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- 6. Co-registration tools available within IntraSight 7 configuration via
- 7. IMV ServiceTrak 2018 X-ray Cardiovascular Systems.
- Data shown is an average, based on the comparison between remotely connected and non-remotely connected systems. Data sample from 2018 for Allura FD and Azurion systems (n=9955).
- Physiology tools, such as IntraSight interventional platform and Philips Interventional Hemodynamic system, and coronary guidance tools, such as StentBoost Live and Dynamic Coronary Roadmap.
- 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.
- 11. Compared to Philips 10" Flat Detector
- 12. It is the user's responsibility to ensure that Philips network requirements (such as performance, VPN) for IntelliSpace Cardiovascular are met.
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- (95% CI of 53%, 77% for all diagnostic and interventional coronary procedures). The results of the application of dose reduction techniques will vary depending on the clinical task, patient size, anatomical location and

- clinical practice. The interventional cardiologist assisted by a physicist as necessary has to determine the appropriate settings for each specific clinical task.
- 20. Results based on total dose area product from a single center prospective controlled randomized study (University Hospital Gent, Belgium) on 122 patients (42 for Allura Xper and 80 for AlluraClarity) undergoing coronary procedures. Of the 122 patients, 102 (83.6%) had a diagnostic procedure without intervention and 51 (41.8%) resulted in a diagnosis of no coronary disease. Patient radiation exposure was quantified using cumulative dose area product as collected from Radiation Dose Structured Reports and/or Allura Reports. Baseline dose was maintained by configuring both systems to power up with the lowest dose settings as default and default procedure settings for cardio were used. Exam duration and fluoro time was consistent between the systems and an increase in number of exposure images and runs with the AlluraClarity was attributed to the biplane configuration compared to the monoplane configuration of the Allura Xper.
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28. Summary of safety and effectiveness – PTCA catheter AngioSculpt Evo PTCA important safety information

The AngioSculpt Evo scoring balloon catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis and complex type C lesions, for the purpose of improving myocardial perfusion.

The AngioSculpt Evo catheter should not be used for coronary artery lesions unsuitable for treatment by percutaneous revascularization, and coronary artery spasm in the absence of a significant stenosis.

Possible adverse effects include, but are not limited to: death; heart attack (acute myocardial infarction); embolism, total occlusion of the treated coronary artery; coronary artery dissection, perforation, rupture, or injury; pericardial tamponade; no/slow reflow of treated vessel; emergency coronary artery bypass (CABG); emergency percutaneous coronary intervention; CVA/stroke/ embolic stroke; pseudoaneurysm; restenosis of the dilated vessel; unstable angina; thromboembolism or retained device components; irregular heart rhythm (arrhythmias, including life-threatening ventricular arrhythmias); severe low (hypotension)/high (hypertension) blood pressure; coronary artery spasm; hemorrhage or hematoma; need for blood transfusion; surgical repair of vascular access site; creation of a pathway for blood flow between the artery and the vein in the groin (arteriovenous fistula); drug reactions, allergic reactions to x-ray dye (contrast medium); and infection. This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

Prescription Use Statement

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How to reach us
Please visit www.philips.com
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Defining the future

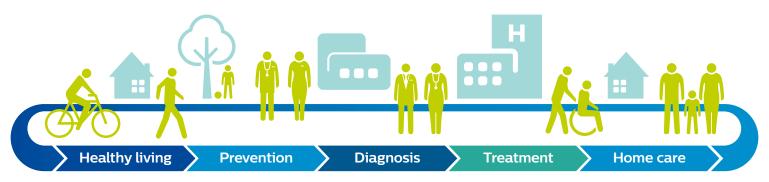
of Image Guided Therapy

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. So you can be confident in your performance and in the fact your patients are receiving exceptional care. Together we aim to shape and create the future of image guided therapy.

Introducing Clinical Suites

Helping to bring across our comprehensive clinical propositions

Onco suite Coronary suite EP suite SHD suite Vascular suite Lung suite Spine suite Confidence and Efficiency Critical insights for Perform spine surgery PCI procedures drives EP excellence in Structural Heart for vascular treatment based on what you see, superior care in with confidence into confident care Interventional Oncology

Coronary suite

Transforming complex PCI procedures into confident care

Boost your performance today

As the prevalence of coronary artery disease (CAD) grows, interventional cardiologists are feeling the strain. With an everincreasing caseload and a squeeze on resources, delivering efficient, cost-effective and high-quality care presents significant challenges. Moreover, smart management of X-ray dose to protect your patients, your staff and yourself remains a central issue.

At Philips, we recognize that the cath lab is a complex landscape, made up of different information and systems. Our Coronary suite is a fully integrated ecosystem – designed to support confident decisions and deliver insight into treatment success, while improving cath lab performance.

Advanced clinical and workflow applications, therapeutic and diagnostic devices, and leading services, all work intelligently together to efficiently support every step of coronary procedures. From diagnosis to restoring vessel patency.

To exceed expectations in the future

The Coronary suite ecosystem is designed to improve your today, but it is also your launching pad to the future:

- Imagine if you could combine system performance data to improve departmental performance
- Imagine if you could aggregate all patient cardio data to improve procedural decision making

When you invest in Philips Coronary suite, you are investing in a road map to the future. As we move from a mainly transactional to a value-based pathway in healthcare, integration, usability and artificial intelligence will drive the industry forward. It's exciting to think of what's possible when care providers can access the tools and technologies, they need to create a fully integrated and transformed interventional cardiology service.

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

Cornerstones of Coronary suite

- Azurion image guided therapy platform.
 Proven tools and workflow innovation
 empower you to decide, guide, treat and
 confirm with confidence
- IntraSight, a comprehensive suite of clinically proven¹⁻⁵ physiology, IVUS and co-registration⁶ tools on a modern, secure platform
- Advanced therapeutic and diagnostic devices and technologies to personalize treatment decisions
- Safeguard clinical performance and enhance lab security over time (Windows 10 platform)
- Best service performance⁷ which enables you to treat more patients⁸

Key benefits

- Easy access to applications and imaging tools to improve cath lab performance
- Solutions for every step of coronary procedures, from diagnosis to restoring vessel patency
- Scalable platform that will be ready to provide you with new innovations and tools as they become available in the future

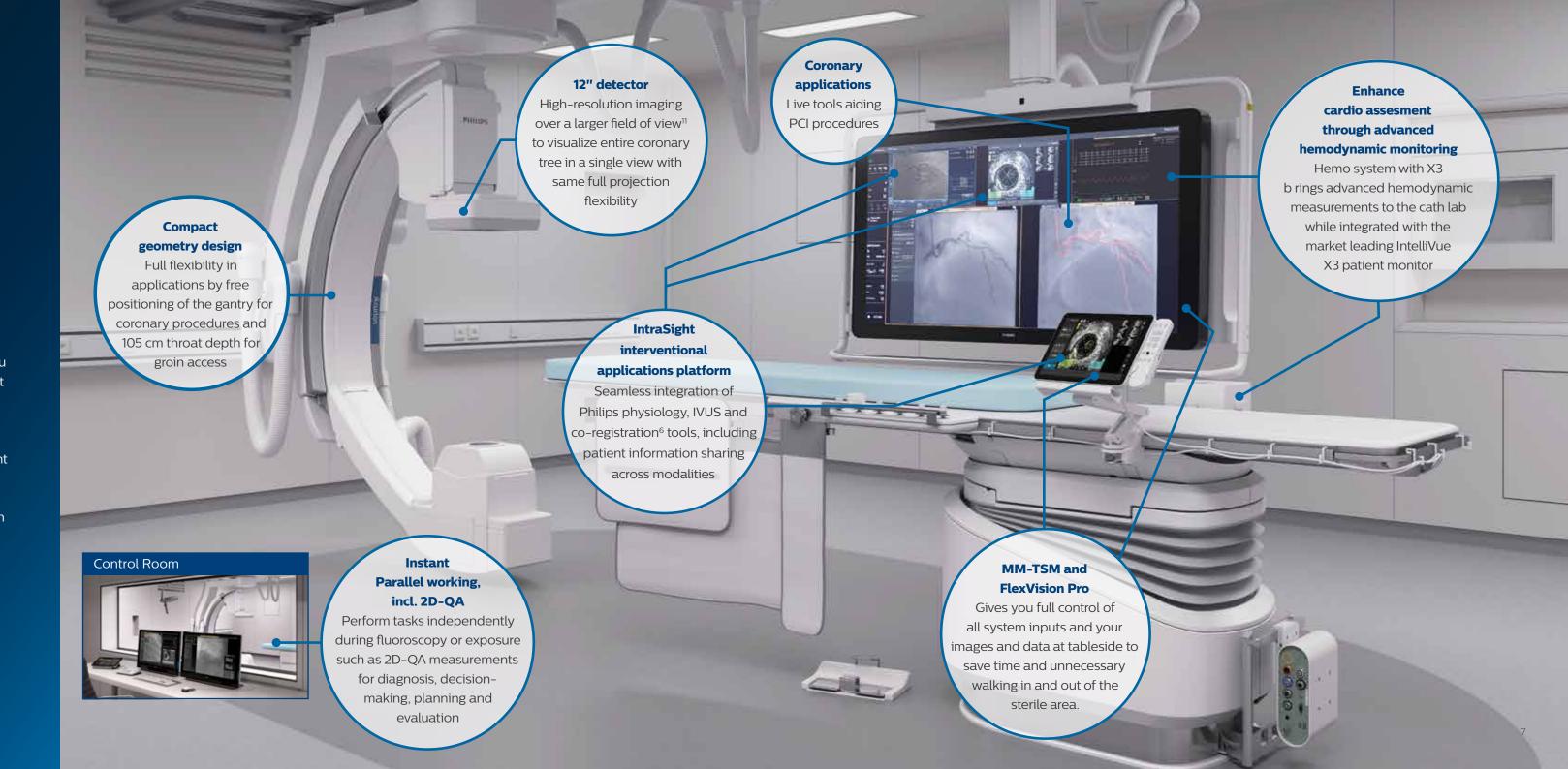


With Azurion, performance and superior care become one

With the Azurion image guided therapy platform, the core of the Coronary suite, your medical teams benefit from a seamless user experience and the simplicity of touch screen control that can improve cath lab workflow. From one touch screen at the table, you can control specialty⁹ cardiac diagnostic and therapy tools without breaking sterility, enabling safe and effective treatment for a wide variety of routine and complex cardiology interventions.

Lab integration saves valuable procedure time by reducing equipment and workflow steps in the cath 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 ClaritylQ and Zerodose 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%¹⁰, potentially letting you treat more patients each day



Philips IntraSight

Interventional applications platform



Smart. Simple. Seamless.

IntraSight unites best-in-class imaging, physiology and co-registration⁶ tools on a secure applications based platform to simplify complex interventions and help you provide superior patient care. An intuitive user interface and simplified workflow contribute to an outstanding user experience. With a tableside touchscreen control, systems integration, data management and remote service diagnostics, IntraSight helps you optimize your cath lab performance.

Unrivaled security.

IntraSight is the only interventional platform protected by the advanced data encryption technology of Windows 10, your best defense against cybersecurity threats.

Customizable access and data management settings and policies are available to fit your organization's individual security needs.



Tools that see beyond the angiogram to help provide superior care.



Choice of evidence-based iFR and FFR modalities enable you to quickly assess ischemia, and iFR pullback technology for physiologic guidance.



Broad portfolio of coronary and peripheral applications, including high-resolution rotational IVUS and Philips' exclusive plug-and-play digital IVUS.



Combine iFR and IVUS data with the angiogram for improved treatment outcomes using Philips' exclusive iFR and IVUS Co-registration⁶ technology.

Orchestrating your interventional

cardiology workflow

IntelliSpace Cardiovascular¹²

Is designed to streamline workflow throughout the cardiovascular care continuum. Providing a single point of access anytime and virtually anywhere to support informed decision–making. The cardiology timeline maintains an overview of the complete cardiac history of the patient enabling easy navigation to the information needed. 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 patient multi-modality data at the table side in the exam room on IntelliSpace Cardiovascular with Azurion FlexVision Pro, without having to break scrub
- 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 cath 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.

mmmmmm.

Key benefits

- Improved communication in the interventional lab by visualizing hemodynamic analyses in the exam room
- Enhanced workflow through integrated iFR
- · 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.

10

See clearly. Treat optimally.

Support across the entire treatment pathway



Integrate FFR and iFR measurements

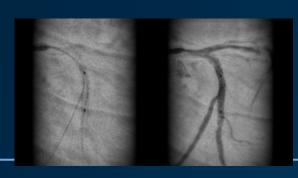
With Verrata/Verrata Plus pressure guidewires, you can easily integrate iFR or FFR measurements into your daily PCI routines. iFR allows you to reduce cost, time, and patient discomfort versus FFR.^{1,2,3}

Guide



Advanced physiological measurements

iFR Co-registration⁶ can be used when the lesions are more complex and advanced insights are required by mapping the physiology gradients onto the angiogram.



Enhance stent visualization post-stenting Confirm stent positioning and apposition to wall with StentBoost image enhancement.

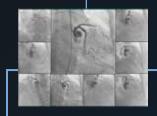


Post intervention advanced imaging

IVUS can be used to evaluate the result of the intervention and to verify whether additional treatment is needed.

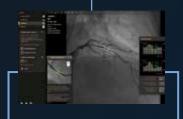
Confirm.

Decide



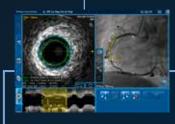
Efficient diagnostic acquisition Cardiac Swing of LCA and RCA gives an overview of the coronary vasculature, providing additional

anatomical insights13



Quick measurements of lesions

2D-QA measures lesion stenosis on an angiogram during the procedure, now possible to do in parallel to fluoroscopy with Instant Parallel Working.



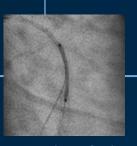
Advanced imaging IVUS Co-registration

IVUS Co-registration on SyncVision helps you obtain insights to more easily plan stent diameter, length, and landing zones.



Live guidance

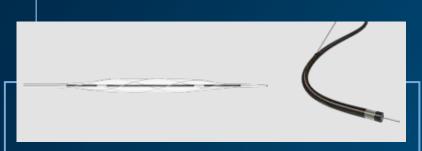
Dynamic Coronary
Roadmap creates a motioncompensated, real-time
roadmap of the coronary
arteries that is superimposed
in real-time on live fluoroscopy
to support guidewire
positioning distal to the lesion.



Treat

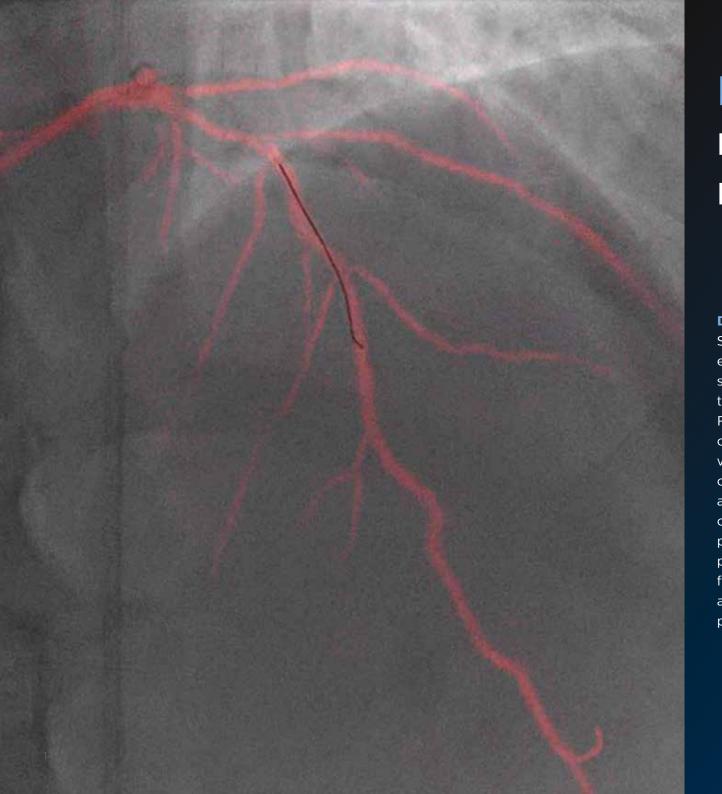
Pre-stenting evaluation

StentBoost Live enhances live stent visualization during positioning to verify lesion coverage.



Therapy devices

During treatment, you have to decide it if is safe to treat the lesion, and what size and type of device should be used for best long term patency. Philips Image Guided Therapy Devices provides a portfolio of coronary solutions that allow you to personalize treatment decisions for each patient. For example, the AngioSculpt Evo scoring balloon is designed to address complex lesions found in the coronary arteries and ELCA coronary laser atherectomy catheters are designed to cross, prepare and treat the most difficult coronary lesions.



Real confident, real-time navigation

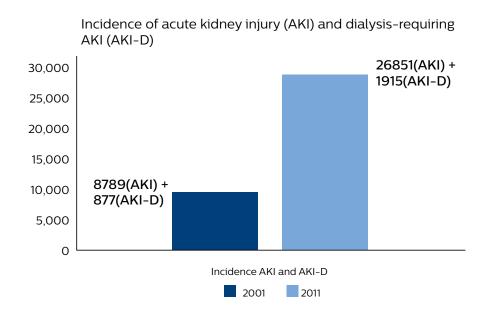
Dynamic Coronary Roadmap

Seeing better can make your job a whole lot easier. Positioning devices in the coronaries sometimes requires use of contrast puffs to support navigation. Dynamic Coronary Roadmap, a Philips-exclusive technology, creates a motion-compensated, real-time view of coronary arteries. A highlighted coronary angiogram is superimposed on a live 2D fluoroscopic image, creating a colored roadmap that adjusts automatically, providing continuous visual feedback on positioning of wires and catheters. It's also fully integrated with the system and features automatic storage and easy re-display of previously acquired roadmaps to enhance.

How **Dynamic Coronary Roadmap** benefits you:

- Real-time, automatic, motion-compensated coronary imaging for easier image guidance
- Easy storage and re-display of previously acquired roadmaps to enhance procedure efficiency
- Seamless integration into standard-of-care workflow and daily clinical practice

One of the most common complications of PCI is acute kidney injury (AKI), primarily induced by the use of nephrotoxic contrast medium. PCI patients who develop AKI have an increased risk for complications, length of stay, and additional acute care costs.¹⁴ The graph is reproduced from data presented by Brown et al.¹⁴ The results of this study show that contrast medium reduction should be a priority in today's PCI procedures.



Angioplasty of LAD with bifurcation lesion





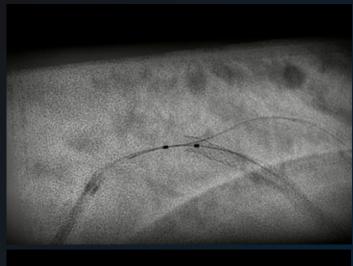




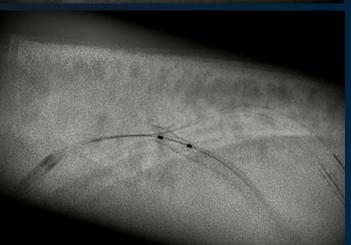




A severe lesion is located at the mid-portion of the LAD, immediately distal to a large diagonal branch. Because of the complicated location of the lesion, the guide wire tracks down the diagonal branch instead of the LAD. Anchoring the wire in the LAD is required to provide enough stability to cross the lesion with the stent. With Dynamic Coronary Roadmap, you can retrieve and selectively advance the wire to the targeted vessel, in this case, without required additional contrast test injections.







Post-stenting balloon dilation with a high pressure balloon

To avoid vessel injuries, a high-pressure balloon must be accurately placed within a stent. However, advances in stent design have made visualization of struts and stent edges more difficult, creating a challenge for accurate balloon placement. StentBoost Live is used to visually guide the high-pressure balloon to the proximal end of stent. Continuous stent visualization shows the placement of the balloon fully within the stent.

66 StentBoost Live enables placements of multiple stents and achieves the right amount of overlap – or avoids overlap in case of BVS. ??

According to the personal opinion of Dr. B. Drieghe, Interventional Cardiology and Electrophysiology, University Hospital Gent, Gent, Belgium

Enhanced visualization made easy

StentBoost Live

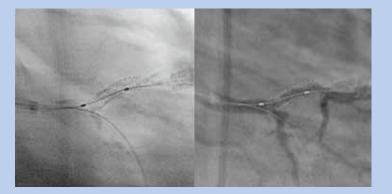
Accuracy is everything in your job – but stents are getting harder to see. Building on a decade of innovation and experience, our StentBoost Live¹⁵ offers Philip's most advanced live stent visualization technology yet. It quickly helps you verify positioning before and after deploying balloons, stents, and intra-coronary devices to display underdeployment and confirm full expansion. And it's all done in real-time, so you no longer need to wait for new images before you reposition.

Key benefits:

- Live enhanced visualization of device positioning and deployment in real-time
- Designed for procedural effectiveness and greater efficiency with enhanced visualization of moving intracoronary devices
- Seamless integration into standard of care workflow for optimized PCI

Stentboost and Stentboost Subtract

Stentboost is a simple, quick, and cost-effective tool to enhance stent visualization in the coronary arteries. With the StentBoost Subtract feature, you can see the stent in relation to the vessel wall as you are working. These functionalities can aid in several clinical scenarios, for instance in determining the need for post dilation to assure correct stent apposition, it can help you assess the neocarina in bifurcation stenting, determine whether there is adequate coverage following overlapping stenting, and allow for prediction of the mandatory extent of vessel preparation of calcified lesions. Oh et al. investigated the clinical outcomes of Stentboost guided PCI and showed that the use of Stentboost can help with lower rates of late loss and binary restenosis compared with the no-StentBoost group at 6 months follow up. At 12 months, StentBoost group had significantly lower incidence of target lesion revascularization.¹⁶



Proven outcomes. Superior value. 1,2,3

iFR modality



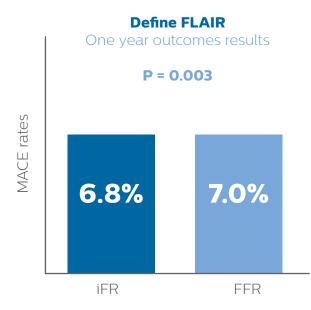
prospective randomized controlled trails

Published in
The New England
Journal of
Medicine



Reduced costs per patient

Cost effectiveness analysis of DEFINE FLAIR demonstrates a per patient annual cost reduction of \$896 for the US system when using iFR compared to FFR.³



An iFR-guided strategy is statistically comparable to an FFR-guided strategy for patient outcomes*

*p-values are for noninferiority of an iFR-guided strategy versus an FFR-guided strategy with respect to 1-year MACE rates; pre-specified non-inferiority margins were 3.4% and 3.2% in DEFINE FLAIR an iFR Swedeheart, respectively.



Improved care

DEFINE FLAIR demonstrates that you can achieve a 90% reduction in patient discomfort during procedures without hyperemia.^{1,2}



Workflow optimization

DEFINE FLAIR reported an average procedural time of 40.5 minutes in the iFR arm, vs. 45.0 minutes in the FFR arm.¹



Our ClarityIQ X-ray imaging technology provides superb image quality at significantly lower dose across clinical areas, patients, and operators.¹⁷ In routine coronary procedures,¹⁸ ClarityIQ technology may reduce patient radiation dose (as total dose-area product) by 67%¹⁹ for the total procedure without affecting the procedural performance (fluoroscopy time and number of exposure images) as compared to equivalent procedures on an Allura Xper system, as demonstrated in one single-center study.²⁰

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 over patient care and staff safety, with a comprehensive suite of radiation dose management tools, training, and integrated product technologies.

Allura Xper



Left Coronary Artery (RAO30°, CAUD25°)

ClarityIQ

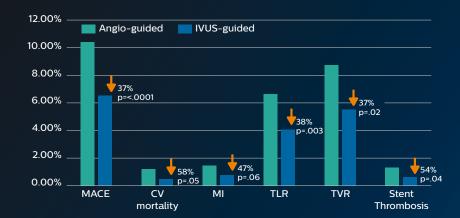


Left Coronary Artery (RAO30°, CAUD25°)

18

Elgendy meta-analysis of 7 Randomized trials²¹

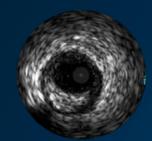
37% reduction in MACE and appearance of lower mortality at a mean of 15 months



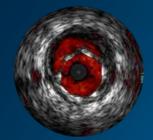








IVUS imaging



Simplicity, confidence, and quality care

Intravascular imaging

Recent randomized trials corroborate what was already suggested by a preponderance of clinical data: IVUS benefits patients. IVUS is associated with changes in treatment strategy, improved outcomes, and cost-effectiveness especially in challenging patient subsets.^{22, 23, 24} Philips makes it easy by offering a choice in technologies and leadership in ease of use to support the needs of your cath lab.

Key benefits:

- **Simple workflow:** Fast plug-and-play simplicity only offered by Philips.
- Advanced insight: Compatible with SyncVision IVUS Co-registration. Allows you to clearly see where the disease lies on the angiogram, and facilitates easy length measurements without the need for a pullback device.
- **Multiple options:** Choice of digital and rotational IVUS technologies, grayscale, and ChromaFlo imaging.

Preparing the vessel with ELCA²⁷ coronary laser and/or AngioSculpt Evo RX PTCA²⁸ scoring balloon catheter

Certain patient and lesion types are at greater risk for poor vessel compliance and inadequate stent expansion. Plaque modification to improve vessel compliance helps enable full stent expansion, which is related to a reduction in future restenosis and thrombosis.²⁵



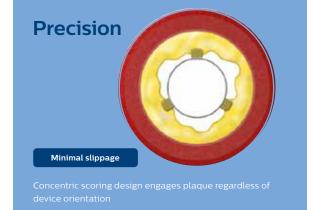
AngioSculpt Evo RX PTCA scoring balloon

The most deliverable specialty balloon.²⁹ Provides the precision and power required to deliver more luminal gain with minimal risk to safely dilate resistant lesions.³⁰⁻³²



ELCA coronary laser

ELCA laser atherectomy can safely cross, prepare and treat a wide range of complex lesion types, modifying plaque to provide easier stent delivery, more predictable stent expansion and better stent apposition, while decreasing the risk of vessel dissection.³⁶







IVUS imaging with ChromaFlo

20

Lab performance and dose management



Procedure cards. checklists, protocols





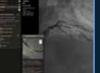
Flexible Zero dose workspots positioning



ClarityIQ

Dedicated coronary applications





2D-QA

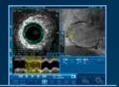


iFR Co-registration6



Dynamic Coronary Roadmap





IVUS Co-registration⁶

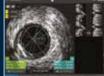
Therapeutic and diagnostic technologies



Verrata Plus FFR/iFR Pressure quidewire



iFR Spot and iFR Scout



IVUS Grayscale



AngioSculpt Evo ELCA RX PTCA scoring Coronary laser



Refinity ST Rotational IVUS



Eagle Eye Platinum Digital IVUS



IVUS ChromaFlo





IntelliSpace <u>Ca</u>rdiovascular



Ultrasound CX50





with IntelliVue X3



Xper IM



DoseAware and DoseWise Portal

Increase value

throughout your Coronary Suite lifecycle

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110 010 1010 1010	State-of-the-art security	⊘	②		
	Latest available Operation System	⊘	②		
⊑ ∳	Computer HW refresh to support software upgrade	⊘	⊘		
	Application training for new or enhanced functionality (days)	0	2	2	
PHILIPS	New version of existing iApps	⊘	⊘		
PHILIPS	Future iApps in one clinical suite (Coronary, EP, SHD, Vascular, Neuro, Onco, Spine or Lung)		②		
PHILIPS 'S	Future iApps in one clinical domain (Cardiac or Vascular)				