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Philips Ultrasound X11-4t White Paper

Introducing the Philips X11-4t mini 3D TEE

How the X11-4t from Philips helps deliver imaging excellence for patients across the age and size spectrum

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Innovation from necessity: The evolution of cardiovascular ultrasound

Over the last 30 years, global deaths from cardiovascular disease (CVD) jumped 60%: In fact, CVD was the leading cause of death worldwide in 2021.¹ As demand for fast and accurate diagnostics increases, health system challenges persist at each level of care.

Global deaths from cardiovascular disease jumped up to

60%

Around 81% of physicians say they're overworked, while 86% say they're concerned about the healthcare system's ability to care for an aging population.² With an anticipated shortage of around 100,000 critical healthcare

workers by 2028³, rising numbers of traveling providers, and varying experience levels among staff members, cardiology care teams need diagnostic and treatment tools they can trust.

The evolution of <u>cardiovascular ultrasound</u> technology is a driving force behind continued improvements in patient care. Essential to the field of cardiology, echocardiographic improvements are intended to provide higher accuracy with less risk in both diagnostic and treatment processes. Ideally, these advancements build on existing technology, easily integrating into departmental workflows for a consistent, efficient, and, most importantly, accurate experience for cardiovascular specialists and patients alike.

Pediatric cases have represented a particularly significant treatment gap. Every year in the United States, approximately 40,000 children – around 1% of annual births – are born with congenital heart disease (CHD). Until recently, one of the most important diagnostic and treatment modalities, the transesophageal echocardiogram (TEE), was unavailable to patients weighing less than 25 kilograms, profoundly limiting imaging applications in pediatric populations. Thanks to innovations in device size and adaptability, however, this story is beginning to change; with more babies born with heart defects living longer and healthier lives.

Shifting patient trends highlight growing 3D TEE needs

Technology must keep pace to serve the greatest number of patients possible, and more often, TEE offers the advanced diagnostic options needed due to its minimally invasive nature, cost-effectiveness, and versatility. The development of 3D TEE imaging technology, in particular, has dramatically improved diagnostic and treatment accuracy. Reliance on traditional 2D imaging has meant gathering less information about the unique needs of complex patient cases on both ends of the age spectrum. New 3D technologies offer enhanced imaging capabilities for small, complex anatomies, reflecting the unique anatomical variations of pediatric patients.

40,000 children are born with congenital heart disease (CHD)



We do the full range of procedures in our hospital, from complex catheter procedures to complex surgeries on neonates, all the way up to adolescence and beyond. We've been quite practiced at using 3D echocardiography TEE for a number of years now. What we haven't had up until very recently is the ability to do this in the smaller patients."

 Saleha Kabir, Lead Pediatric Cardiac Imager, Lead of Advanced Echocardiography at Evelina Children's Hospital, London, UK

On the other hand, the growing number of tricuspid valve procedures, around 8,000 annually⁶, reflects the increase in structural heart diagnoses in an aging population. Physicians must be able to capture detailed images during echo studies to make accurate diagnoses and initiate timely care. This is true regardless of case severity, but especially



for increasingly frail patients who are more likely to respond negatively to prolonged

intubation and general anesthesia. Reducing the use of general anesthesia during TEE is another emerging goal, reflecting a shift toward improving patient safety and comfort that's represented through technological innovation.

This advancement doesn't just impact cardiology, either. Patients in various specialties, including oncology, neurology, and pulmonary disease present to the echo lab for evaluation, and 3D

TEE provides real-time imaging that's essential to precise diagnosis. This influx of patients drives the development of better diagnostic and treatment tools that allow clinicians to provide care for more people.

Doing more with less: Challenges across the clinical continuum

The complexity of patients' personal anatomy is only part of the story, as clinicians continually balance high-quality care delivery with efficient management of an ever-growing caseload.

For interventional and pediatric cardiologists, the drive to improve quality of care while maximizing patient satisfaction may result in problems like difficulty attracting and retaining staff. A fast-paced work environment, complex cases, rigorous workflows, and higher demand from patients all contribute to staffing challenges. Since the 2020 coronavirus pandemic, it's not unusual for traveling clinicians to fill staffing gaps – and while this satisfies the need for more specialists in practice, it can also interfere with the consistency of care.

Clinicians are doing more with less, even as patient cases evolve over time. A patient's size impacts the choice of equipment used, while case severity determines the type of ultrasound study required, the urgency of the examination, and the level of expertise needed to make an accurate diagnosis.

Since the patient's risk of aspiration, discomfort with TEE probes, and cooperation during the procedure can all impact results, clinicians must weigh the use of conscious sedation or intubation while performing any kind of cardiovascular ultrasound.

- The X11-4t may contribute to lower levels of sedation in some procedures and thus better workflow. I've used the X11-4t on 79 patients to date, and I've been able to acquire diagnostic level quality on all my patients from 50 kilograms to 150 kilograms – and the images are incredible."
 - Dr. Daniel Berson, Chief of Anesthesia, Heart Hospital of New Mexico, Albuquerque, NM, US

Even beyond patient factors, cardiology specialists face operational hurdles. Learning new ultrasound devices and imaging interfaces can be time-consuming, impacting workflow efficiency. Scheduling challenges resulting from issues with anesthesia and high patient demands outpacing staff resources can also disrupt case throughput and may result in reduced patient satisfaction or suboptimal outcomes.

Healthcare providers need solutions to expand access to fast and effective cardiovascular care. As a trusted partner in clinical care, Philips has decades of industry-leading experience with the unique challenges of the healthcare workforce. Our partnership embraces innovation and collaboration, leading to the development of products and services that integrate seamlessly into existing lab workflows.

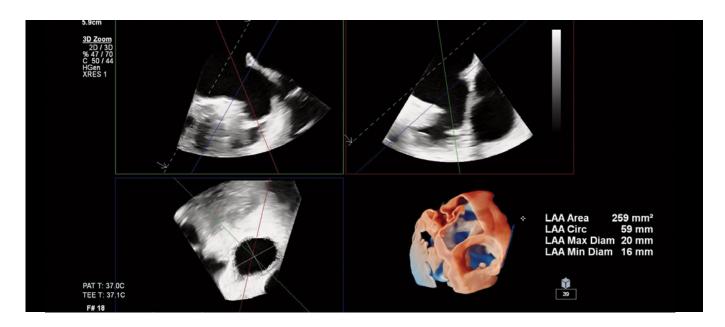
The Philips X114t mini 3D TEE transducer – It fits right

The Philips X11-4t mini 3D TEE fulfills a critical need in cardiology care. In contrast to its predecessors, the X11-4t transducer accommodates a more complete range of patients, from pediatric to older, more frail adults. Its smaller tip fits into narrower spaces, allowing for 3D imaging even in patients as small as five kilograms. This revolutionizes the scope of modern cardiac care that, before the introduction of the X11-4t, may not have had access to appropriate diagnostic or treatment tools.

Interventional imaging, including TEE, is absolutely critical for us. In our practice, the vast majority of the most complex procedures are undertaken in the first two years of life.

Up to now, those patients have not been able to have procedural TEE imaging with 3D. The introduction of the new 3D TEE probe has completely revolutionized that practice. We can now bring 3D imaging for surgeries for those patients in a way that we could not do before. In our experience over the past few months with the probe, the imaging is every bit as good, if not better, as the previous probe."

 Dr. John Simpson, Professor of Pediatric and Fetal Cardiology at Evelina Children's Hospital, London, UK





The transducer's insertion tube features 4-way articulation to allow for better imaging of the heart from multiple angles, including gastric views, so clinicians can accurately diagnose patients with complex conditions. The small, pill-shaped tip design helps to minimize intubation risks among pediatric or frail older patients.

As a result of its miniaturized size, the X11-4t may help lessen the reliance on conscious sedation, improving both experience and recovery times for patients. The reduced need for sedation may also help cut procedure times, allowing for better patient throughput and reducing scheduling challenges.

To seamlessly integrate with workflows, the design of the X11-4t mirrors the Philips X8-2t probe, with the same controls, handle and interface. Therefore, clinicians will only need minimal training to operate the equipment with skill. Using xMatrix Array and PureWave technology, the probe provides detailed 3D images of cardiac structures, a benefit that can be used in real-time surgical cases as intraoperative imaging supports improved patient outcomes.

- With its excellent image quality and small footprint, the X11-4t transducer has the potential to reduce the complications of prolonged transesophageal imaging which can occur during our most difficult structural heart procedures."
 - Dr. Rebecca Hahn, Professor of Medicine at Columbia University Irving Medical Center and Director of Interventional Echocardiography at the Columbia Structural Heart & Valve Center, New York US

Zooming out, the device fits seamlessly into the full Philips portfolio of trusted products, featuring compatibility with EPIQ CVx/CVxi, EchoNavigator, and VeriSight Pro 3D ICE Catheter. This enhances existing workflows and boosts efficiency without requiring excessive training or investment. Synergy between Philips cardiovascular ultrasound systems, transducers, and AI-powered software tools allows clinicians to access critical resources across all platforms, further enhancing workflow efficiency and patient outcomes, Combined, these departmental impacts ladder up to long-term enterprise value for integrated health systems.



Harnessing AI for streamlined procedural workflows

At Philips, continual innovation is at the heart of everything we do. We recently introduced a new AI software solution, 3D Auto Tricuspid Valve Quantification, to help clinicians quickly and accurately evaluate cardiac structures with reproducible results, helping to improve clinical efficiency before and during procedures. Specifically, the 3D Auto TV tool provides 14 automated 3D measurements of the complex tricuspid valve annulus anatomy in a complete heart cycle, improving clinical efficiency before and during procedures.

To learn more, read our new white paper: [PLACEHOLDER FOR LINK]



X11-4t product specifications

Designed for precision and versatility, the X11-4t mini retains many of the familiar features of the existing X8-2t probe – however, the X11-4t's smaller design makes it more adaptable for a wider range of patients with diverse cardiovascular needs.

- Compared to the X8-2t's tip width of 16.9 millimeters, the X11-4t features a tip width of just 11 millimeters, making it suitable for pediatric patients as small as 5 kilograms or patients with exceedingly narrow anatomical spaces.
- The pill-shaped design of the tip features 4-way articulation with 3D imaging capabilities, including 2,500 matrix elements, providing more image angles for superior image quality.
- The X11-4t features a 101.3-centimeter insertion tube length, making it the ideal choice for gastric views of the heart in adults and larger patients.
- The X11-4t retains the same handle design as the X8-2t, minimizing the need for additional training and preventing existing workflow disruptions.
- Multiple imaging modalities, including 2D, 3D, and xPlane, are supported by the X11-4t. The probe is also compatible with the EPIQ CVx/CVxi platform, EchoNavigator, and VeriSight Pro 3D ICE Catheter, allowing clinicians to meet a variety of diagnostic needs.
- In many of our smallest patients undergoing complex intracardiac procedures like valve repairs, 3D TEE will give us a new and much needed perioperative tool. For example, the X11-4t can help us visualize atrioventricular valves en-face. In many cases, this is a view that is difficult to achieve with traditional 2D TEE. 3D TEE will also be a more effective tool to communicate with the surgeons, and will enable us to give good 'surgeon views' of intracardiac structures."
 - Dr. Brian Soriano, Pediatric Cardiologist, Washington, US

Parameter	X11-4t	X8-2t (Comparison)
Tip Width	11 mm	16.9 mm
Minimum Patient Weight	5 kg	30 kg
Insertion Tube Length	101.3 cm	101.4 cm
Insertion Tube Diameter	7.0 mm	10.4 mm
Frequency Range	11-4 MHz	8.2 MHz
Articulation	Four-Way	Four-Way
Matrix Elements	2,500	2,500
Imaging Modes	2D, 3D, xPlane	2D, 3D, xPlane



Ensuring 3D TEE accessibility for every patient

The Philips X11-4t mini 3D TEE transducer provides superior adaptability and imaging features while maintaining a familiar interface and design for clinical teams. Its smaller tip, high-resolution 3D capabilities, and ergonomic features make it an essential tool for modern cardiology. As part of a wider cardiology suite, Philips Ultrasound solutions not only empower clinicians to make more confident diagnostic and treatment decisions but also help deliver a higher standard of care to patients who need it most.

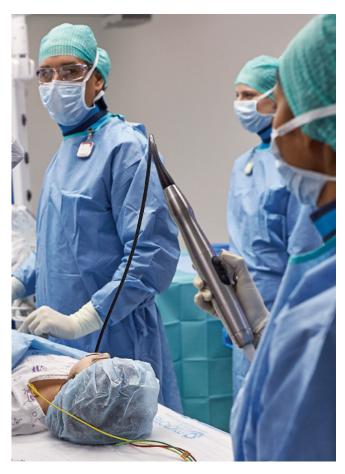
Probe to start using, and the image quality is absolutely amazing. It's the first time we've been able to get these images live on the table, on the smallest patients who need it most. I think we're only beginning to understand what we can do with it."

 Saleha Kabir, Lead Pediatric Cardiac Imager, Lead of Advanced Echocardiography at Evelina Children's Hospital, London, UK



From the smallest pediatric patients to our elderly population, and everyone in between, the latest innovations in cardiovascular ultrasound technology are enabling better access to care and improved outcomes for a greater number of people, while easily integrating into existing workflows. The X11-4t is the solution cardiovascular specialists have been looking for, and with patients at the center of ongoing innovations, physicians can look to Philips to continue to lead in this new frontier of imaging excellence.

To learn more about the X11-4t, contact our team: [PLACEHOLDER FOR LINK].



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