DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

March 6, 2017

Elizabeth Kirkman
2709 Water Ridge Parkway
Suite 200
Charlotte, NC 28217

Exempt from Review – Replacement Equipment

Record #:	**2154**
Facility Name:	Carolinas HealthCare System NorthEast
FID #:	943049
Business Name:	The Charlotte Mecklenburg Hospital Authority
Business #:	1770
Project Description:	Replace Electrophysiology Lab
County:	Cabarrus

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of January 6, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Phillips AlluraClarity Xper FD10 to replace the Omega OMI-CS-10 Digital X-Ray. This determination is based on your representations that the existing 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,

Gregory F. Yakaboski
Project Analyst,
Certificate of Need

Martha J. Frisone
Assistant Chief,
Certificate of Need

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

Carolinas HealthCare System

January 6, 2017

Ms. Martha Frisone, Assistant Section Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health & Human Services
809 Ruggles Drive
Raleigh, NC 27603

RE: Replacement and Temporary Relocation of Electrophysiology Lab licensed under The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System NorthEast.

Dear Ms. Frisone:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System NorthEast (CHS NE) is planning to replace its existing electrophysiology lab (EP Lab) with new, technologically comparable equipment. CHS NE intends to purchase a Philips AlluraClarity Xper FD10 to replace an Omega OMI-CS-10 Digital X-Ray that was installed new in the summer of 2005 and is currently located at CHS NE. The existing equipment is near the end of its useful life and is at risk for service interruptions due to downtime.

As a part of Project ID #F-8219-08, CHS NE plans to permanently locate the EP Lab equipment on the first floor of the new construction. The new construction is currently under development but not yet complete. Given the need to replace the existing EP Lab equipment now, CHS NE proposes to temporarily locate the new equipment in room 12326. The existing equipment is located in room 26302 but this room will not accommodate the new equipment. Once the new construction is complete, CHS NE will permanently move the EP Lab equipment to the new construction. The cost to relocate and install the EP Lab to the new construction are included in Project ID #F-8219-08.

The Philips AlluraClarity Xper FD10 will be used for the same types of procedures as the existing equipment and it will not be used to provide a new health service. A chart comparing the existing equipment and the replacement equipment is included in Attachment A along with supporting documentation. The equipment is currently in use and documentation provided in Attachment B indicates 458 procedures were performed from September 2015 through August 2016.

The total cost to acquire, install and make operational the replacement equipment is $1,948,474 which includes construction costs of $524,000, consultant fees of $95,000, other fees of $35,000, and the Replacement Equipment of $1,294,474 ($1,199,244 for the X-ray which includes tax and freight, $89,000 for the ViewMate Ultrasound Imaging Console with Battery and P4-1C Trans-thoracic Transducer (ICE equipment) which includes freight and $6,230 for sales tax). Attachment C provides the quote for the EP Lab from Philips with equipment costs. Please see Attachment D for a letter documenting the equipment will be taken out of service and removed from North Carolina. The total capital cost schedule and certified cost estimate of the renovation required to install the new equipment are provided in Attachment E.

The North Carolina Certificate of Need statutes provide a definition of replacement equipment in N.C.G.S. 131E-176(22a). The definition requires the replacement equipment be comparable to the existing medical equipment and cost less than $2,000,000 when installed. The statutes further provide in 131E-184(a)(7) an exemption from certificate of need review for replacement equipment projects if prior notice is provided to the CON Section.

This letter serves as prior notification of our intent to proceed with this project. We would appreciate your written concurrence that this project is exempt from CON review. If you have any questions or require further information regarding this project, please contact me at 704-446-8475.

Sincerely,

Elizabeth Kirkman

Elizabeth Kirkman, Assistant Vice-President
CHS Strategic Services Group

Attachments

Attachment A

Comparison of Existing and Replacement Equipment

EQUIPMENT COMPARISON

Type of Equipment (List each component)	Existing Equipment	Replacement Equipment
Manufacturer of Equipment	Omega OMI-CS-10 Digital X-Ray	Phillips AlluraClarity Xper FD10
Tesla Rating for MRIs	N/A	N/A
Model Number	OMI-CS-10	100241
Serial Number	3043	Not Available Until Installed
Provider's Method of Identifying Equipment	CHS Asset # / Serial #	CHS Asset # / Serial #
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	Summer 2005	April 2017
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.) <Use Attached Form>	$728,416	$1,948,474
Total Cost of Equipment	$533,600	$1,294,474
Fair Market Value of Equipment	$26,680	N/A
Net Purchase Price of Equipment	$533,600	$1,294,474
Locations Where Operated	CHS NE – 920 Church St. N	CHS NE – 920 Church St. N
Number Days in Use/To Be Used in N.C. per Year	260	260
Percent of Change in Patient Charges (by procedure)	None	None
Percent of Change in Per Procedure Operating Expenses (by procedure)	None	None
Type of Procedures Currently Performed on Existing Equipment	Device Implants, EPS, Ablations, Tilt Table	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Device Implants, EPS, Ablations, Tilt Table

Electrophysiology Imaging

Single and Dual Plane Fluoroscopic Imaging Systems

Time Proven Performance and Reliability

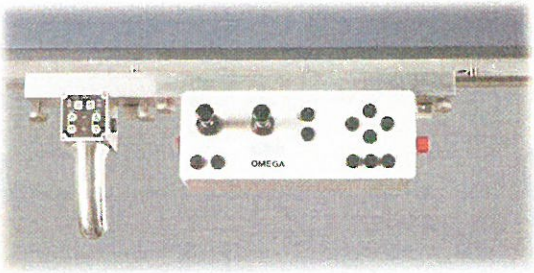
Omega Medical Imaging
Electrophysiology Imaging Systems

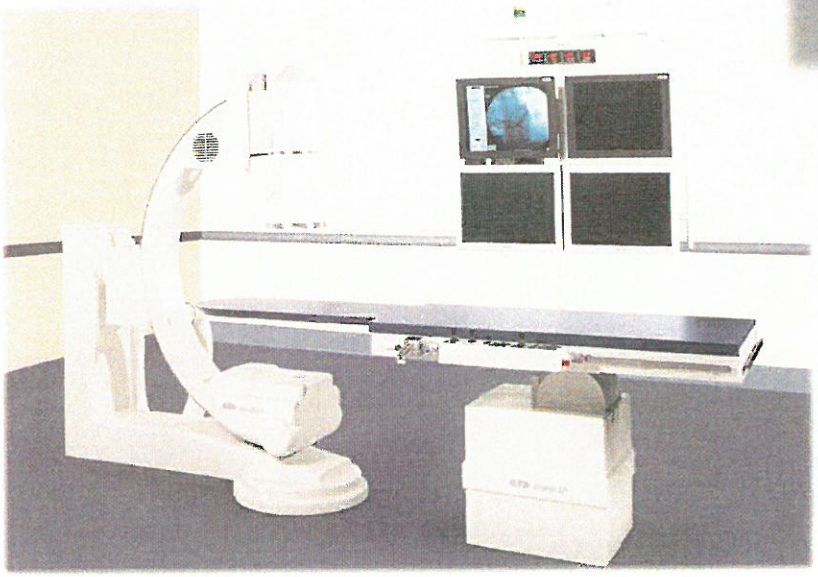
EP Digital Fluoroscopic Imaging Systems

Single Plane Imaging Flexibility

Omega's EP systems are offered in Single Plane and Dual Plane configurations. Two options for imaging are available on all systems – Fluoro & Fluoro Loop or Fluoro. Fluoro Loops and Cine are available to optimize individual department needs while providing a cost-effective solution for a full range of EP procedures.

All Omega EP systems feature RayStar,™ a proprietary integrated digital image processor tailored for high definition cardiac imaging. RayStar™ offers unmatched visualization of a variety of diagnostic and therapeutic EP catheters for catheter positioning. The all-digital platform provides fully integrated DICOM compatible networking capabilities. As a specialist in design and development of EP fluoroscopic imaging systems, Omega strives to manufacture cutting-edge technology at a competitive price point ensuring the highest value of investment in the industry.



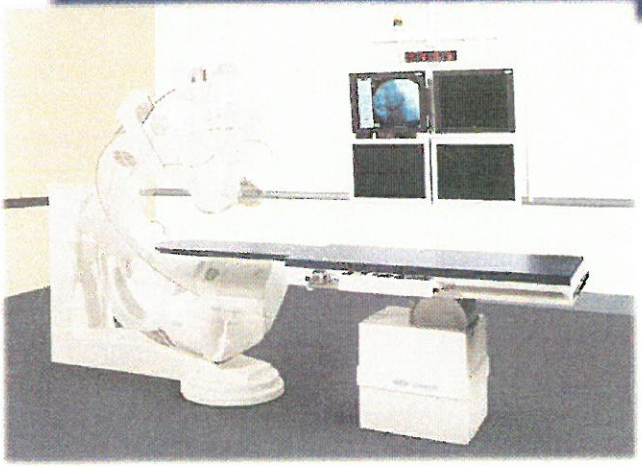


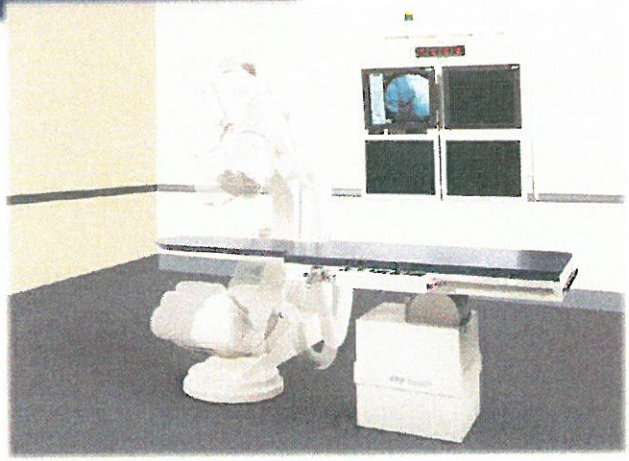
Single Plane System Controls

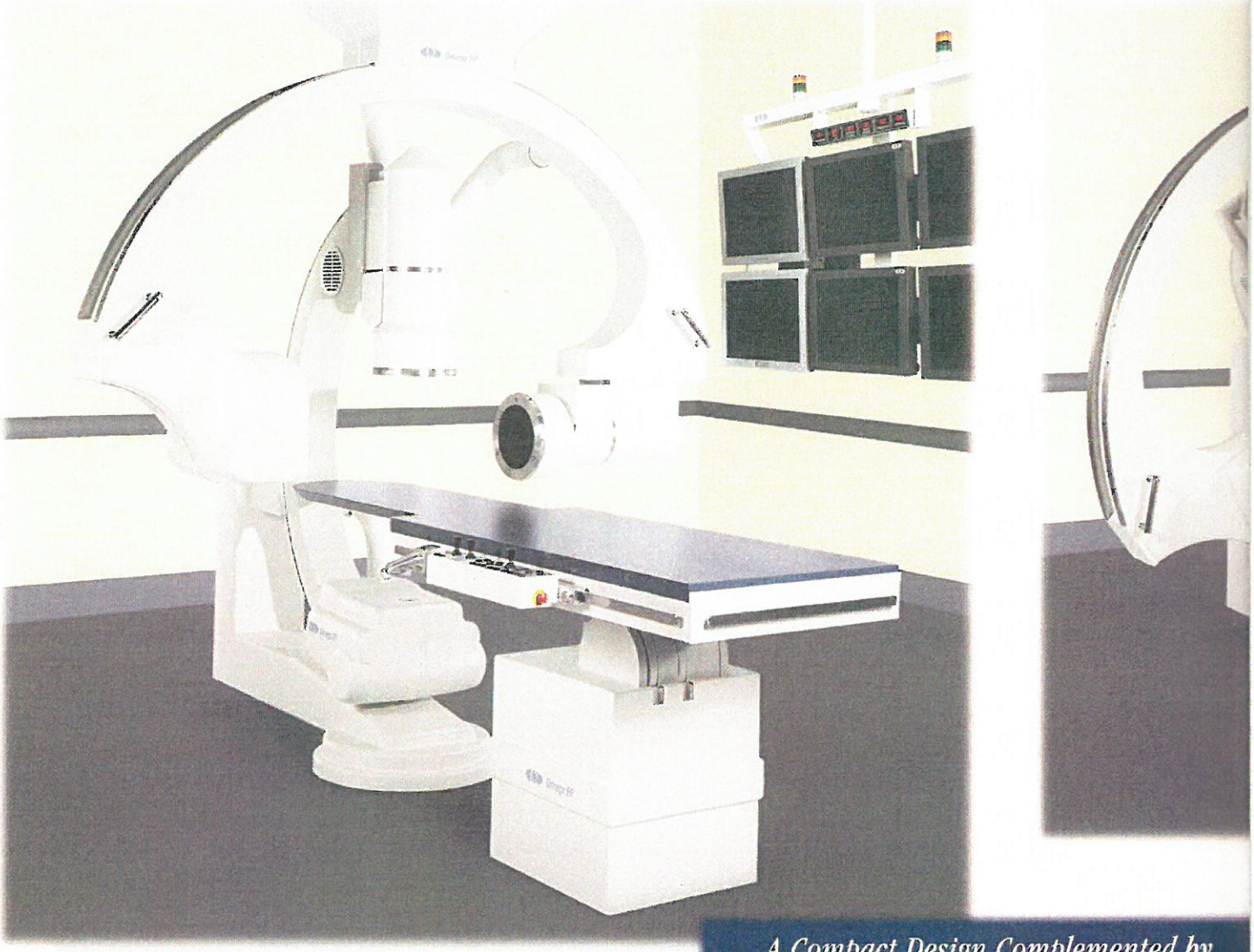
The Single Plane table controls consist of: panning handle, table elevation, and tilting functions.

The intuitive system controls consist of: joysticks for positioner movement, touch pads for image intensified MAG modes, variable SID and beam collimation. Both table and L/C positioner controls may be placed on either side of table, or the foot end of table.

Unmatched maximum positioner flexibility







A Compact Design Complemented by Unmatched Ease of Operation

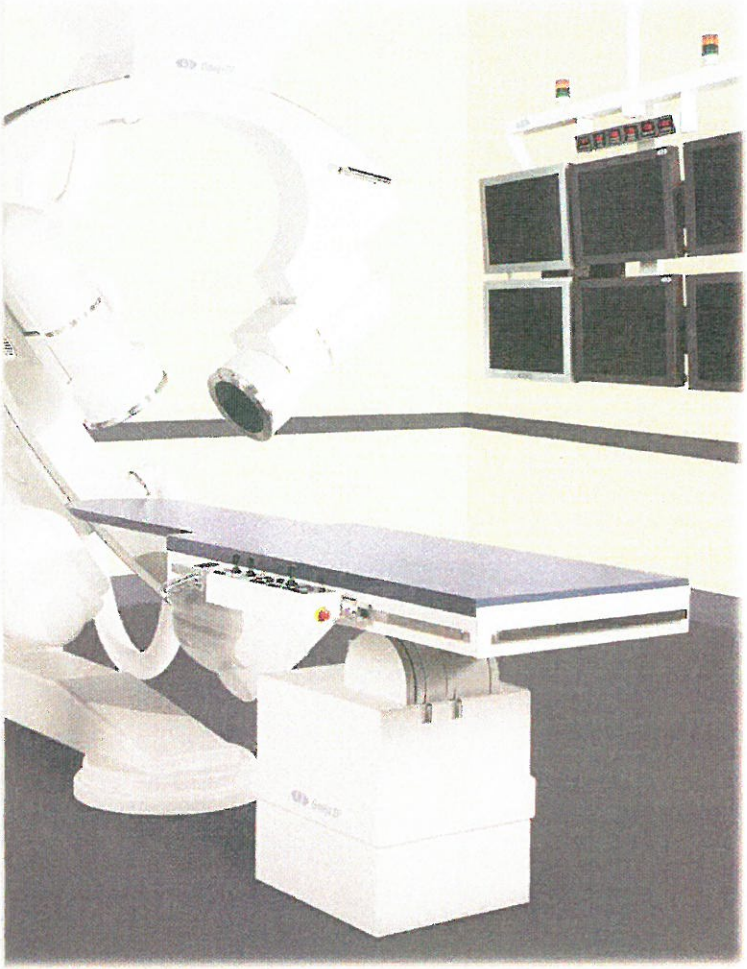
Dual Plane Imaging Considerations

The requirements for Dual Plane Fluoroscopic Imaging System have become more acute. The need to decrease procedure time and reduce radiation exposure to both patient and staff has become paramount in deciding between Single and Dual Plane Systems. In keeping with Omega's goal of maintaining its leadership position in price/value relationship, three cost-effective solutions for Dual Plane imaging are offered:

- Fluoro & Fluoro Loops
- Fluoro, Fluoro Loops and Digital cine
- Fluoro, Fluoro Loops, Digital Cine Frontal Plane and Fluoro, and Fluoro Loops Lateral Plane

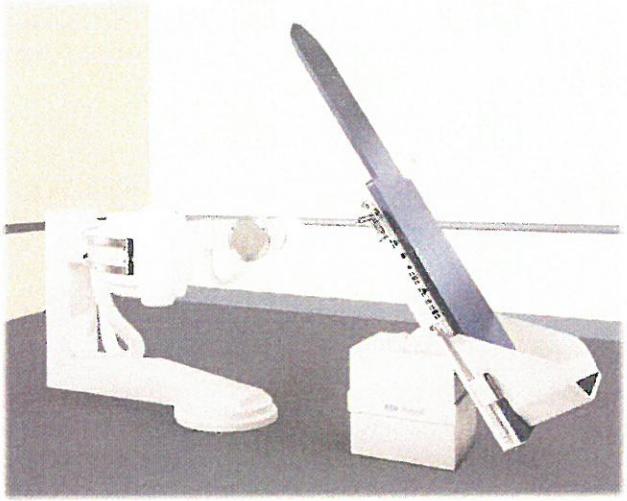
Synchronized Movement

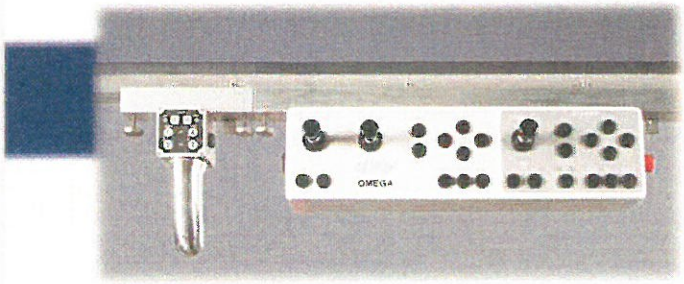
Omega's Dual Plane Fluoroscopic Imaging System allows the operator to position the frontal and lateral plane positioner independently of each other. Additionally, the operator may engage the interlock mode, which allows synchronous angulation of the positioners in LAO/RAO projections around the isocenter using a single joystick. Ease of operation is a benchmark of the Omega Dual Plane Fluoroscopic Imaging System. Outstanding image quality combined with performance reliability has established Omega's EP Fluoroscopic Imaging Systems as the industry leader.



Tilting/Elevating Table

Omega pioneered the pedestal EP table that features a four way floating tabletop. It is an ideally suited table for cardiac imaging that incorporates tabletop elevation and tilting, 15 degrees Trendelenburg and 80 degrees vertical. A safety interlock prevents longitudinal tabletop movement when tilting the top, while an "emergency down" tabletop feature provides a fast transition of the tabletop from the vertical to horizontal position.





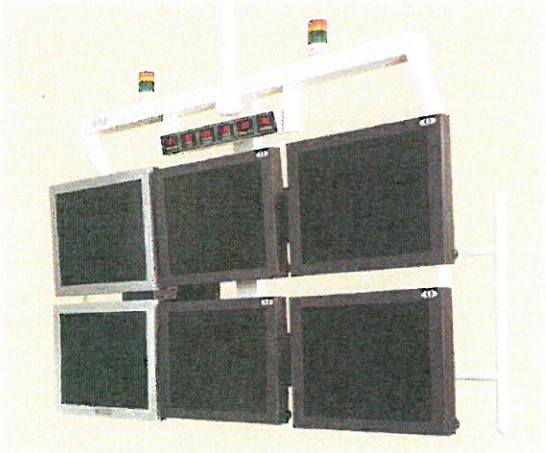
Dual Plane System Controls

The Dual Plane system controls consist of the same panning handle and operator controls that are utilized in the single plane system. Additionally, there are separate controls for operation of the lateral positioner.

When the Dual Plane mode is selected, a unique interlock function allows the lateral and frontal plane positioners to be operated synchronously with a single joystick.

TV Monitor-Suspensions

Ceiling mounted TV monitor suspensions are included with all Omega's EP Fluoroscopic Imaging Systems. These suspensions provide the required space for two TV imaging monitors (Single Plane), four TV imaging monitors (Dual Plane), along with additional space for EP slave and mapping monitors. All Omega monitor suspensions are moveable and can be positioned either right or left side of table.



Industry Leadership for Today's Demanding Requirements

The requirements for electrophysiology imaging have changed dramatically over the past few years. Omega Medical Imaging is the only manufacturer of dedicated electrophysiology imaging systems that has kept pace with today's demanding application requirements. Our Single and Dual Plane Fluoroscopic Imaging Systems are fully integrated and designed exclusively to fulfill the needs of EP, Pacemaker and ICD procedures.

A pioneer in the development of a dedicated EP tilting/elevating table, Omega's digital fluoroscopic image processing has set new standards in image quality. From inception, Omega's EP Fluoroscopic Imaging Systems have allowed viewing from the groin to the heart without interference from the x-ray positioner. These product features performance levels that exceed today's demanding requirements for EP exams.

Price/Value...

In 1991 Omega designed, developed and installed the first dedicated Electrophysiology Fluoroscopic Imaging System. Specializing in EP imaging, Omega has the knowledge and expertise to understand the needs of these demanding procedures. From our inception, Omega's EP Fluoroscopic Imaging Systems have lead the industry in providing reliable high quality imaging systems at a reasonable price/value relationship. All of Omega Medical Imaging systems are configured to optimize system flexibility and image quality by combining proven Table, Positioner and RayStar™ digital image processing technology.

- **Compact floor mounted tilting/elevating pedestal table**
  - ✔ four way floating tabletop with two-way tilting
  - ✔ fast action emergency down tabletop tilting
- **Floor mounted L/C positioner**
  - ✔ isocentric three axis positioner specifically designed for electrophysiology with all motorized movements combined with automatic image rotation
  - ✔ ergonomically designed movable tableside operator controls with touch sensitive joysticks for smooth and precise control of the positioner
  - ✔ easy to read digital displays for positioner and table
- **RayStar™ Digital Imaging System Processor**
  - ✔ true CCD 1024 x 1024 x 12 bit image resolution
  - ✔ cardiac digital processor for image acquisition and enhancement
  - ✔ X-ray generator featuring high performance variable pulsed fluoroscopy
- **Modular Design**
  - ✔ Omega is the only manufacturer that offers the ability for customers to purchase a single plane system that can later be upgraded to a dual plane system without any loss of the original investment in the single plane system

Specifications...

Today's electrophysiology systems require special features that provide distinct benefits to the operators and patients. Omega's systems are designed exclusively for EP imaging applications and performs with unsurpassed functionality for the demanding requirements of today and beyond.

- Variable pulsed fluoroscopy for radiation dose reduction
- Carbon fiber tabletop, designed for increased strength and radiation dose reduction
- Low absorption tabletop pad for radiation dose reduction
- High capacity x-ray tube for extended fluoroscopic times, digital spot or cine applications
- Cardiac digital imaging processor with user-friendly graphic imaging software
- High resolution Medical Grade flat panel displays
- Premium image monitor suspension with space allocation for EP slave and mapping monitors

Turning Possibilities into Solutions

A Sensible and Cost-Effective Approach

In selecting an electrophysiology imaging system, you'll want a product that leads – not follows – industry performance standards. With Omega Medical Imaging, you'll experience equipment that provides effective diagnostic results and leading edge technology, such as digital imaging, as well as a manufacturer dedicated to utilizing its knowledge and experience to turn possibilities into cost-effective solutions. With a history of leadership in EP imaging, Omega's commitment is to the development of cutting-edge technology in electrophysiology imaging systems.

Omega Medical Imaging, Inc., is the world leader in design, development and manufacture of dedicated electrophysiology imaging systems. Omega's mission is to deliver state-of-the-art technology imaging equipment at cost-effective prices. Customer satisfaction remains our steadfast goal. We pride ourselves on continuing product improvement programs, which include design review with direct feedback from customers and EP LAB team members.

As a medical equipment manufacturer, Omega operates its business in accordance with FDA's Quality Systems Regulations. Our products are certified to UL Standards and comply with uniform hospital electrical safety standards.

Omega headquarters and production facility in Sanford, Florida

Omega products are represented nationally through a partnership with our exclusive distributors, specializing in cardiac sales and service. Over the years, this partnership has developed into a relationship based on professional and knowledgeable personnel who are experts in Cardiac imaging. Omega's national support program provides factory-trained engineers and application staff who assist distributors through regularly scheduled training programs.

Look to Omega Medical as your best source for experience and knowledge in EP imaging – our people, products, service and support – for imaging systems of today and tomorrow.

Unsurpassed simplicity, performance and reliability...

Omega Medical Imaging
Cardiac and Vascular Imaging Systems

Omega Medical Imaging, Inc.
675 Hickman Circle
Sanford, FL 32771

(407) 323-9400
(407) 323-9331 Fax

Making the difference with Philips Live Image Guidance

Philips AlluraClarity family FD10 specifications

PHILIPS

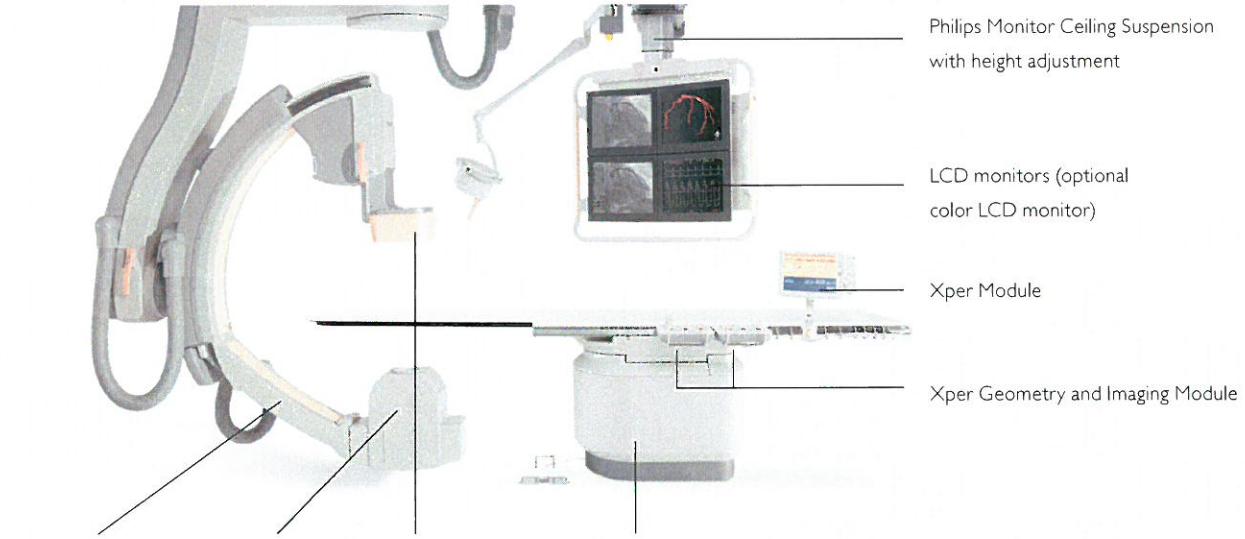
Contents

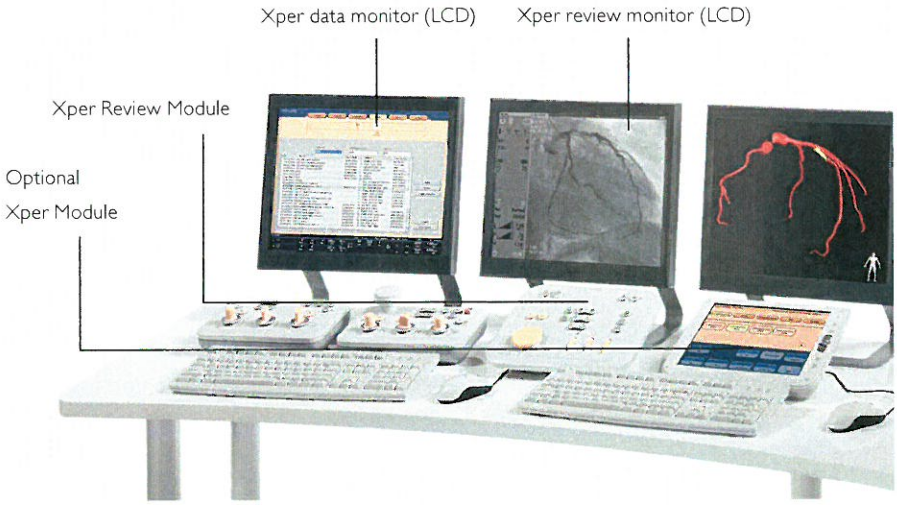
Making the difference where it really matters

Philips AlluraClarity family, see with confidence - every time

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 low dose levels.

Example configuration for the system





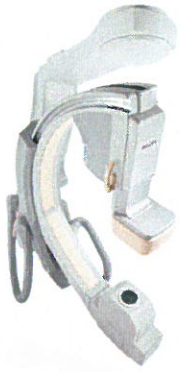
The Philips AlluraClarity family FD10 comprises the Philips Allura Xper FD10 system model AlluraClarity and the Philips Allura Xper FD10 OR Table system model AlluraClarity.

1 Geometry

1.1 Stand

The G-shaped stand maximizes speed and provides excellent patient access. The rock stable stand design offers fast and easy tableside operation. The stand, monitor suspension, and operating modules can be freely positioned for full applicational flexibility. The unique G-shaped of the stand allows you to reach the groin without repositioning and allows a wide range of projections.

The exclusive BodyGuard patient protection mechanism is designed to protect the patient from unexpected contact between the detector and the body. It uses capacitive sensing to prevent collision, while allowing stand positioning at up to 25°/s.



FD10 Ceiling G-stand

FD10 Floor G-stand[1]

Features	Specifications
Iso-center to floor	FD10 ceiling and floor is 106.5 cm (41.9 inch)
Longitudinal movement	FD10 ceiling has a motorized and manual range of 260 cm (102.4 inch) at 15 cm/s (6 inch/s.). It includes auto stops at the park position, cardio position, neuro position and lower peripheral position
	FD10 floor has no longitudinal movement. It pivots on the stand base for -90° to + 90°
L-arm rotation	FD10 ceiling has motorized and manual movement, over 180° with snap positions at 90°, -0°, -90° to allow patient access from three sides of the table
G-stand rotation / speed	FD10 ceiling and floor in head-end position: 120° LAO, 120° RAO up to 25°/s FD10 ceiling in side position: 45° LAO, 45° RAO up to 18°/s
G-stand angulation / speed	FD10 ceiling and floor in head-end position: 45° cranial, 45° caudal up to 18°/s FD10 ceiling in side position: 120° cranial, 120° caudal up to 25°/s
Focal spot to iso-center	76.5 cm (30.1 inch)
Source Image Distance	86.5 - 123 cm (34.1 to 48.4 inch)
G-stand depth	105 cm (41.3 inch)
Programmable positions	Two positions standard

Optional

Automatic Position Controller (APC)	Functionality for the stand is accessed through the Xper Module at the patient tableside. • This option includes a programmable position extension, which allows you up to ten different stand positions per clinical procedure • Another feature of the APC is reference-driven positioning. This allows you to recall stand positions by referring to the images at the reference monitors, which means that the rotation, angulation, SID, and detector orientation are restored to the original settings of the reference image.

Optional

FlexMove²

Many clinicians are depending more and more upon high quality X-ray imaging to perform minimally invasive and open surgical procedures in one room. But how can team members work efficiently around this and other equipment in such a crowded environment? FlexMove provides the answer. It is a option for our AlluraClarity family that offers exceptional flexibility for the hybrid OR. FlexMove can be moved longitudinally and transversally, allowing you to examine the patient without panning the table and tangling up wires and tubes. This full range of movement frees up the operating area so physicians and staff can work in their normal positions and easily access the patient.
The X-ray system provides full body coverage and does not clutter up floor space.

Benefits:

- Works around you. Lateral standby position for quick access when needed and to improve patient access
- Saves space and time. During open surgical procedures, FlexMove can be parked in the corner
- Accommodates laminar air flow units and frees up floor space to simplify room cleaning

"We are delighted with the way the FlexMove ceiling suspension allows you to bring the imaging system to the table, the way you can park it away from the table, the way you can rotate it, and the way you can bring it to exactly the position you want."

Prof. Mario L. Lachat M.D.

Specifications	
Ceiling Height:	FlexMove is compatible with two different ceiling heights: 2900 mm (short L-arm + 20 cm FlexMove construction) or 3100 mm (normal L-arm + 20 cm FlexMove construction)
Length of Y-rails (parallel to center line of table):	6621 mm (movement range 4356 mm) 7621 mm (movement range 5356 mm)
Distance between Y-rails (perpendicular to center line of table):	3700 mm (movement range 2600 mm)

1.2 Xper tables

The Xper Table Standard and Xper table are dedicated interventional X-ray tables that supports a full range of applications. A feather-light free floating tabletop helps maintain your region of interest and reduce effort. It has very high patient loadability and CPR can be performed on the table.

Xper Table Standard (without options)	
Table height (min.-max.)	74.5 cm - 102.5 cm (29.3 inch - 40.4 inch)
Table top length	319 cm (125.6 inch)
Table top width	50 cm (19.7 inch)
Longitudinal float range	120 cm (47.2 inch)
Lateral float range	36 cm (14.2 inch)
Max. table load	325 kg (715 lbs)
Max. patient weight	275 kg (606.3 lbs) + 500 N additional force max. tabletop extension in case of CPR

Optional

Auto isocenter positioning

With this option, the X-ray beam automatically adapts to the table movement to keep the region of interest in the isocenter of rotation and angulation of the stand. This FD20 ensures that your region of interest always remains centered.

Store and recall

Reproducing precise coordinates (height, longitude and latitude) is critical for obtaining accurate visualizations. The optional automatic position controller brings the Xper table back to the original table position stored, without applying additional X-ray dose.

Pivot

Transradial access, upper extremity angiography, and patient transfer have never been simpler with our optional Pivot feature. One finger push-to-pivot allows effortless patient positioning. It moves with less friction, making it easier to move larger patients. A secure mechanism locks the tabletop in place to prevent it from moving.

Tilt

Our option tilt functionality allows you to tilt the table for gravity oriented or puncture procedures. As the table tilts, the X-ray beam automatically adapts to the movement to keep the region of interest in the isocenter of rotation and angulation of the stand. As a result, your region of interest always remains centered.

Tilt and cradle

Many electrophysiology and non-vascular procedures benefit from additional positioning options. Our Xper table with isocentric tilt and cradle-tilt functionality puts your gravity oriented or guided puncture procedures at the required angle.

Technical specifications

Options	
Auto Isocenter positioning	Automatic Position Controller in table
Store/Recall table position	Automatic Position Controller in table
Pivot	-90°/+180° or -180°/90°
Swivel (includes pivot)	Extended longitudinal range: 78.2 cm (30.8 inch) Height: +8.5 cm (3.3 inch), Pivot range: -180°/90° only
Tilt and Cradle	Tilting range: ±17° iso-centric, Cradle tilting range: ±15°, Height: min +4 cm (1.6 inch), max +1 cm (0.4 inch)
Tilt	Tilting range: ±17° iso-centric, Table height: min. +4 cm (1.6 inch), max. + 1 cm (0.4 inch)

Interface to MAGNUS OR Table

In addition to the Xper table, the AlluraClarity family can be equipped with an interface to the MAGNUS operating table system (fixed column), manufactured by MAQUET. This allows you to use a fully OR compliant patient table with the AlluraClarity family. This integration helps enhance:

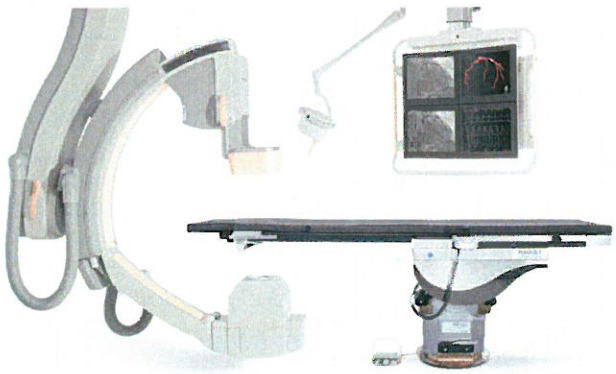
Enhanced Care

- With the integrated emergency stop, all motorized movements (including table) are stopped when the Allura emergency stop button is pressed.
- With the integrated collision detection, all motorized movements (including table) are slowed down or stopped when BodyGuard detects the patient.

Workflow

- All patient positioning movements are supported via the Xper Geometry module and MAGNUS (MAQUET) user interface controls, including transporter, table height, tilt, cradle, longitudinal/ lateral movement, reset geometry, and synchronized patient orientation.

Advanced functionality includes the isocentric tilt feature that tilts the tabletop while keeping the point of rotation fixed in the isocenter of the imaging system. The syncra tilt feature synchronizes the stand orientation with the isocentric tilt movement so that the view stays perpendicular to the tabletop surface.



FD10 with Xper OR Table

The OR table is available with two different tabletops, the modular tabletop for open surgery and the radio translucent tabletop for endovascular and hybrid procedures. The tabletops can be easily exchanged using the transporter, allowing smooth transfer of patients between procedures.

The exceptionally balanced, modular design of the OR tabletops facilitates extreme positioning, allowing both microsurgery and larger operations to be carried out. The special height adjustment options allow clinicians to work in a comfortable position.

With the innovative slope saddle technology of the table columns and the extreme positioning options, MAGNUS already fulfills the requirements of tomorrow, today. The fixed column version is used in combination with the AlluraClarity family.

Superb advantages

Thanks to its highly modular design, the OR table can be quickly adapted to meet the needs of new interventional and surgical requirements.

OR table configurations are available for every specialist field. The OR table can be positioned at extreme tilt and slope angles to provide improved patient access during surgery and may help to reduce cut-and-stitch times during minimally invasive procedures. With the radio translucent OR table, the length and width of the radio translucent areas have been extended to support larger imaging spaces.

Please see MAQUET Brochure 1180_MSW_ BR_10000045 for additional specifications on the modular version and MAQUET Brochure 1180_MSW_ BR_10000815 for additional specifications on the carbon fiber table top version.

1.3 Philips Monitor Ceiling Suspension

The Philips Monitor Ceiling Suspension allows flexible, freely rotating positioning with a concave set-up of the monitors for an excellent viewing angle. This option works only with Philips monitors and it is not available for FlexMove. FlexMove requires third party ceiling booms to mount display monitors. A separate integration kit is available for third party monitor suspensions and ceiling booms.

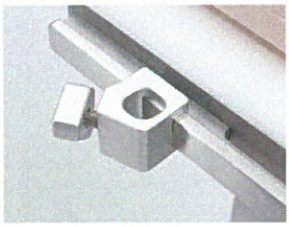
Feature	Specifications
Number of monitors	One, two, three, four, six or eight monitors
Rotation range	350°
Transversal movement	Over a distance of 300 cm (118.1 inch)
Longitudinal movement	Over a distance of 330 cm (129.9 inch)

1.4 Accessories

Standard accessories

Mattress
Patient straps
Set of arm supports (if cradle option is chosen)
Drip stand
OP rail accessory clamps
Cable holders (15 pieces)

Mattress (standard delivery of one piece per table)



OP rail accessory clamps

Optional

Optional accessories

Panhandle
Neuro Mattress (if Neuro tabletop)
Longer Cardio Mattress
Head support
Arm support, incl. arm pad
Neuro wedge
Table clamp
Set handgrips and clamps
Additional OP-rail with cable extension kit for Xper Modules
Ratchet compressor
Additional OP-rail
Auxiliary OP rail for table base
Examination light
Arm support (height adjustable)
Table X-ray protection
Peripheral X-ray filter
Pulse cath arm support
Ceiling suspended radiation shield

Head support

Ceiling suspended radiation shield

Panhandle

Table X-ray protection

2 User Interface

Tailor made customized operating User Interface is available per user (groups) and per desired application. Xper stands for "X-ray Personalized", and reflects the expert nature of the AlluraClarity family, which is based on several generations of proven technology.

2.1 Xper User Interface in the examination room

In the examination room, the Xper User Interface comprises the On-Screen Display, the Xper Module, and the Xper Imaging and Geometry Modules. Information is displayed on the On-Screen display in the examination room.

The Xper Geometry and Imaging Module can be positioned on three sides of the patient table. The Modules adjust to the position to retain the intuitive button operation. Both the Xper Geometry and Imaging Module have a protection bar that prevents unintended activation of system.

Xper Viewpad Controls

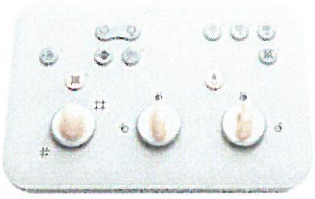
Xper Module

Xper User Interface
X-ray indicator
X-ray tube temperature condition
Radiographic parameters: kV, mA, ms
Rotation and angulation of the stand positions
Source Image Distance (SID)
Table height
Detector field size display
General system messages
Selected frame speed
Fluoroscopy mode
Integrated fluoroscopy time
Air Kerma dose (both rate and accumulated X-ray dose)
Dose Area Product (both rate and accumulated X-ray dose)
Graphical bars for body zone specific X-ray dose rate and accumulated Air Kerma levels related to the 2Gy level for cardiac procedures
Stopwatch

Xper Viewpad controls
Run and image selection
Exam and run cycle
Review speed
Run and exam overview
Laser pointer
Active exam sub files (exposure image/runs, reference images, print file)
Flagging exam and run for storage
Digital zoom
Storing reference run or image to reference monitors
Select reference monitors for review and/or processing of previous run exposures
Subtraction and image mask selection

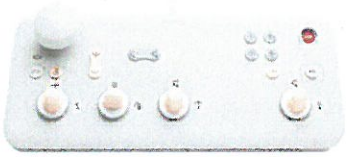
Xper Module
Acquisition setting
Image Processing
USB port for data transfer
Automatic Position Control (APC), optional
Quantitative Analysis (QA), optional
Table Automatic Position Controller, optional
Interventional tools table side control, optional
Xcelera table PACS side control, optional
Xper Flex Cardio table side control, optional
CX50 table side control, optional

Xper Geometry Module[3]



Xper Imaging Module

Xper Geometry Module



Xper Geometry Module Tilt FlexMove

Xper Geometry Module Tilt OR Table FlexMove

Xper Geometry Module
Tabletop float
Tabletop motorized float[3]
Table height position
Table tilt angle (if the tilt option is selected)
Table cradle angle (if the cradle option is selected)
Source Image Distance selection
Stand positioning
Longitudinal and lateral movements (FlexMove only)
Longitudinal movement of the stand along the ceiling
Stand rotation in an axis perpendicular to the ceiling
Store and recall of two scratch stand positions including SID and detector orientation
Emergency stop button
Accept button of the Automatic Positioning Control
Geometry reset button, which resets stand and table to a default service configure able starting position

Xper Imaging Module
Fluoroscopy mode selection as defined via Xper settings
Positioning of shutters and wedges without radiation
Manual or automatic wedge including position on the last image without radiation
Xper fluoro storage to record fluoroscopy up to 999 images
Selection of the detector field size
Preferred beam width
Reset of the fluoroscopy buzzer
Selection of Roadmap Pro function
Selection of SmartMask function

2.2 Xper User Interface in the control room

The Xper Viewing Console comprises a LCD color data monitor for patient data and system information management, including radiographic parameters, and a monochrome review monitor and Review Module enabling efficient exam viewing and post-processing. The monitors have the ability to extend the screen area to multiple screens.

Xper Data Monitor
Scheduling
Preparation
Acquisition
Review
Report
Archive

System information
Stopwatch and Time
System guidance information
Dose Area Product (DAP) and Air Kerma X-ray Dose (both rate and accumulated X-ray dose)
Frame speed settings, fluoroscopy mode and accumulated fluoroscopy time
Exposure and fluoroscopy settings, such as Voltage (kV), Current (mA) and pulse time (ms)
Stand position information, such as rotation, angulation and SID

Xper Review Monitor

The Xper review monitor is a monochrome LCD monitor that has the ability to extend the screen area to multiple screens.

Xper Review Monitor
Step through file, run or images
File and run overview
Image processing features such as contrast, brightness and edge enhancement
Flagging of runs or images for transfer
Image annotation
Automatic printing
Video invert
Zoom and pan image
Electronic shutters
Toggle switch physio
Store/delete images/runs
Store fluoro
Pixel shift
Quantitative Analysis Packages, optional
Subtraction, optional
Move or renew mask, optional
Landmarking (increase/decrease of subtraction degree), optional
View trace, optional

Xper Review Module

The Xper Review Module is a review station for basic interventional X-ray viewing needs. The most often used functions can be controlled by the touch of a button.

Xper Review Module
Power on/off of the system
Tagarno wheel to control the review of a patient exam
File and run cycle
Adjustment of contrast, brightness, and edge enhancement
File, run and image stepping
Run and file overview
Basic review functionality, such as image invert and digital zoom
Go to default settings
Reset fluoroscopy timer and switch X-ray on/off

2.3 User Interface options

Optional

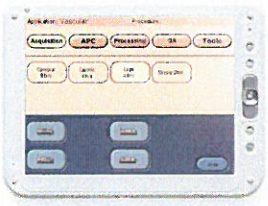
Xper Pedestal[3]

The Xper Pedestal creates a flexible workspot for operating the system from the examination room. The pedestal is equipped with an Xper Geometry and Imaging Module and can also hold the X-ray footswitch. The Xper Pedestal can be positioned freely around the patient table and can be put aside when not in use.

Xper Pedestal with Xper Module and Footswitch

Second Imaging or Geometry Module. Third Xper Module

The FD10 can be extended with additional Xper Modules that have the same functionality as the Xper Module in the examination room. Adding a second Imaging or Geometry Module in the control room works in a master-slave configuration.



Up to three Xper Modules

Contrast Injectors

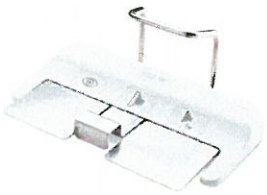
The system can be connected to contrast injectors to enhance procedures.

Second Xper Geometry Module

Second Xper Imaging Module

Wireless Footswitch

Our Wireless Footswitch[4] streamlines workflow, reduces clutter, and simplifies preparation and clean-up where it's needed most – at the point of patient treatment. Clinicians can wirelessly control the X-ray system from any convenient position around the table. No sterile covers are needed with the IPX8 certified waterproof design. It's one of Philips Live Image Guidance solutions for X-ray environments.



Wireless Footswitch

3 X-ray generation

3.1 X-ray generator

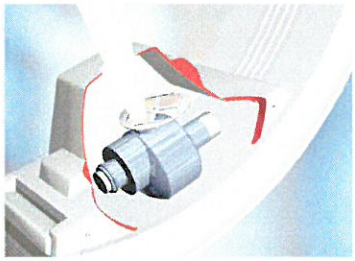
The Certeray generator is enhanced for the latest interventional X-ray needs.

Features	Specifications
Generated power	Microprocessor-controlled, 100 kW high frequency generator with MOSFET technology
Minimum switching time	Quartz-controlled power switch, with a minimum switching time of one ms
Voltage range	40 to 125 kV
Maximum current	1000 mA at 100 kV
Maximum continuous power	2.5 kW for 0.25 hours and 1.5 kW for 8 hours
Nominal power (highest electrical power)	100 kW (1000 mA at 100 kV)

With Xper settings on the Xper Module, different exposure protocols can be customized for every clinical application.

3.2 X-ray tube

The AlluraClarity FD10 is provided with the legendary high power MRC-GS 0508 X-ray tube which allows for very high heat dissipation, enabling SpectraBeam filtration to manage the patient X-ray dose.



SpectraBeam filtration

Features	Specifications
Focal spot size and loadability	0.5/0.8 nominal focal spot values with maximal 45 respectively 85 kW loadability based on 250 W anode reference power
Grid-switched pulsed fluoroscopy	Yes
Fluoro power for 10 minutes	4,500 W
Fluoro power for 20 minutes	3,500 W
Maximum anode cooling rate	910 kHU/min
Max. anode heat storage	2.4 MHU
Max. assembly heat storage	5.4 MHU
Anode heat dissipation	11,000 W
Continuous anode heat dissipation	3,200 W
Max. assembly continuous heat dissipation	3,500 W
Extra pre-filtration	SpectraBeam dose management with 0.2, 0.5, and 1.0 mm Copper equivalent SpectraBeam filters
Cooling liquid	Oil cooled X-ray tube with thermal safety switch
Anode cooling method	Direct anode oil cooling system with 200 mm anode diameter

4 Dose Management

Philips new generation of interventional X-ray systems, the AlluraClarity gives you unparalleled live image guidance during treatment. What's more, you can confidently manage low X-ray dose levels without changing your way of working. In short, you can see what you have to regardless of patient size.

4.1 ClarityIQ technology

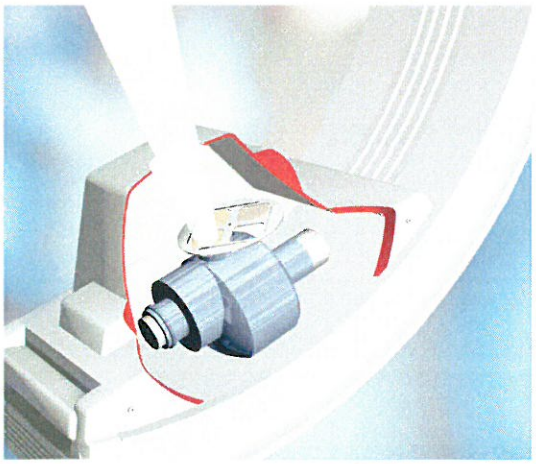
Excellent visibility at low dose levels with patients of any size

We are aware 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.

Of course, you could increase the amount of X-ray dose used. Yet an increase in abdominal width of just an inch necessitates twice the level of radiation in order to maintain image quality. We have tackled this issue head on with ClarityIQ technology.

SpectraBeam

The combination of SpectraBeam with the MRC-GS 0407 tube allows increased X-ray output with better filtration of soft radiation. This manages patient X-ray dose for interventional X-ray applications, while maintaining the same excellent image quality.



Spectrabeam with unique beam filtration

Specifications
Copper filters: 0.2, 0.5, and 1.0 mm Cu equivalent
The filters can be programmed via Xper settings
Three fluoroscopy/cine modes per application can be selected at tableside

Xper Beam Shaping

Xper Beam Shaping allows for virtual collimation of the shutters and wedges on the last X-ray image, eliminating additional X-ray dose during collimation changes.

Double shutters / wedge filters

Double wedge filters provide outstanding image quality in all projections. The wedge filters allow exceptional exposure and hence excellent image quality is maintained (with low patient entrance X-ray dose).

Anatomical filters

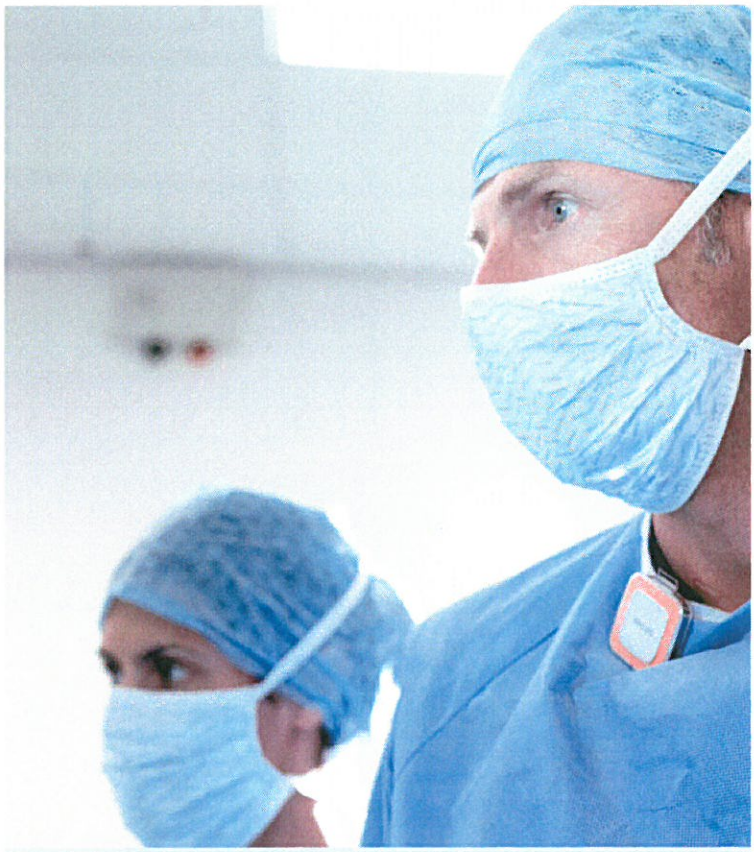
Filters are designed to compensate for large absorption differences in the anatomy of interest. There are special filters for cerebral angiography and the optional lower peripheral angiography.

Automatic wedge positioning

Wedge filters can be positioned automatically according to stand positions.

X-ray indicator light

The FD20 biplane has an integrated "X-ray On" indicator light located above the LCD monitors that is clearly visible from virtually anywhere in the room.



4.2 Dose awareness

Real-time dose information at tableside

Relevant dose information is integrated in the On-Screen User Interface of the LCD exam room monitors of the FD10 system. It provides the user with relevant X-ray dose information, including accumulated and rate values of patient Air Kerma and X-ray Dose Area Product. In addition, body zone specific X-ray dose rates are displayed for cardiac procedures. X-ray dose rates can be controlled by the user at tableside, by choosing a different fluoro mode.

X-ray dose information in the control room

X-ray dose information is also available in the control room. Cumulative X-ray dose is displayed on the Xper data monitor.

X-ray dose information in the examination report

Examination report data can be provided via the RIS/CIS DICOM two-way interface, to the RIS/CIS (MPPS protocol). An X-ray dose report can optionally be printed or e-mailed (in background) at the end of each examination at the touch of a button. Body zone specific information is included.

DICOM Radiation Dose Structured Report

Collection of dose relevant parameters and settings with export possibility to a DICOM database[5] (e.g. PACS, RIS). The reported data can be used for analysis, to further manage X-ray dose. The DICOM RDSR function collects and exports the required data. The software to provide the DICOM data for analysis and alerting needs to be acquired separately.

The Secondary Capture Dose Report function allows you to save & transfer, manually or automatically, a patient Dose Report to PACS in DICOM secondary capture format.

DoseAware family

Real-time dose feedback to increase radiation awareness and promote healthier working practices Philips DoseAware family of real-time dose feedback tools is designed to make it easier for people working in X-ray environments to monitor their radiation exposure in daily work and adopt healthier working practices.

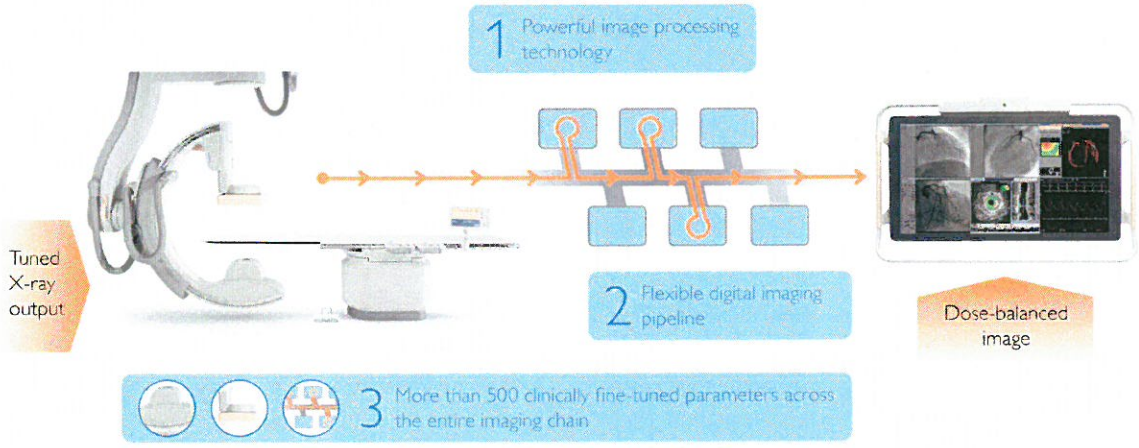
DoseAware Xtend is a dedicated solution for rooms with Philips FlexVision XL display that provides feedback on scattered X-ray dose per procedure received by staff and proactively encourages healthy radiation practices. DoseAware is a flexible solution that can be used in any X-ray room to provide real-time feedback on scattered X-ray exposure.

Together we can make a difference to the health of medical professionals who work in the interventional environment.

5 Imaging

Interventions are becoming increasingly complex. This, in turn, lengthens fluoroscopy time and increases the need for high resolution imaging. New devices can be more difficult to visualize, making it harder to position them precisely and the prevalence of patients with a high BMI can necessitate increased dose levels in order to visualize anatomy. All of these factors inspired us to completely redefine the balance in interventional X-ray with our new Philips AlluraClarity family.

Revolutionizing interventional imaging with unique ClarityIQ technology



5.1 ClarityIQ technology

How do we continue to make the difference in interventional imaging? By drawing upon our unique imaging expertise and collaborating closely with highly-critical interventional physicians around the world. To create a breakthrough in interventional imaging and dose management, we evaluated the performance of the system as a whole instead of its individual components. During this process we clinically fine-tuned more than 500 parameters, improved relevant system components and ultimately redesigned the entire digital imaging pipeline.

1.Powerful image processing technology

Clarity IQ technology includes state-of-the-art, real-time image processing, developed by Philips Research and based on the latest parallel computing technology. Benefits include

- Noise and artifact reduction, also on moving structures and objects;
- Image and edge enhancements;
- Automatic real-time patient and accidental table motion correction on live images.

2. Completely redesigned, flexible digital imaging pipeline

ClarityIQ technology utilizes a flexible digital imaging pipeline from tube to display that is tailored for each and every application area such as cardio or neuro. This gives the flexibility to select virtually unlimited application-specific configurations and obtain superb images on your full range of clinical applications and patient types including patients with a high BMI.

3. More than 500 clinically fine-tuned system parameters and enhanced relevant system components across the entire imaging chain

With ClarityIQ technology over 500 system parameters are fine-tuned for each application area with ClarityIQ technology; the result of years of Philips' clinical leadership. ClarityIQ technology also enhances some essential system components. It is now possible to manage radiation by increased filtering, use small focal spot sizes as well as shorter pulses with the grid switching technology of Philips MRC tube and accompanying generator.

5.2 Dynamic Flat Detector

The dynamic Flat Detector of Philips provides excellent image quality.

Features	Specifications
Size of detector housing	37 cm (14 inch) diagonal, including BodyGuard
Physical detector size	28 cm (11 inch) diagonal
Maximum field of view	25 cm (10 inch) diagonal
Image matrix	1024 x 1024 pixels at 14 bits depth
Detector zoom fields	20 and 15 cm (8 and 6 inch) diagonal square formats
Pixel pitch	184 x 184 µm
Detector bit depth	14 bits
Nyquist frequency	2.72 lp/mm
DQE (0)	75% at 0 lp/mm
Digital output	$1k^2$ and 512^2 at 8 or 10 bit depth resolution
MTF at 1 lp/mm	> 60%

5.3 Fluoroscopy

Per application, three fluoro modes are available at tableside which can be programmed via Xper settings. Each mode can be programmed with a different composition of ClarityIQ parameters. ClarityIQ technology provides a flexible digital image pipeline, powerful image processing technology and clinically fine-tuned parameters across the entire imaging chain.

Features	Specifications
Extra pre-filtration	SpectraBeam filters: 0.2, 0.5 and 1.0 mm CU equivalent
Fluoroscopy image processing	Noise and artifact reduction on moving structures and objects, automatic motion compensation to eliminate blur on live images and image enhancement and edge sharpening
Pulse rates	Default at 3.75, 7.5, 15 and 30 pulses per second
Frame grabbing of static fluoroscopy images	Yes
Fluoroscopy storage	Default storage of the last 10s, programmable up to 999 images of fluoroscopy for reference or archiving
Grid-switched pulsed fluoroscopy	Yes

Acquisition frame rates

	1024 x 1024 matrix
Standard configuration	3,75, 7,5, 15 and 30 images/s.

Up to 30 images/s. acquisition at a 1024 x 1024 matrix is optionally available

Up to 60 images/s. acquisition at a 512 x 512 matrix is optionally available

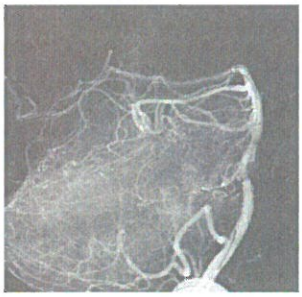
Storage capacity

	1024 x 1024 matrix
Standard configuration	50.000 images
Storage extension (optional)	100.000 images

5.4 Clinical enhancements

Roadmap Pro

Roadmap Pro is based on Philips new double contrast, Digital Subtraction Angiography (DSA) vessel technique. It provides the optimal balance of image quality and X-ray dose for visualizing vessels and devices. It also delivers an unsubtracted roadmap, which overlays the relevant roadmapping information to live fluoroscopy. A choice of low, normal, and high patient X-ray dose settings helps manage radiation exposure. This technique delivers strong and consistent imaging performance to support all anatomical areas and interventional applications.



The roadmapping tool tailored for specific clinical applications

5.5 Digital acquisition

The AlluraClarity FD10 system can be customized with a virtually unlimited number of acquisition programs for digital angiography and digital subtraction angiography. Image resolution is up to 2048 x 2048 pixels for vascular imaging and 1024 x 1024 pixels for cardiac imaging when Frame Rate Extension option is selected.

5.6 Subtraction package

The Digital Subtraction Angiography (DSA) extends the vascular applicational functionality of the AlluraClarity system. DSA features real-time digital subtraction at low frame speeds of 0.5, 1, 2, 3, or 6 frames per second. The DSA programs can be selected via the Xper settings. The exposure technique provides exceptional image quality for subtracted images. It also offers run-subtract to perform subtraction per run. This feature can be applied in the Rotational Scan and Bolus Chase Subtract options.

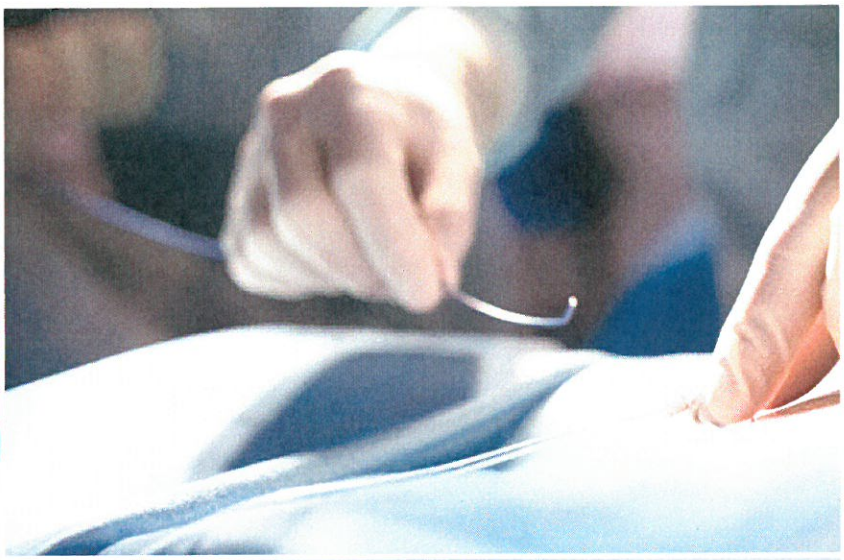
Optional

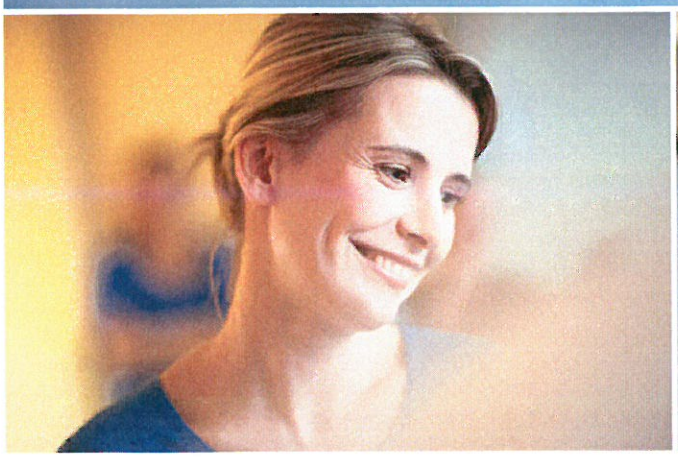
SmartMask

SmartMask simplifies roadmapping procedures by overlaying fluoroscopy with a selected reference image on the live monitor. The reference and fluoro images can be faded to taste on the monitors.

Frame Rate Extensions

There are two options available for increasing system frame rate for cardiac applications: "Extension to 30 fps", which includes 15 fps, and, "Extension to 60 fps".





6 Viewing

6.1 Monitors

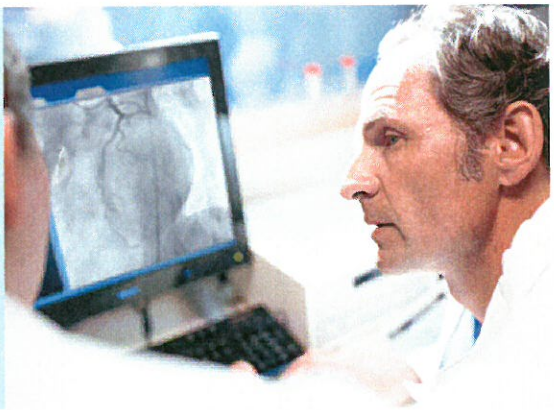
The system is delivered standard with two monochrome LCD monitors and one LCD color monitor in the examination room (optional 21"). These monitors are mounted on the Philips Monitor Ceiling Suspension. FlexMove requires ceiling booms to mount display monitors. A LCD color monitor and monochrome LCD monitor are standard in the control room.

	Monochrome LCD monitor	Color LCD monitor
Features	**Specifications**	**Specifications**
Format	Native format of 1280 x 1024 SXGA	Native format 1280 x 1024 SXGA
Grey-scale resolution	10 bit with grey-scale correction	
Wide viewing angle	Yes (approximately 170°)	Yes (approximately 170°)
High brightness	Yes (max 600 Cd/m² with 18 inch, max 1000 Cd/m² with 19 inch, default 500 Cd/m²), with ambient light dependent brightness control	Controlled brightness (200 Cd/m²) with ambient light dependent brightness control
Protection screen	Yes, in the examination room	
Video signal	Compatible with video signals up to 1920x1200 and from Ultrasound and IVUS	Compatible with video signals up to 1920x1200 and from Ultrasound and IVUS

Optional

Second reference monitor

A second reference monitor (monochrome) in the examination room can display both reference images and reference runs. The User Interface on this reference monitor is accessed via the Xper ViewPad.



Optional

MultiSwitch

Xper MultiSwitch enables the Xper workspot in the control room to be shared with other applications that are loaded on separate PC modalities. The MultiSwitch option lets you switch the color LCD data monitor, keyboard and mouse that are normally connected to the AlluraClarity system.

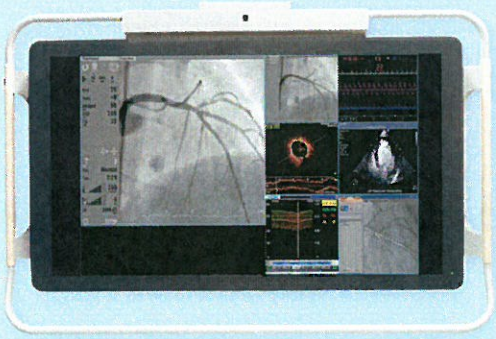
The Xper data monitor can be switched to Radiology/Cardiology Information Systems via the web-based browser (HTML) or X-window (Exceed). It makes full use of the RIS/CIS facilities and existing support for automatic handling of logistic tasks (e.g. automatic tracking, purchasing of supplies and billing) that are available.

MultiVision

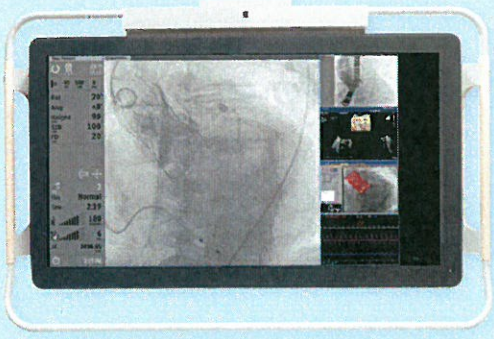
The MultiVision video switch is the integrated video switch for high quality, progressive display video sources on the color LCD monitor. It can switch either black and white or color signals, and supports up to four inputs to one output. MultiVision enables an extra color monitor in the ceiling suspension in the examination room to be shared between the system and other sources, such as a DICOM viewer, StentBoost, Allura 3D-CA software, etc. The switch is controlled via the Xper Module.

FlexVision XL

Philips has introduced a 56 inch display: FlexVision XL. FlexVision XL is a viewing concept that provides outstanding viewing flexibility, using a large, high definition LCD screen, it allows you to display multiple images in a variety of layouts - each tailored for your specific procedure. The SuperZoom feature lets you enlarge small details of anatomy, devices and data (ECG signals and hemodynamic data) for excellent visibility to enhance decisions during challenging procedures.



FlexVision XL allows you to display multiple images in variety of layouts



Now you are able to see a complete overview of all the relevant images without having to leave the examination room

7 Additional options

7.1 Subtracted Bolus Chase

Routine examinations can be performed quickly and confidently with Bolus Chase. A hand-held speed controller is used to constantly match table speed to the speed of the contrast run-off, which is displayed in real-time on the monitor screen. After the contrast run, the recorded speed profile can be used to acquire mask images with the subtraction results. The result is an efficient, run-off study that may help to reduce the need for repeat exposures. Bolus Chase gives fast results for increased patient throughput and enhanced patient management.

7.2 2D Quantification packages

Quantitative Coronary Analysis (QCA)

This software package provides quantification of stenosis measurements in the coronary arteries. It includes the following functions:

- Diameter measurement along the selected segment
- Cross sectional area
- Percentage of stenosis
- Pressure gradient values
- Stenotic flow reserve
- Calibration routines

Left Ventricular Analysis (LVA)

The Left Ventricular package quantifies the status of the left ventricle using various relevant. It includes the following functions:

- Various Left Ventricular volumes
- Ejection Fraction
- Cardiac Output
- Wall Motion (Centerline, Regional, Slager)
- Calibration routines

Right Ventricular Analysis (RVA)

This software package is used to assess ejection fraction and right ventricular volumes. It allows you to perform right ventricular analysis from angiograms. The calculations can be executed from single plane projections. The package is intended especially for pediatric cardio applications and focuses on easy and efficient wall contour detection.

It includes the following functions:

- Calibration routines
- Various Right Ventricular volumes
- Ejection Fraction
- Cardiac output
- Wall Motion (Centerline, Regional, Slager)

Quantitative Vascular Analysis (QVA)

QVA is an analytical software package for quantitative analysis. It includes the following functions:

- Calibration routines to enter the scale into the programs (based on the size of the catheter visible in the image).
- Automated Vessel Analysis. This program uses contour detection to calculate vessel dimensions and analyzes stenosis.
- Vessel diameter and stenotic index. This program measures vessel size and calculates the degree of stenosis.

Full Autocal

The Full Autocal option can be used in conjunction with the quantitative analysis packages. When the object to be analyzed (e.g., Left Ventricle, Vessel Segment) is placed in the iso-center, full autocal avoids the need to:

- Acquire an additional image series containing a sphere or grid for calibration purposes, or
- Calibrate manually on a calibration object (e.g., catheter) displayed in the image or image series to be analyzed

Measurement

Measurement is an analytical software package for angle-, length-, ratio-, and density measurements, as well as many others, This option does not include stenotic measurements.

7.3 Workflow enhancer options

XperSwing

During a dual axis rotation scan, the G-stand operates on two axes simultaneously, enabling it to swing in a three-dimensional arc around the patient, providing a flexibility of movement that allows it to capture the

required coronary images in fewer 'runs'. The system rotates with curved trajectories around the patient, thereby allowing imaging in all desired anatomical views in a single run. The trajectories are pre-programmed and are optimized to increase the clinical image content. Dedicated trajectories are available for the left and the right coronary arteries.

Rotational Scan

Rotation image data can be used for advanced post processing, like 3D reconstructions. Rotational Scan acquires a range of projections to create real-time, 3D impressions of complex 'cardiovascular' vessels. Rotational Scan can save considerable time and contrast, while providing the image detail required for diagnostic and therapeutic decisions. A rotational scan can be done in both the head and side positions as a result of rotational scan.

Physio Viewing with ECG triggering

Physio Viewing provides acquisition, storage and display of physiological signals on the FD10 system.
Four physiological data signals can be acquired and stored. One signal can be displayed when reviewing images. Physio Viewing includes ECG triggering that offers the possibility to acquire one fluoroscopic image per heart cycle, each at the same phase (e.g. end-diastolic or end-systolic). For each heartbeat the system generates a trigger pulse and only one image is acquired. Acquiring only one image per cardiac cycle phase has two major advantages:

- Manages patient and operator X-ray dose.
- Cardiac motion is eliminated from the images. This allows the physician to focus on relevant items only (e.g. moving catheters) without the movement caused by the cardiac contraction being visible.

Integrated CX50 compact ultrasound

To provide additional support for your interventional procedures, you can extend the power of your Philips AlluraClarity system with unique compact xtreme ultrasound integration solution. The CX50 is a compact ultrasound system that enables you to have premium image quality ultrasound available right where you need it, when you need it. The CX50 system can be fully integrated into the AlluraClarity system via a one-click connection. The CX50 is controlled at the table side by the Xper module with the ultrasound image displayed on the Allura's ceiling suspended monitor system.
In addition, all patient data is shared automatically between the X-ray and ultrasound system eliminating workflow duplication.

Features Rotational Angio		Specifications
G-stand in head position	Maximum rotation speed	55°/s.
	Maximum rotation angle	240°
G-stand in side position	Maximum rotation speed	30°/s.
(ceiling mounted only)	Maximum rotation angle	180°
Frame speeds		15 to 30 and 60 fps.

Users can designate speed, as well as a start and end position, through Xper settings.

The acquired images from the rotational scan or XperSwing can be sent automatically to Allura 3D-CA for a 3D reconstruction.

8 Interventional Tools

In close partnership with our clinical partners, Philips continues to enhance the capabilities of the Interventional Tools on AlluraClarity systems. Recent Philips innovations have expanded the clinical utilization by further enhancing the acquisition protocols and reducing reconstruction times, while expanding the range of applications for cardiovascular and electrophysiology procedures.

8.1 Innovative cardiovascular tools

Interventional cardiology is rapidly evolving requiring better insight and precision to perform an increasing number of interventions, with greater efficiency. Precise navigation is crucial, whether maneuvering through tortuous coronary vasculature or accurately implanting an aortic valve. Our unique imaging capabilities provide detail-rich insight so you can effectively plan the procedure, select devices and vascular routes. With our innovative cardiovascular tools, you can now reach target areas, deploy devices, and gauge treatment in real-time.

Allura 3D-CA

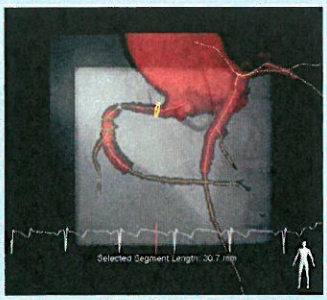
Allura 3D-CA creates a 3D model of 2D coronary artery images. It can help with diagnosis by providing superb visualization into the structure of the coronary tree that leads to an enhanced assessment of lesions and bifurcations. It also gives you superb working angles.

Enhance interventional preparation to:

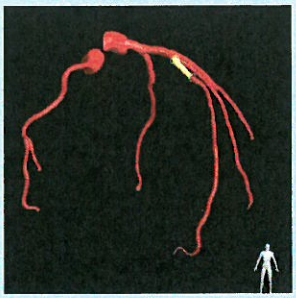
- Select the right stent length
- Select view of lesion or bifurcation with "TrueView" map

Enhance interventional execution to:

- Work with optimal viewing angles of lesions and/or bifurcations
- Place the right stent with the right length in the right place



The combination of CT TrueView and CTO Navigator, provides the excellent view and insight to the distal trajectory of the occluded coronary arteries



Allura 3D-CA: Create a 3D model of 2D coronary arteries to enhance assessment of lesions and bifurcations

CT Trueview

CT TrueView is a feature of Allura 3D-CA that connects the Cath lab to the CT room. It provides all the benefits of Allura 3D-CA based on a CT diagnostic image.
It offers:

- Excellent G-stand positioning on Philips CT data sets to minimize foreshortening when assessing lesions or bifurcations.
- CTO Navigator provides an overlay of a 2D exposure run over the previous acquired segmented cardiac CT data. The images are matched manually or automatically for images in the same part of the ECG signal.
- Easy to use user interface, on the EBW and interventional tools.

StentBoost – real-time stent visualization

StentBoost with its unique StentBoost Subtract* feature allows you to see your stent in relation to the vessel wall. So you can immediately check positioning, before and after deploying balloons and stents, and confirm stent expansion.

StentBoost is an excellent alternative to intravascular ultrasound (IVUS) when it is not available or when a quick result is required. Potential problems can be corrected immediately, without applying additional fluoroscopy.

Vascular StentBoost

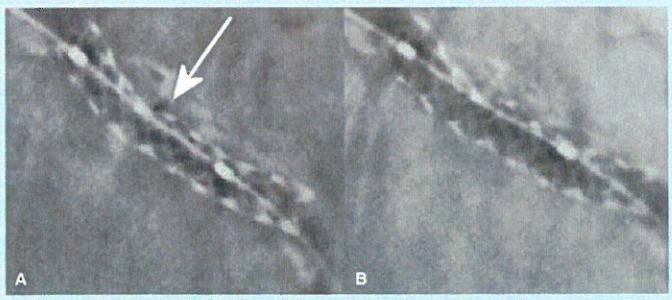
Cardiac labs that also perform peripheral procedures can now use the unique Vascular StentBoost – based on the enhanced workflow and technology of StentBoost – to advance visualization of balloons and stents for vascular interventions.

HeartNavigator

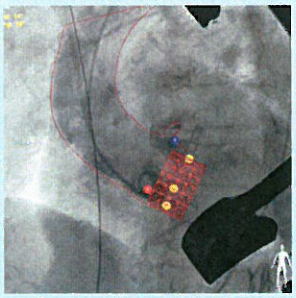
Philips HeartNavigator is an interventional planning and guidance tool designed to increase clinician confidence in carrying out complex structural heart disease procedures like trans-catheter aortic valve replacements.

- Simplifies planning, device selection and choice of X-ray projection
- Provides insight into calcified plaque distribution in the ascending aorta and ostia of the coronaries
- During the procedure, it combines previously acquired CT images with live fluoroscopy to provide live image guidance during device placement
- Tracks table and L-arm movement to maintain registration during procedures

*Subtraction feature is available only with Philips Allura Xper FD series onwards.



(A) Image after initial stent deployment showing malapposition.
(B) Image after post dilation showing correct apposition of the stent with the vessel wall.



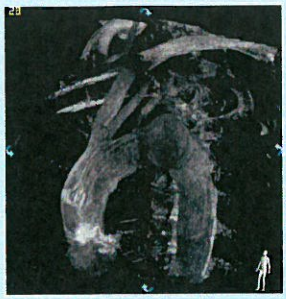
Philips HeartNavigator is designed to increase your confidence in carrying out structural heart disease procedures.

Allura 3D-RA

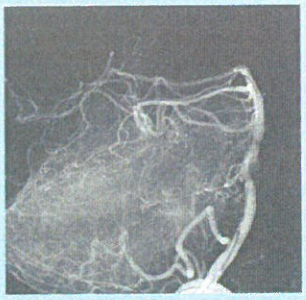
Allura 3D-RA provides extensive three-dimensional (3D) visualization into vascular pathologies and great vessels in congenital heart disease from a single rotational angiographic X-ray acquisition. Paired with the unique whole body coverage of the Allura, which is specifically designed for 3D-imaging, Allura 3D-RA is able to cover any anatomy, including cerebral, abdominal and peripheral vasculature. The 3D-RA functionality is fully integrated with the Allura system, and can be fully controlled at the table side. 3D-RA volumes can be matched with any previous acquired CT and/or MR scan, enabling enhanced procedure management for aneurysms, AVMs, stroke, congenital heart disease or surgical planning.

Dynamic 3D Roadmap and MR/CT Roadmap

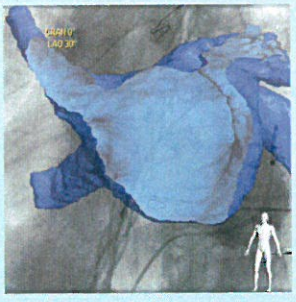
Dynamic 3D Roadmap is based on the visualization of the vessel tree from a 3D-RA, CTA or MRA scan combined with a live 2D fluoroscopy image. Integrated 3D-RA functionality rapidly reconstructs the rotational angiography X-ray run into a 3D volume. A previously acquired CT angio or MR angio scan can be imported into the system and registered with a low dose 3D-RA scan. The "live" 2D fluoroscopy image is overlaid with the 3D volume of the vessel tree and is automatically displayed on the 3D roadmap monitor in both the examination and control rooms.



Excellent image quality of a 3D-RA image showing an aneurysm at the aorta arch



The roadmapping tool tailored for specific clinical applications



EP Navigator: show the catheters and the 3D anatomy in real-time to confirm the position of the catheters or lead

EchoNavigator

EchoNavigator brings TEE and fluoroscopic images together, in real-time, so you can understand where you are in the 3D space quickly. The TEE transducer position and orientation is tracked in the X-ray image. The TEE field of view (cone) is displayed as an outline in the fluoroscopic view, so you always have a consistent reference point while working. The two images are moved in sync, displaying the same orientation and perspective; the echo image automatically follows the fluoroscopic image when the C-arm gantry is repositioned. Markers placed on the soft tissue structures within the echo image automatically appear on the X-Ray for context and guidance.

An intuitive combination of live X-ray and 3D TEE that provides greater confidence in anatomy and device targeting.

8.2 Innovative electrophysiology tools

In the dynamic field of electrophysiology, exceptional skill and creativity is needed to perform an increasing number of new and challenging procedures. The ability to orchestrate disparate technologies and move quickly from one procedure to another is critical. Afib ablation requires high image quality of the left atrium. CRT implant scheduling needs rapid analysis and fast room turnaround. Our advanced imaging support delivers immediate in-suite 3D reconstruction overlays with live fluoro to guide catheter navigation.

EP navigator

EP navigator provides a fluoroscopy overlay of a 3D image of the heart, based on either a pre-interventional CT image or an 3D atriography acquisition. EP navigator shows the catheter and the 3D anatomy in real-time in one image, allowing electrophysiologists to confirm within seconds the position of any catheter or lead with respect to detailed 3D cardiac anatomy in the EP intervention lab.

3D EP Rotational Scan

An up-to-date view of the cardiac anatomy is vital for guiding EP interventions. Obtaining good CT scans is often difficult, time consuming and expensive. With 3D atriography, you can create 3D images of the left atrium in your own lab and use this information to guide your catheters.

9 Integration solutions

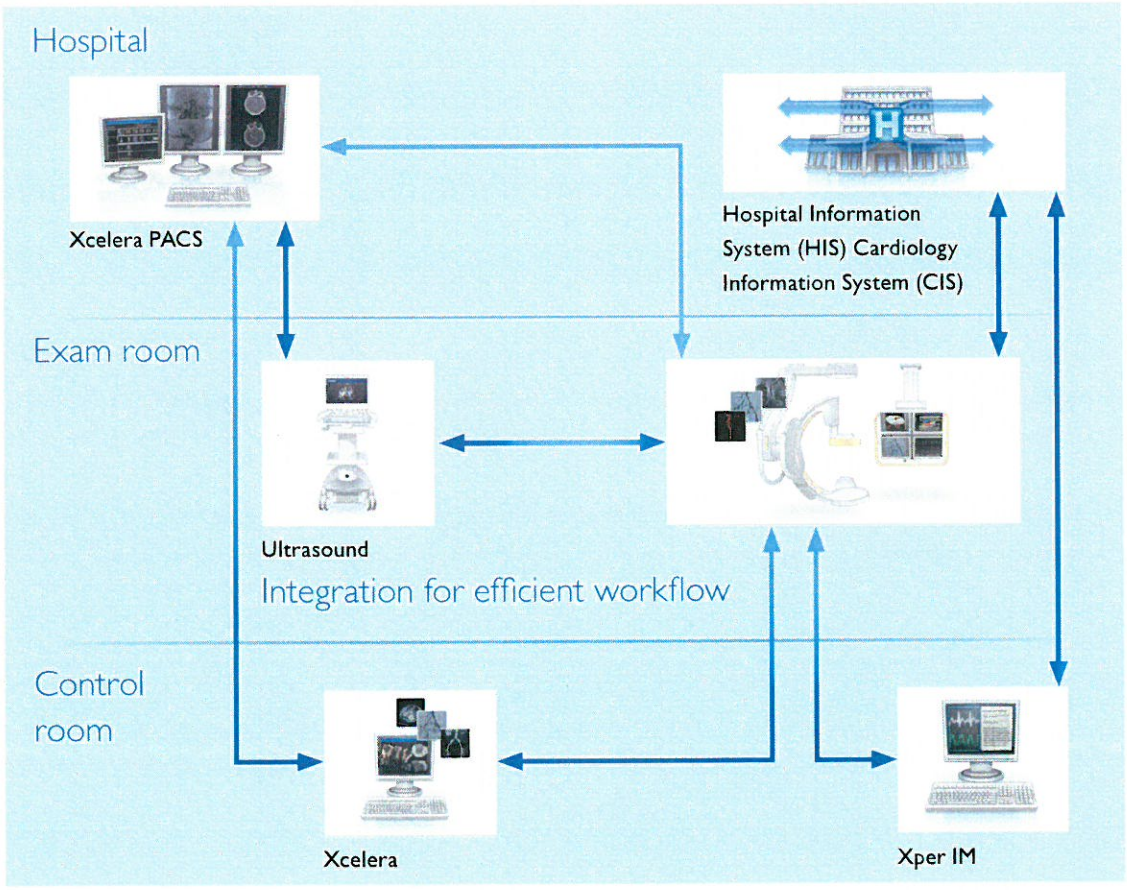
The Xper DICOM Image Interface enables clinical images to be exported to a destination, such as ViewForum, Xcelera or any third party PACS. The system exports clinical studies in DICOM XA Multi Frame or DICOM Secondary Capture formats.

The Xper DICOM Image Interface speeds up image transfer through its fast Ethernet link, making images available on-line within seconds. The archiving process can be configured via Xper settings:

- The image archiving is done in the background during or after the procedure
- The images can be archived automatically in the background with the Continuous Autopush option
- The export format is configurable in 512^2, 1024^2, or $2k^2$ (unprocessed) matrix
- The Xper DICOM Image Interface can distribute the examination images to multiple destinations for archiving and reviewing purposes
- The Xper DICOM Image Interface provides DICOM Store and DICOM Store Commitment Services
- The Query/Retrieve function allows older DICOM studies to be uploaded in the system

9.1 DICOM Radiation Dose Structured Report

Collection of dose relevant parameters and settings and export to a DICOM database[5] (e.g. PACS, RIS). The reported data can be used for analysis, to further manage X-ray dose. The DICOM RDSR function collects and exports the required data. The software to provide the DICOM data for analysis and alerting needs to be acquired separately.



Optional

Continuous autopush

This option provides an additional processor board that is dedicated to archiving. This decreases interruptions that are caused by other functions that require the image processor, such as patient review. Using the continuous autopush option speeds up archiving and availability of clinical images for review at other PACS destinations.

DICOM Print

DICOM Print provides an interface to any DICOM Printer. It provides Print Preview, Print Compose, Print Manual Overrides, Print Job submission, and Print Job management via automated printing protocols.

Intercom

The remote Intercom is used for communication between the examination and control room.

Lab reporting

This option allows the clinical user to generate and print a report in modality stand-alone situations. The user can incorporate free text, clinical images and X-ray dose information. The report is printed or sent by e-mail. Part of the report is generated automatically from administrative data (e.g. patient/exam data, hospital name) and acquired data (e.g. run log, X-ray dose information and event log).

RIS/CIS DICOM Interface

This interface option enables two-way communication between the FD10 and a local Information System (CIS or RIS) or hemodynamic system. The interface uses the DICOM Worklist Management (DICOM WLM) and Modality Performed Procedure Step (DICOM MPPS) standards. If an information system is present, it is possible to receive patient and examination (request) information and to report examination results.

This option provides the following benefits:

- Eliminates the need to retype patient information on the system
- Can help prevent errors in typing patient name or registration number, which allows for consistency of information throughout the department to prevent problems in archive clusters
- Provides information to and from the information system about the acquired images and radiation dose. Upon request from the system, the complete worklist with all relevant patient and examination data is returned to the system.

Standard line rate video output

The standard line rate video output option is 625 (525) lines for a 50 (60) Hz video output unit. This option is required to connect a medical DVD/VCR or an additional TV monitor. This option enables you to store fluoro and acquisition data on a DVD/CD as X-ray is being generated during fluoroscopy and exposure.

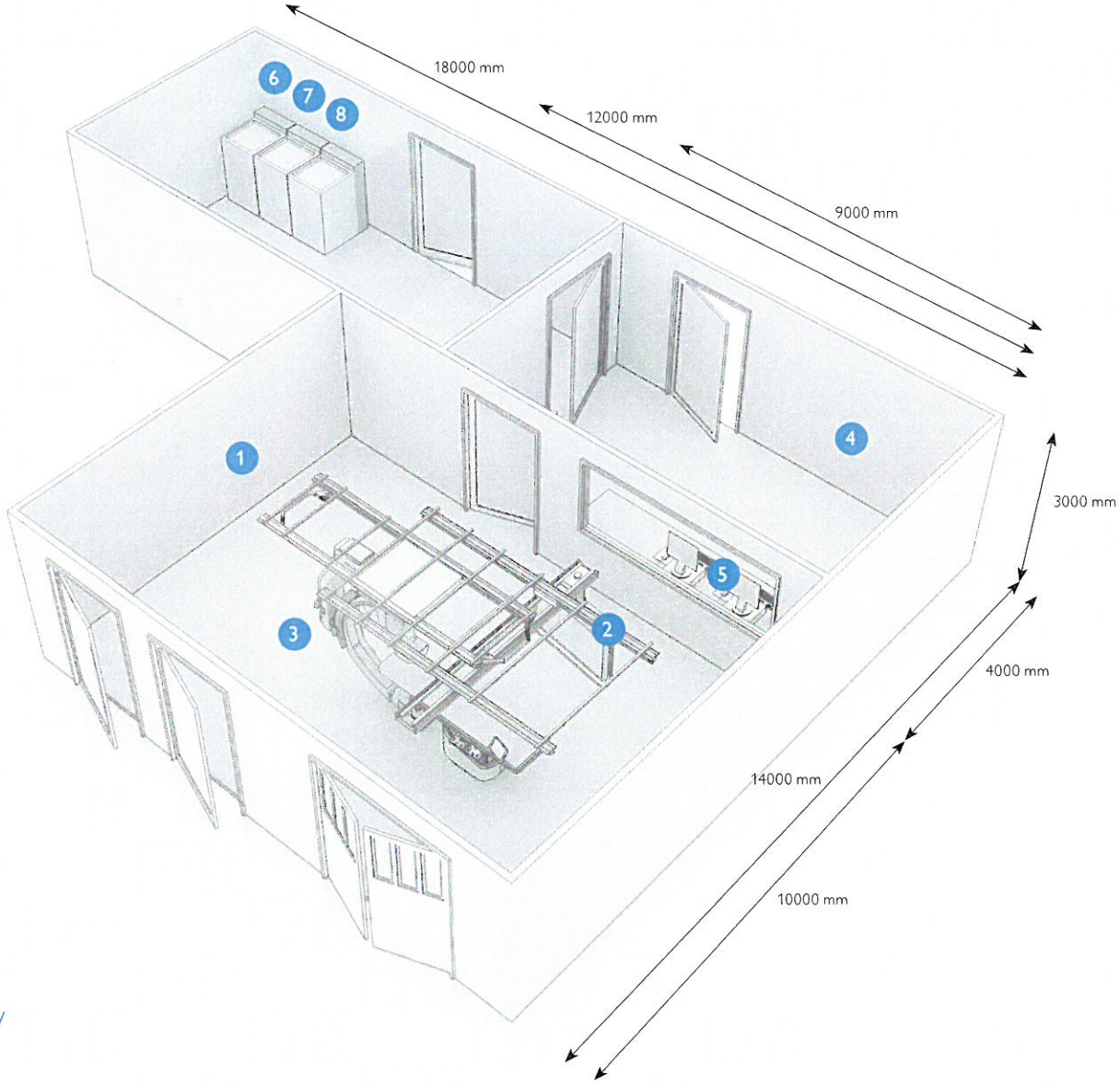
Cath lab experience

The Philips cath lab experience brings together AlluraClarity systems, Xper Information Management and Philips Xcelera Cardiology PACS to build powerful solutions that take complexity, time and effort out of diagnosing and treating. We design our solutions for cardiovascular interventions to simplify the cath lab workflow. This encompasses advanced image acquisition and visualization tools, multimodality access, hemodynamic monitoring and integrated reporting. The Philips cath lab experience creates a fluid workflow that works for you and your patients.

Xcelera

Xcelera is a robust multimodality cardiology image management, analysis and reporting solution that provides patient centric access to cardiology data and examinations. The system is highly configurable, scalable and customizable with the potential, via optionally available software licenses, to support different examination types. Xcelera performs the necessary functions for exam storage and review. Xcelera additionally offers various analysis and quantification packages, clinical reporting and archiving features.

10 Room layout

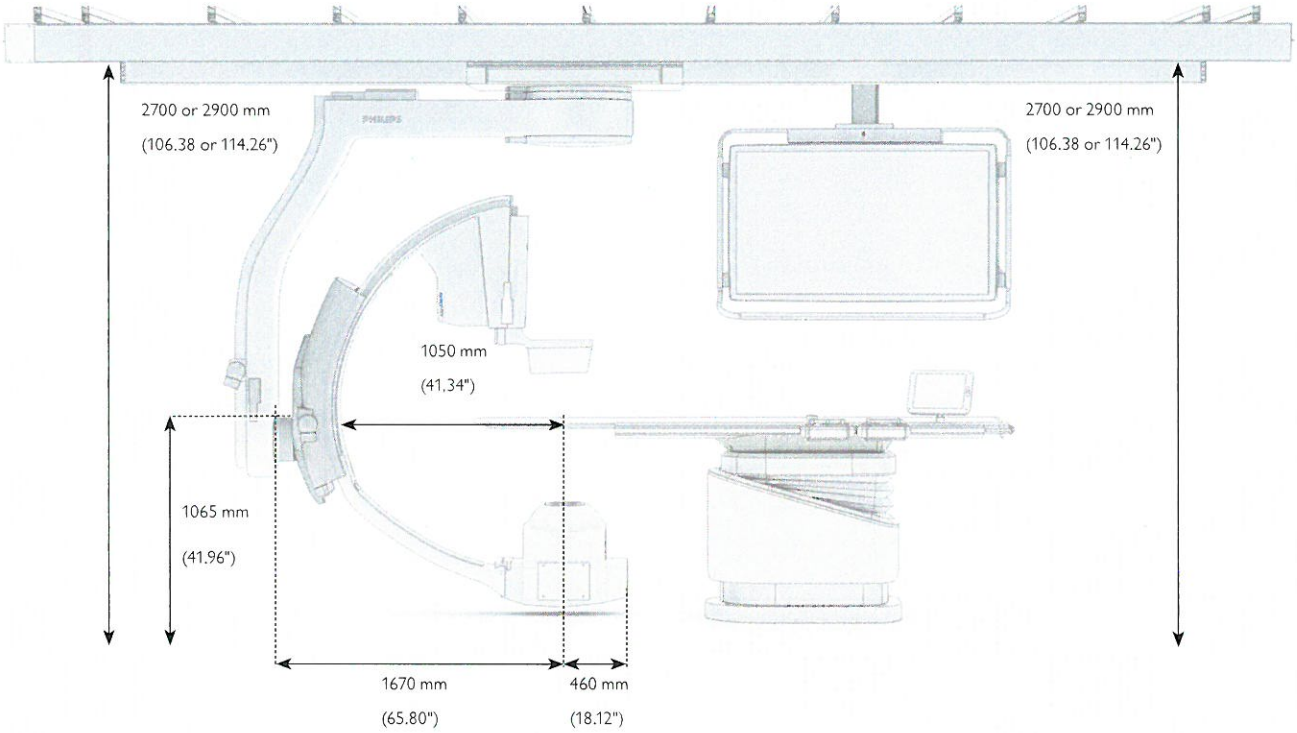


Conceptual drawing of a room layout

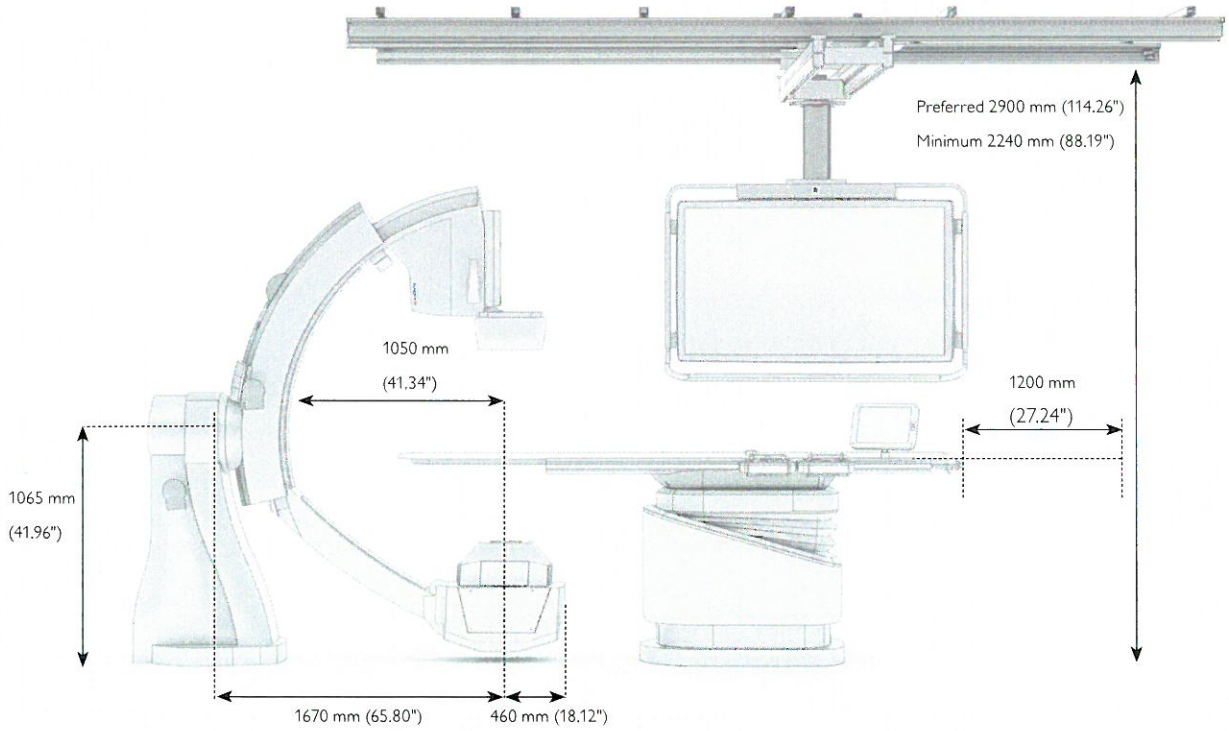
Top view

1. Examination room
2. LCD monitor ceiling suspension
3. Ceiling mounted G-stand
4. Control room
5. Xper Viewing console
6. Velara CFD generator
7. Geometry cabinet
8. System cabinet

Front view ceiling mounted



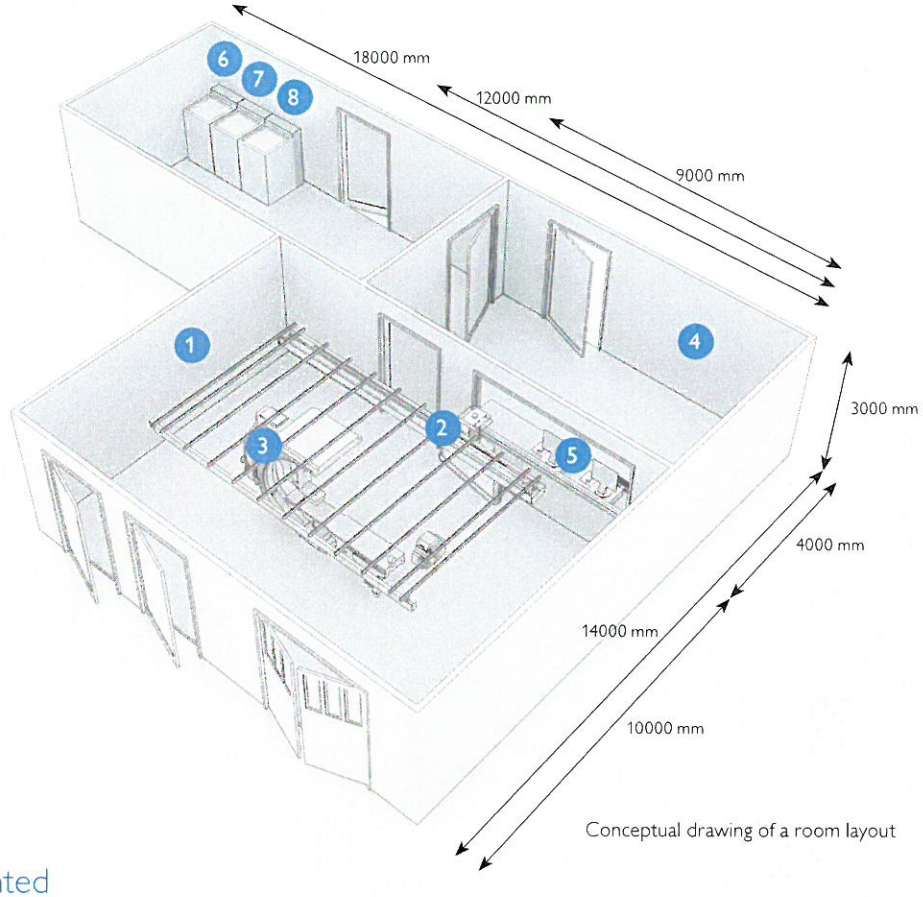
Front view floor mounted



11 Room lay-out with FlexMove and OR Table

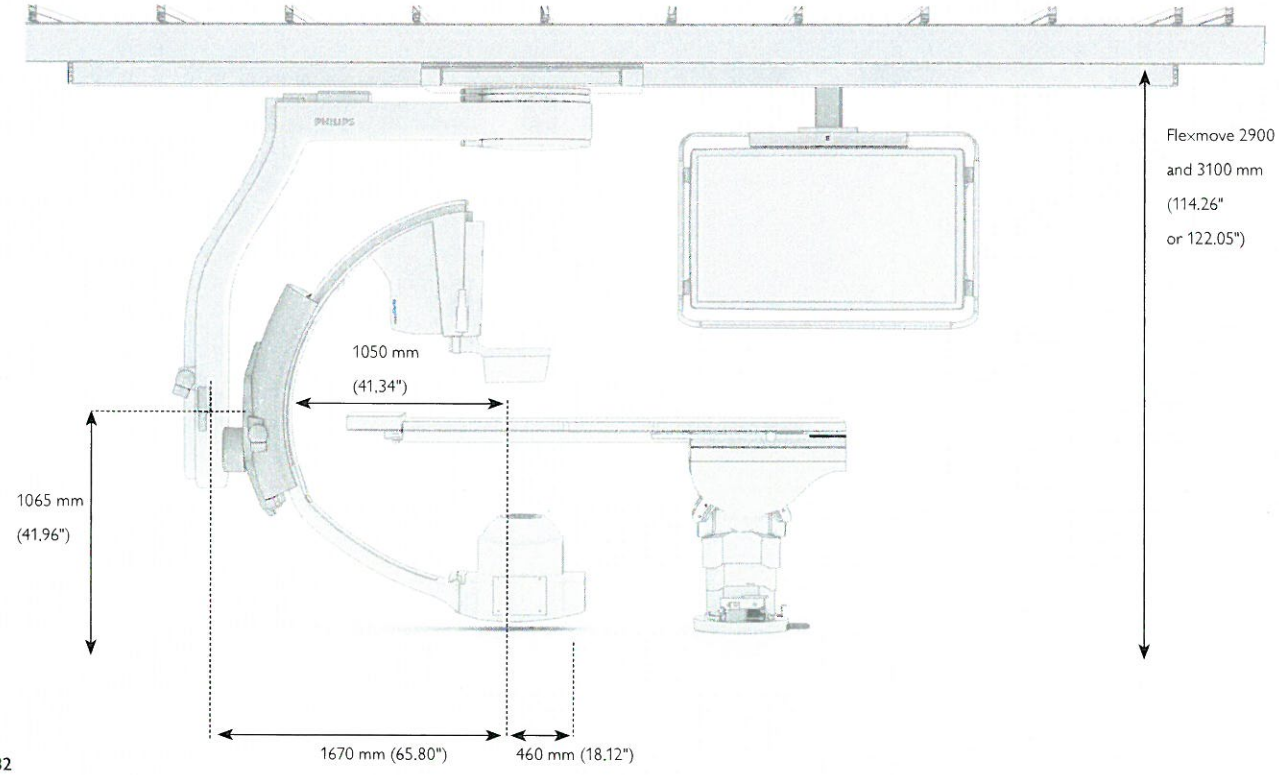
Top view

1. Examination room
2. LCD monitor ceiling suspension
3. Ceiling mounted G-stand
4. Control room
5. Xper Viewing console
6. Velara CFD generator
7. Geometry cabinet
8. System cabinet



Conceptual drawing of a room layout

Front view ceiling mounted



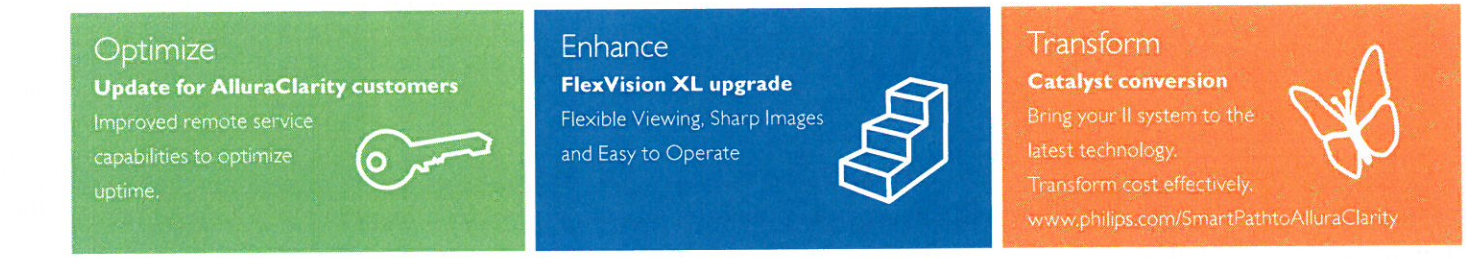
12 SmartPath

Your Philips imaging system is designed to be reliable and efficient. Ensuring that it remains so from day one forward, is our commitment to you.

Philips SmartPath is a way to give you easy access to the latest updates, upgrades and innovations throughout the cycle of product ownership. By maintaining your equipment at peak performance, you can realize your full clinical and operational potential and be ready to quickly benefit from next-generation solutions.

From small enhancements to major system conversions, we help you maximize your investment, for success today and into the future.

Please visit http://www.healthcare.philips.com/us_en/products/smartpath/ixray.wpd for more information



Philips Healthcare is part of Royal Philips

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800 285 5585 (toll free, US only)

References

1 The floor stand version is not available with the FD10 OR Table

2 FlexMove is only available with monoplane ceiling versions of the AlluraClarity system

3 Only in combination with Philips Allura Xper FD10 OR Table

4 Standard with Philips Allura Xper FD10 OR Table

5 According IEC60601-2-43, 3rd Edition

6 These products do not replace the thermoluminescent dosimeter (TLD) as a legal dosimeter

asimpleswitch.com

This document is intended for United States only

Please visit www.philips.us/AlluraClarity

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4522 991 01921 * APR 2014

Attachment B

Equipment Use Documentation

NorthEast EP Lab Replacement and Temporary Relocation

Sep-15	43
Oct-15	35
Nov-15	31
Dec-15	30
Jan-16	37
Feb-16	25
Mar-16	46
Apr-16	40
May-16	37
Jun-16	49
Jul-16	43
Aug-16	42
Total	458

Attachment C

Equipment Vendor Quote

PHILIPS HEALTHCARE
A division of Philips Electronics North America Corporation
22100 Bothell Everett Highway
P.O. Box 3003
Bothell, Washington 98041-3003

PHILIPS

Quotation #: 1-15A3CB9	**Rev:** 10	**Effective From:** 09-Nov-16	**To:** 08-Jan-17

Presented To:

CAROLINAS MEDICAL CENTER NE
920 CHURCH ST N
CONCORD, NC 28025-2927

Tel:

Alternate Address:

Presented By:

Brett Kimball
Account Manager
Tel:
Fax:

Amy Morrow
Regional Manager
Tel: (828) 553-3118
Fax:

Date Printed: 21-Dec-16

Submit Orders To:

22100 BOTHELL EVERETT HWY
BOTHELL WA 98021

Tel: (888) 564-8643 Fax:(425) 458-0390

IMPORTANT NOTICE: Health care providers are reminded that if the transactions herein include or involve a loan or discount (including a rebate or other price reduction), they must fully and accurately report such loan or discount on cost reports or other applicable reports or claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, such as may be required by state or federal law, including but not limited to 42 CFR 1001.952(h).

Quote Solution Summary

Line #	Product	Qty	Price
	100241 Allura Xper FD10	1	$1,199,243.68
		Equipment Total:	$1,199,243.68

Solution Summary Detail

Product	Qty	Each	Monthly	Price
100241 Allura Xper FD10	1	$1,199,243.68		$1,199,243.68

Buying Group: **CAROLINAS HEALTHCARE SYSTEM SCA** **Contract #:** **CAA0013200**

Addt'l Terms:

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

Payment Terms: 0% Down, 80% Upon Delivery, 20% Due When the Product is Available for First Patient Use, Net due 30 days from date of invoice

Quote Summary

100241 Allura Xper FD10

Qty	Product
1	NNAE499 EP Cockpit XL with ISM Premium Audio
1	**NNAE860 AlluraClarity_FD10 Ceiling**
2	FCV0587 Xper Live/Ref Slaving
1	NCVA088 Standard Line Rate Video Output
1	NCVB879 Aut Pos Contr Xper sys & table
1	NCVA086 Rotational Scan
1	NCVA121 FULL AUTOCAL
1	NCVC199 Wireless footswitch: mono-plane version
1	NCVA097 Cath Arm Support
1	NCVA098 Pulse Cath Arm Support
1	NCVA783 Pivot for table base.
1	NCVA791 Xper Table Tilt
1	NCVB882 Cradle extension
1	NCVC425 Table base Auxiliary OP rail
1	FCV0510 Long mattress cardio
2	FCV0017 CABLE CARRIER CS
1	FCV4894 Add.op-rail with cable ext.kit
1	NCVA566 Interventional Hardw.(RT prep)
1	NCVA590 Real time image link
1	NCVC409 EP Navigator R5
1	NCVC419 3D EP Rotational Scan R5
1	NCVB294 Set of 2 additional 21in. LCDs
1	980406190009 PIVOTING TABLE-MOUNTED RADIATION SHIELD
1	989801220012 Cable Spooler
1	989801220037 M LED 3MC Light
2	989801220273 Ceiling Track w/Column & Handle Ext
1	989801220284 ISM Premium Audio Package
1	989801220345 Personal Wireless Bidirectional Audio
1	989801220346 Add'l Wireless Microphone Set for Personal Audio
2	989801220373 Contoured Rad Shield w/lead curtain
1	989801220375 Black Anti-fatigue Floor Mat w/logo.
1	989801292098 IXR Additional Training 16 Hours OnSite
1	989801299784 XD9702 Flexvision XL eLearn

Quote Summary

100241 Allura Xper FD10

Qty	Product
1	989801299780 XD3894 ALLURA XPER REL8.2 ESSENTIAL
1	989801299617 XD8982ALLURAXPERCLARITYREL8.2CTC5D
1	NCVC005 Equipment Rack DVI
1	989600207421 Equipment rack Predelivery set
1	NCVC413 Electrical Accessory kit OSC
1	NCVC414 Pre-Install Bracket
1	NCVC415 Pneumatic Regulator
1	989600213942 AD5 TO XPER TABLE ADAPT. PLATE
1	989801220282 25 kVA Fluoro Only UPS - UTS
1	SP005 Contract Labor
1	Third Party Item Bariatric table extender
1	SP019 Trade in Allowance

100241 Allura Xper FD10

System Type: New
Freight Terms: FOB Destination
Warranty Terms: Part numbers beginning with two (2) asterisks (**) are covered by a System 12 Months Warranty. All other part numbers are third (3rd) party items.
Special Notations: Contingencies must be removed 120 days before scheduled shipment to assure delivery on specified date. Any rigging costs are the responsibility of the Purchaser.
Additional Terms:

Line #	Part #	Description	Qty
1	**NNAE499	**EP Cockpit XL with ISM Premium Audio**	1

EP Cockpit XL with Image Stream Premium Audio Package

EP cockpit XL for Allura Xper mono-plane system with large 58-inch high resolution color LCD screen in the Exam Room
EP cockpit XL is an integrated EP lab solution supporting an efficient working environment, integrated workflow and enabler for complex procedures.
The EP cockpit XL provides the ability to:

- Reduce the amount of cables, keyboards and displays in the Exam Room and Control Room
- Display information from up to 8 sources simultaneously (incl. third party systems) on the Philips large 58-inch high resolution color LCD screen in the Exam Room.
- Resize & enlarge information at any stage during the case on the Philips large 58-inch high resolution color LCD screen in the Exam Room.
- Select, customize & save viewing lay-outs of the Philips large 58-inch high resolution color LCD screen via the Allura Xper table-side module
- Display information (incl. third party systems) on any of the Philips ultra high-brightness 21-inch color LCD displays in the Control Room.
- Operate connected equipment (incl. third party systems) via the Allura Xper module in the Control Room.
- Select a predefined display setup and keyboard/mouse configuration, or save a custom configuration as a new preset configuration.
- Store any image on any screen and/or all images on all screens as a DICOM Secondary Capture image.

The EP cockpit XL consists of:

OmniSwitch

- The OmniSwitch is a 15 channel video-switch and 8 channel keyboard/mouse switch, operated from the Allura Xper Module in the Control Room and/or from the Allura Xper table-side module.
- The OmniSwitch allows the user to direct the video output of all connected medical equipment to the Philips large 58-inch high resolution color LCD screen in the Exam Room (up to 8 sources simultaneously) and to the Philips ultra high-brightness 21-inch color LCD displays in the Control Room (6 or 7 displays).
- The OmniSwitch allows the user to switch keyboard/mouse control for the connected medical equipment.
- The OmniSwitch can be connected to up to 8 medical equipment systems. These systems can be selected and controlled with 1 or 2 keyboard/mouse combinations in the Control Room.

100241 Allura Xper FD10

Line #	Part #	Description	Qty

Medical grade, large screen high resolution color LCD display in the Exam Room

- This display support the image quality requirements for monochrome X-ray images, color EP signals as well as other images and replace all displays normally delivered with an Allura Xper system for the Exam Room.
  Main characteristics are:
  - 58-inch, 8 Megapixel color LCD display
  - Native resolution: 3840x2160
  - Brightness: max 700 Cd/m2 (typical)
  - Contrast ratio : 4000:1 (typical)
  - Wide viewing angle (approx. 176 degrees)
  - Constant brightness stabilization control
  - Lookup tables for gray-scale, color and DICOM transfer function
  - Full protective screen
  - Ingress Protection: IP-21

Large 58-inch color LCD screen control

- Resize & enlarge information at any stage during the case via the Allura Xper table-side module in the Exam Room and/or the Allura Xper module in the Control Room.
- Select, customize & save viewing lay-outs via the Allura Xper table-side module in the Exam Room
- Select, customize & save viewing lay-outs via Allura Xper module in the Control Room

Ultra high-brightness, medical grade, color LCD displays
A total of 6 x ultra high-brightness, medical grade, color LCD displays are provided with EP cockpit XL for use in the Control Room.
These displays support the image quality requirements for monochrome X-ray images, color EP signals as well as other images and replace all displays normally delivered with an Allura Xper system.
Main characteristics are:

- 21.3 inch, 2 Megapixel color LCD display
- Display resolution (up to) : 1600x1200
- Input resolution (up to) : 1920x1200
- Brightness: 550 Cd/m2
- Contrast ratio : 800:1
- Wide viewing angle (approx. 170 degrees)
- Constant brightness stabilization control
- Independently selectable brightness settings for monochrome and color images
- Independently selectable lookup table for gray-scale, color and DICOM transfer function

Monitor ceiling suspension

- A Monitor ceiling suspension for use in the Exam Room carry the large 58-inch color LCD screen, providing highly flexible viewing capabilities.
- The monitor ceiling suspension is height-adjustable and moveable along ceiling rails. It can be positioned on both sides of the table and replaces the Allura monitor ceiling suspension.

- Note: Two 21" additional displays (same as used in Control Room) are optional and located on top of the monitor ceiling suspension frame which carry the large 58-inch color LCD screen.

Control Room set-up

- The 6 x ultra high-brightness color LCD displays, the 2x keyboard/mouse combination and Allura Xper module are designed to support an efficient workflow within the Control Room.
- Equipment connected to EP cockpit XL can be operated via the Allura Xper module.
- Display information (incl. third party systems) on any of the Philips ultra high-brightness 21-inch color LCD displays in the Control Room.
  - Note: The Allura Xper module is delivered with EP cockpit XL (EP cockpit)

Snapshot functionality

- The snapshot function allows the user to store/save a screen-capture of any image on any EP cockpit display as a DICOM Secondary Capture image to a connected PACS.
- The snapshot-all function allows the user to store/save a
- screen-capture for each displayed image in the Exam Room / Control Room as separate DICOM Secondary Capture images

Wall Connection Boxes

- A total of 9 x Wall Connection Boxes are provided with EP cockpit XL.
- Through Wall Connection Boxes a wide range of 3rd party equipment can be connected to the EP cockpit XL OmniSwitch.
- The Wall Connection Boxes provides galvanically isolated connections: Video (DVI), Network (RJ45) and Keyboard/mouse (USB) .
- The Wall Connection Boxes can be located in the Technical Room, Control Room and/or Exam Room.
- In case of an Equipment Rack: 1 x Wall Connection Box is permanently placed on the Equipment Rack.
- Notes:
  - Life-supporting equipment cannot be connected to the Wall Connection Boxes
  - EP cockpit XL displays are not powered by an Uninterruptible Power Supply. Equipment that requires a (fail-safe) power connection (UPS) for the video output need an additional display connected to that equipment's UPS.
  - Medical equipment with dedicated keyboards or displays should not be connected without consent of the manufacturer. Please contact your 3rd party equipment vendor for information and clearance.

Compatibility
EP cockpit XL is compatible with:

- Allura Xper FD10 series from Release 7.6 onwards
- Allura Xper FD20 series from Release 7.6 onwards

Clinical Education Program for EP Cockpit

Line #	Part #	Description	Qty

CV EP Cockpit OnSite Education: Clinical Education Specialists will provide sixteen (16) hours of CV EP Cockpit OnSite Education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. Education expires one (1) year from equipment installation date (or purchase date if sold separately).Ref# 263-100615

The Premium Audio Package is comprised of the following items:

1. Control System - Touchscreen Control Package offers touchscreen control with 7" Touch panel
2. Advanced Audio Communication System with Hands Free Telephony - Advanced audio uses an echo cancelling audio communication system with the EasySuite touchscreen to call or receive a telephone call. The hands-free system utilizes O.R. loudspeakers and 1 boom mounted microphones with no handset required.
3. MP3 Audio and Charging Interface - Universal MP3 music interconnection system allows any 3.5mm jack-enabled personal audio device to play music through the Advanced Audio System. Provides integrated charging capability via USB.
4. Speaker Upgrade for AAC (adds 2 additional speakers for Exam Room) Upgrade adds two recessed ceiling mounted speakers to the Standard Audio System, or Advanced Audio System, for a total of four speakers per Operating Room.
5. PTT Control Room Communication System with Control Room Loudspeakers - Push to talk intercom microphone system for control room plus two recessed ceiling mounted speakers for Control Room.
6. Ambient Room Lighting Control Enables touch panel control of room lights using customer provided lighting controller. Functions include on/off and ability to select multiple lighting presets.

Line #	Part #	Description	Qty
2	**NNAE860	AlluraClarity_FD10 Ceiling	1

The AlluraClarity FD10 (Ceiling) single-plane cardiovascular system comprises a ceiling mounted G-arm stand and digital imaging X-ray system for cardiovascular diagnostic and interventional procedures.
ClarityIQ technology is the foundation of AlluraClarity systems touching every part of the imaging system.

ClarityIQ incorporates powerful state-of-the-art image processing technology, developed by Philips research, all working in real-time enabled by the latest computing technology:

- Noise and artifact reduction, also on moving structures and objects
- Image enhancement and edge sharpening;
  Automatic real-time patient and accidental table motion correction on live images.
- Flexible digital imaging pipeline
- ClarityIQ systems have a flexible digital imaging pipeline from tube to display that is tailored for each and every application area such as Cardio or Neuro. This gives the flexibility to select virtually unlimited application-specific configurations.
- With ClarityIQ over 500 system parameters are fine-tuned for each application area; the result of years of Philips clinical leadership. It is now possible to filter out more X-ray radiation, use smaller focal spot sizes, shorter pulses, thereby fully utilizing the unique capabilities of the Philips MRC X-ray tube.

The AlluraClarity FD10 system uses an integrated single-host concept. The system is comprised of five functional building blocks: Geometry, X-ray Generation, Image Detection, Viewing, and User Interface. Each functional building block is explained in further detail including accessories.

GEOMETRY

The AlluraClarity FD10 Stand

The ceiling suspended geometry segment is comprised of the following features:

- A motorized, ceiling suspended Poly Diagnost G-arm, which can be ceiling rotated to allow a three-sided patient approach at maximum free floor space with full body coverage.
- All stand movements are motorized. The motorized and manual parking movement consists of ceiling rotation and a longitudinal movement. The counterbalanced Dynamic Flat Detector can also be positioned manually or motorized. Angulation and rotation of the Poly-Diagnost G-arm are motorized at high speeds.
- Parking and longitudinal movement of the Poly-Diagnost G-stand, can be performed either manually either motorized. The longitudinal movement comprises electronic auto-stop positions, to facilitate positioning in the iso-center with ease and accuracy.
- Single operator control of stand parking or longitudinal positioning provides motorized base rotation at 12 degrees per second from +90 to -90 degrees, and motorized longitudinal movement at 15 cm/s over a maximum range of 260 cm.
- The projection angles for the Poly-Diagnost G-arm in the head position (orientated parallel to the table) are:
  - Rotation 120 degrees LAO to 120 degrees RAO
  - Angulation 45 degrees cranial to 45 degrees caudal
- Motorized stand movements are variable speed with a configurable maximum speed, allowing:
  - rotation speed up to 25 degrees per second
  - angulation speed up to 18 degrees second
- The depth of the Poly-Diagnost G-arm is 105 cm.
- The stand features BodyGuard capacitive sensing collision avoidance for patient protection.
- The variable source image distance range between the x-ray tube foci and the Dynamic Flat Detector input screen is 86.5 to 123 cm.

Patient Support

Xper Table

- Patient support provided with a flat carbon fiber tabletop
- Tabletop length of 319 cm and tabletop width of 50 cm
- Floating tabletop movement of 120 cm longitudinal and 35 cm transverse
- Motorized height adjustment from 74.5 to 102.5 cm
- Maximum cantilever of 223 cm , for full patient coverage
- Maximum patient weight 250 kg plus 500 N for CPR (or 225 kg plus 1000 N) in any longitudinal position of the table top
- Xper Geometry and Imaging Modules for exam room controls.
  - The operating modules can be attached to either side of the table.

Patient Support Accessories

- Three rail accessory clamps

- Mattress pad
- Translucent catheterization armrest
- IV Pole
- Set of Cable Holders
- Set of Arm Supports (FCV0248)
- Arm Support (FCV0258)
- Patient straps
- Table-mounted radiation shield
- Antifatigue Mat with Philips logo

X-RAY GENERATION

The AlluraClarity FD10 comprises an integrated dedicated X-ray system, micro-processor controlled 100kW generator, based on high frequency converter technology. The user interface control of this X-ray Generator is incorporated into the Xper module, Xper Desktop Console, and the Xper on-screen displays.

The Certeray generator comprises:

- X-ray generator: 100 kW
- Voltage range: 40 - 125 kV
- Program selection:
  - Pulsed X-ray up to 3.75 , 7.5 , 15 , 30, frames/s for digital dynamic exposures
  - Pulsed X-ray for pulsed fluoroscopy (3.75, 7.5, 15, 25, 30 frames/s).
  - Minimum exposure time of 1ms.
  - ECG triggered acquisition: allows acquiring one exposure for each QRS peak with selectable delay time
  - Automatic kV and mA control for optimal image quality prior to run to save dose
  - Optimal X-ray tube load incorporated in the Certeray generator
- An X-ray collimator with single semi-transparent wedged filter with manual and automatic positioning.
- SpectraBeam filtering of low energy radiation to optimize image quality and dose efficiency with the MRC-GS 0508 X-ray tube.
- Xper Beam Shaping, which means that, both shutters and wedges can be positioned on the Last Image Hold without the need for X-ray radiation.

Fluoroscopy

Three programmable fluoroscopy modes can be selected from the Xper Imaging T.S.O. Each mode has a different composition of dose rate, pulse speed, filter setting, and image processing (noise reduction, adaptive contour enhancement, and adaptive harmonization).

Xper Fluoro Storage, a grab function allows storage and archiving of a single fluoro frame or the last 20 seconds of fluoroscopy. These images or runs can be archived as a regular run.

X-ray Tube

The AlluraClarity FD10 includes a Maximus ROTALIX Ceramic tube assembly MRC-GS 05 08 and cooling unit CU 3101 for cardio-vascular systems. Comprising:

- 0.5/0.8 mm nominal focal spot values maximal 45 and 85 kW

Line #	Part #	Description	Qty

IMAGE DETECTION

The Allura Clarity FD10 comprises the following image detection chain:

- A 25 cm (10 in.) diagonal triple-mode Dynamic Flat Detector. It comprises a 6"/8"/10" triple mode Dynamic Flat Detector
- The outer detector box diameter is 37 cm diagonal square
- The digital output of the Flat detector is a 1024 x 1024 matrix at 14 bit depth and the detector pixel pitch is 184 micron by 184 micron
- The DQE (0) is 75% providing high conversion of X-ray into a digital image, while maintaining a high MTF.

VIEWING

The AlluraClarity FD10 comprises the following components in order to display the clinical images in the control and examination rooms:

Displays

Examination Room

Two 19-inch monochrome LCD monitors

- 19-inch monochrome TFT-LCD display
- Native format 1280x1024 SXGA
- 10-bit gray-scale resolution with gray-scale correction

These monitors are not delivered when FlexVision XL, EP Cockpit or EP Cockpit XL is selected.

The monitor ceiling suspension in the exam room can be configured to accommodate 3, 4, 6, or 8 LCD monitors and includes motorized height adjustment. The height adjust feature is dependent on the room ceiling height. When FlexVision XL, EP Cockpit or EP Cockpit XL is selected the monitor ceiling suspension is configured for one of those options.

- The first reference channel is for the display of reference images or runs, controlled by infra-red remote-control Xper Viewpad.
- The On-Screen Display provides status information on stand rotation, angulation, display of system messages, X-ray tube load status, selected fluoroscopy mode, selected detector Field of View, and both the rate and accumulation of the dose area product and skin dose.

Control Room

One 19-inch color LCD monitor

- 19-inch color TFT-LCD display

Control Room

One 19-inch monochrome LCD monitor

- 19-inch monochrome TFT-LCD display

- Native format 1280x1024 SXGA
- 10-bit gray-scale resolution with gray-scale correction

These control room monitors are not delivered when EP Cockpit or EP Cockpit XL is selected.

Acquisition

The acquisition segment coordinates the parameters for automatic exposure control. The program is selected via the Xper module or Xper Desktop Console.

This AlluraClarity offers a storage capacity of:

- 100,000 images at matrix size of 1024 x 1024, 10-bit
- Maximum number of examinations is 999, with no limit to the maximum number of images per examination

USER INTERFACE

Xper is comprised of three elements: 1) Xper Settings, which customizes the system to each user preferred settings; 2) Xper User Interface 3) Xper Integration, which makes advanced integration functionality available such as DICOM Query / Retrieve, background archiving, and Xper Fluoro Storage.

The Xper User Interface comprises a range of User Interface modules in the Examination Room, including On-Screen Display.

On-Screen Display

- X-ray indicator and X-ray tube temperature condition
- Gantry position in rotation and angulation and Source Image Distance
- Detector field size display
- Selected Frame speed
- Fluoroscopy mode
- Integrated fluoroscopy time
- Stopwatch
- Skin Dose: dose rate with X-ray, cumulated dose with no X-ray
- Dose Area Product: dose rate with X-ray, cumulated dose with no X-ray
- Graphical bars for indication of Body Zone specific dose rate and accumulated skin dose levels, related to the 2 Gy level

Remote Intercom

A separate intercom, which is connected independently from the system that allows separate placement of the intercom at the preferred working position in the control room and examination room.

Xper ViewPads

The Xper ViewPad contains the preprogrammed function settings. The system is provided with two Xper ViewPads. The following functions are provided:

- Run and image selection
- File and run cycle
- File overview

- Store to Reference image file
- Copy image to photo file
- Digital (fixed) zoom and panning
- Recall reference images, which means switching control of Xper ViewPad function from live to reference monitor
- Laser pointer, intended to point at regions of interest on the imaging monitors
- LED indication of laser pointer on/off and battery low

Tableside Modules

One Xper Module is provided for use at either the tableside or in the control room. This module uses a touch screen, which can be operated when draped with sterile covers. The Xper Module contains the following functionality:

- Acquisition settings
- Selection of Xper Setting allows the user to set frame rates and x-ray generation settings applicable for the type of the preferred intervention
- Automatic positioning recall to allow the stand position to match the reference image.
- Image Processing

The Xper Geometry T.S.O. module can be positioned on all sides of the patient table, while keeping the button operation intuitive. The Xper Geometry T.S.O. provides the following functionality:

- Tabletop float and table height position
- Source Image Distance selection
- longitudinal movement of the Gantry along the ceiling
- Gantry rotation in an axis perpendicular to the ceiling
- Store and recall of two scratch gantry positions including SID
- Emergency stop button

The Xper Imaging T.S.O. module can also be positioned at three sides of the patient table, while keeping the button operation intuitive. The Xper Imaging T.S.O. provides the following functionality:

- Fluoroscopy Flavor selection defined per Xper Setting
- Shutters and Wedge positioning
- Xper Fluoro Storage and Grab
- Selection of the Detector field size
- Shutters positioning
- Reset of the fluoroscopy buzzer

Pan Handle

The Pan Handle is an extension of the control facility for floating movements of the table top.

Control Room

The control room comprises an Xper Review Module, a keyboard, a mouse. The Xper Review Module offers the basic functions for review. The Xper Review Module contains the following functionality:

- Power on/off
- Tagarno wheel to control the review of a patient file
- File and run cycle
- Contrast, Brightness, and Edge enhancement settings
- File, Run, Image stepping and run and file overview
- Delete run
- Image invert and digital zoom
- Reset fluoroscopy timer and enable/disable X-ray

System information is displayed on the bottom of the data monitor:

- Stopwatch and Time
- System guidance information
- Dose Area Product (DAP), Skin Dose, and accumulative dose
- Frame speed settings, fluoroscopy mode, and accumulated fluoroscopy time
- Exposure and fluoroscopy settings as Voltage (kV), Current (mA) and pulse time (ms)
- Geometry information as rotation, angulation, and SID

The workflow is divided in scheduling, preparation, acquisition, review, and archive.

Any Allura system built after Jan 1, 2017, will use and include Windows 7 (embedded standard).

Scheduling

The patients can be added, listed and selected per date, physician, and intervention type. Previous DICOM patient studies can be uploaded with the DICOM Query Retrieve function.

Patient management protocols are flexible and allow for multiple studies to be selected under one patient identification number. This means that new studies can be appended to an earlier patient file. Furthermore, each study can contain multiple examinations to allow for split administrative purposes. Each examination contains multiple files, i.e. acquisition file, reference file, and QA results file.

Preparation

The preparation page provides the information of the room and patient preparation of each individual physician. The preparation page is customizable per Xper Setting and allows each physician to provide his or her own room protocols.

Acquisition

The acquisition page contains information on the current selected patient.

Review

The review page allows for reviewing of patient's:

- Previous examination cases
- Review of other DICOM XA or DICOM SC st udies.

Coronary Quantification Software Package

Functions:
diameter measurement along the selected segment
- cross sectional area
- %-stenosis
- pressure gradient values
- stenotic flow reserve
- calibration routines

In addition the package allows manual measurements of line lengths (absolute and ratio's) and angulations. Multiple measurements in one image are possible.

Analysis of the targeted vessel segment has been simplified by the single click function: positioning of the mouse on or close to the stenotic area and apply one click is enough to get the relevant segment detected, including the reference diameters and stenosis diameter.

RIS/CIS DICOM Interface

This package allows communication of the Allura Xper system with a local information system (CIS or RIS). The interface uses the DICOM Worklist Management (DICOM WLM) and Modality Performed Procedure Step (DICOM MPPS) standards.

If a hospital has an Allura Xper system and an information system it can receive patient and examination request information from the information system and report examination results in order to:

-Eliminate the need for retyping patient information on the Allura Xper
-Prevent errors in typing patient names and registration numbers (ensuring consistency with IS information to prevent problems in archive clusters auto-search for a name in case of later retrieval)
-Inform the IS about the acquired images and radiation dose

Upon request from the Allura Xper system the complete worklist with all relevant patient and examination data is returned from the IS to the Allura Xper system. For each patient the following information will be shown on the Allura Xper after it has been retrieved from the IS:

Patient Identification:

- Patient name
- Patient ID
- Birth date
- Sex

Examination/Request Information:
- Accession number
- Scheduled procedure step start time

- Scheduled performing physician's name

It is possible at all times to enter patient demographics information manually within the Allura Xper system in case of an emergency or in case the local Information System connection is down.

On request of the clinical user the Allura Xper will report the following information about the selected patient to the IS:
Patient Identification:

- Patient name
- Patient ID
- Birth date
- Sex

Examination/Request Information:

- Accession number
- Performed procedure step status start/end date and time
- Performing physician's name
- Referenced image sequence

Radiation dose:

- Total time of fluoroscopy
- Accumulated fluoroscopy dose
- Accumulated exposure dose
- Total dose
- Total number of exposures
- Total number of frames

Further detailed information can be found in the Allura Xper DICOM Conformance Statement.

The interface requires an EasyLink (hardware and software) if the IS is not compliant with DICOM Work List Management and Modality Performed Procedure Step.

Radiation Dose Structured Report Collection of dose relevant parameters and settings and export to a DICOM database (e.g. PACS, RIS), according IEC60601-2-43, 2nd Edition.
The reported data can be used for, for example:

- Quality improvement: evaluating trends in X-ray dose performance per facility, system and operator.
- RDSR enables analysis of average dose levels & variance for routinely performed exams and procedures.
- Typical system usage can be extracted from the data.

Secondary Capture Dose Report

- The Secondary Capture Dose Report function allows the user to save & transfer, manually or automatically, a patient Dose Report to PACS in DICOM secondary capture format.
- The dose report will be stored in the related patient image folder.

Archive

Continuous Autopush

Continuous Autopush is an archive accelerator which ensures that background archiving continues with minimal disruptions.

Clinical studies can be archived to a CD or a PACS. The archive process can be completely automated and customized with Xper Settings. Parameters like multiple destinations and archive formats can be selected to the individual needs.

The Xper DICOM Image Interface enables the export of clinical images to PACS. The export formats are based on DICOM 3.0 protocols. The system exports clinical studies in Cardiac DICOM XA Multi-Frame or DICOM Secondary Capture formats.

- The export format is configurable in 512x512 or 1024x1024.
- The examination can be sent to multiple destinations for archiving and reviewing purposes.
- The Xper DICOM Image Interface provides DICOM Storage and DICOM Storage Commitment Services.
- The DICOM Query/Retrieve function allows older DICOM XA MF and DICOM SC studies to be uploaded in the system. Furthermore, additional information can be appended to a study, while keeping the patient identification the same.

If Philips begins commercially selling a core system that it identifies as the direct successor for the core system ordered in this quote, and that system is not yet in production, then Customer may convert the ordered core system to the identified successor system. To communicate this option to Customer, Philips shall present a revised quote for Customer approval, which quotation will include the successor system, substantially similar feature configurations and options as the ordered system, and no change to the system's price. If Customer wants to change the configuration or options on the successor system, then Philips will adjust the quoted price of the successor system. To exercise this option, Customer must approve the revised quote prior to production beginning on the ordered system and prior to the deadline provided by Philips at the time of re-quoting. If customer does not approve the revised quote during this period, then Customer will be deemed to have declined the option and this system quotation will continue to apply.

Clinical Education Program for Allura SystemsEssentials OffSite Education: Philips will provide up to two (2) Cardiovascular Technologists, Registered Technologists Registered Nurses, or other system operator as selected by customer, with in-depth didactic, tutorial, and hands-on training covering basic functionality and work-flow of the cardiovascular imaging system. In order to provide trainees with the ability to apply all fundamental functioning on their system, and to achieve maximum effectiveness, this class should be attended no earlier than two weeks prior to system installation.

In the event that an EP Navigator workstation has also been ordered, the offsite training course will be tailored to focus on the electrophysiology functionality of the FD system and the EPN workstation.

In the event that your main FD system will be dedicated to Cardiac applications your offsite training course will be tailored to focus on the Cardiac functionality.

This twenty-eight (28) hour class is located in Cleveland, Ohio, and is scheduled based on your equipment configuration and availability. Due to program updates, the number of class hours is subject to change without notice. Customer will be notified of current, total class hours at the time of registration. This class is a prerequisite to your equipment handover OnSite Education. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. **Travel and lodging are not included, but may be purchased through Philips. It is highly recommended that 989801292102 (CV Full Travel Pkg OffSite) is purchased with all OffSite courses.**

Line #	Part #	Description	Qty

Handover OnSite Education:

Philips Education Specialists will provide twenty-eight (28) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. Students should attend all 28 hours, and must include the two OffSite education attendees. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Site must be patient-ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. **It is highly recommended for systems that are fully loaded or for customers with a large number of staff members to also purchase 989801292099 (CV Add OnSite Clin Educ 24h).**

Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref# 106107-110915

3	**FCV0587	Xper Live/Ref Slaving	2

This option contains a kit to split the Live or Ref video source from the Allura Xper. The total amount of Xper Live/Ref Slaving that can be selected is maximal. 4. Additional monitors are not included in this option and must be ordered separately. This kit contains a video splitter and a cable set for one slave monitor. The Slave monitor is not powered by Allura.

4	**NCVA088	Standard Line Rate Video Output	1

This interface provides image output to standard line rate video peripherals, such as VCRs or paper printers. This option also comprises automatic start and stop of a VCR, synchronous to the generation of X-ray (fluoroscopy and exposures).

5	**NCVB879	Aut Pos Contr Xper sys & table	1

This Automatic Position Controller (APC) combines APC for Allura Xper FD10 and FD20 systems with table APC.
System APC provides two modes of operation:
Preset Position Sequence: the sequence of projections is determined through personnalized Xper Settings. Each set contains a maximum of 10 positions. Positions can be recalled in sequence or directly. The projection sequence comprises rotation angulation and SID settings related to the selected reference image.
Reference driven positioning: The projections on the reference monitors can be recalled with the push of a button. The reference driven positioning recollects the C-arm rotation angulation Flat detector image format and SID.
Table APC
The Automatic Position Controller (APC) for the table provides two modes of operation:
Auto positioning. The tabletop position and table height will be adjusted automatically to the pre-defined default point of interest. This to save time and x-ray dose at the start of an exam or for setting up the system for rotation scans.
Store/recall of a position of the table top. This includes the height-, longitudinal- and lateral position of the table top.

6	**NCVA086	Rotational Scan	1

Rotational Scan provides real-time 3D impressions of complex vasculature and the coronary artery tree. It acquires multiple projections with just one contrast injection.

Rotational Scan can be used during screening procedures to quickly determine the optimal projection for the study as the angle (rotation/angulation) of the projection is indicated on each image.

Compared with traditional angiography Rotational Scan can save considerable time dose and contrast while providing image detail required for diagnostic and therapeutic decisions.

Rotational Scan is possiblewith the Allura Xper systems in the side position (ceiling mounted systems) and in the head position which provides the flexibility to perform procedures virtually from head to toe.

With Allura Xper FD20

C-arm in side position:

- Max. rotation speed: 30°
- Max. rotation angle: 180°

C-arm in head position:

- Max. rotation Speed: 55°
- Max. rotation Angle: 305°

With Allura Xper FD10:

Poly G in side position (ceiling version):

- Max. rotation Speed: 30°
- Max. rotation Angle: 90°

Poly G in head position:

- Max. rotation Speed: 55°
- Max. rotation Angle: 240°

Maximum speeds are given by the framespeed specifications of the system configuration.

The speed and range of rotation are the highest available (see table). The very high speed allows using less contrast whereas the very wide rotation range provides a complete evaluation of the anatomy.

The stand is designed forvery high mechanical stability. It offers precise positioning and high reproducibility assuring you of high quality images and excellentstudies.

Operation of Rotational Scan is extremely easy. The procedure is selected set up and executed virtually within a matter of seconds supporting the highest patient throughput. A set of dedicated acquisition programs is available on the Xper Module and can be selected at the touch of a button. The rotation endand start positions are easily selected. The procedure is controlled from theexposure hand

- or foot-switch.

100241 Allura Xper FD10

Line #	Part #	Description	Qty
7	**NCVA121	**FULL AUTOCAL**	1

The AutoCal option is a software package to be used in conjunction with quantitative analysis software packages. It provides an auto calibration procedure for an object to be analyzed that is placed in the iso-center. When the object to be analyzed (e.g. Left Ventricle Vessel Segment) is placed in the iso-center AutoCal avoids the need to:

- acquire an additional image series containing a sphere or grid for calibration purposes
- calibrate manually on a calibration object (e.g. catheter) displayed in the image or image series to be analyzed

8	**NCVC199	**Wireless footswitch: mono-plane version**	1

One wireless footswitch in the examination room.

Key benefits
• Reduces clutter around the examination table
• Simplifies preparation and cleanup
• Streamlines workflow in the interventional suite

Reduce clutter and streamline workflow
The wireless footswitch option streamlines workflow, reduces clutter, and simplifies preparation and cleanup in the interventional suite. Clinicians can use the footswitch to wirelessly control the X-ray system in the examination room, from any convenient position around the table. No sterile covers are needed with the IPX8 certified waterproof design.

Specifications
• The mono-plane wireless footswitch is a 3 pedal version; one pedal for fluoroscopy, one for exposure and one to control the room light/single shot. The pedals can be configured according customers preferred lay-out.
• The wireless footswitch is working via RF technology and is fully tested and released for medical use. It has an active range up to 10 meters, depending on structures within this range.
• The wireless footswitch has a lithium battery which only needs to be recharged once per week. During recharging the footswitch still can be used and is fully functional. In parallel, a wired footswitch can also be used.
• The status of the battery is indicated by an LED-indication on the footswitch itself, so that the user can decide when the footswitch needs to be recharged.
• The wireless footswitch has high water ingress protection standard (IPX8), it can easily be cleaned in water.
The wireless footswitch has an on/off switch. It can be switched off when not in use. When the footswitch is active, but not in use, it will go into a sleep-mode. It will be re-activated when touched or when one of the pedals is pressed.

9	**NCVA097	**Cath Arm Support**	1

For brachial catheterisation and digital imaging technique
The support is made of X-ray transparent material with exception of the fixingclamp and pivots.

10	**NCVA098	**Pulse Cath Arm Support**	1

Facilitates catheterization trough the pulse and provides room for placing catheterization instruments. It is a flat radio translucent board and is placed under the patient while a part projects at either the left or right side of the tabletop to support the arm.

Size: 100 x 85 cm
Material: carbon-fibre reinforced material

Line #	Part #	Description	Qty

11 ****NCVA783** **Pivot for table base.** **1**

For angiographic- and interventional procedures of the upper peripherals.
Provides improved table access for patient transfer.
Allows pivoting of the table base around its vertical axes.
Pivot range from -90 degrees to + 180 degrees (or -180 to +90 degrees) with locked positions on 0, -13/+13 (facilitating arm-angiography) and -90/+90 and 180 degrees.

Comprising:

- pivot device with graduated scale to be mounted on the universal floor plate of the table.

Compatible with Xper Table

12 ****NCVA791** **Xper Table Tilt** **1**

This innovating SyncraTilt enhances the accuracy and efficiency of gravity-oriented procedures. It is available as an option for the Xper table in Allura Xper series systems.

SyncraTilt is ideal for interventional, myelography, phlebography and head down procedures because it provides more precise imaging of contrast medium, blood, or objects in the body.

With SyncraTilt, the isocentre is automatically located at the isocentre of rotation and angulation of the stand. If the longitudinal position of the stand changes, the tilt isocentre is changed to match with the new stand position. As a result, the region of interest is always centred

As the table tilts, the X-ray beam automatically coordinates to the movement.

The table floats even when tilted, and the region of interest can be followed by panning the tabletop.

When combined with the Bolus Chase option, SyncraTilt enables phlebography to be performed with a head-up tilted patient.

The option provides:

- maximum tilt range:
- 17 degrees (head down) to +17 degrees (head up).
- tilt speed: 2 degrees/sec
- automatic safeguarding system with manual override
- panning range in tilted plane: equal to the standard
- tabletop specifications (longitudinal 120cm, lateral 35cm)
- easy to use controls
  Comprising:
  - Tilt drive with user controls `

Line #	Part #	Description	Qty

Compatible with:
. Xper table in Allura Xper FD series Rel 3 onwards (monoplane versions) and Rel 2 onwards (biplane verions)
. Bolus Chase
. Pivot for table base
. swivel for table base

13 ****NCVB882** **Cradle extension** **1**

• Moves the tabletop in a cradle motion from side to side to support surgical and puncture procedures
• Improves access to patients
• Allows precise imaging of contrast medium or blood

Precise imaging during surgery and puncture procedures
To obtain high quality imaging results and help in avoiding re-takes during surgical or puncture procedures, it can be useful to swing the tabletop from side to side in a cradle movement. This extension moves the tabletop in a cradle motion to improve access to patients. It also allows precise imaging of contrast medium or blood.

14 ****NCVC425** **Table base Auxiliary OP rail** **1**

• Position operating modules and/or accessories conveniently
• Work comfortably at the head end of the table

Work comfortably at the head end of the table
To provide more flexibility when working at the head end of the table, the auxiliary OP (operation profile) rail can be used to position operating modules and/or accessories closer to the head end of the tabletop. This allows the user to work comfortably when performing pacemaker implantations, venous jugular catheter insertions, and other procedures near the patient's head.

15 ****FCV0510** **Long mattress cardio** **1**

• Enhances patient comfort
• Adapts to the shape of the patient's body

Enhance patient comfort during cardio exams
To enhance patient comfort during cardio exams, the inflatable, latex free mattress can be used. It is extra-long to accommodate the patient on the tabletop, and adapts to the shape of the patient's body. The pressure within the mattress is evenly distributed so that it recovers its original shape quickly.

Dimensions of the mattress:
Length: 3165mm
Width: 500mm
Height: 70mm
Radius: 150mm

16 ****FCV0017** **CABLE CARRIER CS** **2**

Additional carrier for suspension of cable hose from X-ray tube assembly or TV monitor.

17 ****FCV4894** **Add.op-rail with cable ext.kit** **1**

The content of the additional OP-Rail kit is:

- [A] One additional OP-Rail (mechanical)
- [B] Cable Extension for OP-Rail
  - One Extension cable for Geo Module
  - One Extension cable for Imaging Module
  - One connection box (wherein the extension cables are coupled with the UI-Module cables.

Line #	Part #	Description	Qty

[A]

- An extension for the table op-rail (30cm).
- The additional op-rail can be mounted at the both sides of the tabletop part where no op-rails are mounted.
- The additional op-rail is compatible with AD5 and XperTable (cardio and neuro) patient-tabletops.
- The op-rail has the same profile /dimensions as the current standard op-rail
- The maximum load (downwards) on the additional op-Rail is 100 N (F=100N)
  - (this is limited by the tabletop of the Patient Table)
- The maximum mechanical moment on the additional op-Rail is 40Nm downwards and 20Nm upwards
  - (this is limited by the tabletop of the Patient Table)

[B]

- The cable extension consists out of two cables with a length of 1.3 m; one for the Geo and one for the Imaging module, and an interface box were the coupling to the
- Geo and Imaging module cables can be made.

18 ****NCVA566** **Interventional Hardw.(RT prep)** **1**

The interventional hardware is a special platform designed for the Philips interventional software Integris 3D-RA, StentBoost and/or Allura 3D-CA

The Interventional Hardware comprises at least:

- Dell Workstation
- 2048 MB memory
- Primary hard disk for the Operating system
- Secondary 72 GB hard disk for application data
- Internal CD-ROM
- External DVD writer
- Operating Software
- Microsoft Windows XP Professional UK Operating System

Conditionally:

- Integris 3D-RA Calibration Tool Kit
- Grids for pincushion distortion and focus shift calibration
- Phantom for geometry calibration
- Phantom for user validation
- Allura 3D-CA
- Phantom for geometry calibration
- StentBoost
- Phantom for user validation

Compatible with:
· Integris series with connectivity release
· Allura Xper series

Line #	Part #	Description	Qty
19	**NCVA590	Real time image link	1

Real Time digital image link to an off-line Allura Interventional Hardware station. This applies on the applications 3D-RA, StentBoost and 3D-CA on the Interventional Hardware. This dedicated digital link sends raw or processed image data (depending on the application) real time during monoplane exposures to the connected Interventional Hardware station, to allow instant results of the applicable reconstruction after the exposure run.

In biplane systems, this digital link is available for the frontal channel only.

Line #	Part #	Description	Qty
20	**NCVC409	EP Navigator R5	1

EP navigator facilitates catheter navigation in ablation procedures, by providing a three-dimensional (3D) overlay of the real patient anatomy onto live fluoroscopic images. The 3D anatomy is registered to the fluoroscopy and shows the position of all catheters in relation to the anatomy. EP navigator follows the rotation of the C-arc and the movement of the table.

The 3D anatomy is obtained using an intra-procedural 3D rotational scan or a pre-procedural cardiac CT or MR scan, from which the cardiac structures (left atrium, right atrium, left ventricle, right ventricle, aorta, coronary sinus, and trachea) are segmented. Automatic segmentation is provided for the left atrium and trachea. User-aided segmentation is possible for other anatomic structures.

In addition to the overlay functionality onto live fluoroscopic images, the segmented 3D rotational scan, CT or MR anatomy from EP navigator can be seamlessly transferred to a compatible mapping system. This allows navigating catheters on images with real 3D anatomical detail without using X-ray.

Using the Endo View function, the endocardial surface can be visualized, providing a view of important anatomical structures such as, in the left atrium, the pulmonary veins and the ridge to the left atrial appendage. The Point Tagging function allows the placement of tag markers on the surface of the anatomy, to mark sites of interest such as ablation lesions. Using the snapshot functionality, a screen image of the live screen can be made, perfectly suitable for reporting or teaching purposes

Comprehensive parts coverage for EP Navigator including replacement. Labor will be provided if the base plan includes labor coverage or if labor is purchased as an option. If not, labor will be available for purchase at preferred labor rate.

Comprehensive parts coverage for EP Navigator including replacement. Labor will be provided if the base plan includes labor coverage or if labor is purchased as an option. If not, labor will be available for purchase at preferred labor rate.

Clinical Education Program for EP Navigator

CV EP Navigator OnSite Education:

Clinical Education Specialists will provide sixteen (16) hours of CV EP Navigator OnSite Education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref# 230-100615

Line #	Part #	Description	Qty

21 ****NCVC419** **3D EP Rotational Scan R5** **1**

3D EP rotational scan reconstructs three-dimensional (3D) cardiac anatomy from a rotational angiography. It provides real-time and 3D anatomic detail during the intervention, in the EP lab itself.

When used as an overlay onto live fluoroscopic images, this 3D anatomy is used in EP navigator as a roadmap to guide catheter navigation. Alternatively, the segmented 3D anatomy can be transferred to a compatible mapping system to navigate catheters on images with real 3D anatomical detail without using X-ray.

The 3D EP rotational scan features a unique reduced angular rotation range in head and nurse position to simplify the workflow, e.g. not interfere with anesthesia logistics. All EP navigator functions, such as Endo View and Point Tagging, are available when using 3D EP rotational scan

22 ****NCVB294** **Set of 2 additional 21in. LCDs** **1**

Two 21inch additional displays are located on top of the monitor ceiling suspension frame which carry the 56 inch large screen color LCD display.

These 2 additional LCD's can be used to display additional video sources or used as display back up for Hemo and Xray Live images. These LCD's have a fixed content.

Main characteristics of back-up displays are:

- 21.3 inch, 2 Megapixel color LCD display
- Max. resolution: 1600x1200
- Brightness: 450 Cd/m2
- Contrast ratio : 550:1
- Wide viewing angle (approx. 170 degrees)
- Constant brightness stabilization control
- Independently selectable brightness settings for monochrome and color images
- Independently selectable lookup table for gray-scale, color and DICOM transfer function

FCV0587, "XPer Live/Ref Slaving" required when displaying X-Ray Live as back-up.

23 ****980406190009** **PIVOTING TABLE-MOUNTED RADIATION SHIELD** **1**

Table-mounted radiation shield for additional protection of physician and staff against scatter radiation. The shield consists of two protective parts: a lower shield and an upper shield. The shield is specially designed for use with the AD5 patient table.

The table mounted radiation shield provides the following features:

- Mounting to either the right orleft tableaccessory rails;
- Pivoting into the required working position;
- Pivoting into the parking underneath the tabletop facilitating patient preparation;
- The upper shield can be positioned upright providing optimal protection or can be folded down for free access to the patient.

Line #	Part #	Description	Qty

The table mounted radiation shield includes:

- Lower shield measuring 70 cm high 80 cm wide 0.5 mm Pbequivalence;
- Upper shield measuring 40 cm high 50 cm wide 0.5 mm Pbequivalence;
- Mounting clamp;

Docking device for wall mounting.

24 ****989801220012** **Cable Spooler** **1**

25 ****989801220037** **M LED 3MC Light** **1**

MAVIG M3 MC LED - Multi Color / power Supply Included
Includes Portegra2 Ext Spring Arm 75/90cm

26 ****989801220273** **Ceiling Track w/Column & Handle Ext** **2**

Mavig 2.5m Ceiling Track with Ceiling trolley, 360 degree column, and brake handle extension.

27 ****989801220284** **ISM Premium Audio Package** **1**

The Premium Audio Package is comprised of the following items:

Control System - Touchscreen Control Package offers touchscreen control with 7" Touch panel

Advanced Audio Communication System with Hands Free Telephony - Advanced audio uses an echo cancelling audio communication system with the EasySuite touchscreen to call or receive a telephone call. The hands-free system utilizes O.R. loudspeakers and 1 boom mounted microphones with no handset required.

MP3 Audio and Charging Interface - Universal MP3 music interconnection system allows any 3.5mm jack-enabled personal audio device to play music through the Advanced Audio System. Provides integrated charging capability via USB.

Speaker Upgrade for AAC (adds 2 additional speakers for Exam Room) Upgrade adds two recessed ceiling mounted speakers to the Standard Audio System, or Advanced Audio System, for a total of four speakers per Operating Room.

PTT Control Room Communication System with Control Room Loudspeakers - Push to talk intercom microphone system for control room plus two recessed ceiling mounted speakers for Control Room.

Ambient Room Lighting Control Enables touch panel control of room lights using customer provided lighting controller. Functions include on/off and ability to select multiple lighting presets.

28 ****989801220345** **Personal Wireless Bidirectional Audio** **1**

Personal Wireless Bidirectional Audio with One Wireless Microphone Set - Provides bidirectional audio comunication for one user with one wireless microphone set.

29 ****989801220346** **Add'l Wireless Microphone Set for Personal Audio** **1**

Additional Wireless Microphone Set for Personal Bidirectional Audio - Adds a second user to Personal Wireless Bidirectional Audio Option plus additional wireless microphone set.

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Line #	Part #	Description	Qty
30	**989801220373	**Contoured Rad Shield w/lead curtain**	2

Ceiling mounted X-ray protective shield with curtain incl. 1 box of sterile covers (CE, FDA)

Portegra2 extension-/spring-arm combination including lead acrylic shield for femoral and radial access with flexible curtain.

The curtain, (flexible strips) mounted on the bottom of the shield. The special design and the flexibility of the curtain allows it to perfectly adapt to the patient's body without producing gaps between the strips, reducing the scatter radiation emitting from the patient's body in the direction of the user.

Line #	Part #	Description	Qty
31	**989801220375	**Black Anti-fatigue Floor Mat w/logo.**	1

Black Anti-fatigue Floor Mat with Philips Logo

36" x 60"

Line #	Part #	Description	Qty
32	**989801292098	**IXR Additional Training 16 Hours OnSite**	1

Clinical Education Specialists will provide sixteen (16) hours of CV OnSite Education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. CEU credits may be available for each participant that meets the guidelines provided by Philips. Note: Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. Education expires one (1) year from the earlier of equipment delivery date or purchase date.

Line #	Part #	Description	Qty
33	**989801299784	**XD9702 Flexvision XL eLearn**	1

Course Number: XD9702
Course Title: FlexVision XL
CSIP Level: All course materials are on CSIP level 1
Course Length: 10 hours
Delivery Method(s): Standard eLearning
Modality: IGT Systems
Location: Online
Target Audience: Field Service Engineers and Licensed Representatives
System Code(s): Not applicable

DESCRIPTION:

This e-learning module will familiarize the engineer with FlexVision XL basics with regards to:

- System Architecture
- Signal Flow
- Setting to Work
- Monitor replacement

This course has a one question exam only. You have to declare that you studied and understood the content in order to be certified as trained.

PREREQUISITES:

All of the below courses:

- FC9002 – Safety
- FC9003 – Imaging Systems Safety

* PHILIPS PROPRIETARY MATERIALS SUCH AS DIAGNOSTIC SOFTWARE AND SERVICE DOCUMENTATION ARE NOT INCLUDED IN THE

Line #	Part #	Description	Qty

TRAINING AND WILL NOT BE AVAILABLE FOR USE OUTSIDE OF THE TRAINING ENVIRONMENT. THE TRAINEE MUST RETURN ALL PROPRIETARY MATERIALS RECEIVED DURING THE TRAINING AT THE END OF THE TRAINING. CUSTOMER ACKNOWLEDGES AND AGREES THAT NEITHER CUSTOMER NOR TRAINEE WILL RECEIVE A LICENSE TO SUCH PROPRIETARY MATERIALS AND THAT THE TRAINEE MAY NOT BE ABLE TO FULLY UTILIZE THE TRAINING WITHOUT THE USE OF SUCH PROPRIETARY MATERIALS. (CERTAIN LICENSES MAY BE OBTAINED THROUGH PURCHASE OF A PHILIPS RIGHTFIT SERVICE AGREEMENT.) Course dates and location to be finalized by Philips. Philips shall attempt to accommodate Customer requested dates and training location. The price quoted includes course tuition. Travel and living expenses are not included, but may be purchased separately through Philips.

IMPORTANT Notes Regarding Admission to Philips Customer Engineer Training Courses:

Trainee must meet all prerequisites
Course expires one (1) year from equipment installation date (or purchase date if sold separately)
Customer must sign Philips Nondisclosure statement
Trainee must sign Philips Nondisclosure statement
Customer must sign Philips terms and conditions of training

34 ****989801299780** **XD3894 ALLURA XPER REL8.2 ESSENTIAL** **1**

PHILIPS PROPRIETARY MATERIALS SUCH AS DIAGNOSTIC SOFTWARE AND SERVICE DOCUMENTATION ARE NOT INCLUDED IN THE TRAINING AND WILL NOT BE AVAILABLE FOR USE OUTSIDE OF THE TRAINING ENVIRONMENT. THE TRAINEE MUST RETURN ALL PROPRIETARY MATERIALS RECEIVED DURING THE TRAINING AT THE END OF THE TRAINING. CUSTOMER ACKNOWLEDGES AND AGREES THAT NEITHER CUSTOMER NOR TRAINEE WILL RECEIVE A LICENSE TO SUCH PROPRIETARY MATERIALS AND THAT THE TRAINEE MAY NOT BE ABLE TO FULLY UTILIZE THE TRAINING WITHOUT THE USE OF SUCH PROPRIETARY MATERIALS. (CERTAIN LICENSES MAY BE OBTAINED THROUGH PURCHASE OF SUPPORT OR ASSIST AGREEMENT.) Course dates and location to be finalized by Philips. Philips shall attempt to accommodate Customer requested dates and training location. The price quoted includes course tuition. Travel and living expenses are not included, but may be purchased separately through Philips.

IMPORTANT Notes Regarding Admission to Philips Customer Engineer Training Courses:

1. Trainee must meet all prerequisites

2. Course expires one (1) year from equipment installation date (or purchase date if sold separately)

3. Customer must sign Philips Nondisclosure statement

4. Trainee must sign Philips Nondisclosure statement

5. Customer must sign Philips terms and conditions of training

Course Number:

XD3894

100241 Allura Xper FD10

Line #	Part #	Description	Qty

Course Title:

Allura Xper release 8.2 Essentials

CSIP Level:

All course materials are on CSIP level 1

Course Length:

9 days

Delivery Method(s):

ILT

Modality:

iXR

Location:

PHC, CTC, SLC, HCA

Target Audience:

Field Service Engineers (multi-modality)

Licensed Representatives

System Code(s):

Associated system codes: 722-026, 722-027, 722-028, 722-029, 722-033, 722-034, 722-035, 722-036, 722-038, 722-039, 722-058, and 722-059

Document Date:

2015-05-26

DESCRIPTION:

After successfully finishing this training the Engineer reaches compliance to work on the above mentioned system codes. The training is performed on "basic" system configurations.

Commercially available system options are only partially covered; these are offered as separate courses.

Aims of this training are :

- The engineer will learn how to:
- perform planned maintenance.
- execute a repair of the system.
- perform 1st line fault diagnosis on the system.

Topics covered:

- Planned Maintenance
- plan visits
- perform preparation:
- customize planned maintenance modules
- determine visit type
- get latest planned maintenance instructions
- determine needed tools and materials
- operate the system; basic understanding of system operation
- use software service tools; field service framework and the Xper management tool on a basic level.
- perform the following planned maintenance instructions:
- general planned maintenance
- adjust generator, adjust image detector and perform level 1 Image Quality measurements
- adjust geometry
- patient support AD7X(N)T
- radiation safety
- electrical safety
- XtraVision release 8.8.1/9.0.x
- finishing activities

Repair

For these repairs it is assumed that the fault diagnosis has been done by remote support, tier 2 or tier 3.

- Identify "all" Field Replaceable Units of the Allura Xper rel. 8.2 system
- Find the correct service instruction to replace a Field Replaceable Unit
- Identify connections between parts using the corrective maintenance manual
- Perform replacement cases; demonstrate replacement of various parts using the appropriate repair manual.

First line fault diagnosis

Use the Corrective maintenance manual for faultfinding

- diagnostic flows (90%)
- functional diagrams (5%)
- led indications (5%)

Line #	Part #	Description	Qty

- Learn how power is distributed
- Escalate to helpdesk
- Perform various fault finding cases
- power on problems
- movement problems
- acquisition problems

PREREQUISITES:

All of the below courses:

- FC9002 – Safety
- FC9003 – Imaging Systems Safety
- XD3007 – X-Ray Systems basic part 2
- XD9903 – Anatomy and pathology of the heart and bloodvessels
- XD9904 – Allura Xper Operation and Clinical Workflow
- FC9017 – Basic Networking

COURSE OBJECTIVES:

Upon successful completion of the course the learner will be able to:

- perform planned maintenance on the system according the planned maintenance instructions.
- execute a repair of the system with the help of available repair manuals.
- perform 1st line fault diagnosis on the system using the corrective maintenance manual.

35 ****989801299617** **XD8982ALLURAXPERCLARITY REL8.2CTC5D** **1**

Allura Xper / Clarity release 8.2

Course Number: XD8982
System Codes: 722-026, 722-027, 722-028, 722-029, 722-033, 722-034, 722-035, 722-036, 722-038, 722-039
Course Title: Allura Xper / Clarity release 8.2
Course Length: 5 days
Delivery Method(s): ILT
Modality: iXR-CV
Location: PHC and CTC
Target Audience: CS Field Service Engineers

DESCRIPTION:
This course will provide information on and in insights in the differences between Allura Xper release 8.1 and Allura Xper / Clarity release 8.2.

PREREQUISITES:

Line #	Part #	Description	Qty

XD3970, Allura Xper Rel 7.6 part 1(Or history courses XD3966 & XD9065 or XD3875 & XD9065);

Field experience;

XD9906, Allura Xper update to R8.1;

FC9021 Cat Tool.

COURSE OBJECTIVES:
Upon completion of this course and using the appropriate service manuals, the FSE can:
• Identify differences between the 8.1 release and the 8.2 release.
• Recognize new system parts.

- Certeray Generator

- motion control Clea-stand

- FD20 and FD15 detector

- AD7XT and AD7XNT table

- Power Supply gPDU

- Cabinet layout and cable routing
• Identify and sequence the steps to installing an 8.2 release.
• Identify the new service documentation structure
• Identify the Diagnostic CM procedures.

* PHILIPS PROPRIETARY MATERIALS SUCH AS DIAGNOSTIC SOFTWARE AND SERVICE DOCUMENTATION ARE NOT INCLUDED IN THE TRAINING AND WILL NOT BE AVAILABLE FOR USE OUTSIDE OF THE TRAINING ENVIRONMENT. THE TRAINEE MUST RETURN ALL PROPRIETARY MATERIALS RECEIVED DURING THE TRAINING AT THE END OF THE TRAINING. CUSTOMER ACKNOWLEDGES AND AGREES THAT NEITHER CUSTOMER NOR TRAINEE WILL RECEIVE A LICENSE TO SUCH PROPRIETARY MATERIALS AND THAT THE TRAINEE MAY NOT BE ABLE TO FULLY UTILIZE THE TRAINING WITHOUT THE USE OF SUCH PROPRIETARY MATERIALS. (CERTAIN LICENSES MAY BE OBTAINED THROUGH PURCHASE OF SUPPORT OR ASSIST AGREEMENT.) Course dates and location to be finalized by Philips. Philips shall attempt to accommodate Customer requested dates and training location. The price quoted includes course tuition. Travel and living expenses are not included, but may be purchased separately through Philips.

IMPORTANT Notes Regarding Admission to Philips Customer Engineer Training Courses:

1. Trainee must meet all prerequisites

2. Course expires one (1) year from equipment installation date (or purchase date if sold separately)

Line #	Part #	Description	Qty

3. Customer must sign Philips Nondisclosure statement

4. Trainee must sign Philips Nondisclosure statement

5. Customer must sign Philips terms and conditions of training

36 ****NCVC005** **Equipment Rack DVI** **1**

The Equipment Rack for EP cockpit allows users of the Philips Allura Xper[Clarity] system to organize all the equipment used in an EP Lab on one moveable rack and removes cable clutter through a cable conduit. This provides a much "cleaner" organized look for the busy EP Lab. The ceiling-mounted Equipment Rack, located in the Exam Room, can support 3rd party equipment. Cabling for this equipment is guided up through the ceiling mounted suspension. It can be moved by swiveling the ceiling mounted boom. The Equipment Rack can be positioned within a circular range of 1.6 meters.
The Equipment Rack consists of:
• 5 shelves and 1 drawer with flexible mounting position and can support 150kg of equipment weight.
• An infusion extension rod
• An extension arm with a standard VESA mounting plate, on which different types of equipment can be mounted
• A Wall Connection Box (1 of the standard EP cockpit Wall Connection Boxes) with Power (230V, 50Hz), Grounding, Network (RJ45), Keyboard/mouse (USB) and Video (DVI) connections
• 10 country-specific power connectors
Note: For USA/Canada 16 country specific power connectors
• 4 Ethernet network connectors
• Ergonomically operating handles with electric brakes
• Standard gas outlets for O2, NO2, and Vacuum
Notes:
• Life-supporting equipment cannot be connected to the Equipment Rack.
• Medical equipment with dedicated keyboards or displays should not be connected without consent of the manufacturer. Please contact your 3rd party equipment vendor for information and clearance.
• Please contact 3rd party equipment vendor for information and clearance in case of cable routing through equipment rack.
• The Wall Connection Box can be used to connect 3rd party equipment that complies with the following requirements:
• Qualified medical electrical equipment [IEC 60601-1]
• IEC 950 only if connected to an EP cockpit Wall Connection Box mains (230V) connection in the Control Room or otherwise isolated from hospital mains according IEC60601-1.
• Connected to the same earth as the Philips Protective Conductor Bar (PPCB).
• Can be operated with a standard AT 101-key US English keyboard connected through a USB connection.
• Provide video-output that matches the display range of the Color monitor that is used for display. Standard VESA video formats up to 1920x1200 are supported

37 ****989600207421** **Equipment rack Predelivery set** **1**

Pre-delivery for Equipment Rack.

38 ****NCVC413** **Electrical Accessory kit OSC** **1**

39 ****NCVC414** **Pre-Install Bracket** **1**

100241 Allura Xper FD10

Line #	Part #	Description	Qty
40	**NCVC415	Pneumatic Regulator	1
41	**989600213942	AD5 TO XPER TABLE ADAPT. PLATE	1
42	**989801220282	25 kVA Fluoro Only UPS - UTS	1

Fluoroscopy Only Solution using 25 kVA UPS and Universal Transfer Switch With 12.5 Minute Battery System. Release 8.2 Ready

This proposal includes the following components:
25 kVA UPS

- Wired: 480v AC 3 phase input; 480v AC 3 phase output*
- Fully rated Static Bypass Switch
- Input Isolation Transformer; Output AutoTransformer
- Dimensions: 36.3D x 20"W x 59.8H"
- Weight: 998 lbs (approximate).

Battery Cabinet

- 12.5 Minutes of runtime at full load
- 31"D x 17.5"W x 47.4"H
- Weight: 880lbs (approximate)

Universal Transfer Switch

- Dimensions: 12"D x 24"W x 36"H
- Weight: 150 lbs (approximate)

DC Power Supply

- Artesyn/Emerson Part Number 73610129
- Single Unit Included for Mono Plane Systems
- Dimensions: 13.9" L x 6" W x 3" H
- Weight: 40 lbs (approximate).

43	SP005	Contract Labor	1

Labor to remove and dispose of existing Omega EP Lab.

44	Third Party Item	Bariatric table extender	1

Bariatric table extender with velcro straps for square-end AD7 table.

100241 Allura Xper FD10

Line #	Part #	Description	Qty
45	SP019	Trade in Allowance	1

Customer represents and warrants that (i) Customer has, and shall have when title passes, good and marketable title to the equipment being traded in and (ii) has the authority to effect such trade in.

Product: OMEGA E/P LAB
Serial Number: 64-05
Manufacturer: OMEGA MEDICAL IMAGING

Trade-In authorization number: 42517

Trade-In Value: $0.00

De-install Date: 4/25/2017

Customer will be trading-in equipment that is described on the attached System Disclosure Form (the "Trade-In"), which Trade-In the parties agree (i) will be removed on the De-install Date and (ii) is currently in the condition as represented on the System Disclosure Form. In addition, the parties agree as follows:

1. Customer represents and warrants that Customer has good and marketable title to the Trade-In as of the date of this Quotation and will have good and marketable title when Philips removes the Trade-In from Customer's site (the "Removal Date");
2. Title to the Trade-In shall pass from Customer to Philips on the Removal Date, unless otherwise agreed by Philips and the Customer;
3. Notwithstanding anything to the contrary in any Business Associate Addendum, Customer represents and warrants that as of the Removal Date all Protected Health Information will have been de-identified or removed from the Trade-In;
4. Philips may test and inspect the Trade-In prior to de-installation. If the condition of the Trade-In is not substantially the same on the Removal Date (ordinary wear and tear excepted) as it is identified on the System Disclosure Form, then Philips may reduce the price quoted for the Trade-In;
5. If the removal date is delayed until after the De-Install Date, unless Philips causes the delay, then Philips may reduce the price quoted for the Trade-In by six percent (6%) per month.
6. Philips is responsible for normal de-installation costs of the Trade-In.
7. The trade-in value will not include costs associated for any facility modifications and/or rigging required for de-installation and must be accounted for separately.
8. Customer is responsible for all plumbing necessary to properly drain coolant from chiller system and cap the lines.
9. Prior to the Removal Date, Customer shall remove from the room all equipment that is not being de-installed.

********PROMOTIONS********

Promotion Name	Description
Mono Closer 2016-Q4	Philips is pleased to offer this special promotional discount of $50,000 with the purchase of a monoplane Allura system. To be eligible for this promotion, orders must be received by December 30, 2016.
AlluraClarity New System Promotion (Monoplane) 2016-Q4	Philips is pleased to offer this special $50,000 discount for customers purchasing AlluraClarity systems. To take advantage of this promotion, customer orders must be placed prior to December 30, 2016.
EP Navigator Promotion 2016-Q4	Philips is pleased to offer this special promotional discount of $40,000 with the purchase of EP Navigator. To be eligible for this promotion, orders must be received by December 30, 2016.
EP Cockpit Promotion, 2016-Q4	Philips is pleased to offer this special promotional discount of $40,000 with the purchase of EP Cockpit. To be eligible for this promotion, orders must be received by December 30, 2016.

100241 Allura Xper FD10

NET PRICE $1,199,243.68

Buying Group: CAROLINAS HEALTHCARE SYSTEM SCA Contract #: CAA0013200

Addt'l Terms:

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

Price above does not include any applicable sales taxes.

The preliminary delivery request date for this equipment is:_____.

If you do not issue formal purchase orders indicate by initialing here_____.

Tax Status:

Taxable_____ Tax Exempt_____

If Exempt, please indicate the Exemption Certification Number:_____, and attach a copy of the certificate.

Delivery/Installation Address:

_____

_____

_____

Invoice Address:

_____

_____

_____

Contact Phone #:

_____

Contact Phone #:

_____

Purchaser approval as quoted:

_____

Date:

_____

Title:

_____

This quotation is signed and accepted by an authorized representative in acknowledgement of the system configuration, terms and conditions stated herein.

PHILIPS PRODUCT WARRANTY

CARDIOVASCULAR (CV) SYSTEMS

This product warranty document is an addition to the terms and conditions set forth in the quotation to which this warranty document is attached. The terms and conditions of the quotation are incorporated into this warranty document. The capitalized terms herein have the same meaning as set forth in the quotation.

TWELVE-MONTH SYSTEM WARRANTY
Philips warrants to Customer that the Philips Vascular and Cardiac Systems (the "System") as delivered to Customer will perform in substantial compliance with its performance specifications for a period of twelve (12) months upon first patient use. Any glassware or flat detectors provided with the System is subject to special warranty terms set forth below.

PLANNED MAINTENANCE
During the warranty period, Philips personnel will schedule planned maintenance visits, in advance, at a mutually agreeable time on weekdays, between 8:00 A.M. and 5:00 P.M. local time, excluding Philips observed holidays.

SYSTEM UPGRADES
Any commercially available upgrade to the System which is hereafter installed by Philips during the original term of the System warranty shall be subject to the warranty terms contained in the first paragraph of this warranty, except that such warranty shall expire on the later of: a) upon termination of the initial twelve (12) month warranty period for the System on which the upgrade is installed or b) after ninety (90) days for parts only from the date of installation.

MRC X-RAY TUBES
Philips warrants to Customer, for the warranty periods further specified in this section, that the Philips X-Ray tube will be substantially free from defects in material and manufacturing workmanship, which impair performance under normal use as specified in Philips product descriptions and specifications.

The warranty period for MRC tubes provided with Customer's purchase of a new or refurbished X-ray system shall be the shorter of thirty-six (36) months after installation or thirty-eight (38) months after date of shipment from Philips. The warranty period for purchases of replacement tubes shall be the shorter of twelve (12) months after installation or fourteen (14) months after date of shipment from Philips.

MRC TUBE WARRANTY EXCLUSION
The above warranty shall not apply to X-ray tubes outside the United States and Canada. Philips' obligations under the product warranty do not apply to any product defects resulting from: improper or inadequate maintenance or calibration by Customer or its agents; Customer or third party supplied software, interfaces, or supplies; use or operation of the product other than in accordance with loss, or damage in transit; improper site preparation; unauthorized maintenance or Philips' applicable product specifications and written instructions; abuse, negligence, accident, modifications to the product; or, to viruses or similar software interference resulting from the connection of the product to a network.

MRC TUBE WARRANTY REMEDIES
If a tube is found to fail during the warranty period, and if, in the best judgment of Philips, the failure is not due to neglect, accident, improper installation, use contrary to instructions, or the exclusions stated above, Philips' tube warranty liability hereunder is limited to, at Philips option, the repair or replacement of the tube. Any replacement tube would have a warranty period equal to the balance of the warranty period left on the tube replaced.

IMAGE INTENSIFIER TUBES
Philips warrants the image intensifier tubes provided with the System, if any, will be free from defects in material and manufacturing workmanship for twenty-four (24) months. Claims must be made within twenty-four (24) months after installation or twenty-seven (27) months after date of shipment from Philips, whichever occurs first. If an image intensifier tube fails to meet this warranty, as Customer's sole and exclusive remedy, upon return of the tube, Philips will provide a prorated credit towards the purchase of a replacement tube from Philips as follows:

USAGE				CREDIT
0	to within	12	months	100%
12	to within	13	months	50%
13	to within	14	months	46%
14	to within	15	months	42%
15	to within	16	months	37%
16	to within	17	months	33%
17	to within	18	months	29%
18	to within	19	months	25%
19	to within	20	months	21%
20	to within	21	months	17%
21	to within	22	months	12%
22	to within	23	months	8%
23	to within	24	months	4%

Tubes received by Philips under this warranty that are found to meet all test specifications will be returned to the Customer and the warranty will continue as of the original date of installation. Examination of the returned tube may necessitate its destruction, but Philips' liability shall, in any case be limited to repair or replacement as aforesaid, only if in its sole opinion the tube has been properly used, installed and applied and has not been subjected to neglect, accident, or improper installation, or use. Transportation charges and risk of loss, both ways, of returned or replaced tubes shall be at the expense of the Customer.

DYNAMIC FLAT DETECTORS
Philips warrants the flat detectors provided with the System, if any, will be free from defects in material and manufacturing workmanship for twelve (12) months. Claims must be made within twelve (12) months after installation or fifteen (15) months after date of shipment from Philips, whichever occurs first. If a detector fails to meet this warranty, as Customer's sole and exclusive remedy, upon return of the detector, Philips will provide Customer a replacement detector at no additional charge.

SYSTEM SOFTWARE AND SOFTWARE UPDATES
The software provided with the System will be the latest version of the standard software available for that System as of the 90th day prior to the date the System is delivered to Customer. Updates to standard software for the System that do not require additional hardware or equipment modifications will be performed as a part of normal warranty service during the term of the warranty.

All software is and shall remain the sole property of Philips or its software suppliers. Use of the software is subject to the terms of a separate software license agreement. Customer must sign all such license agreements prior to or upon the delivery of the product. No license or other right is granted to Customer or to any other party to use the software except as set forth in the license agreements.

Any Philips maintenance or service software and documentation provided with the product and/or located at Customer's premises is intended solely to assist Philips and its authorized agents to install and to test the System, to assist Philips and its authorized agents to maintain and to service the System under a separate support agreement with Customer, or to permit Customer to maintain and service the System. Customer agrees to restrict the access to such software and documentation to Philips' employees and those of its authorized agents, and to authorized employees of Customer only.

WARRANTY LIMITATIONS
Philips' obligations under the System warranty are limited, at Philips' option, to the repair or the replacement of the System or a portion thereof, or to a credit or refund of a portion of the purchase price paid by Customer. Any refund or credit will be paid to Customer when the System is returned to Philips. Certain of the parts used in the manufacture or installation of, or in the replacement parts for, this System may contain refurbished components. If such components are used, they will be subject to the same quality control and inspection procedures as all other components in the System. Any System warranty is made on condition that Philips receives written notice of a System defect during the warranty period, and within thirty (30) days following the discovery of the defect by Customer. Philips' obligations under the System warranty do not apply to any System defects resulting from: improper or inadequate maintenance or calibration by Customer or its agents; Customer or third party supplied software, interfaces, or supplies; use or operation of the product other than in accordance with loss, or damage in transit; improper site preparation; unauthorized maintenance or Philips' applicable product specifications and written instructions; abuse, negligence, accident, modifications to the System; or to viruses or similar software interference resulting from the connection of the product to a network. Philips does not provide a warranty for any such third party products furnished to Customer by Philips; however, Philips shall use reasonable efforts to extend to Customer the third party warranty for the product. The obligations of Philips described above are Philips' only obligations and Customer's sole and exclusive remedy for a breach of a System warranty. Repairs or replacement parts do not extend the term of this warranty.

THE WARRANTIES SET FORTH IN THIS WARRANTY DOCUMENT WITH RESPECT TO THE SYSTEM (INCLUDING THE SOFTWARE PROVIDED WITH THE SYSTEM), GLASSWARE, AND DETECTORS ARE THE ONLY WARRANTIES MADE BY PHILIPS IN CONNECTION WITH THE SYSTEM, SOFTWARE, GLASSWARE, DETECTORS, AND THE TRANSACTIONS CONTEMPLATED BY THE QUOTATION, AND ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ACCESS TO SYSTEM

Philips shall have full, free and safe access to the System and Customer's operation, performance and maintenance records for the System, on each scheduled or requested warranty service visit. Philips shall also have access to and use of any machine, service, attachment, features or other equipment required to perform the necessary service contemplated herein at no charge to Philips. Customer waives warranty service if it does not provide such access to the System and Customer's records. Should Philips be denied access to the System and Customer's records at the agreed upon time, a charge equal to the appropriate hourly rate will be accepted by Customer for "waiting time."

WARRANTY SERVICE

In the event it is not possible to accomplish warranty service within normal working hours (8:00 A.M. to 5:00 P.M., Monday through Friday, excluding Philips observed holidays), or in the event Customer specifically requests that warranty service be performed outside of Philips normal working hours, Customer agrees to pay for such services at Philips standard service rates in effect. Maintenance Agreements are available for extended coverage.

TRANSFER OF SYSTEM

In the event Customer transfers or relocates the System, all obligations under this warranty will terminate unless Customer receives the prior written consent of Philips for the transfer or relocation. Upon any transfer or relocation, the System must be inspected and certified by Philips as being free from all defects in material, software and workmanship and as being in compliance with all technical and performance specifications. Customer will compensate Philips for these services at the prevailing service rates in effect as of the date the inspection is performed. Any System which is transported intact to pre-approved locations and is maintained as originally installed in mobile configurations will remain covered by this warranty.

CONDITIONS

This warranty is subject to the following conditions: the System (a) is to be installed by authorized Philips representatives (or is to be installed in accordance with all Philips installation instructions by personnel trained by Philips), (b) is to be operated exclusively by duly qualified personnel in a safe and reasonable manner in accordance with Philips written instructions and for the purpose for which the products were intended, (c) is to be maintained and in strict compliance with all recommended and scheduled maintenance instructions provided with the System, and (d) Customer is to notify Philips immediately in the event the System at any time fails to meet its printed performance specifications.

LIMITATIONS OF LIABILITY AND DISCLAIMERS

The liability, if any, of Philips AND ITS AFFILIATES for damages whether arising from breach of the terms in the quotation, breach of warranty, negligence, indemnity, strict liability or other tort, or otherwise with respect to the products and services is limited to an amount not to exceed the price of the product or service giving rise to the liability.

IN NO EVENT SHALL PHILIPS OR ITS AFFILIATES BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOST REVENUES OR PROFITS, OR THE COST OF SUBSTITUTE PRODUCTS OR SERVICES WHETHER ARISING FROM BREACH OF THE TERMS IN THIS QUOTATION, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT. PHILIPS SHALL HAVE NO LIABILITY FOR ANY GRATUITOUS ADVICE PROVIDED TO THE CUSTOMER.

FORCE MAJEURE

Philips and Customer shall each be excused from performing its obligations arising from any delay or default caused by events beyond its reasonable control including, but not limited to: acts of God, acts of third parties, acts of the other party, acts of any civil or military authority, fire, floods, war, embargoes, labor disputes, acts of sabotage, riots, accidents, delays of carriers, subcontractors or suppliers, voluntary or mandatory compliance with any government act, regulation or request, shortage of labor, materials or manufacturing facilities.

Philips system specifications are subject to change without notice Document Number 4535 983 03234 999

ViewMate™ Ultrasound Imaging Console
Capital Purchase Agreement

This Agreement is entered into by and between St. Jude Medical S.C., Inc., ("USD"), a Minnesota corporation with its principal place of business in Austin, Texas and Carolinas Medical Center Northeast, Concord, NC, customer number 1000010764 ("Account"). The foregoing will be collectively referenced herein as "the Parties". This Agreement will be effective upon full execution by authorized signatories of the Parties.

Offer is valid through April 18, 2017.

PURCHASE TERMS AND CONDITIONS

Account will issue one purchase order ("P.O.") in the amount of $89,000 (plus any applicable shipping and taxes) covering the cost of the Products detailed in the table below at the quantities set forth therein.

PRODUCT DESCRIPTION	ORDER No.	Qty	Customer Price
		Capital Equipment Total	**$89,000**
		North Carolina State Tax (7.0 %)	**$6,230**
ViewMate™ Ultrasound Imaging Console with Battery	H701336	1	$77,000
P4-1C Trans-thoracic Transducer • Phased Array (4-1 MHz) transducer designed to address Adult Echocardiography, Trans-cranial and Abdominal Vascular Imaging. The transducer offers fourteen frequencies within 2D and M-Mode, Tissue Harmonics, Color/Power, PW Doppler, Compound Harmonics, and Compound Imaging. Up to 30 cm penetration. Advanced, fully featured ultrasound system optimized for 64-element phased array intra-cardiac echo (ICE) visualization. System works with the ViewFlex™ family of ICE catheters. The ViewMate System includes the SmartCart and SmartCart battery for operation without plugging into AC power. Software: • Cold Boot-up time, approximately 30 seconds • Modes: 2D/B, M, Color Doppler (CD), Power Doppler, Pulse Wave (PW), Continuous Wave (CW), AUX CW, ECG, TEE and Tissue Harmonics • Auto Opt with ZST – Instantly equalizes tissue gain and brightness. ZST automatically compensates for differences in sound speed propagation from patient echo information. Hardware: • SmartCart battery allows up to 1.5 hours of operation without plugging into AC power • Connects up to 3 transducers simultaneously • Interface Module for ICE • Multifunction USB port, Wireless ready, Digital video • Minimum 120 GB Hard Drive Storage on SmartCart • 19" color, high resolution LCD display mounted on articulating arm of SmartCart • LED display for customizable image mode menus • HDMI/DVI digital video output • CD/DVD burner with integrated DICOM viewing software	H701554	1	$12,000

• Customized, durable baskets to carry supplies Instructions For Use Initial One Year Manufacturer Warranty			

CUSTOMER SERVICE
USD provides 24-hour customer service. For general questions and questions about orders, contact our Customer Service department:

Phone: 855-4stjude
Mail: One Lillehei Plaza
St. Paul, MN 55117
Email: USDCSCapital@sjm.com
Fax: 952-933-0307

Customer Service is open from 7:00 a.m. to 6:30 p.m. U.S. Central time, Monday through Friday, except holidays.

To, contact your **local sales representative** or for urgent issues outside of Customer Service business hours, call 800-PACE-ICD (800-722-3423).

PURCHASE ORDER REQUIREMENTS
Account agrees to issue, or to have its authorized agent issue, USD a purchase order ("P.O.") reflecting the contract number referenced herein and the purchase value referenced above for the Products (plus any applicable shipping and taxes) promptly upon execution of this Agreement. No Products will be shipped and no services will be performed prior to receipt of this P.O. In the event a third-party authorized agent of Account issues the P.O. on Account's behalf, Account hereby guarantees payment upon default of any such agent.

SUBMISSION OF PURCHASE ORDER ABSENT A FULLY EXECUTED AGREEMENT
The terms and conditions set forth in this Agreement constitute an offer from USD to Account relative to Account's purchase of the products covered hereby from USD. In the event that Account submits a purchase order to USD for the products referenced herein without signing this Agreement, the submission of such purchase order shall constitute Account's acceptance of the terms and conditions herein.

PAYMENT TERMS
Net 30 days from date of invoice.
USD accepts payment via wire transfers, Automated Clearing House (ACH) and checks.

COMPLIANCE WITH LAWS
(a) Account shall, in connection with this Agreement, comply with all applicable federal and state laws, regulations, and other authorities, specifically including but not limited to the federal health care program anti-kickback law, 42 U.S.C. § 1320a-7b(b) ("Anti-Kickback Law").
(b) Account hereby acknowledges its legal obligations to fully and accurately report the discounts and/or rebates it receives under all applicable federal and state laws, regulations, and other authorities, specifically including but not limited to the Anti-Kickback Law. As part of the cost reporting process or otherwise, Account may be obligated to report and provide information concerning any discounts, rebates, or other price reductions provided under this Agreement pursuant to 42 U.S.C. section 1320a-7b(b)(3)(A) (the discount exception to the Anti-Kickback Law) and/or 42 C.F.R. § 1001.952(h)(the discount safe harbor to the Anti-Kickback Law), other federal or state laws, or agreement with third party payers. Account should retain this Agreement and any other documentation of discounts, rebates, or other price reductions and make such information available to federal or state health care programs upon request.
(c) USD and Account agree and acknowledge that there may be circumstances in which USD will offer Account, and/or health care professionals affiliated with Account, technical training on its products. This may involve USD's reimbursement for reasonable out-of-pocket expenses, including costs associated with meals, travel and lodging.
(d) USD is an equal opportunity employer and hereby provides notice of its compliance with 41 CFR 60-1.4, 41 CFR 60-250.5, 41 CFR 60-300.5, 41 CFR 60-741.5 and 29 CFR 471 App A, which are incorporated herein by reference.

SHIPPING
Shipping terms are FOB Origin freight prepaid and included.

ADDITIONAL INITIAL SERVICE AND INSTALLATION TERMS
The Product Assurance Plus Warranty Coverage is effective from the completion of installation or first clinical use, whichever occurs first and extends for a period of 12 months thereafter. If following installation of the Product and for its first sixty (60)

days of use, the System becomes inoperable for one (1) day or longer and has to be repaired and/or components replaced, USD will extend the warranty thirty (30) days beyond the standard twelve (12) month period.

ACCOUNT'S OBLIGATIONS

Account shall, at its expense provide all necessary labor and materials for plumbing service, carpentry work, conduit wiring, power switches, network ports and other preparations required for such installations and connection. All such labor and materials shall be completed and available at the time of delivery of the Products by USD. Additionally, Account shall provide free access to the installation site and, if necessary, safe and secure space thereon for storage of Products and equipment prior to installation by USD. Account shall be responsible, at its sole cost and expense, for obtaining all permits, licenses and approvals required by any federal, state or local authority in connection with the installation and operation of the Products, including but not limited to any certificate of need and zoning variances. Account shall provide at its sole cost and expense, that its premises are free of asbestos, hazardous conditions and any concealed, unknown or dangerous conditions and that all site requirements are met.

MAINTENANCE; ALTERATIONS

(a) Should Account need to move the Products to a different location from that where originally placed, Account agrees, to contact USD for assistance with such relocation. Relocations services shall be subject to an additional service charge.

(b) Account will at all times operate the Products in accordance with the Products Instructions for Use (the "IFU") provided to Account by USD and use reasonable care to prevent the Products from being damaged while the Products are in Account's possession and control.

(c) Account will be responsible for the cost of any repairs to the Products as a result of Account's failure to use the Products in accordance with the IFU, or Account's failure to use reasonable care to prevent the Products from being damaged while the Products are in Account's possession and control.

(d) Account will not, without the prior written consent of USD, make any changes or substitutions to the Products. Any and all replacement parts, accessories, authorized changes and/or substitutions for the Products shall become part of the Products and subject to the terms of this Agreement.

INSTALLATION

USD will provide installation services to Account as part of this agreement and at no additional charge, subject to the fulfillment of the provisions set forth in section "ACCOUNT'S OBLIGATIONS" above. The Products covered herein shall be installed by and at the expense of USD except that USD shall not provide site preparation services as defined under section "ACCOUNT'S OBLIGATIONS" unless otherwise agreed to in writing by USD for an additional charge. Installation services shall be included in the purchase price and performed by qualified and trained technical personnel, provided that the installation can be performed during normal business hours. Any overtime charges or other special expenses shall be an additional charge to the prices herein. Installation includes travel and lodging for USD staff to Account's location within the United States. Installation date will be coordinated with Account and total time to install system is not expected to exceed two (2) business days. Should installation time be extended due to factors out of USD's control but within Account's control (e.g. room is not made available on agreed upon date), then Account will be subject to an additional service charge. Installation services include, but are not limited to, the following:

(a) Uncrating and assembly of Products
(b) Placement of Products in Account's desired location
(c) Initial functional testing of Products
(d) Account will be provided a copy of the Installation Report

Installation does not include the running of cables through conduit.

NOTICES

All notices required or permitted under this Agreement shall be sufficient if sent via U.S. mail or express courier delivery to such party at the address set forth in this Agreement, or at such other address as such party may designate to the other party in writing from time to time. Any notice mailed via U.S. mail shall be effective three days after it has been duly addressed and postmarked via the U.S. postal service. Any notice provided to Account or USD shall be directed to the following.

Northeast Medical Center Attention: Director of Purchasing 920 Church Street North Concord, NC 28025	St. Jude Medical S.C., Inc. Attention: Contract Operations 6300 Bee Cave Road Bldg. Two, Suite 100 Austin, Texas 78746

INDEMNIFICATION

(a) USD and Account shall indemnify, hold harmless and defend each other, all of each other's parent and affiliated entities ("Entities"), and each other's and their respective Entities' employees, trustees, directors, officers, agents, assigns, patients, insurers and users of the purchased products from and against all actions, suits, liability, claims, fines, damages, losses and expenses (including reasonable attorney's fees through trial and upon appeal) related to or arising out of: a) the injury of any

person or the injury or destruction of any property arising out of and caused by the grossly negligent acts or omissions of such party, any of its employees, subcontractors or authorized agents (collectively "Staff"); b) the material breach by such party of the terms and conditions of this Agreement; c) violation of any law by such party or its Staff; and d) as to USD's indemnification obligations only, the infringement of any patent by reason of the sale or use of any Products purchased or furnished hereunder.
(b) The indemnified party shall give the indemnifying party prompt notice of any claim that could give rise to a claim for indemnity under this Agreement and the indemnified party shall cooperate with the indemnifying party in the defense of any claim for which indemnity is provided. The indemnifying party shall be permitted to defend the claim and make all decisions thereto, including but not limited to hiring counsel of its choosing. The indemnifying party shall also have the sole right to settle any indemnified legal claim provided that it obtains a complete release for the indemnified party. This Section shall survive the termination or expiration of this Agreement for any reason.

CONFIDENTIALITY
The pricing, terms and conditions offered herein is confidential and proprietary and Account shall not disclose such pricing, terms or conditions to any third party, excepting to its Accountants and attorneys, unless required to do so by law. The confidentiality requirement includes the prohibition of disclosure, whether blinded as to its source or otherwise, to any group purchasing organization, consultant, online comparative source, subcontractor, or temporary employee which may, from time to time, be retained by Account for the purpose of rendering a service. This confidentiality requirement is not only specific to the proposal herein but also to any resultant agreement to purchase. With any breach of this confidentiality requirement, the non-breaching party may rescind or terminate the proposal immediately and may seek any and all remedies available to it as a result of this breach including injunctive relief and damages.

DEFAULT
Any of the following events or conditions shall constitute an Event of Default: (a) if Account defaults in its performance of any of its obligations under this Agreement, upon notice and a fifteen (15) day opportunity to cure; (b) if Account ceases doing business as a going concern; (c) if Account becomes insolvent or makes an assignment for the benefit of its creditors; (d) if a petition or proceeding is filed by or against Account under any bankruptcy or insolvency law; or (e) if a receiver, trustee, conservator, or liquidator is appointed for Account or any of its properties.

Upon the occurrence of any one or more Events of Default, USD will have the right to exercise any one or all of the following remedies (which shall be cumulative), simultaneously or serially, and in any order: (a) to terminate this Agreement; (b) with or without notice, demand or legal process, to retake possession of any or all of the Products (and Account authorizes and empowers USD to enter upon the premises during reasonable business hours wherever the Products may be found) and peaceably retake such Products; or (c) to pursue any other remedy permitted at law or in equity.

ASSIGNMENT
ACCOUNT shall not assign or pledge this Agreement, in whole or in part, nor shall ACCOUNT sublet or lend any product referenced hereunder without prior written consent of St. Jude Medical. Any such attempt by ACCOUNT to sublet or lend any equipment, or assign or pledge this Agreement shall be null and void and of no effect against St. Jude Medical.

NON-WAIVER
No waiver of any of Account's obligations, conditions or covenants shall be effective unless contained in a writing signed by USD. Failure to exercise any remedy which USD may have shall not constitute a waiver of any obligation with respect to which Account is in default.

GOVERNING LAW AND VENUE
This Agreement shall be interpreted and governed by the substantive and procedural laws of the State of Minnesota. The Parties hereto both consent to the jurisdiction of Minnesota courts to resolve any dispute arising from this Agreement.

SEVERABILITY
In the event any sections, sentences, clauses or phrases of this Agreement shall be found to be invalid, void, and/or unenforceable, for any reason, neither the Agreement generally nor the remainder of this Agreement shall, as a result, be rendered invalid, void, and/or unenforceable.

HEADINGS
The section headings set forth in this Agreement are for purposes of convenience only and shall have no bearing whatsoever on the interpretation or actual content of this Agreement.

REMEDIES
In the event of a breach of this Contract, the parties acknowledge that the other party will have available to it all available remedies in law or equity, specifically including, without limitation, monetary damages and/or entitlement as a matter of course to an injunction or similar equitable relief, without bond or with a nominal bond if allowed by law.

CONFLICT BETWEEN CONTRACT AND PURCHASE ORDER

This Agreement contains the entire Agreement between the parties related to the subject matter hereof, and terms of this Agreement shall supersede and replace all prior or conflicting agreements, representations, promises or conditions between the parties with respect to the sale of the products covered hereunder to Account, including but not limited to any additional or conflicting provisions contained in purchase orders or other documentation submitted by Account. This Agreement may not be amended or assigned except by written agreement signed by both parties.

St. Jude Medical S.C., Inc.

By:_____
Signature

Printed Name:_____

Title:_____

Business Phone # of Signatory:_____

Date:_____

Account

By:_____
Signature

Printed Name:_____

Title:_____

Business Phone # of Signatory:_____

Date:_____

Attachment D

Equipment Disposal Letter

PHILIPS

October 27, 2016

Dear Who It May Concern:

This letter is to confirm that the 2005 Omega Medical Imaging CV Lab, Trade-in Opportunity 42617, located at Carolinas Healthcare Systems Notheast, in Concord, North Carolina will be traded-in to Philips Healthcare. Philips will pay for this system to be removed by Imexsal. Imexsal will de-install and remove the equipment out of the State of North Carolina. The cost of removing the equipment is included in the purchase price of the new equipment.

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

Attachment E

Capital Cost Schedule and Architect Signature

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project name: CHS NorthEast EP Lab Renovation

Provider/Company: Carolinas Healthcare System

A.	**Site Costs**			
(1)	Full purchase price of land			$0
	Acres	Price per Acre	$ 0	
(2)	Closing costs			$0
(3)	Site Inspection and Survey			$0
(4)	Legal fees and subsoil investigation			$0
(5)	Site Preparation Costs			
	Soil Borings		$0	
	Clearing-Earthwork		$0	
	Fine Grade for Slab		$0	
	Roads-Paving		$0	
	Concrete Sidewalks		$0	
	Water and Sewer		$0	
	Footing Excavation		$0	
	Footing Backfill		$0	
	Termite Treatment		$0	
	Other (Specify)		$0	
	Sub-Total Site Preparation Costs			$0
(6)	Other (Specify)			$0
(7)	**Sub-Total Site Costs**			**$0**
B.	**Construction Contract**			
(8)	Cost of Materials			
	General Requirements		$524,000	
	Concrete/Masonry		$0	
	Woods/Doors & Windows/Finishes		$0	
	Thermal & Moisture Protection		$0	
	Equipment/Specialty Items		$0	
	Mechanical/Electrical		$0	
	Other (Specify)		$0	
	Sub-total Cost of Materials			$0
(9)	Cost of Labor			$0
(10)	IT Cabling			$25,000
(11)	**Sub-Total Construction Contract**			**$549,000**
C.	**Miscellaneous Project Costs**			
(12)	Building Purchase			$0
(13)	Fixed Equipment Purchase/Lease			$1,199,243.68
(14)	Movable Equipment Purchase/Lease			$95,230.00
(15)	Furniture			$0
(16)	Landscaping			$0
(17)	Consultant Fees			
	Architect and Engineering Fees		$80,000	
	Legal Fees		$0	
	Market Analysis		$0	
	Other (Permit Fee)		$15,000	
	Other (Abatement)		$0	
	Sub-Total Consultant Fees			$95,000
(18)	Financing Costs (e.g., Bond, Loan, etc.)			$0
(19)	Interest During Construction			$0
(20)	Other (Signage)			$10,000
(21)	**Sub-Total Miscellaneous**			**$1,399,473.68**
(22)	**Total Capital Cost of Project** (Sum A-C above)			**$1,948,473.68**

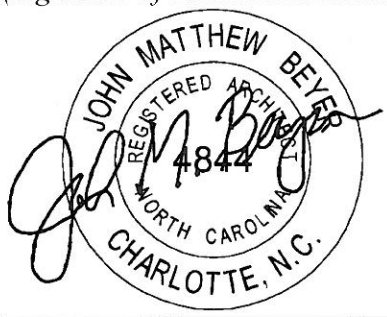
PROPOSED TOTAL CAPITAL COST OF PROJECT

Project Name: **CHS NorthEast EP Lab Renovation**
Provider/Company: Carolinas Healthcare System

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

NC Lic. No 4844

(Signature of Licensed Architect or Engineer)



November 30, 2016

Hannah Kinrade, MHA
Management Associate II
Planning & Development
CHS Management Company
Carolinas HealthCare System
2709 Water Ridge Parkway
Charlotte, NC 28217

Re: CHS NorthEast Medical Center
EP Lab Renovation Upfit
Concord, North Carolina
WMBA # 2928.01
OSR #: 2930214

Ms. Hannah,

I am the Principal-In-Charge of the above referenced project and registered architect licensed by the State of North Carolina, certificate number 4844. This project modifies existing shell space within the CHS NE Surgery Department to create an EP Lab and associated Control Room. These rooms replace an existing EP Lab that is located in another area of the Hospital. The New EP Lab location will include the installation of new EP Lab Equipment and decommission of the existing EP Lab.

The EP Lab Equipment is being replaced as part of a separate CERP previously authorized by Carolinas Healthcare System. For this reason, this equipment replacement cost is not included in this estimate.

I hereby certify that, to the best of my knowledge, the projected costs required for the above reference project are as follows:

Construction Cost including Contingency	$524,000
Professional Design Fees	$80,000
DHSR/Permitting Fees	$15,000
Signage and Move Management	$10,000
Furniture/Soft Goods	$0
IT Infrastructure and Cabling	$25,000
Total Project Cost	$654,000

Please contact me if you have any questions.

Sincerely,
Wright McGraw Beyer Architects, p.a.

John Matthew Beyer, AIA, NCARB
Managing Principal

JMB/hh

CC: Brad Lucas, Project Manager, Carolinas Healthcare System

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