North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

July 1, 2015

W. Stan Taylor, Vice President, Corporate Planning
WakeMed
3000 New Bern Avenue
Raleigh NC 27610

Exempt from Review – Replacement Equipment

Record #:	**1616**
Facility Name:	WakeMed
FID #:	943528
Business Name:	WakeMed Raleigh Campus
Business #:	2030
Project Description:	Replace cardiac catheterization equipment
County:	Wake

Dear Mr. Taylor:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 19, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(f). Therefore, you may proceed to acquire, without a certificate of need, the Philips Xper FD 20 cardiac catheterization system. This determination is based on your representations that the unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

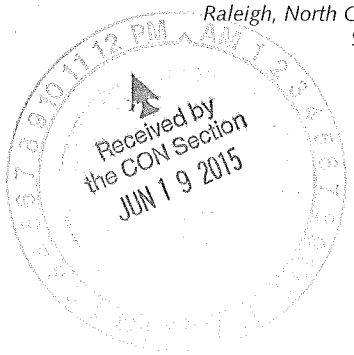
Michael J. McKillip
Project Analyst

Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR
Assistant Chief, Healthcare Planning
Acute and Home Care Licensure and Certification Section, DHSR

WakeMed
WakeMed Health & Hospitals
3000 New Bern Avenue
Raleigh, North Carolina 27610
919-350-8000

June 19, 2015



943528
1616

Ms. Martha Frisone, Assistant Chief
Mr. Michael J. McKillip, Project Analyst
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Request for Exemption from Certificate of Need Review to Replace Cardiac Catheterization Equipment at WakeMed Raleigh Campus

Dear Ms. Frisone and Mr. McKillip:

This letter is to inform you of WakeMed's intent to replace the cardiac catheterization equipment located in Room 4 at WakeMed Raleigh Campus. The equipment in Room 4 was purchased in 2005 and utilizes technology which is outdated and no longer meets current standards of care. It will be replaced with a Philips Allura Xper FD20, which has state-of-the-art imaging technology (see Attachments 1 and 2). It will be able to perform coronary diagnostic and therapeutic interventions, peripheral vascular procedures, and electrophysiology procedures, all of which are currently provided at WakeMed Raleigh Campus.

The proposed capital cost is $2,691,599, which includes the equipment and renovation of the room (see Attachment 3 for a certified cost estimate of the project). The footprint of the room will not change; however, renovation is required to configure the room for the new equipment and to meet current building codes.

The original equipment in Room 4 was purchased prior to 1993, when a certificate of need was not required for cardiac catheterization equipment. See Attachment 4, which includes pages from WakeMed's 1992 licensure renewal application indicating that it operated four pieces of cardiac catheterization equipment. The equipment was replaced the first time as part of Project I.D. J-4947-93, which was approved to expand the Heart Center at WakeMed Raleigh Campus (see Attachment 5). It was replaced again in 2005 with the current equipment, which did not require a certificate of need.

The project was approved by WakeMed's Board of Directors on June 2, 2015. Renovation will begin upon receipt of your approval and it is expected that the project will be completed in November 2015. At that time, the current equipment will be removed from service within the state of North Carolina and will no longer be used by WakeMed (see Attachment 6).

Applicable certificate of need standards are shown below:

(f) The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the two million dollar ($2,000,000) threshold set forth in G.S. 131E-176(22a) if all of the following conditions are met:

(1) The equipment being replaced is located on the main campus.

(2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.

(3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

(g) The Department shall exempt from certificate of need review any capital expenditure that exceeds the two million dollar ($2,000,000) threshold set forth in G.S. 131E-176(16)b. if all of the following conditions are met:

(1) The sole purpose of the capital expenditure is to renovate, replace on the same site, or expand the entirety or a portion of an existing health service facility that is located on the main campus.

(2) The capital expenditure does not result in (i) a change in bed capacity as defined in G.S. 131E-176(5) or (ii) the addition of a health service facility or any other new institutional health service facility or any other new institutional health service other than that allowed in G.S. 131E-176(16)b.

(3) The licensed health service facility proposing to incur the capital expenditure shall provide prior written notice to the Department along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

WakeMed believes that this request meets all of criteria shown above. The equipment being replaced is located on WakeMed Raleigh Campus, which is the main campus and is a licensed health service facility. The capital expenditure will not result in the addition of a health service facility or any other new institutional health service. The replacement equipment will be placed in the same room as the old equipment. This letter and supporting documentation serve as providing prior written notice to the Department that WakeMed Health & Hospitals meets the exemption criteria of this subsection.

Thank you for your consideration of this request. If you have any questions or need additional information, please contact me at 919-350-8108.

Sincerely,

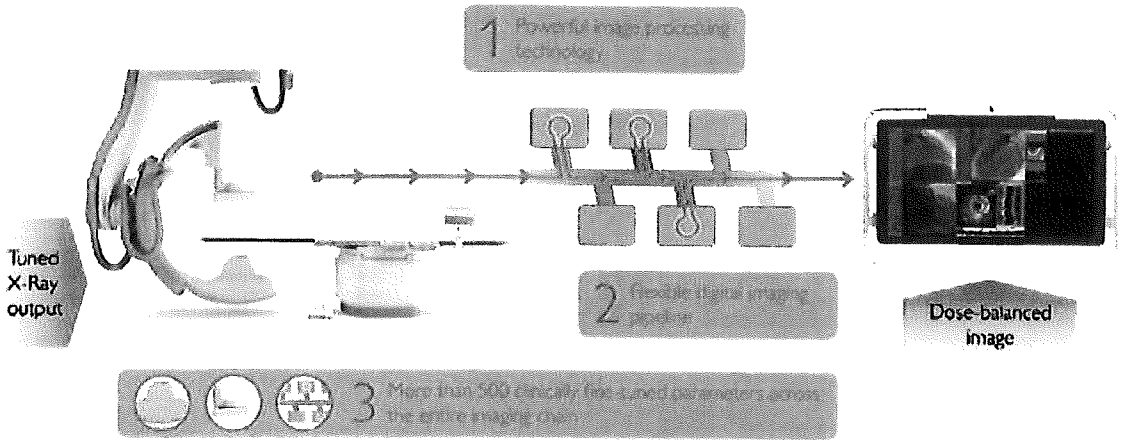
W. Stan Taylor
Vice President, Corporate Planning

Attachment 1

Intended for distribution in the United States of America.

ClarityIQ technology

X-ray dose is a main concern for physicians working with an interventional X-ray system. In interventional X-ray, a reduction in X-ray exposure has generally been associated with a decrease in image quality. In the recently introduced AlluraClarity family with ClarityIQ technology, provides high quality imaging for a full range of clinical procedures at ultra low dose levels.



Executive summary

During interventions you want to see with confidence – every time. AlluraClarity with ClarityIQ technology gives you this confidence. Philips' AlluraClarity family – a revolutionary new generation of interventional X-ray systems – provides high quality imaging for a full range of clinical procedures at ultra low dose levels.

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 came from a total system optimization in stead of an optimization of individual components. These 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 AlluraClarity 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, ClarityIQ technology is anticipated to achieve a significant staff dose reduction.

PHILIPS

Introduction

Over the last decades, interventional X-ray 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[1] (figure 1).

We appreciate 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.
Of course, you could increase the amount of X-ray dose used. Yet an increase in abdominal width 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 interventional X-ray devices.[2] Market research shows that radiation dose is the number one concern[3] for physicians who are using an interventional X-ray system.

In interventional X-ray, a reduction in X-ray exposure has generally been associated with a decrease in image quality (IQ). Philips, as a market leader in interventional X-ray, has a history of providing industry leading image quality and X-ray dose reduction measures. In the recently introduced AlluraClarity family with ClarityIQ technology, Philips has achieved high quality imaging for a full range of clinical procedures at ultra low dose levels.

Clinical evidence to date is based on a study conducted in the interventional neuroradiology department at the Karolinska University Hospital, Stockholm, Sweden.[1] This study showed that on average, 80% of the cumulative air kerma could be attributed to DSA exposure, 19% to fluoroscopy, and 1% to three-dimensional techniques.

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

In this paper, by "patient dose" without further specification, patient entrance dose is meant: 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)[4] (equal to the formerly used Interventional Reference Point (IRP)). Insight is also provided on the changes that have been made to the acquisition settings for the AlluraClarity systems that are responsible for the significant dose reduction achieved.

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

Lowering X-ray dose

According to the recommendations of the International Commission on Radiological Protection[5] 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 is acceptable than during stent placement.

For interventional X-ray 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 image quality. As an example, consider two different tasks: localization and characterization.

For **localization**, fluoroscopy images can be used. X-ray images are 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**, exposure or DSA images can be used. X-ray images are used to characterize and thereby diagnose pathology, such as identifying the specific characteristics of small cerebral

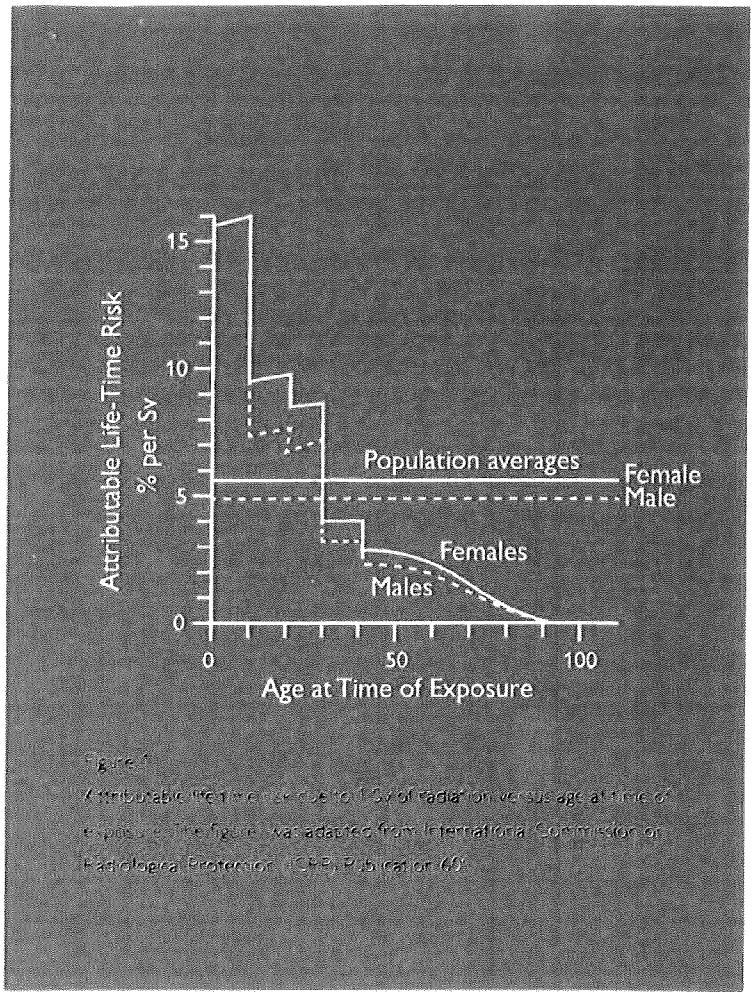


Figure 1
Attributable lifetime risk due to 1 Sv of radiation versus age at time of exposure. The figure was adapted from International Commission on Radiological Protection (ICRP) Publication 60.

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,[7] 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.

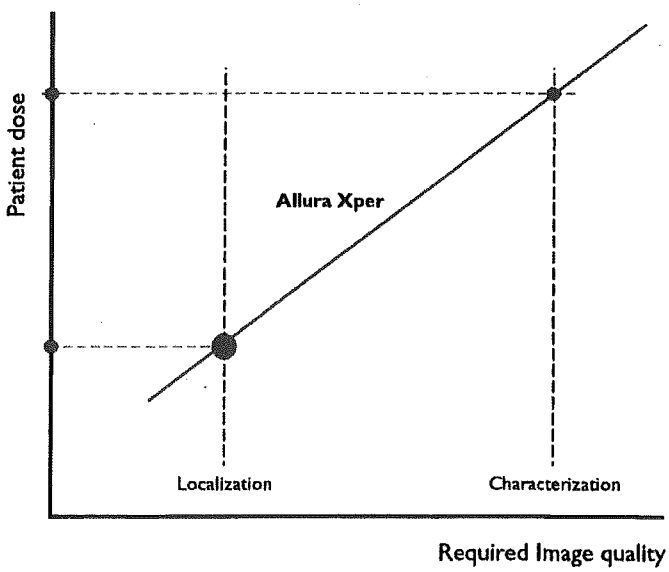


Figure 2: Graph of the relationship between IQ and patient X-ray dose for the Allura Xper. The positions for localization and characterization were chosen arbitrarily and will be different for each application. Patient thickness and projections will also affect the graph.

Now, thanks to ClarityIQ technology, the AlluraClarity family takes a big step forward in providing high-quality imaging at ultra low dose levels.
The next section explains how this improvement was achieved.

ClarityIQ technology

ClarityIQ technology is enabled by Philips state-of-the-art computer technology. It is based on three pillars, see also Figure 3.

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

ClarityIQ technology touches every part of the AlluraClarity system, from tube to display, to enable ultra low dose settings. Where the Allura Xper system needs a certain amount of patient dose to create an image of sufficient image quality for a given procedure, the AlluraClarity system needs only a fraction of that patient dose. The new ClarityIQ image processing technologies have allowed us to use ultra low dose settings.

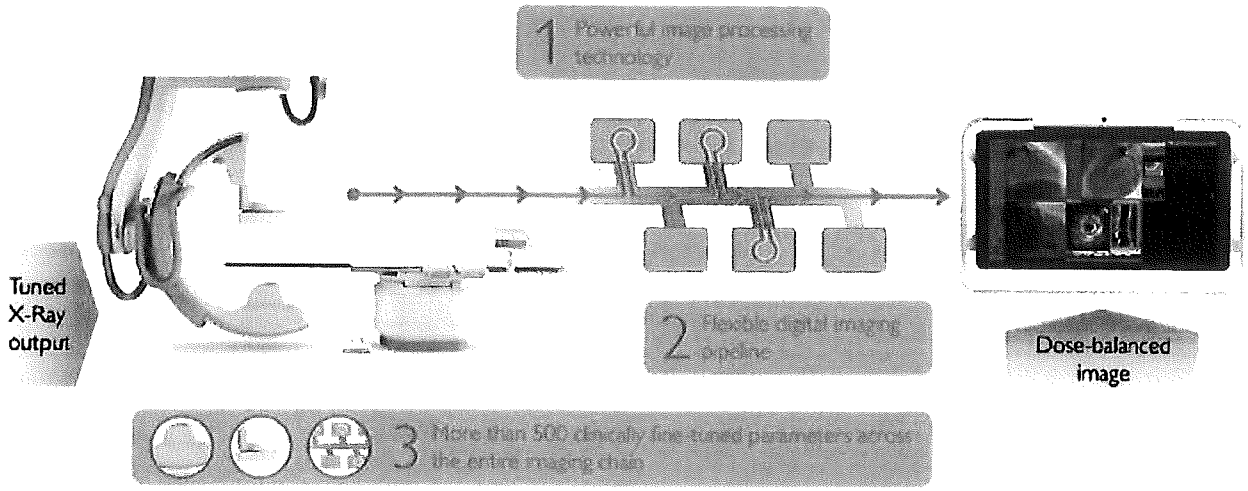


Figure 3: The three pillars of ClarityIQ technology, enabling the large patient dose reduction for the AlluraClarity family, compared to the Allura Xper series.

Powerful image processing technology

ClarityIQ technology incorporates powerful state-of-the-art image processing technology, developed by Philips Research, all working 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 2.

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.

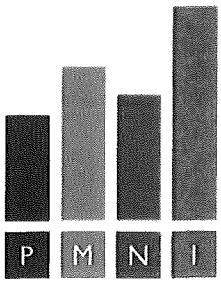


Figure 4: Image processing elements for ClarityIQ technology

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 4.

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 interventional X-ray systems, however, this is usually a post processing function that requires an operator to manually correct the images. The AlluraClarity system 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 AlluraClarity is the only X-ray system on the market today that 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 5.

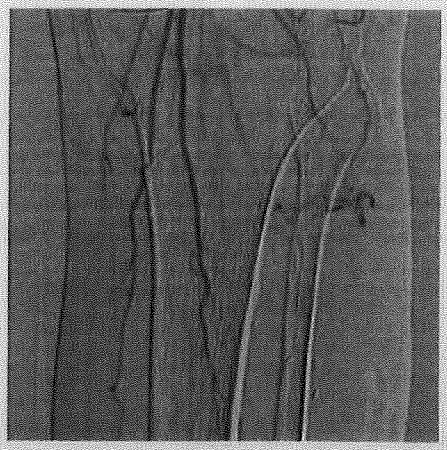


Figure 5a

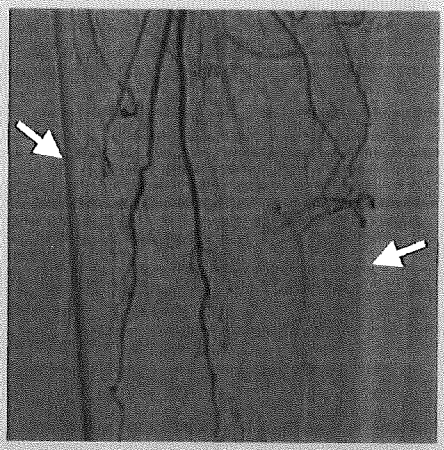


Figure 5b

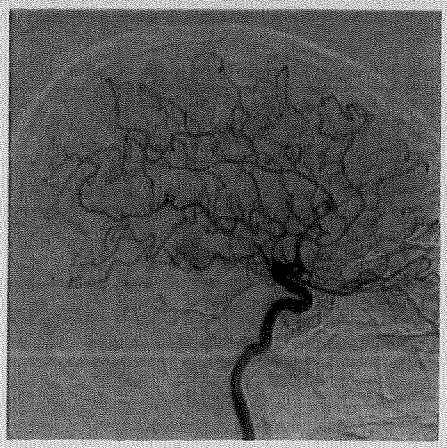


Figure 5c

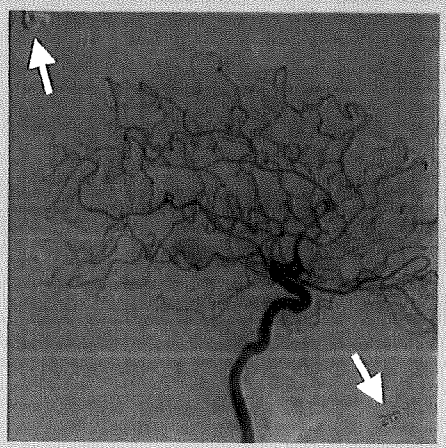


Figure 5d

Figure 5: 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).

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.

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.[8] 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 provide hgh-quality imaging at ultra low dose levels.

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 (=$\sqrt{n}$). That is, if 16 frames are averaged (n=16), the signal-to-noise ratio would be increased by a factor of 4 (=$\sqrt{16}$).

Motion detection is essential when performing temporal noise reduction. Without being able to detect motion, ghost images of moving structures would appear, see Figure 6.

Image processing algorithms used in conventional X-ray 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 AlluraClarity family

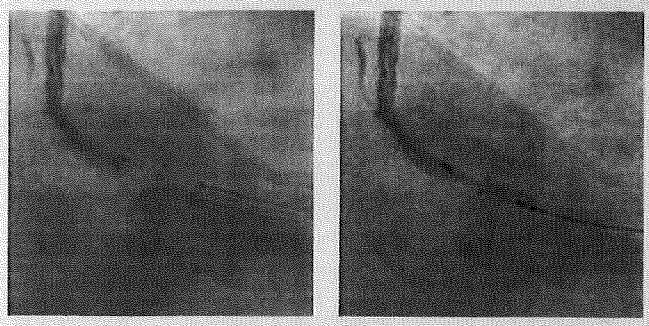


Figure 6a Figure 6b

Figure 6: Example of motion compensation. Figure 6a shows a temporally filtered image of the heart without motion compensation applied. Figure 6b shows the same image filtered with motion compensation applied.

offers a new **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 7.

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 8.

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 9.

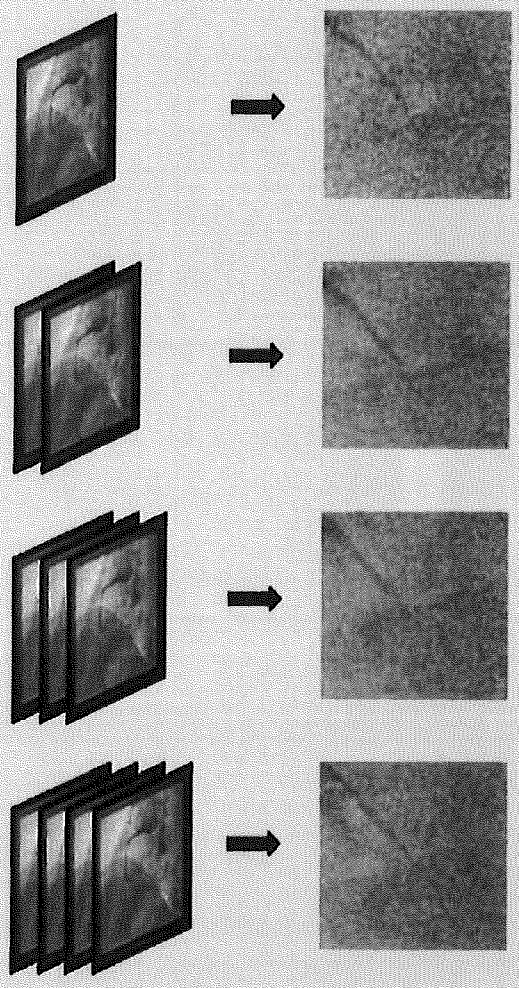


Figure 7: Example of temporal noise reduction. The noise is filtered by averaging over several frames. The signal is aligned (motion compensation) and then averaged. From top to bottom, the effect on the noise of using more images is shown.

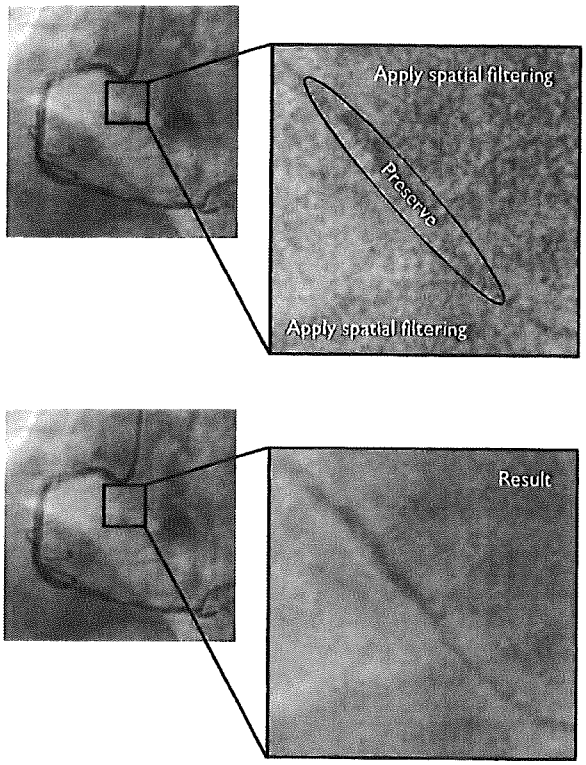


Figure 8: Example of spatial noise reduction. The signal or clinically relevant features and noise are distinguished. The noise is filtered out, while the signal is preserved.

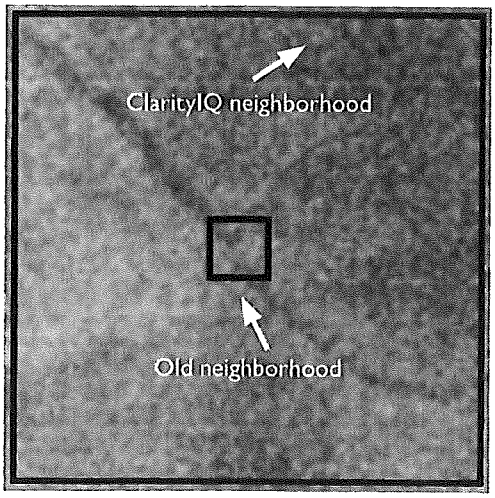


Figure 9: The old neighborhood used for spatial noise reduction (small square) and the new neighborhood (large square) now used with ClarityIQ technology. Averaging over a larger surface or neighborhood will reduce more noise. A larger neighborhood also makes it easier to identify clinically relevant structures, while avoiding signal distortion.

The result of these enhancements in spatial and temporal filtering enable high-quality imaging at ultra low dose levels.

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,[9] 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 10. 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 with shortest delay. This means that 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 AlluraClarity 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 AlluraClarity system 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 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

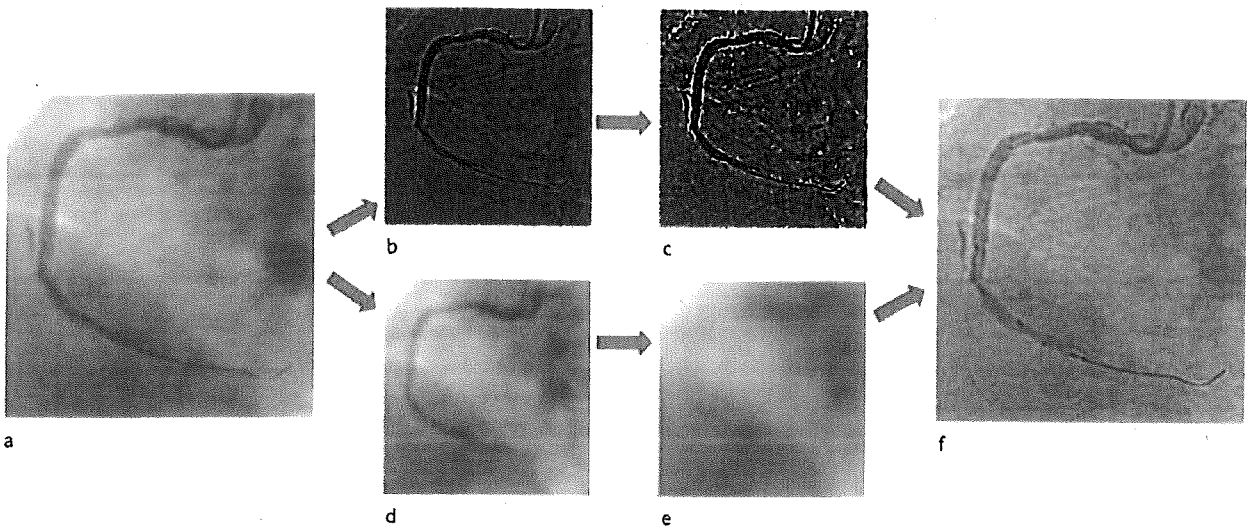


Figure 10: Example of image enhancement. Figure 10a is the original image. This is processed in the spatial frequency domain. For simplicity, only a high frequency image (b) and a low frequency image (d) are displayed here. The high frequency image, containing small details, is enhanced (c), while the 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.

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.

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 11a and 11b. This sophisticated design allows the AlluraClarity 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 perform optimally for the entire range of clinical applications.

An example of the flexibility of the pipeline is shown in Figure 12.

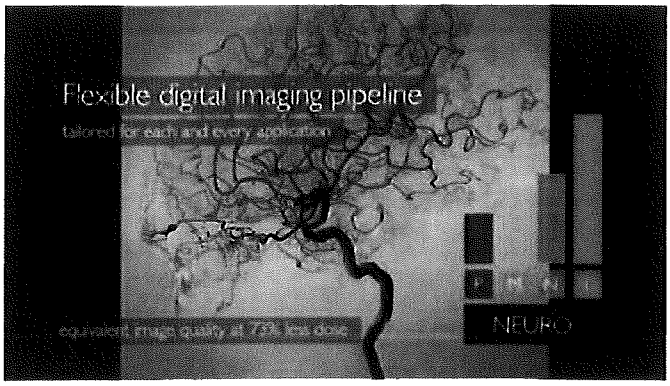


Figure 11a: The real-time pixel shift, noise reduction, and image enhancement modules are used for interventional neuroradiology procedures

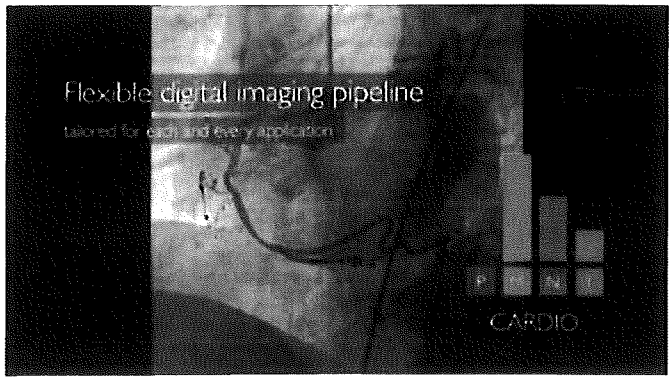


Figure 11b: The motion compensation, noise reduction and image enhancement modules are used for interventional cardiology

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 Allura Xper and AlluraClarity Interventional X-ray systems is formed by a large database of all system settings. This EPX[10] 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 new level of clinical flexibility to be achieved with the AlluraClarity system. 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.

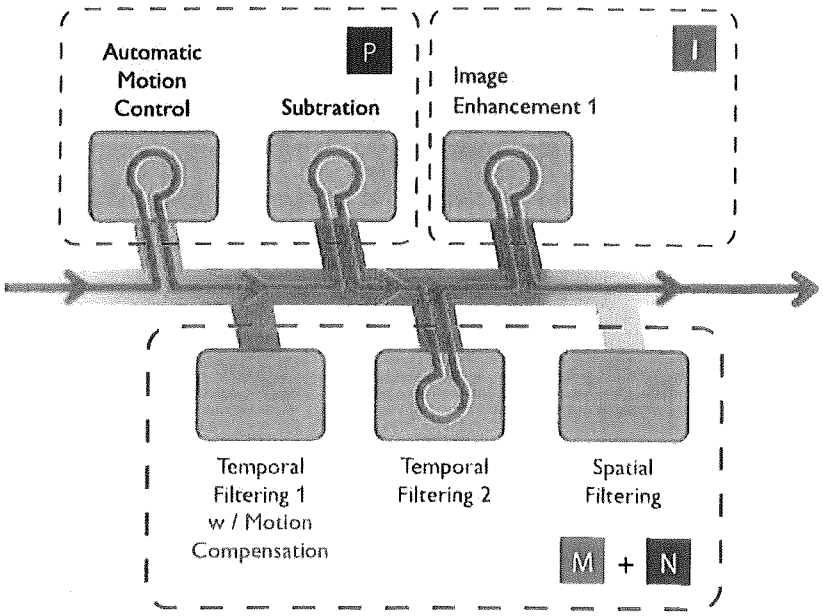


Figure 12: Illustration of the flexible digital imaging pipeline. In this imaginary example, the image goes through the subsequent processing steps of AMC, subtraction, temporal filtering and image enhancement. The letters P, M, N and I refer to the modules mentioned in Figure 4.

During the development of the AlluraClarity family, 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.

Philips' AlluraClarity family – a revolutionary new generation of interventional X-ray systems – provides high quality imaging for a full range of clinical procedures at ultra low dose levels. Dose reductions can be achieved for almost the entire range of patient thicknesses and projections.[11]

Fluoroscopy and exposure in the Allura Xper and AlluraClarity systems

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

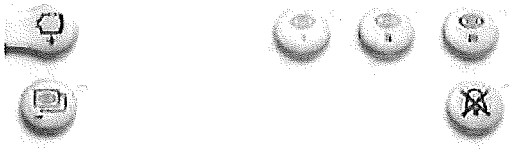


Figure 13: Position and labeling of the three fluoroscopy flavors on the user interface of the AlluraClarity and Allura Xper systems

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 (for example for large size patients or steep projections). 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.

For exposure, the Allura Xper system has one flavor per procedure. The AlluraClarity can have more exposure flavors, with different patient dose rates, for greater flexibility in having the appropriate X-ray dose and image quality. These settings can be enabled by a Philips Field Service Engineer or Application Specialist 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 AlluraClarity? 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 AlluraClarity 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. For the AlluraClarity system the amount of copper filtration has been increased even further, again making optimal use of the high tube output of the MRC tube.

For AlluraClarity, 0.4 mm Cu[12] 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%.

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 application or procedure, the amount of copper filtration is fixed over the full range of patient thicknesses, for both the AlluraClarity 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.

How Philips filters out soft radiation

The Allura Xper and AlluraClarity 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 AlluraClarity 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.

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[13] will increase when smaller detector formats are used.

Cardiac exposure

For cardiac exposure our standard settings for AlluraClarity can allow for much lower dose than those for Allura Xper.

While the Allura Xper has one exposure flavor, the AlluraClarity can have multiple exposure flavors for some cardiac procedures (e.g. Left & Right Coronary 15 fps). The Low Dose setting can be used for small patients or when extra low patient X-ray dose levels are required.

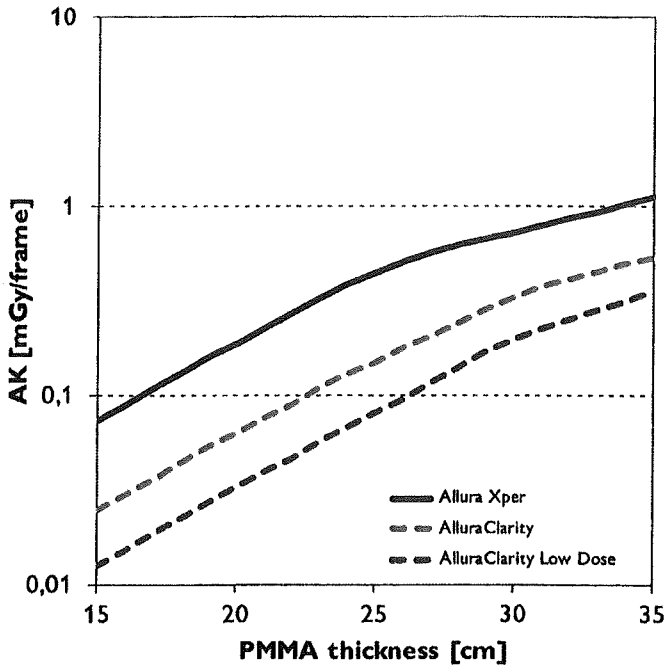


Figure 14: Cardiac exposure patient dose comparison for the Left Coronary 15 fps procedure, measured with an SID of 1 m for the largest detector format, measuring point is the PERP. The values have been measured on two separate FD10 systems (one AlluraClarity system and one Allura Xper system). Typical equivalent water thicknesses for interventional cardiology are around 25.8 cm with a standard deviation of 4 cm.

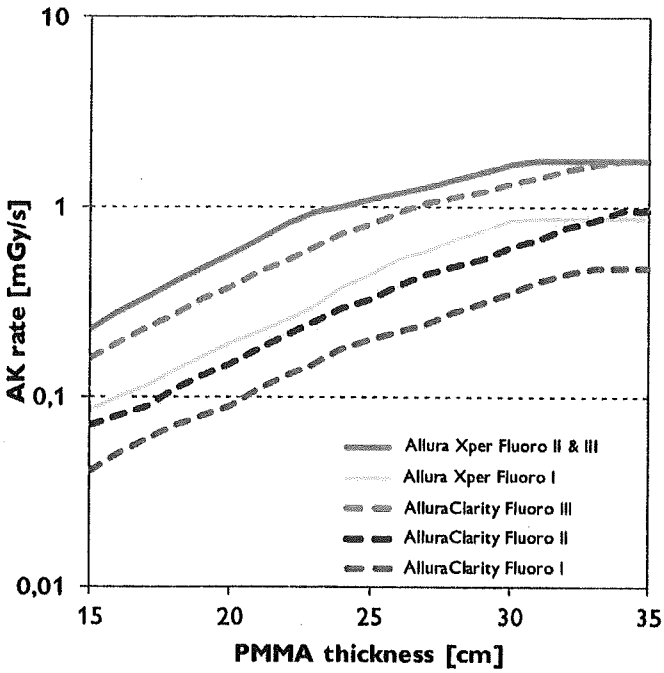


Figure 15: Cardiac fluoro patient dose rate comparison measured with an SID of 1 m for the largest detector format, measuring point is the PERP. Measurements have been performed on two separate FD10 systems (AlluraClarity and Allura Xper). The dose rates of Allura Xper Fluoro II and III are equal, the difference is in the frame speed: 15 and 30 fps respectively

Figure 14 shows the patient dose for the different flavors for different patient equivalent thicknesses in centimeters of water[14] for the Allura Xper and AlluraClarity systems for the Left Coronary 15 frames per second (fps) procedure. The dose values in the graph are valid for systems with an FD10 detector.

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

Other parameters for the AlluraClarity 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 our standard settings for AlluraClarity can allow much lower dose than those for Allura Xper. This section is valid for systems with an FD10 detector.

Figure 15 shows the patient entrance dose rate for the different fluoro flavors for different patient thicknesses.

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

Parameter	Allura Xper	AlluraClarity	AlluraClarity Low Dose
Copper filtration	None	0.1 mm Cu	0.4 mm Cu

Table 1: Cardiac exposure copper filtration parameters for Left Coronary 15 fps.

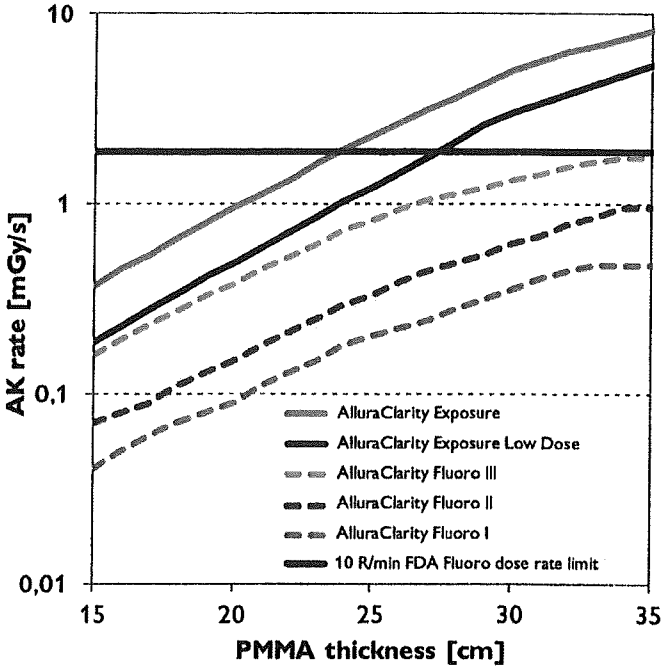


Figure 16: Comparison of patient dose rates settings for cardiac exposure and cardiac fluoroscopy for the AlluraClarity system with an SID of 1 m for the largest detector format, measuring point is the PERP. Note that patient dose rates for exposure are now close to fluoroscopy

For cardiac fluoro, going from the Allura Xper flavor II and AlluraClarity flavor III to the AlluraClarity 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 AlluraClarity flavor II to AlluraClarity 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 at 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 16 shows what this means in clinical practice. It compares patient dose rates for cardiac exposure and cardiac fluoroscopy for the AlluraClarity 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 settings 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 AlluraClarity Low Dose exposure flavor.

Parameter	Allura Xper II	AlluraClarity III	AlluraClarity II	AlluraClarity I
Typical patient dose rates[15, 16]	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

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)

Pediatric exposure

For pediatric exposure our standard settings for AlluraClarity 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. AlluraClarity 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 17 the patient entrance dose per frame is shown as function of the equivalent patient thickness for comparable pediatric exposure programs of the Allura Xper and AlluraClarity systems. The blue line represents the Allura Xper system with the following settings: 5-15 kg and 15 fps program. The greenline represents the AlluraClarity system with settings: below 40 kg and 15 fps program. All AlluraClarity pediatric settings below 40 kg use 0.4 mm copper filtration and a small focal spot.

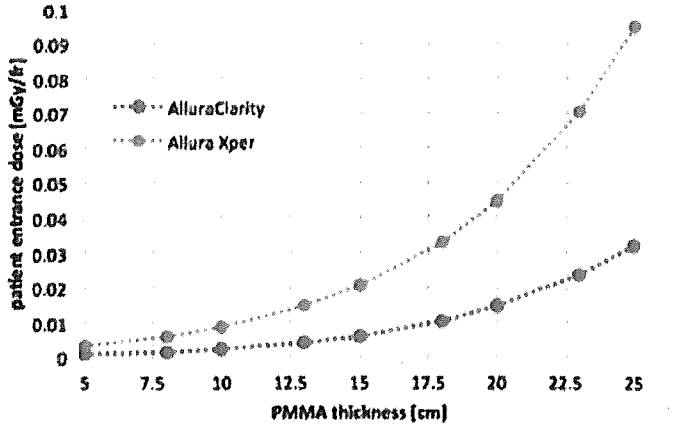


Figure 17:

Patient exposure dose rate comparison for the AlluraClarity 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[13]. 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).[17]

Pediatric fluoroscopy

As with the pediatric exposure settings, the pediatric fluoroscopy standard settings for AlluraClarity allow for much lower dose than those for Allura Xper. For the AlluraClarity systems 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 as for pediatric exposure are distinguished for pediatric fluoroscopy.

Table 3 shows the patient entrance dose rate for the three fluoro flavors of an AlluraClarity system with an FD10 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 AlluraClarity pediatric settings below 40 kg use 0.4 mm copper filtration and a small focal spot; the pulse duration is maximum 3 ms.

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

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

In Figure 18 the patient entrance dose rate is shown as function of the patient equivalent thickness for comparable pediatric fluoroscopy programs of the Allura Xper and AlluraClarity systems.. The blue line represents the Allura Xper system with the following settings: 5-15 kg, 15 fps, low fluoro flavor. The green line is for the AlluraClarity system with settings: below 40 kg, 15 fps, fluoro flavor I (default).

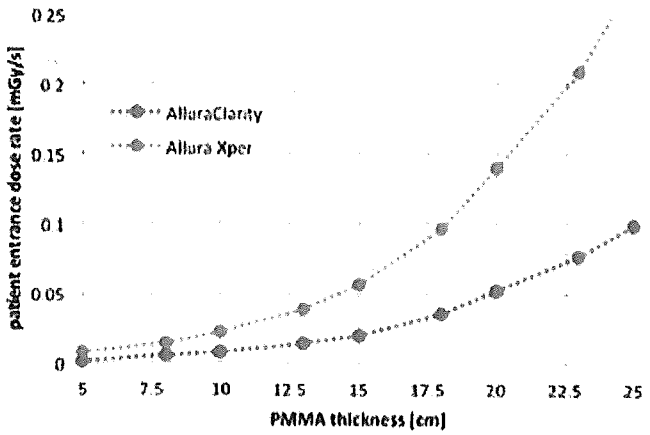


Figure 18:

Pediatric patient fluoroscopy dose comparison for the AlluraClarity 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[14]. 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).[17]

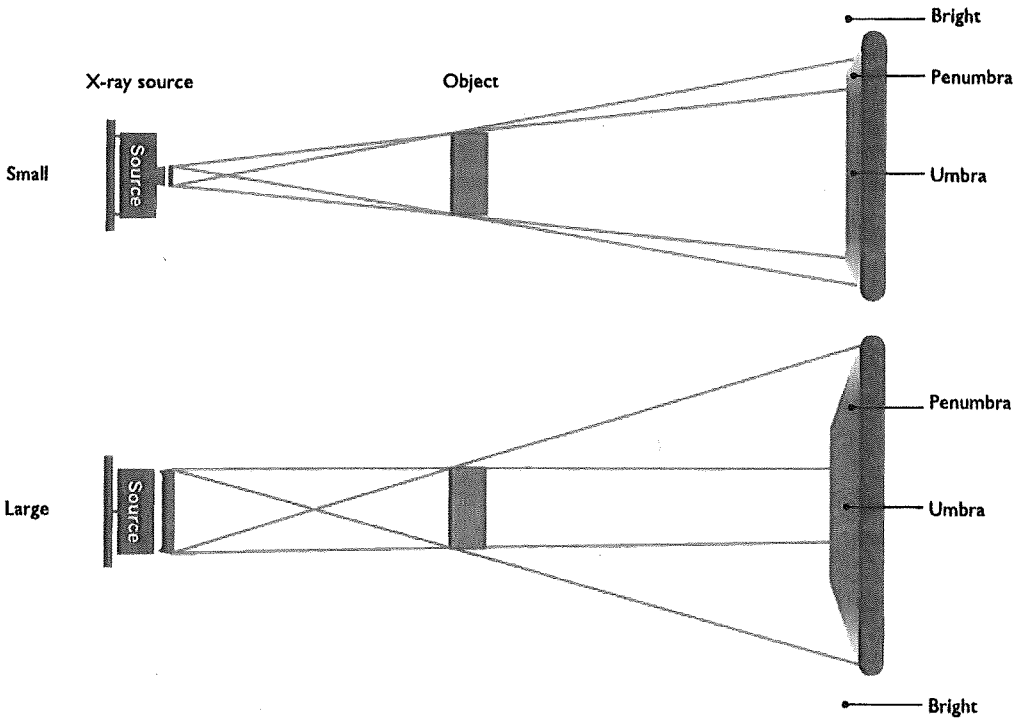


Figure 19: Exaggerated illustration of the effect of a large and small focal spot on the sharpness of a relatively small object in an image.

Neuro DSA exposure

For neuro DSA exposure the Neuro Cerebral 2 fps procedure will be described.

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 19.

Figure 20 shows the patient entrance dose for different patient thicknesses in for the Allura Xper and AlluraClarity systems for the Neuro Cerebral 2 fps procedure. Patient X-ray dose rates are given for systems with an FD20 detector.

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 AlluraClarity system. This results in more contrast and a constant contrast impression for a wider range of patients.

Parameter	Allura Xper	AlluraClarity
Focal spot	Large (0.7)	Small (0.4)
Filtration	0.1 mm Cu	0.1 mm Cu
Typical tube potential	78 kV	75 kV

Table 4: Neuro Cerebral 2fr/s acquisition parameters. Focal spot sizes are given for FD20 systems. The focal spot sizes for FD10 systems are 0.5 (small) and 0.8 (large).

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 AlluraClarity.

Figure 21 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 expected 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[18], however, it is still expected that the staff dose savings with ClarityIQ technology will be significant.

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.

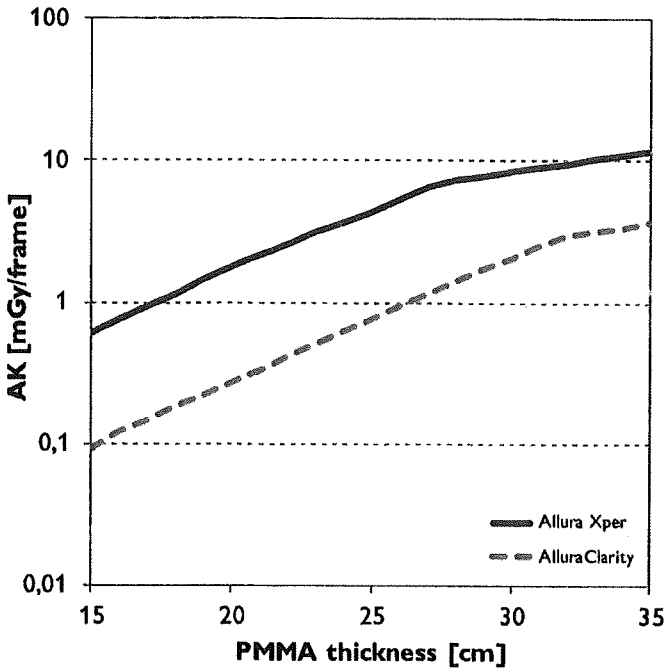


Figure 20: Neuro DSA Cerebral 2 fps patient dose comparison measured with an SID of 1 m for the largest detector format, measuring point is the PERP. Measurements have been performed on two separate FD20 systems (AlluraClarity and Allura Xper). Typical equivalent water thicknesses for interventional neuroradiology are around 23.7 cm with a standard deviation of 1.9 cm.

Parameter	Allura Xper III	AlluraClarity III	AlluraClarity II	AlluraClarity I
Typical[19] 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

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

When tube currents (mA) or pulse durations (ms) are reduced, the relative portion of soft radiation in the beam (beam quality) does not change.

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 are given in the Instructions for Use for the Allura Xper[20] and AlluraClarity systems and are repeated in Table 5.

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

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

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 AlluraClarity system, 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 AlluraClarity 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.

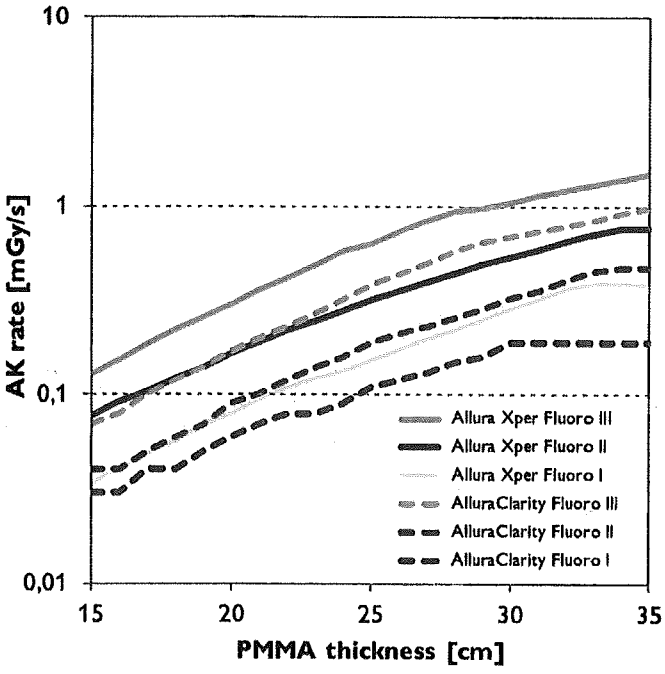


Figure 21: Vascular & Neuro fluoro patient dose rate comparison, measured with an SID of 1 m for the largest detector format, measuring point is the PERP. Measurements have been performed on two separate FD20 systems (AlluraClarity and Allura Xper).

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 interventional X-ray system introduced in 2003 and regularly enhanced since then. Many systems are still sold today.
AlluraClarity system	Latest generation Philips interventional X-ray system, introduced in July 2012. The AlluraClarity family 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] BEIR 2006. Health Risks From Exposure to Low Levels of Ionizing Radiation: BEIR VII, Washington, DC: National Academic Press; 2006.

[2] Sources and Effects of Ionizing Radiation, UNSCEAR 2008 Report. United Nations Scientific Committee on the Effects of Atomic Radiation, New York, 2010.

[3] 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, radiologists, electrophysiologists, and surgeons in Germany and the US.

[4] IEC 60601-1-3:2008, 3.43, IEC 60601-2-54:2009, 203.5.2.4.5.101 (d).

[5] International Commission on Radiological Protection ICRP publication 103. Ann ICRP 2007;37:1–332.

[6] ICRP, 1991.1990 Recommendations of the International Commission on Radiological Protection.ICRP Publication 60. Ann. ICRP 21 (1-3)

[7] 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

[8] 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.

[9] 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.

[10] 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.

[11] 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 AlluraClarity family uses lower X-ray doses at equivalent image quality levels, it reaches these limitations at larger thicknesses than the Allura Xper system. So the smaller dose reduction at larger thickness is accompanied by better IQ.

[12] 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.

[13] Reference Air Kerma (Rate) for AlluraClarity family and Allura Xper FD series. Document version 8.0, document number 4522.203.12121.

[14] In the measurements, polymethyl methacrylate (PMMA) is used instead of water. This has similar X-ray properties.

[15] 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.

[16] 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.

[17] AlluraClarity 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.

[18] 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.

[19] 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.

[20] Instructions for use for Philips Allura Xper FD series. Supplementary Information Document version 8.0, Philips number 4522.203.02191, May 2012.

Philips Healthcare is part of
Royal Philips

How to reach us
www.philips.com/healthcare
healthcare@philips.com

Asia
+49 7031 463 2254

Europe, Middle East, Africa
+49 7031 463 2254

This document is intended for distribution in the USA

Please visit www.philips.com/AlluraClarity

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WakeMed Raleigh Campus, Room 4 Cardiac Catheterization Equipment **Attachment 2**

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Cardiac Catheterization	Cardiac Catheterization
Manufacturer of Equipment	Philips	Philips
Tesla Rating for MRIs	NA	NA
Model Number	722018	Allura Xper FD20
Serial Number	10	Available upon delivery
Provider's Method of Identifying Equipment	Fixed Asset Tag	Fixed Asset Tag
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	NA
Date of Acquisition of Each Component	May 20, 2005	October 2015
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.)	NA	$2,619,599
Total Cost of Equipment	$1,130,044	$1,657,845
Fair Market Value of Equipment	NA	$1,657,845
Net Purchase Price of Equipment	NA	$1,657,845
Locations Where Operated	WakeMed Raleigh Campus, Room 4	WakeMed Raleigh Campus, Room 4
Number Days In Use/To be Used in N.C. Per Year	Available 365 days/year; in operation 240 days/year	Available 365 days/year; in operation 240 days/year
Percent of Change in Patient Charges (by Procedure)	NA	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0%
Type of Procedures Currently Performed on Existing Equipment	Diagnostic & interventional cardiac catheterization	NA
Type of Procedures New Equipment is Capable of Performing	NA	Diagnostic & interventional cardiac catheterization, electrophysiology

Attachment 3

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project Name: **WakeMed Raleigh Campus Cardiac Catheterization Replacement Equipment, Room #4**

Provider/Company: **WakeMed Health & Hospitals**

A. **Site Costs**				
(1) Full purchase price of land.....				
Acres _____ Price per Acre				
(2) Closing costs.....				
(3) Site Inspection and Survey.....				
(4) Legal fees and subsoil investigation				
(5) Site Preparation Costs				
Soil Borings.....				
Clearing-Earthwork...				
Fine Grade For Slab...				
Roads-Paving.....				
Concrete Sidewalks....				
Water and Sewer.....				
Footing Excavation....				
Footing Backfill.....				
Termite Treatment....				
Other (Specify).....				
Sub-Total Site Preparation Costs			$0	
(6) Other (Specify)				
(7) **Sub-Total Site Costs**				$0
B. **Construction Contract**				
(8) Cost of Materials				
General Requirements				
Concrete/Masonry				
Woods/Doors & Windows/Finishes				
Thermal & Moisture Protection				
Equipment/Specialty Items				
Mechanical/Electrical				
Other (Specify)				
Sub-Total Cost of Materials.....			$284,788	
(9) Cost of Labor.....			$348,075	
(10) Other (Specify).....			$63,286	
(11) **Sub-Total Construction Contract**				$696,149
C. **Miscellaneous Project Costs**				
(12) Building Purchase.....				
(13) Fixed Equipment Purchase/Lease			$1,657,845	
(14) Movable Equipment Purchase/Lease			$175,000	
(15) Furniture			$7,605	
(16) Landscaping			$0	
(17) Consultant Fees				
Architect and Engineering Fees		$73,500		
Legal Fees.....				
Market Analysis.....				
Other (Specify).....		$2,500		
Other (Specify).....				
Sub-Total Consultant Fees			$76,000	
(18) Financing Costs (e.g. Bond, Loan, etc.).				
(19) Interest During Construction.				
(20) Other (Specify)			$7,000	
(21) **Sub-Total Miscellaneous..**				$1,923,450
(22) **Total Capital Cost of Project** (Sum A-C above)				$2,619,599

I certify that, to the best of my knowledge, the above construction related costs of the proposed project named above are complete and correct.

_____
(Signature of Licensed Architect or Engineer)

I assure that, to the best of my knowledge, the above capital costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

_____ Signature of Office Authorized to Represent Provider/Company)

(Title of Officer)

Attachment 4

DEPARTMENT OF HUMAN RESOURCES
DIVISION OF FACILITY SERVICES
HEALTH CARE FACILITIES BRANCH
701 BARBOUR DRIVE
PO BOX 29530
RALEIGH, NORTH CAROLINA 27626-0530
TELEPHONE (919) 733-2786

Please don't write on this

file copy

OFFICE USE ONLY
Lic. #
Provider #
Hospital Type
Lic. Bed. Cap.

General	Rehab.	Psych.

LTC	Chemical	Depend.
Hospice NF	Detox	Trtment

1992 APPLICATION FOR LICENSE TO OPERATE A HOSPITAL
PLEASE TYPE OR PRINT ALL INFORMATION

Legal Identity of Applicant: Wake County Hospital System, Inc.
(full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service for which this form is submitted)

Name(s) under which the hospital or services are advertised or presented to the public: (d/b/a's)

Primary: Wake Medical Center
Other:
Other:

Are the above names identical to the names on the current license? YES X NO ___
If no, please check the reason for the change:

Change of Ownership [ ] Name change only [ ] Other (specify)

Facility Site Address: 3000 New Bern Avenue

City: Raleigh County: Wake Zip Code: 27610

Facility Mailing Address: P. O. Box 14465

City: Raleigh County: Wake Zip Code: 27620-4465

Chief Executive Officer: Raymond L. Champ Title: President
-Designated Agent (individual) responsible to the governing body (owner) for the management of the licensed facility-

AUTHENTICATING SIGNATURE: The undersigned submits application for the above named hospital in accordance with G.S. 131E, Article 5, and rules and codes adopted thereunder and certifies the accuracy of this information.

Chief Executive Officer:

Name (Please Type): Raymond L. Champ Title: President

Signature: Raymond L. Champ Date: 12/2/91

NOTE: Please identify the contact person for questions regarding this form.

Name W. Stan Taylor Telephone (919) 250-8108

DFS-4032 Rev. 8/91

OPERATING ROOMS AND OTHER PROCEDURE ROOMS

A. Report surgical operating rooms built to meet specifications and standards for operating rooms utilized by the Construction Section of the Division of Facility Services and which are fully equipped to perform surgical procedures. Rooms not meeting this definition should be included in Part C. below.

Use	No. of Rooms	Inpatient Cases	Ambulatory Cases
Rooms in use solely for inpatient surgery			xxxx
Rooms in use solely for ambulatory surgery		xxxx	
Rooms in use and shared - inpatient/outpatient surgery	16	7,164	3,453
Rooms not in use	1	xxxx	xxxx
TOTAL OPERATING ROOMS	17		

B. Of the rooms in A. above, please report the number of surgical operating rooms and cases by any dedicated use.

Dedicated Use *	No. of Rooms	Inpatient Cases	Ambulatory Cases
General	2	1,413	353
Orthopedics	2	1,118	880
Ophthalmology	(one room dedicated to	22	33
Otolaryngology	all three uses)	133	155
Plastic Surgery	1	91	21
Gynecology		821	1,556
Open Heart	2	1,012	xxxx
Thoracic (other than open heart)	4	59	xxxx
Urology		301	301
Caesarean Section	2		xxxx
Neurosurgery		1,398	127
Other (specify) Vascular	2	796	27
Rooms Not in Use	1	xxxx	xxxx
Total OR's (should equal total in A above)	17	7,164	3,453

*primary use, not totally dedicated

C. Other rooms not equipped or meeting all the specifications for an operating room, dedicated to the performance of other procedures. (Do not list a room for more than one use.)

Use	No. of Rooms	Cases
Lithotripsy	Mobile	26
Cardiac catheterization (diagnostic)	4	3,301
Cardiac catheterization (angioplasty)	2	1,158
Obstetric delivery	30	3,903
Cystoscopy		
Endoscopy	2	1,672
YAG Laser		
Sutures		
Cast Procedures		
Other (specify)		

Attachment 5

State Of North Carolina

Department Of Human Resources
Division Of Facility Services
Certificate Of Need

Project Identification Number J-4947-93 Effective Date April 30, 1994

Issued to: Wake County Hospital System, Inc., Wake Medical Center
3000 New Bern Avenue, P. O. Box 14465
Raleigh, NC 27620-4465

The North Carolina Department of Human Resources, pursuant to the North Carolina Health Planning and Resource Development Act of 1978, G.S. § 131-175, et seq., as amended and recodified, G.S. §131E-175, et seq., hereby finds and certifies that the new institutional health service proposed by the person listed above is consistent with, or as conditioned is consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. The findings of the Department are attached hereto and incorporated by reference.

This Certificate affords the person listed above the opportunity to proceed with development of the proposed new institutional health service in a manner consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. This Certificate includes and is limited to:

SCOPE: See Reverse Side

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: 3000 New Bern Avenue, Raleigh, NC

MAXIMUM CAPITAL EXPENDITURE: $21,080,444.00

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: August 1, 1994

This Certificate is limited to the person listed above and is not transferable or assignable. This Certificate may be withdrawn as provided in G.S. §131E-189, and the rules and regulations promulgated thereunder.

Issuance of this Certificate does not supplant provisions or requirements embodied in codes, ordinances, statutes other than G.S. §131E-175, et seq., rules regulations or guidelines administered or enforced by municipal, state or federal agencies or the agent thereof.

Assistant Director
~~Chief, Certificate of Need Section~~
Division of Facility Services

DFS-8001CN (Rev. 3/85)

SCOPE: Construct a 113,350 square foot, four story addition to Wake Medical Center for the relocation and consolidation of selected existing cardiac services at Wake Medical Center, and for the development of leasable medical office space and family care space. The ground floor of the building will house patient registration, pre-registration testing and leasable medical office space; the first floor will house leasable medical office space; the second floor will house diagnostic and therapeutic cardiac services; and, the third floor will house a 26 room Family Care Center (i.e., unlicensed hotel-style rooms). The project also includes the construction of a 250 space parking garage and the acquisition of replacement and other medical equipment.

CONDITIONS:

1. Wake County Hospital System, Inc. shall materially comply with all representations made in its certificate of need application.

2. At completion of this project, Wake County Hospital System, Inc. shall have no more than four cardiac catheterization/cardiac angioplasty rooms and one electrophysiology room.

3. Wake County Hospital System, Inc. shall not develop or provide pediatric cardiac catheterization/angioplasty as part of this project.

4. In the scope of this project, Wake County Hospital System, Inc. shall not acquire equipment or incur expenses for any items listed in Table II.3 Detailed Capital Projects Budget that are not included in the project's proposed capital expenditure in Section VIII of the application.

5. Wake County Hospital System, Inc. shall include in its progress reports for development of this project all costs related to renovation of existing space in the hospital that is being vacated or remodeled as a result of this project.

6. Prior to the issuance of the certificate of need, Wake County Hospital System, Inc. shall acknowledge in writing to the CON Section acceptance and compliance with all conditions stated herein.

Conditions acknowledged and accepted in letter dated April 14, 1994.

TIMETABLE:

Completion of preliminary drawings----------July 1, 1994
Completion of final drawings and specifications----------November 1, 1994
Approval of final drawings and specifications by
Construction Section, DFS----------January 3, 1995
Approval of Site by Construction Section, DFS----------February 1, 1995
Contract Award----------March 1, 1995
25% completion of construction----------August 1, 1995
50% completion of construction----------December 1, 1995
75% completion of construction----------May 1, 1996
Completion of construction----------September 30, 1996
Occupancy/offering of service(s)----------October 1, 1996
Ordering equipment----------January - June 1996
Arrival of equipment----------January - June 1996
Operation of equipment----------June - October 1996

Attachment 6

PHILIPS

May 27, 2015

Ms. Martha Frisone, Assistant Chief
Mr. Michael J. McKillip, Project Analyst
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

Dear Ms. Frisone and Mr. McKillip:

WakeMed has selected Philips as its vendor to replace the cardiac catheterization equipment located in Room 4 at WakeMed Raleigh Campus. Prior to the installation of the new equipment, Philips will de-install the existing equipment, Integris Allura 9 (Serial Number 10) and remove it from North Carolina. Please accept this letter as documentation that the Integris Allura 9 will be removed from the State of North Carolina by Philips.

If you have any questions, please feel free to contact me.

Thanks

Mike

Michael Vitagliano
Director, Trade-in and Asset Management
Refurbished Systems
Philips Healthcare
595 Miner Road
Cleveland, Ohio 44143

Phone (440) 483-5931
Fax (440) 483-4302

michael.vitagliano@philips.com