?

### Development & Internal Validation

EIQ's goal was to produce an artificial intelligence-powered decision support algorithm (AI-DSA) using echocardiographic measurements to help identify the severe AS phenotype. The hypothesis was that such a system would (i) provide a high degree of accuracy in identifying AS relative to the incumbent gold standard, and (ii) accurately identify those at risk for subsequent mortality.

#### The Brains Behind the Operation

The development of EchoSolv involved training a robust Mixture Density Network (MDN) on echocardiographic data from over 631,824 individuals across 1.08 million echocardiograms sourced from Australia's National Echo Database (NEDA).

An MDN is a specialised form of neural network designed to model uncertainty and produce probabilistic outputs rather than single deterministic predictions. Put simply, regular neural networks provide a single 'best guess', whereas MDNs provide a set of plausible predictions with associated probabilities.

In the case of EchoSolv, the MDN was designed to estimate the distribution of the AVA for each patient's echo, given all the other echo measurements as inputs. The goal was to determine how likely it is that the patient truly has  $AVA < 1.0 \text{ cm}^2$ . By predicting a full distribution for AVA, the model can compute a probability of severe AS (essentially the portion of the MDN's output distribution falling below the  $1.0 \text{ cm}^2$  threshold).

The choice of an MDN as the foundational algorithm was motivated by the nature of echo data: real-world echocardiography reports often have incomplete or inconsistently recorded measurements, and the relationships between measurements (e.g. valve gradients, flow, and dimensions) can be complex or even multi-modal. The MDN handles this by effectively modelling multiple possible outcomes. During development, the team explicitly addressed data sparsity – many echocardiograms lacked certain values – by using techniques within the MDN framework to learn from whatever subset of features was available for each case. In fact, the model was engineered to perform inference with arbitrary sets of available measurements, meaning it could still generate a probability even if some inputs were missing.

**Figure 4: table displaying the measurement fill rate used by EchoSolv across all studies**

EchoSolv
Echo Quality Report
Period: 2021-01-31 - 2025-03-01

**Full measurement fill rate**

The below lists the fill rates for all measurements used by EchoSolv across all studies.

Aorta at sinotubular junction diameter	21 (1.55%)	Left ventricular systolic diameter base parasternal long axis	237 (17.45%)
Aorta at sinuses diameter	21 (1.55%)	Left ventricular systolic diameter M mode	21 (1.55%)
Aortic arch diameter	21 (1.55%)	Left ventricular systolic length 2 chamber	22 (1.62%)
Aortic regurgitation pressure half time	22 (1.62%)	Left ventricular systolic length 4 chamber	22 (1.62%)
Aortic root diameter	30 (2.21%)	Left ventricular systolic volume 4 chamber area length method	21 (1.55%)
Aortic root diameter M mode	21 (1.55%)	Left ventricular systolic volume biplane method of discs method	21 (1.55%)
Aortic valve mean velocity	32 (2.36%)	Left ventricular systolic volume method of discs 2 chamber method	24 (1.77%)
Aortic valve peak gradient	32 (2.36%)	Left ventricular systolic volume method of discs 4 chamber method	24 (1.77%)
Aortic valve velocity ejection time	21 (1.55%)	Left ventricular systolic volume Teichholz method	235 (17.3%)
Ascending aorta diameter	30 (2.21%)	Left ventricular systolic volume Teichholz method M mode	21 (1.55%)
AV Mean Gradient	488 (35.94%)	LV Lateral E Prime Velocity	67 (4.93%)
AV Peak Velocity	1,072 (78.94%)	LV Mass Index (ASE)	78 (5.74%)
AV VTI	34 (2.5%)	LV Mass Index (MM)	25 (1.84%)
AVA	479 (35.27%)	LV Septal E Prime Velocity	71 (5.23%)
Average E/e'	181 (13.33%)	LVEF	800 (58.91%)
Body height	1,125 (82.84%)	LVOT Diameter	40 (2.95%)
Body mass index calculated	1,107 (81.52%)	LVOT Peak Velocity	36 (2.65%)
Body weight	1,125 (82.84%)	LVOT VTI	34 (2.5%)
BSA	1,153 (84.9%)	Main pulmonary artery diameter	13 (0.96%)
Heart rate	25 (1.84%)	Mitral A wave duration	25 (1.84%)
Isovolumic relaxation time	21 (1.55%)	Mitral A wave velocity	30 (2.21%)
IVC diameter expiration	21 (1.55%)	Mitral E Wave Velocity	86 (6.33%)
IVC diameter inspiration	14 (1.03%)	Mitral E/A Ratio	133 (9.79%)
IVS diastolic thickness	21 (1.55%)	Mitral regurgitation aliasing velocity	27 (1.99%)
IVS diastolic thickness M mode	31 (2.28%)	Mitral regurgitation effective regurgitant orifice area PISA	228 (16.79%)
IVS systolic thickness M mode	28 (2.06%)	Mitral regurgitation flow convergence radius	361 (26.58%)
IVS to PW ratio	30 (2.21%)	Mitral regurgitation peak velocity	27 (1.99%)
LA Volume Index	634 (46.69%)	Mitral regurgitation velocity time integral	337 (24.82%)
Lateral mitral annular tissue doppler E to E prime ratio	50 (3.68%)	Mitral valve area pressure half time	27 (1.99%)
Left atrial AO ratio	29 (2.14%)	Mitral valve deceleration time	25 (1.84%)
Left atrial AO ratio M mode	29 (2.14%)	Mitral valve mean gradient	30 (2.21%)
Left atrial area 2 chamber view	21 (1.55%)	Mitral valve mean velocity	30 (2.21%)
Left atrial area 4 chamber view	21 (1.55%)	Mitral valve peak gradient	30 (2.21%)
Left atrial length 4 chamber view	21 (1.55%)	Mitral valve peak velocity	30 (2.21%)
Left atrial systolic diameter M mode	21 (1.55%)	Mitral valve pressure half time	28 (2.06%)
Left atrial systolic diameter parasternal long axis	31 (2.28%)	Mitral valve regurgitant fraction	249 (18.34%)
Left atrial volume	32 (2.36%)	Mitral valve regurgitant volume	268 (19.73%)
Left ventricular diastolic area method of discs 4 chamber method	23 (1.69%)	Mitral valve velocity time integral	30 (2.21%)
Left ventricular diastolic area PSAX for LV mass assessment	21 (1.55%)	Planimetered mitral valve area	13 (0.96%)
Left ventricular diastolic diameter M mode	21 (1.55%)	Pulmonary acceleration time	22 (1.62%)
Left ventricular diastolic diameter parasternal long axis	33 (2.43%)	Pulmonary regurgitation diastolic velocity	22 (1.62%)
Left ventricular diastolic length 2 chamber	22 (1.62%)	Pulmonary regurgitation peak velocity	21 (1.55%)
Left ventricular diastolic length 4 chamber	21 (1.55%)	Pulmonary valve mean gradient	21 (1.55%)
Left ventricular diastolic volume 4 chamber area length method	21 (1.55%)	Pulmonary valve mean velocity	21 (1.55%)
Left ventricular diastolic volume method of discs 2 chamber method	24 (1.77%)	Pulmonary valve peak gradient	27 (1.99%)
Left ventricular diastolic volume method of discs 4 chamber method	24 (1.77%)	Pulmonary valve peak velocity	27 (1.99%)
Left ventricular diastolic volume method of discs biplane method	21 (1.55%)	Pulmonary valve velocity time integral	21 (1.55%)
Left ventricular diastolic volume Teichholz method	33 (2.43%)	Pulmonary vein A duration	21 (1.55%)
Left ventricular diastolic volume Teichholz method M mode	21 (1.55%)	Pulmonary vein A wave reversal velocity	21 (1.55%)
Left ventricular ejection fraction biplane method of discs method	26 (1.91%)	Pulmonary vein diastolic velocity	21 (1.55%)
Left ventricular ejection fraction Teichholz method	1,126 (82.92%)	Pulmonary vein S to D ratio	21 (1.55%)
Left ventricular ejection fraction Teichholz method M mode	37 (2.72%)	Pulmonary vein systolic velocity	21 (1.55%)
Left ventricular fractional shortening M mode	21 (1.55%)	Right atrial area	21 (1.55%)
Left ventricular fractional shortening plax	22 (1.62%)	Right atrial pressure	29 (2.14%)
Left ventricular mass area length method	21 (1.55%)	Right atrial volume	21 (1.55%)
Left ventricular mass ASE method	21 (1.55%)	Right atrial volume index	21 (1.55%)
Left ventricular mass index area length method	21 (1.55%)	Right ventricular diastolic basal diameter	21 (1.55%)
Left ventricular mass M mode	22 (1.62%)	Right ventricular outflow tract mean velocity	23 (1.69%)
Left ventricular outflow tract stroke volume	34 (2.5%)	Right ventricular outflow tract peak gradient	27 (1.99%)
Left ventricular posterior wall diastolic thickness	25 (1.84%)	Right ventricular outflow tract peak velocity	28 (2.06%)
Left ventricular posterior wall diastolic thickness M mode	31 (2.28%)	Right ventricular outflow tract velocity time integral	23 (1.69%)
Left ventricular relative wall thickness	26 (1.91%)	Right ventricular systolic pressure	489 (36.01%)
Left ventricular stroke volume method of discs 2 chamber method	24 (1.77%)	Stroke volume index	271 (19.96%)
Left ventricular stroke volume method of discs 4 chamber method	24 (1.77%)	Systolic blood pressure	21 (1.55%)
Left ventricular stroke volume method of discs biplane method	25 (1.84%)	Thoracic aorta diameter	19 (1.4%)
Left ventricular stroke volume Teichholz method	31 (2.28%)	TR Peak Velocity	476 (35.05%)

The fill rate is the percentage of scans where inference has had to be made for that specific data point. Not only does this table provide information on the ability of EchoSolv to impute across all parameters, but it also highlights the number of parameters observed in an echocardiogram report.

Another notable design choice was that EchoSolv's input feature set excluded the direct calculation of AVA. All measurements related to the continuity equation (left ventricular outflow tract (LVOT) diameter, LVOT velocities/VTIs, etc.) were withheld from the model's training. The rationale was to force the AI to infer severe AS from peripheral signs (like secondary hemodynamic markers and cardiac remodelling parameters) rather than relying on the direct AVA calculation. In other words, the MDN had to "learn" the phenotype of severe AS indirectly – for instance, recognizing combinations of high jet velocity, certain valve morphology, hypertrophied ventricles, or other patterns – without being given the explicit formula output. After training on these constrained inputs, the MDN's output distribution for AVA was evaluated against known AVA values, and by integrating the MDN's predicted distribution the team could calculate each patient's predicted probability of AVA <1 cm<sup>2</sup>.



This has allowed EchoSolv to be both highly predictive and generalisable – the model isn't overly tailored to one formula or device, and it remains robust when some measurements are unavailable. In the real world, this means easy integration into almost every echo workflow.

## Training the Model

Training and validation of EchoSolv is thoroughly documented in the study – *Enhanced detection of severe aortic stenosis via artificial intelligence: a clinical cohort study* – published in “Open Heart” in July 2023. EIQ used 1,077,145 echos from 631,824 individuals aged 18 or over during the period from 29 May 1985 to 26 June 2019. Individual all-cause mortality was established during a median of 4.3 year follow up from last echocardiogram. A total of 280 individual echocardiographic variables, representing base measurements and calculations as part of a standard echocardiography examination, were provided. Importantly, the training was agnostic to patient outcomes – the model learned to predict AVA purely from echo measurements, without knowing patients' survival or interventions. Mortality status was not provided and did not form part of the EchoSolv training. Individuals with prior AVR were excluded.

The data set was split into two groups – one for model training (70%, comprising 442,276 individuals and their 754,503 echocardiograms) and the other for test/validation of the trained model (30%). As previously mentioned, left ventricular outflow tract (LVOT) data relevant to the continuity equation was withheld from the test set model. The MDN was then used to predict the probability of severe AS, defined by an AVA  $<1\text{cm}^2$ . The trained model was designed to be general purpose and perform inference using arbitrary sets of available information. After iterative tuning, the final MDN could output, for any given echo study, a probability that the case meets the severe AS criteria.

Once developed, the model's performance was independently evaluated using data from the 30%, comprising 189,548 individuals and their 322,642 echocardiograms. The performance of the model was strikingly high – the algorithm achieved an AUC of 0.986 for detecting severe AS. This indicates that the model's discriminative ability was excellent.

EIQ developers evaluated various probability thresholds to determine the optimal balance between catching as many true cases of severe aortic stenosis as possible (sensitivity) and ensuring that the positive predictions were accurate (positive predictive value). They computed the F1 score – the harmonic mean of precision and recall – for a range of thresholds applied to the MDN's output probability. The 23.5% cut-off emerged as the point at which the F1 score was maximized, meaning that at this threshold the algorithm best balanced the trade-off between precision and recall. In practical terms, when the MDN computes a probability of severe AS of 23.5% or higher for an individual echocardiogram, that study is flagged as likely representing severe disease.

Using this operating point, roughly 5% of the validation cohort fell into the high-probability severe AS category – a prevalence that aligns with real-world expectations for severe AS in an echo population. Notably, the model identified not only the obvious severe AS cases that meet guideline cutoffs, but also atypical presentations: among the AI-flagged high-probability cases in validation, about 23% did not meet the strict guideline definition of severe AS. Many of these were likely low-flow, low-gradient AS or other nuanced phenotypes that clinicians often debate – precisely the cases where an AI alert can add value. Crucially, the prognostic significance of the AI's output was validated by linking to outcomes: patients labelled high-risk by EchoSolv had far worse 5-year survival than those labelled low-risk (e.g. in one analysis, ~68% 5-year mortality in the AI high-probability group versus ~19% in the low-probability group, a  $>2.4\times$  relative risk after adjusting for age/sex. This provides confidence that the AI wasn't just predicting an arbitrary number – it was identifying a phenotype truly associated with higher mortality if untreated.

## Guideline Logic Integration

To make the tool clinically safe and acceptable, the developers incorporated a simple rule-based overlay: any patient who already meets guideline-defined severe AS criteria (for example, an aortic jet velocity  $\geq 4$  m/s, mean gradient  $\geq 40$  mmHg, or measured AVA  $\leq 1.0$  cm<sup>2</sup>) is automatically flagged by EchoSolv, regardless of the MDN's probability score.

In practice, this “guideline quarantine” means EchoSolv will never miss a case that a human following current guidelines would consider severe – it essentially guarantees 100% sensitivity for guideline-positive cases by design. Those obvious cases are still identified by the AI (since the inputs include those measurements), but this feature provides an extra failsafe. The real power of EchoSolv lies in its ability to go beyond guidelines – finding high-risk echoes that don't meet all criteria on paper but look concerning when all data are considered in concert.

## External Validation

### BIDMC – 2024

At the Beth Israel Deaconess Medical Center (BIDMC) in Boston, US, a retrospective observational validation study of EchoSolv was conducted, evaluating the algorithm's ability to accurately and reliably detect severe AS using routine echocardiography reports. BIDMC is a renowned teaching hospital affiliated with Harvard Medical School. The study collected comprehensive data from 31,141 individuals who underwent transthoracic echocardiography (TTE) at BIDMC between 2003 and 2017, including demographic information, clinical history and comorbidities, detailed echocardiographic measurements, and linked outcome data such as all-cause mortality and aortic valve replacement.

Patients were divided into four groups:

- Group 1: individuals with a probability above the F1 threshold ( $>0.235$ ) who met guideline criteria for severe AS;  $n=1,549$ .
- Group 2: comprised those above the F1 threshold but not meeting the clinical criteria;  $n=463$ .
- Group 3: patients with a probability between the F2 threshold ( $>0.0625$ ) and the F1 threshold (indicative of moderate AS);  $n=979$ .
- Group 4: those with a probability below the F2 threshold (low probability for severe AS);  $n=28,150$ .

F1 and F2, as outlined earlier, are specific probability thresholds generated in the development and internal validation of EchoSolv. F1 was determined to be the optimal cutoff for identifying severe AS (i.e. 0.235 is the optimal probability of severe AS determined by the model). F2 distinguishes patients with moderate AS from those with low probability of severe AS.

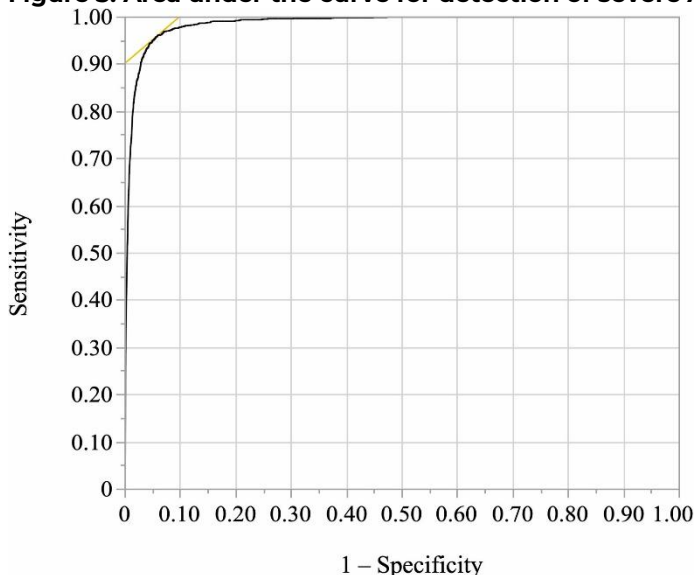
Out of the 31,141 individuals included in the study, AVA measurements were available for 4,115 patients, representing approximately 13.2% of the cohort. Because BIDMC's laboratory policy is to report an AVA only when the aortic peak velocity exceeds 2 m/s – a threshold typically met by patients with severe AS – these 4,115 AVA measurements likely include all individuals with an AVA  $<1.0$  cm<sup>2</sup>. Of these, 1,422 (34.6%) had an AVA  $<1.0$  cm<sup>2</sup> (i.e. severe AS).

EchoSolv achieved an AUC of 0.986 for detecting severe AS. Area under the curve (AUC) refers to the area under the Receiver Operating Characteristic (ROC) curve. Think of the ROC curve as a graph that shows how well the AI algorithm can distinguish between those who do have severe AS and those who do not, across all possible probability thresholds. An AUC of 1 would mean perfect discrimination – the



algorithm would always currently identify severe cases as severe and non-severe cases as non-severe. An AUC of 0.5 would mean the algorithm is no better at random guessing. In essence, an AUC of 0.986 means that EchoSolv showed near-perfect discrimination between those with true severe AS and non-severe AS.

**Figure 5: Area under the curve for detection of severe AS**



The study evaluated the performance of EchoSolv at both F1 and F2, yielding impressive results.

**Figure 6: EchoSolv performance at different thresholds of severity probability**

Metric	F1 Threshold (>0.235)	F2 Threshold (>0.0625)
Sensitivity	82.2%	95.2%
Specificity	98.1%	94.8%
Positive Predictive Value	67.4%	46.4%
Negative Predictive Value	99.2%	99.8%

The table illustrates a trade-off in the algorithm’s performance based on the chosen threshold. With the F1 threshold, EchoSolv achieves a balance of high specificity (98.1%) and positive predictive value (67.4%), meaning that when the algorithm identifies a case as severe AS, it is more likely to be correct – this minimizes false positives. In contrast, the F2 threshold, offers higher sensitivity (95.2%) and negative predictive value (99.8%), which would capture nearly all true severe AS cases but at the cost of lower specificity (94.8%) and PPV (46.4%), thereby increasing false positives.

These findings highlight how EIQ likely chose F1 for practical use, because, while it will miss a few true cases compared to F2, its higher specificity and PPV ensure that the cases flagged as severe AS are indeed high probability, reducing unnecessary further testing or referrals. Finding a balance is crucial in clinical settings – overdiagnosis can result in unnecessary AVR procedures.

This external validation study also reiterated EchoSolv’s applicability in people with compromised heart function, indicated by lower left ventricle ejection fraction (LVEF). LVEF is a measure of how much blood the left ventricle pumps out with each contraction, expressed as a percentage. Normal LVEF is typically between 55% and 70%. Where LVEF was less than 50% (5,966 individuals in the study), EchoSolv using F1 demonstrated AUC of 0.984, 87.2% sensitivity, and 97.1% specificity. Where LVEF was less than 30% (n=1,611), EchoSolv demonstrated AUC of 0.981, sensitivity of 89.4%, and specificity of 95.6%. Evidently, the algorithm is robust and still performs reliably in even sicker populations.

The study compared EchoSolv-guided diagnosis to standard-of-care clinical evaluation for severe AS phenotype:

- Group A: as judged by both EchoSolv and clinical interpretation; n=978 (3.1%).
- Group B: as judged only by EchoSolv; n=1,034 (3.3%).
- Group C: as judged only by clinical interpretation; n<11.
- Group D: non-severe AS as judged by both EchoSolv and clinical interpretation; n=29,124 (93.5%).

Although Groups A and B were similar in many clinical and echocardiographic characteristics, Group B's aortic valve (AV) parameters were more like those seen in moderate AS rather than severe AS. This suggests that the AI may be detecting a subtle phenotype not always captured by clinical interpretation alone.

Data from this trial also re-affirms the importance of correctly identifying severe AS: 5-year mortality rates in groups A and B (75.9% and 73.5% respectively) far exceeded that of group D (44.6%). The hazard ratios (2.48 for Group A and 2.21 for Group B) demonstrate that patients identified as severe by either method have more than twice the risk of death compared to those with non-severe AS. This evidence further underscores the clinical practicality of a tool that improves accuracy and reliability of AS diagnosis and categorisation.

All in all, the BIDMC study revealed that EchoSolv performed exceptionally well in detecting severe AS in a large, real-world cohort of individuals. It demonstrated high AUC and robust sensitivity and specificity. Importantly, it not only identified nearly all cases of severe AS that were confirmed by clinical interpretation but also flagged an additional subset of patients with a severe AS phenotype. This group experienced similarly high 5-year mortality yet were less likely to receive AVR. The findings suggest that integrating EchoSolv into routine echocardiography reporting could enhance the early detection and management of severe AS.

### **Baylor Scott & White – 2024**

The Baylor Scott & White study evaluated EchoSolv to assess its ability to improve the identification of severe AS compared to human-only diagnosis, using real-world echocardiographic data collected over a seven-month period. Findings from the study were presented by Dr. Pedro Covas at the New York Valves (Structural Heart Summit).

EchoSolv identified 792 of 8,547 echocardiograms displayed a high-risk phenotype for AS. Within this group, 700 echocardiograms met severe AS criteria via clinical interpretation, and 92 did not. Of the 700, 131 were chosen for further analysis. This group met severe AS criteria and were identified by EchoSolv to have high AS risk. We will call this group A. Of the 92 that did not meet the criteria for severe AS, 50 were chosen for further analysis. This can be called group B.

Results: of group A, EchoSolv and the echocardiographer on agreed severe AS was present in 87% of cases (concordant) and disagreement in 13% of cases (discordant). Of these discordant cases, 9 of 17 showed evidence of cardiac abnormalities such as left/right ventricular dysfunction. This suggests that these individuals may have still presented as high risk for AS despite clinical interpretation ruling out this possibility.

In group B, there was a 32% concordance rate (16/50) and a 68% discordance rate (34/50). In other words, EchoSolv identified 34 cases as high risk that the echocardiographer interpreted as non-severe. 14 of those 34 discordant cases had cardiac abnormalities such as left/right ventricular dysfunction or significant valve calcification.

Overall, these results indicate that EchoSolv not only reliably confirms many of the same severe AS cases identified by standard clinical reads, but also highlights a subset of potentially high-risk patients who might otherwise be missed. This was evidenced by the high proportion of cardiac abnormalities among discordant cases.

### **St. Vincent's Hospital – 2022-2023**

A flagship study at St. Vincent's Hospital (Melbourne) in 2022-2023 provided an eye-opening validation. In this trial, EchoSolv was run on 8,257 echocardiograms from the hospital's database and its alerts for severe AS were compared to what the treating cardiologists had originally reported for those patients. The AI's performance was impressive on multiple fronts: it identified 100% of the cases that doctors had diagnosed as severe AS (proving it's at least as sensitive as standard care), and more importantly, it caught a large number of missed cases. Specifically, EchoSolv found 317 patients (3.8% of the cohort) with guideline-defined severe AS, whereas the original clinical reports had only identified 175 such patients – meaning the AI uncovered 142 additional severe AS patients that were previously overlooked. In other words, EchoSolv improved detection by ~45% in absolute terms. Put differently, EchoSolv flagged 72% more patients with severe AS than were detected by humans alone.

The trial also reported downstream clinical impacts: of the patients EchoSolv identified as severe AS, 57% went on to receive AVR when clinicians were made aware of the findings, whereas among those severe cases that had been missed initially, only ~23% received such life-saving therapy. This highlights the value of the AI alert – patients who are flagged have a much better chance of being referred for appropriate intervention than those who fly under the radar.

## **And Away We Go**

### **FDA Clearance**

Echo IQ achieved a pivotal regulatory when EchoSolv-AS secured FDA 510(k) clearance in October 2024. This approval enables EchoSolv-AS to be marketed and adopted by healthcare professionals across the United States. The FDA determined EchoSolv-AS demonstrated substantial equivalence to existing predicate devices, underscoring the technology's safety, effectiveness, and its potential to improve the accuracy and reliability of diagnosing severe AS.

Beyond AS, Echo IQ is advancing regulatory clearance for additional indications, notably heart failure. Echo IQ has lodged a pre-submission meeting request with the FDA to confirm the trial design for EchoSolv-HF, a heart failure clinical decision support tool. Preliminary clinical studies have demonstrated impressive results: EchoSolv-HF standalone AI detected 86% of heart failure cases compared to 46% by standard clinical practices. When combined with clinical evaluation, accuracy further increased to 97% for high-risk individuals. The heart failure market represents a significant commercial opportunity for Echo IQ, with an estimated annual healthcare expenditure of approximately US\$70 billion in the US alone.

### **Commercialisation Strategy**

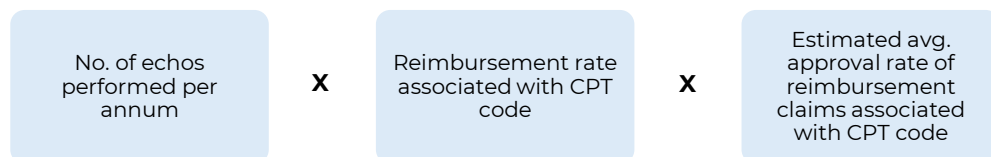
Echo IQ has rapidly initiated commercialisation activities, marked by the flagship integration of EchoSolv-AS at Beth Israel Deaconess Medical Center, a world-renowned Harvard Medical School teaching hospital. Beth Israel conducts approximately 30,000 echocardiograms annually, providing a critical validation platform and increasing the visibility of EchoSolv-AS within the broader US healthcare market. Four additional hospitals located in New York, Alabama, Dallas, and Oklahoma have also adopted EchoSolv-AS through the company's integration with existing software platforms such as Studycast. In March of this year, EIQ announced a strategic partnership with ScImage, a cloud and integrated workflow management platform with over 1,200 users, specialising in the collation of medical images and secure, real-time access to patient information. Under the agreement, EchoSolv-AS will initially be deployed across 36 affiliated hospitals and cardiology



practices. Furthermore, EchoIQ has a pipeline of 60 additional hospital sites which may integrate EchoSolv-AS, providing a substantial initial client base poised for revenue generation in the near term.

A critical factor driving commercial adoption in the US healthcare sector is the reimbursement landscape. Echo IQ successfully identified a Miscellaneous Reimbursement Code (93799) for EchoSolv-AS, providing an estimated reimbursement rate of between US\$100 to US\$150 per use. The Company is actively pursuing a dedicated Category III CPT code, which would further streamline reimbursement processes, with approval anticipated in mid-2025. This reimbursement strategy is expected to catalyse adoption across hospital groups, facilitating broader commercial integration and utilisation.

Echo IQ employs a subscription revenue model for the commercialisation of its EchoSolv-AS technology, designed to align closely with reimbursement frameworks available to healthcare providers in the United States. Under this model, hospitals and healthcare institutions enter into annual subscription agreements to access and utilise EchoSolv-AS. The annual subscription fee is calculated as:



The number of echos performed per annum is roughly calculated as the previous 12 months' number multiplied by the growth rate over a lookback period of a few years. This calculates the number of expected echos for the year ahead, the figure with which the subscription price is calculated. When it comes to distribution of EchoSolv via ScImage, the commercial arrangement between hospital and Echo IQ remains the same. The hospital pays the annual subscription fee to Echo IQ based on the previously mentioned formula.

For the Miscellaneous Reimbursement code, approval rates for reimbursement claims range from 20% to 40% - relatively low compared to Category III and Category I codes. This is because miscellaneous codes are generally less standardised, require more rigorous justification for use, and often involve case-by-case approval processes by insurers.

Material revenue uplift is expected upon achieving a dedicated Category III CPT code. Category III CPT codes are assigned to new and emerging technologies and typically receive higher reimbursement approval rates from insurers, usually between 40-60%. Echo IQ has filed an application for a Category III CPT code with the Centers for Medicare & Medicaid Services (CMS) and anticipates receiving approval by mid-2025. This code will streamline the reimbursement process, boosting both institutional adoption rates and overall revenue generation as healthcare providers experience greater confidence and predictability in reimbursement claims.

The most substantial revenue enhancement is projected following the eventual receipt of a Category I CPT code. Category I codes signify widespread clinical acceptance and usage and typically result in the highest approval rates for reimbursement claims, generally between 80-100%. The achievement of a Category I CPT code not only enhances the reimbursement approval rate substantially but also typically increases the reimbursable amount, further improving Echo IQ's revenue potential.

The key distinctions between these CPT code categories lie in their perceived clinical validation and payer acceptance. Miscellaneous codes are broadly applicable to various emerging technologies and require individualised claim evaluation, resulting

in lower and less predictable reimbursement approval rates. Category III codes, while still designated for emerging technologies, indicate a higher level of clinical validation and offer improved reimbursement consistency. Finally, Category I codes represent a mature and widely accepted technology within clinical practice, leading to the highest reimbursement rates and consistency, significantly expanding the potential patient coverage and financial returns.

## IP Portfolio

Echo IQ's intellectual property (IP) strategy forms a foundational element of its long-term competitive advantage, crucially underpinning the commercial viability and uniqueness of EchoSolv. The company has taken proactive steps to fortify its IP portfolio, filing multiple patents across strategic international markets, notably the United States, European Union, and key Asia-Pacific territories. These patent filings aim to protect EchoSolv-AS's proprietary algorithms, methodologies for echocardiogram analysis, and associated processes that enhance the accuracy and reliability of diagnosing aortic stenosis.

The significance of Echo IQ's IP protection strategy is heightened by the inherent risk of replicability common to software-driven medical technologies. Given the global trend towards integrating AI within diagnostic workflows, potential competition from companies seeking to develop analogous technologies is considerable. Thus, Echo IQ's success in obtaining and maintaining comprehensive patent coverage will play a critical role in mitigating this risk and securing market exclusivity.

Moreover, Echo IQ holds exclusive rights to the world's largest longitudinal patient outcomes database related to echocardiography, the NEDA database, enhancing its data-driven competitive edge significantly. This exclusive access not only provides a barrier to entry for competitors but also facilitates continuous improvement of EchoSolv-AS through ongoing refinement of its machine learning models based on real-world data.

Despite these strategic advantages, Echo IQ faces some vulnerabilities inherent to IP management in the healthcare technology sector. Patent processes, particularly in complex fields such as AI and machine learning algorithms, are nuanced and potentially subject to litigation. Furthermore, the scope of software patents can sometimes be narrow, and alternative approaches to algorithm design or data processing might circumvent existing protections. Therefore, while Echo IQ's IP portfolio is robust, the risk remains that competitors could develop similar, non-infringing solutions that deliver comparable diagnostic performance.

## 3. One and done? There's more to come.

### Heart Failure

#### The What and Why

Echo IQ is developing EchoSolv-HF, a clinical decision-support tool designed to assist with the diagnosis of heart failure (HF). Defined as a chronic, progressive condition where the heart is unable to pump blood effectively, it does not mean that the heart has stopped working, rather that it's functioning less efficiently. The key characteristics of heart failure include: reduced cardiac output – the heart can't pump enough oxygen-rich blood to vital organs; fluid accumulation – blood and fluids can back up into the lungs, abdomen, liver, and lower limbs, leading to symptoms like swelling and breathlessness; and increased pressure in the heart – as the heart struggles, it can enlarge ("cardiomegaly"), hypertrophy, or dilate its chambers.

HF, despite being a leading cause of hospitalisation worldwide, is a frequently underdiagnosed condition. Results from a 2023 study - *Missed opportunities in the diagnosis of heart failure: a real-world assessment* – revealed that of the patients experiencing their first HF hospitalisation who had existing, recorded signs/symptoms of HF in primary care electronic health records, 43% of patients had no prior adequate clinical management. Among this group, 50% of patient received inadequate follow up care after signs and symptoms were documented.

According to the *HF Stats 2024: Heart Failure Epidemiology and Outcomes Statistics* report, approximately 6.7 million Americans over the age of 20 currently live with heart failure, a figure projected to rise to 8.7 million by 2030, 10.3 million by 2040, and a staggering 11.4 million by 2050. To put this into perspective, the lifetime risk of HF has increased to 24% - approximately 1 in 4 persons will develop HF in their lifetime. Estimates by GlobalData suggest the HF market will grow at a 9.6% CAGR from US\$13.5b in 2022 to \$33.7bn in 2032 in the 7MM (US, France, Germany, Italy, Spain, UK, and Japan). And it is expected that the US will contribute the most to this growth partially due to the substantially higher cost of prescription medications.

When it comes to the HF diagnostic market specifically, Precision Business Insights suggests that this was valued at approximately US\$3.94 billion in 2023 and is expected to grow at a CAGR of 4.8% from 2024 to 2030.

## HF Types

HF is classified according to ejection fraction (EF), specifically left ventricular ejection fraction (LVEF) – how much blood the left ventricle pumps out with each contraction.

- HF with reduced EF (HFrEF) – LVEF <40%
- HF with mid-range EF (HFmrEF) – LVEF 40-49%
- HF with preserved EF (HFpEF) – LVEF >50%

HFrEF is the most prevalent, accounting for a touch over 50% of total HF cases. This group often exhibits higher mortality rates than the others – HFrEF is associated with an 85% increased risk of 5-year mortality compared to HFpEF.

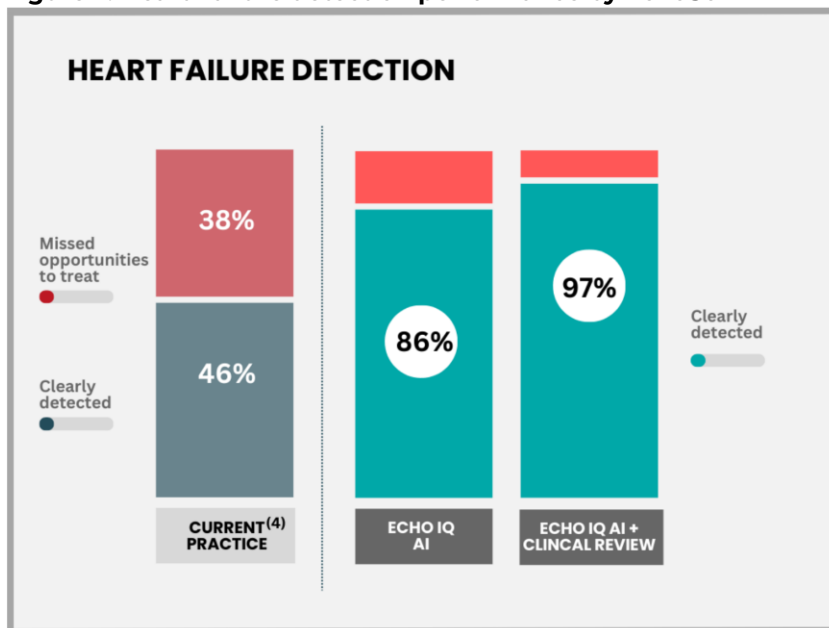
## Current Standards & The Potential for EchoSolv-HF

The current standard-of-care for diagnosing HF typically involves a combination of clinical evaluation, echocardiography, blood biomarker testing (such as BNP or NT-proBNP), and supportive imaging techniques. Echocardiography remains the cornerstone, providing essential insights into cardiac structure, function, and ejection fraction. However, the diagnosis is often complex and subjective, relying heavily on clinician interpretation of imaging and symptomatic presentation, which can lead to variability and underdiagnosis – particularly in early-stage or atypical HF presentations. These diagnostic gaps underscore the potential value of EchoSolv-HF.

As part of a clinical validation study in collaboration with the St Vincent's institute of Medical Research, EchoSolv-HF was retrospectively applied to the echocardiographic and clinical data from SCREEN-HF patients. The SCREEN-HF study was a large, community-based Australian trial that evaluated the use of NT-proBNP screening and echocardiography to identify individuals at risk of developing heart failure and monitor the progression of left ventricular dysfunction over time. As outlined in a September 2024 market announcement, EchoSolv-HF correctly identified 86% of patients with HF without human intervention.

EchoSolv-HF was also applied to data from NIL-CHF (an Australian study looking at the effectiveness of a long-term, nurse-led, multidisciplinary programme of home/clinic visits in preventing progressive cardiac dysfunction in individuals at risk of developing de novo chronic HF). EchoSolv-HF achieved 97% accuracy in identifying high-risk individuals who subsequently developed HF.

**Figure 7: Heart Failure detection performance by EchoSolv-HF**



So, while EchoSolv-HF was not used prospectively during original screening in either study, the data provides insight into the critical, real-world applicability of the tool.

### Where to From Here?

Echo IQ is now transitioning into the critical regulatory phase for EchoSolv-HF, with the near-term milestones clearly mapped out. Central to this process is the upcoming pre-submission meeting with the U.S. Food and Drug Administration (FDA), anticipated to occur in the coming months. This meeting is a pivotal step, allowing Echo IQ to seek guidance and concurrence on the design and objectives of their planned validation study. Successful alignment with FDA expectations at this stage significantly streamlines the subsequent regulatory journey and reduces the potential for delays or unforeseen requirements later in the process.

Following confirmation of the clinical validation study protocol with the FDA, Echo IQ is poised to initiate this validation study in partnership with prominent U.S.-based healthcare institutions. The validation study, expected to commence shortly after the FDA meeting, will serve as the critical piece of evidence demonstrating EchoSolv-HF’s diagnostic accuracy, consistency, and utility in real-world clinical settings. The company has indicated advanced negotiations with leading clinical sites, underscoring strong industry interest and readiness to participate, thus positioning Echo IQ to swiftly operationalise the study upon regulatory approval of the protocol.

The validation trial will provide the final set of clinical data required for Echo IQ’s submission for FDA clearance via the 510(k) regulatory pathway. The 510(k) process is anticipated to commence towards the end of the calendar year, marking a significant inflection point. Given that Echo IQ recently navigated the FDA’s regulatory pathway successfully for its EchoSolv-AS solution, the company now has both experience and precedent to guide the EchoSolv-HF submission, potentially facilitating an efficient review and approval process.

With the validation study projected to complete within the planned timeline, Echo IQ anticipates securing FDA clearance for EchoSolv-HF in the second half of CY2025. This regulatory clearance would open a substantial commercial opportunity, given the sizeable addressable heart failure diagnostics market in the United States. Echo IQ’s strategic groundwork in parallel to regulatory activities—including early reimbursement pathway alignment—positions EchoSolv-HF for rapid commercial uptake upon approval.



## Pulmonary Hypertension

The third rung on Echo IQ's ladder is Pulmonary Hypertension (PH). PH is a complex and progressive condition characterized by elevated blood pressure in the pulmonary arteries, leading to right heart failure if left untreated. The global market for PH treatment was valued at approximately USD 7.66 billion in 2023 and is projected to grow at a CAGR of 5.4% from 2024 to 2030, reflecting the increasing prevalence and recognition of the disease.

Diagnosing PH is inherently challenging due to its nonspecific symptoms and the need for specialized investigations. The current diagnostic pathway typically begins with TTE. As outlined in our discussion of AS diagnosis, the accuracy of TTE is operator-dependent, and may not definitively diagnose PH. Consequently, right heart catheterization (RHC) remains the gold standard for diagnosis, providing direct hemodynamic measurements. However, RHC is invasive, carries procedural risks, and is not suitable for widespread screening.

Echo IQ has recognised the unmet need for more accurate, efficient and non-invasive diagnostic tools for PH. The Company plans to develop and refine the EchoSolv platform for PH, with a pilot study intended for Q4 this calendar year.

## 4. EchoSolv – Best of The Bunch?

It should come as no surprise that significant investment is being made into AI for health diagnostic capabilities. In fact, as of January 2025, there are 161 FDA-cleared AI algorithms specific to cardiology. In total, the FDA has cleared more than 1,000 clinical AI algorithms for direct patient care – cardiology ranks second behind radiology.

In this section, we discuss three forms of competition for Echo IQ: direct competitors developing/selling AI-powered echocardiography diagnostic tools; indirect competitors applying AI to other cardiac imaging modalities; and lastly, imaging technology innovators who are improving hardware, image enhancement & workflow solutions. The premise is that, in this fast-moving space, competition may arise from multiple sources, whether it be Ultromics developing AI for echocardiographic diagnosis of HF (direct) or Butterfly network developing an AI-integrated ultrasound probe.

### Direct Competitors – AI-Powered Echocardiography Diagnostics

These companies offer AI-based tools for echocardiography interpretation, directly competing with EchoSolv. These companies pose the greatest threat to Echo IQ and the Company's ability deliver on their value proposition to investors. It must be noted that a clear line differentiates this group of competitors: those that use AI to analyse the echo reports (e.g. Echo IQ) and those that use AI to analyse the echo images themselves (e.g. Ultromics and Us2.AI).

#### Ultromics – EchoGo Heart Failure

Ultromics is an Oxford University spin-out founded in 2017 that focuses on AI analysis of echocardiograms. It's cloud-based EchoGo platform applies AI to automatically detect disease. In December 2022, the Company received 510(k) clearance for EchoGo Heart Failure, which has been developed specifically for HFpEF.

Ultromics collaborated with the Mayo Clinic for development. The model was trained and validated on a data set comprising 6,756 patients (2,971 cases and 3,785 controls) with 7,249 TTEs. Specifically, the model was fed a single apical four-chamber view video clip from each TTE. Classification performance testing yielded AUCs of 0.97 and



0.95 in the training and validation data sets respectively. This corresponded to a sensitivity of 88.7% and specificity of 85.4% in the validation data set.

Independent testing of EchoGo on a 1,284-patient pool (646 cases, 638 controls) reaffirmed strong performance of the model: 87.8% sensitivity and 81.9% specificity; 83.6% PPV and 86.5% NPV. Importantly for Ultrasonics, the model-maintained performance across age, sex, clinical comorbidities, and other variables. It also showed perfect repeatability of all model outputs.

Further external validation studies have reinforced these findings. For instance, research published in Nature Communications indicated that EchoGo® Heart Failure produced fewer indeterminate results (15%) compared to the H2FPEF score (62%). Additionally, a diagnostic positive result from EchoGo® was associated with a nearly threefold increase in the risk of heart failure hospitalization, underscoring its prognostic value. It must however be noted that a rate of 15% of analyses resulting in indeterminate results is not ideal. In a real-world scenario, this means that, on top of the pool of patients not accurately diagnosed, a further pool of patients can't be diagnosed using the tech.

### EchoGo Amyloidosis

Ultrasonics' second product – EchoGo Amyloidosis – is a tool designed to improve the detection and management of cardiac amyloidosis. Cardiac amyloidosis is an infiltrative cardiomyopathy characterized by the deposition of misfolded amyloid proteins in the heart's extracellular space. This accumulation leads to increased ventricular wall thickness, resulting in restrictive cardiomyopathy and diastolic dysfunction. Over time, the heart's ability to pump blood effectively diminishes, potentially leading to heart failure and arrhythmias. The condition is often underdiagnosed due to its nonspecific symptoms and similarities to other cardiac diseases.

Like EchoGo Heart Failure, this tool leverages AI to analyse a single apical four-chamber view, providing a diagnostic output categorising the findings as either 'suggestive' or 'not suggestive' of disease. It has demonstrated 84.5% sensitivity and 89.7% specificity within its target population, which includes individuals aged 65 and older with HF. The FDA granted EchoGo Amyloidosis Breakthrough Device Designation, which facilitates expedited development and review processes.

### Echo IQ vs Ultrasonics

**Figure 8: EchoSolv vs EchoGo**

	EchoSolv	EchoGo
Data Input	Analyses echocardiographic measurement data extracted from the report. It does not require access to raw images.	Requires access to raw echocardiographic images, specifically utilising standard views such as apical four-chamber view.
Application Method	In a matter of seconds, provides risk assessment of patient using prop. algorithm. Interpretation by clinician.	In 20 minutes, derives functional cardiac metrics of patient using prop. algorithm. Interpretation by clinician.
Integration	Seamless integration into existing clinical workflows.	Integrates with Picture Archiving and Communications Systems (PACS) and operates through cloud-based platform.

The above table outlines the differences between EchoSolv and EchoGo. The key difference is that EchoSolv analyses echocardiogram data from previously generated reports while EchoGo analyses the actual echocardiogram recording. This is rather significant: EchoSolv can be rapidly deployed with minimal disruption, making it highly scalable across various clinical settings whereas EchoGo requires more infrastructure and coordination (due to PACS integration requirement or manual DICOM export/upload to a cloud platform). This entails higher setup complexity. However, where EchoSolv is dependent on the quality and completeness of the initial echo interpretation and report, EchoGo interprets the raw image, allowing new measurements to be extracted and evaluated. This could mean that the model is less



dependent on operator experience and provide more robust detection of complex conditions that aren't always included in echo reports. In practice, EchoSolv has proven to address the risk of user error with its ability to flag improbably/impossible data points from the echo report.

Looking at rollout, by August 2023 (8 months on from FDA clearance), the EchoGo Heart Failure had been deployed in approximately 15 hospitals across the US and had processed an estimated 120,000 cases. While no up-to-date numbers are available in the public domain, it can be assumed that this figure has likely grown substantially.

**Figure 9: EchoGo reimbursement structure**

Code	Type	Reimbursing Entity	Payment	Setting	How It Works
0932T	Cat III CPT Code	Medicare (CMS) + Private Insurers	~US\$299.91	Outpatient + physician Use	Temporary CPT code created by the AMA; providers bill for EchoGo.
NTAP	CMS Add-on Payment Program	CMS	Up to US\$1,023.75 per case.	Hospital inpatient	Medicare program that helps hospitals cover the cost of newly approved technologies; Medicare pays 65% of difference up to payment amount (see left) if EchoGo is used during hospital stay and its cost exceeds the regular Medicare payment.
APC 5743	CMS Payment Category	CMS	~US\$299.91	Hospital outpatient	EchoGo is grouped into this APC by CMS; each APC has a national payment rate. Hospitals billing EchoGo using CPT 0932T get paid under this category.

When it comes to reimbursement, Ultromics is well-positioned. Hospitals can bill for EchoGo in both inpatient (NTAP) and outpatient (CPT 0932T & APC 5743) settings. Physicians may bill CPT 0932T for the professional interpretation of the AI results. While specific details about an application for a Category I CPT code by Ultromics are not publicly available, the company is actively working to establish coverage with commercial payers and to support the adoption of EchoGo® Heart Failure. Achieving a Category I designation would depend on further evidence of clinical efficacy and widespread utilization.

As previously discussed, EchoSolv-HF is yet to be covered and EchoSolv-AS is covered by miscellaneous CPT code 93799, which serves as a temporary billing mechanism until a category III code is established. The estimated reimbursement ranges from US\$100 to US\$150 per use and is applied 20-40% of the time.

Under the assumption that healthcare providers are highly unlikely to adopt two AI diagnostic tools at once, at least in the near term, it could be assumed EIQ and Ultromics are in a race to build the most comprehensive and clinically useful suite of heart disease-diagnosing AI tools. The initial decision healthcare providers face is whether they want a lightweight, fast, cheaper risk assessment and screening tool (EchoSolv) or a slower, costlier but detailed diagnostic tool (EchoGo). Different clinical settings will have different requirements and therefore will prefer one or the other. Regardless, the decision will be guided by the diagnostic breadth of the platform. Given that the EchoGo platform is more indication-focused (i.e. targeting HFePF), we believe EchoSolv will see widespread adoption, particularly upon FDA clearance for EchoSolv-HF.

**Us2.ai**

Us2.ai is a Singaporean company offering an AI software platform for fully automating echocardiography analysis and reporting. Their technology, Us2.v2, received 510(k) clearance in April 2024. It functions as an advanced image post-processing analysis tool (i.e. algorithm is applied to the raw echo images), generating 45 echocardiographic measurements in 2-3 minutes. Key capabilities include automated strain imaging analysis, comprehensive quantitative analysis of cardiac

structure and function, and left/right atrial and ventricular linear dimensions, volumes, systolic and diastolic function measurements.

Us2.v2 has been tested on data from 8 ultrasound device vendors representing manufacturers most widely used in US clinical settings. The system's measurements have been validated as interchangeable with expert human readers, addressing a significant pain point in echocardiography - measurement variability. Us2.ai has built its market presence on the foundation of its previous FDA-cleared and CE-marked solution, Us2.v1. The company offers connectivity options for various ultrasound devices, from GE Vivid CARTs to mobile devices like EchoNous Kosmos.

Looking at market positioning, Us2.v2 is marketed as a comprehensive measurement and workflow enhancement platform. EchoSolv is a decision-support that is condition-specific and focuses on risk assessment. A way of looking at this is that Us2.v2 automates the image analysis process for clinicians, outputting quantifiable data whereas Echo IQ uses existing data to provide risk assessments for disease and severity of disease. Therefore, it's quite plausible one, to see these as non-competing products, and two, to question whether Us2.v2 is actually adding to diagnostic capabilities.

The answer to part one is that the tool, while not providing a 'yes or no' output, provides information that a professional can use to arrive at a 'yes or no'. The answer to part two is that the tech automates advanced diagnostic parameters, facilitating comprehensive disease detection.

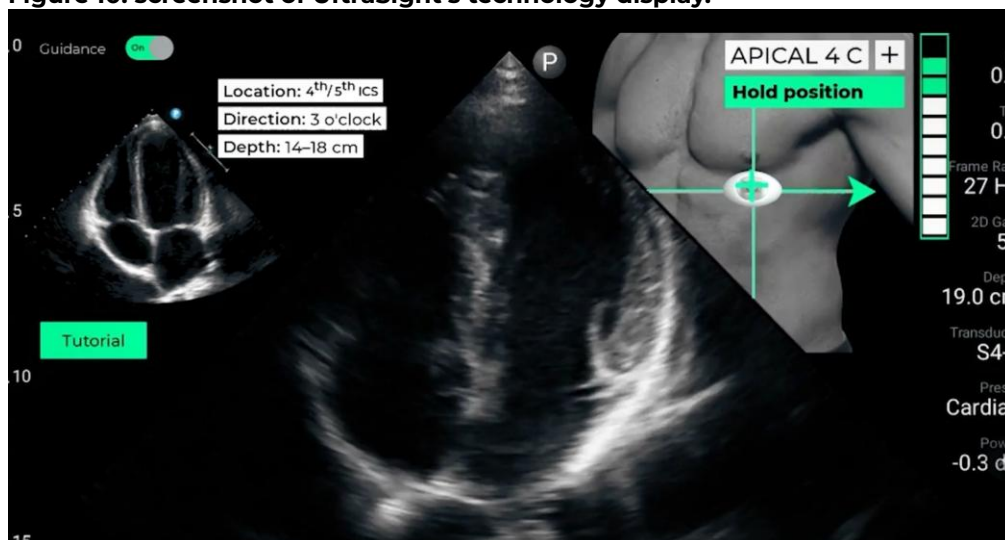
Ultimately, what serves as competition for Echo IQ in this case is that, to date, Us2.v2 offers a broader application across cardiac pathologies. At this stage, this solution may be a more attractive investment for healthcare providers. Given the company is private and there is limited public information on its rollout, it is hard to say whether this product is being widely adopted and truly helping in a real-world environment.

## **UltraSight & Caption Health**

These two companies developed respective AI systems that guide ultrasound image acquisition. Caption's flagship, Caption AI, provides real-time guidance on how to position and angle the probe to capture standard echo views. It received FDA clearance in 2020 for the AI-guidance of cardiac ultrasound and an automated EF calculation tool. UltraSight's real-time AI was granted FDA clearance in 2023. The fundamental value proposition of these technologies is that they assist medical professionals without top-of-the-line sonography experience to capture clinically useful ultrasound images. This is particularly helpful in point-of-care settings outside of the cardiology wards such as community clinics, and rural areas. Both technologies provide on-screen prompts that effectively coach the user in real time.

As it pertains to EchoIQ, the only form of competition lies in the respective technologies' abilities to overcome user error. As discussed previously, EchoSolv provides the great benefit of flagging improbable/impossible data points and then imputing likely values. This means that if the sonographer incorrectly measures a certain data point, EchoSolv not only identifies this (through inference across the package of data points in the report) but also imputes the most probable value. In the real-world, it is most likely that Ultrasight & Caption's technologies are highly complementary to EchoSolv.

**Figure 10: screenshot of UltraSight's technology display.**



## Indirect Competitors – AI in Other Imaging Modalities

AI integration within cardiac MRI and CT has focused predominantly on automating measurements, improving diagnostic precision, and stratifying patient risk more accurately. Companies active in this space, including Arterys (acquired by Tempus Labs), Circle Cardiovascular Imaging, HeartFlow, Cleerly, Elucid, Caristo Diagnostics, and the Australian-listed company Artrya (ASX:AYA), provide insights into how AI-based diagnostics are reshaping clinical practice.

Cardiac MRI, leveraged by companies such as Arterys and Circle Cardiovascular Imaging, is valued clinically for its high-resolution imaging, detailed myocardial tissue characterisation, and quantification of cardiac volumes and function. Arterys, which operates primarily in cardiac MRI and CT spaces, has achieved multiple FDA clearances for its cloud-based AI platform, enabling automated cardiac volume and blood flow assessments. Similarly, Circle Cardiovascular Imaging's widely-used software, cvi42, automates complex analyses, significantly reducing manual processing and potentially reducing human variability. Both solutions have secured regulatory approval and have been adopted widely within specialised cardiology and radiology departments internationally.

Cardiac CT imaging is another significant area for AI deployment, particularly in the evaluation of coronary artery disease. HeartFlow's FDA-cleared AI software utilises computational fluid dynamics and advanced algorithms to non-invasively measure fractional flow reserve (FFR-CT), assisting clinicians in assessing the severity of coronary artery disease without invasive procedures. Similarly, Cleerly and Elucid use AI-driven image analysis to characterise coronary artery plaque composition and assess vulnerability, which assists clinicians in stratifying patient risk for acute coronary syndromes. Caristo Diagnostics provides a complementary approach, utilising CT imaging and AI-derived inflammation indices around coronary arteries to predict future cardiac events. These methods offer clinicians diagnostic alternatives to echocardiography, particularly in assessing coronary disease severity and planning therapeutic interventions.

Within Australia, Artrya (ASX:AYA) offers another AI-driven solution for cardiac CT analysis. Its Salix Coronary Anatomy product leverages artificial intelligence to analyse coronary CT angiograms, identifying and quantifying coronary artery disease, including plaque burden and characteristics. Artrya's technology achieved FDA clearance, TGA registration in Australia and CE Mark clearance for use in Europe.

From a clinical perspective, MRI and CT AI tools are not direct substitutes for echocardiography-based solutions like EchoSolv, but rather complementary

technologies. MRI and CT excel in specialist clinical environments or tertiary care settings where detailed anatomical and tissue characterisation are required, while Echo IQ's EchoSolv technology targets rapid, scalable population screening and early identification of structural cardiac disease, making it suitable for broader clinical contexts, including primary care or resource-limited environments.

### **Competition for HF & PH Plans?**

Echo IQ's planned expansion of EchoSolv into heart failure (HF) and pulmonary hypertension (PH) diagnosis is unlikely to be significantly impeded by companies using MRI and CT-based AI diagnostic solutions, but some indirect competition may exist depending on clinical use cases and diagnostic settings.

When it comes to HF, cardiac MRI is highly accurate for assessing cardiac anatomy, myocardial fibrosis, and function, including precise measurements of ejection fraction, myocardial strain, and tissue viability. Clinically, MRI is typically employed to evaluate specific subtypes or causes of heart failure (e.g., cardiomyopathy, myocarditis, infiltrative disease such as amyloidosis, sarcoidosis) rather than as a frontline screening tool for initial detection of heart failure.

Cardiac CT can evaluate coronary artery disease (a common cause of ischemic heart failure), detect calcium deposition, and assess cardiac structure, though it is less commonly utilised for direct assessment of heart function due to its radiation exposure and contrast-related considerations. CT is usually indicated when coronary artery anatomy or coronary disease risk is a specific clinical question. It is rarely the initial diagnostic choice purely for determining cardiac function or identifying general heart failure.

TTE is widely accepted as the frontline standard-of-care diagnostic tool for HF due to its accessibility, low-cost, and real-time functional evaluation capabilities. EchoSolv-HF will obviously be used in this context – early detection, more efficient diagnosis. MRI and CT-based AI solutions primarily serve as downstream confirmatory diagnostics, reserved for more complex or ambiguous cases of HF, or for detailed assessment once HF is already suspected or diagnosed. While they may share overlapping clinical indications, MRI and CT-based diagnostics are generally not considered direct substitutes for an echocardiography-driven screening or frontline diagnostic tool like EchoSolv-HF.

When it comes to PH, echo is the initial screening tool. Invasive catheterisation for confirmation and accurate haemodynamic assessment follows. Cardiac MRI is used secondarily, providing complementary information regarding cardiac structure, ventricular function, right ventricular strain, and pulmonary artery flow dynamics. It is helpful in identifying secondary causes of PH (e.g., congenital heart disease, chronic thromboembolic pulmonary hypertension). CT imaging also contributes to PH evaluation, specifically identifying pulmonary embolism (chronic thromboembolic PH) and assessing pulmonary artery dilation. Nonetheless, as with heart failure, echocardiography remains the standard first-line imaging modality for initial suspicion and diagnosis of PH due to accessibility, safety, and real-time functional assessment.

EchoSolv expansion into pulmonary hypertension diagnosis would thus align with the established clinical workflow, providing AI-enhanced diagnostic accuracy during routine echo examinations. MRI and CT modalities, supported by AI or not, typically serve in secondary, confirmatory roles once initial suspicion of PH has been established through echocardiography.

## **Advances In Imaging Technology**

Recent advances from imaging technology innovators, including handheld ultrasound device manufacturers and major ultrasound OEMs such as Butterfly Network, EchoNous, Exo, Clarius, GE Healthcare, Siemens Healthineers, and Philips,



represent potential indirect competition to Echo IQ. These companies have introduced significant technological enhancements that simplify and improve cardiac imaging, particularly echocardiography, through innovations like semiconductor-based ultrasound chips (Butterfly), AI-guided handheld ultrasound probes (EchoNous and Exo), and advanced onboard AI software embedded in imaging hardware from GE, Philips, and Siemens. Such advancements improve the accessibility, usability, image quality, and diagnostic automation at the point of care, thereby potentially reducing the need for standalone AI diagnostic tools like EchoSolv. For example, handheld ultrasound solutions equipped with integrated AI capabilities might provide rapid and sufficiently accurate diagnoses directly at the patient's bedside, which could limit the additional clinical value EchoSolv provides. Moreover, major ultrasound OEMs continue to integrate sophisticated, FDA-cleared diagnostic features directly into their imaging platforms, streamlining echo analysis workflows. While Echo IQ's approach remains distinct, improvements in image acquisition, embedded diagnostic AI, and simplified clinical workflows from these technology innovators represent a credible competitive threat by potentially diminishing the incremental value of separate diagnostic solutions such as EchoSolv.

## Valuation

### M&A Precedents

#### Philips & DiA Image Analysis

Philips' US\$100 million acquisition of DiA Imaging Analysis in May 2023 exemplifies the strategic value large medical technology firms place on AI-driven cardiac imaging solutions, establishing a critical precedent for companies like Echo IQ. The deal, priced at ~30x its annual revenue, underscores the premium placed on validated AI platforms with regulatory traction – DiA held nine FDA clearances, including real-time cardiac image guidance (LVivo IQS) and automated ventricular analysis. Philips leveraged the acquisition to integrate DiA's AI into its Epiq CVx and Affiniti CVx ultrasound systems, enhancing capabilities in automated mitral regurgitation quantification and wall motion analysis while addressing sonographer shortages through workflow efficiency gains. This followed a two-year partnership and minority investment. The transaction aligns with broader industry consolidation, as seen in GE's purchase of Caption Health, highlighting the urgency among imaging OEMs to embed AI-driven automation into their portfolios to meet rising clinical demand. For investors, this precedent reinforces the attractiveness of specialized AI vendors like Echo IQ that demonstrate clinical validation, regulatory milestones, and integration potential with major platforms.

#### GE HealthCare & Caption Health

GE HealthCare's \$150 million acquisition of Caption Health in February 2023 further illustrates the strategic premium placed on AI-driven cardiac imaging platforms, reinforcing the M&A thesis for specialized developers like Echo IQ. The deal—structured with \$127 million upfront, \$10 million in deferred consideration, and \$13 million in performance-based earn-outs—valued Caption Health at ~2.5x its total venture funding (\$60 million), reflecting investor confidence in AI's capacity to democratize complex diagnostics. Caption's FDA-cleared AI platform, which provided real-time guidance for cardiac ultrasound acquisition and automated ejection fraction calculations, addressed critical pain points in echocardiography by enabling novice clinicians to perform reliable exams, particularly in point-of-care and home settings. GE immediately integrated the technology into its \$3.4 billion ultrasound business, prioritizing handheld devices to expand access in resource-constrained environments while leveraging Caption's partnerships with Butterfly Network for portable implementations. The acquisition complemented GE's post-spinoff growth strategy, following its purchase of CT guidance firm Imactis, and mirrored Philips' parallel move with DiA—demonstrating a sector-wide race to embed AI workflow solutions that mitigate sonographer shortages and improve diagnostic yield. With Caption's technology already validated across 20+ clinical studies and deployed in novel care settings, the transaction underscores how





regulatory-cleared AI algorithms with demonstrated clinical utility command premium valuations from imaging OEMs seeking to future-proof their portfolios.

## Key Assumptions

Echo IQ has only recently arrived at the commercialisation stage, hence small revenues to date and anticipated for FY25. As is the norm with novel diagnostic tools, initial market penetration is slow. Moreover, this business model is in its infancy resulting in hesitancy on the part of prospective counterparts.

## Reimbursement Dynamics

Central to the revenue potential of EchoSolv-AS is attaining a category III CPT code. We anticipate this will occur in July 2025. We assume that reimbursement under the code is US\$150. Furthermore, we anticipate EchoSolv-AS attaining a category I CPT code by the end of financial year 2027, reimbursed at a rate of US\$200 per scan. These rates fall in-line with current reimbursement benchmarks in cardiology.

In the near-term, we anticipate Miscellaneous Code 93799 will be reimbursed at US\$100 per scan, which is the lower end of the range suggested by Echo IQ (US\$100-150 per scan). It is our understanding that Echo IQ is placing a 30% average approval rate of reimbursement claims associated with the miscellaneous code as it pertains to their subscription price calculation. Under the category III and I codes, we assign likelihoods of reimbursement at 50% and 80% respectively.

**Figure 11: Portrayal of EIQ's subscription model performing 10,000 echos per annum**

	FY25	FY26	FY27	FY28	FY29	FY30
Number of echos p.a.	10,000	10,000	10,000	10,000	10,000	10,000
Reimbursement rate (USD)	\$100	\$150	\$150	\$200	\$200	\$200
Percentage of echos reimbursed	30%	50%	50%	80%	80%	80%
Subscription Revenue (USD)	\$300,000	\$750,000	\$750,000	\$1,600,000	\$1,600,000	\$1,600,000

The table above outlines how EIQ's revenues per hospital would materially increase with (i) increased reimbursement rates under category III and then category I CPT codes, and (ii) the increased proportion of total echos reimbursed. Note that this is a representation of a hypothetical scenario where the hospital in question performs 10,000 relevant echos per annum.

## Adoption

On top of the 5 existing counterparties – BIDMC and four other hospitals across the US – we expect EIQ to have deployed EchoSolv-AS across 41 sites come the end of FY25. We expect that deployment to the 36 ScImage/MedAxiom-affiliated hospitals will complete prior to the end of FY25. While it is plausible (and potentially likely) that EIQ execute further deals before the end of the financial year, for the sake of conservatism, we keep it at 41.

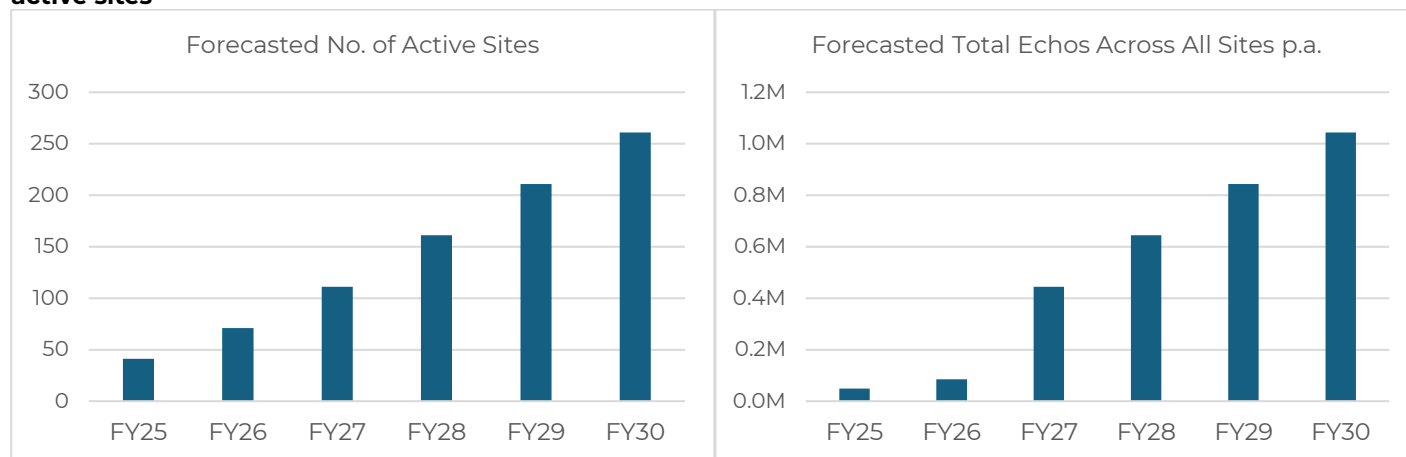
By the end of FY26, we expect EIQ will deploy across an additional ~30 sites, on the basis the company is able to convert a decent portion of its existing pipeline. Thereafter, we expect EchoSolv adoption to grow to 261 sites across the US by the end of FY30. This would represent less than 4.5% of the >6,000 hospitals in the US. We assume that new site additions occur in a linear fashion over the course of the financial year and therefore, we apply a 50% 'delay factor' to revenue from new sites per financial year. Moreover, to account for the 3-month free-trial period provided to new counterparties, we apply a 25% 'free trial factor' to revenue from new sites, effectively 'pushing back' the onset of revenue generation for these new hospitals.

It is likely that not all future revenues will be generated via the subscription model. As it is more important for the company to scale quickly that maximise every cent of revenue coming in, it is probably that there will be some contracts signed incorporating an alternative revenue generation model. For example, a fee-sharing model: the service provider (EIQ) earns a portion of the revenue that the hospital generates from deploying the service in reimbursable activity. The hospital bills payors (CMS, insurers) for the service rendered and EIQ receives a pre-agreed percentage of that reimbursement. We expect that for the bigger hospital owners



(such as HCA healthcare, Ascension, and Tenet Healthcare (NYS: THC)), EQ will have to accept a fee-sharing arrangement. In essence, the subscription model EQ is deploying is a fee-sharing arrangement where EQ keeps 100% of the revenue and the hospital breaks even while improving the service provided to patients.

**Figure 12: a table (left) displaying Evolution's forecasts for active site rollout, and another table (right) displaying our forecast for the total number of echos per annum applicable to EQ's subscription-based model across all active sites**



### Other Assumptions

We assume that EQ does not take out any debt in the forecasted period and makes no further investment in property, plant and equipment, nor will they make any acquisitions. To expedite development of EchoSolv for HF and PH, we anticipate a capital raise of A\$10 million in FY26, incurring A\$600k in transaction costs. This expected raise would also create a necessary cash buffer while the influx of recently onboarded sites use EchoSolv-AS under the free trial. Furthermore, we assume no options are exercised and no performance rights are exercised nor any further issues of either. To limit speculation, we do not factor-in any potential revenues from EchoSolv-PH.

### DCF

Ultimately, the valuation story of EQ relies on the company's ability to scale across the US. Scale will come with further FDA clearances for HF and PH indications, as well as 'success-founded adoption' – as the product is validated in the 'real world', we should expect more and more hospitals to adopt the technology.

**Through DCF methodology, we place a fair valuation on EQ of A\$0.74 per share, approximately 155% upside from the current share price of A\$0.29.**

We apply a WACC of 12.36% to discount forecasted net cash flows. Our calculation includes a beta of 0.78 (calculated on 1-year returns against the small ordinaries index), a risk-free rate of 4.1%, cost of equity of 15% and target gearing of 15%. The DCF model incorporates a 2.5% long-term growth rate. Other key assumptions include gross margins of 90%, resulting in EBTIDA margins of between 30% (FY26e) and 42.5% (FY30e).

**Figure 13: DCF summary calculation table.**

EQ Valuation (A\$M)	
Terminal Growth Rate	2.5%
Discount Rate	12.36%
Terminal Value (TV)	725.28
Present Value of TV	363.93
<b>Enterprise Value</b>	<b>271.29</b>
<b>Equity Value</b>	<b>457.98</b>
Undiluted ord shares	621.85
<b>Implied (Target) Price</b>	<b>\$0.74</b>

## Key Risks

### Regulatory and Clinical Development Risks

Echo IQ's commercial success is heavily dependent on obtaining and maintaining regulatory approvals, such as FDA 510(k) clearances and reimbursement codes from entities like the Centers for Medicare & Medicaid Services (CMS). EchoSolv-AS has recently secured FDA clearance; however, EchoSolv-HF remains subject to approval, which introduces uncertainty around timing and outcomes of regulatory reviews. Any delays or adverse regulatory decisions could significantly impact market entry timelines and potential revenue streams.

### Reimbursement Risk

EchoSolv's widespread adoption in clinical settings relies substantially on the availability of adequate reimbursement from healthcare payors, including Medicare and commercial insurance providers. Although Echo IQ has identified a Miscellaneous Code (93799) for EchoSolv-AS, which offers reimbursement between US\$100 to US\$150 per use, the more comprehensive Category III CPT code has yet to be secured. There is no guarantee that reimbursement levels will remain at these levels or that future reimbursement codes (Category I CPT) will be obtained in a timely manner. Inadequate reimbursement could severely limit market penetration and overall product uptake, therefore limiting future revenues.

### Market Adoption and Competition Risk

Echo IQ operates in the rapidly evolving and highly competitive medical technology market. Several direct and indirect competitors already exist or may emerge, developing AI-enhanced diagnostic solutions that could compete with EchoSolv-AS and EchoSolv-HF. Any new or existing competitive technologies demonstrating superior performance, cost-effectiveness, or ease of integration could diminish EchoSolv's market share or impede its uptake in clinical practice. Furthermore, physician and hospital adoption rates of new technologies can be unpredictable and slow, affecting Echo IQ's ability to scale effectively.

### Intellectual Property (IP) Risk

Echo IQ's long-term commercial value is closely tied to its intellectual property, including proprietary algorithms and access to large datasets such as the National Echo Database Australia (NEDA). Although the company has filed multiple patents in key jurisdictions, there is no assurance that these patents will be granted or effectively enforceable. Additionally, the company could face litigation or infringement claims from third parties that may affect its ability to commercialise its products. There remains the risk of replication.

### Data Security and Privacy Risk

Echo IQ's products rely on access to and analysis of large volumes of patient data. Data breaches or failures in cybersecurity could lead to substantial damage to the company's reputation, legal liabilities, and potentially significant financial penalties. Given the sensitivity of health data, stringent regulations around data protection in various jurisdictions may also create additional compliance costs or constraints.

### Access to Capital and Funding Risk

While Echo IQ currently maintains adequate cash reserves and has successfully raised funds via equity issuances, continued development, commercialisation activities, and potential expansions may require additional capital. There is no guarantee that future capital will be available on favourable terms or at all. The inability to secure necessary funding could significantly delay or halt the company's growth strategies and product roll-outs.

### Personnel Risk

Echo IQ's operational success is dependent on its executive management and specialised technical staff, especially given recent strategic appointments in the US



market. The loss of key personnel or inability to attract and retain skilled professionals in the highly competitive AI and healthcare markets could adversely affect the company's ability to execute its commercialisation strategy effectively.

### Technological Development and Product Performance Risk

While early trials and clinical validation studies have demonstrated strong performance for EchoSolv-AS and EchoSolv-HF, real-world outcomes may differ from controlled environments. The products might encounter unforeseen technical issues, lower-than-expected accuracy in certain clinical settings, or difficulties with integration into hospital workflows. Such issues could lead to decreased product acceptance and slower-than-anticipated revenue growth.

### Economic and Market Conditions Risk

General macroeconomic conditions, including economic downturns, market volatility, and changes in healthcare policies and spending priorities, particularly in key markets such as the US, could adversely affect healthcare providers' capital expenditure decisions and patient volumes. Such economic factors might slow the adoption rate of new technologies like EchoSolv, thereby affecting Echo IQ's overall market penetration and revenue projections.

## Appendix Financial Statements

Income Statement						Statement of Cashflows					
A\$'000s	FY23a	FY24a	FY25e	FY26e	FY27e	A\$'000s	FY23a	FY24a	FY25e	FY26e	FY27e
Revenue	0.11	0.04	0.43	7.31	40.12	Net profit for period	-7.86	-5.41	-5.33	2.18	9.55
Other Income	0.07	2.00	2.13	1.49	-	Depreciation & Amortisation	0.61	0.60	0.59	0.58	0.40
<b>Total Revenue</b>	<b>0.18</b>	<b>2.04</b>	<b>2.56</b>	<b>8.81</b>	<b>40.12</b>	Changes in working capital	-0.84	1.15	0.56	0.84	-0.07
Operating expenses	-7.84	-6.85	-7.30	-5.12	-26.08	Other	-	-0.27	-	-	-
<b>EBITDA</b>	<b>-7.66</b>	<b>-4.81</b>	<b>-4.74</b>	<b>3.69</b>	<b>14.04</b>	<b>Operating cash flow</b>	<b>-8.09</b>	<b>-3.92</b>	<b>-4.18</b>	<b>3.59</b>	<b>9.88</b>
D&A	-0.61	-0.60	-0.59	-0.58	-0.40	Payments for PPE	-0.01	-	-	-	-
<b>EBIT</b>	<b>-8.27</b>	<b>-5.41</b>	<b>-5.33</b>	<b>3.11</b>	<b>13.65</b>	Other payments	-0.33	-	-	-	-
Net Interest	-	-	-	-	-	Proceeds from asset sale	0.28	-	-	-	-
<b>NPBT</b>	<b>-8.27</b>	<b>-5.41</b>	<b>-5.33</b>	<b>3.11</b>	<b>13.65</b>	<b>Investing cash flow</b>	<b>-0.06</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
Tax expense	-	-	-	-0.93	-4.09	Equity raised	3.49	-	7.11	10.00	-
Discontinued operations	0.41	-	-	-	-	Transaction costs	-0.19	-	-0.46	-0.60	-
<b>NPAT</b>	<b>-7.86</b>	<b>-5.41</b>	<b>-5.33</b>	<b>2.18</b>	<b>9.55</b>	Proceeds from exercise of options	2.58	2.76	-	-	-
<b>Balance Sheet</b>						Borrowings	-	-	-	-	-
A\$'000s	FY23a	FY24a	FY25e	FY26e	FY27e	Other	-	-	-	-	-
Cash	3.28	2.12	4.58	17.57	27.45	<b>Financing cash flow</b>	<b>5.88</b>	<b>2.76</b>	<b>6.64</b>	<b>9.40</b>	<b>-</b>
Receivables	0.64	0.10	0.17	1.83	7.62	<b>Free cash flow</b>	<b>-8.15</b>	<b>-3.92</b>	<b>-4.18</b>	<b>3.59</b>	<b>9.88</b>
Other	0.07	0.24	0.33	-	-	<b>Net cash flow</b>	<b>-2.27</b>	<b>-1.16</b>	<b>2.46</b>	<b>12.99</b>	<b>9.88</b>
<b>Current assets</b>	<b>3.98</b>	<b>2.45</b>	<b>5.08</b>	<b>19.40</b>	<b>35.07</b>	Effects of exchange rate	-0.01	0.00	-	-	-
Receivables	-	-	-	-	-	Cash year end	3.28	2.12	4.58	17.57	27.45
PPE	0.03	0.01	-	-	-	<b>Investment Fundamentals</b>					
Intangible assets and Other	6.37	5.79	5.54	4.49	4.23	FY23a	FY24a	FY25e	FY26e	FY27e	
<b>Non-current assets</b>	<b>6.41</b>	<b>5.80</b>	<b>5.54</b>	<b>4.49</b>	<b>4.23</b>	<b>Liquidity</b>					
<b>Total assets</b>	<b>10.38</b>	<b>8.26</b>	<b>10.62</b>	<b>23.89</b>	<b>39.31</b>	Quick Ratio	0.2	0.2	0.5	1.2	1.0
Trade and other payables	2.90	1.36	1.10	1.23	7.39	<b>Solvency</b>					
Borrowings	0.10	0.13	-	-	-	Debt to Equity	0.0	0.0	0.0	0.0	0.0
Other	0.10	0.13	-	0.36	0.06	Debt to Assets	0.0	0.0	0.0	0.0	0.0
<b>Current liabilities</b>	<b>3.00</b>	<b>1.49</b>	<b>1.10</b>	<b>1.59</b>	<b>7.45</b>	LT Debt to Assets	0.0	0.0	0.0	0.0	0.0
Borrowings	-	-	-	-	-	<b>Profitability</b>					
Other liability	-	-	-	-	-	Net Margin	n/a	n/a	n/a	25%	24%
<b>Non current liabilities</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	ROA	-76%	-58%	-56%	13%	30%
<b>Total Liabilities</b>	<b>3.00</b>	<b>1.49</b>	<b>1.10</b>	<b>1.59</b>	<b>7.45</b>	ROE	-106%	-76%	-65%	14%	35%
<b>Net Assets</b>	<b>7.38</b>	<b>6.77</b>	<b>9.53</b>	<b>22.30</b>	<b>31.86</b>	<b>Valuation</b>					
Contributed Equity	36.00	41.53	49.62	60.22	60.22	P/E	n/a	n/a	n/a	n/a	n/a
Retained earnings	-35.19	-39.10	-44.43	-42.25	-32.70	EV/EBITDA	n/a	n/a	n/a	n/a	n/a
Reserves/Other	6.58	4.33	4.33	4.33	4.33	P/B	3.69	6.12	4.94	2.23	1.56
<b>Total equity</b>	<b>7.38</b>	<b>6.77</b>	<b>9.53</b>	<b>22.30</b>	<b>31.86</b>						

## Leadership Team

### **Dustin Haines** CEO

Dustin Haines brings 25 years' experience in leading global businesses in pharmaceuticals, biotechnology, and medical devices. Most recently, Mr. Haines was head of Asia, Middle East, Turkey, and Russia for Gilead Sciences where he managed over \$1.2B in revenue. As a leader, Mr. Haines has launched innovative technologies globally with extensive experience in regulatory approvals, reimbursement, commercialization, and scaling business.

### **Sam Dribin** CTO

Sam Dribin is a seasoned Chief Technology Officer (CTO) with deep expertise in biotech software development, AI, DevOps, and cloud architecture. With a strong background in building FDA, ISO-13485, and HIPAA-compliant software, Sam specializes in designing secure, scalable, and regulatory-compliant solutions for healthcare and biotech industries. Sam was the Chief Technology Officer at CureMetrix for nine years, where he oversaw the development and FDA clearances of AI software to help physicians identify breast cancer and arterial calcifications in routine mammograms. Sam has a passion for developing innovative software solutions and has played a key role in the success of previous companies.

### **Deon Strydom** CCO

Deon is an accomplished Chief Commercial Officer with 15 years of experience driving innovation in the Pharmaceutical, Biotechnology, and Medical Device industries. His expertise spans global corporations, early-stage ventures, and startups, where he has successfully led Go-To-Market strategies, strategic partnerships, M&A, licensing, and commercialization efforts. Deon has a proven track record of delivering growth and market expansion across the US, APAC, and EU.

### **Andrew Grover** Exec. Chairman

Andrew Grover brings 25 years' experience in growing successful businesses across a diverse range of industries. As a founder and investor in numerous innovative companies, his businesses have been featured in BRW Fast 100 and Deloitte's Fast 50 over several years.

### **Steven Formica** NED

Steven Formica brings to the company significant business management and development experience. He has led a number of privately held business ventures across multiple industry sectors. Mr. Formica is currently the non-executive chairman of ASX listed Ragnar Metals (ASX:RAG), non-executive chairman of ASX listed Albion Resources Ltd (ASX: ALB), non-executive chairman of ASX listed Kaiser Reef Limited (ASX: KAU), non-executive director of ASX listed Bindi Metals (ASX:BIM), non-executive director of ASX Listed Great Northern Minerals Limited (ASX: GNM), and a successful investor in a number of ASX listed entities. Mr. Formica has previously held directorships with ASX listed companies Jade Gas Holdings (ASX:JGH), Labyrinth Resources Ltd (ASX: LRL), Bowen Coking Coal Ltd (ASX: BCB) and Lindian Resources Limited (ASX:LIN).

### **Steve Picton** NED

Steve Picton is an experienced Board Director and business leader. As CEO of mobile virtual network operator goTalk Limited, he increased revenues to more than \$100M. Mr. Picton holds a Bachelor of Science in technology and a Master of Science (Business) from London Business School and is both a Chartered Engineer and a Member of The Institute of Company Directors. He is also a Sloan Fellow which was awarded to him in 1993 by the Sloan Foundation as part of the joint MIT, Stanford and LBS programme. Mr Picton is currently the non-executive chairman of ASX listed FlexiRoam Ltd (ASX: FRX).

### **Ken Nelson** NED

Ken Nelson is a leading US-based medical technology and healthcare executive with over 20 years' industry experience. During his career he has been pivotal in leading successful commercialisation efforts with multiple cardiac-focused digital health companies including remote cardiac and diagnostics monitoring business, BioTelemetry, wearable device company, iRhythm and ambulatory ECG solutions monitoring group, Bardy Diagnostics. Currently, he serves as partner in the Medtech Advantage Fund, which has an exclusive partnership with Medtech Innovator ([www.medtechinnovator.org](http://www.medtechinnovator.org)), the largest medical technology and digital health startup accelerator globally.

In addition to this, Ken serves as Chairman to the Board of Israeli-based medical technology company, CardiaCare, and is an active Board member of other cardiac-focused digital health and medical technology companies including HeartBeam (NASDAQ: BEAT), Acarix (NASDAQ: ACARIX), US-based company Eritel, and European-based platform Happitech. Ken also sits on a number of advisory boards and planning committees for early-stage medical technology companies, as well as several industry groups including the Innovation Advisory Board of Heart Rhythm Society, the Health Tech Innovation Business Advisory Board and the Heart & Brain Accelerator of the American Heart Association.

**Jessamyn Lyons**  
Company Secretary

Jessamyn (Jess) Lyons is a Chartered Secretary, a Fellow of the Governance Institute of Australia and holds a Bachelor of Commerce from the University of Western Australia with majors in Investment Finance, Corporate Finance and Marketing. Jess is a highly experienced Company Secretary and has held positions with Macquarie Bank, UBS (London) and Patersons Securities.

**Evolution Capital Pty Ltd**

Level 8, 143 Macquarie Street Sydney, NSW 2000

Tel: +61283792960

[www.eveq.com](http://www.eveq.com)

## Disclaimer & Disclosures

Evolution Capital Pty Ltd (ACN 652 397 263) is a corporate Authorised Representative (number 1293314) of Evolution Capital Securities Pty Ltd (ACN 669 773 979), the holder of Australian Financial Services Licence number 551094. The information contained in this report is only intended for the use of those persons who satisfy the Wholesale definition, pursuant to Section 761G and Section 761GA of the Corporations Act 2001 (Cth) ("the Act"). Persons accessing this information should consider whether they are wholesale clients in accordance with the Act before relying on any information contained. Any financial product advice provided in this report is general in nature. Any content in this report does not take into account the objectives, financial situation or needs of any person, or purport to be comprehensive or constitute investment advice and should not be relied upon as such. You should consult a professional adviser to help you form your own opinion of the information and on whether the information is suitable for your individual objectives and needs as an investor. It is important to note that Evolution Capital, or its agents or representatives, engaged and received a financial benefit by the company that is the subject of the research report. The financial benefit may have included a monetary payment or certain services including (but not limited to) corporate advisory, capital raising and underwriting. In addition, the agent or representative drafting the advice may have received certain assistance from the company in preparing the research report. Notwithstanding this arrangement, Evolution Capital confirms that the views, opinions and analysis are an accurate and truthful representation of its views on the subject matter covered. Evolution Capital has used its best endeavours to ensure that any remuneration received by it, or by an agent or representative, has not impacted the views, opinions or recommendations set out in this research report. The content of this report does not constitute an offer by any representative of Evolution Capital to buy or sell any financial products or services. Accordingly, reliance should not be placed solely on the content of this report as the basis for making an investment, financial or other decision.

Recipients should not act on any report or recommendation issued by Evolution Capital without first consulting a professional advisor in order to ascertain whether the recommendation (if any) is appropriate, having regard to their investment objectives, financial situation and particular needs. Any opinions expressed are subject to change without notice and may not be updated by Evolution Capital. Evolution Capital believes the information contained in this report is correct. All information, opinions, conclusions and estimates that are provided are included with due care to their accuracy; however, no representation or warranty is made as to their accuracy, completeness, or reliability. Evolution Capital disclaims all liability and responsibility for any direct or indirect loss, or damage, which may be incurred by any recipient through any information, omission, error, or inaccuracy contained within this report. The views expressed in this report are those of the representative who wrote or authorised the report and no part of the compensation received by the representative is directly related to the inclusion of specific recommendations or opinions. Evolution Capital and / or its associates may hold interests in the entities mentioned in any posted report or recommendation. Evolution Capital, or its representatives, may have relationships with the companies mentioned in this report – for example, acting as corporate advisor, dealer, broker, or holder of principal positions. Evolution Capital and / or its representatives may also transact in those securities mentioned in the report, in a manner not consistent with recommendations made in the report. Any recommendations or opinions stated in this report are done so based on assumptions made by Evolution Capital. The information provided in this report and on which it is based may include projections and / or estimates which constitute forward-looking statements. These expressed beliefs of future performance, events, results, or returns may not eventuate and as such no guarantee of these future scenarios is given or implied by Evolution Capital. Any forward-looking statements are subject to uncertainties and risks that may mean those forecasts made by Evolution Capital are materially different to actual events. As such, past performance is not an indicator of future performance.