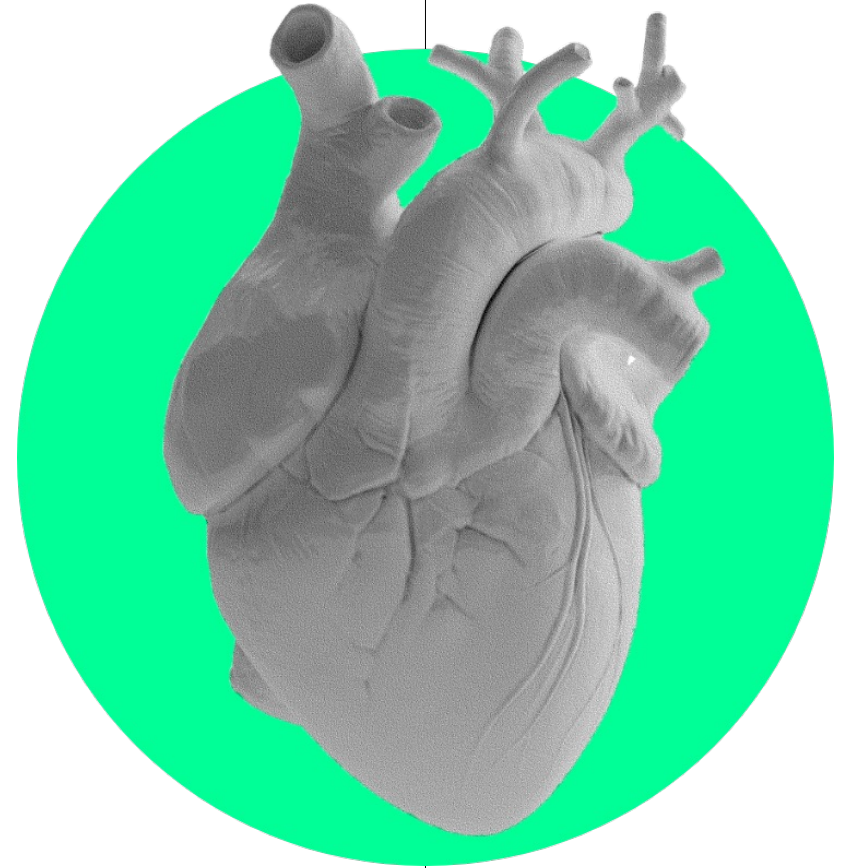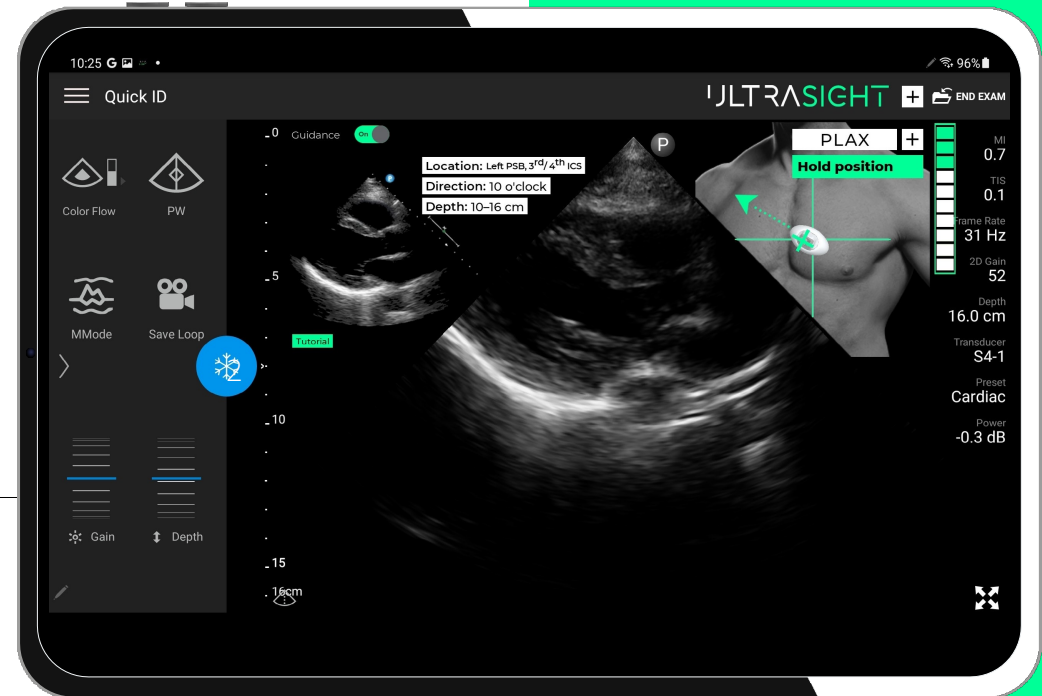# ULTRASIGHT

AI REAL TIME GUIDANCE PIVOTAL STUDY RESULTS

ULTRASIGHT'S AI REAL TIME GUIDANCE CARDIAC ULTRASOUND SOFTWARE

Real-time guidance and quality assessment for the easy capture of high-quality cardiac images by minimally trained clinical personnel
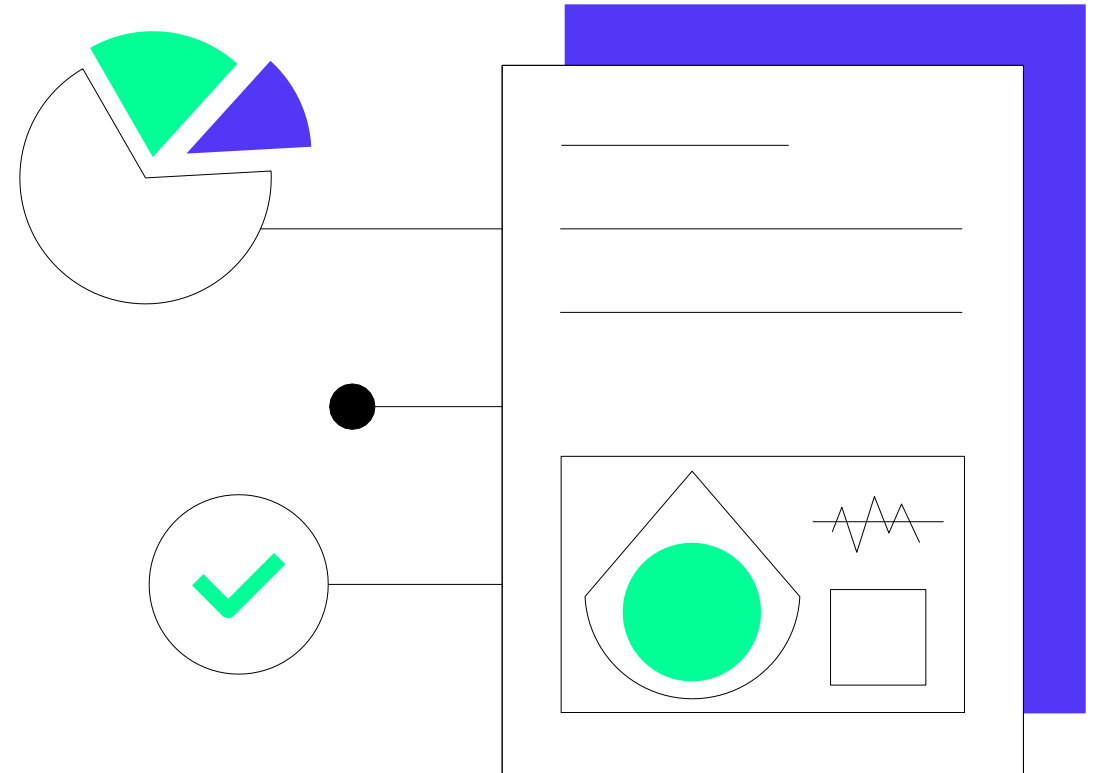
ULTRASIGHT'S LANDMARK PIVOTAL STUDY

UltraSight has successfully concluded its multicenter pivotal study at two U.S. locations, the University of Chicago and Aurora St. Luke's Medical Center in Milwaukee, Wisconsin, and at the Sheba Medical Center in Israel.

The goal of the study was to assess in a prospective study the quality of echocardiographic exams performed by inexperienced users guided by UltraSight AI Guidance software and evaluate their suitability for diagnostic interpretation of basic cardiac pathology and quantitative analysis of cardiac chamber and function.

PIVOTAL STUDY DESIGN

Healthcare Providers

6 registered nurses and 3 medical residents with no prior echocardiography experience, participated in a training program to learn cardiac point of care ultrasound (POCUS) and use of UltraSight's guidance software

Training: 2h lecture, 6h of hands-on practice and 8 practice scans

Subject Enrollment

240 subjects underwent limited echo scans performed by both novice and expert sonographers

Aurora Health Center
(81 subjects)

University of Chicago
(75 subjects)

Sheba Medical Center
(84 subjects)

Examination Evaluation

480 examinations were evaluated by 5 expert cardiologists who were blinded to the operator type

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PIVOTAL STUDY RESULTS – PRIMARY ENDPOINTS

NUMBER OF EXAMS WITH SUFFICIENT DIAGNOSTIC QUALITY TO EVALUATE SPECIFIED CLINICAL DATA

	LV Size	LV Function	RV Size	Pericardial Effusion
Novice User	99.2%	99.6%	92.9%	100%
Expert Sonographer	100%	100%	97.9%	100%

Novice User   Expert Sonographer
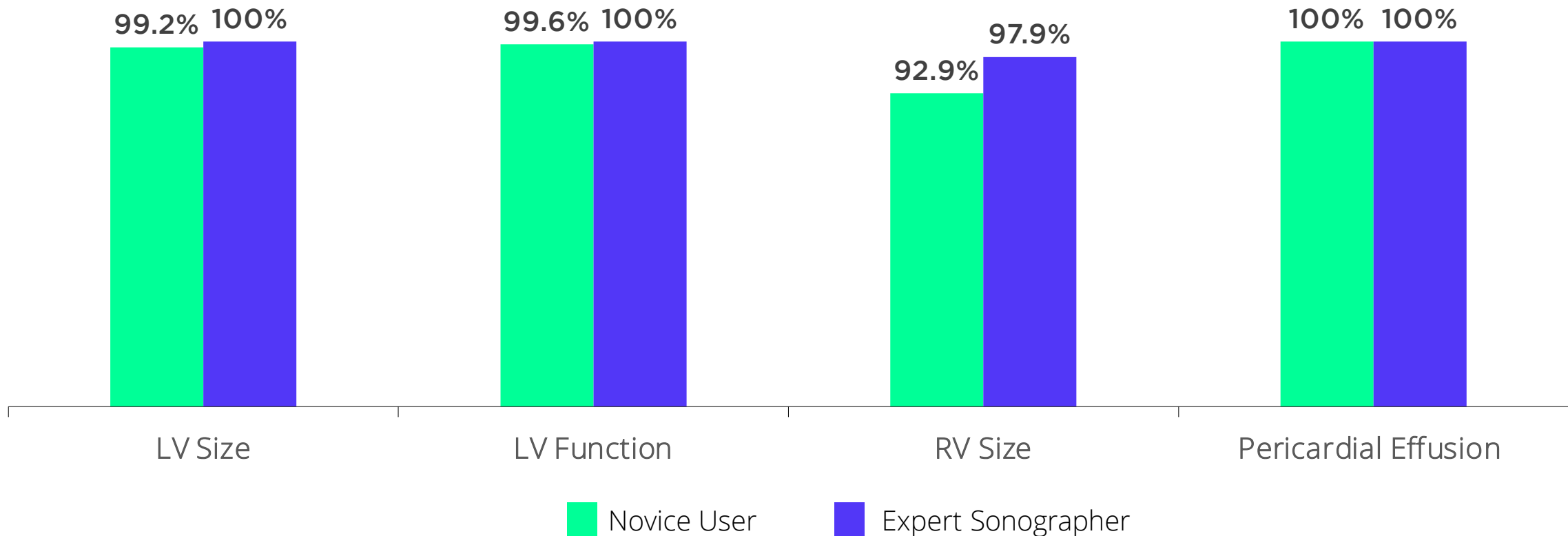
PIVOTAL STUDY RESULTS – SECONDARY ENDPOINTS
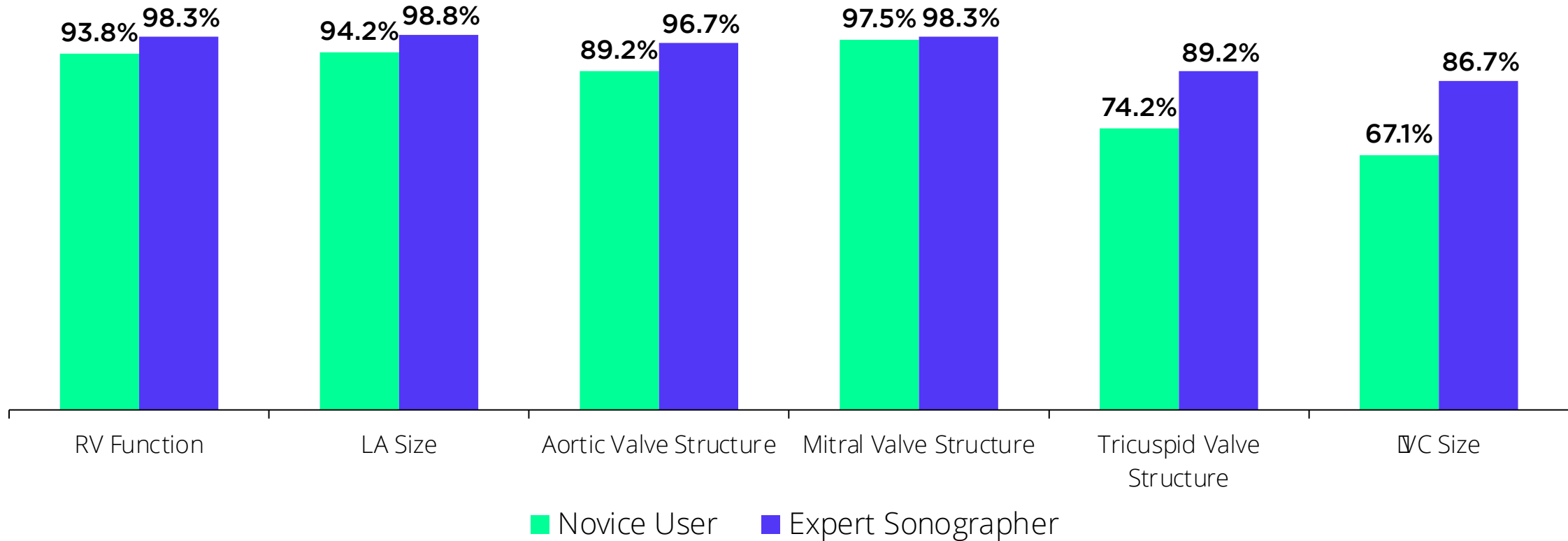
NUMBER OF EXAMS WITH SUFFICIENT DIAGNOSTIC QUALITY TO EVALUATE SPECIFIED CLINICAL DATA

	RV Function	LA Size	Aortic Valve Structure	Mitral Valve Structure	Tricuspid Valve Structure	IVC Size
Novice User	93.8%	94.2%	89.2%	97.5%	74.2%	67.1%
Expert Sonographer	98.3%	98.8%	96.7%	98.3%	89.2%	86.7%

■ Novice User ■ Expert Sonographer

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EXAM QUALITY AND DIAGNOSIS AGREEMENT BETWEEN NOVICE VS SONOGRAPHERS

Percentages of exams with sufficient quality to allow diagnostic interpretation (center) and percentages of exams resulting in concordant diagnostic interpretation from images acquired by sonographers and by novices (right)

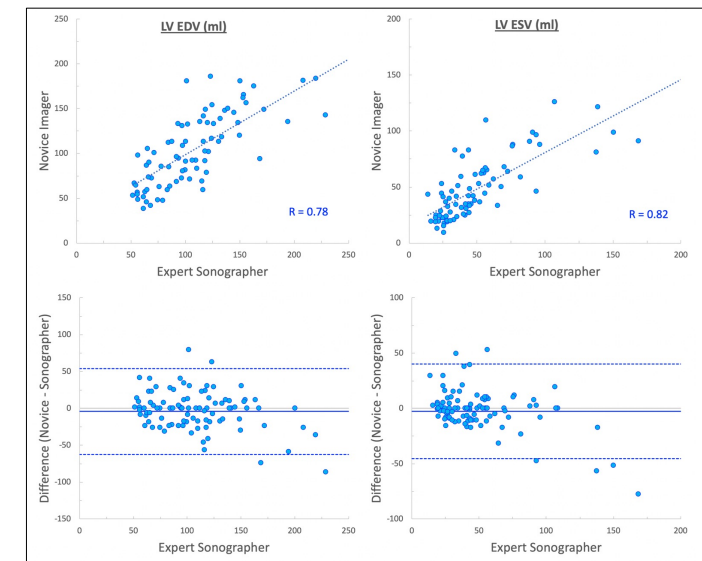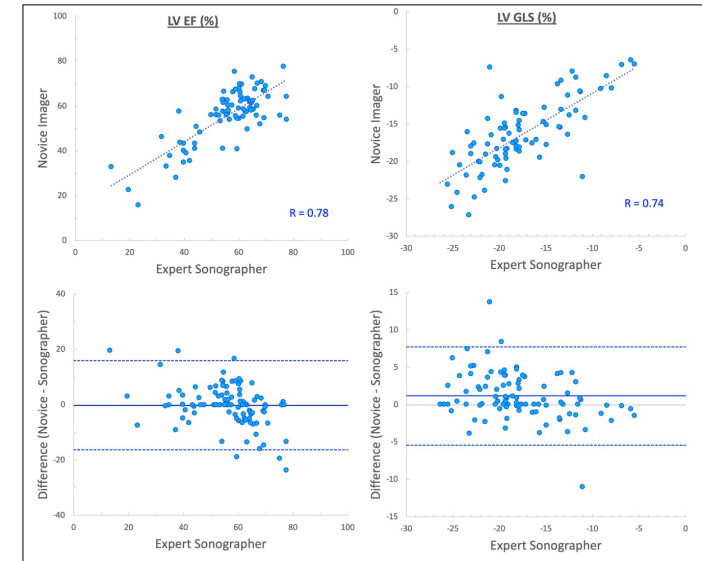|	% Diagnostic quality (CI)		% Diagnostic agreement
	Sonographers	Novices	
LV size	100% (98-100)	99% (99-100)	96% (92-98)
LV function	100% (98-100)	100% (97-100)	86% (81-90)
RV size	98% (96-99)	93% (89-99)	87% (82-91)
Pericardial effusion	100% (98-100)	100% (98-100)	94% (90-96)
RV function	98% (97-100)	94% (90-98)	96% (93-98)
LA size	99% (98-100)	94% (90-97)	83% (77-87)
AV structure	97% (97-100)	89% (84-93)	88% (82-91)
MV structure	98% (97-100)	98% (95-99)	90% (96-93)
TV structure	89% (86-99)	74% (67-80)	95% (90-97)
IVC size	87% (82-90)	67% (59-75)	85% (78-90)

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ADDITIONAL ANALYSIS – NOVICE VS SONOGRAPHER CORRELATION

LV FUNCTION, VOLUME AND STRAIN*

	Sonographers	Novices	Delta	R-value (p)
LVEF (%)	58 (52 – 64)	58 (52 – 63)	-0.2 ± 8.2	0.78 (<0.001)
LVEDV (ml)	102 (75 – 126)	97 (70 – 135)	-4 ± 30	0.78 (<0.001)
LVESV (ml)	42 (27 – 57)	41 (25 – 64)	-2 ± 22	0.82 (<0.001)
GLS (%)	-18 (-21 – -15)	-17 (-19 – -14)	1.2 ± 3.3	0.74 (<0.001)

LVEF – Left Ventricle Ejection Fraction; LVEDV – Left Ventricle End Diastolic Volume; LVESV – Left Ventricle End Systolic Volume; GLS – Global Longitudinal Strain

*Subset follow-up analysis on 100 participants

PIVOTAL STUDY RESULTS

The results demonstrated that after minimal training with the novel real-time guidance software, novice users can acquire images of diagnostic quality approaching that of expert sonographers in the majority of patients, allowing qualitative diagnostic interpretation and quantitative analysis.

CE MARK

Achieved in

August 2022

UKCA

Achieved in

December 2022

FDA 510(K) CLEARED

Achieved in

July 2023

ISRAELI AMAR

Acheived in

September 2023

FOR MORE INFORMATION ABOUT ULTRASIGHT'S CARDIAC ULTRASOUND GUIDANCE SOLUTION, VISIT OUR WEBSITE.

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THANK YOU.