Regulatory Clearances for Clinical Use

Regulatory cleared and marketed in 28+ countries CE 2797 FDA

Us2.AI

Indications for Use

Us2.ai software is used to process acquired transthoracic cardiac ultrasound images, to analyze and make measurements on images in order to provide automated estimation of several cardiac structural and functional parameters, including left/ right atrial and ventricular linear dimensions, volumes, systolic function and diastolic function, measured by B mode, M mode and Doppler (PW, CW, tissue) modalities. The data produced by this software is intended to be used to support qualified cardiologists, sonographers, or other licensed professional healthcare practitioners for clinical decision-making. Us2.ai is indicated for use in adult patients.

Us2.ai Software

Main Findings

- LV systolic function
- LV diastolic function
- LV geometry
- LV size
- RV function
- RV size
- RA size
- LA size

Automated Measurements

Us2.v1		Us2.v2		Us2.v2 (EU)	
LV	DecT	LV	LV GLS	TrV	TR Vena Contracta
LV	MV-A	LV	A4C LV GLS	TrV	TR Jet Area
LV	MV-Adur	LV	A3C LV GLS	RV	RV area A4C (d)
LV	MV-E	LV	A2C LV GLS	RV	RV area A4C (s)
LV	e' lateral	LV	LV Regional Strain	RV	RVEDV MOD A4C
LV	e' septal	RV	TAPSE	RV	RVESV MOD A4C
LV	a' lateral	RV	RV E'	PV	PV VTI
LV	a' septal	RV	RV A'	RVOT	RVOT VTI
LV	s' lateral	RV	RV S'	RVOT	RVOT proximal
LV	s' septal	Aorta	Sinotubular Junction	IVC	IVC max
LV	LVEDV MOD biplane	Aorta	Sinus valsalva	IVC	IVC min
LV	LVEF MOD biplane	LVOT	LVOT Diameter	Aorta	Asc. Ao
LV	LVESV MOD biplane	LVOT	PW LVOT Vmax	LA	MR Jet Area
LV	LVSV MOD biplane	LVOT	PW LVOT VTI	LA	MR Jet Ratio
LV	IVSd	LVOT	PW LVOT Pmax	LA	CW MR VIT
LV	LVIDd	LVOT	PW LVOT Pmean	LA	CW MR VMax
LV	LVIDs	AoV	CW AoV Vmax	LA	CW MR Vmean
LV	LVPWd	AoV	CW AoV VTI	LA	CW MR Pmax
LV	E/e' mean	AoV	CW AoV Pmax	LA	CW MR Pmean
RV	RVIDd	AoV	CW AoV Pmean	LA	GLS
LA	LAESV MOD biplane	AoV	AVA	LV	LVEDV MOD biplane (contrast)
RA	RAA	AoV	VR	LV	LVESV MOD biplane (contrast)
TRV	TR Vmax			LV	LVEF MOD biplane (contrast)

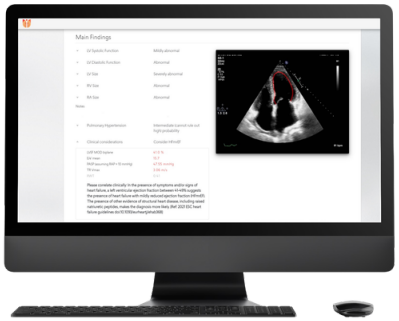
Disease Detection

Heart Failure (HF)
HF with reduced ejection fraction | HF with preserved ejection fraction | HF with mid-range ejection fraction

Pulmonary Hypertension

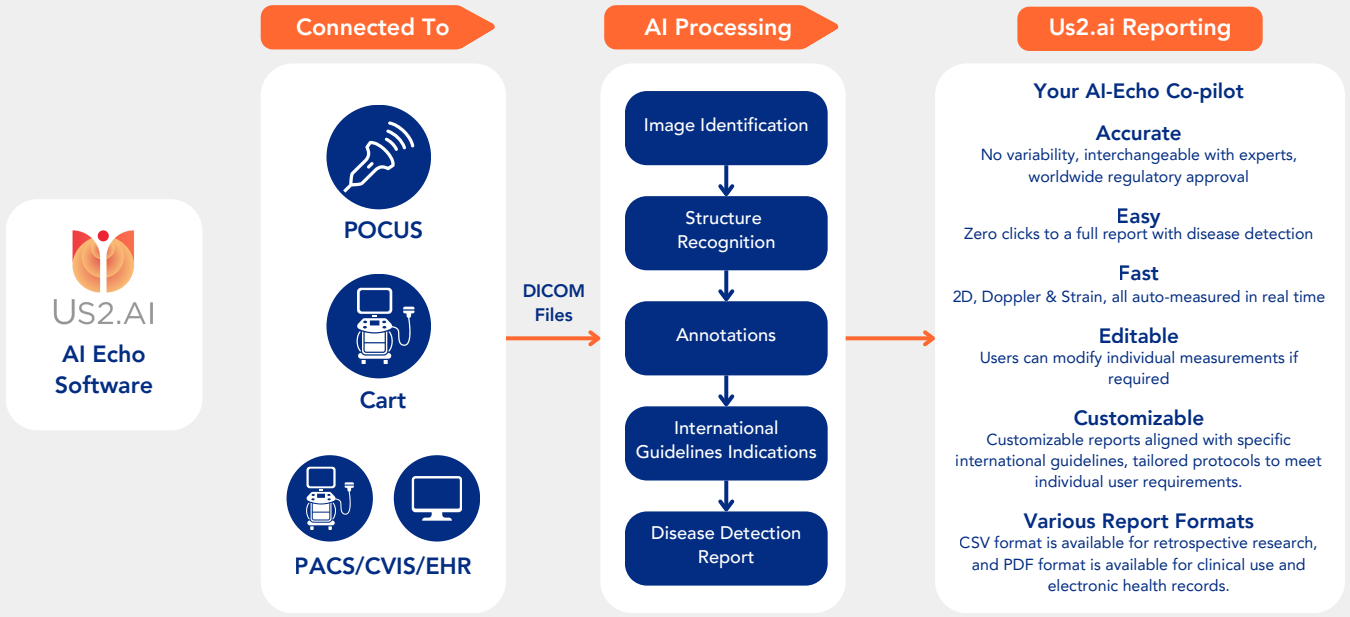
Cardiac Amyloidosis

Valvular Disease
Aortic Stenosis



Website: www.us2.ai/ Publications:https://us2.ai/clinical-evidence/ Contact Us: www.us2.ai/contact-us/ | info@us2.ai

Product Workflow, Processing Steps & Report Structure



Use Cases

AI Echo Along the Disease Management Pathway

'Out of Hospital'– GP/ Primary Care → Referral to Secondary Care → Diagnostic Tests → Diagnosis → Follow Up

Use Case 1

POCUS device connected to the Us2.ai software

Users
Novices trained on AI-guided POCUS device / Trained sonographers

Benefits
Opening new and efficient pathways for disease detection, screening, and follow-up outside of hospital – in clinics, primary care, and at home care

Scientific Validation & Case Studies
Huang, W., Koh, T., Tromp, J., Chandramouli, C., Ewe, S. H., Ng, C. T., Lee, A. S. Y., Teo, L. L. Y., Hummel, Y., Huang, F., & Lam, C. S. P. (2024). Point-of-care AI-enhanced novice echocardiography for screening heart failure (PANES-HF). Scientific Reports, 14(1), 13503. https://doi.org/10.1038/s41598-024-62467-4

Use Case 2

Standardized echo reporting for retrospective and prospective studies

Configurations
Connect echo carts, CVIS, EMR, PACS or POCUS to Us2.ai software (Cloud or on-premise)

Benefits
- Zero variability
- Full suite of measurements
- Volume - population health level scale
- Time and labor efficient

Scientific Validation & Case Studies
Sakamoto, A., Kagiyama, N., Sato, E., Nakamura, Y., Murata, A., Kaneko, T., Miyazaki, S., Ashikawa, Y., Sugihara, K., & Minamino, T. (2025). Artificial Intelligence–Based Automated Echocardiographic Analysis and the Workflow of Sonographers: A Randomized Crossover Trial (AI-Echo RCT). Journal of the American Heart Association, 15(1), e045637–e045637. https://doi.org/10.1161/jaha.125.045637

Use Case 3

Longitudinal surveillance and PACS-based case finding at scale

Configurations
Connect echo carts, CVIS, EMR, PACS or POCUS to Us2.ai software (Cloud or on-premise)

Benefits
- Greater efficiency in workflow
- Reduced variability in measurements
- Results interchangeable with experts

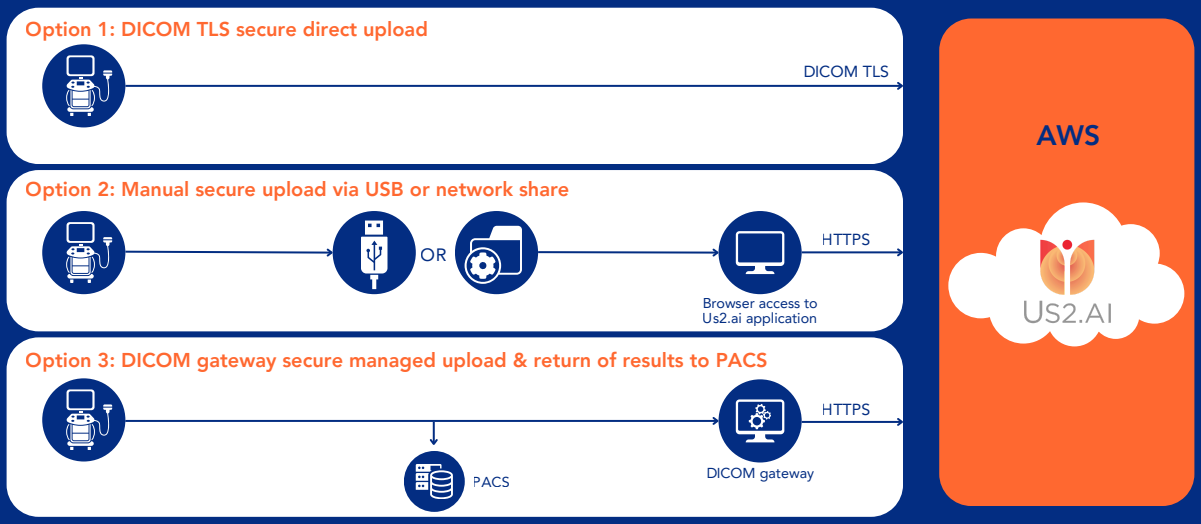
Scientific Validation & Case Studies
Oo, M. M., Gao, C., Cole, C., Hummel, Y., Guignard-Duff, M., Jefferson, E., Hare, J., Voors, A. A., de Boer, R. A., Lam, C. S. P., Mordi, I. R., Tromp, J., & Lang, C. C. (2024). Artificial intelligence-assisted automated heart failure detection and classification from electronic health records. ESC heart failure, 11(5), 2769–2777. https://doi.org/10.1002/ehf2.14828

Configurations

Us2.ai is vendor agnostic, compatible with all echo devices and PACS manufacturers.

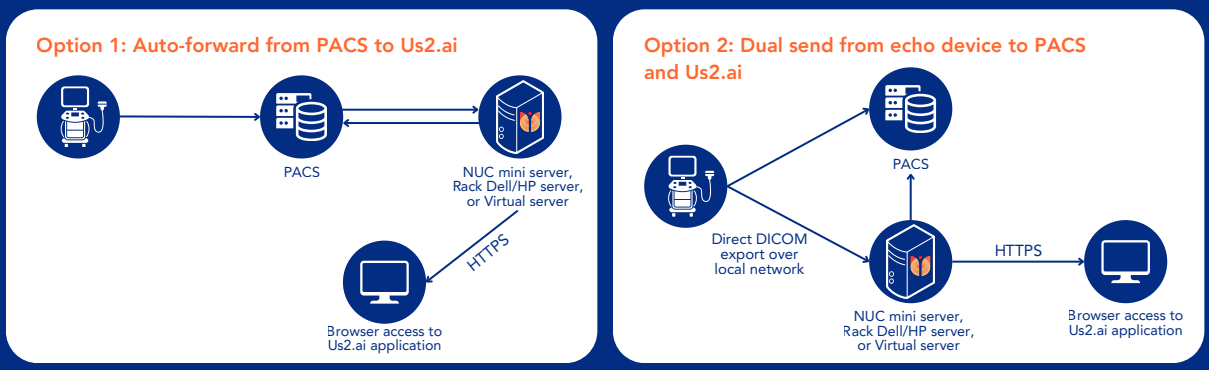
Cloud Server

- Us2.ai cloud software is hosted on secure region specific AWS servers
- Direct send from echo device or PACS to Us2.ai cloud. Results and reports are accessible via browser and/or sent to the PACS or EMR.



On-site Server

- Local server installation keeps all patient data secure within the local network.
- The local server runs Us2.ai and connects to PACS and the echo device, with results and reports accessible via browser and/or sent to the PACS or EMR.



Software Pricing, Installation & Other Costs

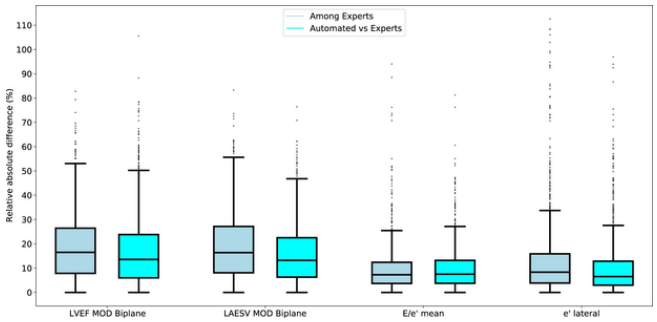
Us2.ai offers a volume-based pricing model, with installation and associated costs varying by configuration. For detailed pricing and setup options, please contact us at info@us2.ai for a formal quotation.

US2.AI

Scientific Validation

Us2.ai validation study

In a study of 600 patients, all point estimates of the Individual Equivalence Coefficient (IEC) were < 0, indicating that disagreement between AI measurements and human readers was lower than the disagreement among three expert echocardiography readers. The study demonstrated excellent agreement between AI processing and expert human interpretation across a wide range of echocardiographic measurements.



Tromp, J., Bauer, D., Claggett, B. L., Frost, M., Iversen, M. B., Prasad, N., Petrie, M. C., Larson, M. G., Ezekowitz, J. A., & Solomon, S. D. (2022). A formal validation of a deep learning-based automated workflow for the interpretation of the echocardiogram. Nature communications, 13(1), 6776. https://doi.org/10.1038/s41467-022-34245-1

Clinical advantages of Us2.ai

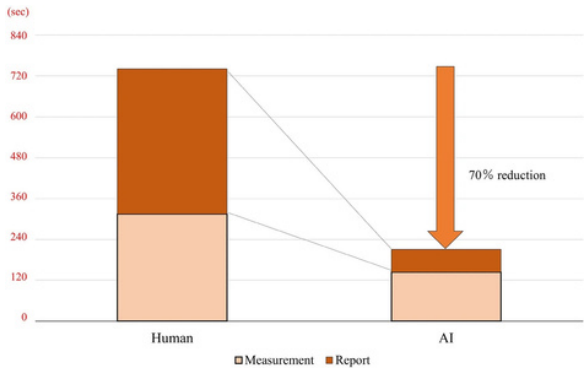
This randomized crossover trial investigated the impact of an AI-based automated echocardiographic analysis tool on clinical workflow efficiency. The study demonstrated that AI-based automatic analysis significantly improves the efficiency of screening echocardiography by reducing examination time, while maintaining image quality and reducing sonographer fatigue in real-world clinical practice.

- Increase in number of daily examinations
- Reduction in echo examination time
- Richer clinical data by providing more measurements
- Reduced mental and physical fatigue of sonographers
- Improved image quality

Sakamoto, A., Kagiyama, N., Sato, E., Nakamura, Y., Murata, A., Kaneko, T., Miyazaki, S., Ashikawa, Y., Sugihara, K., & Minamino, T. (2025). Artificial Intelligence–Based Automated Echocardiographic Analysis and the Workflow of Sonographers: A Randomized Crossover Trial (AI-Echo RCT). Journal of the American Heart Association, 15(1), e045637–e045637. https://doi.org/10.1161/jaha.125.045637

Time efficiency with Us2.ai

This study demonstrated how fully automated AI software reduces echocardiographic analysis time by 70% while maintaining accuracy, streamlining workflow for faster diagnoses and improved patient experience.



Hirata, Y., Nomura, Y., Saijo, Y. et al. Reducing echocardiographic examination time through routine use of fully automated software: a comparative study of measurement and report creation time. J Echocardiogr 22, 162–170 (2024). https://doi.org/10.1007/s12574-023-00636-6

For additional scientific publications, please visit our website:https://us2.ai/clinical-evidence/