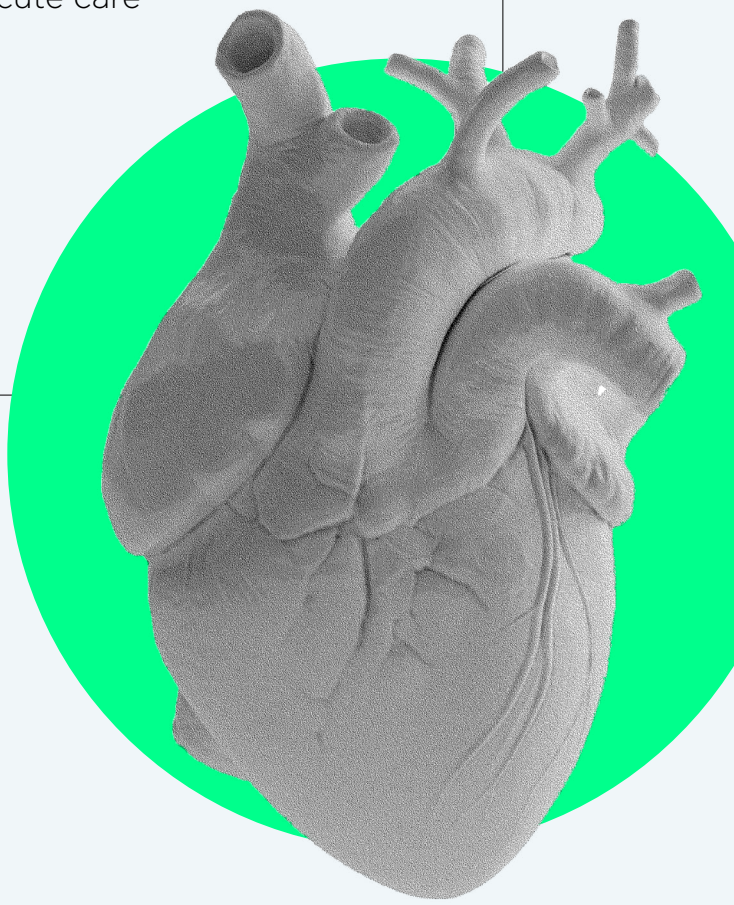
ULTRASIGHT

CASE STUDY

UltraSight AI real-time guidance software enables any medical professional to obtain diagnostic quality images

A promising future of increased POCUS use in acute care



In the ever-evolving landscape of medical diagnostics, cardiac ultrasound stands as a cornerstone in the assessment of cardiovascular health. From its humble beginnings to the sophisticated technology we employ today, the journey of cardiac ultrasound parallels the advancement witnessed across various domains of human endeavor. Much like the transition from manual calculations with slide rulers to the seamless precision of calculators in mathematics, the evolution of cardiac ultrasound has undergone a remarkable transformation from relying solely on human expertise to the integration of Artificial Intelligence (AI).

A CRITICAL NEED: GLOBALLY THERE ARE 130 MILLION PEOPLE LIVING WITH HEART DISEASE

With an estimated 130 million people currently living with cardiovascular disease, it is the leading cause of death globally,[1] taking an estimated 17.9 million lives each year. It is vital to detect cardiovascular disease as early as possible,[2] and echocardiograms are at the frontline in detecting and diagnosing structural heart disease, with over 7 million echocardiograms performed yearly in the U.S. alone.[3] However, performing a diagnostic-quality exam has required extensive skill and experience on the part of a sonographer. A sonographer captures images via direct patient contact, relying on experience to optimize image quality. [4] Because of the increasing number of patients with cardiovascular disease and the soaring growth in demand for echocardiographic studies, there is a mismatch between the volume of patients needing exams and the supply of available sonographers.[5] Given the acute shortage[6] , new strategies are needed for the acquisition of echocardiograms by non- experts. Today, many healthcare providers do not use ultrasound at the point of care, forgoing a valuable diagnostic tool, due to a lack of skill in acquiring and interpreting images. [7]

AI CAN INCREASE ACCESS TO POINT-OF-CARE ULTRASOUND FOR MILLIONS OF PATIENTS IN THE EMERGENCY DEPARTMENT

Development of high-quality, hand-held ultrasound devices places the power of echocardiography literally in the hands of healthcare professionals directly at the point of care. However, use of these tools to provide reliable, diagnostic-quality images has required a professional sonographer with an average of two years of extra training and experience; and unfortunately, this profession is currently experiencing a significant shortage – The Bureau of Labor Statistics forecasts that by 2024 the U.S. will experience a shortage of over 27,000 sonographers.[8]

1 Circulation. 2023;147:e93–e621. DOI: 10.1161/CIR.0000000000001123

2 Cardiovascular diseases (who.int)W

3 Assisted probe guidance in cardiac ultrasound: A review - NCIBI

4 The application of artificial intelligence in the sonography profession: Professional and educational considerations - PMC (nih.gov)

5 Artificial Intelligence and Echocardiography - PMC (nih.gov)

6 The Supply and Demand of the Cardiovascular Workforce - PMC

7 Machine Learning for Medical Ultrasound: Status, Methods, and Future Opportunities - PMC (nih.gov)

8 Work Related Musculoskeletal Disorders In Sonography

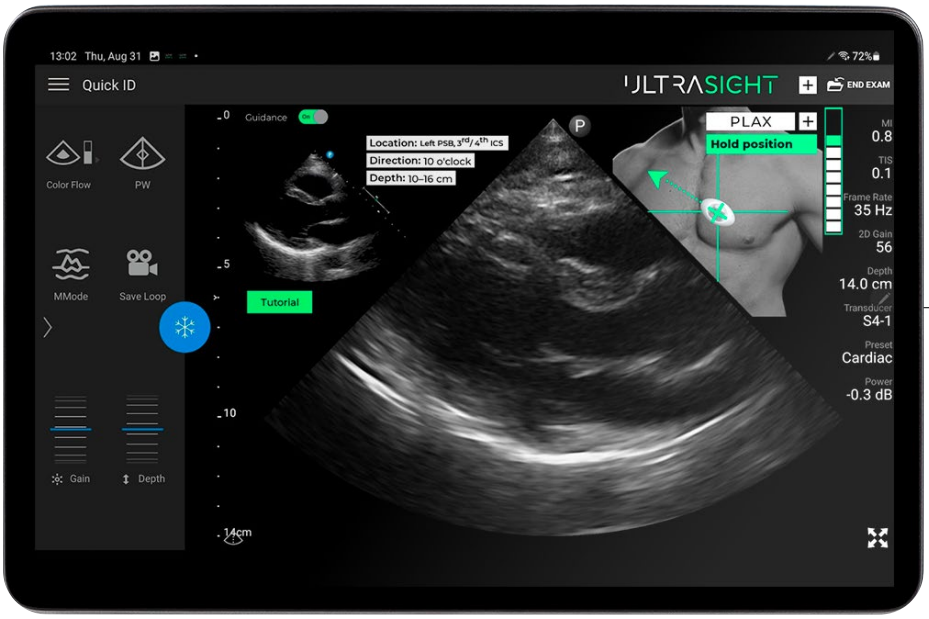
Can AI guidance be used to enable a wider spectrum of healthcare professionals to step into the gap? The American Society of Echocardiography (ASE) has openly advocated AI development in ultrasound imaging:

> *ASE is a strong proponent for innovation in the field of ultrasound and has been actively engaged in fostering artificial intelligence (AI) to assist guidance of optimal image acquisition for cardiovascular ultrasound. We believe this type of innovation could be an ally to help meet the demands of a growing number of people who are in need of cardiovascular care…* [9]

Experts in the field agree that AI could help:

> *AI has influenced all steps of echocardiography, from image acquisition to automatic measurement and interpretation. Considering that echocardiography often is affected by inter-observer variability and shows a strong dependence on the level of experience, AI could be extremely advantageous in minimizing observer variation and providing reproducible measures, enabling accurate diagnosis.*[10]

At UltraSight, we stepped up to meet the need and developed our AI real-time guidance software to enable the easy capture of high-quality ultrasound images by minimally trained clinical personnel using point-of-care cardiac ultrasound (POCUS). By utilizing our access to a unique database with millions of echocardiographic images traced, measured, and characterized by human experts over the years, we used AI and machine learning to create a software application that guides users in real time exactly how to place the ultrasound transducer in the optimal position and orientation needed to take an accurate image of a variety of standardized views of the heart. Our unique neural network was trained to guide the acquisition of standard views of the heart via three acoustical windows that are universally used for diagnosing cardiac problems[11] . The intuitive display is similar to that of a computer gamer's controls tracking hand's movements and indicates when the quality of the image is best.



9 ASE Statement Regarding AI and Ultrasound (asecho.org)

10 Artificial Intelligence and Echocardiography ibid

11 Real-Time Artificial Intelligence–Based Guidance of Echocardiographic Imaging by Novices: Image Quality and Suitability for Diagnostic Interpretation and Quantitative Analysis | Circulation: Cardiovascular Imaging (ahajournals.org)

Can AI guidance be used to enable a wider spectrum of healthcare professionals to step into the gap? The American Society of Echocardiography (ASE) has openly advocated AI development in ultrasound imaging:

The UltraSight team put the software to the test in a recently concluded prospective multicenter study[12] of the quality of echocardiographic exams performed by inexperienced users compared to the same exams done by experienced sonographers (published in American Heart Association's journal Circulation: Cardiovascular Imaging). The clinical study, which was performed at three major medical centers, was designed to evaluate the ability of medical professionals without prior training in echocardiography to perform limited transthoracic echocardiography (LTTE) at a level of quality to enable diagnosis and clinical evaluation, while using the UltraSight Echocardiography Guidance software.

> *Our conclusion: "After minimal training with the real-time guidance software, novice users can acquire images of diagnostic quality approaching that of expert sonographers in most patients."*

CASE STUDY: ULTRASIGHT AI REAL TIME GUIDANCE SOFTWARE ENABLES ANY MEDICAL PROFESSIONAL TO OBTAIN DIAGNOSTIC QUALITY IMAGES

In our clinical study, six registered nurses and three 5th -year medical residents,[13] with no prior ultrasound imaging experience, were given an 8-hour training course that included lectures on cardiac anatomy, basic principles of ultrasound cardiac imaging, demonstrations, and supervised hands-on training on the device and software. Following this training, each novice imaged patients with AI guidance, capturing 10 standard echocardiographic views with each exam. Imaging was performed independently. In the same setting, each patient also underwent imaging by an expert cardiac sonographer, who acquired the same 10 standard views using the same imaging equipment, but without using AI guidance.

Both groups used the Philips Lumify handheld ultrasound system, which has been cleared by the United States Food and Drug Administration for AI software guidance (FDA K162549). Both groups completed exams on the same 240 patients. Each exam captured 10 standard views used by cardiologists. All of the images acquired by both novices and expert sonographers were reviewed by five expert readers to compare their quality, suitability for diagnostic interpretation, and detection of basic pathology.

12 Real-Time Artificial Intelligence–Based Guidance

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Most images acquired by both the sonographers and the novice users were deemed suitable for diagnostic evaluation by the majority of the expert readers (blinded to the identity of the operators).
The scores were only slightly higher for sonographers (88%–100% deemed suitable for diagnostic evaluation, depending on the specific view), compared with novices (81%–94%). According to a majority of the expert reviewers, the exams performed by the novice users had sufficient quality in 93-100% of cases to assess the four primary endpoints which answer the most common clinical questions: left ventricle size, left ventricle function, right ventricle size, and pericardial effusion. The study found that the subjects' body mass index, age, gender, or the presence of cardiac abnormalities appeared to make no difference in the quality of the exams performed by the novice users.

Here are the results by feature of clinical interest (CI):

	% 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)

Figure 1: Data are listed by the echocardiographic feature of interest with the corresponding CIs. AV indicates aortic valve; IVC, inferior vena cava; LA, left atrium; LV, left ventricle; MV, mitral valve; RV, right ventricle; and TV, tricuspid valve.

AN INTERESTING SIDELIGHT: NURSES ARE EMPOWERED TO ACQUIRE IMAGES OF SUFFICIENT QUALITY USING ULTRASIGHT'S GUIDANCE

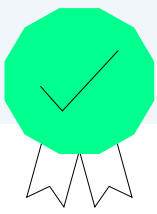
Of the 240 exams, 165 were performed by nurses, and 75 by medical residents. The proportions of images with sufficient quality were slightly higher for the nurses. Expanding the administration of ultrasound exams beyond just MDs and sonographers, and empowering nurses and other medical professionals to use POCUS can open up more opportunities for healthcare systems to increase workflow efficiency and provide better care to more patients. Increasing the ranks of available talent and introducing more flexibility at the point of care is especially important in light of what observers are calling "the Great Resignation," where the healthcare field lost an estimated 20% of its workforce in just two years.[14] Data from our study suggests that nurses and other hands-on healthcare professionals can, with the help of AI guidance, quickly develop the skills to deliver diagnostic-quality cardiac ultrasound imaging at the point of care.

14 The Great Resignation's Toll on Healthcare | HealthLeaders Media

the point of care is especially important in light of what observers are calling "the Great Resignation," where the healthcare field lost an estimated 20% of its workforce in just two years. Data from our study suggests that nurses and other hands-on healthcare professionals can, with the help of AI guidance, quickly develop the skills to deliver diagnostic-quality cardiac ultrasound imaging at the point of care.

	Nurses	Medical residents
	% Diagnostic quality (CI)	% Diagnostic quality (CI)
LV size	100% (98-100)	97% (89-100)
LV function	100% (98-100)	99% (91-100)
RV size	95% (90-99)	99% (67-99)
Pericardial effusion	100 (98-100)	100% (95-100)
RV function	95% (90-99)	91% (74-99)
LA size	96% (91-98)	91% (82-96)
AV structure	89% (82-94)	89% (79-95)
MV structure	98% (95-100)	96% (88-99)
TV structure	77% (69-84)	68% (55-79)
IVC size	67% (55-77)	68% (57-78)

Conclusion: A promising future of increased POCUS use in acute care



The results of our study demonstrate 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. Putting AI technology in the hands of a wider pool of potential ultrasound operators can ease the backlog between the number of patients needing immediate echocardiography and the limited supply of experts available, lowering costs and increasing access and workflow efficiency.