

## AI-BACKED SOLUTION ACCURATELY DETECTS HEART FAILURE IN 86% OF PATIENTS AND 97% OF HIGH-RISK INDIVIDUALS

### Highlights:

- **Echo IQ recently completed two clinical studies to evaluate the performance of its Heart Failure AI system in detecting new onset heart failure:**
  - **EIQ's AI-alone detects 86% of heart failure cases (vs 46% detection observed in current standard clinical practice)**
  - **Combination of AI and clinical evaluation increases diagnosis accuracy to 97% in high-risk individuals**
- **Heart failure is the leading cause of re-hospitalisation in the US, accounts for 17%<sup>(1)</sup> of all US healthcare expenditure and is a US\$60bn<sup>(2)</sup> market annually.**
- **Results were presented by invitation at Late Breaking Science sessions at the European Society of Cardiology (ESC) Congress 2024, the world's largest and most renowned cardiology congress.**
- **Positive results form the basis for FDA application for EIQ's AI solution as a diagnostic aid for the detection of heart failure.**
- **Groundbreaking results highlight EIQ's potential ability to positively impact heart failure health economics – Reimbursement strategy being progressed.**
- **Significant commercial interest established and expected to scale in light of significance of results.**

**Sydney:** Artificial Intelligence and Medical Technology company Echo IQ Limited (“the Company”) (ASX: EIQ) is pleased to provide the following ground breaking results from its two recently completed clinical studies performed in collaboration with leading Australian research centres: The Screen-HF Study with St. Vincent’s Institute of Medical Research (“SVI”) (refer ASX announcement: 21 May 2024), and the NIL-CHF Study The University of Notre Dame, Fremantle, for its novel AI-algorithm as a heart failure decision support tool.

The results were presented following peer review and invitation to participate in two late-breaking science presentations at the ESC Congress 2024 in London on 30 August 2024. The ESC Congress is the world’s preeminent forum for advancing cardiovascular research and treatment, and is hosted by the European Society of Cardiology.

### Image:

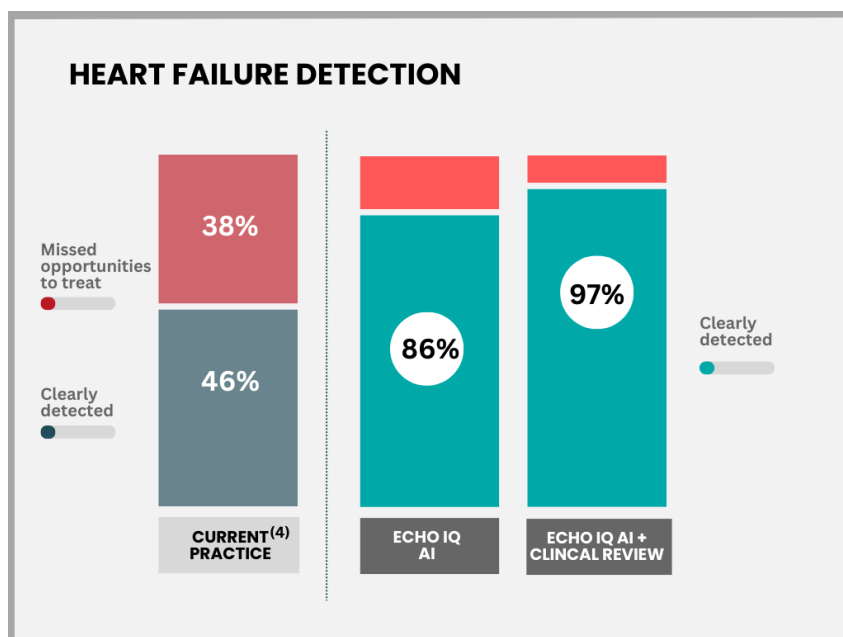
*Professor Geoff Strange presenting results of the Screen-HF Study using Echo IQ’s AI for Heart Failure*



## Groundbreaking study results

Echo IQ is pleased to provide the following overview of positive results from two recently completed clinical studies, which highlight the effectiveness of its AI-backed solution for heart failure when compared to an observed detection rate of 46%<sup>(3)</sup> in clinical practice. Key findings demonstrate that:

1. Echo IQ's AI technology without human review clearly and correctly identified 86% of patients with heart failure, in comparison to a matched group without heart failure (data from the application of the Echo IQ AI technology to participants from the SCREEN-HF study).
2. Echo IQ's AI to aid human review of patients identified 97% of high-risk individuals that subsequently developed heart failure (data from the application of the Echo IQ AI technology to participants from the NIL-CHF study)



**Figure one:** The current diagnosis rates of heart failure in clinical practice without using EIQ's AI technology, EIQ's AI applied only to echocardiography measurement data, and the overall benefits of human clinical patient review alongside EIQ's AI technology. Results obtained from the clinical study and have not yet been applied to clinical practice.

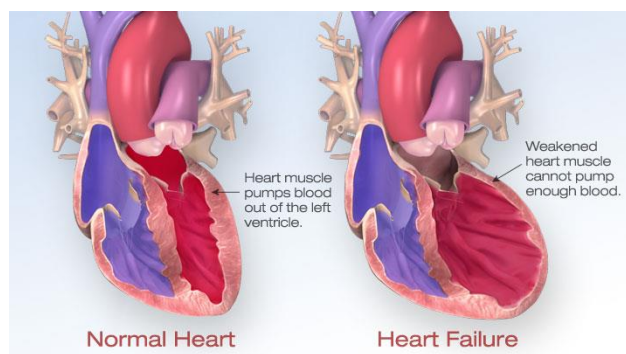
Further, when the Company's AI was applied to data from NIL-CHF early in the individual's healthcare journey, before any heart failure was present on clinical review, the Echo IQ AI was able to accurately predict future heart failure. For example, those deemed high risk for heart failure by Echo IQ's AI at baseline were subsequently hospitalised at almost ten times the rate of those found to be low risk. This is a major finding, given the high costs of emergency and inpatient care in hospital settings and reinforces the potential economic benefits to be derived from the application of this AI to identify patients at risk of future events.

The results from this clinical study highlight that the Company's AI solution could significantly improve the detection of heart failure and when used in collaboration with human review has an

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accuracy of 97%. This provides Echo IQ with considerable confidence that it can improve health and economic outcomes in a total addressable market valued at US\$60Bn<sup>(2)</sup> per annum.

Heart failure symptoms can include breathlessness, leg swelling and fatigue. Since the symptoms are not specific to heart failure, it is difficult to diagnose heart failure from symptoms alone. Current guidelines mandate additional evidence from echocardiography to confirm the diagnosis. Once the diagnosis is correctly made, treatment for heart failure is clearly defined according to Clinical Practice Guidelines<sup>(3)</sup>, and has a significant impact survival. Hence, making an accurate diagnosis is of utmost importance. The Company expects its AI-backed solution may enhance a doctor's potential to identify people with, or at risk of, heart failure, potentially optimising treatment choices for these individuals.



**Figure two:** Example of Heart Failure compared with a normal heart

### Management commentary

**Echo IQ Chief Medical Advisor, Prof. David Playford said:** *“The results of these two clinical studies back up the groundbreaking initial results from application of the AI to the National Echo Database of Australia (NEDA). The findings are compelling and illustrate the capacity of Echo IQ’s AI-backed technology to enhance the diagnostic skills of doctors. As a cardiologist, I am focused on improving the lives of my patients, and look forward to the opportunity to enhance my clinical skills with the use of AI solutions such as this. Heart failure is a major global health priority, and widespread application of Echo IQ’s heart failure AI has the potential to improve countless lives by improving the detection rates of heart failure.*”

*“The current status quo is not acceptable, since many patients with heart failure do not receive a clear diagnosis, and similarly other individuals at risk of heart failure may not be identified. The results of these studies demonstrate our ability to positively change the diagnostic landscape and to improve on current practices, with the goal of enhancing our patients lives.”*

**Echo IQ Executive Chair, Mr Andrew Grover added:** *“To have been invited to present these results at the world’s leading international cardiology conference has provided Echo IQ with an exceptional springboard to broaden its footprint in a major global market, which has a number of diagnostic related challenges. The results which were presented and the feedback the Company received from the event have highlighted that our innovation is a medical necessity for improving patient outcomes.*”

*“Over recent months, we have had very strong interest from a number of companies who operate in the sector and we anticipate that these results from the studies will help advance these*

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discussions further. Further, the Company remains focused on fast tracking engagement with the FDA to fully unlock value for shareholders.”

### **Proposed regulatory pathway and commercial opportunities:**

Following the presentation of these results at ESC Congress 2024, the Company remains well placed to advance its regulatory strategy with an application for US FDA clearance for its heart failure solution. Work is now underway toward a pre-submission meeting with the regulator, which will provide additional insight into its clearance pathway.

Concurrently, Echo IQ has been engaging with a number of leading global pharmaceutical companies and device manufacturers, with both on-market and planned therapies for heart failure and associated conditions. These results are expected to advance these discussions ahead of potential commercial uplift with counterparties.

### **Reimbursement opportunities**

As previously advised, the Company has appointed specialist US advisors to secure CMS (Centers for Medicaid and Medicare Services) codes for its solutions, allowing healthcare providers to obtain cost reimbursement from insurers for the use of EchoSolv in assisting in heart failure diagnosis.

This process relies on being able to demonstrate clinical value over and above existing practices. Following recent results, the Company is confident that its solution can significantly improve early detection and diagnosis of heart failure as well as enhance risk predictions to improve the health economics of this condition.

For reference, new reimbursement codes have recently been issued for an image-based tool designed to improve detection of heart failure valued at US\$284<sup>(4)</sup> (inpatient) and US\$1,023<sup>(4)</sup> (outpatient).

Echo IQ remains focused on advancing the potential for reimbursement to ensure CMS codes for its solutions can be issued, as close to regulatory approval as possible.

### **Study Methodologies**

**BACKGROUND:** Echocardiography is the cornerstone of heart failure diagnosis since clinical diagnosis of heart failure is unreliable.

**TRAINING:** We trained an AI model using echocardiographic measurement data alone, using 126,136 individual echocardiograms (“echos”) to train our imputation model, followed by a new set of 254,735 individual echos to train the heart failure AI system.

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**TESTING within NEDA:** (National Echo Database of Australia (“NEDA”) is the World’s largest mortality linked echocardiographic database which EIQ have exclusive access to for the development of AI systems.) A further new set of 81,509 echos (not previously seen by the AI system) were used to test the system’s performance. This cohort reflected the typical individual undergoing echocardiography in Australia (mean age ~62.5 years, ~51% male). The heart failure AI produced an output even when traditional guidelines were “indeterminate” (e.g. in the 45.2% of patients with normal ejection fraction but indeterminate filling pressures). The higher the heart failure AI output, the more likely patients were to have the echo findings typically associated with heart failure, and were more likely to die. The lowest percentile had 5-year mortality of 5.7% in men and 2.3% in women, compared with the highest percentile having 66.3% and 64.2% 5-year mortality in men and women, respectively.

**REAL-WORLD TESTING 1 – SCREEN-HF:** We randomly selected 145 patients with clinically-confirmed heart failure at follow-up, and matched them with 145 patients without heart failure at follow-up. The area under the receiver operating characteristic curve (“AUROC”) was 0.86 (95% confidence interval 0.81-0.90),  $p < 0.001$ .

**REAL-WORLD TESTING 2 – NIL-CHF:** 453 patients at high risk without heart failure were selected. Their 3-year clinical follow-up, then further 5-year heart-failure hospitalisation data, was used. At 3 years, 93 individuals developed clinical heart failure - the AUROC for the AI to identify clinical heart failure was 0.89 (95% CI 0.85-0.93),  $p < 0.001$ . For 133 patients the AI identified to be at high risk at 3 years (whether or not they were identified clinically at the time), the addition of clinical information (symptoms) identified 97% of patients who would develop clinical heart failure or hospitalisation due to heart failure in the next 5 years.

-ENDS-

- (1) *Global burden of heart failure: a comprehensive and updated review of epidemiology* | *Cardiovascular Research* | Oxford Academic ([oup.com](https://academic.oup.com))
- (2) *Economic Issues in Heart Failure in the United States* - PubMed ([nih.gov](https://pubmed.ncbi.nlm.nih.gov/))
- (3) *Disparity in the Setting of Incident Heart Failure Diagnosis* - PMC ([nih.gov](https://pubmed.ncbi.nlm.nih.gov/))
- (4) <https://www.ahajournals.org/doi/full/10.1161/CIR.0000000000001063>
- (5) *Ultromics Receives HOPPS Code for EchoGo Heart Failure in Outpatient Setting Following Inpatient Reimbursement Earlier this Year* | *MedTech Genie*

**Authorised for release by the Board of Directors of Echo IQ Limited.**

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**ABOUT ECHO IQ**

Echo IQ uses AI-driven technology and proprietary software to improve decision making in Cardiology. The company is based in Sydney, Australia.