

The Philips logo, consisting of the word "PHILIPS" in a bold, blue, sans-serif font, is positioned within a white rectangular area that has a curved bottom right corner. This white area is set against a dark blue background that also features a curved bottom right corner.

PHILIPS

Interventional X-ray

Making the difference with Live Image Guidance

Allura**Clarity** – Clinically proven

Key benefits

Dramatically reduces X-ray dose, resulting in reduced risk of complications from radiation exposure for patients^{a,b}

Decreases scatter radiation, thereby reducing long-term health risk for physicians and staff^{f,a,b}

Dramatically reduces X-ray dose, thereby enabling longer procedures to treat obese and high-risk patients^{a,b}



Every day we see how much of a difference we are making to the quality of people's lives. And the spontaneous reactions just keep flowing back to us. Today the interventional community is showing us that the AlluraClarity family of X-ray systems with ClarityIQ has fulfilled its ambition and promise.

Every day the body of evidence grows. For a product like this, 18 peer-reviewed studies with 3840 patients is a first. The conclusion is clear.

Significantly lower dose —
across clinical areas, patients and operators^a

Significantly lower dose – across clinical areas, patients and operators^a

Clinically proven

- In diagnostic neuro procedures, ClarityIQ technology **reduces patient dose by 62%**, compared to an Allura Xper system^{2 c,d}
- In interventional neuro procedures, ClarityIQ technology **reduces patient dose by 65%**, compared to an Allura Xper system^{2 c,d}
- In diagnostic coronary angiography, ClarityIQ technology **reduces patient dose by 75%** while maintaining diagnostic image quality, compared to an Allura Xper system^{4 c,e}
- In iliac DSA, ClarityIQ technology **reduces patient dose by 83%** while maintaining equivalent image quality, compared to an Allura Xper system^{10 c,g}

Now with the AlluraClarity, you can decide with confidence, at dramatically lower X-ray dose levels, without changing your way of working.

Together we are creating life-changing opportunities for millions of people around the world.



But don't take our word for it.
Download the peer-reviewed papers at www.philips.com/clinicallyproven



Lower barriers for minimally invasive interventions

As you know, it's become more challenging than ever to objectively evaluate X-ray dose and image quality in the interventional world. There are dozens of ways to measure and influence X-ray dose and few benchmarks to go by. Image quality is another intangible. Each clinical area has its own requirements for contrast, noise, movement artifacts, etc. And each clinical user has their own subjective way of judging image quality.

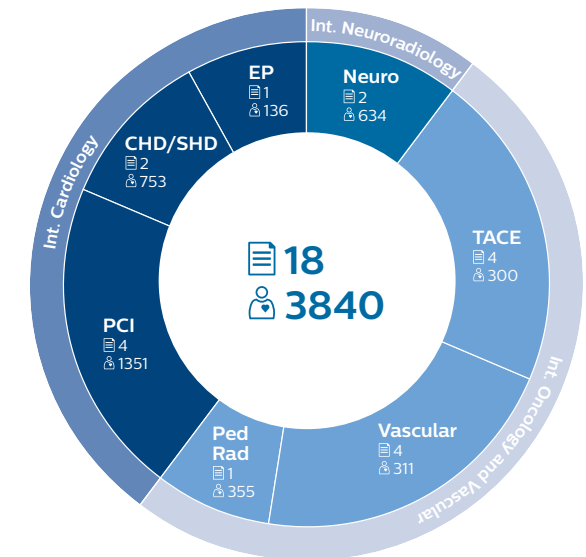
To evaluate these challenging questions, we took the same route that the scientific community takes when it is confronted with a complex issue. We initiated and encouraged clinical studies on the AlluraClarity in each clinical area, and a number of other investigators initiated their own independent studies.



The clinical wheel shows a snapshot of the 18 peer-reviewed papers performed on 3840 patients to date across all clinical areas in hospitals around the world. They confirm significantly lower dose – across clinical areas, patients and operators. With the superb image quality you expect from Philips. These results open the way for fewer patient complications and reduced long-term health risks for caregivers from radiation exposure with the AlluraClarity.

“AlluraClarity goes to the very heart of what Philips is in fact. Because Philips historically for the past 50 years and longer, has been known for producing superior image quality and has always been concerned about X-ray dose.”

Dr. B.T. Katzen
Medical Director, MCVI, USA

Distribution of peer-reviewed papers per clinical area



 Number of papers published
 Patients included



Philips, a true pioneer in dose reduction and image quality

With Philips, your healthcare facility benefits from leading edge dose management strategies and techniques for interventional procedures. Our dose reduction solutions specific to Philips Allura interventional X-ray systems are known collectively as DoseWise Allura. It is a unique combination of techniques, programs and practices, that provides clinically relevant image quality during each interventional application, while significantly reducing dose.

For decades, DoseWise Allura has put Philips interventional X-ray systems at the forefront of the technological advances that continue to improve patient care and safety.

Breakthroughs like our SpectraBeam filtration, GridSwitch fluoroscopy and advanced detector technology. AlluraClarity with ClarityIQ technology is another dose innovation that opens new ways to benefit the health and safety of physicians, patients and healthcare staff.

- Dr. M. Söderman, et al.¹ – in neuro DSA, ClarityIQ technology reduces patient dose by 75% while maintaining equivalent image quality, compared to an Allura Xper system^{c,h}
- Dr. M. Söderman, et al.² – in diagnostic and interventional neuro procedures, ClarityIQ technology reduces patient dose by 62% and 65%, respectively, compared to an Allura Xper system^{c,d}

Interventional neuroradiology

Key highlights

To date, two peer-reviewed comparative studies^{1,2} have been performed on a total of 634 patients at the interventional neuroradiology department at Karolinska University Hospital in Stockholm, Sweden. Patients underwent aneurysm repair and anterior-venous malformation treatments, as well as other diagnostic and interventional neuroradiology procedures. These procedures are among the most demanding in the interventional neuroradiology world, requiring images which show very fine anatomical details.

The first study¹ was a single center prospective patient dose comparison between AlluraClarity and Allura Xper DSA runs on 20 patients acquired on a biplane system (double injection). It included a DSA image quality assessment.

The second study² was a single center retrospective, historically controlled cohort study focusing on procedural patient dose comparison between the AlluraClarity (312 patients) and the Allura Xper (302 patients).

“ This dose reduction is at least in my mind, a real quantum leap in reducing the dose and improving thereby the procedure both for the patient and for us. I think it’s really fantastic.”

Dr. T. Andersson

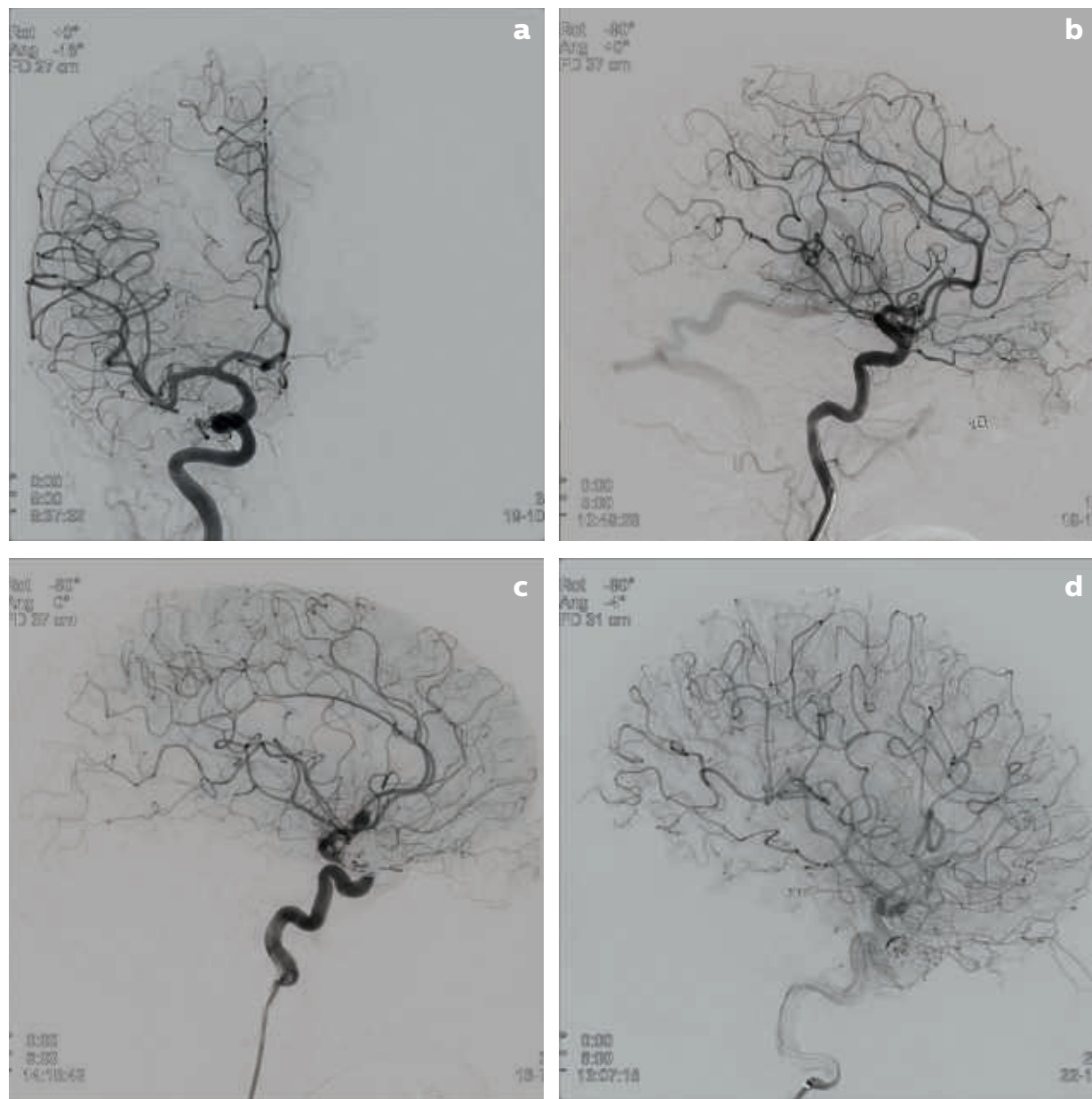
Interventional Neuroradiologist, Karolinska University Hospital, Stockholm, Sweden

“ We had three readers and it turned out that all three readers actually valued the image quality from the reduced dose better than the original images.”

Dr. M. Söderman

Interventional Neuroradiologist, Karolinska University Hospital, Stockholm, Sweden

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Images produced by AlluraClarity system: a. Check after placing coils in anterior communicating artery in a rather small aneurysm. b. image during diagnostic cerebral procedure. c. Diagnostic angio before treatment of patient with multiple cerebral aneurysms shows that anterior communicating artery aneurysm is growing. d. Check after placing coils in rather large aneurysm in the internal carotid artery. Images courtesy of Dr. M. Soderman, Karolinska University Hospital, Stockholm, Sweden and Dr. T.H. Lo, Utrecht University Hospital, Utrecht, The Netherlands.

- Dr. Y. Taeymans, et al.⁴ – in diagnostic coronary angiography, ClarityIQ technology reduces patient dose by 75% while maintaining diagnostic image quality, compared to an Allura Xper system^{c,e}
- Dr. T. Ten Cate, et al.⁵ – in cardiac cine, clarityIQ technology reduces patient dose by 53% while maintaining equivalent image quality, compared to an Allura Xper system^{c,f}
- Dr. L.R. Dekker, et al.¹³ – in EP procedures, ClarityIQ technology reduced patient dose by 43%, compared to an Allura Xper system^{c,i}
- Dr. S. Nakamura, et al.⁶ – reports significant patient dose reduction for PCI procedures^c

Interventional cardiology

Key highlights

To date, seven peer-reviewed comparative studies have been performed for cardiac interventions on a total of 2140 patients in various hospitals around the world. The majority were percutaneous coronary interventions. One study each has been performed for pediatric and adult congenital heart disease interventions,⁷ transcatheter aortic valve implantations (TAVIs)⁸ and electrophysiology interventions.¹³

The study by Dr. T. Ten Cate, et al.⁵ was performed on a beta version of the AlluraClarity system that only had a 50% dose reduction setting, which accounts for the 53% dose reduction achieved during the study.

The study by Dr. Y. Taeymans, et al.⁴ was performed on a commercially released version of the AlluraClarity system which had a 75% dose reduction setting, in addition to the 50% dose reduction setting. This explains the different findings by the two studies. This extra dose reduction setting is now part of the AlluraClarity product.

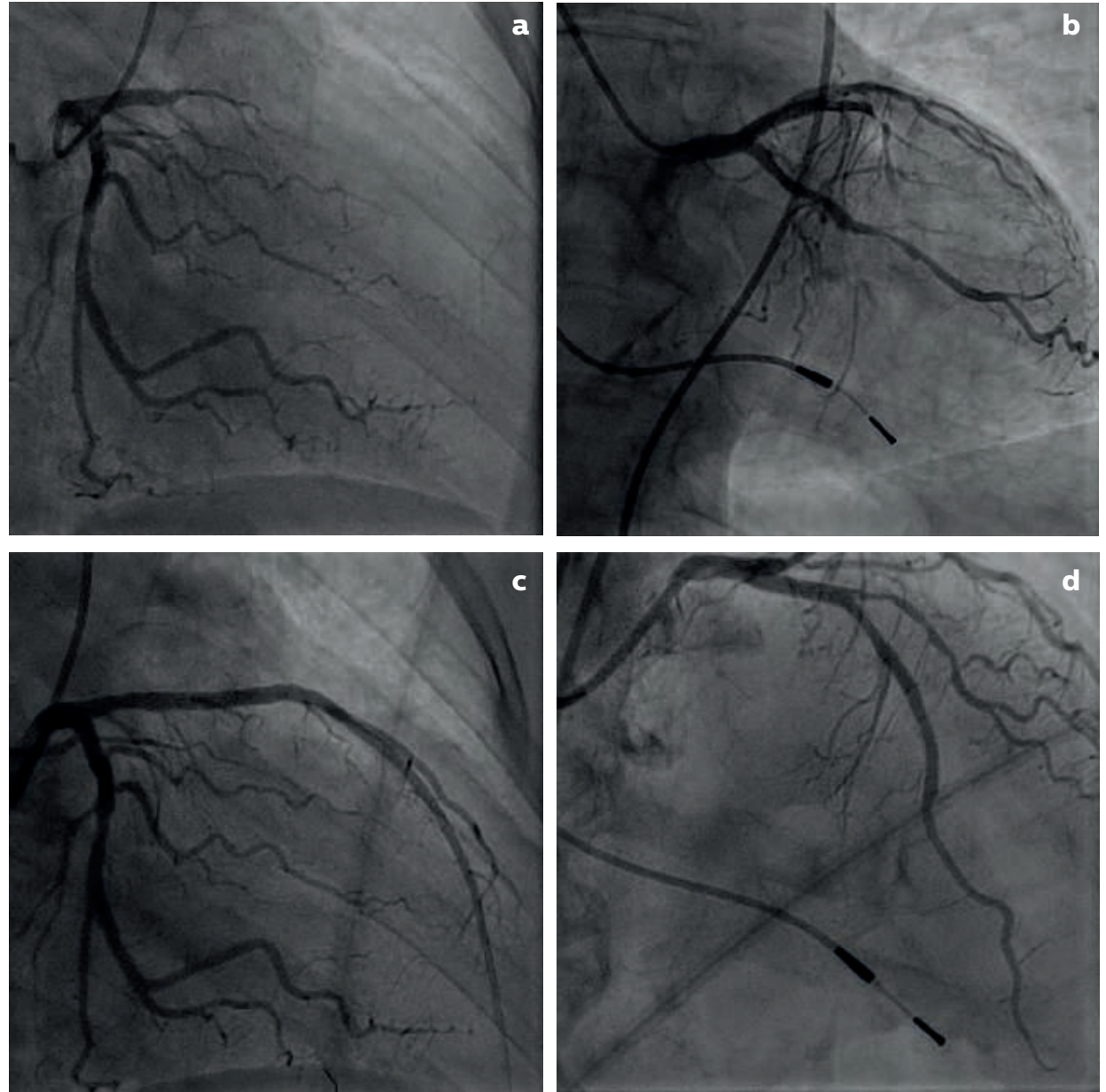
In addition, radiation dose management is very important in patients with congenital heart diseases because they undergo several catheterization procedures during their lifetime. In a large retrospective cohort study⁷ of 667 consecutive patients, substantial dose reduction in the AlluraClarity group (329 patients) was achieved among three groups of patients (below 10 kg, between 10–40 kg and above 40 kg) compared to Allura Xper (338 patients), despite no other relevant changes in fluoroscopy time and contrast medium for both diagnostic and interventional procedures.

“ I think now this is the gold standard for interventional cardiology, for structural interventions – for sure. I have no doubt about that.”

Dr. Bruno Garcia

Interventional Cardiologist, Hospital Vall d'Hebron,
Barcelona, Spain.

**Download the interventional
cardiology peer-reviewed
papers at [www.philips.com/
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Images produced by AlluraClarity system: a. Angioplasty and stenting of a long segmental stenosis. 95% LAD stenosis post 1st diagonal. Pre stent deployment. b. Angioplasty and stenting to LAD stenosis 99% and CX stenosis 80%. c. Angioplasty and stenting of a long segmental stenosis. 95% LAD stenosis post 1st diagonal. Post stent deployment. d. Angioplasty and stenting to LAD stenosis 99% and CX stenosis 80%.

- Dr. M.J.L. van Strijen, et al.¹⁰ – in iliac DSA, ClarityIQ technology reduces patient dose by 83% while maintaining equivalent image quality, compared to an Allura Xper system^{c,g}
- Dr. R.F.F. van den Haak, et al.¹¹ – in aortoiliac endovascular procedures, ClarityIQ technology reduces patient dose by 72%, compared to an Allura Xper system.^{c,j} In EVAR procedures, ClarityIQ technology reduces patient dose by 57% compared to an Allura Xper system^{c,k}
- Dr. R. Li, et al.¹⁶ – in repetitive TACE procedures, ClarityIQ technology reduces patient dose by 50% while maintaining image quality, compared to an Allura Xper system^{c,l}
- Dr. J.F. Geschwind, et al.¹⁵ – The new imaging platform significantly reduced radiation exposure for TACE procedures without increased radiation time or negative impact on DSA image quality.^c

Interventional oncology and vascular

Key highlights

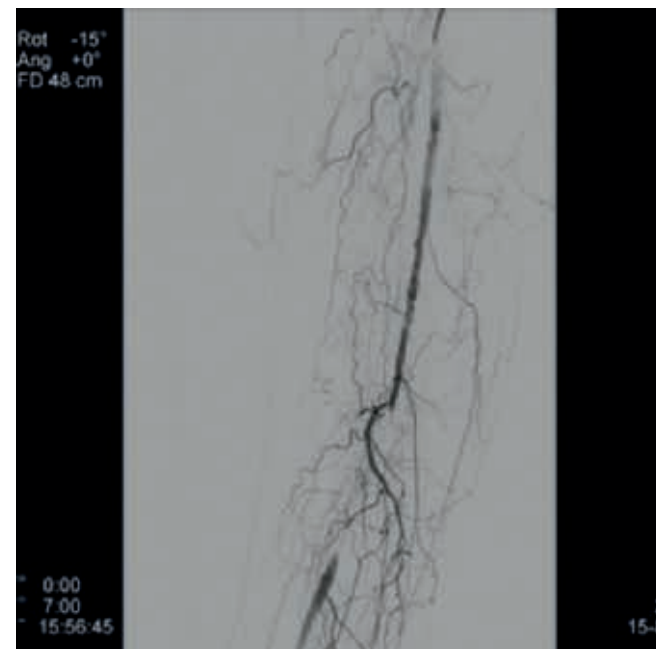
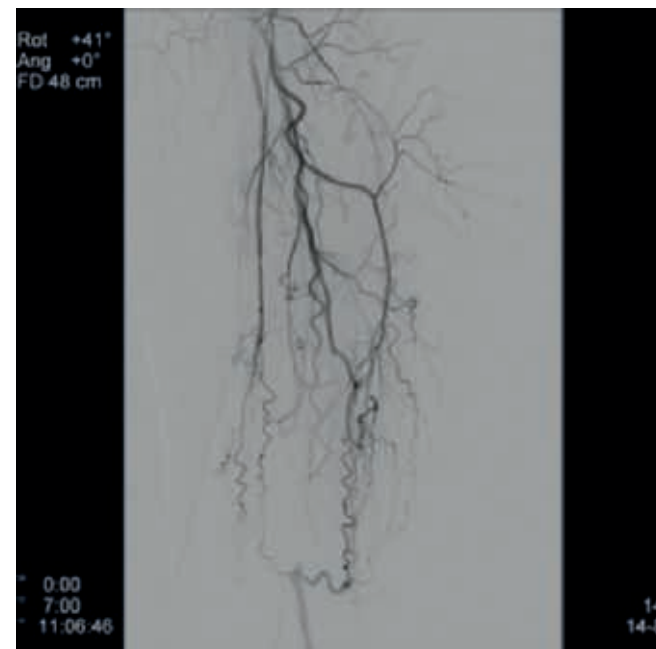
To date, nine peer-reviewed comparative studies have been performed on a total of 966 patients for diverse vascular interventions. These range from adult iliac artery and EVAR procedures to pediatric abdominal procedures. Four peer-reviewed studies have also been conducted for TACE procedures.

The vascular studies were all single center studies that compared the patient dose between the AlluraClarity and the Allura Xper systems. All other studies focused on comparing procedural radiation dose. For example, one study¹¹ was a prospective historically controlled cohort study focusing on iliac and EVAR procedures. For iliac procedures, AlluraClarity reduced patient dose by 72%, compared to an Allura Xper system. For EVAR procedures, AlluraClarity reduced patient dose by 57% compared to Allura Xper. This radiation dose reduction was achieved despite no other changes in terms of fluoroscopy time and contrast medium volume. Another retrospective historically controlled study⁹ showed comparable results for EVAR procedures.

“ The results obtained herein show a substantial reduction in the dose of radiation to patients and staff in the hybrid OR suite after the introduction of the new CIQ technology without having to change the standard way of working”¹¹

“ Another important finding was that the image quality of DSA runs by means of subjective assessment of hepatic vessel visualization was not affected by the significant reduction of radiation exposure.”¹⁵

Download the
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and vascular peer-reviewed
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Images produced by AlluraClarity system.
Top: Diagnostic examination of a patient with a SFA occlusion.
Bottom: Pre-recanalization series of a patient with a SFA occlusion.
Courtesy of St. Antonius Hospital Nieuwegein, The Netherlands.



Increased economic value

As the healthcare landscape evolves, new treatments and procedures have to be balanced with the rising costs of healthcare services to treat aging populations. This requires new levels of efficiency and effectiveness. The purchase of an interventional suite demonstrates a long-term commitment to patients, personnel and your community. Our AlluraClarity solution provides

leading-edge technology, service and support options to help you succeed both clinically and financially.

Stand out with an exceptional treatment environment

Our AlluraClarity system breaks new ground in managing radiation dose exposure for patients and staff. This exceptional treatment environment

can help you attract new referrals and qualified personnel.

Confidently meet new dose requirements

Our AlluraClarity and DoseWise Allura program can help you lower your current X-ray dose levels and track your performance to meet new radiology dose requirements. Find out more at <http://www.philips.com/dosewise>

Open the door to new treatment options

With the low dose capabilities of the AlluraClarity, your interventionalists can perform longer, more complex procedures. They can treat obese and high-risk patients, who might not otherwise be eligible for these procedures, with confidence.

Enhance your investment

To reflect the cost pressures you face, we have taken steps to make our AlluraClarity technology widely available. Philips customers who have an Allura Xper interventional X-ray system can upgrade to the AlluraClarity system via our SmartPath Catalyst program. You gain the most advanced enhancements in workflow, dose management and imaging quality with the equipment you already own. Find out more at <http://www.philips.com/catalyst>

“ We now have the advantage of being able to carry out very complex procedures with very low radiation exposure. Our patients tell us explicitly that this has led to them selecting our hospital.”

Dr. Michael Gross

Chief Cardiology Consultant, Charité
Berlin, Germany

“ We like Catalyst because it saves us time and money. To me there is no difference when compared to a brand new system. The installation was seamless and the service and the product are amazing. It's remarkable that you can re-use an existing system in this way.”

Tom Summitt

Director of Cardiology Services, Methodist
Main San Antonio, December 2014



Greater insight and confidence

Reduce motion artifacts for neuro and vascular cases

By aligning images with each other before subtraction, Real-time Pixel Shift helps reduce motion artifacts that potentially obscure clinically relevant information. The AlluraClarity performs pixel shifting automatically and in real-time using the Automatic Motion Control (AMC) feature. This is particularly important when placing small devices at the base of the skull. Real-time Pixel Shift also eliminates the need for manual post-processing of pixel shift.

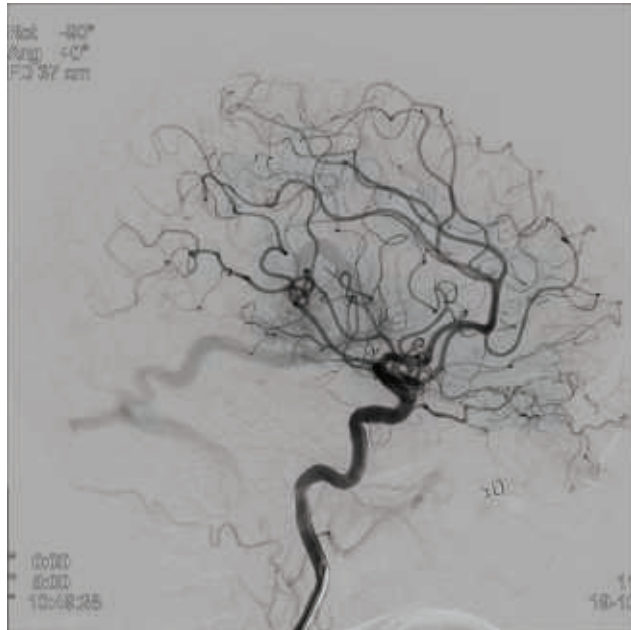


Image during diagnostic cerebral procedure produced by AlluraClarity system. Courtesy of Dr. M. Söderman, Karolinska University Hospital, Stockholm, Sweden.

“ ClarityIQ provides fantastic image quality. You cannot believe, because you have the feeling to see the brain itself without the skull”

Prof. Dr. L. Spelle
Neuroradiologist, Brain Vascular Center Beaujon University Hospital, France

Enhance clinically relevant structures for vascular procedures

ClarityIQ uses advanced spatial filtering to produce exceptional visualizations of clinically relevant structures at dramatically low levels of detector X-ray dose – especially beneficial for endovascular cases. To filter out noise pixel by pixel over larger areas, ClarityIQ uses enhanced processing capabilities. This makes it possible to reduce more noise and visualize clinically relevant structures with greater specificity.

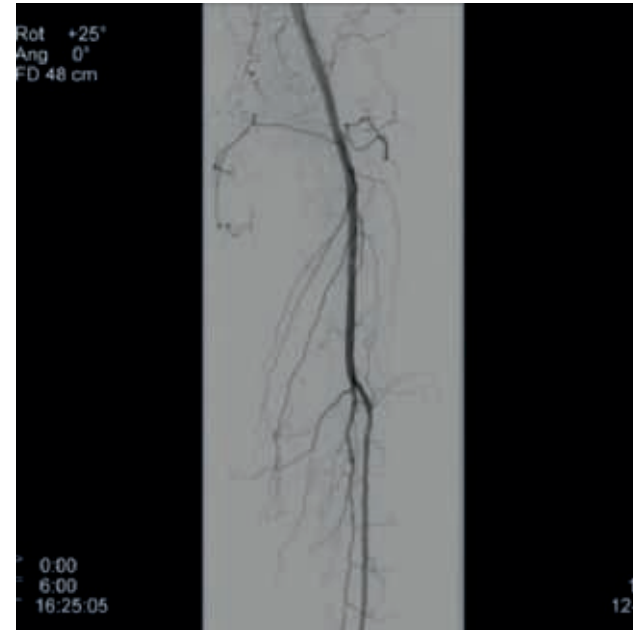


Image produced by AlluraClarity system. Post PTA series of patient with peripheral artery disease. Courtesy of St. Antonius Hospital, Nieuwegein, The Netherlands.

Enhance clinically relevant structures for cardiac procedures

Reducing X-ray dose without losing clinically relevant information is challenging in dynamic cardiac anatomy.

ClarityIQ technology uses a new motion compensation feature to reduce image blur on moving objects in part of an image and thereby enhance the quality of the image. Because of this, far less patient dose can be used to create an image that contains the same clinically relevant information. This feature is useful for fast moving areas of anatomy, such as the heart and GI tract. The look of the AlluraClarity cardiac images can be adjusted during system installation to meet the preferences of physicians.



Images produced by AlluraClarity system. (left) Post angioplasty and stenting of a long segmental stenosis (+90%) in middle third of right coronary artery. (right) Angioplasty and stenting of a total occlusion in proximal third of right coronary artery.

Expand treatment options for high risk and high BMI patients

As interventions become increasingly complex, your challenges multiply. One challenge is the growing number of patients with a high BMI. Visualizing their anatomy can necessitate increased dose levels and lengthen fluoroscopy time. AlluraClarity's low dose imaging gives you more flexibility for managing dose levels and extending fluoroscopy time to image obese and high risk patients.



Take advantage of a new level of clinical flexibility

ClarityIQ combines advanced real-time image noise reduction algorithms with state-of-the-art hardware to reduce patient entrance dose significantly. At the heart of it all is a flexible digital imaging pipeline which has been designed to carry out the individual image processing algorithms in a more efficient way. This unlocks unprecedented dose management capabilities and clinical flexibility for healthcare facilities.

Unlike many conventional systems that carry out image processing in a sequential manner, the AlluraClarity's digital imaging pipeline performs many image processing blocks in parallel. This enables the system to process more images, more quickly. This parallel processing is further accelerated by a staging mechanism. Each stage begins processing as soon as data are available, allowing more extensive image processing to take place in the same amount of time with no noticeable delay between acquisition and display.

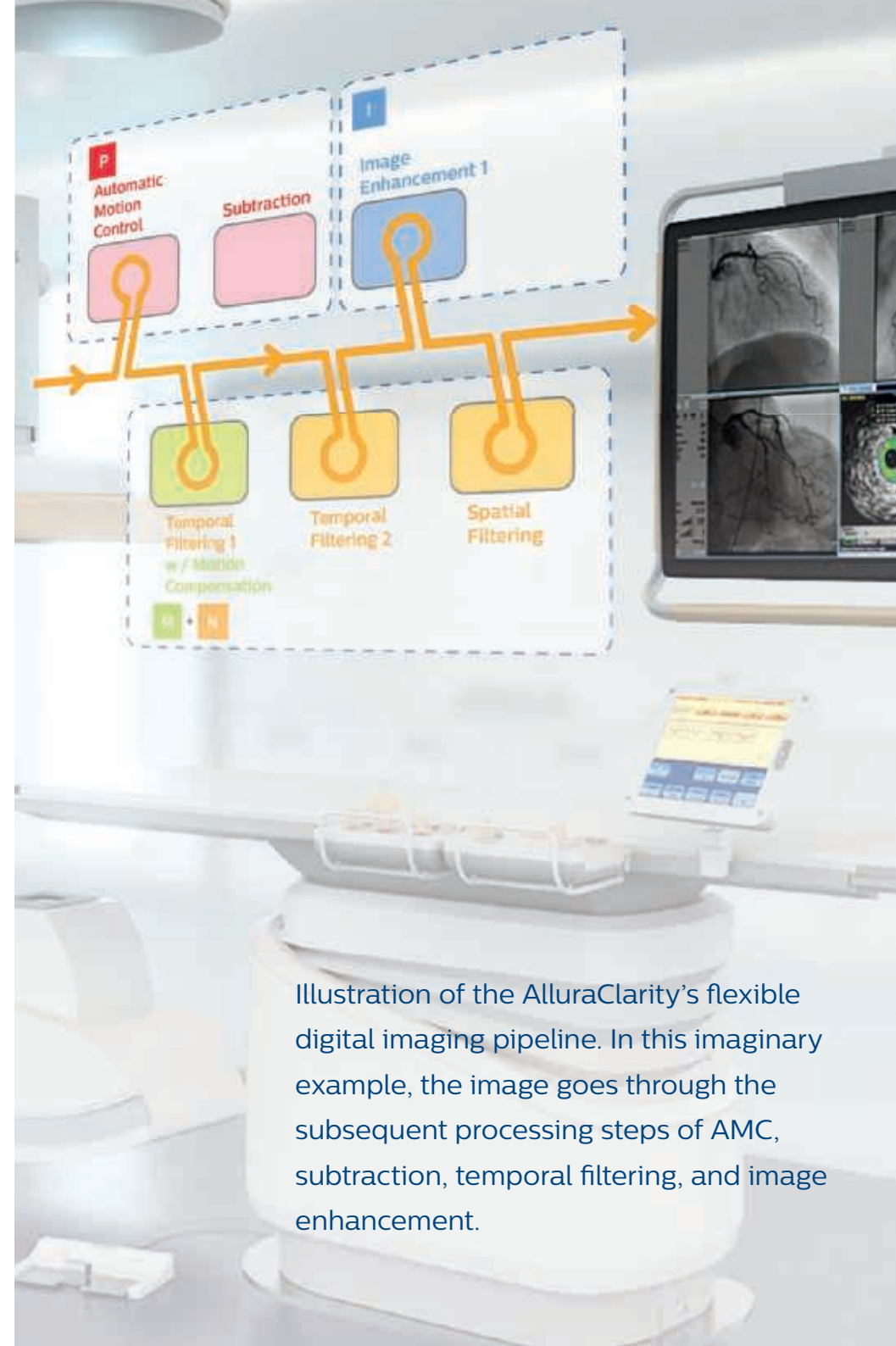
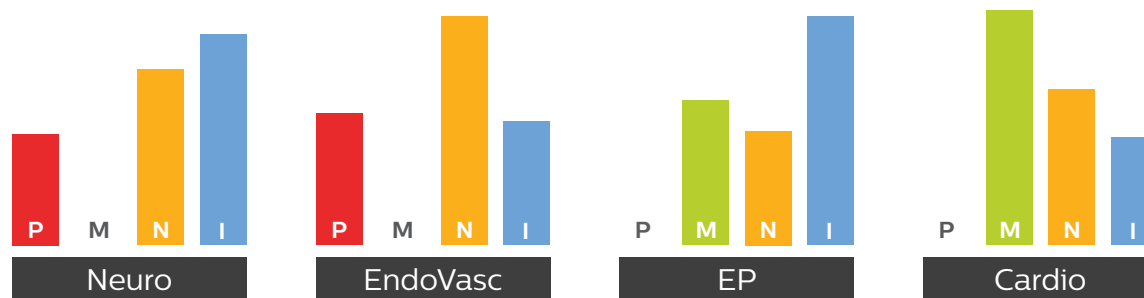


Illustration of the AlluraClarity's flexible digital imaging pipeline. In this imaginary example, the image goes through the subsequent processing steps of AMC, subtraction, temporal filtering, and image enhancement.

Different elements for different clinical applications

For example, the Real-time Pixel Shift feature with Automatic Motion Control is applied for interventional neuroradiology procedures to enhance visualization of tiny vessels, while Motion Compensation is used for cardiology interventions to apply stronger temporal noise reduction to images of the beating heart.



Real-time Pixel Shift

Corrects for patient or accidental table motion, automatically and in real-time to reduce motion artifacts in DSA



Motion compensation

Reduces artifacts on moving parts of an image to enhance image quality



Noise reduction

Reduces image noise adaptively for different clinical tasks, allowing reduction in X-ray dose with equivalent image quality



Image enhancement

Performs a variety of image enhancements to create different flavors for images according to user preferences

For more information
about AlluraClarity
with ClarityIQ
technology

www.philips.com/AlluraClarity

This product received 510(k) clearance from the FDA in 2013 and is available in the US. This document is not intended for marketing purposes in the U.S.

Footnotes

- a In 18 individual comparative studies, Philips ClarityIQ was associated with reductions in patient radiation exposure.¹⁻¹⁸
- b Relationship between radiation exposure and risk of complications, long-term health risk, procedure time and patient characteristics, procedure complexity, as reported in medical guidelines.¹⁹
- c 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 radiologist assisted by a physicist as necessary has to determine the appropriate settings for each specific clinical task.
- d Results based on total dose area product from a single center retrospective, historically controlled cohort study on 614 patients (302 for Allura Xper without ClarityIQ and 312 for Allura Xper with ClarityIQ). Procedural performance (fluoroscopy time and number of DSA images) of the physicians did not significantly differ between the two cohorts.²
- e Results based on total dose area product from a single center, prospectively randomized cohort study on 70 consecutive patients (35 for Allura Xper without ClarityIQ and 35 for Allura Xper with ClarityIQ). Number of cine images and contrast medium did not significantly differ between the two cohorts, while fluoroscopy time was significantly higher for the ClarityIQ group. Image quality was based on subjective assessment of two cine runs selected from each patient in two specific projections. Ratings for image contrast, resolution and general appearance were not statistically different. Image noise was more apparent for ClarityIQ images.⁴
- f Results based on cine dose area product per frame from a single center prospective study on 39 patients. Cine runs for Allura Xper with ClarityIQ and Allura Xper without ClarityIQ were acquired on the same patient under same condition of geometry, field of view and injection protocol. Image quality comparison is based on subjective assessment (side-by-side, score: equal or better than the other, blinded review by 6 independent cardiologists).⁵
- g Results based on DSA dose area product per frame from a single center prospective randomized study on 48 patients. DSA runs for Allura Xper with ClarityIQ and Allura Xper without ClarityIQ were randomly acquired on the same patient under same condition of geometry, field of view and injection protocol. Image quality was based on subjective assessment (side-by-side, equal or superior than the other, blinded review by 5 independent radiologists).¹⁰
- h Results based on DSA dose area product per frame from a single center prospective study on 20 patients. DSA runs for Allura Xper with ClarityIQ and Allura Xper without ClarityIQ were acquired on the frontal and lateral channel on the same patient under same condition of geometry, field of view and injection protocol. Image quality was based on subjective assessment (score 1-5, 1=very poor, 5=excellent, blinded review by 3 radiologists involved in the study).¹
- i Results based on total dose area product from a single center prospectively randomized cohort study on 136 patients (68 for Allura Xper without ClarityIQ and 68 for Allura Xper with ClarityIQ). Procedural performances (fluoroscopy time and number of cine images) of the physicians did not significantly differ between the two cohorts.¹³
- j Results based on total dose area product from a single center prospective historically controlled cohort study on 101 patients (34 for Allura Xper without ClarityIQ and 67 for Allura Xper with ClarityIQ). Procedural performances (fluoroscopy time and contrast medium) of the physicians did not significantly differ between the two cohorts.¹¹
- k Results based on total dose area product from a single center prospective historically controlled cohort study on 37 patients (18 for Allura Xper without ClarityIQ and 19 for Allura Xper with ClarityIQ). Procedural performances (fluoroscopy time and contrast medium) of the physician did not significantly differ between the two cohorts.¹¹
- l Results based on total dose area product from a single center prospectively randomized cohort study on 50 consecutive patients randomly assigned to the Allura Xper system with ClarityIQ or Allura Xper system without ClarityIQ. Fluoroscopy time and number of DSA images did not significantly differ between the two cohorts. Fluoroscopy and DSA images of each case were subjectively assessed in blinded, offline reading (score 0-5) by three experienced interventional radiologists. DSA image quality was equally rated between cohorts, while fluoroscopy images of Allura Xper with ClarityIQ were slightly (significantly) degraded.¹⁶

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