



PRESS RELEASE

Us2.ai receives FDA clearance for the first fully automated solution measuring both 2D and Doppler cardiac ultrasound images to produce a complete patient report

- FDA clearance for 23 fully automated echo parameters¹
- External validation study at Brigham & Women's Hospital of Harvard Medical School
- World's first fully automated solution for both 2D and Doppler images

SINGAPORE, 14 September 2021 – Us2.ai, a Singapore-based medtech firm backed by Sequoia India and EDBI, has received FDA clearance for Us2.v1, a complete automated decision support tool for echocardiography.

After multiple trials with global pharmaceutical partners, and a validation study at the Brigham & Women's Hospital, Us2.ai is pleased to announce that Us2.v1 is now available for clinical use in the US. Us2.v1 is a patented, automated clinical workflow solution that recognizes and analyzes 2-dimensional and Doppler echo images for comprehensive cardiac measurements needed for the diagnosis, prediction and prognosis of heart disease.

"With this release, we've moved the field of AI beyond just a narrow feature for echocardiography, to a complete decision-support solution for cardiologists and primary care providers," said James Hare, CEO and co-founder of Us2.ai. "Us2.v1 eliminates the manual workflows and lack of transparency from semi-automated, single measurement, black box AI approaches, creating a complete and fully automated patient report with editable annotations, conclusions and comparisons to international reference guidelines."

Us2.v1 automated measurements include 2-dimensional (cardiac volumes, all 4 chambers of the heart), M-mode (e.g. tricuspid annular plane systolic excursion), spectral Doppler (blood flow across all valves, both PW and CW measurements) and tissue Doppler; thus covering the vast majority of standard measurements for adult transthoracic echocardiography recommended by the American Society of Echocardiography, European Association of Cardiovascular Imaging, and British Society of Echocardiography. Fully automated Us2.v1 measurements were shown to be completely interchangeable with expert human measurements. Furthermore, Us2.v1 measurements were completely reproducible for a given patient study, with image processing/analysis algorithm computation time of approximately 2 minutes per study.²

Us2.v1 will help to accelerate the diagnosis of diseases such as pulmonary hypertension and heart failure (HF), especially in light of the company's recently announced partnership with EchoNous, the leader in ultra-portable, AI-guided point-of-care ultrasound (POCUS) tools and maker of Kosmos, the only handheld ultra-mobile tool offering diagnostic grade imaging with Continuous-Wave (CW) Doppler capability.

Us2.v1 also automates the detection of pulmonary hypertension according to the ESC/ERS (European Society of Cardiology/ European Respiratory Society) guideline definition for echocardiographic detection of pulmonary hypertension. Pulmonary hypertension remains under-detected, leading to treatment delays and poor outcomes.

Similarly, heart failure is a commonly missed diagnosis, particularly in general practices where access to echocardiography is currently limited. "AstraZeneca is excited to partner with Us2.ai because we believe it has the potential to transform the management of heart failure, bringing early access to echocardiography, including expert-level analyses, to primary care settings, the general community and even to patients' home. Together, we look forward to helping improve care for patients with heart failure and keeping them out of hospital", said Joris Silon, Senior Vice President, CVRM, BioPharmaceuticals Business Unit, AstraZeneca.

¹ Measurements validated at the Brigham & Women's Hospital:

Left ventricle: DecT, MV-A, MV-Adur, MV-E, e' lateral, e' septal, a' lateral, a' septal, s' lateral, s' septal, LVEDV MOD biplane, LVEF MOD biplane, LVESV MOD biplane, LSVV MOD biplane, IVSd, LVIDd, LVIDs, LVPWd, E/e' mean

Left atrium: LAESV MOD biplane

Right ventricle: RVIDd

Right atrium: RAa

Tricuspid valve: Tr Vmax

² Total time for interpretation of a study can depend on other factors such as the interpreting physician and preparation for uploading DICOMs for analysis.

About Us2.ai

Us2.ai uses machine learning to automate the fight against heart disease. The company's software tools improve clinical decision making and cardiovascular research for clinical trials using echocardiography, the safest and most common cardiac imaging modality. Us2.ai connects institutions and imaging labs around the world on a platform of ready to use automation tools for view classification, segmentation and federated learning across diverse, anonymous patient and disease cohorts. Us2.ai is a fast-growing startup backed by Sequoia India and EDBI.

Media Contact:

Laura Cooke

Explore Communications

+65 9115 7617

SOURCE Us2.ai