PHILIPS

ClarityIQ

White paper

ClarityIQ technology

X-ray dose is a main concern for physicians working with an image guided therapy system. In image guided therapy, a reduction in X-ray exposure has generally been associated with a decrease in image quality. In the Azurion platform with ClarityIQ technology[a], Philips has achieved a dramatic reduction in X-ray dose, while maintaining an equivalent image quality.

Executive summary

ClarityIQ technology is clinically proven to deliver significantly lower dose - based on 28 peer-reviewed clinical studies with over 15,000 patients.[1-29, b-d] X-ray dose reductions between 43% and 83% have been achieved in interventional neuroradiology, interventional cardiology, interventional vascular and interventional oncology studies.[1-29, b-d]

ClarityIQ technology is enabled by Philips state-of-the-art computer technology. It is based on three pillars:

- Powerful image processing technology
- Flexible digital imaging pipeline
- Clinically fine-tuned parameters across the entire imaging chain

Key enhancements for the powerful image processing compared to previous systems are:

- Real-time, fully automatic reduction of motion artifacts for DSA and Roadmap Pro through Automatic Motion Control
- Stronger temporal noise reduction on moving objects like the heart via motion compensation
- Stronger spatial noise reduction via larger neighborhoods and better signal recognition
- More powerful image enhancement capabilities

The flexible digital imaging pipeline allows the Azurion systems to do a lot more processing within the processing power available and time constraints. In order to use ClarityIQ technology to its full potential, over 500 system parameters have been fine-tuned for each application area.

Besides patient X-ray dose reductions, a significant staff dose reduction can also be achieved with ClarityIQ technology[e]

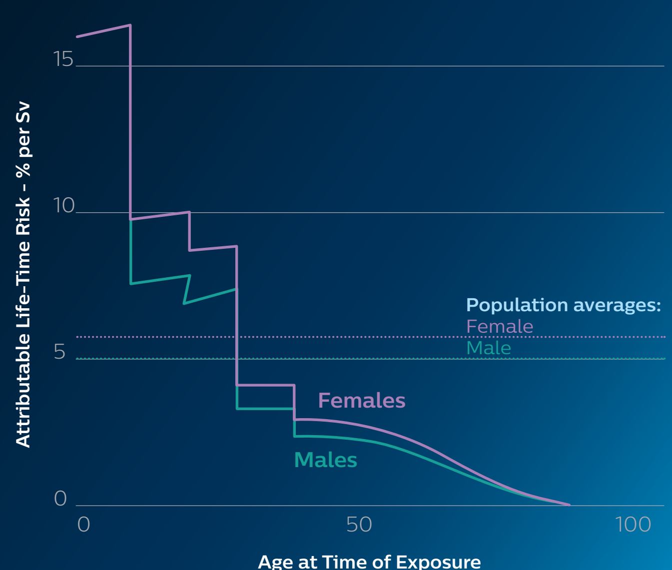
Introduction

Over the last decades, image guided therapy technologies have made a tremendous contribution to the health and well-being of many people around the world. With the continuous improvements in diagnostics and treatment, minimally invasive procedures are on the rise and will continue to increase in the future.

Unfortunately, these imaging modalities use ionizing radiation that has been proven to cause damage to DNA and increase the chance of developing cancer later in life. In fact, pediatric populations have a greater lifetime risk of developing radiation-induced cancers than adult patients[30] (**Figure 1**).

We recognize that performing minimally invasive treatment on seriously overweight patients often adds another significant challenge to those you already face. Image quality tends to degrade with above-average BMIs, particularly when the excess weight is in the abdominal area. This can naturally lead to frustration; you cannot see what you want to in order to proceed with the intervention. One could increase the amount of X-ray dose used. Yet an increase in abdominal diameter of just 3 cm necessitates twice the level of radiation in order to maintain image quality. This can increase risks to patient and staff.

As a result, radiation exposure from medical sources to patients and staff is expected to increase. The main source of patient X-ray is CT, followed by image guided therapy systems.[31] Market research shows that radiation dose is the number one concern[32] for physicians who are using an image guided therapy system.



In image guided therapy, a reduction in X-ray exposure has generally been associated with a decrease in image quality (IQ). Philips, as a market leader in image guided therapy, has a history of providing industry leading image quality and X-ray dose reduction measures. In the Azurion platform with ClarityIQ technology, Philips has achieved a dramatic reduction in X-ray dose, while maintaining an equivalent IQ.

ClarityIQ technology is clinically proven to deliver significantly lower dose - based on 28 peer-reviewed clinical studies with over 15,000 patients.[1-29, b-d] X-ray dose reductions between 43% and 83% have been achieved in interventional neuroradiology, interventional cardiology, interventional vascular and interventional oncology studies.[1-29, b-d]

This document has been prepared to provide more information about Azurion systems with ClarityIQ technology and the differences between ClarityIQ and Xper technologies. It starts with an introduction of how X-ray dose can be lowered while maintaining image quality. The technology is then explained in detail: the three pillars of ClarityIQ and their effect on patient dose.

In this paper, when the general term "patient dose" is used, it means patient entrance dose - the radiation measured in the center of the X-ray beam without backscatter. This is equivalent to the Reference Air Kerma, measured at the Patient Entrance Reference Point (PERP),[33] formerly known as the Interventional Reference Point (IRP). Insight is also provided into the changes that have been made to the acquisition settings of the Azurion systems with ClarityIQ technology that are responsible for the significant dose reduction achieved.

For more information about the Azurion platform or ClarityIQ technology, please contact your local Philips sales representative.

Figure 1: Attributable life time risk due to 1 Sv of radiation versus age at time of exposure. The figure[30] was adapted from International Commission on Radiological Protection (ICRP) Publication 60.[35]

Lowering X-ray dose
while maintaining equivalent IQ

According to the recommendations of the International Commission on Radiological Protection[34] the guiding principle for every exposure of human beings to ionizing radiation should be the ALARA principle: As Low As Reasonably Achievable. However, there is a strict relation between IQ (and information content in the image) and patient dose. The required IQ varies: during catheter introduction a lower IQ may be acceptable, while a higher IQ may be required during stent placement.

For image guided therapy procedures this requires a high level of flexibility from the X-ray system. The X-ray dose depends highly on the anatomy of the patient and the projections used. Also, the wide range of clinical tasks and types of procedures requires a range of flexibility in image quality. As an example, consider two different tasks: localization and characterization.

For **localization**, fluoroscopy images can be used to visualize devices and pathology in relation to other anatomy, such as visualizing a catheter as the user navigates to a target area. Images of a lesser quality can be used for localization, meaning images with high noise and low contrast and sharpness. For **characterization**, cine and DSA images can be used to characterize and thereby diagnose pathology, such as identifying the specific characteristics of small cerebral vessels. This requires high quality images, meaning images with high contrast and sharpness and low noise.

A rule of thumb is that applying a higher patient dose produces better image quality, for the same patient and projection. Conversely, that means applying a lower X-ray dose produces lower quality images. This is depicted in **Figure 2**. This figure shows the relation between X-ray dose and IQ for a given patient and projection. On the horizontal axis, the level of IQ required for the task is given. The vertical axis shows the patient X-ray dose applied by the system. Because there is no widely recognized method to measure the IQ,[36] no units are shown. No units are shown for patient dose as well, since the dose depends highly on the patient anatomy and the chosen projection.

The optimal relation between IQ and dose is represented by the diagonal line shown in **Figure 2**. In reality the shape of this line will depend on the units chosen. To keep things simple, it will be considered as a linear relation. Any point on this line can be created by tuning the system. Points below the line are not possible. If one would operate at a point above the line, this would not adhere to the ALARA principle, since too much X-ray dose would be applied for the required image quality. The principle is the same for other types of examinations, including electrophysiology, cardiology, endovascular, and neuroradiology procedures. One could even consider plotting all procedures in the same figure. This figure would have EP on the bottom left and neuroradiology on the top right.

X-ray systems with Xper technology are engineered to provide the highest possible IQ at the lowest possible X-ray dose for the clinical application and task. With ClarityIQ technology, the Azurion platform takes a big step forward in X-ray dose reduction. It makes it possible to reduce X-ray dose by 43% to 83%[1-29, a-c] compared to systems with Xper technology, while maintaining equivalent image quality. This means that for the same patient, application, and projection, the Azurion system applies significantly less X-ray dose without compromising IQ. See **Figure 3**.

The next section explains how this improvement is achieved.

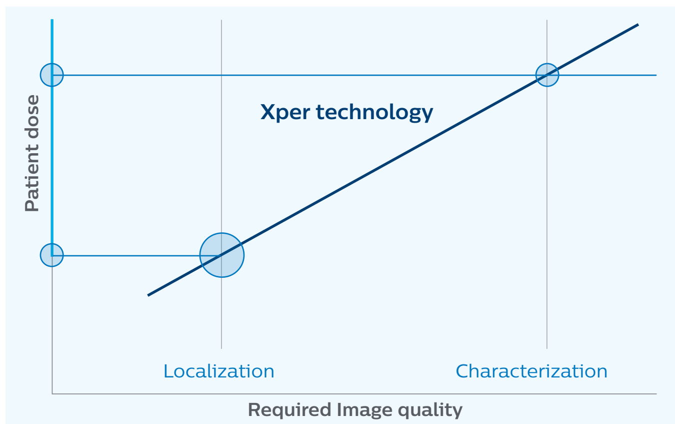


Figure 2: Graph of the relationship between IQ and patient X-ray dose for the Xper technology. The positions for localization and characterization were chosen arbitrarily and will be different for each application. Patient thickness and projections will also affect the graph.

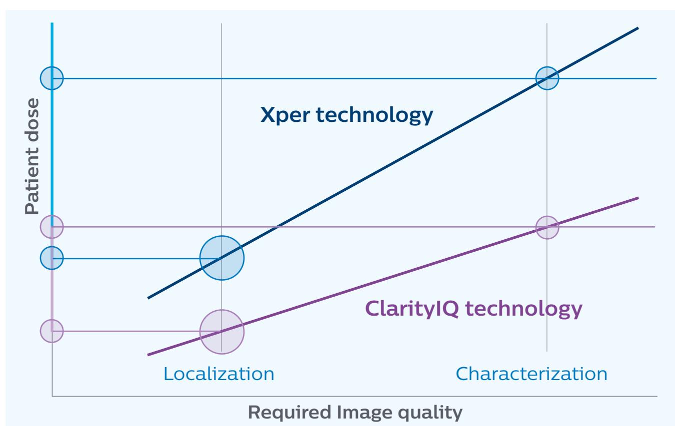


Figure 3: Graph of the relationship between IQ and patient dose for the Xper technology and ClarityIQ technology for a typical clinical application. The purple line for the ClarityIQ technology shows that the patient dose has been significantly reduced to achieve the required IQ. That means, for instance that it is now possible to visualize the morphology of tiny cerebral vessels at 75% less X-ray dose[1].

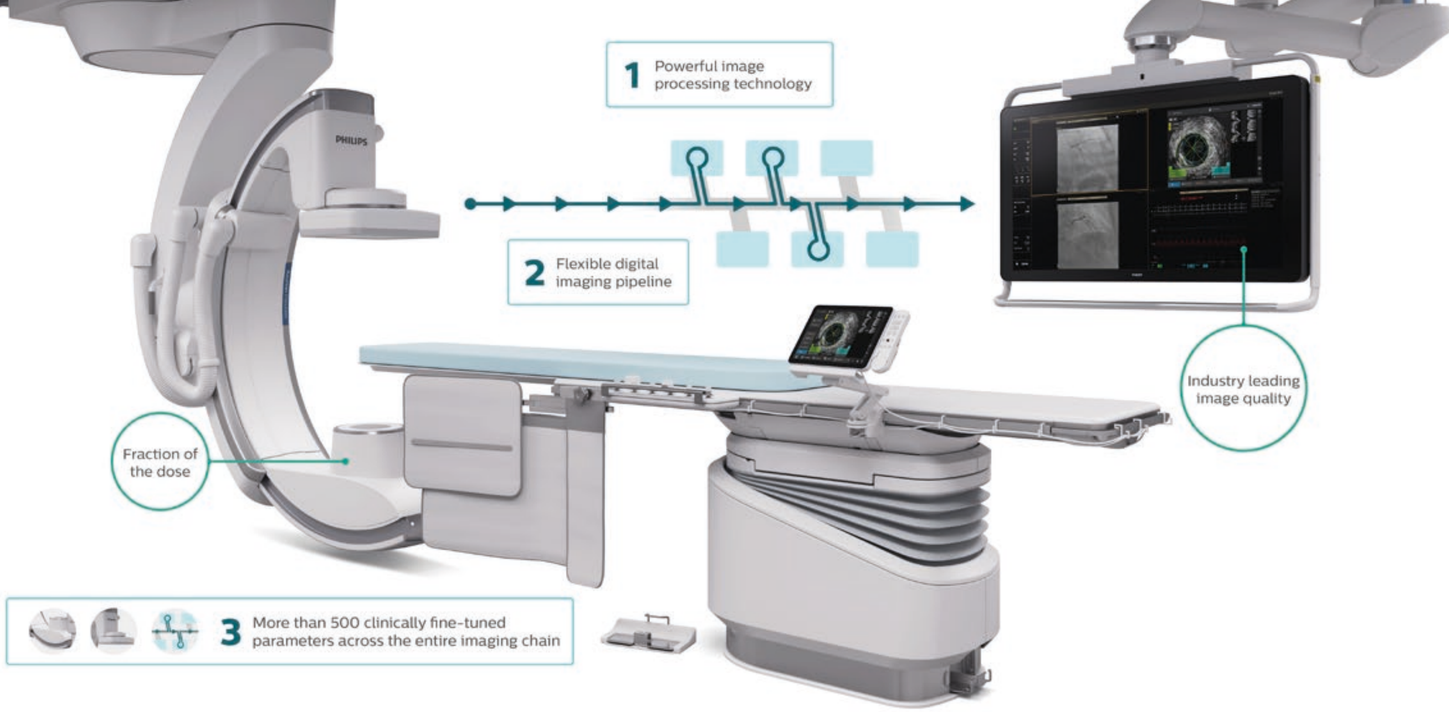


Figure 4: The three pillars of ClarityIQ technology, enabling the patient dose reduction with equivalent image quality.

ClarityIQ technology

ClarityIQ technology is enabled by Philips state-of-the-art computer technology. It is based on three pillars shown in **Figure 4**.

- Powerful image processing technology
- Flexible digital imaging pipeline
- Clinically fine-tuned parameters across the entire imaging chain

ClarityIQ technology touches every part of the Azurion system, from tube to display, to dramatically reduce X-ray dose, while maintaining equivalent IQ. Whereas Xper technology needs a certain amount of patient dose to create an image of sufficient image quality for a given procedure, the ClarityIQ technology needs only a fraction of that patient dose (43% - 83% as clinically proven in interventional neuroradiology, interventional cardiology, interventional vascular and interventional oncology studies.[1-29, b-d]), depending on the application, to create an image with the same image quality. The ClarityIQ image processing technologies have allowed us to make this dramatic step forward in X-ray dose reduction without sacrificing IQ.

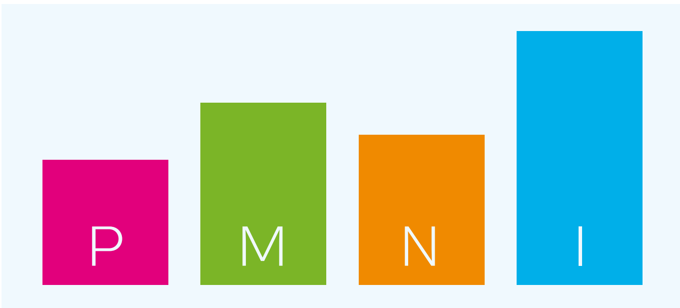


Figure 5: Image processing elements for ClarityIQ technology

Powerful image processing technology

ClarityIQ technology incorporates powerful state-of-the-art image processing technology developed by Philips Research. All image processing works in real-time, enabled by the latest computing technology. It:

- Corrects for patient or accidental table motion, automatically and in real-time on live images
- Reduces noise and artifacts, also on moving structures and objects
- Enhances images and sharpens edges

Image processing, and specifically noise reduction, enhances image quality without increasing patient dose. One can also view this as follows: with image processing, less patient dose is required to create an image that is comparable in image quality to an image created without image processing at higher patient dose levels. This was demonstrated in **Figure 3**.

Image processing has a major effect on image quality. Explaining the individual image processing parameters is beyond the scope of this paper. However, the main image processing blocks used will be discussed.

ClarityIQ uses the following powerful image processing technology:

- Real-time Pixel shift (P) with Automatic Motion Control
- Motion compensation (M)
- Noise reduction (N)
- Image enhancement (I)

See also **Figure 5**.

Real-time Pixel shift (P) with Automatic Motion Control

In Digital Subtraction Angiography (DSA) procedures, subtraction is done to enhance visualization of vessels by removing disturbing background structures like soft tissue or bones from the image. Patient or accidental table movements can create motion artifacts during subtraction, visible as black and white structures. With surfaces that look rough under X-ray, like the inside of the skull with its calcifications, additional noise-like artifacts can occur in the image, even with small movements.

Real-time Pixel shift aligns images with each other before subtraction, so that fewer motion artifacts will appear. It is already used in Philips image guided therapy systems, however, this is usually a post processing function that requires an operator to manually correct the images. The Azurion system with ClarityIQ technology now performs pixel shifting automatically and in real-time using the Automatic Motion Control (AMC) feature.

The AMC feature compares images taken prior to injection (mask image) with images containing contrasted vessels (live image or contrast image). AMC finds the optimal alignment with sub-pixel accuracy before subtraction. AMC is performed on every single image in the run – fully automatically, in real-time – without requiring any user interaction.

This:
- Reduces subtraction artifacts
- Produces a better starting image for additional image processing elements to act upon, which allows, for instance, stronger noise reduction and contrast enhancement
- Saves time for the user by eliminating all manual steps

AMC is also used for the Roadmap Pro functionality.

The Azurion system with ClarityIQ technology provides real-time, fully automatic motion control during DSA. In most conventional systems, the procedure requires the user to manually shift the mask image, which achieves less precise results compared to automatic pixel shifting. Some systems use automatic pixel shift, however it does not perform in real-time and still requires some user interaction, like clicking a release button. Other suppliers do not have automatic pixel shift technology at all.

The alignment with Automatic Motion Control is so sophisticated that stationary objects which are not linked to the movements of the patient (such as shutters, wedges, head rest, markers) will now appear in the image. However, these objects are usually outside the clinically relevant area, see **Figure 6**.

Through better image alignment and fewer motion artifacts, a better starting image is created for other image processing algorithms to act upon, such as noise reduction and image enhancement. This allows stronger noise reduction processing and higher contrast enhancement to be applied as explained in the next sections.

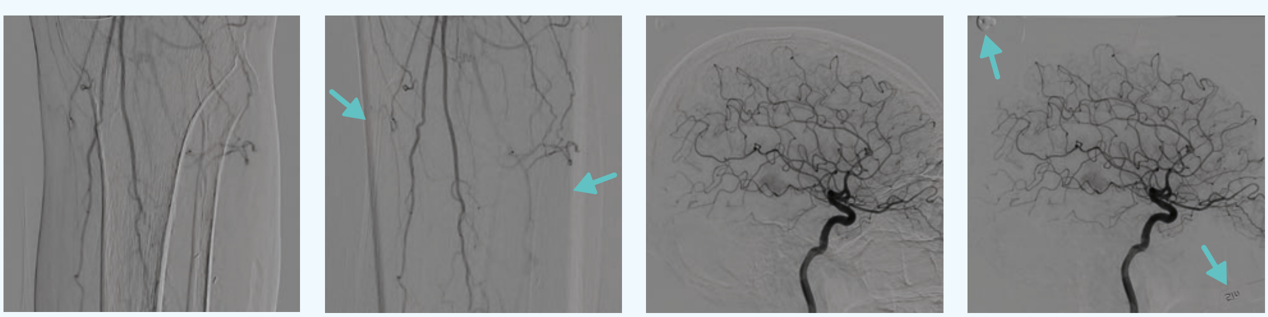


Figure 6a | Figure 6b | Figure 6c | Figure 6d

Figure 6: Two examples of Automatic Motion Control applied to an image of a leg (a, b) and a head (c, d). The figures on the left (a, c) show a real-life example without AMC and the figures on the right (b, d) show the same images, corrected with AMC. Notice the edges of stationary objects that appear, such as the edges of wedges (b) and the “Sin” marker and the screw of the head rest (d).

Noise reduction (N)

Noise is a random phenomenon. Noise reduction first makes a distinction between the random nature of the noise and the more or less constant signal for X-ray absorption of the anatomy and objects, such as catheters or coils. The different characteristics between noise and signal are used to filter out a large part of the noise. This results in an enhanced image quality.

Noise reduction consists of both temporal and spatial noise reduction. Temporal refers to processing that is carried out over time, so over subsequent images, and spatial refers to processing carried out over an area within one image. The sophisticated algorithms distinguish between signal/objects and noise. As noise is random it can be reduced by averaging the pixel intensity over multiple pixels in time or in space. This averaging is called filtering.

The filtering algorithms applied are adaptive, meaning they perform different operations on noise than they do on a vessel or catheter.[37] There are two ways to reduce noise in an image: one is to apply more X-ray dose and the other is to apply better noise reduction algorithms. ClarityIQ technology uses novel noise reduction algorithms to enhance the quality of the image, and because of this far less patient dose can be used to create an image of the same image quality.

Temporal noise reduction

Temporal noise reduction reduces noise by averaging several frames over time: the more frames that are averaged, the higher the noise reduction. The signal-to-noise ratio is increased by approximately the square root of the number of frames averaged (=√n). That is, if 16 frames are averaged (n=16), the signal-to-noise ratio would be increased by a factor of 4 (=√16).

Motion detection is essential when performing temporal noise reduction. Without being able to detect motion, ghost images of moving structures would appear, see **Figure 7**.

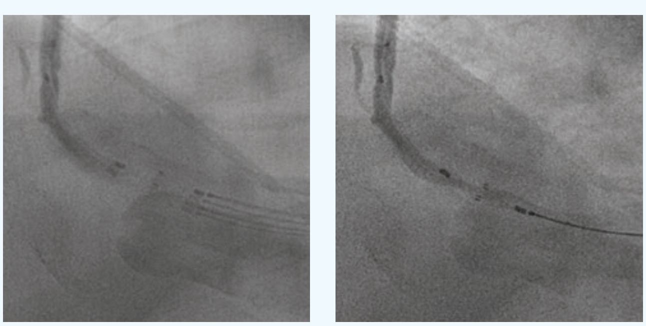


Figure 7a Figure 7b

Figure 7: Example of motion compensation. Figure 7a shows a temporally filtered image of the heart without motion compensation applied. Figure 7b shows the same image filtered with motion compensation applied.

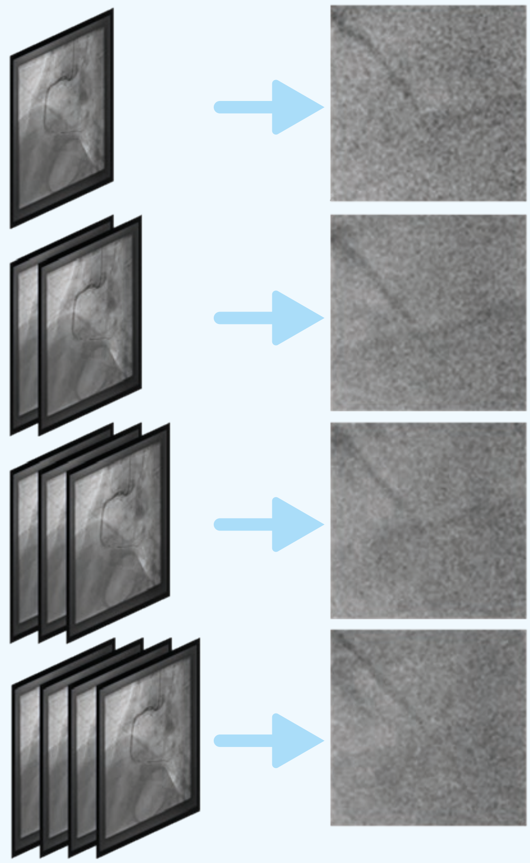


Figure 8: Example of temporal noise reduction. The noise is filtered by averaging over several frames. The signal is aligned (motion compensation) and then averaged. From top to bottom, the effect on the noise of using more images is shown.

Image processing algorithms used in conventional image guided therapy systems prevent ghosting by performing motion detection. When motion is detected the temporal filter is switched off in the area of the image where motion is detected. This prevents ghosting, but at the same time it reduces the number of frames that can be used for temporal noise reduction in the presence of motion. The Azurion platform offers a Motion compensation (M) feature that aligns the moving structures before averaging, so that more frames can be used and stronger temporal filtering can be applied. This results in better noise reduction for stationary and moving structures, see **Figure 8**.

Please note that this Motion compensation feature is different from the Automatic Motion Control (AMC) feature. AMC aligns entire images before subtraction, while motion compensation aligns moving objects in parts of the image before applying temporal noise reduction.

Spatial noise reduction
Spatial noise reduction finds the noise within a single image and filters out the noise pixel by pixel, by averaging it with the pixels surrounding it in its so-called neighborhood. For (potentially) clinical relevant features, the averaging adapts to structures, such as vessels and guidewires to avoid blurring, see **Figure 9**.

When performing spatial noise reduction, it takes a great deal of processing power to average the neighborhood for every single pixel in the image. These processing power requirements increase with the square of the size of the neighborhood. ClarityIQ technology makes use of the latest processing capabilities to support these higher processing power requirements and thereby allows the system to average significantly larger neighborhoods with the new spatial filtering algorithms. Since more surrounding pixels are used for averaging, more noise is reduced. Taking into account a larger neighborhood also makes it possible to identify clinically relevant structures with greater specificity, so that stronger spatial filtering can be applied with less blurring of the signal, see **Figure 10**.

The result of these enhancements in spatial and temporal filtering is a dramatic decrease in the amount of detector X-ray dose required to maintain image quality.

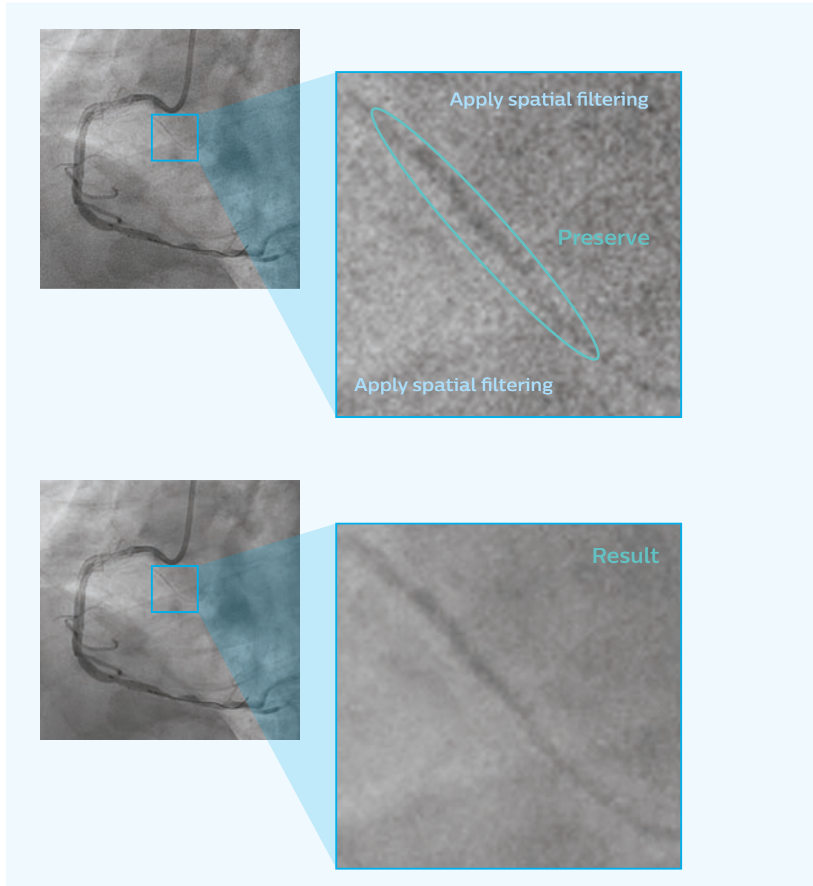


Figure 9: Example of spatial noise reduction. The signal or clinically relevant features and noise are distinguished. The noise is filtered out, while the signal is preserved.

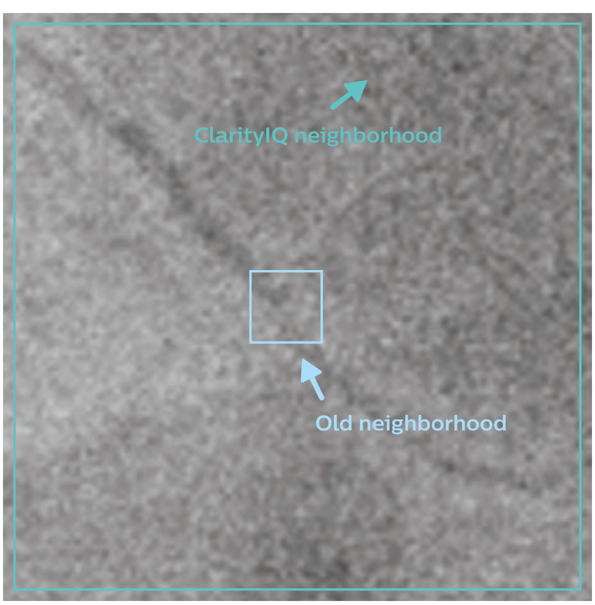


Figure 10: The old neighborhood used for spatial noise reduction (small square) and the new neighborhood (large square) now used with ClarityIQ technology. Averaging over a larger surface or neighborhood will reduce more noise. A larger neighborhood also makes it easier to identify clinically relevant structures, while avoiding signal distortion.

Image enhancement (I)

Image enhancement creates different flavors for images. It performs edge enhancement, contrast enhancement, harmonization (reducing background contrast), brightness control, and other image enhancements. Image enhancement has a limited effect on the objective image quality,[38] as it mainly enhances subjective image quality. It allows images to be adapted to the user's preference and experience. Some users like very sharp images, while others prefer high contrast or low noise images. If one of the attributes is enhanced, the others are automatically reduced.

Image enhancement makes use of so-called spatial frequencies. Low frequencies correspond to shapes that change slowly in space (background, lungs), while high frequencies correspond to fine details and abrupt spatial changes in the image (catheters, but also noise). Like an audio equalizer, each frequency can be independently controlled and enhanced.

An example of image enhancement is shown in **Figure 11**. Note that this is a very simple example that shows only harmonization and edge enhancement. In reality, much more advanced enhancements, such as contrast dependent and intensity dependent processing are performed.

ClarityIQ technology makes use of advanced algorithms to apply more powerful enhancements across all frequencies. This greatly enhances the visualization of small details for applications, such as neuroradiology.

Flexible digital imaging pipeline

To support good hand to eye coordination for the physician manipulating the catheter, it is important to display images with a short delay. This means that the imaging pipeline needs to use the available processing power in an efficient way. The imaging pipeline is a series of special algorithms, which perform specific image processing operations on the data received from the detector to achieve better image quality.

The Azurion system uses a flexible digital imaging pipeline which has been designed to carry out the individual image processing algorithms in a more efficient way. Unlike many conventional systems that carry out image processing in a sequential manner, the digital imaging pipeline of the Azurion system performs many image processing blocks in parallel. This enables the system to process more image data, more quickly.

This parallel processing is further accelerated by a staging mechanism. Each stage in the pipeline begins processing as soon as data are available, so the system does not have to wait for the entire image to be received from the previous stage before starting the next processing step. This results in much more efficient performance compared to conventional systems. More extensive image processing can take place in the same amount of time, with no noticeable delay between acquisition and display.

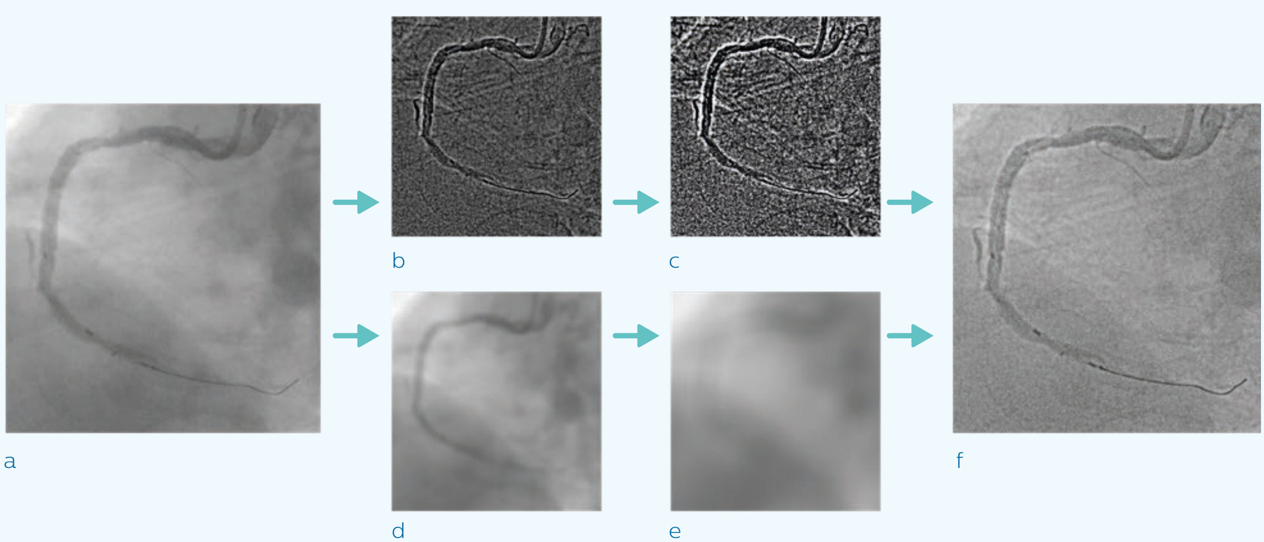


Figure 11: Example of image enhancement. Figure 11a is the original image. This is processed in the spatial frequency domain. For simplicity, only a high frequency image (b) and a low frequency image (d) are displayed here. The high frequency image, containing small details, is enhanced (c), while the low spatial frequency image, containing mainly background, is reduced (e). The final image (f) after its re-transformation to the spatial domain is a sharpened and harmonized version of the original image.

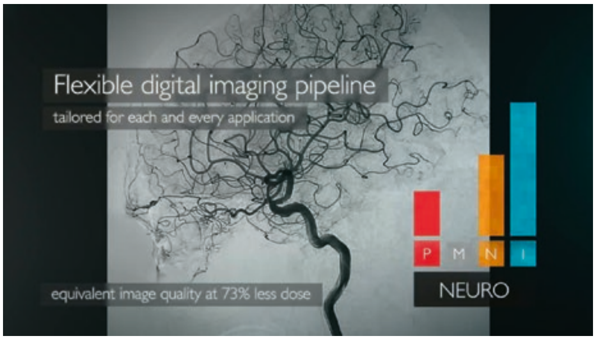


Figure 12a: The real-time pixel shift, noise reduction, and image enhancement modules are used for interventional neuroradiology procedures

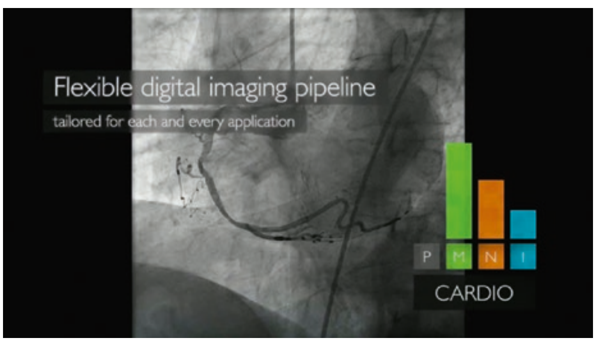


Figure 12b: The motion compensation, noise reduction and image enhancement modules are used for interventional cardiology

Besides reducing time delays, this flexible design also allowed developers to select the optimal combination of processing steps for specific applications. For example, the Real-time Pixel shift module will be applied for interventional neuroradiology procedures to enhance visualization of tiny vessels, while motion compensation will be used for interventional cardiology to apply stronger temporal noise reduction to images of the beating heart. For interventional neuroradiology, motion compensation for temporal filtering is less applicable since less motion and lower frame rates are involved, see **Figure 12a** and **12b**. This sophisticated design allows the Azurion systems to do a lot more processing within the processing power available and time constraints.

Besides optimizing the modules within the imaging pipeline, specific parameters within the P, M, N and I modules are also further optimized for each application area. Depending on the application area, the modules will even apply different algorithms. For example, different temporal noise reduction algorithms are used for different frame speeds. At lower frame speeds, fewer frames are averaged and the algorithms are optimized to deal with that in the best way. This allows the imaging system to optimize performance for the entire range of clinical applications.

An example of the flexibility of the pipeline is shown in **Figure 13**.

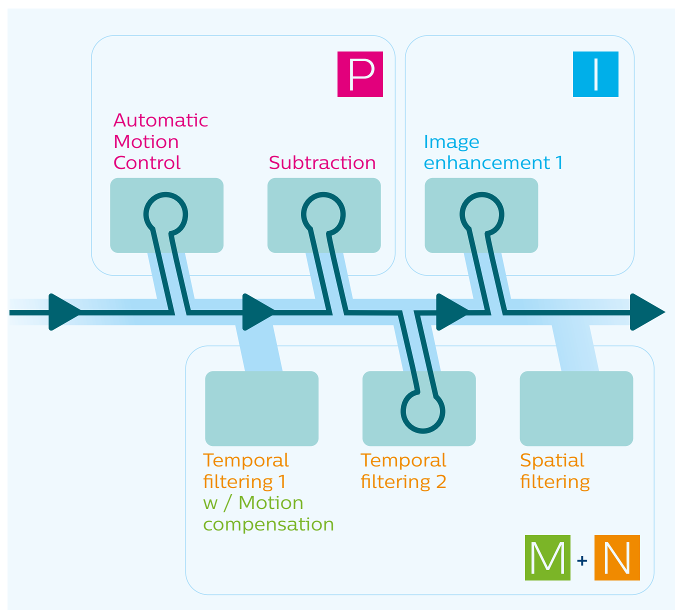


Figure 13: Illustration of the flexible digital imaging pipeline. In this imaginary example, the image goes through the subsequent processing steps of AMC, subtraction, temporal filtering and image enhancement. The letters P, M, N and I refer to the modules mentioned in Figure 5.

Figure 5: Image processing elements for ClarityIQ technology

Clinically fine-tuned parameters across the entire imaging chain

In order to use ClarityIQ technology to its full potential, over 500 system parameters (tube, detector, image processing) have been fine-tuned for each application area.

The EPX database of system parameters

The heart of the Philips Azurion image guided therapy systems is formed by a large database of all system settings. This EPX[39] database (Examination, Patient, and X-ray information) is a structure of data on system level that contains predefined parameter settings for different procedures that can be performed with the system.

The image processing system consists of many sophisticated components that can be changed or programmed and the final image quality depends on the combination of individual programming parameters used. The content of the EPX database has been defined and fine-tuned during system development, to ensure the right image quality at the lowest possible dose for each application. Parameters that control the "flavor" of the images, such as contrast, brightness, and sharpness can be changed by the user on the user interface.

Fine-tuning system parameters in clinical practice

The flexible digital imaging pipeline allows a higher level of clinical flexibility to be achieved with the Azurion system (with ClarityIQ technology). However, the image quality of different applications is very subjective so feedback from clinicians is required to create and validate these settings. The only way to set the parameters in the EPX database is by optimizing the IQ and X-ray dose for every single application and procedure in clinical practice over a period of time. This ensures that the imaging results are relevant for the full spectrum of clinical applications. More information about the X-ray dose-related system parameters is provided in the next section.

During the development of the ClarityIQ technology, the EPX parameters for each clinical procedure were fine-tuned in leading hospitals during normal operation. After thorough preparation in the Philips development department, an initial EPX was installed, including image acquisition and image processing parameters. Several physicians then used this procedure setting in their daily work and provided feedback on the image quality and X-ray patient dose. In an interactive process that sometimes took several months to complete, the parameters were fine-tuned. All possible patient sizes (from small to obese) and a large range of different examinations during that period were included in the settings.

X-ray dose reduction for various clinical applications

This section provides examples of the significant patient X-ray dose reductions achieved with ClarityIQ technology for some of the most frequently used clinical applications. Patient X-ray dose levels will be shown for exposure or fluoroscopy techniques, for various water-equivalent thicknesses of a patient. "Water-equivalent thickness" means the thickness of an object with the same X-ray absorption properties, when it would consist entirely of water. Note that the water-equivalent thicknesses of the patient depends on the projections used: the steeper the angulation, the more tissue needs to be penetrated by the beam, and the higher the water equivalent thickness will be.

This section will also provide some insights into the X-ray dose related parameters that have been adjusted in order to achieve the X-ray dose reductions. It concludes with some comments on how ClarityIQ technology is expected to influence X-ray staff dose.

ClarityIQ technology has been shown to reduce X-ray dose by 75% for neuroradiology.[1] In this section, dose reductions will be expressed in percentages that refer to the current X-ray dose levels of Xper technology. Dose reductions can be achieved for almost the entire range of patient thicknesses and projections.[40]

Figure 14: Position and labeling of the three fluoroscopy flavors on the user interface of the Azurion and Allura Xper systems

Fluoroscopy and exposure in the Allura Xper and Azurion systems

Before explaining the X-ray dose values, it is important to understand how the Allura Xper and Azurion are designed. The Allura Xper and the Azurion systems both have three fluoroscopy flavors on their user interface (buttons are labeled I, II, and III, with I having the lowest dose and III the highest IQ).

The philosophy here is that the user can start by using the lowest dose setting and switch to higher dose levels if better IQ is required. This choice of fluoro settings allows users to apply the lowest possible X-ray dose during procedures, according to the ALARA principles. Fluoroscopy parameters and X-ray dose levels are set according to the selected application (head, abdomen, etc.). The fluoro settings differ per application, so the system actually has far more fluoro flavors than the three buttons on the user interface might suggest.

The Azurion system can have more exposure flavors, with different patient dose rates, to provide flexibility in obtaining the appropriate X-ray dose and image quality. These settings can be enabled by a Philips Field Service Engineer or Application Specialist and by the Azurion User Interface if desired. All exposure settings have been tuned and validated in a clinical setting.

X-ray dose parameters adjusted to lower X-ray dose

So what X-ray dose related parameters have been adjusted in order to achieve the dose reductions possible with the Azurion? In general, X-ray dose reduction can be achieved by modifying the following parameters:

- Amount of copper filtration: mm Cu
- Tube potential in kilo-volts: kV
- Pulse duration in milli-seconds: ms
- Tube current in milli-amperes: mA

When preparing the X-ray patient dose related parameters for the Azurion systems, the parameters of the Allura Xper systems were used as the starting reference.

Copper filtration

Based on the industry-leading MRC X-ray tube, it was possible in the Allura Xper system to use copper filtration for many applications to reduce the low-energy radiation in the beam. With ClarityIQ technology the amount of copper filtration has been increased even further, again making optimal use of the high tube output of the MRC tube.

With ClarityIQ technology, 0.4 mm Cu[41] is used, if sufficient tube power is available. In most cases, at least 0.1 mm Cu is used. Inserting 0.1 mm copper into the radiation beam without modifying the other parameters, like mA, ms, and kV, reduces X-ray dose by about 50%. Increasing copper from 0.1 mm to 0.4 mm reduces X-ray radiation dose by about an additional 50%[44].

After the maximum amount of copper filtration possible was applied, other parameters were changed, like mA and ms, depending on the application. This is explained in more detail in the next sections.

Please note that within a chosen fluoro flavour or procedure, the amount of copper filtration is fixed over the full range of patient thicknesses, for both the Azurion and Allura Xper system, independent of system usage. That means, for example that the copper filter will never be removed, even when imaging very large patients. The focus size will also not be changed, not even when using steep angles or a large source to image distance (SID). Using fixed copper filtration and focal spot size in all situations, ensures a consistent balance between patient X-ray dose and IQ throughout the procedure, without any sudden changes in X-ray dose or IQ when changing projections.

In the next sections, the dose values for specific clinical applications are given based on the largest detector format. If a smaller detector format is chosen, noise will become more apparent in the image, due to magnification. In order to keep the noise impression the same for the various detector formats, Air Kerma (AK) values[42] will increase when smaller detector formats are used.

How Philips filters out soft radiation

The Allura Xper and Azurion systems use strong SpectraBeam copper (Cu) filters in fluoro and exposures to remove unwanted "soft radiation", low energy X-rays that are for a large part absorbed in the patient and therefore do not reach the image detector. In this way, filtering significantly reduces patient X-ray dose and scattered radiation for the staff while maintaining a high image quality.

However, because the SpectraBeam filters are such strong barriers, conventional X-ray tubes cannot sustain the high output and heat load that is necessary to drive enough useful X-rays through the filter. Fortunately, the MRC tubes used in the Allura Xper and Azurion systems were specially designed for such high-powered performance. In MRC tubes, the additional heat conduction via the spiral-groove bearing allows an extremely high average continuous load. This means that, in practice, working speed is not restricted by the limitations of the anode or rotor system, as it is in conventional tubes.

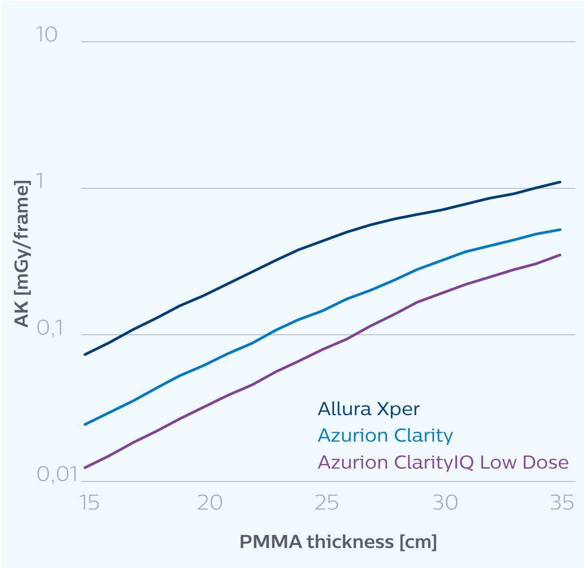


Figure 15: Cardiac exposure patient dose comparison for the Left Coronary 15 fps procedure, measured with an SID of 1 m for the largest detector format, measuring point is the PERP. The values have been measured on two separate FD12 systems (one with ClarityIQ technology and one with Xper technology). Typical equivalent water thicknesses for interventional cardiology are around 25.8 cm with a standard deviation of 4 cm.

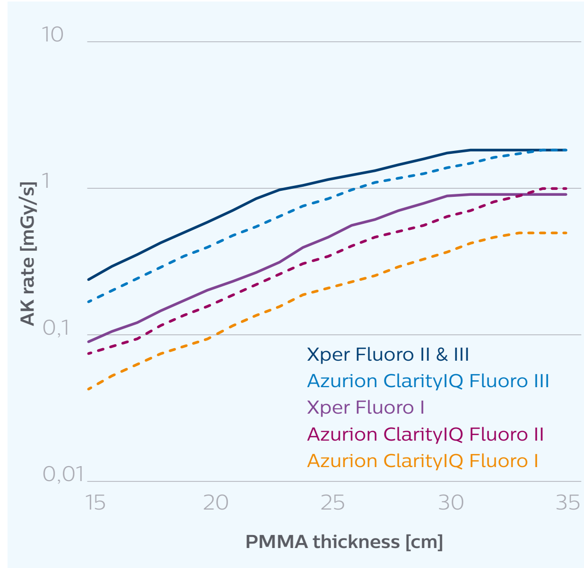


Figure 16: Cardiac fluoro patient dose rate comparison measured with an SID of 1 m for the largest detector format, measuring point is the PERP. Measurements have been performed on two separate FD12 systems (one with ClarityIQ technology and one with Xper technology). The dose rates of Xper Fluoro II and III are equal, the difference is in the frame speed: 15 and 30 fps respectively

Cardiac exposure

In cardiac cine, ClarityIQ technology reduces patient dose by about 53% while maintaining equivalent image quality, compared to a system without ClarityIQ.[5, d]

While the Allura Xper has one exposure flavor, the Azurion can have multiple exposure flavors for some cardiac procedures (e.g. Left & Right Coronary 15 fps). The default flavor is tuned to provide the same image quality as the Allura Xper with an average dose reduction of approximately 50%.[5,44] The Low Dose setting with a dose reduction of approximately 70% compared to the Allura Xper can be used to support ALARA (as low as reasonably achievable) dose levels are required.

Figure 15 shows the patient dose for the different flavors for different patient equivalent thicknesses in centimeters of water[43] for the Allura Xper and Azurion systems for the Left Coronary 15 frames per second (fps) procedure. The dose values in the graph are valid for systems with an FD12 detector.

For cardiac exposure, X-ray dose has been reduced by adding copper filtration. **Table 1** compares the Allura Xper and Azurion settings for X-ray dose reduction and filtration.

Other parameters for the Azurion system like kV, mA, ms, have stayed the same as those of the Allura Xper system. Pulse durations are kept below 10 ms, to keep motion blur (unsharpness due to movements of the heart) as low as possible.

Cardiac fluoroscopy

For cardiac fluoro in the Azurion platform a dose reduction of approximately 50% has been achieved compared to the Allura Xper systems (comparing the same fluoro settings[44]). Again, all dose values in this section are valid for systems with an FD12 detector.

Figure 16 shows the patient entrance dose rate for the different fluoro flavors for different patient thicknesses.

The Azurion fluoro flavor II was tuned to apply approximately the same IQ as the Allura Xper fluoro flavor II. The fluoro flavor III of Azurion corresponds approximately to the Allura Xper fluoro flavor II with respect to dose.

For cardiac fluoro, going from the Allura Xper flavor II and Azurion flavor III to the Azurion flavor II, X-ray dose was reduced by first increasing copper filtration from 0.1 to 0.4 mm. As a second step, going from Azurion flavor II to Azurion flavor I, the pulse duration has been decreased from 4 ms to 2 ms, as shown in **Table 2**. For adult interventional cardiology, reducing pulse durations can help to reduce motion blur, while increasing copper filtration to 0.9 mm brings relatively few benefits compared to 0.4 mm, and tube power may become a limiting factor.

It is standard practice to measure X-ray dose at a 20 cm object thickness, however, actual patient thicknesses are much higher and can easily reach up to 35 cm. It is therefore more relevant to show the dose reduction over a range of thicknesses. **Figure 17** shows what this

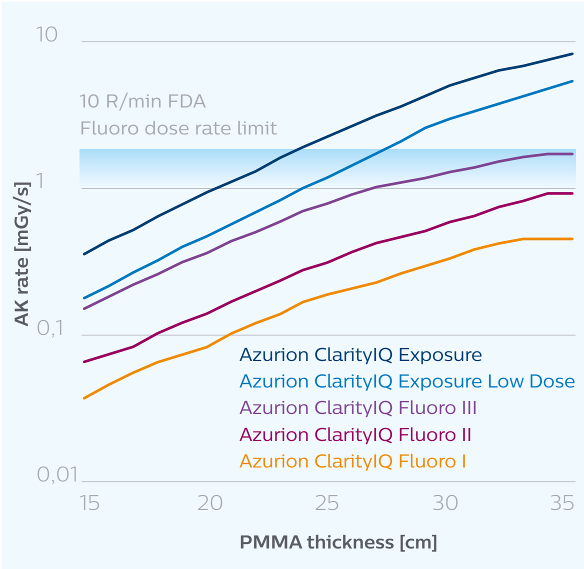


Figure 17: Comparison of patient dose rates for cardiac exposure and cardiac fluoroscopy for the Azurion system with an SID of 1 m for the largest detector format, measuring point is the PERP. Note that patient dose rates for exposure are now close to fluoroscopy

means in clinical practice. It compares patient dose rates for cardiac exposure and cardiac fluoroscopy for the Azurion system. As shown, for the entire range of relevant patient thicknesses, the patient entrance dose rates for exposure have been lowered significantly and they are now very close to the patient entrance dose rates for fluoroscopy. The fluoro and exposure flavors cover a wide range of dose levels, suitable for each and every situation.

For thinner patients, the low exposure flavor could even be called fluoroscopy, and fluoroscopy flavor II might even be sufficient for diagnosis, using the Fluoro Store feature. For very challenging patients and angles, it is only a small step in dose from fluoroscopy flavor III to the Azurion Low Dose exposure flavor.

Table 1: Cardiac X-ray dose exposure parameters for Left Coronary 15 fps.

Parameter	Allura Xper	Azurion	Azurion Exposure Low Dose
X-ray dose reduction[44]	Reference	50%	70%
Copper filtration	None	0.1 mm	0.4 mm Cu

Table 2: Cardiac fluoro EPX parameters. Please note that the order of the buttons in the table is the opposite as the order on the user interface (lowest dose fluoro button I is located on the left hand side on the user interface)

Parameter	Allura Xper Fluoro II	Azurion Fluoro III	Azurion Fluoro II	Azurion Fluoro I
Typical patient dose rates[45,46]	1.2 mGy/s	0.9 mGy/s	0.4 mGy/s	0.2 mGy/s
Copper filtration	0.1 mm Cu	0.1 mm Cu	0.4 mm Cu	0.4 mm Cu
Typical[16] **pulse duration**	4 ms	4 ms	4 ms	2 ms

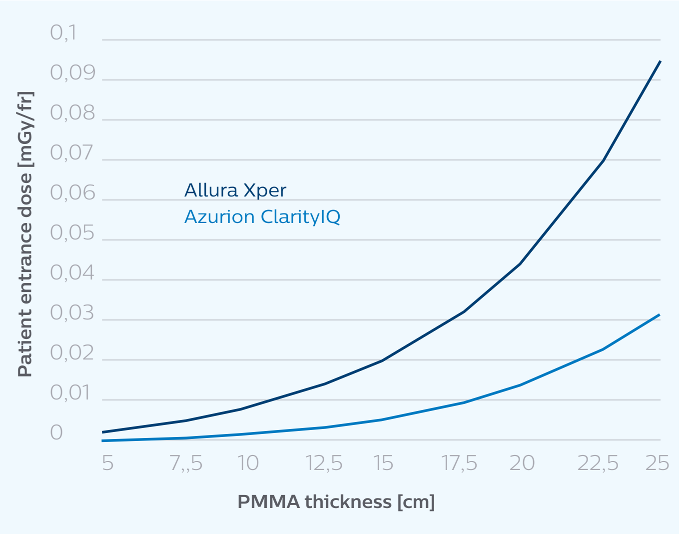


Figure 18: Patient exposure dose rate comparison for the Azurion pediatrics 15 fps low dose procedure (below 40 kg settings) with the Allura Xper pediatrics 15 fps low contrast procedure (5-15 kg settings). The measurements have been performed on systems with an FD20 detector, with detector formats of 27 cm and a fixed SID of 105 cm. The patients are represented by PMMA blocks of variable thickness positioned at a fixed distance from the X-ray source.[43] The dose values have been measured at the entrance point of the PMMA blocks and corrected to obtain values at the patient entrance reference point (according to IEC 60601-2-43).[47]

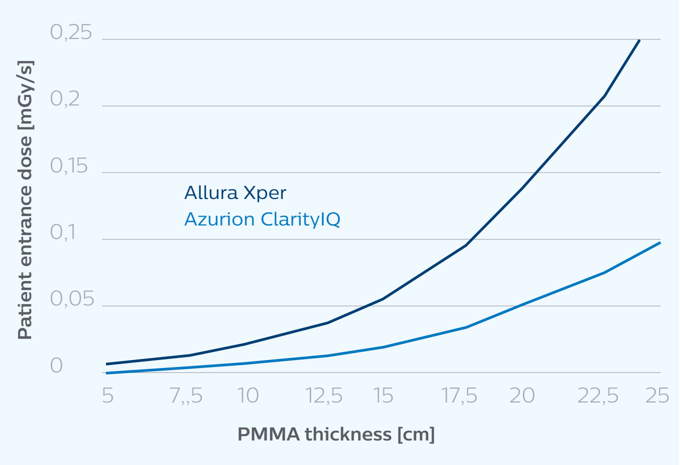


Figure 19: Pediatric patient fluoroscopy dose comparison for the Azurion pediatrics default low fluoro flavor(below 40 kg settings, 15 fps) with the Allura Xper low fluoro flavor (5-10kg settings, 15 fps). The measurements have been performed for systems with an FD20 detector, with detector formats of 25 cm and a fixed SID of 105 cm. The patients are represented by PMMA blocks of variable thickness positioned at a fixed distance from the X-ray source.[43] The dose values have been measured at the entrance point of the PMMA blocks and corrected to obtain values at the patient entrance reference point (according to IEC 60601-2-43).[47]

Pediatric exposure

For pediatric exposure our standard settings for Azurion can allow for much lower dose than those for Allura Xper. Allura Xper systems offer different settings for four different weight groups: below 5 kg, 5-15 kg, 15-70 kg, and above 70 kg. Azurion is designed in such a way that a division into only two different weight groups is sufficient, namely below 40 kg and above 40 kg.

In **Figure 18** the patient entrance dose per frame is shown as a function of the equivalent patient thickness for comparable pediatric exposure programs of the Allura Xper and Azurion systems with ClarityIQ technology. The blue line represents the Allura Xper system with the following settings: 5-15 kg and 15 fps program. The light blue line represents the Azurion system with settings: below 40 kg and 15 fps program. All Azurion pediatric settings below 40 kg use 0.4 mm copper filtration and a small focal spot.

Pediatric fluoroscopy

As with the pediatric exposure settings, the pediatric fluoroscopy standard settings for Azurion allow for much lower dose than those for Allura Xper. For the Azurion systems with ClarityIQ technology the default fluoro flavor is the lowest fluoro flavor I. If higher image quality is required, the user can switch to the higher fluoro flavors II or III. The same two weight groups used for pediatric exposure, below 40 kg and above 40 kg, are used for pediatric fluoroscopy.

Table 3 shows the patient entrance dose rate for the three fluoro flavors of an Azurion system with ClarityIQ technology with an FD12 detector and settings below 40 kg. A patient equivalent thickness of 15 cm (PMMA) is chosen as a representative value, but it is noted that actual pediatric patient thickness may be highly variable. All Azurion pediatric settings with ClarityIQ technology below 40 kg use 0.4 mm copper filtration and a small focal spot; the pulse duration is maximum 3 ms.

In **Figure 19** the patient entrance dose rate is shown as a function of the patient equivalent thickness for comparable pediatric fluoroscopy programs of the Allura Xper and Azurion systems with ClarityIQ technology. The blue line represents the Allura Xper system with the following settings: 5-15 kg, 15 fps, low fluoro flavor. The light blue line is for the Azurion ClarityIQ with settings: below 40 kg, 15 fps, fluoro flavor I (default).

Table 3: Patient entrance dose rate for Azurion fluoroscopy flavors I, II, III with settings below 40 kg, valid for an equivalent patient thickness of 15 cm.

Parameter	Azurion Fluoro I	Azurion Fluoro II	Azurion Fluoro III
Patient entrance dose rate (15 cm equivalent patient thickness)	0.025 mGy/s	0.037 mGy/s	0.051 mGy/s

Table 4: Neuro Cerebral 2fr/s acquisition parameters. Focal spot sizes are given for FD20 systems.

Parameter	Allura Xper	Azurion
X-ray dose reduction[44]	Reference	75%
Focal spot	Large (0.7)	Small (0.4)
Filtration	0.1 mm Cu	0.1 mm Cu
Typical tube potential	80 kV	75 kV

Neuro DSA exposure

For neuro DSA exposure the Neuro Cerebral 2 fps procedure will be described. This is the same procedure that was used during the clinical study at Karolinska University Hospital in Stockholm, Sweden, ClarityIQ technology reduces patient dose by 75% while maintaining equivalent image quality, compared to Xper technology.[1]

For this procedure a different X-ray dose reduction strategy was followed. It focused on reducing the tube current rather than using more copper filtration. This enabled the use of the small focal spot of the tube (which allows approximately half of the tube current of the large focal spot). The main advantage of using a small focal spot is the increased sharpness of the image, which is very important when visualizing tiny cerebral vasculature, see **Figure 20**.

Figure 21 shows the patient entrance dose for different patient thicknesses for the Allura Xper and Azurion systems for the Neuro Cerebral 2 fps procedure. Patient X-ray dose rates are given for systems with an FD20 detector.

With the Azurion procedure the patient entrance dose has been reduced by approximately a factor of 4 while maintaining equivalent IQ.

The main acquisition parameters are given in **Table 4**. Besides smaller tube currents enabling the use of the small focal spot, also the range of patient thicknesses for which the kV is kept constant was increased and the kV was lowered for the Azurion system. This results in more contrast and a constant contrast impression for a wider range of patients.

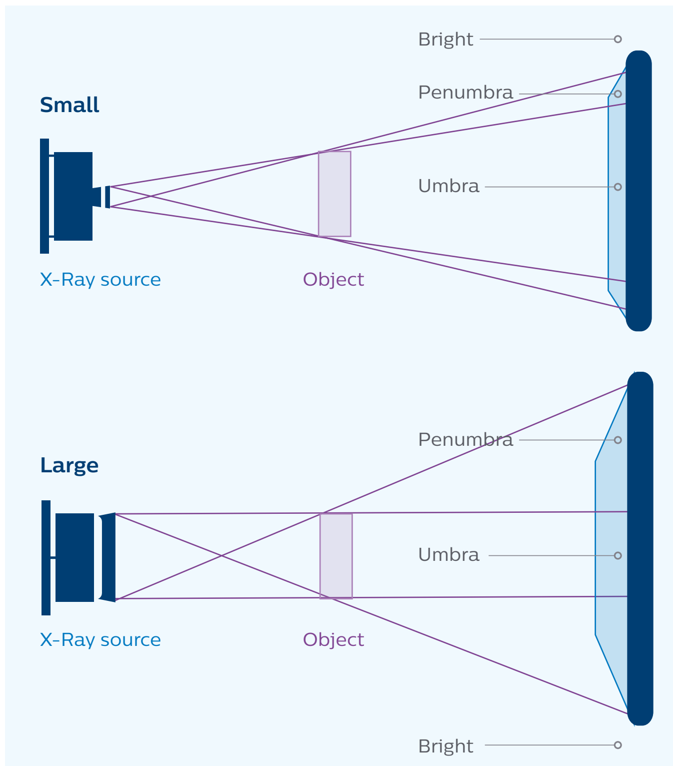


Figure 20: Exaggerated illustration of the effect of a large and small focal spot on the sharpness of a relatively small object in an image.

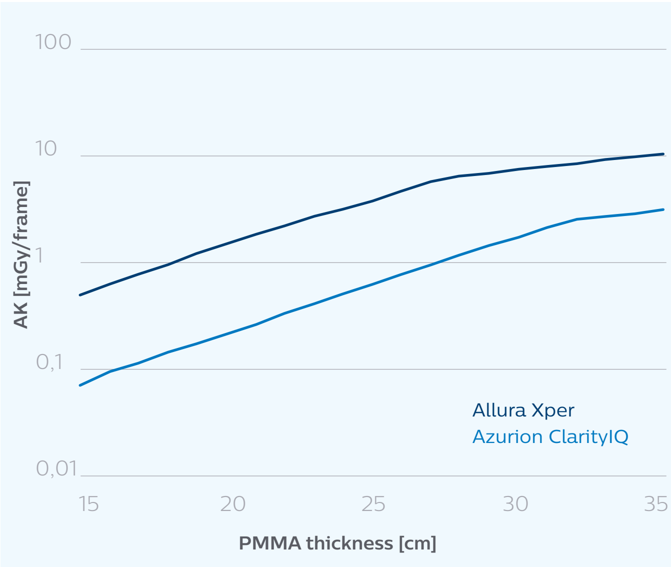


Figure 21: Neuro DSA Cerebral 2 fps patient dose comparison measured with an SID of 1 m for the largest detector format, measuring point is the PERP. Measurements have been performed on two separate FD20 systems (Azurion and Allura Xper). Typical equivalent water thicknesses for interventional neuroradiology are around 23.7 cm with a standard deviation of 1.9 cm.

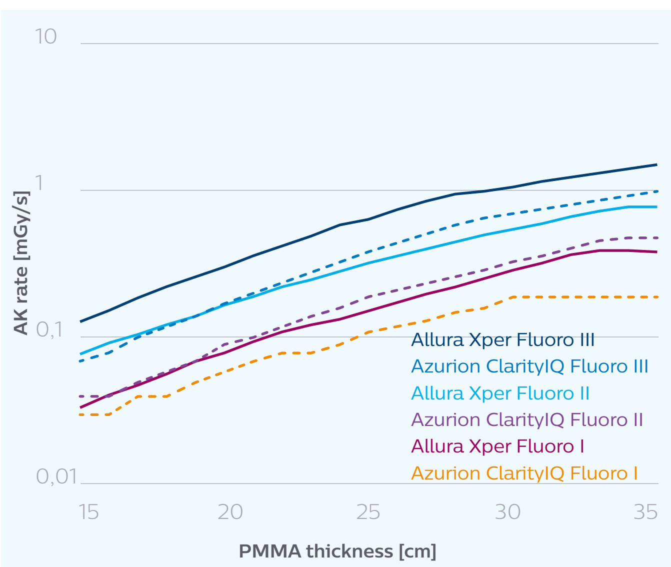


Figure 22: Vascular & Neuro fluoro patient dose rate comparison, measured with an SID of 1 m for the largest detector format, measuring point is the PERP. Measurements have been performed on two separate FD20 systems (Azurion and Allura Xper).

Neuro fluoro

Our experience with the clinical tuning sites has been that the lowest dose flavor I was the setting most frequently used in neuroradiology. Therefore, the target for neuro fluoro has been to reduce X-ray dose by 50% for fluoro flavor I, going from 2.5 R/min for Allura Xper to 1.2 R/min for Azurion.

The maximum dose rate of fluoro flavor II (3R/min) was chosen to provide an adequate IQ enhancement compared to flavor I, and the same for fluoro flavor III (7R/min) compared to fluoro flavor II. Neuro fluoro flavor III was hardly used at the clinical tuning sites. One exception was difficult procedures like gluing with RoadMap Pro.

Figure 22 shows the patient entrance dose rate for the different fluoro flavors for different patient thicknesses. All dose values in this section are valid for systems with an FD20 detector. The data in this section are also valid for the second phase of Roadmapping in interventional neuroradiology.

The effect of ClarityIQ on staff dose

It is known that adding copper filtration has less of an effect on reducing staff dose than on reducing patient dose[48], however, a significant staff dose reduction can also be achieved with ClarityIQ technology.

The main reason for this difference is that dose received by the staff is scatter radiation of the patient. The skin of the patient acts as a kind of additional filter, removing part of the low energy radiation. This is the same effect as copper filtration, and therefore the use of copper filtration has less effect on the staff dose reduction.

When tube currents (mA) or pulse durations (ms) are reduced, the relative portion of soft radiation in the beam (beam quality) does not change and expected staff reductions are equal to patient entrance dose reductions.

Via simulations of X-ray penetration to the various organs in the human body, factors can be found that show the relative effect of copper filtration on staff dose compared to patient dose. Typical factors can be found in **Table 5**.

Table 5: Neuro fluoro EPX parameters. Note that for endovascular fluoroscopy the same patient dose levels and parameter settings are valid.

Parameter	Allura Xper Fluoro III	Azurion ClarityIQ III	Azurion ClarityIQ II	Azurion ClarityIQ I
Typical[49] patient dose rates	0.6 mGy/s	0.3 mGy/s	0.15 mG/s	0.08 mGy/s
Copper filtration	0.1 mm Cu	0.1 mm Cu	0.4 mm Cu	0.4 mm Cu
Typical tube current	160 mA	135 mA	160 mA	60 mA

So the relation between staff dose reduction and patient dose reduction depends on changes in the beam quality, as the following examples will show.

1 For the Azurion system with ClarityIQ technology, the patient dose reduction between cardiac fluoro flavor II and I is 50% by reducing pulse durations, while the beam quality remains the same. This means that the staff dose is also expected to be reduced by 50%.

2 In Cardiac exposure the reduction between Allura Xper and Azurion is 50% by going from no copper to 0.1 mm copper filtration. Compared to patient dose, staff dose with 0.1 mm copper will be a factor of 1.2 higher than without copper filtration, see **Table 6**. Therefore 50% * 1.2 = 60% staff dose remains. A staff dose reduction of 100% - 60% = 40% is expected, instead of 50%.

In these examples it is assumed that all other factors such as use of system (angulation, collimation) and user behavior (use of lead screens, stepping out of the room or standing in the shadow of a colleague) are equal.

So the effect of ClarityIQ technology on staff dose savings is anticipated to be significant, also when X-ray dose has been achieved by introducing more copper filtration.

Table 6: Relation between patient dose and staff dose when copper filtration is used.

Amount of Cu	Staff dose relative to patient dose
-	1.0
0.1 mm	1.2
0.4 mm	1.36

Table of abbreviations

ADRC	Automatic Dose Rate Control
AK	Air Kerma
ALARA	As Low As Reasonably Achievable
AMC	Automatic Motion Control
CT	Computed Tomography
DSA	Digital Subtraction Angiography
EPX	Examination, Patient, and X-ray information
FPS	Frames per second
I	Image enhancement
IQ	Image quality
IRP	Interventional Reference Point
KERMA	Kinetic Energy Released per unit Mass
M	Motion compensation
N	Noise reduction
P	Real-time Pixel shift
PEDR	Patient entrance dose rate
PERP	Patient Entrance Reference Point (previously called IRP)
PMMA	Polymethyl methacrylate
SID	Source to image distance

Definitions

Allura Xper system
Philips image guided therapy system introduced in 2003 and regularly enhanced since then.

Azurion system
Latest generation Philips image guided therapy system, introduced in 2017. The Azurion platform uses ClarityIQ technology, which results in a dramatic radiation dose reduction while maintaining equivalent image quality compared to the Allura Xper system.

Roadmap Pro
A Roadmap is created by superimposing live subtracted fluoro with a vessel mapping image. Roadmap Pro offers a flexible range of features to support all anatomical areas and types of interventions.

Imaging pipeline
Series of special algorithms which perform specific image processing operations on the data received from the detector to achieve high image quality.

References

1. Söderman M, Holmin S, Andersson T, Palmgren C, Babic D, Hoornaert B. . Image noise reduction algorithm for digital subtraction angiography: clinical results. Results based on DSA dose area product per frame from a single center prospective study on 20 patients. Image quality was based on subjective assessment, blinded review by 3 radiologists involved in the study. Radiology. 2013 Nov;269(2):553-60.
2. Söderman M, Mauti M, Boon S, Omar A, Marteinsdóttir M, Andersson T, Holmin S, Hoornaert B. Radiation dose in neuroangiography using image noise reduction technology: a population study based on 614 patients. Neuroradiology. 2013 Nov;55(11):1365-72.
3. Bracken JA, Mauti M, Kim MS, Messenger JC, Carroll JD. A Radiation Dose Reduction Technology to Improve Patient Safety During Cardiac Catheterization Interventions. J Interv Cardiol. 2015 Oct;28(5):493-7.
4. Eloot L, Thierens H, Taeymans Y, Drieghe B, De Pooter J, Van Peteghem S, Buytaert D, Gijs T, Lapere R, Bacher K. Novel X-ray imaging technology enables significant patient dose reduction in interventional cardiology while maintaining diagnostic image quality. Catheter Cardiovasc Interv. 2015 Nov;86(5):E205-12.
5. Ten Cate T, van Wely M, Gehlmann H, Mauti M, Camaro C, Reifart N, Suryapranata H, de Boer MJ. Novel X-ray image noise reduction technology reduces patient radiation dose while maintaining image quality in coronary angiography. Neth Heart J. 2015 Nov;23(11):525-30.
6. Nakamura S, Kobayashi T, Funatsu A, Okada T, Mauti M, Waizumi Y, Yamada S. Patient radiation dose reduction using an X-ray imaging noise reduction technology for cardiac angiography and intervention. Heart Vessels. 2016;31:655-663.
7. Haas NA, Happel CM, Mauti M, Sahyoun C, Tebart LZ, Kececioglu D, Thorsten Laser K. Substantial radiation reduction in pediatric and adult congenital heart disease interventions with a novel X-ray imaging technology. IJC Heart & Vasculature. 2015;6:101–109.
8. Lauterbach M, Hauptmann KE. Reducing Patient Radiation Dose With Image Noise Reduction Technology in Transcatheter Aortic Valve Procedures. Am J Cardiol. 2016 Mar 1;117(5):834-8.
9. De Ruiter QM, Moll FL, Gijsberts CM, van Herwaarden JA. AlluraClarity Radiation Dose-Reduction Technology in the Hybrid Operating Room During Endovascular Aneurysm Repair. J Endovasc Ther. 2016 Feb;23(1):130-8.
10. Van Strijen MJ, Grünhagen T, Mauti M, Zähringer M, Gaines PA, Robinson GJ, Railton NJ, van Overhagen H, Habraken J, van Leersum M. Evaluation of a noise reduction imaging technology in iliac digital subtraction angiography: noninferior clinical image quality with lower patient and scatter dose. J Vasc Interv Radiol. 2015 May;26(5):642-50.e1.
11. Van den Haak RF, Hamans BC, Zuurmond K, Verhoeven BA, Koning OH. Significant Radiation Dose Reduction in the Hybrid Operating Room Using a Novel X-ray Imaging Technology. Eur J Vasc Endovasc Surg. 2015 Oct;50(4):480-6.
12. Durrani RJ, Fischman AM, van der Bom IM, Kim E, Scott Nowakowski F, Patel RS, Lookstein RA. Radiation dose reduction utilizing noise reduction technology during uterine artery embolization: a pilot study. 2016 May-Jun;40(3):378-81.
13. Dekker LR, van der Voort PH, Simmers TA, Verbeek XA, Bullens RW, Veer MV, Brands PJ, Meijer A. New image processing and noise reduction technology allows reduction of radiation exposure in complex electrophysiologic interventions while maintaining optimal image quality: a randomized clinical trial. Heart Rhythm. 2013 Nov;10(11):1678-82.
14. Kohlbrenner R, Kolli KP, Taylor AG, Kohi MP, Fidelman N, LaBerge JM, Kerlan RK, Agarwal VK, Lehrman ED, Nanavati S, Avrin DE, Gould R. Patient Radiation Dose Reduction during Transarterial Chemoembolization Using a Novel X-Ray Imaging Platform. J Vasc Interv Radiol. 2015 Sep;26(9):1331-8.
15. Schernthaner RE, Duran R, Chapiro J, Wang Z, Geschwind JF, Lin M. A new angiographic imaging platform reduces radiation exposure for patients with liver cancer treated with transarterial chemoembolization. Eur Radiol. 2015 Nov;25(11):3255-62.
16. Wen X, Jiang X, Li R, Zhang J, Yang P, Shen B. Novel X-Ray Imaging Technology Allows Substantial Patient Radiation Reduction without Image Quality Impairment in Repetitive Transarterial Chemoembolization for Hepatocellular Carcinoma. Acad Radiol. 2015 Nov;22(11):1361-7.
17. Dave JK, Eschelman DJ, Wasserman JR, Gonsalves CF, Gingold EL. A Phantom Study and a Retrospective Clinical Analysis to Investigate the Impact of a New Image Processing Technology on Radiation Dose and Image Quality during Hepatic Embolization. J Vasc Interv Radiol. 2016 Apr;27(4):593-600.
18. Stecker, M.S., et al., Guidelines for Patient Radiation Dose Management. Journal of Vascular and Interventional Radiology, 2009. 20(7): p. S263-S273.
19. Van der Marel K, et al. Reduced Patient Radiation Exposure during Neurodiagnostic and Interven- tional X-Ray Angiography with a New Imaging Platform. Am J Neuroradiol. 2017;38(3):442-49. DOI: 10.3174/ajnr.A5049.
20. Van Dijk JD, Ottervanger JP, Delnoy PPHM, et al. Impact of new X-ray technology on patient dose in pacemaker and implantable cardioverter defibrillator (ICD) implantations. J Interv Card Electrophysiol. 2017;48:105–110. https://doi.org/10.1007/s10840-016-0200-z
21. Sullivan PM, Harrison D, Badran S, et al. Reduction in Radiation Dose in a Pediatric Cardiac Catheterization Lab Using the Philips AlluraClarity X-ray System. Pediatr Cardiol. 2017;38: 1583–91. https://doi.org/10.1007/s00246-017-1700-z
22. Gislason-Lee A, et al. Impact of latest generation cardiac interventional X-ray equipment on patient image quality and radiation dose for trans-catheter aortic valve implantations. BJR. 2016; 89:1067.
23. Kastrati M, Langenbrink L, Piatkowski M, et al. Reducing Radiation Dose in Coronary Angiography and Angioplasty Using Image Noise Reduction Technology. Am J Cardiol. 2016;118(3):353-56. https://doi.org/10.1016/j.amjcard.2016.05.011
24. Abuzeid W, Abunassar J, Leis JA, et al. Radiation safety in the cardiac catheterization lab: A time series quality improvement initiative. Cardiol Vasc Med. 2017;18(5):S22-S26.
25. Gunja A, Pandey Y, Xie H, et al. Image noise reduction technology reduces radiation in a radial-first cardiac catheterization laboratory. Cardiol Vasc Med. 2017; 18(3):197-201.

26. Balter S, Brinkman M, Kalra S, et al. Novel Radiation Dose Reduction Fluoroscopic Technology Facilitates Chronic Total Occlusion Percutaneous Coronary Interventions. EuroIntervention. 2017;13(12):e1468-e1474. doi: 10.4244/EIJ-D-16-00216. PMID: 28741573.
27. Faroux L, Blanpain T, Nazeyrollas P, et al. Minimizing exposure to radiation in invasive cardiology using modern dose-reduction technology: evaluation of the real-life effects. Cath CardioVasc Inter. 2017;91(7):1194-1199.
28. Baumann F, Peña C, Kloeckner R, et al. The Effect of a New Angiographic Imaging Technology on Radiation Dose in Visceral Embolization Procedures. Vasc Endovascular Surg. 2017 May;51(4):183-187.
29. Strauss KJ, Racadio JM, Johnson N, et al. Estimates of Diagnostic Reference Levels for Pediatric Peripheral and Abdominal Fluoroscopically Guided Procedures. AJR Am J Roentgenol. 2015 Jun;204(6):W713-9.
30. BEIR 2006. Health Risks From Exposure to Low Levels of Ionizing Radiation: BEIR VII. Washington, DC: National Academic Press; 2006.
31. Sources and Effects of Ionizing Radiation, UNSCEAR 2008 Report. United Nations Scientific Committee on the Effects of Atomic Radiation, New York, 2010.
32. In an extensive market study on unmet needs conducted by Strategyn, radiation exposure related issues were the number 1, 2, 4 and 7 most important needs from a list of about 50 needs. This study was conducted with about 300 interventional cardiologists.
33. IEC 60601-1-3:2008, 3.43, IEC 60601-2-54:2009, 203.5.2.4.5.101 (d).
34. International Commission on Radiological Protection ICRP publication 103. Ann ICRP 2007;37:1–332.
35. ICRP, 1991.1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Ann. ICRP 21 (1-3).
36. AAPM report No. 125, “Functionality and Operation of Fluoroscopic Automatic Brightness Control/Automatic Dose Rate Control Logic in Modern Cardiovascular and Interventional Angiography Systems, 2012.
37. In the design and development of the image processing algorithms, special attention has been given to the fact that no clinical content may be removed, added, or changed. This has been thoroughly evaluated both in-house, using a database of “difficult” clinical images and in lengthy clinical evaluations in hospitals.
38. Image enhancement can, however, have a significant impact on objective image quality measurements, such as noise, sharpness and contrast. Therefore, using objective image quality parameters after image enhancement is not useful.
39. For more information about the EPX parameters, see Gislason, A.J., et al, “Allura Xper cardiac system implementation of automatic dose rate control,” Aug 2011, Philips white paper number 4522.962.71201.
40. At large patient thicknesses, less dose reduction may be achieved. This can be explained by the limitations (legal or system) that occur in extreme cases, when the maximum patient X-ray dose is reached. For thicknesses above this maximum level, the X-ray dose can no longer increase and IQ will decrease instead. Since the ClarityIQ technology uses lower X-ray doses at equivalent image quality levels, it reaches these limitations at larger thicknesses than the Xper technology. So the smaller dose reduction at larger thickness is accompanied by better IQ.
41. When copper filtration is used, 1 mm of aluminum is also used. This is approximately equal to an additional 0.1 mm of copper. When 0.4 mm Cu is mentioned, in practice this is 1 mm Al + 0.4 mm Cu = 0.5 mm Cu equivalent.
42. Reference Air Kerma (Rate) for AlluraClarity family and Allura Xper FD series. Document version 8.0, document number 4522.203.12121.
43. In the measurements, polymethyl methacrylate (PMMA) is used instead of water. This has similar X-ray properties.
44. The values given for X-ray dose reduction in this table and the following ones are the values expected to be achieved, based on simulations or phantom measurements. An exception is the X-ray dose reduction for the Neuro Cerebral 2 fps procedure, for which an X-ray dose reduction of average 75% has been proven by a clinical trial.[1]
45. For fluoroscopy in some countries there is a legal maximum of 10 R/min, measured at 30 cm in front of the detector. For example, for an SID of 1.0 meters on the Allura FD10 (for which PERP = 0.615 m), the X-ray dose measured in the PERP is ((1.0-0.3))/0.615)2 = 1.30 times higher than measured at 30 cm in front of the detector. With 1.0 R = 8.77 mGy/min, the 10 R/min limit becomes a limit of 114 mGy/min in the PERP at an SID of 1.0 meter.
46. Typical: at water-equivalent patient thicknesses typical for interventional cardiology. Typical patient thicknesses are 25.8 cm water equivalent with a standard deviation of 4 cm.
47. Azurion FD20 vs AlluraXper FD20; Patient entrance dose comparison. XCX612-130069. The values given are measured in-house with an experimental setup that closely follows the IEC standard on patient entrance dose measurements.
48. Reduction of radiation exposure while maintaining high-quality fluoroscopic images during interventional cardiology using novel X-ray tube technology with extra beam filtering, A. Den Boer et al., Circulation 1994;89;2710 – 2714.
49. Typical: at water-equivalent patient thicknesses typical for interventional neuroradiology. Typical patient thicknesses are 23.7 cm water equivalent with a standard deviation of 1.9 cm.
50. Instructions for use for Philips Allura Xper FD series. Supplementary Information Document version 8.0, Philips number 4522.203.02191, May 2012.

a) In this paper, the name Azurion refers to Azurion with ClarityIQ technology. ClarityIQ technology is an option on the Azurion systems.

b) In 28 individual comparative studies, Philips ClarityIQ was associated with reductions in patient radiation exposure.[1-29]

c) Relationship between radiation exposure and risk of complications, long-term health risk, procedure time and patient characteristics, procedure complexity, as reported in medical guidelines.[18]

d) 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.

e) In 3 individual comparative studies, Philips ClarityIQ was associated with reductions in staff [11-13], or scatter radiation exposure [10].

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