

# Regulatory Clearances for Clinical Use

Regulatory cleared and marketed in 28+ countries  



## 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

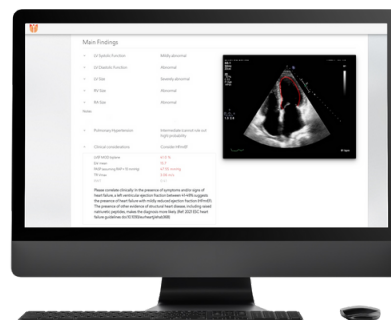
- LV systolic function
- LV diastolic function
- LV geometry
- LV size
- RV function
- RV size
- RA size
- LA size

### Automated Measurements

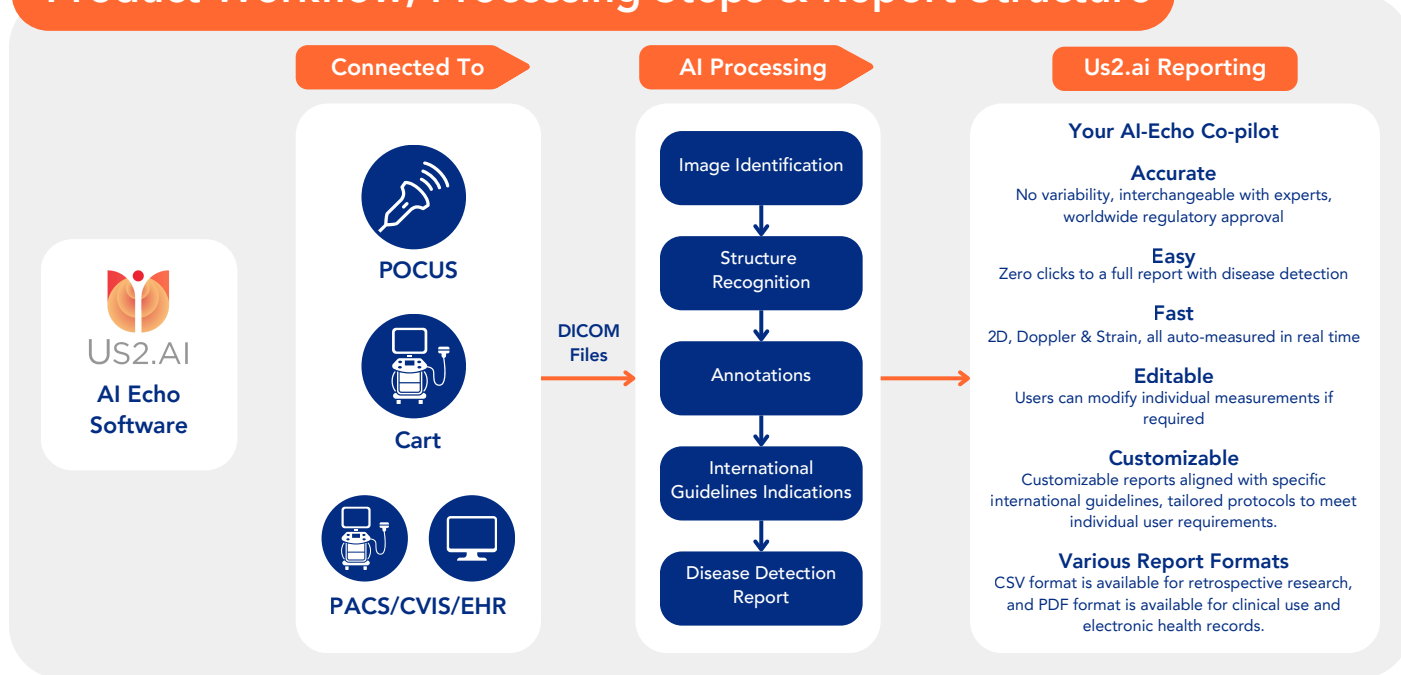
Us2.v1		Us2.v2	
Us2.v2 (EU)			
LV	DecT	LV	LV GLS
LV	MV-A	LV	A4C LV GLS
LV	MV-Adur	LV	A3C LV GLS
LV	MV-E	LV	A2C LV GLS
LV	e' lateral	LV	LV Regional Strain
LV	e' septal	RV	TAPSE
LV	a' lateral	RV	RV E'
LV	a' septal	RV	RV A'
LV	s' lateral	RV	RV S'
LV	s' septal	Aorta	Sinotubular Junction
LV	LVEDV MOD biplane	Aorta	Sinus valsalva
LV	LVEF MOD biplane	LVOT	LVOT Diameter
LV	LVESV MOD biplane	LVOT	PW LVOT Vmax
LV	LVSV MOD biplane	LVOT	PW LVOT VTI
LV	IVSd	LVOT	PW LVOT Pmax
LV	LVIDd	LVOT	PW LVOT Pmean
LV	LVIDs	AoV	CW AoV Vmax
LV	LVPWd	AoV	CW AoV VTI
LV	E/e' mean	AoV	CW AoV Pmax
RV	RVIDd	AoV	CW AoV Pmean
LA	LAESV MOD biplane	AoV	AVA
RA	RAA	AoV	VR
TRV	TR Vmax	LV	LVEDV MOD biplane (contrast)
		LV	LVESV MOD biplane (contrast)
		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

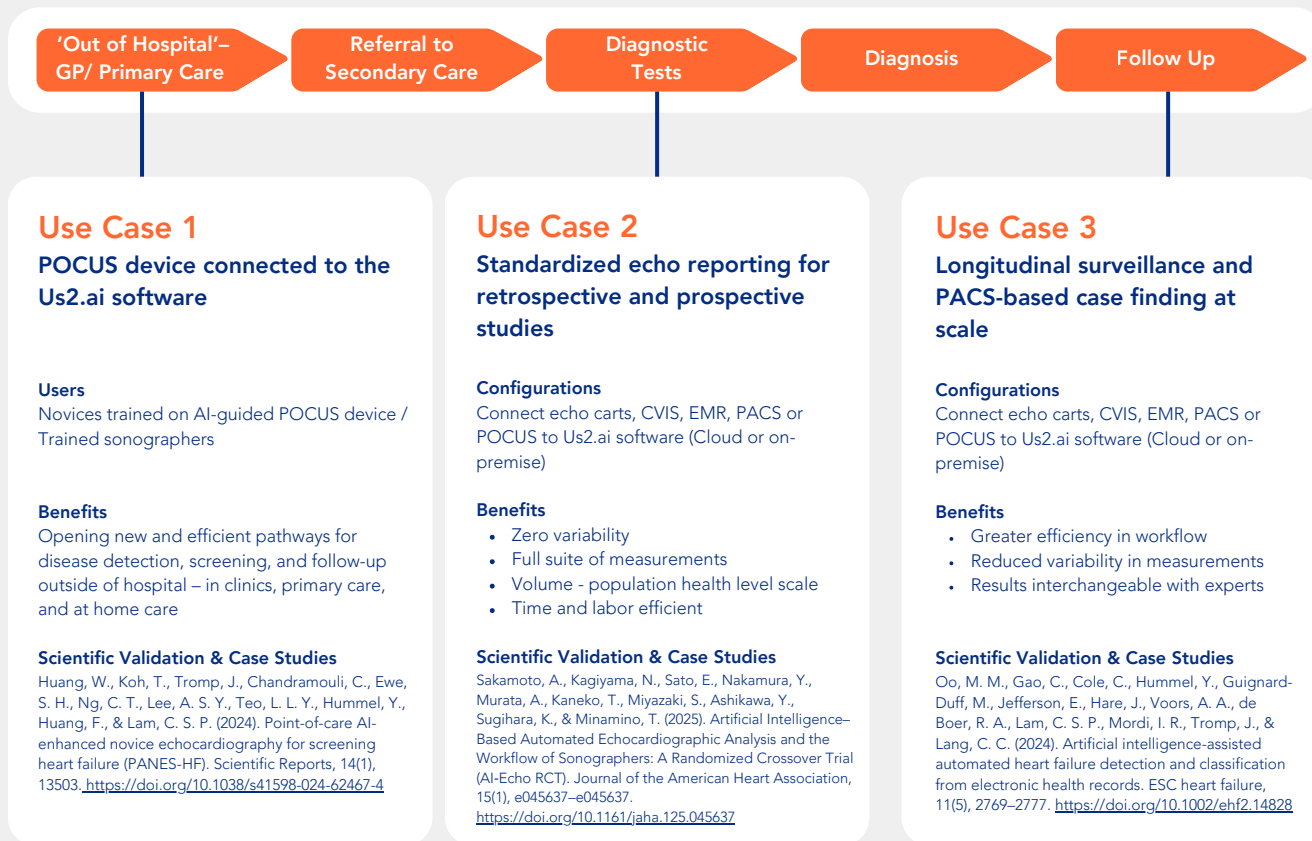


## Product Workflow, Processing Steps & Report Structure



## Use Cases

### AI Echo Along the Disease Management Pathway



## Configurations

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

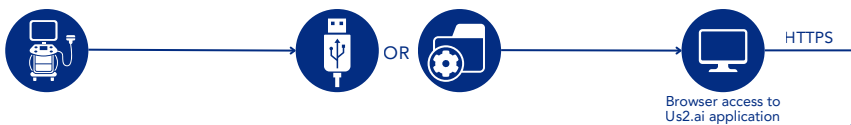
### Cloud Server

- 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.

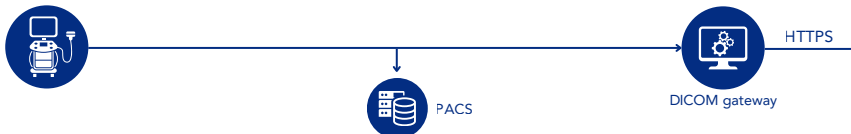
#### Option 1: DICOM TLS secure direct upload



#### Option 2: Manual secure upload via USB or network share



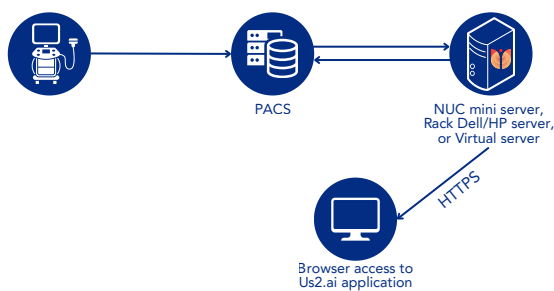
#### Option 3: DICOM gateway secure managed upload & return of results to PACS



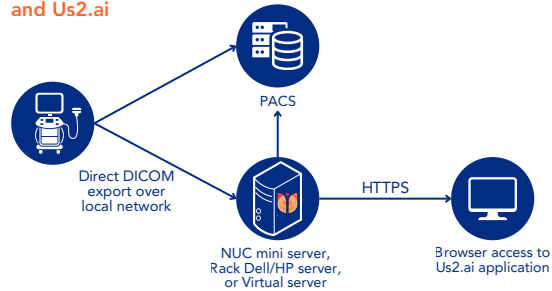
### On-site Server

- 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.

#### Option 1: Auto-forward from PACS to Us2.ai



#### Option 2: Dual send from echo device to PACS and Us2.ai



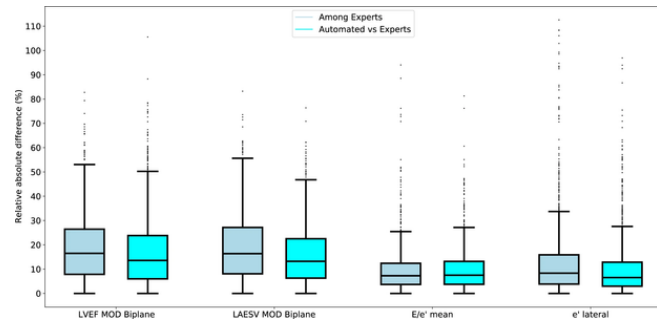
## Software Pricing, Installation & Other Costs

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](mailto:info@us2.ai) for a formal quotation.

## 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



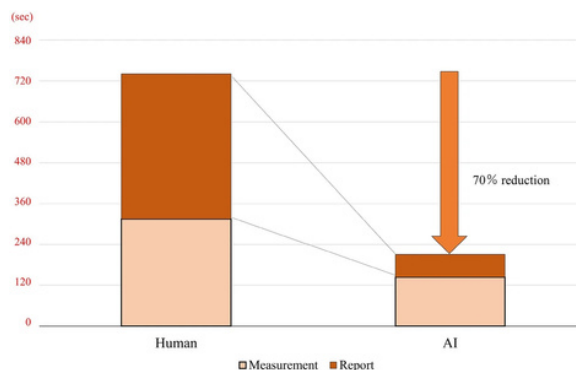
Improved image quality

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: [www.us2.ai/publications/](http://www.us2.ai/publications/)