



**NC DEPARTMENT OF
HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

December 11, 2018

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

Exempt from Review – Replacement Equipment

Record #: 2814
Facility Name: Carolinas Healthcare System NorthEast
FID #: 943049
Business Name: The Charlotte-Mecklenburg Hospital Authority
Business #: 1770
Project Description: Replace and relocate cardiac catheterization lab #1
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 December 4, 2018, 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 Philips Azurion 7 M12 cardiac catheterization lab to replace the Philips Allura Xper FD20C cardiac catheterization lab and relocate it to the new patient tower under development on the campus. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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,

Gloria C. Hale
Team Leader

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Melinda Boyette, Administrative Assistant, Healthcare Planning, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 2701 Mail Service Center, Raleigh, NC 27699-2701
www.ncdhhs.gov/dhsr/ • TEL: 919-855-3750 • FAX: 919-733-2757

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



Atrium Health



December 4, 2018

Ms. Martha Frisone, 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: Notice of Exemption for Two Projects on the campus of The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System NorthEast: 1) Replace and Relocate Cardiac Catheterization Lab Equipment in Cardiac Catherization Lab #1 and 2) Replace and Relocate Cardiac Catheterization Lab Equipment in Cardiac Catherization Lab #2

Dear Ms. Frisone:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System NorthEast (CHS NE) is planning to replace and relocate two of its existing cardiac catheterization labs with new, technologically comparable equipment. The existing equipment is currently located in the Cardiac Catheterization Suite on the second floor of the Cabarrus Memorial Building on the main campus of CHS NE. The replacement equipment will be relocated to the new patient tower that is currently under development on the main campus of CHS NE pursuant to previously approved Project ID #F-8219-08. As part of these projects, CHS NE is also planning to install a laminar air flow HVAC system in each cardiac catheterization lab in the new patient tower. The laminar air flow HVAC system is important for infection prevention and will help maintain sterile conditions within the cardiac catheterization labs.

Pursuant to N.C.G.S. 131E-176(22a) which defines replacement equipment and N.C.G.S. 131E-184(a)(7), which provides an exemption from certificate of need review for replacement equipment projects if prior notice is provided to the CON Section, the following letters serve as prior notification of our intent to proceed with the two projects discussed above. We would appreciate your written concurrence that these projects are 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, Assistant Vice-President
Atrium Health Strategic Services Group



Atrium Health

December 4, 2018

Ms. Martha Frisone, 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: Replace and Relocate Cardiac Catheterization Lab Equipment on the campus of 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 and relocate one of its existing cardiac catheterization labs with new, technologically comparable equipment. CHS NE intends to purchase a Philips Azurion 7 M12 to replace a Philips Allura Xper FD20C that was installed in 2008 and is near the end of its useful life and is at risk for service interruptions due to downtime. The existing equipment is currently located in Cardiac Catheterization Lab #1 in the Cardiac Catheterization Suite on the second floor of the Cabarrus Memorial Building on the main campus of CHS NE. The replacement equipment will be relocated to the new patient tower that is currently under development on the main campus of CHS NE pursuant to previously approved Project ID #F-8219-08.

The Azurion 7 M12 will be used for the same types of procedures as the existing equipment and 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 634 procedures were performed in Cardiac Catheterization Lab #1 from November 2017 through October 2018. As part of this project, CHS NE is also planning to install a laminar air flow HVAC system in the cardiac catheterization lab in the new patient tower. The laminar air flow HVAC system is important for infection prevention and will help maintain sterile conditions within the cardiac catheterization lab.

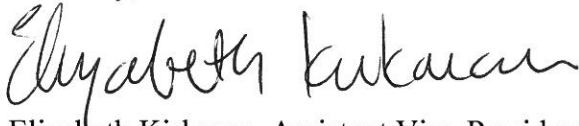
The total cost of this project is \$1,469,795.80, which includes the cost to acquire, install and make operational the replacement equipment and install the laminar air flow HVAC system (construction costs of \$168,500, architect/engineering fees of \$12,750, and the replacement equipment cost of \$1,288,545.80). The cost of the development of the room that the equipment will be relocated to in the new patient tower is included in the capital cost approved under Project ID #F-8219-08. Attachment C provides the quote for the cardiac catheterization equipment. 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 worksheet is 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,

A handwritten signature in black ink that reads "Elizabeth Kirkman". The signature is written in a cursive style with a horizontal line above the name.

Elizabeth Kirkman, Assistant Vice-President
Atrium Health Strategic Services Group

Attachments

Attachment A

EQUIPMENT COMPARISON – Cardiac Catheterization Lab #1

	Existing Equipment	Replacement Equipment
Type of Equipment (List each component)	Cardiac Catheterization Lab	Cardiac Catheterization Lab
Manufacturer of Equipment	Philips	Philips
Tesla Rating for MRIs	N/A	N/A
Model Number	Allura Xper FD20C	Azurion 7 M12
Serial Number	1512	Not Available Until Installed
Provider's Method of Identifying Equipment	Internal Asset # / Serial #	Internal 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	September / October 2008	June / July 2019
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>	\$1,519,095	\$1,379,898
Total Cost of Equipment	\$1,103,537	\$1,288,546
Fair Market Value of Equipment	\$1,103,537	\$1,288,546
Net Purchase Price of Equipment	\$1,103,537	\$1,288,546
Locations Where Operated	CHS NE Cardiac Catheterization Suite (Cabarrus Memorial Building)	CHS NE Modernization Tower
Number Days in Use/To Be Used in N.C. per Year	365 days/year	365 days/year
Percent of Change in Patient Charges (by procedure)	0%	0%
Percent of Change in Per Procedure Operating Expenses (by procedure)	0%	0%
Type of Procedures Currently Performed on Existing Equipment	Cardiac Catheterization	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Cardiac Catheterization



PHILIPS

Image guided therapy

Azurion 7

With **Azurion**,
performance and superior
care become one

The print quality of this copy is not an accurate representation of the original.

Treating patients. It's what you do. You strive every day to provide the best patient care, quickly and reliably, no matter which procedure you are performing. So try to imagine an increased number of procedures, for more patients, carried out consistently and efficiently with fewer preparation errors. Workflow can be optimized and performed on an intuitive platform designed to make your day a lot easier.



Azurion enables you to provide superior care



Azurion helps you optimize your lab performance



An easy-to-use platform supports you in quickly and easily performing diverse procedures

This is exemplified by our Azurion 7. This next-generation image guided therapy platform allows you to easily and confidently perform a wide range of routine and complex procedures with a unique user experience, helping you optimize your lab performance and provide superior care. Azurion is powered by ConnectOS, a real-time multi-workspot technology designed specifically for the Azurion interventional suite.

Intensive user testing has guided the entire development process to make the system easy to use. With this latest Philips innovation in image guided therapy, we reinforce our commitment to you and your patients. Our goal is to help you effectively meet today's challenges so that you are ready for the future.







Azurion enables you
**to provide
superior care**

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In a simulation study with over 60 users globally,

100% believe that the possibility to display Checklists & Protocols on the system will help minimize preparation errors¹

As patient volumes rise and procedures become more complex, how do you maintain high standards of quality and safety in your healthcare facility?

Simplified set-up and operation

The Azurion 7 uses a range of ProcedureCards to help optimize and standardize system set-up for all your cases, from routine to advanced procedures. The system will automatically select the appropriate ProcedureCard(s) based on the RIS/HIS/CIS code of the scheduled procedure.

ProcedureCards can increase the consistency of exams by offering presets (e.g. most-frequently used, default protocols and user-specified settings) on the procedure, physician or department level. In addition, hospital checklists and/or protocols can be uploaded into the ProcedureCards to help safeguard the consistency of interventional procedures and reduce preparation errors.

Full control at table side through FlexVision Pro

With FlexVision Pro you have full control, at table side, of all applications in the interventional lab. Not only does this improve workflow within the exam room, it helps reduce the need for team members to leave the sterile area and walk to the control room during procedures. This can save time and help avoid delays.

Insightful image guided therapy

We have pioneered a steady stream of innovations in Live Image Guidance that help clinicians determine the most advantageous course of treatment with confidence, including StentBoost Live, Dynamic coronary roadmap, aneurysm flow, EchoNavigator, HeartNavigator, EP Navigator, OncoSuite, XperCT and many more. All these advanced interventional tools are seamlessly integrated into the Azurion 7 to support your clinical workflow.

“The FlexVision Pro is fantastic! I can **control everything** from table side without sterility breaks.”

Marco van Strijen, MD

High standards of safety and **low radiation exposure**

As you look for new radiation dose management strategies to continue to enhance patient and staff safety, while maintaining and enhancing your level of care, we can support you in meeting your goals.

Managing dose efficiently

Several Azurion 7 features have a positive impact on dose. Our Dose management solutions help you take control over patient care, staff safety, and regulatory compliance with a comprehensive suite of radiation dose management tools, training, and integrated product technologies. The MRC200+ X-ray tube incorporates SpectraBeam filtration, which helps maintain image quality at a low dose. The Zero Dose Positioning function lets you pan the table, change table height or field-of-view on your Last Image Hold (LIH) image. This means you can already see the effect of moving the table or changing the field-of-view on your region of interest to prepare your next run without using fluoroscopy.

High quality images at a low x-ray dose

ClarityIQ technology that provides high quality imaging for a comprehensive range of clinical procedures, achieving excellent visibility at low X-ray dose levels for patients of all sizes.

Over 500 system parameters have been fine-tuned to use the full potential of ClarityIQ technology for each application area, enabling superb visualization in many different application areas.

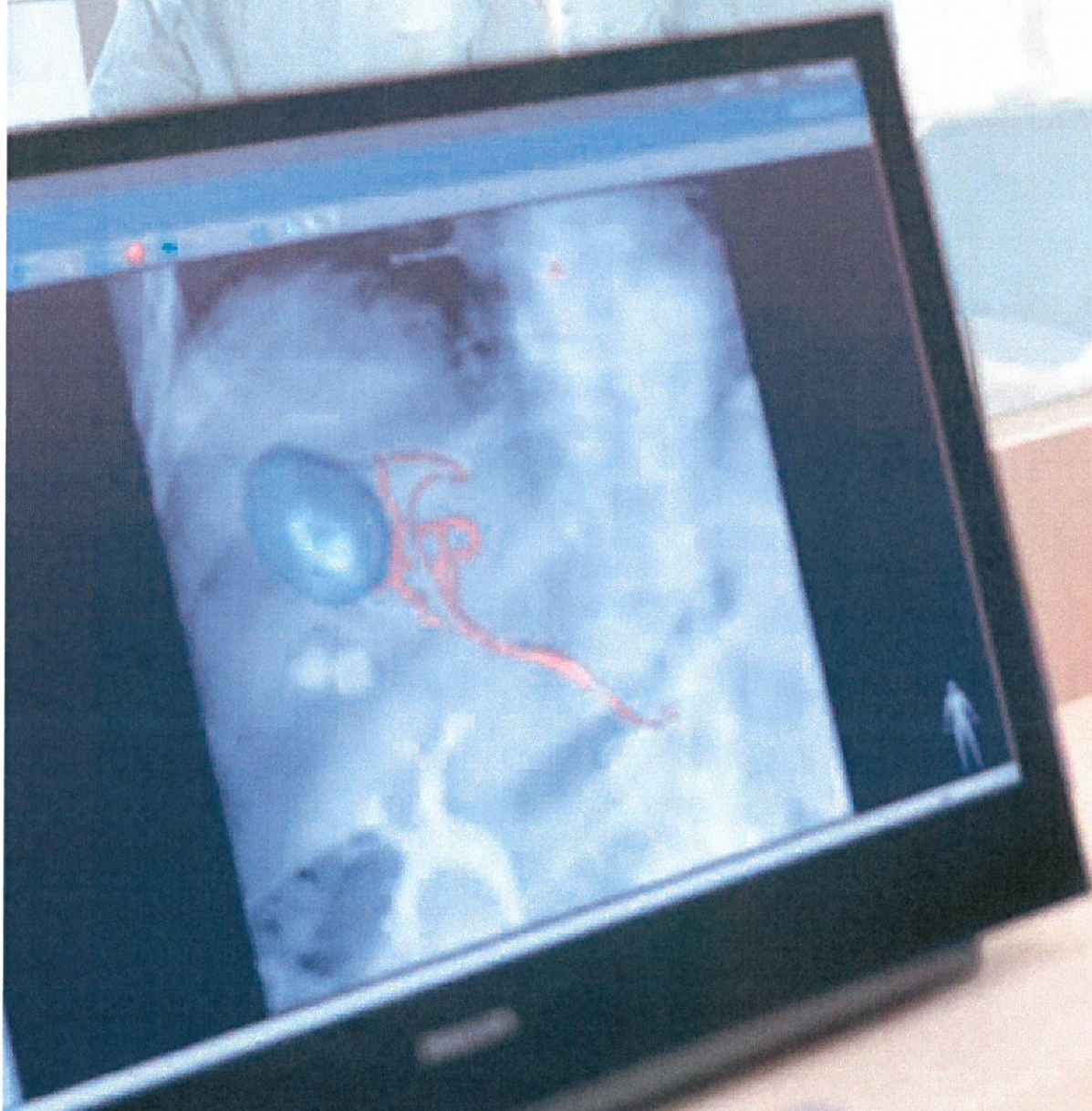
Managing dose across your organization

Philips DoseAware provides instant, time-stamped feedback in the exam room so you can immediately adjust working habits to manage radiation exposure with your staff.

A critical component in providing exceptional patient care is strong radiation control and management. We can help you create a comprehensive dose management program with DoseWise Portal at its core. This turnkey dose management solution gives you control over patient dose and staff occupational dose. It increases transparency across the entire enterprise and enables you to make data-driven decisions concerning quality initiatives and radiation management.



With Azurion we help you to
**optimize your lab
performance**



To address rising cost pressures, what can you do to improve efficiency and productivity in your lab?

Save time through Instant Parallel Working

The Azurion 7 interventional suite has been specifically designed to save time by enabling interventional team members to do two tasks at the same time in the exam room and control room - without interrupting each other. As an example, while fluoroscopy/exposure is taking place, a technologist in the control room can instantly review previous images from the same patient, prepare the next exam or finish reporting on another patient. This leads to higher throughput and faster exam turnover without compromising quality of care.

Imagine an easier work day

You can combine different user centric workspots (FlexVision Pro, FlexSpot and touch screen modules) to view control and run applications where and when needed. So you have the tools in hand to manage procedure quality and patient care. Together these flexible workspots allow you to customize your workflow to boost efficiency.

In a simulation study with over 60 users globally,

91% believe that the system will help reduce procedure time¹



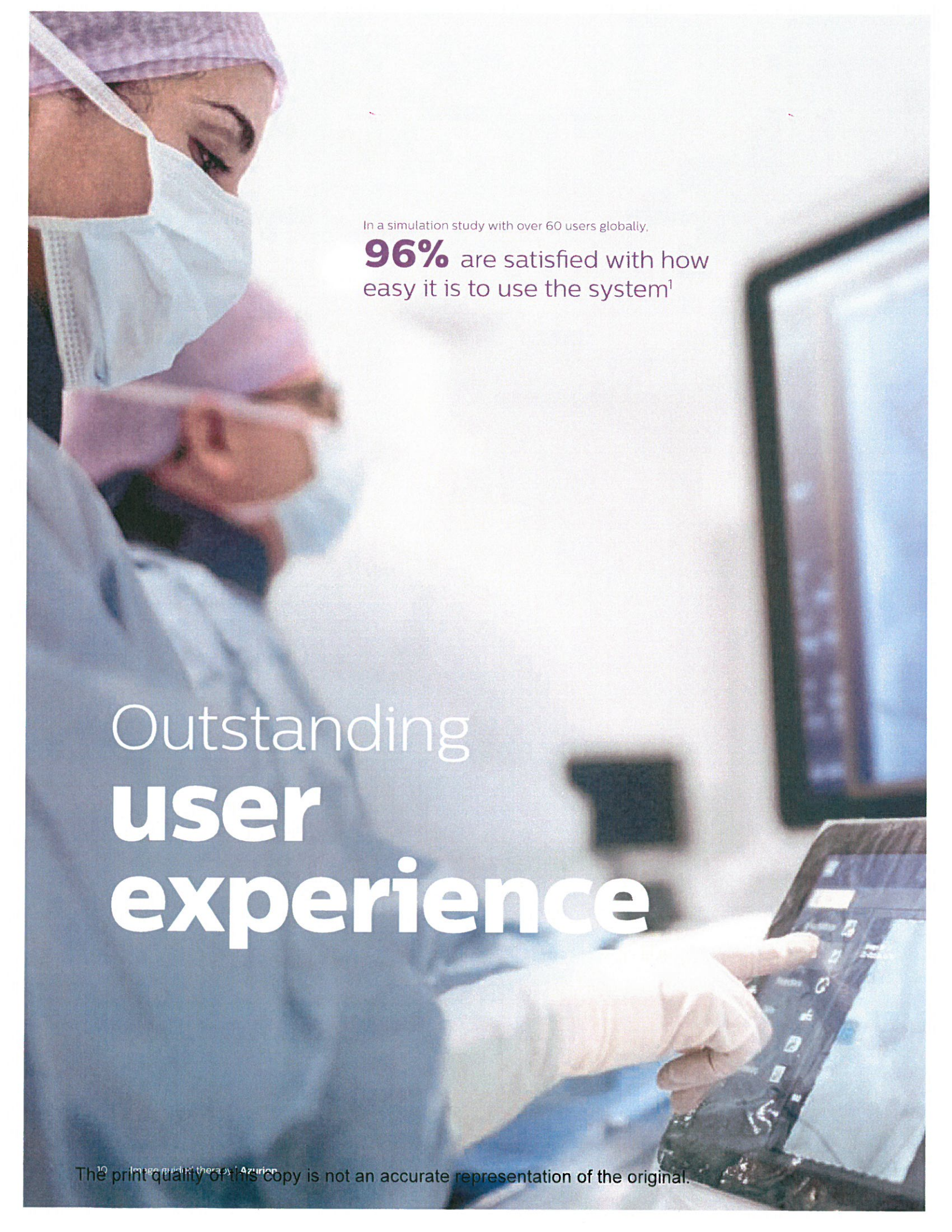
Touch screen module Pro



FlexSpot




FlexVision Pro

A photograph of two surgeons in an operating room. They are wearing blue scrubs, white masks, and purple hairnets. One surgeon is in the foreground, looking down at a tablet computer held in their gloved hand. The other surgeon is slightly behind and to the right, also looking at the tablet. In the background, a large monitor is visible on the wall. The lighting is bright and clinical.

In a simulation study with over 60 users globally,

96% are satisfied with how easy it is to use the system¹

Outstanding **user experience**



Studies have documented the adverse impact that poor usability, design and ergonomics can have on medical procedures and patient safety.² How can you make it easy for your staff to use imaging solutions?

We do this by:

Giving you cutting edge guidance, ease of use and responsiveness in our standardized Azurion user interface. It is designed to anticipate what you need, when you need it, to make procedures flow intuitively and easily. An extensive user-centric design process was carried out for the Azurion system. Clinical users tested the user interface at different stages during the iterative development process to ensure that the system would be easy to use, learn and remember. The new workflow approach was further evaluated by 61 physicians and technologists in Europe and the USA in a simulated environment.

Designed around you and your procedure

All Azurion systems and interventional tools use the same standardized user interface to support training. Use has been further simplified through a sophisticated help function. You can access digital user guides with one click for on-the-spot assistance.

The next step in ease of use

All controls feature the latest advances in ease of use. On screen, you can see easily information against the distinctive black background where active applications are highlighted. Backlit icons and distinctly shaped buttons on the Control Module promote intuitive operation. The touch screen module Pro² offers tablet-like control at table side – select, zoom and pan with your fingertips and display X-ray images on its screen. All controls are designed for easy cleaning to meet stringent sterility requirements.

Less clutter and faster workflow

FlexSpot gives you access to all applications from Philips and other vendors in one compact, customizable workplace that can significantly reduce clutter and accelerate workflow. You can drag and drop applications and set the display to re-arrange and re-size as applications are opened and closed.

The next-generation **image guided therapy platform**

Azurion is the next-generation Image Guided Therapy platform that provides a foundation for today and the innovations of tomorrow. It is backed by innovative services and support that offer a lifetime of benefits, reinforcing our commitment to you and your patients.

Enjoy a lifetime of benefits

The entire Azurion family is designed around a single, standardized hardware and software platform. New solutions and innovations are added as they evolve. And as your requirements change you can easily integrate additional functionality and third-party applications.

Azurion 7

You can choose a system with either a 12" or a 20" Flat Detector to meet your application requirements. With its new 12" Flat Detector, the 7 Series provides high-resolution imaging over a large field-of-view with flexible projection capabilities, making it ideal for cardiac interventions. The entire coronary tree can be visualized in a single view with minimal table panning. Enhance visibility for diverse cardiac and vascular procedures with the excellent image quality and broad coverage of the next generation 20" Flat Detector. For a hybrid suite solution, the Azurion 7 the next generation 20" Flat Detector can be combined with the FlexMove option.



Azurion 7 C12



Azurion 7 C20

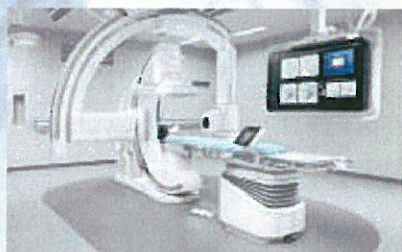


Azurion 7 biplane

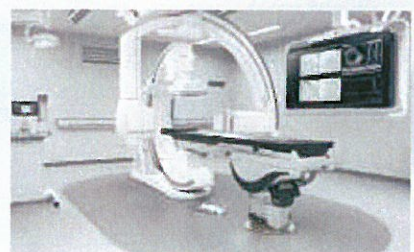
The Azurion 7 biplane is available in different configurations to support neuro, congenital heart, structural heart, electrophysiology and other complex cardiac and vascular interventions. The biplane system with two 12" Flat Detectors provides high-resolution imaging and positioning flexibility to reveal critical anatomical information during congenital heart and electrophysiology procedures. Enhance insight and certainty during neuro interventions with the perfect fit design that pairs a 20" frontal with a 15" lateral detector. The biplane system with a 20" and 12" Flat Detector provides exceptional clarity of detail and navigational precision to support a wide range of challenging cardiac and vascular interventions.



Azurion 7 B12/12



Azurion 7 B20/15



Azurion 7 B20/12 with OR table



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High productivity combined **with low cost of ownership**

Flexible financing and advanced service and support help you maintain peak performance and deliver cost-efficient care.

Increase your return on investment

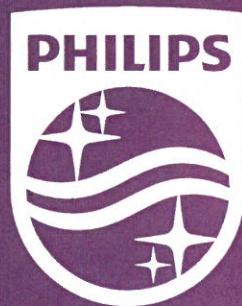
To help you fully leverage your financial, technological and staffing resources and realize a high return on your investment, we offer professional support through our experienced network of over 7,000 field service engineers, as well as a flexible service offering that includes innovative financing solutions tailored for the healthcare community. Our broad range of healthcare consulting and education programs can help you further enhance the efficiency and efficacy of your care delivery process.

Make the most of every day

Staying on top of today's complex healthcare environment is challenging enough without a constant concern of keeping your systems up and running smoothly. We are dedicated to tackling whatever issues you may have, and if needed will be working day and night until the job is done. Philips Remote Services aim to help you maintain peak performance of your equipment, deliver uninterrupted patient care and address your most complex technical problems before they impact patient care. Our RightFit service portfolio provides software and hardware updates to ensure that your system is up to date. Together, this approach can extend the utilization and lifetime of your suite.

Unlock your potential

Philips Healthcare Education can help unlock the full potential of your staff, technology and organization to meet new challenges through innovative, meaningful and evidence-based healthcare education. Our comprehensive clinical, technical and business-related courses, programs and learning paths are designed to help you meet the challenges of controlling costs, streamlining workflow and improving patient care.



Some features are optionally available.
Not all features are available on all systems.
Please check with your Philips representative for local availability.

1. Results obtained during user tests performed in the period of November 2015–February 2016. The tests were designed and supervised by Use-Lab GmbH, an independent and objective usability testing engineering consultancy and user interface design company. The tests involved 31 US-based clinicians (16 physicians and 15 technicians) and 30 European-based clinicians (15 physicians and 15 technologists), who performed procedures using Azurion in a simulated interventional lab environment.
2. Gurses A, Ozok AA, Pronovost PJ. Time to accelerate integration of human factors and ergonomics in patient safety. *BMJ Qual Saf.* 2012;21:347–51.

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How to reach us
Please visit www.philips.com/azurion
healthcare@philips.com

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Attachment B

CHS NE Cath Lab #1 Volumes

Month	Volume
Nov-17	50
Dec-17	34
Jan-18	49
Feb-18	54
Mar-18	59
Apr-18	58
May-18	44
Jun-18	53
Jul-18	61
Aug-18	52
Sep-18	52
Oct-18	68
Total	634

Attachment C

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



Quotation #: 1-1QUOTJE	Rev: 9	Effective From: 16-Nov-18	To: 15-Jan-19
Presented To: CAROLINAS MEDICAL CENTER NE 920 CHURCH ST N CONCORD, NC 28025-2927 Tel: Alternate Address:	Presented By: Kimberly Bates <i>Account Manager</i> John Hill <i>Regional Manager</i>	Tel: (704) 577-2484 Fax: Tel: (800) 722-7900 x6806 Fax:	
Date Printed: 16-Nov-18			
Submit Orders To: 22100 BOTHELL EVERETT HWY BOTHELL WA 98021 Tel: (888) 564-8643		Fax: (425) 458-0390	

This quotation contains confidential and proprietary information of Philips Healthcare, a division of Philips North America LLC ("Philips") and is intended for use only by the customer whose name appears on this quotation. It may not be disclosed to third parties without the prior written consent of Philips.

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

<u>Line #</u>	<u>Product</u>	<u>Qty</u>	<u>Price</u>
	100233 Azurion 7 M12	1	\$1,198,647.80
Equipment Total:			\$1,198,647.80

Solution Summary Detail

<u>Product</u>	<u>Qty</u>	<u>Each</u>	<u>Monthly</u>	<u>Price</u>
100233 Azurion 7 M12	1	\$1,198,647.80		\$1,198,647.80

Buying Group: CAROLINAS HEALTHCARE SYSTEM SCA

Contract #: CAA0013200

Add'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

100233 Azurion 7 M12

Qty	Product
1	NNAE592 Azurion 7 C12 Catalyst Upgrade
1	NNAE996 CORE IVUS - Cardiac
8	FCV0588 Isolated Wall Connection Box
1	NCVD067 ClarityIQ
1	FCV0834 coupling to video switching
1	NCVC542 Dynamic Coronary Roadmap
2	FCV0824 video WCB on rear side 1st MCS
1	NCVD221 MRC200+ GS 05/08
1	NCVD061 optional ref monoplane
1	NCVC493 Prep table for Volcano
1	NCVA783 table pivot option
1	NCVC199 Wireless footswitch: mono-plane version
1	NCVD064 extension to FlexVision Pro
1	NCVA780 Digital subtracted Angio
1	459800660501 Clip rail 390 cm G-Stand
1	NCVD031 FlexVision XL + 2 LCD's
1	FCV0510 Long mattress cardio
1	FCV0765 DoseAware Xtend pack
1	FCV0563 Personal Dose Meter (1 piece)
1	NVLV010 SyncVision
1	980406041009 Rad Shield w/ Arm (Contoured) 61X76
1	980406190009 PIVOTING TABLE-MOUNTED RADIATION SHIELD
1	989801220158 Mark 7 Arterion, Table Mount
1	989801220273 Ceiling Track w/Column & Handle Ext
2	989801220375 Black Anti-fatigue Floor Mat w/logo.
1	989801256476 IGT Addl Azurion Essentials 28 Hour OffSite
1	989801256032 iXR Additional Training 16 Hours OnSite
1	989801220380 Full Load Remote UPS
1	NNAE597 iXR Dynamic Coronary Roadmap OnSite Education
1	989600213942 AD5 TO XPER TABLE ADAPT. PLATE

100233 Azurion 7 M12

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	Each	Price
1	**NNAE592	Azurion 7 C12 Catalyst Upgrade	1	\$505,954.00	\$505,954.00

The Philips Catalyst Conversion Program is a cost-effective way to transform your current system into the Philips Azurion 7C12. The end result after conversion is fully equal to a completely new Philips Azurion 7C12 system, including lifetime support, compatibility, functionality and upgradeability.

The Philips Azurion 7C12 is an advanced solution for performing full range of mainstream and complex cardiac and mixed interventions.

Key benefits

- See superb anatomical details with the 12 inch detector that offers an up to 39% bigger field of view while maintaining projection flexibility
- Optimized utilization of your lab by procedure based workflow
- Superb image quality to evaluate small details and vessels with clarity.
- Intuitive user interaction delivering an easy to use, easy to learn system
- Significant reduction of room reconstruction costs and down time

Enhancing confidence and insight

With our Live Image Guidance we aim to remove barriers to safer, effective and reproducible treatments, delivering clinical value where it's needed most - at the point of patient treatment. Intelligent and intuitive integration of live imaging, patient information, and procedure-based applications optimize real time therapy guidance.

The Philips Azurion 7C12 system is designed to support the full range of mainstream and complex cardiac interventions, including percutaneous coronary interventions, chronic total occlusion, bifurcation treatment and multi-vessel diseases. This future proof solution is designed around a single, standardized hardware and software platform that can be expanded as new needs arise or requirements change. A new workflow approach aims to support interventional teams in carrying out procedures for their patients, consistently and efficiently with great ease of use.

The Philips Azurion 7C12 uses a range of Procedure Cards to help optimize and standardize system set-up for your cases, from routine to mixed procedures.

Procedure Cards can increase the consistency of exams by offering presets (e.g. most-frequently used, default protocols and user-specified settings) on procedure-, physician- or departmental level. In addition, hospital checklists and/or protocols can be uploaded into the Procedure Cards to help safeguard the consistency of interventional procedures and help to minimize preparation errors.

The Philips Azurion 7C12 interventional X-ray suite has been specifically designed to save time by enabling the interventional team to work on all activities in the exam room - and at one or more work spots in the control room at the same time - without interrupting each other. This leads to higher throughput and faster exam turnover and contributes to quality of care.

To improve dose management, Philips Zero dose positioning enables you to move the stand and table to the region of interest shown on the last clinical image hold before a new acquisition is started, without any radiation.

Specifications

The Philips Azurion series contain a number of features to support a flexible and patient centric

100233 Azurion 7 M12

Line #	Part #	Description	Qty	Each	Price
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procedural workflow.

The Philips Azurion series (within the limits of the used Operating Room table) are intended for use to perform:

- Image guidance in diagnostic, interventional and minimally invasive surgery procedures for the following clinical application areas: vascular, non-vascular, cardiovascular and neuro procedures.
- Cardiac imaging applications including diagnostics, interventional and minimally invasive surgery procedures.

The Philips Azurion 7 C12 system comprises five functional building blocks:

1. Geometry
2. X-ray Generation
3. Image Detection
4. User Interface
5. Viewing

Each functional building block is explained in further detail including accessories.

1. Geometry

A. 7 C12 stand

The ceiling suspended Poly Diagnost G stand offers full cardiovascular projection possibility. This configuration comprises 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. Angulation and rotation of the Poly Diagnost G-arm is motorized at high speeds.
- Parking and longitudinal movement of the Poly Diagnost G stand, can be done both manually and motorized.
- Comfortable, single operator control of stand parking or longitudinal positioning. It provides motorized base rotation at 12 degrees/s from +90 to -90 degrees, and motorized longitudinal movement at 15 cm/s over a maximum range of 440cm (Y stroke) by 260cm (X stroke)

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

The projection angles for the Poly Diagnost G-arm in the left or right position of the patient (orientated perpendicular to the table):

- rotation 45 degrees LAO to 45 degrees RAO
- angulation 120 degrees cranial to 120 degrees caudal

Motorized stand movements with variable speed and configurable max speed, allowing:

- rotation up to 25 degrees/s
- angulation up to 18 degrees/s

The depth of the Poly Diagnost G arm is 105 cm. The stand features BodyGuard capacitive sensing for safe and fast positioning of the stand and the Dynamic Flat Detector. The variable source image distance between focus and Dynamic Flat Detector input screen is 890 to 1235 mm. The Dynamic Flat Detector is counter-balanced, which means it can be positioned both manually and motorized.

B. Patient Support

The patient table standard provides very light manual float movement, even for heavy patients, thanks to the mono-bearing technology. The long flat carbon fiber tabletop provides ample space

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- to place e.g. catheters and guidewires. It comprises:
- Table top length of 319 cm, width of 50 cm
 - Metal-free cantilever 125 cm
 - Floating table-top movement of 120 cm longitudinal and 2 x 18 cm transversal
 - Motorized height adjustment from 74.5 - 102.5 cm
 - Maximum load: 275 kg (up to 250 kg patient weight plus 25kg accessories or 225kg patient weight plus 50kg accessories) plus 500 N for CPR in any longitudinal position of the table top.
- Arm Support Board
 - Set of Elbow Supports

2. X-ray Generation

A. Generator

The 7 C12 system comprises an integrated, micro-processor controlled Certeray generator based on high frequency converter technique. The user interface control of this X-ray Generator is incorporated in the touch screen module, review module, and the on-screen displays. The Certeray generator comprises:

- X-ray generator 100 kW
- Voltage range is 40 - 125 kV
- Maximum current 1000 mA at 100 kV
- Maximum continuous power for fluoroscopy: 1.5 kW

Program selection:

- Pulsed X-ray up to 3.75 , 7.5 , 15 , 30, 60(optional) 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 1 ms
- ECG triggered acquisition: allows acquiring one exposure for each QRS peak with selectable delay time
- Automatic kV and mA control for excellent image quality prior to run to save dose
- X-ray tube load incorporated in the Certeray generator

B. System intrinsic

- Fully digital imaging chain in maximizing the utilization and technology of the x-ray generator, x-ray tube, flat detector and image processing.
- Customizable EPX protocols to each application according to user preferences for different composition of dose rate, pulse speed, filter setting, and image processing (noise reduction, adaptive contour enhancement, adaptive harmonization)
- Built-in SpectraBeam filtering of low energy radiation to improve image quality and dose efficiency with MRC200+ X-ray tubes.
- Pre-filters of 0.2, 0.5 and 1.0 mm CU equivalent
- Automatic cardiac wedge positioning
- X-ray depth collimator with single semi-transparent wedge filter with manual and automatic positioning.
- 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.
- Xper Fluoro Storage, a grab function allows storage and archiving of both a fluoro image or the last 20 seconds of fluoroscopy run. These images or runs can be archived and reviewed as a regular run.

C. User selections

- removable anti-scatter grid to lower x-ray dose for pediatrics (grid ratio 13:1)
- ECG triggered acquisition, offering the possibility to acquire images at the same phase of the heart cycle. This applies to the low dose fluoro and exposure program for EP applications. This allows patient dose reduction by lowering the pulse rate to 1 pulse per heart and let the physician

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still focus on relevant items
 - three programmable fluoroscopy modes can be selected from the control module. Each mode has a different composition of dose rate, pulse speed, filter setting, and image processing (noise reduction, adaptive contour enhancement, adaptive harmonization)

D. User dose awareness
 DoseWise program: Philips DoseWise program is a set of techniques, programs and practices built into the X-ray system that ensures excellent image quality during each interventional application, while at the same time reducing x-ray dose at every opportunity. The DoseWise comprises of three building blocks to help reduce x-ray dose without compromising diagnostic quality: system intrinsic, user selection and awareness.

On-system monitor display provides and displays body zone specific Air Kerma data (10 zones for cardiac applications) in numeric and graphical bars.
 - Graph displays the accumulated Air Kerma dose for the particular body zone of the actual projection
 - When the accumulated Air Kerma dose of the particular body zone reaches the critical skin dose level of 2 Gy, it will be indicated on the display and made visible to the x-ray operator.

Radiation Dose Structured Report
 Collection of dose relevant parameters and settings and export to a DICOM database (e.g. PACS) (dose information is sent in MPPS message not as Radiation Dose Structure report), 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. Also, typical system usage can be extracted from the data, helping to identify root causes behind deviations and measures to improve.
 - Analysis of individual patient cases: using dose levels and system usage per procedure
 - Alerting for high dose cases, timely identifying patients at risk or deterministic effects, for proper follow-up.

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.

3. Image Detection
 The image chain with the 12 inch flat panel image detector comprises the following:
 - A 28 cm (12 in.) diagonal triple mode Dynamic Flat Detector subsystem for fluoroscopy and cine-fluorography.
 - A 5 modes 11*11/13.5*13.5/16*16/19*19/21*21 [cm] Dynamic Flat Detector
 - The outer detector physical housing is 28.3*28.8 [cm]
 - The digital output of the Flat detector is 1344*1344 pixels at 16 bit depth.
 - The pixel pitch is 154 micron by 154 micron
 - The DQE(0) is 77% providing high conversion of X-ray into a digital image, while maintaining a high MTF.

Philips Azurion has a storage capacity of 100,000 images at matrix size of 1024 x 1024, 10 bit. A maximum number of examinations is 999, with no limit to the maximum number of images per examination.
 Xres is a multi-resolution spatial temporal noise reduction and edge enhancement filter for interventional applications. Xres exploits the full benefits of dynamic digital flat detector imaging to enhance sharpness and contrast and has been designed to reduce noise in fluoroscopy and exposure runs. The settings for Xres Cardio can be customized to improve image quality. Xres is a

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Philips unique image processing algorithm developed at Philips Research for medical applications. Xres is used with Philips MR and US scanners next to Philips Azurion systems.

4. User Interface

User Interface in Examination Room

The User Interface comprises a variety of User Interface modules in the Examination Room. There is the On-Screen Display, the touch screen module, Viewpad and the control modules.

The On-Screen Display is positioned on the left side of the live/ref monitor. The following system information is displayed:

- X-ray indicator
- X-ray tube temperature condition
- Gantry position in rotation and angulation
- Source Image Distance
- Table height
- Table top tilt and cradle angle, if applicable
- Detector field size display
- General System messages ()
- Selected Frame speed ()
- Fluoroscopy mode ()
- Integrated fluoroscopy time ()
- Skin Dose: dose rate during X-ray, cumulated dose when no X-ray ()
- Dose Area Product: dose rate during X-ray, cumulated dose when no X-ray ()
- Graphical bars for Body Zone specific dose-rate and accumulated skin dose levels, related to the 2 Gy level (for cardiac applications)
- Stopwatch

Touch screen module

The touch screen module is provided for use at either the tableside or in the control room. Optionally, it is possible to connect in parallel up to three touch screen modules on the system. The touch screen module has a touch screen, which can be operated when covered with sterile covers. The touch screen module allows control of (depending on configuration):

- 3rd party equipment (e.g. CX50, Interventional Tools, EchoNav, DoseAware)
- Monitor layout (FlexVision, switchable viewing)
- X-Ray settings (Collimation, Projections, Table, Series and Processing)
- Quantitative Analysis (optional) User can only start QA from the touch screen module, nothing more, No Controls

Viewpad

The Viewpad contains the preprogrammed function settings. The system is provided with two 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 Viewpad function from live to reference monitor
- Laser pointer, intended to point at regions of interest on the image monitors
- LED indication of laser pointer on/off and battery low

Control module.

The control module can be positioned at three sides of the patient table, while keeping the button operation intuitively logical. The control module single-plane provides the following functionality:

- Tabletop float

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- Table height position
- Table tilt angle if function is applicable
- Source Image Distance selection
- Gantry positioning
- Gantry rotation in an axis perpendicular to the floor
- Store and recall of two scratch gantry positions including SID
- Geometry reset button, which resets stand and table to a factory-default starting position
- Emergency stop button
- Execute button of the Automatic Positioning Control (APC) if applicable
- Unlocking button for table pivot function (if option is installed)
- Table tilt and cradle controls (if option is installed)
- Fluoroscopy Flavor selection defined per setting
- Shutters and Wedge positioning
- Manual or automatic semi-transparent wedge filter
- Xper Fluoro Storage
- Selection of the Detector field size
- Reset of the fluoroscopy buzzer
- Roadmap Pro activation if function is available

The control module is provided with a protection bar. This removable bar protects the buttons from unintended control.

Pan Handle

The pan handle is an extension of the control possibilities for floating movements of the table top in cardio vascular and neuro systems

Key benefits

- Flexible positioning during cardio and neuro procedures

To allow more flexible positioning during cardio and neuro procedures, the pan handle option can be used to perform floating table movements. The pan handle provides a solid grip of the tabletop and can release and apply the tabletop brakes. It can be attached anywhere along the tabletop and accessory rails without affecting the floating range.

Specifications

Pan handle with cable and connector

Table-top attachment clamp

Accessory-rail attachment clamp

User Interface in Control Room

The control room comprises a review module, data color monitor and review monitor. The data and review functions are controlled by a single keyboard and mouse. The review module offers the basic functions for review. The most prominent functions can be controlled by the push of a button. The review module comprises the following functionality:

- Power on/off
- File and run cycle
- File, Run, and Image stepping

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- Run and file overview
- Reset fluoroscopy timer
- Enable/disable X-ray
- Geo disable

Acquisition monitor. A standard keyboard and mouse control the user interface. The acquisition monitor is intended to follow live case in the ER. System information is displayed on the bottom of the monitor:

- Stopwatch and Time
- System guidance information
- Dose Area Product (DAP) and Skin Dose, as dose rate during X-ray and cumulative dose at no X-ray
- Frame speed settings, fluoroscopy mode, and accumulated Fluoroscopy time
- Exposure and fluoroscopy settings as Voltage (kV), Current (mA) and time (ms)
- Geometry information as rotation, angulation, and SID

Scheduling

In the scheduling page it is possible to add new patients (either querying from RIS/CIS or by creating patient locally). The patients can be listed and selected per date, physician, and intervention type. Previous DICOM patient studies can be uploaded with the DICOM Query Retrieve function in the Philips Azurion system. 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, like acquisition file, reference file, and QA results file.

Procedure Cards

Procedure Cards provide the information of room and patient preparation for each individual physician. Procedure Cards are customizable per setting and allow each physician to provide their own room protocols. Procedure Cards is intended to make hard copies of the protocol instructions redundant.

Acquisition

The acquisition page contains information on the currently selected patient.

Reviewing

The review page allows for reviewing of patients:

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

Quantitative Coronary Analysis

Key benefits

- Allows quantitative quantification of coronary artery dimensions
- Aids confident decision making for device selection, approach angles and follow-up
- Designed for efficiency with single click functions and fast results

Easily obtain objective assessment of coronary artery to support decision making and allow assessment of vasculature during cardiac interventions, the 2D quantitative coronary analysis supports quantification of coronary artery dimensions of about 1 to 6 mm from 2D angiographic images. With one click, the relevant segment is detected and a visualization of the obstruction, healthy vessel, reference diameter, stenosis diameter and plaque area is created.

Specifications

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- Automated segmentation of selected coronary
- Diameter measurement along the selected segment
- Automated obstruction analysis
- Stenosis diameter, stenosis length
- % stenosis diameter, % stenosis area
- Automated and manual calibration routines
- Store result page

Analysis of the targeted vessel segment has been simplified with the single click function. Position the mouse on or close to the stenotic area and click once to detect the relevant segment. The visualization shows the obstruction, healthy vessel, reference diameter, stenosis diameter and plaque area.

Archiving

Clinical cases can be archived to a CD/DVD, USB or a PACS. The archive process can be completely automated and customized with settings. Parameters like multiple destinations, archive formats can be selected to the individual needs and wishes for programming under the settings.

With Philips Azurion the control room comprises of an acquisition monitor and a review monitor. The review monitor is a 24 inch color TFT-LCD medical grade monitor.

The Graphical User Interface on the Review monitor has the following features and possibilities:

- Step through file, run, or images
- File, and run overview
- Contrast, brightness, and edge enhancement settings
- Flagging of runs or images for transfer
- Applying text annotation in images
- DICOM printing if available
- Executing Quantitative Analysis Packages if available
- Subtraction functionality if available

This system is delivered with printed instructions for use and/or electronic instructions for use, as well as a quick start leaflet. A printed paper instructions for use can also be ordered at no additional cost.

5. Viewing

A. Viewing in Examination room

Philips Azurion systems come with one 27 inch high brightness color medical grade LCD monitor for clinical image display in the Examination room. This LCD monitor is intended for viewing in the examination room and is designed for medical applications. The monitors is used for combined viewing of live images and reference display. Selection and storing of live to reference monitor is controlled by the infra-red remote-control viewpad or via touch screen module.

The On-Screen Display provides status information on stand rotation-angulation, table height, 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 Air Kerma dose.

The main characteristics are:

- 27 inch high brightness color TFT-LCD display
- Native format 1920x1080 Full HD
- 10 bit gray-scale resolution with gray-scale correction
- Wide viewing angle (approx. 178 degrees)
- High brightness (max 650 Cd/m², default 400 Cd/m²)
- Long term luminance stability through backlight stabilization circuit
- Automatic brightness control with backlight sensor

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- Control functions on side
- User programmable and standard reference setting
- On-Screen Display
- Internal selectable lookup table for gray-scale transfer function, including DICOM
- Internal power supply (100-240 VAC)
- Integrated LCD protection screen

If applicable included is a flat monitor ceiling suspension for 2 monitors (2F MCS). MCS includes motorized height adjustment. The Ceiling suspension allows flexible monitor positioning over a range of about 360 x 300 cm. At customer request, this 2 monitor MCS can be replaced by a 4 or 6 fold MCS or an MCS integration kit HD for non-Philips MCS. The MCS integration kit HD contains vital parts for system operation.

B. Viewing in Control room

Philips Azurion includes two 24 inch high brightness color LCD monitors. The color monitors are for acquisition and reviewing display.

The main characteristics for color monitor are:

- 24 inch color TFT-LCD display
- Native format 1920x1080 Full HD
- High brightness (max 400 Cd/m2, default 350 Cd/m2)
- Wide viewing angle (approx. 178 degrees)
- Long term luminance stability through backlight stabilization circuit
- Automatic brightness control with backlight sensor
- Control functions on side
- User programmable and standard reference setting
- On-Screen Display
- Internal selectable lookup table for gray-scale transfer function, including DICOM
- Internal power supply (100-240 VAC)
- Integrated USB hub

A Philips Azurion system includes the DICOM Image Interface which enables the export of clinical images to a DICOM destination like a CD-Medical station or a PACS server. 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 DICOM Image Interface transfers through its fast Ethernet link, making images available on-line within seconds. The archive process can be configured by X-ray settings. The images are sent out either in the background, or manually upon completion of the examination. The export format is configurable in 512x512 or 1024x1024 matrix in 8 or 12 bit depth. The examination can be sent to multiple destinations for archiving and reviewing purposes. The 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.

Remote Intercom

Uninterruptable Power System (UPS)

Ensures data integrity

A power failure of the hospital mains during an intervention can cause loss of data. If this occurs, the single phase Uninterruptable Power System (UPS) enables a proper shut-down of the X-ray system processor units.

Specifications

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In case a full three phase UPS is selected, the single phase UPS is not delivered.

Remote service

Access to the system from a Remote location is possible via network or modem connection. Remote access to a system can shorten the time needed for e.g. changing system settings or problem diagnosis.

Environmental

At Philips Healthcare, we feel the responsibility towards society and the environment. The latest 7 C12 system is a perfect example of our EcoVision program. By examining every aspect of the 7 C12 design and development through a green eye, we drastically reduced the products environmental impact.

Clinical Education Program for Azurion System:

The purchase of the Azurion System includes a StartRight entitlement pool that allows for the customized delivery of educational events to improve staff time to proficiency, knowledge on system features, and improve overall lab efficiency. For new users, the recommended series of educational events includes:

Essentials 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. 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. 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. 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

Initial Handover OnSite Education: The primary 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).

FollowUp OnSite Education: Philips Education Specialists will provide sixteen (16) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. Students should attend all 16 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

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patient-ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation.
 Assessment OnSite Year 1: The primary Philips Education Specialist will perform a two day onsite assessment at the customer site on or close to the first anniversary of the Initial Handover. The Specialist will assess through various means not limited to; physical observation of procedure workflow, tool usage data analysis and staff interviews. The Specialist will then review findings with department head and make recommendations thereof. The Specialist may perform refresher training if required.

Education expires one (1) year from installation date (or purchase date if sold separately).
 Ref#296339296340296341296342-20170209

2	**NNAE996	CORE IVUS - Cardiac	1	\$93,725.00	\$93,725.00
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CORE Precision Guided Therapy System

CORE CPU, Operator's Manual, Power Transformer, Cable Pre-Install Kit, Connection Box, two (2) Standard Controller and one (1) bedrail mount, 19"NEC Monitor Kit, Phased Array PIM Body, FFR functionality, DICOM Network Connection, ChromaFlo Functionality.

-Includes VH IVUS End User License Agreement

The customer agrees that use of the VH IVUS Software is subject to the terms of the End User License Agreement. A copy of the End User License Agreement is also available from your VOLCANO representative or online at www.volcanocorp.com/products/pdf-files/software-support-vh-ivus.pdf

iFR Hyperemia-Free Lesion Assessment Modality CORE Interface, Operator's Manual. Customer agrees that use of the iFR Application Software License Application with interface to CORE is subject to the terms of the End User License Agreement. A copy of the End User License Agreement is also available from your VOLCANO representative or online at www.volcanocorp.com

CORE Control Pad

Bedside touchscreen controller offering system control from the sterile field

3	**FCV0588	Isolated Wall Connection Box	8	\$1,513.40	\$12,107.20
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Isolated Wall Connection box to support the display of an external video source on a monitor in the examination room.

Key benefits

- Stream video from other modalities on the interventional X-ray suite:
- Connect external video in the exam room

Easily stream video to other locations

Many interventional facilities use video to record and stream images from other modalities on the interventional X-ray suite for training or presentation purposes. The Video Wall Connection Box facilitates connection of the video source via a standard DVI cable/connector and lossless transfer of the video signal over the approximate 30 meter long cable. It can be mounted in the examination room or in the control room, depending on the location of the video source.

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Specifications

The quantity of the VWCB's has to be calculated as follows:

- For each video signal via MultiVision: 1 VWCB (max = 4)
- For each video signal to FlexVision XL on Cardio System: 1 VWCB (max = 9)
- For each video signal to FlexVision XL on Vascular System: 1 VWCB (max = 8)
- For each 3rd party video signal directly connected to an LCD in the MCS: 1x VWCB.

Note:

No VWCB is required in case a video signal is connected directly to a dedicated LCD from the following sources:

- 1) Live/ref Slaving
- 2) Interventional HW (XtraVision), IntelliSpace Portal, Philips Xcelera (only if workstations are powered by Philips X-ray system)
- 3) XperIM

4	**NCVD067	ClarityIQ	1	\$90,988.00	\$90,988.00
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Significantly lower dose- across clinical areas, patients and operators.

Key benefits

- High-quality imaging at low dose levels
- Enhanced work environment for staff through active management of scatter radiation
- Expands treatment options – enables longer procedures to treat obese and high-risk patients with confidence

See with confidence every time

Interventions are becoming increasingly complex, which 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. The prevalence of patients with a high BMI can also require increased dose levels to visualize anatomy. All of these factors inspired us to completely redefine the balance in interventional X-ray with AlluraClarity.

AlluraClarity with its unique ClarityIQ technology gives you exceptional 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.

Specifications

ClarityIQ technology is the foundation of Philips X-ray systems with AlluraClarity. It offers:

- Noise and artefact reduction, also on moving structures and objects
- Image enhancement and edge sharpening
- Automatic real-time patient and table motion correction on live images
- A flexible digital imaging pipeline from tube to display that is tailored for each application area
- Over 500 clinically fine-tuned system parameters making it possible to filter out more X-ray radiation and use smaller focal spot sizes and shorter pulses with the grid switching technology of Philips MRC tube and accompanying generator.

5	**FCV0834	coupling to video switching	1	\$7,180.60	\$7,180.60
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Key benefits

- Easily display any data or clinical information needed to work efficiently

Simplify workflow with flexible viewing control

Having patient data and clinical information easily available on screen can enhance decision making and efficiency during interventions. Coupling to Video switching enables coupling of maximum 4 color outputs (e.g. Interventional tools, Xcelera, XperIM and IntelliSpace Portal).

Specifications

Video splitter box to enable coupling of maximum 4 color outputs (e.g. Interventional tools, Xcelera, XperIM and IntelliSpace Portal) to the switching concept from our partner.

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In combination with the MultiSwitch option, the Video splitter box is used to connect a maximum of 3 workstation with a total power dissipation of maximum 1380 W.
 For the remaining workstations, up to 4 in total, a second video splitter box needs to be ordered.
 In addition, 4 splitter units are delivered to enable coupling of up to 4 of the X-ray system Live and Ref signals to the partner video switching system.
 The partner system provides fully galvanically isolated DVI extender cables to connect these signals.

6	**NCVC542	Dynamic Coronary Roadmap	1	\$28,446.40	\$28,446.40
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Dynamic Coronary Roadmap

When advancing guidewires and devices through the vasculature during percutaneous coronary interventions, it's important to understand the relationship between the device and the anatomy. Navigation is based on the physician's knowledge of the patient's anatomy as shown on angiograms and live fluoroscopic images. As the physician works, small shots of contrast agent are applied to check the device position shown on the live fluoro image with the anatomical reference provided by the previously acquired angiogram.

Dynamic Coronary Roadmap combines the live fluoro and angiogram image into a single adaptive roadmap image, which provides immediate feedback on the position of the device and its relationship to the anatomy to guide navigation.

Dynamic Coronary Roadmap features include:

- Automatic creation and storage of a dynamic roadmap from each acquired coronary angiogram. Only one roadmap per projection is stored
- Automatic overlay of the dynamic roadmap on live fluoroscopy
- Automatic guidance to reach projections for which a roadmap is available
- The Dynamic Coronary Roadmap functionality is fully integrated in the interventional X-ray system
- Image snapshots or movies can be archived to any DICOM compatible PACS. These include DICOM XA and DICOM SC

Note: when ordering Dynamic Coronary Roadmap and/or StentBoost Live for a non-FlexVision system a single dedicated color monitor must be added to the MCS.

7	**FCV0824	video WCB on rear side 1st MCS	2	\$5,832.80	\$11,665.60
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Isolated Wall Connection box on the rear side of the monitor ceiling suspension to support the display of an external video source on a monitor in the examination room.

Key benefits

- Easily connect external video in the exam room

Specifications

A wall connection box to connect external video (input only), USB and Ethernet. One or two WCB's (option) can be attached on the rear side of the 1st MCS with a bracket. A cable box (also attached to rear side of 1st MCS) can be used to store connected equipment cables. A maximum of two WCBs/cable boxes can be attached.

8	**NCVD221	MRC200+ GS 05/08	1	\$55,071.20	\$55,071.20
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Maximus ROTALIX Ceramic grid switch tube assembly MRC200+ GS 0508.

The MRC200+ GS 05 08 tube assembly and cooling unit CU 3101 for cardiovascular systems comprises:

- 0.5/0.8 mm nominal focal spot values maximal 45 and 85 kW short time load
- Grid switching at pulsed fluoroscopy and low load exposure (to eliminate soft radiation and improve image quality)

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Line #	Part #	Description	Qty	Each	Price
		<ul style="list-style-type: none"> - Continuous loadability: 3400 W (at 21 degrees C room temperature) / 4000 W (= Max assembly continuous heat dissipation) - Application of SpectraBeam dose management - Tube housing ROT 1001 for oil-cooled X-ray tube with thermal safety switch - Cooling unit CU 3101 heat exchanger for use in oil-cooled X-ray tube systems - Maximum anode cooling rate of 1820 kHU/min - High voltage cables 			
9	**NCVD061	optional ref monoplane Additional Ref2 and Ref3 viewport	1	\$5,069.20	\$5,069.20
		<p>Key benefits</p> <ul style="list-style-type: none"> • Easily display any data or clinical information needed to work efficiently <p>Simplify workflow with flexible viewing control</p> <p>Having patient data and clinical information easily available on screen can enhance decision making and efficiency during interventions. Optional ref monoplane offers an additional video output of the X-ray system offering an additional Ref2 and Ref3 viewport on one LCD monitor. Combined with the Dual Fluoro license this enables users to zoom live images during acquisition, while having the Dual Fluoro image visible on the Ref3 viewport.</p>			
10	**NCVC493	Prep table for Volcano	1	\$7,470.40	\$7,470.40
		<p>Prepared for Volcano CORE prepares the XperTable with the cabling needed for an integrated version of the Volcano CORE system. This preparation will facilitate the installation of the integrated system and reduce the cable clutter around the table. The CORE User Interface can be placed on the XperTable OP rails, while the Volcano CORE unit is typically placed in the control room. The Volcano CORE Bedside Utility Box that is used to connect the IVUS and FFR PIM cables can be stored on the Auxiliary OP-Rail mounted at the foot of the table base.</p> <p>The prepared for Volcano CORE option cannot be purchased in combination with the Swivel AND prepared for Table mount Medrad Injector.</p> <p>When selecting the Prepared for Volcano CORE option on the Allura, the Volcano Core unit should be ordered without integrated cable.</p> <p>Content: OP rail at table foot Cables</p>			
11	**NCVA783	table pivot option	1	\$4,738.00	\$4,738.00
		<ul style="list-style-type: none"> • Flexible positioning for upper extremity angiography • Easy patient transfer <p>Flexible positioning and transfers</p> <p>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.</p>			
12	**NCVC199	Wireless footswitch: mono-plane version	1	\$7,465.80	\$7,465.80

100233 Azurion 7 M12

Line #	Part #	Description	Qty	Each	Price
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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.

13	**NCVD064	extension to FlexVision Pro	1	\$38,414.60	\$38,414.60
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Extension to Flexvision large 58 inch high resolution LCD for exam room, enabling flexible screen lay outs and full control (seamless mouse) of up to 11 external sources including third party systems.

Key benefits

- Full control at table side of all applications with seamless mouse control or via touch screen module
- Full flexibility of screen layouts (live resize, drag and drop, unlimited number)
- To simplify and standardize system set-up for your FlexVision Pro, your personalized layout will come up automatically with ProcedureCards.

Easy tableside control

With FlexVision Pro, user can control FlexVision and video sources on FlexVision through wireless mouse in Examination Room as well as virtual keyboard and touchpad on the touch screen module in the Examination Room. An operator can resize images and adjust the screen layout during the procedure without going into configuration.

Specifications

Full control at table side of all applications in the interventional lab (view and control) with a single wireless mouse or with a Touch Screen Module

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Line #	Part #	Description	Qty	Each	Price
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- Integration: control of up to 11 external sources
- Possibility to configure unlimited flexible screen layouts
- Screenshots: with single click all displayed inputs can be captured
- Live resize the video window and adjust the screen layout during the procedure without going into configuration
- Operate all the video sources displayed on the monitor using the wireless mouse at tableside
- Mouse and keyboard function on the touch screen module (TSM) to control (external) sources

14	**NCVA780	Digital subtracted Angio	1	\$16,113.80	\$16,113.80
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Key benefits

- Allows uncompromised image quality of subtracted images
- Allows subtraction on run basis (run-subtract), which can be applied in the Rotational Scan and Bolus Chase Subtract options.
- Allows a vessel map to be created and superimposed with live fluoroscopy (Roadmap Pro). Acquisition runs can be done during Roadmap without losing the vessel map.

Supports navigation without the need to use additional contrast

The DSA-option digital subtraction can be performed for vascular studies. DSA features real-time digital subtraction at low frame speeds of 0.5, 1, 2, 3, or 6 frames per second. The exposure technique allows uncompromised image quality of subtracted images. This option also supports subtraction on a run basis (run subtract), which can be used in the Rotational Scan and Bolus Chase Subtract options.

Specifications

This option will comprise following functionality:

- Roadmap Pro can be selected from the imaging module and touch screen module. A vessel map is created and superimposed with live fluoroscopy. Acquisition runs can be done during Roadmap without losing the vessel map.
- Roadmap Pro features Smart Settings in special clinical modes that are intended to visualize special materials such as coil and glue.
- Live Processing of the vessel map, the device map and the landmark map can be done on the touch screen module.

Automatic Motion Compensation" (AMC) functionality; during roadmapping small movements of the patient can lead to subtraction artifacts. These artifacts might conceal important clinical information. Automatic Motion Compensation compensates for rigid uniform (skeletal/table) translations and is therefore very effective in interventional (Neurology) applications where subtraction imaging is applied.

- Exposure subtract on individual image or run basis
- Mask selection
- Average masking during acquisition as additional subtracted IQ improvement
- Landmarking
- Pixel shift

15	**459800660501	Clip rail 390 cm G-Stand	1	\$2,737.00	\$2,737.00
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Ceiling rails with clip mounting and isolation parts length 390 cm.

16	**NCVD031	FlexVision XL + 2 LCD's	1	\$106,784.40	\$106,784.40
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100233 Azurion 7 M12

Line #	Part #	Description	Qty	Each	Price
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FlexVision XL is an integrated viewing solution designed to give you full control over your viewing environment.

This FlexVision XL is delivered with two 27 inch high brightness color medical grade LCD monitors. The monitors can be mounted on top side or on rear side of the MCS.

Key benefits

- Easily display multiple, up to 8, video inputs (including third party systems) to inform decision making during procedures
- Create custom display templates to support diverse procedures
- The screen layout of the FlexVision XL can also be changed from the control room
- Enlarge images to reveal more details and support comfortable working positions

Diagnostic information easily made available at table side

In today's interventional setting, as you perform more complex procedures with smaller devices in complex anatomy, you rely on various types of diagnostic information to guide you. To inform decision making in the exam room, Philips offers an advanced digital workspace called FlexVision. You can display multiple images in a variety of custom layouts on a large LCD screen. Zoom in and out to enhance fine details, while maintaining an overview of all information. Create custom display templates for specific procedures/physician preferences to easily support diverse procedures.

Specifications

1. DVI video composition unit.

The DVI video composition unit allows the user to direct and switch the video output of all connected medical equipment to specific sub windows of the Philips 58-inch color LCD with LED backlight in the Examination Room.

- The DVI video composition unit is operated from the touch screen module.
- The DVI video composition unit supports a wide variety of display formats (up to 1920x1200)
- Up to 11 external inputs are connected to the DVI video composition unit via wall connection box or boxes.

2. Medical grade, high resolution color LCD in the Examination Room

This display supports the image quality requirements for monochrome X-ray images as well as color images and replaces all displays normally delivered with the system for the Examination Room.

Main characteristics are:

- 58-inch, 8 Megapixel color LCD
- Native resolution: 3840x2160
- Brightness: Max: 700 Cd/m² (typical) stabilized: 400 Cd/m²
- Contrast ratio: 1:4000 (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

3. Large color LCD control (touch screen module)

- Enlarge information at any stage during the case via the touch screen module in the Examination Room or Control Room.
- Select viewing lay-outs via the touch screen module in the Examination Room.
- Create new layouts by matching inputs to desired locations on preset templates.
- Adjust the screen layout during the procedure without going into configuration
- 20 layouts; each layout is customizable, size of viewports can be customized by end user X-ray status area visible with all X-ray details

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Line #	Part #	Description	Qty	Each	Price
		<p>4. Monitor ceiling suspension Monitor ceiling suspension for use in the Examination Room carries the 58-inch color LCD, providing highly flexible viewing capabilities. The monitor ceiling suspension is height-adjustable and moveable along ceiling rails. It can be positioned on either side of the table.</p> <p>5. Snapshot The snapshot function allows the user to store/save a screen-capture of any image on the FlexVision XL as a photo image to the current acquisition patient study.</p>			
17	**FCV0510	<p>Long mattress cardio</p> <ul style="list-style-type: none"> • Enhances patient comfort • Adapts to the shape of the patient's body <p>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.</p> <p>Dimensions of the mattress: Length: 3165mm Width: 500mm Height: 70mm Radius: 150mm</p>	1	\$570.40	\$570.40
18	**FCV0765	<p>DoseAware Xtend pack</p> <p>DoseAware Xtend is an unique solution providing staff working in an X-Ray environment with direct, real time dose feedback, enabling them to pro-actively optimize their behavior and reduce exposure to scattered dose. The DoseAware Xtend is a complete package and comprises off:</p> <ul style="list-style-type: none"> • 1 DoseAware Xtend package (including a reference PDM holder, a radio hub, cables and other items to connect with the Allura FlexVision , ...) • 6 PDMs (one of these to be used as reference PDM) • 1 PDM rack. <p>DoseAware Xtend The DoseAware Xtend system contributes to long-term dose reduction of people who work with or are in the presence of x-ray imaging equipment. This is done by measuring and presenting individual dose exposure in real time for any Personal Dose Meter (PDM) in range when x-ray is used. Based on this information the individual can understand, act and change behavior to reduce the received dose.</p> <p>The DoseAware Xtend combines individual dose information from the PDM with modality procedure data from the Allura and integrates this into real time feedback.</p> <p>DoseAware Xtend product benefits:</p> <ul style="list-style-type: none"> • The DoseAware Xtend screen will be displayed on the FlexVision monitor, which allows for flexible real-time display close to live view or any other preferred position • Smarter read out with dose aware data per procedure by sharing information from the Allura: <ul style="list-style-type: none"> o An advisory when user is advised to take more radiation protection measures, like using lead curtain or lead shielding between themselves and the X-ray Tube o Accumulative dose data per procedure o A relative value as behavior indicator (Relative dose in %) per procedure (normalized data by reference PDM on C-Arm) • Automatic operator dose reporting by email (per lab or per PDM) <p>The PDM dose information is stored within the Hub. Dose data on procedure level will be send automatically by email. Dose data by second can be retrieved by the Dose Manager software (optional) via a standard network interface.</p> <p>The DoseAware Xtend package includes also:</p> <ul style="list-style-type: none"> • a cradle and the DoseView software package that can be installed on a local PC (not included), which has Windows XP, Vista or Windows 7 as operating system. 	1	\$42,683.40	\$42,683.40

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Line #	Part #	Description	Qty	Each	Price
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- A radio hub for the radio communication with the PDM's
- All items (including wall connection box) to integrate the DoseAware Xtend with your Allura FlexVision.

Personal Dose Meters

The Personal Dose Meter (PDM) is a small and easy to wear active X-ray dose meter intended to measure and store received X-ray dose of staff, present in an X-ray room during radiation. The PDM has build-in radio-frequency wireless communication (915 Mhz for USA version, 952,4 MHz for Japan version, 868.3 Mhz for ROW version,) to connect to the DoseAware hub for real time dose-rate indication and has a long battery life for maintenance-free usage. In addition it can be personalized to increase interest and awareness. The PDM not only records warning level profiles every second for a total of 3600 sec (cyclic overwritten), but also stores accumulated dose data every hour for maximum 5 years.

The PDM can be configured via the cradle and DoseView or Dose Manager Software.

The DoseAware Xtend package includes 6 PDM's. One of these PDM's will be used as reference PDM placed in the holder on the C-arc.

19	**FCV0563	Personal Dose Meter (1 piece)	1	\$1,407.60	\$1,407.60
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Personal Dose Meter.

The Personal Dose Meter (PDM) is a small and easy to wear active Xray dose meter intended to measure and store received Xray dose of staff, present in an Xray room during radiation. The PDM has build-in wireless communication to connect to the DoseAware Base Station for real time dose-rate indication and has a long battery life for maintenance-free usage. In addition it can be personalized to increase interest and awareness. The PDM not only records warning level profiles every second for a total of 3600 sec (cyclic overwritten), but also stores accumulated dose data every hour for maximum 5 years. A clip and a lanyard holder are included to facilitate easy wearing.

The PDM can be configured via the cradle and DoseView (and the optional Dose Manager) software for the following attributes:

- Full name (max 40 bytes)
- Display user name (max 16 bytes)
- User group from list
- PDM ID (max 16 characters)
- Position on body
- Date & time = Real Time Clock, synchronized with local time, and being the clock master for the DoseAware system. With each
- connection PDM => Base Station => Dose Manager the timing is synchronized automatically.
- Date of PDM assignment to a person
- Dose history reset
- Sleep mode On/Off
- Annual dose limit

The PDM has following specifications:

- Operational unit: HP10
- Dose range: 1µSv – 10 Sv
- Dose resolution: 1 µSv
- Dose uncertainty: 5% or 1 µSv

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Line #	Part #	Description	Qty	Each	Price
		<ul style="list-style-type: none"> Dose rate range: 10 µSv/hr - 50 mSv/hr (3 nSv/s - 15 µSv/s) Response time: < 4 s, 40 µSv/hr – 100 µSv/hr; < 1 s above 100 µSv/hr Energy dependency X-, Gamma-rays: N40-N160 (33keV – 118 keV) Average battery life: 3 – 5 years, depending on daily use Weight: 30 gr Dimensions: 45 x 45 x 10 mm (w x h x d) Personalization: 8 inlays with colour Communication radio: Center frequency 868.3 Mhz for Europe version 915 Mhz for USA version 			

20	**NVLV010	SyncVision	1	\$72,933.00	\$72,933.00
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SyncVision IVUS Co-registration System

SyncVision IVUS and IFR Co-registration System

SyncVision Workstation CPU, Power Supply, Isolation Transformer Medical Grade, Joystick Controller, Optical USB Mouse and Keyboard, LCD Monitor 19" Philips, Cable Kit, SyncVision System Operator's Guide.

End User License Agreement

Customer agrees that use of the SyncVision software is subject to the terms of the End User License Agreement, as it may be updated by VOLCANO from the time to time ("EULA"). A copy of the EULA is also available online at www.volcanocorp.com/products/pdf-files/end-user.pdf. The terms of the EULA are incorporated herein by reference.

Three (3) Year Software Support Agreement

Customer agrees that the initial term of the Software Support Agreement (SSA) is three (3) years, which term shall automatically commence upon installation of SyncVision, This three-year term may be extended upon mutual agreement of the parties and is subject to earlier termination as provided in the SSA. The SSA provides for unspecified updates to the SyncVision software released during the Term of the SSA at no additional cost (should any be commercially released). In the absence of an SSA, future Updates will be made available at additional cost to be determined by VOLCANO). A copy of the SSA is available from your Volcano Sales Representative on online at www.volcanocorp.com/products/pdf-files/software-support.pdf. The terms of the SSA are incorporated herein by reference.

21	**980406041009	Rad Shield w/ Arm (Contoured) 61X76	1	\$2,704.80	\$2,704.80
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Contoured Rad Shield with Arm rest. 61X76

22	**980406190009	PIVOTING TABLE-MOUNTED RADIATION SHIELD	1	\$2,580.60	\$2,580.60
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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 AD57 patient table.

The table mounted radiation shield provides the following features:

- Mounting to either the right or left table accessory rails;
- Pivoting into the required working position;

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Line #	Part #	Description	Qty	Each	Price
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- 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.

The table mounted radiation shield includes:

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

Docking device for wall mounting.

23	**989801220158	Mark 7 Arterion, Table Mount	1	\$26,220.00	\$26,220.00
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The Mark 7 Arterion Injection System is the latest in MEDRAD's "Mark" series of angiographic injectors. Compared to earlier systems, the Mark 7 Arterion injector head is lighter and easier to use so you can focus more on the patient.

The clear and intuitive user interface guides you through proper set-up, and highlights the information you need to perform safe procedures.

Unique to the market, the front load system simplifies set-up and makes for a cleaner tear down. The clear syringe provides a higher level of confidence that you are ready to inject.

Made from a clear material, the Mark 7 Arterion syringe (Catalog ART 700 SYR) allows you to easily view the inside of the syringe for smoother purging of air. And MEDRAD's famous fluid dots are still there to help-round for fluid, oval for air.

The table mount injector solution ensures the contrast injector is conveniently placed and always available when it is needed. It provides a clean workspace without occupying valuable floor space. System includes:

- Table Mount
- display control panel
- 6 ft. coiled hand switch
- operation manual (CD)
- 10 ft. head cable
- syringe heat maintainer
- imaging system interface cable for the Allura / Allura Xper
- consumables starters kit

For the MEDRAD Mark7 Injector system Philips is only the distributor. MEDRAD provides the service as well as the application support of both versions unless stated differently in the Philips Service Agreement

System Specifications:

- Flow Rate 0.1-45.0 ml/s in 0.1 ml increments
- 0.1-59.9 ml/m in 0.1 ml increments
- Volume 1-150 ml in 1 ml increments
- Pressure Limit 100-1200 psi in 1 psi increments
- (150ml syringe) 689-8273 kPa in 1 kPa increments
- Rise Time 0.0-9.9 seconds in 0.1 increments
- Delay Time 0.0-99.9 seconds in 0.1 increments

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Line #	Part #	Description	Qty	Each	Price
		<ul style="list-style-type: none"> • Fill Speed 1-20 ml/s • Fill Volume 1-150 ml • Syringe Size 150 ml • Syringe Heat Maintainer 35 °C (95 °F) ± 5 °C (9 °F) • Protocol Memory 40 Protocols • Injection Memory History 			
24	**989801220273	Ceiling Track w/Column & Handle Ext Mavig 2.5m Ceiling Track with Ceiling trolley, 360 degree column, and brake handle extension.	1	\$4,057.20	\$4,057.20
25	**989801220375	Black Anti-fatigue Floor Mat w/logo. Black Anti-fatigue Floor Mat with Philips Logo 36" x 60"	2	\$184.00	\$368.00
26	**989801256476	IGT Addl Azurion Essentials 28 Hour OffSite Philips will provide one (1) 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. 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. 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. Travel and lodging are not included, but may be purchased through Philips. It is highly recommended that 989801256034 (CV Full Travel Pkg OffSite) is purchased with all OffSite courses	1	\$3,600.00	\$3,600.00
27	**989801256032	iXR Additional Training 16 Hours OnSite Clinical Education Specialists will provide sixteen (16) hours of iXR 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 equipment installation date (or purchase date if sold separately).	1	\$4,600.00	\$4,600.00
28	**989801220380	Full Load Remote UPS	1	\$41,009.00	\$41,009.00

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Line #	Part #	Description	Qty	Each	Price
		MGE Galaxy 5000 80 kVA Full Load – 40kW UPS with remote capability. Includes top feed cabinet and optional side panels, ISX0001369526 G5TUPSU80KPA adjacent MGE Galaxy 5000 Battery Cabinet with one full string of batteries and standard Galaxy 5000 Adjacent battery Temp sensor. High Voltage 6 Alarm Relays Card MGE GALAXY 5000 Remote Alarm Status Panel MGE SNMP/Web Communication Card Top Feed Auxiliary Cabinet In the event of a power loss the UPS provides emergency power to allow system function and full X-Ray exposure and fluoroscopy for up to 15 minutes.			
29	**NNAE597	IXR Dynamic Coronary Roadmap OnSite Education Philips Imaging Systems Clinical Education Specialist will provide eight (8) hours of education for up to four (4) students, as selected by customer, including technologists from weekend/night shifts as necessary. CEU credits are not available for this portion of training. 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. Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref#296309-20170315 This training requires the purchase of Dynamic Coronary Roadmap.	1		
30	**989600213942	AD5 TO XPER TABLE ADAPT. PLATE	1	\$1,982.60	\$1,982.60

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NET PRICE

\$1,198,647.80

Buying Group: CAROLINAS HEALTHCARE SYSTEM SCA

Contract #: CAA0013200

Add'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

Interventional X-RAY (IXR) Systems Product Warranty

This product warranty document is an addition to the terms and conditions set forth in the quotation to which this warranty document is attached. Unless specifically listed below, this warranty does not apply to replacement parts. 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.

1. Twelve (12) Month System Warranty

1.1 Philips Healthcare a division of Philips North America LLC (Philips) warrants to Customer that the Philips' Interventional X-Ray Systems (System) will perform in substantial compliance with its performance specifications, in the documentation accompanying the System, for a period of twelve (12) months after completion of installation or availability for first patient use, whichever occurs first.

1.2 Any glassware or flat detectors provided with the System is subject to special warranty terms set forth below.

2. Planned Maintenance

2.1 During the warranty period, Philips' service personnel will schedule planned maintenance visits, in advance, at a mutually agreeable time on weekdays, between 8:00 am and 5:00 pm local time, excluding Philips' observed holidays.

3. System Options, Upgrades or Accessories

3.1 Any Philips' authorized options, upgrades, or accessories for the System which are delivered and/or installed on the System during the original term of the System warranty shall be subject to the same warranty terms contained in the first paragraph of this warranty, except that such warranty shall expire on the later of:

3.1.1 upon termination of the initial twelve (12) month warranty period for the System on which the option or accessory is installed,

3.1.2 after ninety (90) days for parts only from the date of installation.

4. MRC X-Ray Tubes

4.1 Philips warrants to Customer, for the warranty periods further specified in this section, that the Philips' X-Ray tubes (tubes) will be substantially free from defects in material and manufacturing workmanship, which impair performance under normal use as specified in Philips' System descriptions and specifications.

4.2 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.

4.3 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.

5. MRC Tube Warranty Exclusions

5.1 The above warranty shall not apply to X-Ray Tubes outside the United States and Canada.

5.2 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 System other than in accordance with Philips' applicable System specifications and written instructions; improper site preparation; abuse, negligence, accident, loss or damage in transit, unauthorized maintenance or modifications to the System; or, to viruses or similar software interference resulting from the connection of the System to a network.

6. MRC Tube Warranty Remedies

6.1 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.

6.2 Any replacement tube would have a warranty period equal to the balance of the warranty period left on the tube replaced.

7. Dynamic Flat Detectors

7.1 Philips warrants the Dynamix Flat Detectors (detector) provided with the System, if any, will be free from defects in material and manufacturing workmanship for twelve (12) months.

7.2 Claims must be made within twelve (12) months after installation or fifteen (15) months after date of shipment from Philips, whichever occurs first.

7.3 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.

8. System Software and Software Updates

8.1 The software provided with the System will be the latest version of the standard software available for that System as of the ninetieth (90th) day prior to the date the System is delivered to Customer.

8.2 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.

8.3 All software is and shall remain the sole property of Philips or its software suppliers.

8.4 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.

8.5 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.

8.6 Any Philips maintenance or service software and documentation provided with the System 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.

8.7 Customer agrees to restrict the access to such software and documentation to Philips employees, those of its authorized agents, and to authorized employees of Customer only.

9. Warranty Limitations

9.1 Philips' sole obligations and Customer's exclusive remedy under any product warranty are limited, at Philips option, to the repair or the replacement of the product or a portion thereof, within thirty (30) days after receipt of written notice of such material breach from Customer (Product Warranty Cure Period) or, upon expiration of the Product Warranty Cure Period, to a refund of a portion of the purchase price paid by the Customer upon Customer's request.

9.2 Any refund will be paid, to the Customer when the product is returned to Philips.

9.3 Warranty service outside of normal working hours (i.e. 8:00 am to 5:00 pm Monday through Friday, excluding Philips' observed holidays), will be subject to payment by Customer at Philips standard service rates.

9.4 This warranty is subject to the following conditions: the product

9.4.1 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);

9.4.2 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; and

9.4.3 is to be maintained and in strict compliance with all recommended and scheduled maintenance instructions provided with the Product.

9.5 Philips' obligations under any product warranty do not apply to any product defects resulting from: improper or inadequate maintenance or calibration by the Customer or its agents; Customer or third party supplied interfaces, supplies, or software including without limitation loading of operating system patches to the Licensed Software and/or upgrades to anti-virus software running in connection with the Licensed Software without prior approval by Philips; use or operation of the product other than in accordance with Philips' applicable product specifications and written instructions; abuse, negligence, accident, loss, or damage in transit; improper site preparation; unauthorized maintenance or modifications to the product; or, viruses or similar software interference resulting from connection of the product to a network.

9.6 Philips does not provide a warranty for any third party products furnished to Customer by Philips under this quotation; however, Philips shall use reasonable efforts to extend to Customer the third party warranty for the product.

9.7 The obligations of Philips described herein are Philips' only obligations and Customer's sole and exclusive remedy for a breach of a warranty.

9.8 THE WARRANTIES SET FORTH HEREIN AND IN PHILIPS WARRANTY DOCUMENT WITH RESPECT TO A PRODUCT (INCLUDING THE SOFTWARE PROVIDED WITH THE PRODUCT) ARE THE ONLY WARRANTIES MADE BY PHILIPS IN CONNECTION WITH THE PRODUCT, THE SOFTWARE, AND THE TRANSACTIONS CONTEMPLATED BY THE QUOTATION, AND ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, WHETHER WRITTEN, ORAL, STATUTORY, EXPRESS OR IMPLIED INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF NON-INFRINGEMENT MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

9.9 Philips may use refurbished parts in the manufacture of the products, which are subject to the same quality control procedures and warranties as for new parts.

10. Philips' Remote Services Network (RSN)

10.1 Customer will

10.1.1 provide Philips with a secure location at Customer's premises to store one Philips Remote Services Network router and provide full and free access to this router, (or a Customer-owned router acceptable to Philips) for connection to the equipment and to Customer's network; or

10.1.2 provide Philips with outbound internet access over SSL; at all times during the warranty period provide full and free access to the equipment and the Customer network for Philips' use in remote servicing of the product, remote assistance to personnel that operate the products, updating the products software, transmitting automated status notifications

from the product and regular uploading of products data files (such as but not limited to error logs and utilization data for improvement of Philips' products and services and aggregation into services).

10.2 Customer's failure to provide such access will constitute Customer's waiver of the scheduled planned maintenance service and will void support or warranty coverage of product malfunctions until such time as planned maintenance service is completed or RSN access is provided.

10.3 Customer agrees to pay Philips at the prevailing demand service rates for all time spent by Philips' service personnel waiting for extended coverage.

11. Transfer of System

11.1 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.

11.2 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.

11.3 Customer will compensate Philips for these services at the prevailing service rates in effect as of the date the inspection is performed.

11.4 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.

12. Limitation of Liability

12.1 THE TOTAL LIABILITY, IF ANY, OF PHILIPS AND ITS AFFILIATES FOR ALL DAMAGES AND BASED ON ALL CLAIMS, WHETHER ARISING OR RELATING TO BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING FROM A PRODUCT, LICENSED SOFTWARE, AND/OR SERVICE IS LIMITED TO THE PRICE PAID HEREUNDER FOR THE PRODUCT, LICENSED SOFTWARE, OR SERVICE GIVING RISE TO THE LIABILITY.

12.2 THIS LIMITATION SHALL NOT APPLY TO:

12.2.1 THIRD PARTY CLAIMS FOR DIRECT DAMAGES FOR BODILY INJURY OR DEATH TO THE EXTENT CAUSED BY PHILIPS' NEGLIGENCE OR PROVEN PRODUCT DEFECT.

12.2.2 CLAIMS OF TANGIBLE PROPERTY DAMAGE REPRESENTING THE ACTUAL COST TO REPAIR OR REPLACE PHYSICAL PROPERTY TO THE EXTENT CAUSED BY PHILIPS' NEGLIGENCE OR PROVEN PRODUCT DEFECT;

12.2.3 OUT OF POCKET COSTS INCURRED BY CUSTOMER TO PROVIDE PATIENT NOTIFICATIONS, REQUIRED BY LAW, TO THE EXTENT SUCH NOTICES ARE CAUSED BY PHILIPS' UNAUTHORIZED DISCLOSURE OF PHI; and,

12.2.4 FINES/PENALTIES LEVIED AGAINST CUSTOMER BY GOVERNMENT AGENCIES CITING PHILIPS' UNAUTHORIZED DISCLOSURE OF PHI AS THE BASIS OF THE FINE/PENALTY, ANY SUCH FINES OR PENALTIES SHALL CONSTITUTE DIRECT DAMAGES.

13. Disclaimer

13.1 IN NO EVENT SHALL PHILIPS OR ITS AFFILIATES BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY OR SPECIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOST REVENUES OR PROFITS, BUSINESS INTERRUPTION, LOSS OF DATA OR THE COST OF SUBSTITUTE PRODUCTS OR SERVICES WHETHER ARISING FROM BREACH CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT.

14. FORCE MAJEURE

14.1 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

Attachment D



CHS Northeast

Atrium Health

920 Church Street North

Concord, NC 28025

November 7, 2018

This letter is to confirm that all components of the Philips Allura Xper FD20 Cardiovascular system (Site ID 42313004), located at Carolinas Medical Center in Concord, North Carolina, will be taken as a trade-in by Philips Healthcare. The system components will be removed from the state of North Carolina and not re-sold in North Carolina without CON approval.

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

Thank you,

Mike Vitagliano

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

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project name: CHS North East Modernization Project Cardiac Cath Lab #1
Provider/Company: Atrium Health

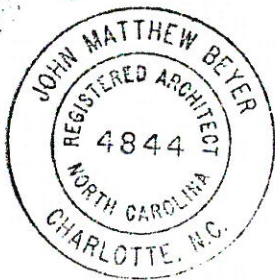
(1) Purchase price of land	_____
(2) Closing costs	_____
(3) Site Preparation	_____
(4) Construction/Renovation Contract	\$168,500
(5) Landscaping	_____
(6) Architect/Engineering Fees	\$12,750
(7) Medical Equipment	\$1,288,545.80
(8) Non Medical Equipment	_____
(9) Furniture	_____
(10) Consultant Fees (CON Fees and Legal Fees)	_____
(11) Financing Costs	_____
(12) Interest During Construction	_____
(13) Other (Sales Tax Value)	_____
(14) Total Capital Cost	\$1,469,795.80

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

J.M. Beyer

(Signature of Licensed Architect or Engineer)

12/4/18
DATE



Sales taxes have been included in these equipment costs. However, because Atrium Health is entitled to a sales tax refund under N.C. Gen. Stat. § 105-164.14(b) and 105-467, the sales tax that Atrium Health initially incurs for this medical equipment purchase will be refunded to Atrium Health, and thus will reduce the capital costs that Atrium Health actually incurs for the equipment by \$89,898.