

PHILIPS

Image guided therapy

Electrophysiology suite

- 1 Results obtained during user tests performed in November 2013 by Use-Lab GmbH, an independent company. The tests involved 30 USA based clinicians (15 physicians teamed up with 15 nurses or X-ray technicians), who performed simulated procedures in a simulated OR environment. None of them had worked with a Philips C-arm or with each other before.
- 2 Chugh SS, Havmoeller R, Narayanan K, et al. Worldwide epidemiology of atrial fibrillation: a Global Burden of Disease 2010 Study. *Circulation*. 2014;129(8):837–847.
- 3 stoptheclot.org/about-clots/afib-2
- 4 cdc.gov/dhdsdp/data_statistics/fact_sheets/fs_atrial_fibrillation
- 5 Results are specific to the institution where they were obtained and may not reflect the results achievable at other institutions; Results obtained by the Interventional Vascular Department at St. Antonius Hospital.
- 6 EPD in-house catheter validation is required.
- 7 It is the user's responsibility to ensure that Philips network requirements (such as performance, VPN) for IntelliSpace Cardiovascular are met.
- 8 While using KODEX-EPD occlusion functionality, always refer to the applicable Cryoballoon technical manual, published literature, and exercise your physician discretion to guide confirmation of pulmonary vein occlusion.
- 9 VMQ 7.0 Claims Evidence Report Document. "Results based on internal comparison between 3D Auto LAA and 3DQ on a set of 15 3D LAA datasets of randomized subjects"
- 10 Results obtained during user tests performed in November 2013 by Use-Lab GmbH, an independent company. The tests involved 30 USA based clinicians (15 physicians teamed up with 15 nurses or X-ray technicians), who performed simulated procedures in a simulated OR environment. None of them had worked with a Philips C-arm or with each other before.
- 11 Data on file. Rosink H. Dose management Zenition 50/70. DHF335436. Internal technical paper. Philips Healthcare. January 2019.
- 12 Sohail, M Rizwan, et al. Incidence, Treatment Intensity, and Incremental Annual Expenditures for Patients Experiencing a Cardiac Implantable Electronic Device Infection: Evidence From a Large US Payer Database 1-Year Post Implantation. *Circ Arrhythm Electrophysiol*. 2016; 9(8).
- 13 Sohail MR, et al. Management and outcome of permanent and implantable cardioverter-defibrillator infections. *J Am Coll Cardiol*. 2007;49:1851–1859.
- 14 Le KY, Sohail MR, Friedman PA, et al. Impact of timing of device removal on mortality in patients with cardiovascular implantable electrophysiologic device infections. *Heart Rhythm* 2011;8:1678 – 85.
- 15 Comparison of average peak push forces required to advance Laser Sheath at 40Hz vs. 80Hz Pulse Repetition Rate through simulated fibrosis material at an advancement rate of 1.0 mm/second. D015722, Data on file at Philips.
- 16 Comparison of ablation force vs. advancement rate of Laser sheath 40Hz vs. 80Hz by use of the data collected in D015786, Data on file at Philips.
- 17 Carillo RG, Tsang DC, Azarrafy R, Boyle TA. Multi-Year Evaluation of Compliant Endovascular Balloon in Treating Superior Vena Cava Tears During Transvenous Lead Extraction. EHRA late-breaking trail. March 19, 2018
- 18 Document on file, D026197. In an animal model with SVC tears up to 3.5 cm, with 2 pacing leads and 1 ICD lead.

Electrophysiology suite

Greater insight and confidence in EP procedures

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Defining the future of image-guided therapy

Innovative solutions across the health continuum

At Philips, we look beyond technology to the experiences of patients, providers and caregivers across the health continuum, from healthy living to prevention, diagnosis, treatment and home care. We unlock insights leading to meaningful innovations from hospital to home.

Our integrated solutions – packaged suites of systems, smart devices, software and services – combine broad and deep clinical expertise, technology and services, actionable data, consultative new business models and partnerships. Together, with our customers, we can transform how care is delivered and experienced, to deliver upon the Quadruple Aim: improved patient experience, better health outcomes, improved staff experience, and lower cost of care.

At Philips Image Guided Therapy, we have played a pioneering role in image-guided minimally invasive therapy for cardiovascular disease since the inception of the field back in the 1950s, thanks to our expertise in X-ray imaging systems. We aim to both improve existing procedures and introduce new procedures so that more patients can benefit from image-guided therapy. We also develop new business models to cater for new care settings, such as ambulatory surgery centers and office-based labs, and drive improved lab performance. Today our clinical partners benefit from complete procedural solutions to treat a wide range of diseases – from cardiovascular disease to stroke, cancer and spine conditions.



Clinical demands are getting more specific. And so are we.

During an interventional procedure you are focused on making the best decisions you can for your patient. Each patient and each disease has very specific challenges, complexities and needs. As the number of procedures and patients grows, you see the need for better image guidance and interventional devices to help make treatment and decision-making more effective. At the same time, you're looking to enhance workflows as the key to improving efficiency. That's why we created our clinical suites; a flexible portfolio of integrated technologies, devices and services for a broad range of interventional procedures.

Each of our clinical suites offers specific image-guided therapy solutions to provide more choice and flexibility for exceptional care. You can be confident your patient is receiving the best possible care with the best technology. Together we aim to shape and create the future of image-guided therapy.

Introducing Clinical Suites

Helping to bring across our comprehensive clinical propositions

| | | | | | | | | |
|--|--|---|---|---|--|---|--|---|
| Coronary suite Transforming complex PCI procedures into confident care | EP suite Greater insight and confidence in EP procedures | SHD suite Confidence and Efficiency in Structural Heart Interventions | CHD suite Gentle care. Powerful insights. | Vascular suite Redefine outcomes for vascular treatment | Neuro suite Neuro decisions are based on what you see, so see more | Onco suite Critical insights for superior care in interventional oncology | Lung suite All-in-one diagnosis and treatment of lung cancer | Spine suite Perform spine surgery with confidence and precision |
| | | | | | | | | |



Electrophysiology suite

Greater insight and confidence in EP procedures

The global burden of cardiac arrhythmias is increasing. Patients with atrial fibrillation (AF), in particular, face an increased risk for stroke, dementia or heart failure. The number of affected patients is expected to double in the next 40 years. Electrophysiology (EP) suite offers solutions to address the growing AF patient population. It can seamlessly integrate all your preferred EP equipment to create an electrophysiology lab solution that fits your requested clinical and financial requirements.

Philips is focused on addressing key unmet needs in EP procedures today. We strive to provide superior imaging with the lowest possible radiation dose, offer more efficient workflow, optimize the quality of care and improve safety for patients.

Our Azurion with ClarityIQ technology enables physicians to deliver fast and effective electrophysiology procedures with an efficient clinical workflow, while delivering excellent visibility at low X-ray dose levels for patients of all sizes.

The KODEX-EPD system provides real-time, high-definition imaging that visualizes true anatomy during atrial fibrillation (AF) procedures using dielectric

imaging. No ionizing radiation or contrast medium is required with this technology. These images show variations in cardiac anatomy, including accessory veins, that might otherwise be missed using conventional imaging and mapping systems.

Azurion and KODEX-EPD together deliver innovation to offer the right tools for the unique procedure and patient. With the streamlined image visualization on FlexVision and FlexSpot, our ablation solutions are here to meet your needs and your staff's needs, every time.

Our Zenition family of mobile C-arms offers proven ease of use without compromising image quality. This portfolio of products can help hospitals and clinicians deliver a flexible and cost-effective solution for cardiac rhythm device implantation.

Only Philips has the imaging expertise and broad portfolio of EP technologies to help you achieve this future. We invite you to join us on this journey.



33.5 million people worldwide suffer from AF²



AFib costs have been estimated at **\$ 6 billion** a year in the US alone³



People with AFib are nearly **5 times** more likely to suffer a stroke than people without AFib⁴



In AFib, the heart beats **100-175** times a minute, compared to a normal range of 60-100

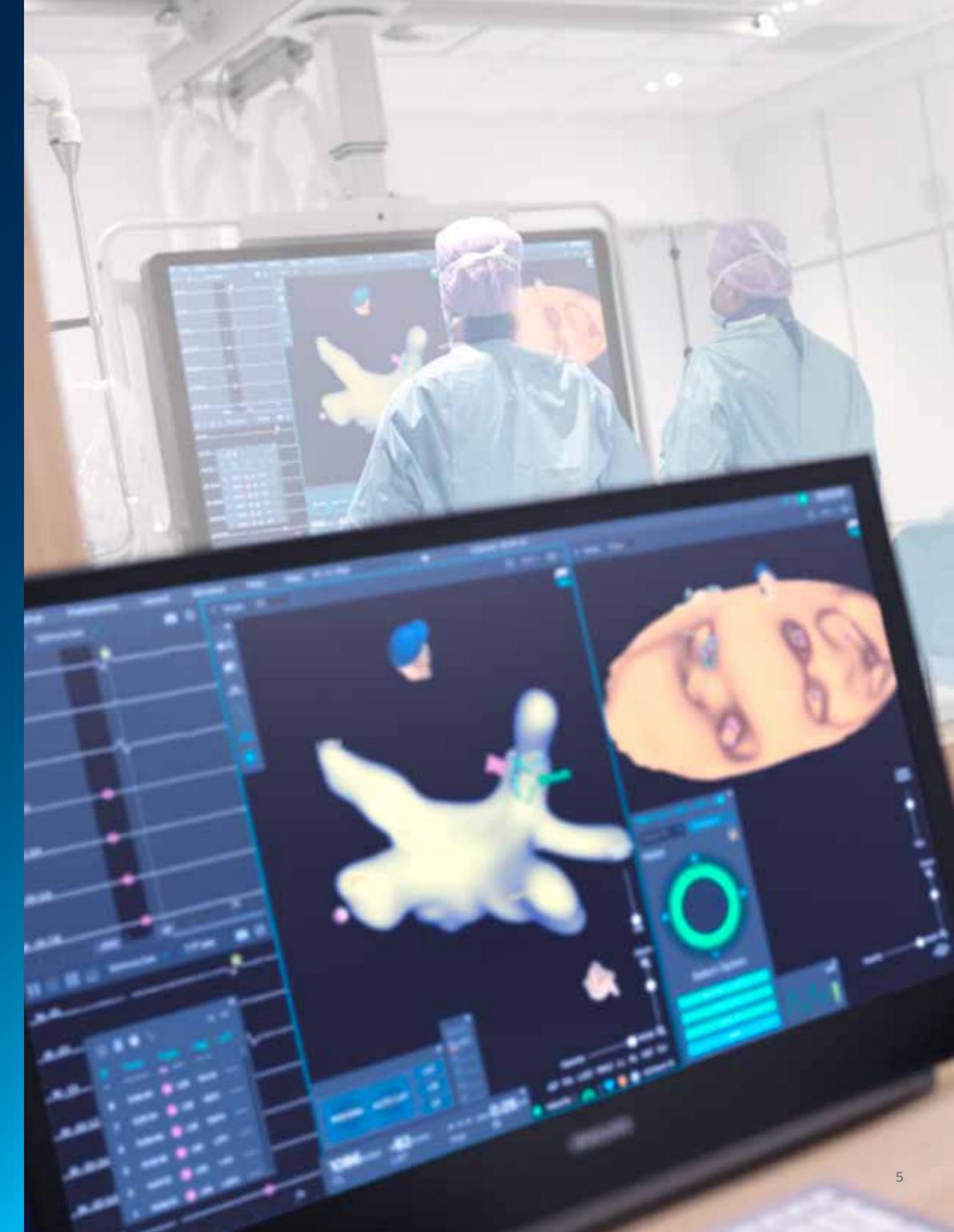
Organize and de-clutter the EP lab

Control room clutter can be a nuisance in EP labs. With the Azurion integrated lab, controlling all compatible applications is easy with the FlexSpot. It gives you access to all compatible applications in one compact, customizable workplace that can be placed in the control room or exam room where needed.

- With FlexVision, you can now control all compatible applications in the interventional lab via the central touch screen module
- The Azurion image-guided therapy platform offers proven tools and workflow innovation that empower you to decide, guide, treat and confirm with confidence
- Advanced therapeutic and diagnostic devices and technologies enable you to personalize treatment decisions

Key benefits

- Clutter-free and comfortable lab environment
- Streamlined workflow through lab integration
- Fast lab turnover between procedures
- Secure clinical performance and enhanced lab security over time (Windows 10 platform)

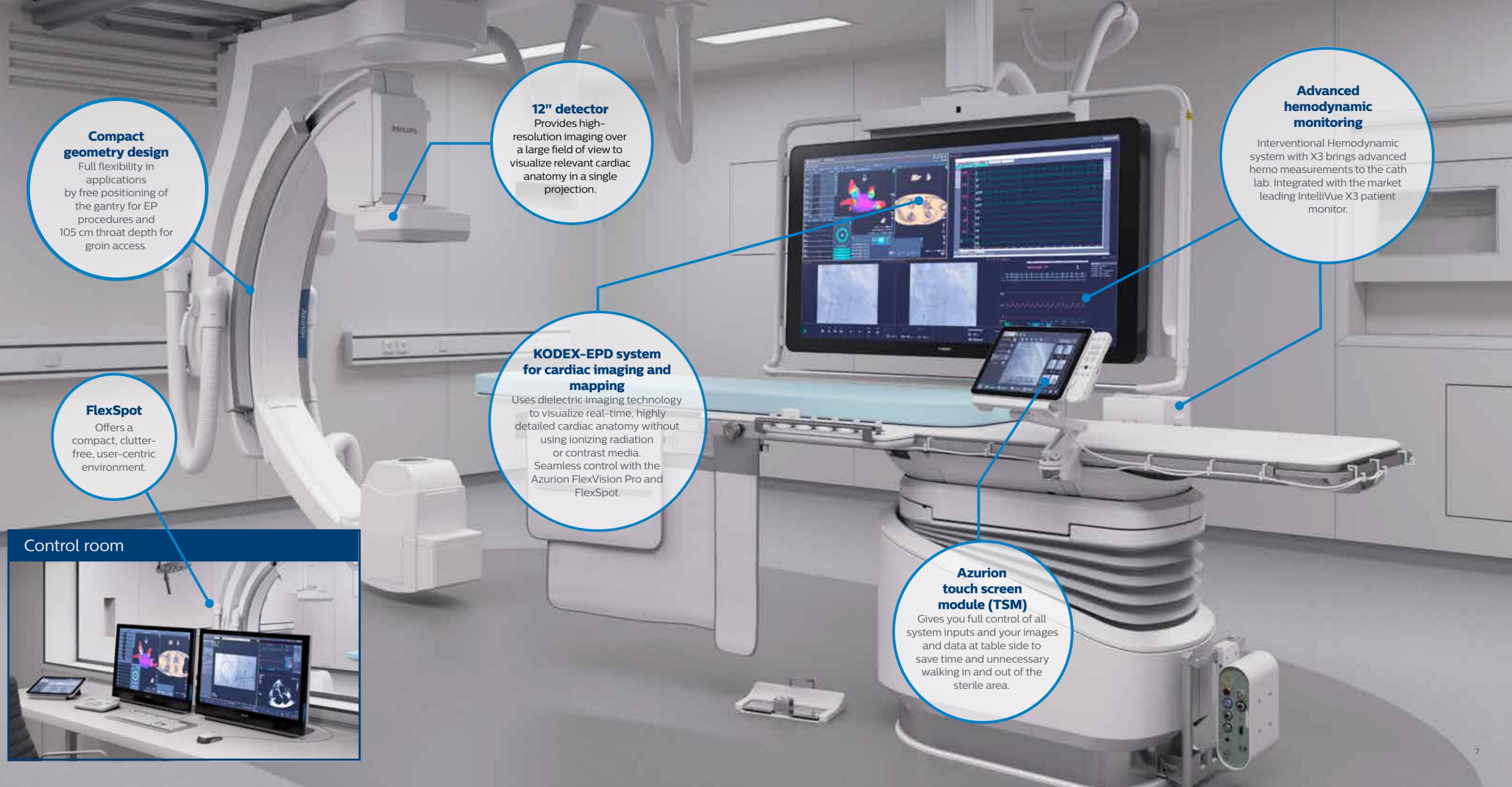


With Azurion, performance and superior care become one

With the Azurion image-guided therapy platform, the core of the EP suite, your medical teams benefit from a seamless user experience and the simplicity of table side control that can improve EP lab workflow. At the table, you can control specialty EP diagnostic and therapy tools for example your EP recording system or pre-operative CT without breaking sterility, enabling safe and effective treatment for a wide variety of routine and complex EP interventions.

Lab integration saves valuable procedure time by reducing equipment and workflow steps in the EP lab. Table side control saves you from going to the control room to access applications. Data entry repetition is reduced by automatically transferring patient information to connected applications, so you only enter patient information once. During procedures, smart solutions like ClarityIQ and Zero Dose positioning provide efficient dose management. This responds to a growing demand for enhanced patient and employee safety by providing low-dose X-ray that does not compromise image quality.

Reduction in procedure time by up to 17%⁵, potentially letting you treat more patients each day



Compact geometry design

Full flexibility in applications by free positioning of the gantry for EP procedures and 105 cm throat depth for groin access.

12" detector

Provides high-resolution imaging over a large field of view to visualize relevant cardiac anatomy in a single projection.

KODEX-EPD system for cardiac imaging and mapping

Uses dielectric imaging technology to visualize real-time, highly detailed cardiac anatomy without using ionizing radiation or contrast media. Seamless control with the Azurion FlexVision Pro and FlexSpot.

Advanced hemodynamic monitoring

Interventional Hemodynamic system with X3 brings advanced hemo measurements to the cath lab. Integrated with the market leading IntelliVue X3 patient monitor.

FlexSpot

Offers a compact, clutter-free, user-centric environment.

Azurion touch screen module (TSM)

Gives you full control of all system inputs and your images and data at table side to save time and unnecessary walking in and out of the sterile area.

Control room



KODEX-EPD system for cardiac imaging and mapping

Advancing imaging in electrophysiology

Despite advances in imaging and mapping technologies for electrophysiology, physicians are still encountering difficult challenges when performing interventions like cryo and RF ablations. The new KODEX-EPD system is an open platform that works with any qualified EP catheter⁶ and uses dielectric imaging to give physicians new insights to guide their interventions. It has been developed to address key unmet needs in EP procedures today. It is a completely new approach to cardiac imaging that shows real-time high-definition imaging of true anatomy and creates voltage and activation maps.

KODEX-EPD uses dielectric sensing to build anatomy, discriminate cardiac structures and assess tissue properties. Dielectric imaging creates high-definition 3D images of a patient's cardiac structures in real-time, without using ionizing radiation or contrast media. This technology overcomes many limitations of the current technologies and offers benefits for both cryo and RF ablation procedures. It has the potential to provide new insights into complex cardiac structures and greatly simplify navigation and therapy delivery.

The KODEX-EPD system is a catheter-based dielectric imaging system to guide EP ablation procedures. This new imaging modality is initially targeted for, but not limited to, atrial fibrillation.

High-resolution images are obtained from the tip of any qualified catheter, with 3D and PANO technology. This is done without using ionizing radiation or contrast medium. The system also provides electroanatomical mapping functionality.

The KODEX-EPD Occlusion Viewer provides an indication of pulmonary vein occlusion for Medtronic's cryoballoon ablation catheter without X-ray.



See **true anatomy** without radiation



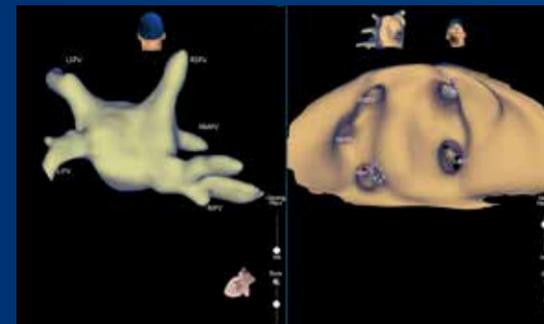
Personalize therapy based on intraprocedural insights



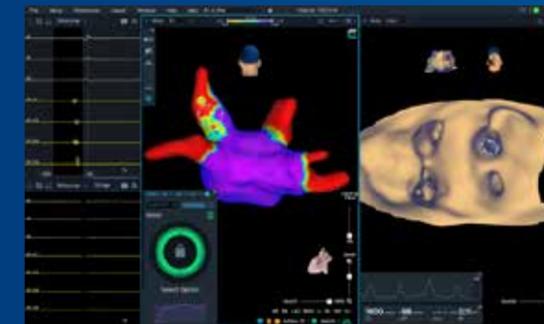
Simplify your workflow for **more efficient procedures**



Optimize your **quality of care**



Left atrium showing an accessory right middle pulmonary vein (RMPV) in 3D posterial view adjacent to an anterior PANO.



Occlusion Viewer using injection protocol, assists with detection of leaks during contrast injection, in addition to traditional techniques for occlusion assessment.



Example showing how KODEX-EPD builds up a detailed 3D image of the left atrium in as little as 3 minutes.

Orchestrating your interventional cardiology workflow

IntelliSpace Cardiovascular

IntelliSpace Cardiovascular combines deep clinical expertise with technological innovation to securely connect patients, care teams and data across the entire cardiovascular care continuum by providing a single point of access anytime and virtually anywhere to support informed decision-making⁷.

The Cardiology Timeline maintains an overview of the complete cardiac history of the patient, enabling easy navigation to the information needed. Within IntelliSpace Cardiovascular you can create, review and finalize structured cardiac implantable electronic devices (CIED) follow-up reports in the Pacing ICD Check module with imported programmer data. It can be viewed and controlled from the FlexSpot and FlexVision Pro of Azurion, allowing for easy intra-procedural check of pre-operative information.

Key benefits

- Allows you to view and control multi-modality patient data at the table side in the exam room on IntelliSpace Cardiovascular with Azurion FlexVision Pro, without having to break scrub
- Enables you to control IntelliSpace Cardiovascular from Azurion FlexSpot in the exam room, or from a workstation in the control room
- Automatic in context patient launch from Azurion to IntelliSpace Cardiovascular (as of 5.1)



Philips Hemo system with IntelliVue X3

Improving productivity and outcomes is vital for healthcare facilities to meet the growing demand for cath lab procedures. To further simplify cath lab workflow, Philips introduces the Interventional Hemodynamic system (Philips Hemo system) which brings advanced hemodynamic measurements to the interventional lab. Integrated with the market leading Philips IntelliVue X3 patient monitor, this unique combination enables continuous patient monitoring throughout the cath lab. By connecting the IntelliVue X3 in the cath lab with the Philips Hemo system, you can continuously monitor a patient. There is no need to change cables, minimizing disruption and giving you more time to focus on your patient.

Key benefits

- Improved communication in the interventional lab by visualizing hemodynamic analyses in the exam room
- Confidently used by all staff members with minimal training

Xper Information Management

Xper IM is designed to enable more efficient cath lab workflows with hemo monitoring and data management. It streamlines workflows in physician reporting, billing, registry reporting and inventory management. Xper IM has a broad range of interfaces, orchestrating disparate patient data across the care continuum to support informed decision making.

Key benefits

- Automated data collection and customized charting workflows, for example for lab results and updates
- Auto populated physician transcription based on the charting input
- Intelligent cardiovascular data management with analytics capabilities

See clearly. Treat optimally.

Support across the entire treatment pathway



Lead management devices
With an aging patient population, more complex devices and expanded indications, lead management devices support physicians in safely managing every CIED lead. These tools provide precision, control and versatility while extracting leads from the vasculature, so that physicians can focus more on the patient's overall health while generating positive outcomes.

Decide



EchoNavigator
EPIQ CVxi makes it possible to view and control the latest innovation in real-time fusion imaging, EchoNavigator. Uses SmartFusion to fuse live TEE and live fluoroscopic images in real time. This allows you to intuitively and quickly guide your device in the 3D space. TEE transducer position and orientation are automatically tracked in the X-ray image, allowing the echo and X-ray images to move in sync when the C-arm is repositioned.

Guide



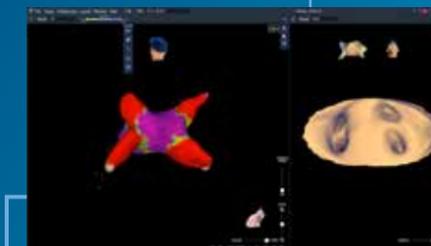
EPIQ CVxi
Philips EPIQ CVxi delivers the exceptional image quality you expect in a premium ultrasound system, along with efficiencies in procedure guidance driven by interventional dedicated tools and a cardiology-focused interface.

Treat



KODEX-EPD – Advanced Imaging
KODEX-EPD visualizes critical structures in cardiac anatomy without fluoroscopy. During Cryoballoon[®] ablation procedures, the Occlusion Viewer provides an assessment of pulmonary vein occlusion, further reducing the dependency on X-ray.

Confirm



KODEX-EPD – Mapping
KODEX-EPD creates continuously updated voltage and activation maps to support efficient collection of additional insights and confirm therapy impact.

EchoNavigator on EPIQ CVxi

Unparalleled visualization of anatomy and devices. Together.

Philips EPIQ CVxi delivers the exceptional image quality you expect in a premium ultrasound system, along with efficiencies in procedure guidance for LAAO, driven by dedicated interventional tools and a cardiology-focused interface.

Advanced automation

At the heart of this powerful architecture is advanced automation, designed to elevate the standards of ultrasound systems with anatomical recognition, protocols for automatic functionality and proven quantification. Exams are easier to perform and more reproducible, and deliver new levels of clinical information.

Simplify navigation, device guidance and evaluation of results

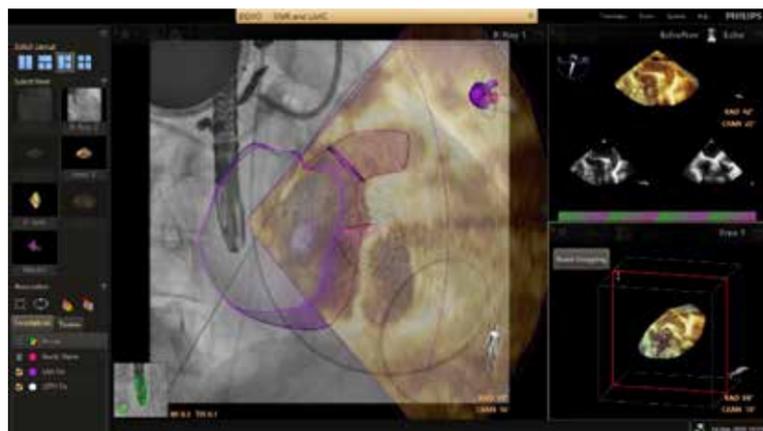
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The EPIQ CVxi's 3D Auto LAA feature can reduce measurement time by 70% on average compared with measuring the LAA features manually⁹

Elevating intra-procedural echo guidance for left atrial appendage occlusion

In LAA occlusion, EchoNavigator enables the following to elevate confidence and boost efficiency:

- Automatic segmentation of 3D ultrasound to derive the left atrium and LAA ostium in order to optimize fluoroscopic projections and provide context for navigation
- Manual markers automatically translated from ultrasound to fluoroscopy to keep sight of targets or critical structures to avoid
- Live-on-live fusion of fluoroscopy and ultrasound including 2D, 3D, and color flow, to visualize occluder deployment



Our Azurion with ClarityIQ technology enables physicians to deliver fast, effective and simplified electrophysiology procedures with an efficient clinical workflow. All while providing high image quality at ultra-low dose levels.

High safety. Low radiation. ClarityIQ technology

High standards of safety and low radiation exposure

Several Azurion features have a focus on dose management. Our dose management solutions help you take control of patient care and staff safety, with a comprehensive suite of radiation dose management tools, training and integrated product technologies.

“ With **Philips ClarityIQ** technology we can further enhance image-guided catheter ablation therapy for complex heart rhythm disorders. The number of people with arrhythmias eligible for catheter ablation therapy is increasing sharply, so treating the condition needs to be made simpler and even safer. In addition to minimizing the risk to patients, reducing X-ray dose is also an important step for medical personnel, because many of them are exposed to X-ray radiation on a daily basis.”

Lukas Dekker, cardiologist, Heart Center at Catharina Hospital, Eindhoven, the Netherlands

Zenition Mobile C-arm

Unlimited potential at your fingertips

Work with ease and confidence, today and tomorrow with Philips Zenition – a series of harmonized mobile C-arms that offers proven ease of use and future-fit capabilities.

Rising patient volumes and longer, more complex procedures put ever greater demands on imaging systems. Being able to quickly visualize critical details of anatomy at any time during a procedure is key to providing excellent patient care. With Zenition, the medical team is superbly equipped to perform a variety of today's and tomorrow's interventional procedures with confidence, while effectively managing radiation dose.

Key benefits:

- Increase efficiency with user-friendly controls and efficient time-savers
- Reduce distractions with Zenition's tablet-like simplicity and communication aids
- 45% less miscommunication during positioning through our patented Unify workflow communication aids¹⁰
- Perform longer and complex procedures to serve a broad patient population
- Up to 49% reduction in Dose Area Product (DAP) with Automatic Shutter Positioning protects patient anatomy and in-room personnel from unnecessary exposure¹¹
- Safeguard clinical performance and extend your system's clinical relevance



Manage every lead

Improved patient outcomes

Lead extraction for CIED infection can be a life-saving procedure. Yet, over 65% of CIED infection patients are treated inappropriately.¹² Any patient with a CIED and an infection should be referred quickly for a lead extraction consultation, as data shows delaying lead extraction can lead to mortality.^{13,14} Philips is dedicated to helping physicians and patients manage every lead – safely, responsibly, predictably with the Philips Lead Management portfolio of safe and effective tools.

GlideLight laser sheath*

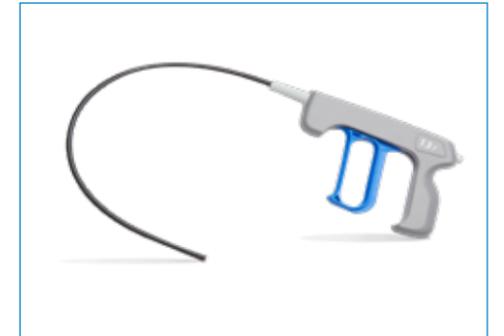
- **Versatility** – No two lead removal procedures are the same. Each binding site is unique, lead designs vary, and every patient's anatomy is different.
- **Efficiency** – Stalled progression during lead removal procedures can lengthen the time they take to complete. GlideLight laser sheath may enable smoother and more consistent progression.
- **Control** – Using a high degree of mechanical force when removing leads can compromise lead integrity. GlideLight laser sheath provides critical control when progressing through binding sites.

Safely and efficiently removing leads depends on tools that give you versatility and control. GlideLight laser sheath offers the unprecedented ability to customize the laser's repetition¹⁵ rate throughout a procedure. At 80 Hz, the GlideLight laser sheath requires up to 55% less advancement force,¹⁵ and advances up to 62% more efficiently through tough binding sites than laser sheath (SLS II).¹⁶



TightRail mechanical rotating dilator sheath

With TightRail mechanical rotating dilator sheath, flexibility meets unparalleled control. The tool's flexible shaft helps physicians remain coaxial to the lead while maintaining forward progression through tortuous vasculature. The dilating blade remains shielded until activated, putting physicians in control and allowing counter-traction at the targeted lead's distal tip.



Bridge occlusion balloon

A tear in the superior vena cava (SVC) during a lead extraction procedure is rare, occurring in just 0.5% of cases.¹⁷ But when a tear does occur, the Bridge occlusion balloon can be quickly deployed to stop blood loss and allow time for transition to surgical repair.¹⁸



* Indications for use: The GlideLight laser sheath is intended for use as an adjunct to conventional lead extraction tools in patients suitable for transvenous removal of chronically implanted pacing or defibrillator leads constructed with silicone or polyurethane outer insulation. Contraindications: Use of the laser sheath is contraindicated: When emergency thoracotomy with cardiopulmonary bypass cannot be performed immediately in the event of a life threatening complication; When fluoroscopy is not available; In patients in whom superior venous approach cannot be used; When the proximal end of the pacing lead is not accessible to the operator; When the lead will not fit into the inner lumen of the laser sheath. Potential adverse events: The following adverse events or conditions may also occur during lead extraction with the laser sheath, but were not observed during the clinical study (listed in alphabetical order): bacteremia, low cardiac output, migration of lead fragments, migration of vegetation, myocardial avulsion/perforation, premature ventricular contractions, pulmonary embolism, stroke, venous avulsion/perforation, ventricular tachycardia.



Increase value throughout your electrophysiology suite lifecycle



| Application | Azurion | Zenition | KODEX-EPD | Laser and mechanical extraction | CVxi & EchoNavigator | Hemo system with IntelliVue X3 |
|----------------------------------|---------|----------|--------------|---------------------------------|----------------------|--------------------------------|
| Ablation procedures | ● | | ● | | | ● |
| Device implants | ● | ● | | | | ● |
| Lead removals/ extractions | ● | ● | | ● | | |
| Hybrid procedures (LAO, Ex-Maze) | ● | | ● Ex-MAZE | | ● | ● |

Stay clinically and operationally relevant with Technology Maximizer

To keep your image-guided therapy suite state-of-the-art with regards to cyber security, clinical and operational advancements, subscribe to IGT Technology Maximizer.

Technology Maximizer secures all your eligible Philips imaging equipment with the same technology release level reducing maintenance complexity and simplifying lifecycle management across hospital departments. Maintain peace of mind with imaging equipment that is always up to date, and enhance patient care knowing you will always be first to take advantage of technology innovations.

Learn more about Technology Maximizer



| | Standard offer | Mid-level offer | Premium offer |
|--|--|--------------------------|---|
| | Technology Maximizer Plus | Technology Maximizer Pro | Technology Maximizer Premium Cardiac/Vascular |
| | Azurion system SW version upgrade | | ✓ ✓ ✓ |
| | State-of-the-art security | | ✓ ✓ ✓ |
| | Latest available Operation System | | ✓ ✓ ✓ |
| | Computer HW refresh to support software upgrade | | ✓ ✓ ✓ |
| | Application training for new or enhanced functionality (days) | | 1 2 2 |
| | New version of existing iApps | | ✓ ✓ ✓ |
| | Future iApps in one clinical suite (Coronary, EP, SHD, Vascular, Neuro, Onco, Spine or Lung) | | ✓ ✓ |
| | Future iApps in one clinical domain (Cardiac or Vascular) | | ✓ |