



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER  
GOVERNOR

MANDY COHEN, MD, MPH  
SECRETARY

MARK PAYNE  
DIRECTOR

February 15, 2018

Elizabeth Kirkman  
CHS Strategic Services Group  
2709 Water Ridge Parkway, Suite 200  
Charlotte, North Carolina 28217

**Exempt from Review – Replacement Equipment**

**Record #:** 2514  
**Facility Name:** Carolinas Medical Center  
**FID #:** 943070  
**Business Name:** The Charlotte-Mecklenburg Hospital Authority  
**Business #:** 1770  
**Project Description:** Replace the existing cardiac catheterization lab #4  
**County:** Mecklenburg

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of February 6, 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 replace the existing cardiac catheterization lab #4, Philips Medical Systems Allura 9F, with a Philips Medical Systems Azurion 7 cardiac catheterization lab located at Carolinas Medical Center. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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

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

**HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION**  
WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704


AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



Sincerely,



Gloria C. Hale  
Team Leader



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

cc: Construction Section, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR  
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR



Carolinus HealthCare System

February 6, 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: Replacement of cardiac catheterization equipment licensed under The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinus Medical Center.

Dear Ms. Frisone:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinus Medical Center (CMC) is planning to replace one of its existing cardiac catheterization labs with new, technologically comparable equipment. CMC intends to purchase a Philips Azurion 7 M12 to replace a Philips Allura that was installed in 2005 and is currently located in cardiac catheterization lab #4 at CMC. The existing equipment is near the end of its useful life and is at risk for service interruptions due to downtime.

The Azurion will be used for the same types of procedures as the existing equipment and it will not be used to provide a new health service. A chart comparing the existing equipment and the replacement equipment is included in Attachment A along with supporting documentation. The equipment is currently in use and documentation provided in Attachment B indicates 1,142 procedures were performed from January 2017 through December 2017.

The total cost to acquire, install and make operational the replacement equipment is \$1,961,812 which includes construction costs of \$377,300, architect/engineering fees of \$71,000, furniture of \$6,500, other fees of \$95,959, and the Replacement Equipment of \$1,411,053 (\$1,312,608 for the cardiac catheterization equipment and \$98,445 for sales tax). Attachment C provides the quote for the cardiac catheterization with equipment costs. Please see Attachment D for a letter documenting the equipment will be taken out of service and removed from North Carolina. The total capital cost schedule and certified cost estimate of the renovation required to install the new equipment are provided in Attachment E.

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

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

Sincerely,

A handwritten signature in black ink that reads "Elizabeth Kirkman". The signature is written in a cursive, flowing style.

Elizabeth Kirkman, Assistant Vice-President  
CHS Strategic Services Group

Attachments

# Attachment A

**2018 CMC Cath Lab #4 Replacement  
EQUIPMENT COMPARISON**

	Existing Equipment	Replacement Equipment
Type of Equipment (List each component)	Cardiac Catheterization Lab	Cardiac Catheterization Lab
Manufacturer of Equipment	Philips Medical Systems	Philips Medical Systems
Tesla Rating for MRIs	N/A	N/A
Model Number	Allura 9F	Azurion 7
Serial Number	202	N/A
Provider's Method of Identifying Equipment	Serial Number	Serial Number
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	2005	2018
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>	\$1,400,000	\$1,961,812
Total Cost of Equipment	\$874,820	\$1,411,053
Fair Market Value of Equipment	\$50,362	\$1,411,053
Net Purchase Price of Equipment	\$874,820	\$1,411,053
Locations Where Operated	Carolinas Medical Center	Carolinas Medical Center
Number Days in Use/To Be Used in N.C. per Year	254	254
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



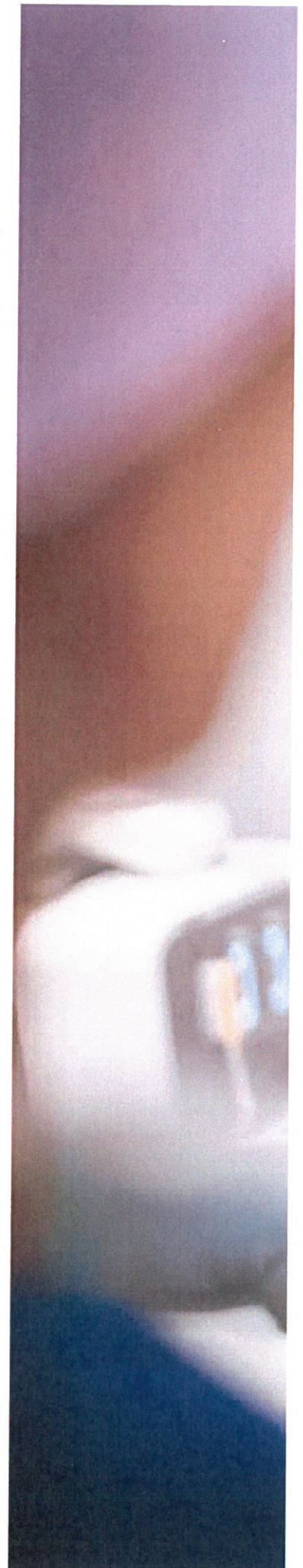
Azurion helps you optimize your lab performance



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**

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

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 errors<sup>1</sup>

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.

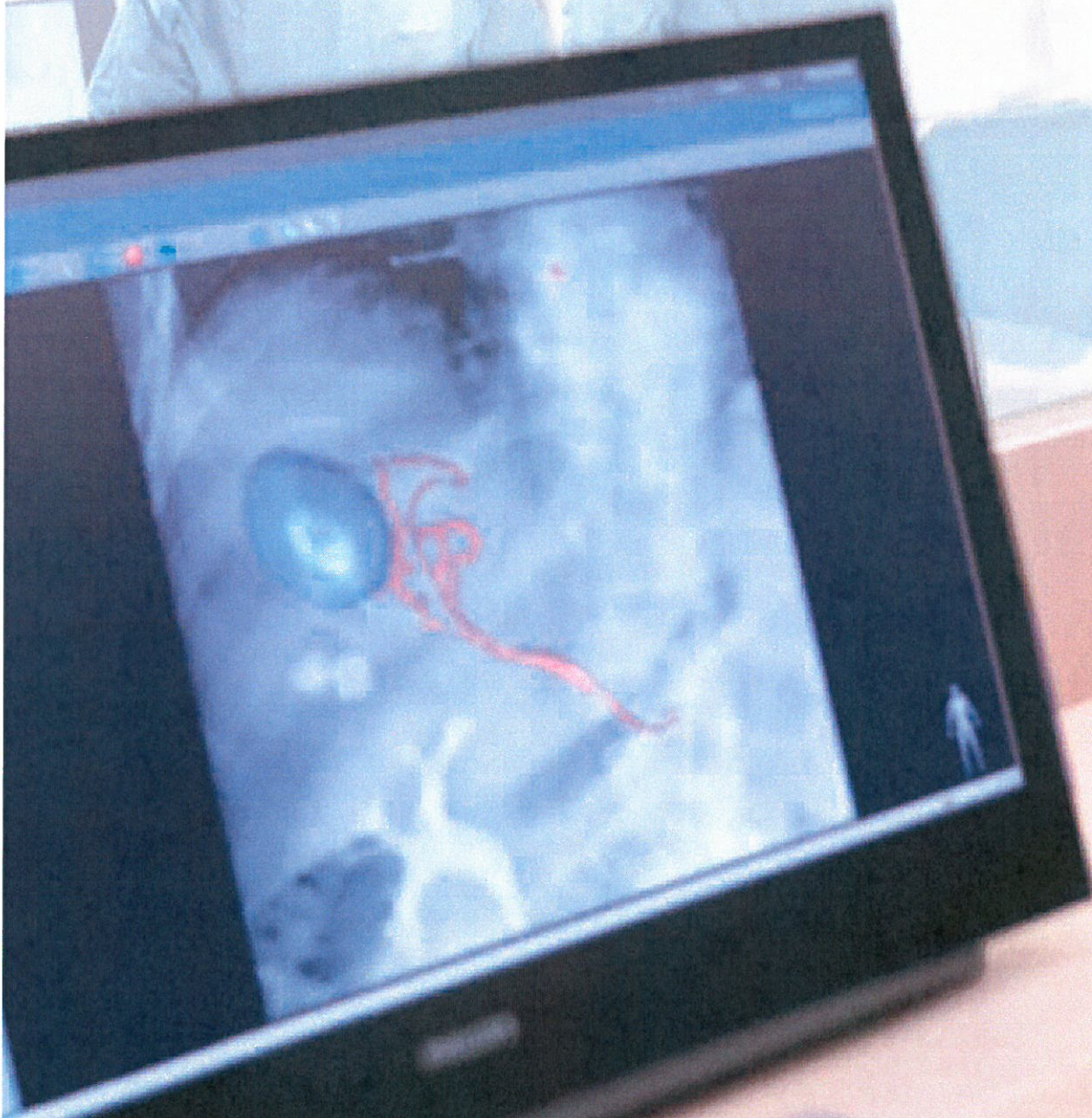
## **Managing dose across your organization**

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

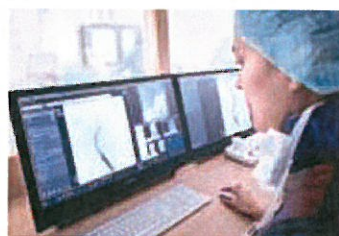
You can combine different user centric workspots (FlexVision Pro, FlexSpot and touch screen modules) to view control and run applications where and when needed. So you have the tools in hand to manage procedure quality and patient care. Together these flexible workspots allow you to customize your workflow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

In a simulation study with over 60 users globally,

**91%** believe that the system will help reduce procedure time<sup>1</sup>



Touch screen module Pro



FlexSpot



FlexVision Pro


A photograph of two surgeons in an operating room. They are wearing blue scrubs, white gloves, and blue surgical masks. They are looking at a tablet computer held by one of them. The background is slightly blurred, showing a large monitor on the wall.

In a simulation study with over 60 users globally,

**96%** are satisfied with how easy it is to use the system<sup>1</sup>

# Outstanding **user experience**





Studies have documented the adverse impact that poor usability, design and ergonomics can have on medical procedures and patient safety.<sup>2</sup> 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 Pro<sup>2</sup> 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.

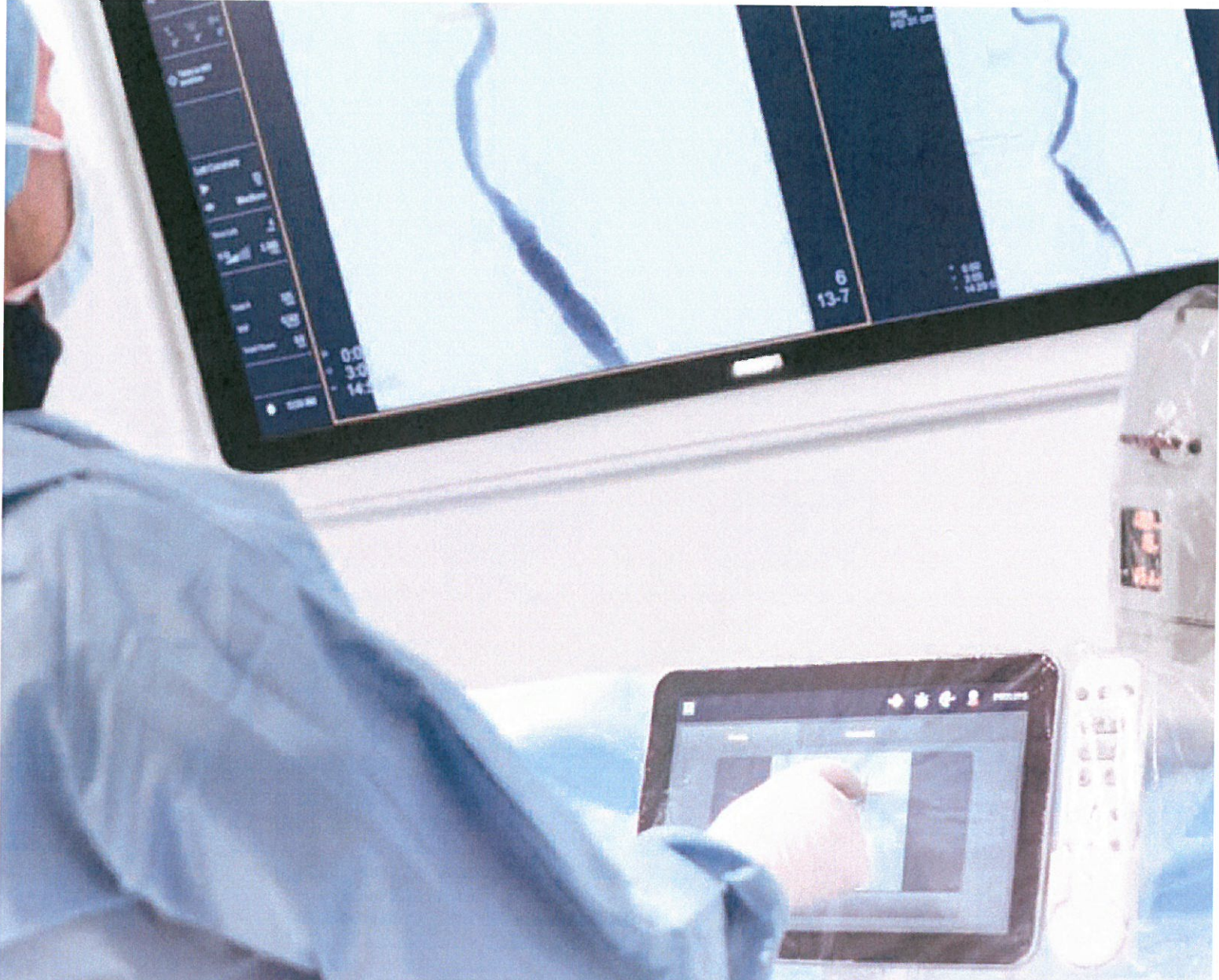


Azurion 7 C12



Azurion 7 C20

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



**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



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



# 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.

© 2017 Koninklijke Philips N.V. All rights reserved. Specifications are subject to change without notice. Trademarks are the property of Koninklijke Philips N.V. or their respective owners.

**How to reach us**  
Please visit [www.philips.com/azurion](http://www.philips.com/azurion)  
[healthcare@philips.com](mailto:healthcare@philips.com)

4522 991 28911 \* JUL 2017

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

# Attachment B

**CMC Cath Lab #4 Volumes**

	<b>2017</b>
<b>Jan</b>	98
<b>Feb</b>	92
<b>Mar</b>	129
<b>Apr</b>	92
<b>May</b>	111
<b>Jun</b>	95
<b>Jul</b>	90
<b>Aug</b>	117
<b>Sep</b>	89
<b>Oct</b>	75
<b>Nov</b>	81
<b>Dec</b>	73
<b>Total</b>	1,142



# Attachment C

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



<b>Quotation #:</b> 1-1NX101X	<b>Rev:</b> 5	<b>Effective From:</b> 16-Jan-18	<b>To:</b> 17-Mar-18
<b>Presented To:</b> CAROLINA MEDICAL CENTER 1000 BLYTHE BLVD CHARLOTTE, NC 28203-5871  Tel:  <b>Alternate Address:</b>		<b>Presented By:</b> Brett Kimball <i>Account Manager</i>  John Hill <i>Regional Manager</i>  Tel: <b>Fax:</b> Tel: (800) 722-7900 x6806 <b>Fax:</b>	
<b>Date Printed:</b> 16-Jan-18			
<b>Submit Orders To:</b> 22100 BOTHELL EVERETT HWY BOTHELL WA 98021  Tel: (888) 564-8643		Fax: (425) 458-0390	

The Service information contained in this Quote is subject to a separate service proposal.

The Lease Information contained in this Quote is subject to a separate leasing proposal.

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

Line #	Product	Qty	Price
	100233 Azurion 7 M12	1	\$1,312,607.90
Equipment Total:			\$1,312,607.90

## Solution Summary Detail

Product	Qty	Each	Monthly	Price
100233 Azurion 7 M12	1	\$1,312,607.90		\$1,312,607.90
60 Month Equipment + Service Lease Fair Market Value	60		\$30,112.28	

The Lease Information contained in this Quote is subject to a separate leasing proposal. If the trade-in equipment is leased with Philips Medical Capital, then the monthly payment does not apply.

SVC0138 Protection POS \$8,433.25

The Service information contained in this Quote is subject to a separate service proposal.

**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	<b>NNAE547 Azurion 7 F12</b>
1	NNAE580 Azurion FlexVision10 Input
1	NCVA115 StentBoost Control for Xper Module
1	NCVC542 Dynamic Coronary Roadmap
1	NCVC265 Prep table for Table Mount inj
1	NCVD058 FlexSpot
1	NCVD067 ClarityIQ
1	FCV0812 live/ref slaving for ER
1	NCVD059 FlexSpot secondary monitor
1	NCVC544 StentBoost Live
1	NCVD100 Left Ventricular Analysis
1	NCVA783 Pivot for table base.
1	NCVD064 extension to FlexVision Pro
1	NCVA780 Digital subtracted Angio
1	NCVD097 DVD writer
1	NCVD177 IW Hardware (FlexSpot)
1	NCVA825 Stentboost subtract
1	NCVD081 Touch Screen Module Pro
1	NCVD031 FlexVision XL + 2 LCD's
1	NCVD137 CardiacSwing
1	NCVD139 rotational scan
1	989801220012 Cable Spooler
1	989801220037 M LED 3MC Light
1	989801220273 Ceiling Track w/Column & Handle Ext
1	SP059D System Admin
1	SP003 Installation Labor

### Options

Qty	Product
1	FCV0807 live/ref slaving for CR
1	NCVD061 optional ref monoplane
1	NCVC199 Wireless footswitch: mono-plane version
1	NCVB266 3D-RA Complete

## Quote Summary

100233 Azurion 7 M12

### Options

Qty	Product
1	NCVD074 60Fr/sec extension (mono)
1	NCVD138 table tilt option
1	NCVD078 FD Dual Fluoro monoplane
1	FCV0604 DoseAware Bundle

**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	**NNAE547	Azurion 7 F12	1	\$749,853.00	\$749,853.00

Versatile 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 with same 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

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.

This floor mounted system is one of the most versatile solutions 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 7 F12 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 7 F12 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 procedural workflow.

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

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

- 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 F12 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 F12 stand

The floor mounted Poly Diagnost G stand offers a full range of cardiac projection possibilities. This configuration comprises the following features:

A motorized dedicated cardiac floor-mounted Poly-Diagnost G-stand. A rotatable base (motorized and manually operated) allows parking to provide a clear area around the patient table. Parking of the Poly Diagnost G stand is provided with electronic autostop positions.

All stand movements are motorized. In addition, the balanced FD-shift allows manual positioning of the flat detector.

Motorized Angulation and Rotation of the Poly Diagnost G-arm allow high speed operation.

- The motorized base rotation movement makes positioning in the iso-center easy and accurate. It also features comfortable, single operator control of stand parking.
- The motorized base rotation has a movement speed 12 degrees/s from +105 to -105 degrees.

The projection angles for the Poly Diagnost G-arm:

- Rotation 120 degrees LAO to 120 degrees RAO
- Angulation 45 degrees cranial to 45 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, providing comfortable head to groin coverage while the C-arc remains in the head position.

The BodyGuard is a detection system for automatic safeguarding of patient and equipment. This detection system senses objects close to the detector and subsequently limits system movements. Therefore the Philips Azurion F12 adapts to the actual size of the patient and allows taking full advantage of the high speed movements.

The variable source image distance between focus and Dynamic Flat Detector input screen is 890

## 100233 Azurion 7 M12

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

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 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.

Table accessory set includes:

- - 3 rail accessory clamps.
- A patient mattress. A slow recovery foam mattress with a Density of 58 kg/m<sup>3</sup>. The mattress has a thickness of 5 cm and adapts to the body shape of the patient. It makes the pressure being divided equally and it recovers when the patient is taken off the mattress. The light yellow cover is easy to clean. Patients are more relaxed due to the comfort of this mattress, supporting long interventional procedures.
- Drip stand.
- Set of cable holders.
- Patient straps
- Arm Support Board
- Set of Elbow Supports

## 2. X-ray Generation

### A. Generator

The 7 F12 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



## 100233 Azurion 7 M12

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

- 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. X-ray tube

The 7 F12 system has the Maximus ROTALIX Ceramic grid switch tube assembly MRC200+ GS 0508 integrated.

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)
- 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

### C. 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.

### D. 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 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, and adaptive harmonization)

## 100233 Azurion 7 M12

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

### E. 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

## 100233 Azurion 7 M12

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

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, EchoNavigator, DoseAware)
- Monitor layout (FlexVision, swit chable 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 fileCopy image to photo file

## 100233 Azurion 7 M12

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

- Digital (fixed) zoom and panningRecall reference images, which means switching control of Viewpad function from life 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
- 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.

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
- 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

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

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
- 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-ra
- Frame speed settings, fluoroscopy mode, and accumulated Fluoroscopy tim
- 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

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

- 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**

- 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.

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

**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
- 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 DICO
- Internal power supply (100-240 VAC)

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

- 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 for the Azurion System. The option includes a separate intercom, which is connected independently from the system. This allows placement of the intercom at the preferred working position in the control room and examination room. The listen function can be separately selected on each intercom. Activating the talk function on a selected intercom automatically disables this function on the other 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

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 F12 system is a perfect example of our EcoVision program. By examining every aspect of the 7 F12 design and development through a green eye, we drastically reduced the products environmental impact.

**System & table APC**

Helps to save time and manage X-ray dose with automatic positioning

Positioning the X-ray system to visualize relevant anatomy from different perspectives can involve a great deal of time and many scout images during interventional procedures. To help save time and manage X-ray dose while working, the Automatic Position Controller (APC) provides an easy way for interventional team members to store and recall stand-related positions.

Specifications



**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

The system APC stand and table positions need to be stored and recalled separately.

**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 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

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

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	**NNAE580	<b>Azurion FlexVision10 Input</b>	<b>1</b>	<b>\$26,356.80</b>	<b>\$26,356.80</b>
---	-----------	-----------------------------------	----------	--------------------	--------------------

Eight 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.

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

Two 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

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

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.

3	**NCVA115	<b>StentBoost Control for Xper Module</b>	1	\$4,248.30	\$4,248.30
---	-----------	---	---	------------	------------

Table Side Module functionality for Allura Xper FD20 used with StentBoost Release 1.0  
For further improvement of interventional procedures efficiency, the physician has all StentBoost functionality needed at tableside available on the Xper module.

4	**NCVC542	<b>Dynamic Coronary Roadmap</b>	1	\$31,538.40	\$31,538.40
---	-----------	---------------------------------	---	-------------	-------------

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.

**IXR Dynamic Coronary Roadmap Imaging Systems 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

5	**NCVC265	<b>Prep table for Table Mount inj</b>	1	\$6,849.30	\$6,849.30
---	-----------	---------------------------------------	---	------------	------------

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

This is only applicable when the Mark 7 Arterion Table Mount injector will be ordered locally. Prepared for Table Mount Injector prepares the XperTable with the cabling needed for a Table Mount install of the MEDRAD Mark 7 Arterion injector head. This preparation will facilitate the install of the Table Mount injector system. It will save an estimated 4 - 8 hours of installation time. The injector base unit can be placed in the technical room, and User Interface and display can be placed in the control room or on the wall of the exam room.

The prepared for Table mount injection table option cannot be purchased in combination with the Swivel AND prepared for Volcano Core option.

6	**NCVD058	<b>FlexSpot</b>	1	<b>\$47,322.90</b>	<b>\$47,322.90</b>
---	-----------	-----------------	---	--------------------	--------------------

Integrated work spot in the Control Room to view, control and manipulate all applications within a single view

**Key benefits**

- Access all applications on one compact workplace in the control room
- Set up unlimited custom screen layouts with all relevant information in one view
- Full flexibility of screen layouts (live resize, drag and drop)
- Clutter free and clean control room

**Simplify control room workflow**

Typical interventional control rooms are equipped with several workstations and controls to support procedures that require extra handling and space. FlexSpot helps you save time and space in the control room by giving you seamless access to all applications on one compact workplace. Easily set up any screen layout desired with all relevant information in one view. Resize, drag and drop items just like a tablet.

**Specifications**

FlexSpot offers an integrated workspot in the Control Room with one or more high resolution QHD (2560x1440) displays.

- Show internal video sources (e.g. Review, CR Live)
- Show up to 11 external video sources (e.g. Ultrasound, EchoNav, etc.)
- Video sources can be flexibly displayed on FlexSpot through user customizable presets. Users can customize the displayed layout and assign video sources to viewports as desired
- Up to 4 video sources can be displayed on a single FlexSpot display (excluding the add-on FlexSpot).
- Per display, the user can choose between 7 different layouts (positioning of viewports)
- FlexSpot offers user interaction through a keyboard and mouse with which users can seamlessly control all video sources on screen. Seamless means that users can move out of one viewport and into another without needing to press a special keyboard shortcut or use a gesture.
- In systems with both FlexSpot and FlexVision, FlexSpot offers convenient control access of FlexVision from the primary FlexSpot workspot.
- Users can define their own preset groups and preset names.
- Through field service, users can assign their own custom name and icon to a video source (also applies to FlexVision)
- The X-ray status area with all X-ray details is always visible on the primary display of the primary FlexSpot workspot.
- Up to 3 Philips workstations can be integrated into the technical room. With this, the workstations are powered from the system and are fully integrated into the system. Users do not need to separately power on/off these workstations.
- The snapshot function allows the user to store/save a screen-capture of any image on the FlexSpot as a photo image to the current Acquisition Patient study.
- 27 inch high brightness color LCD monitor for clinical image display in the Control Room.

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
		<p>The main characteristics for color monitor are:</p> <ul style="list-style-type: none"> <li>- 27 inch color TFT-LCD display</li> <li>- Native format 2560x1440 Quad HD</li> <li>- High brightness (max 500 Cd/m2, default 350 Cd/m2)</li> <li>- Wide viewing angle (approx. 178 degrees)</li> <li>- Long term luminance stability through backlight stabilization circuit</li> <li>- Automatic brightness control with backlight sensor</li> <li>- Control functions on side</li> <li>- User programmable and standard reference setting</li> <li>- On Screen Display</li> <li>- Internal selectable lookup table for gray-scale transfer function, including DICOM</li> <li>- Internal power supply (100-240 VAC)</li> <li>- Integrated USB hub</li> </ul>			
7	**NCVD067	<b>ClarityIQ</b>	1	\$100,878.00	\$100,878.00

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.

8	**FCV0812	<b>live/ref slaving for ER</b>	1	\$6,507.60	\$6,507.60
---	-----------	--------------------------------	---	------------	------------

Live/ref slaving for Exam Room.

**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. The live/ref slaving will enable the option to slave the

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

Live and Ref video source from the X-ray system. The total amount of live/ref slaving that can be selected is max 5, minus the number of FCV0807 Live/ref slaving for CR.

**Specifications**

- Live/ref slaving for ER is possible:
- On Philips MCS (additional monitor excluded from this option)
  - In combination with FCV0519 1 or 2 MCS from Skytron/Steris

9	<b>**NCVD059</b>	<b>FlexSpot secondary monitor</b>	<b>1</b>	<b>\$10,057.20</b>	<b>\$10,057.20</b>
---	------------------	-----------------------------------	----------	--------------------	--------------------

FlexSpot secondary monitor

**Simplify control room workflow**

This option adds a second QHD (2560x1440) high resolution monitor to the primary FlexSpot workspot.

Specifications

2nd Display for FlexSpot enables the user to show up to 8 video sources on a single FlexSpot workspot by combining 2 high resolution displays. Keyboard and mouse control is seamless across the 2 displays, see FlexSpot.

10	<b>**NCVC544</b>	<b>StentBoost Live</b>	<b>1</b>	<b>\$26,616.90</b>	<b>\$26,616.90</b>
----	------------------	------------------------	----------	--------------------	--------------------

When inserting a stent in complex cardiac vasculature, inexact positioning and under deployment are always a challenge. StentBoost Live allows physicians to improve the visualization of balloons and stents in coronary arteries on-the-fly to clarify the situation at any moment during an intervention. The user simply presses and holds the foot pedal to boost visualization during the cine run. He can use StentBoost Live to check the position of a device in real-time and confirm stent expansion while the balloon markers are still in place. He can then take any corrective action immediately if required.

To do this, StentBoost Live automatically detects the balloon markers in each acquired image. The detected markers are aligned with the markers found in previous image(s) and temporal and spatial filtering is applied to enhance all radiopaque material in close proximity to the markers. All of this occurs in a few hundreds of milliseconds to produce an enhanced visualization in real-time. StentBoost Live can be applied to any cine run acquisition and at least four frames of images are required.

StentBoost Live features include:

- Automatic marker detection
- Real-time image enhancement during the StentBoost Live run
- Immediately after acquiring the StentBoost Live run, the run is automatically looped three times to allow for further review
- StentBoost Live 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.

IXR StentBoost Imaging Systems 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

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

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

11	**NCVD100	<b>Left Ventricular Analysis</b>	1	\$11,791.20	\$11,791.20
----	-----------	----------------------------------	---	-------------	-------------

**Key benefits**

- Allows quantitative quantification of left ventricular volumes
- Designed for efficiency with single click functions and fast results

**Easily obtain objective assessment of coronary artery**

To support decision making and allow quantitative assessment of anatomy during cardiac interventions, the 2D Left Ventricular Analysis option supports quantification of left ventricular volumes and local wall motion from monoplane angiographic series. It calculates the ejection fraction and local wall motion parameters in different formats. Wall contours can be easily drawn both automatically and manually.

**Specifications**

- Various LV-volumes: ED, ES, Stroke Volume
- Ejection Fraction
- Cardiac Output
- Centerline Wall Motion
- Slager Wall Motion
- Automated and manual calibration routines
- ECG visualization facilitates image selection for analysis
- Store result pages

12	**NCVA783	<b>Pivot for table base.</b>	1	\$5,253.00	\$5,253.00
----	-----------	------------------------------	---	------------	------------

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

Comprising:

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

Compatible with Xper Table

13	**NCVD064	<b>extension to FlexVision Pro</b>	1	\$42,590.10	\$42,590.10
----	-----------	------------------------------------	---	-------------	-------------

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.

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

**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

- 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	<b>Digital subtracted Angio</b>	1	<b>\$17,865.30</b>	<b>\$17,865.30</b>
----	-----------	---------------------------------	---	--------------------	--------------------

The DSA-option allows to extend the application functions with additional vascular studies. DSA features real-time digital subtraction at low frame speeds of 0.5, 1, 2, 3, or 6 frames per second. The DSA prgrams can be selected per Xper Settings. It offers exposure technique for uncompromised image quality of subtracted images. In addition, this option also allows subtraction on run basis (run-subtract), which can be applied in the Rotational Scan and Bolus Chase Subtract options

This function will comprise following functionality:

- Fluoro-Trace
- Fluoro-Subtract
- Exposure subtract on individual image or run basis
- Mask selection
- Landmarking
- Pixel shift

Compatible with:

- . Allura Xper FD10 Rel 3 onwards
- . Allura Xper FD10/10 Rel 2 onwards

15	**NCVD097	<b>DVD writer</b>	1	<b>\$326.40</b>	<b>\$326.40</b>
----	-----------	-------------------	---	-----------------	-----------------

**Key benefits**

- Store images and information on DVDs for easy sharing

**Store images and information on DVDs for easy sharing**

To provide flexible storage options, a DVD writer is available with the Philips X-ray system. Procedural images and information can be stored on DVDs and used for archiving, training and presentations.

**Specifications**

Export and import of X-ray images and X-ray runs to DVD and/or from DVD

16	**NCVD177	<b>IW Hardware (FlexSpot)</b>	1	<b>\$22,307.40</b>	<b>\$22,307.40</b>
----	-----------	-------------------------------	---	--------------------	--------------------



**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

Hardware for the 3D interventional tools combined with FlexSpot.

**Key benefits**

- Facilitates multimodality viewing in exam room and control room
- Supports DICOM compatible data from CT and MR imaging modalities
- Provides real-time access to images to support fast results

**View multimodality images in exam room and control room**

Images from a variety of sources are being increasingly used during interventions for a variety of Live Image Guidance tools. The Interventional Hardware option provides the hardware for our interventional tools that enables DICOM compatible data from other imaging modalities to be imported and viewed in the exam room and control room. To support fast results, a real-time digital image link is provided between the Interventional Hardware workstation and the X-ray system.

**Specifications**

The Interventional hardware is the hardware for the 3D interventional tools that included Real Time Link. It enables import and viewing of DICOM compatible data from other imaging modalities. The Interventional Hardware comprises at least:

- Computer Workstation
- 16 GB memory
- 1.5 TB disk for the operating system, application software and application data
- Internal CD-ROM / DVD writer
- Mouse tablet to interact with all the interventional tools at the table side.

Conditionally:

FD Calibration Tool Kit for 3D-RA

17	**NCVA825	Stentboost subtract	1	\$20,966.10	\$20,966.10
----	-----------	---------------------	---	-------------	-------------

StentBoost is a simple, quick, and cost-effective tool to enhance stent visualization in the coronary arteries.

**Key benefits**

- Shows fine details of stent struts, as well as thinner and drug-eluting stents
- Supports precise pre and post stent deployment by showing the enhanced stent in relation to the vessel wall
- Allows enhanced positioning and fine control of pre-dilation, stent expansion, and post-dilation

**Enhanced visualization software**

When inserting a stent in complex cardiac vasculature, inexact positioning and underdeployment are always a challenge. StentBoost is a simple, quick, and cost-effective tool to enhance stent visualization in the coronary arteries. With the StentBoost Subtract feature, you can even see the stent in relation to the vessel wall as you are working. StentBoost images support precise pre- and post-stent deployment and allow the team to correct potential problems immediately, without applying additional fluoroscopy.

StentBoost automatically detects the stent delivery markers image after image. In each image StentBoost aligns the markers with the markers of the previous image. By doing this all radiopaque material in the close proximity of the markers will be enhanced resulting in enhanced stent visualization.

**Specifications**

StentBoost can be used with and without contrast. Without contrast the images are acquired with only a short cine run of 1 to 2 sec (recommended with 40 frames out).

With contrast the images are acquired with a cine run of 5 to 6 sec. Contrast media is required only for the last 3 to 5 sec (typical recommendation of total 100 frames which of 100 frames cine run of which last 60 frames are with contrast). A contrast enhanced image run results in a dynamic representation of the enhanced stent in relation with the vessel wall.

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
		<p>The StentBoost Subtract functionality includes, but is not limited to:</p> <ul style="list-style-type: none"> <li>• Pre-defined Region of Interest to indicate the location of the stent/balloon markers.</li> <li>• Manual correction possibility for marker identification</li> <li>• Review of StentBoost runs, before and after processing</li> <li>• Measurements to supports decision-making in determining the percentage of remaining in the stent.</li> <li>• Store image snapshot.</li> <li>• Automatic pre-defined Region of Interest to indicate the location of the stent/balloon markers.</li> <li>• Fading in/out of contrast vessel and StentBoost image.</li> <li>• Viewing selection of StentBoost with and without contrast,</li> <li>• Manual image contrast and brightness adjustment of the boost and contrast image</li> <li>• Manual correction possibility for marker, boost and contrast identification.</li> <li>• Create and store as movie.</li> </ul> <p>Stentboost Subtract data can be exported to:                      Any optional DICOM compatible device(e.g. PACS/Printer), supported are DICOM XA, DICOM SC, DICOM CT and DICOM 3D                      Support archive on one or multiple DVD's, CD-ROM(s)                      Image transfer to a standard PC compatible format (JPEG, AVI)                      Store a subset of exportable objects (snapshots and AVI Movies) to a USB device.</p>			

18	**NCVD081	<b>Touch Screen Module Pro</b>	1	<b>\$29,574.90</b>	<b>\$29,574.90</b>
		Extension of Touch Screen Module for easy control of X-Ray images at table site			

**Key benefits**

- Imaging parameters can be quickly and easily adjusted at tableside
- Clinical image are shown to support easy navigation. Collimate on the clinical image with one finger. Pinch, zoom, pan and flag images for processing. Position shutters and wedges by simply swiping the image on screen.
- All X-ray settings can be easily adjusted to help you effectively manage patient and staff dose

**Enhance image navigation on the touch screen module**

This option extends the functionality of the touch screen module, allowing live X-ray images and source images from reference monitors to be displayed on the touch screen module. Shutters and wedges can also be easily positioned with a fingertip by simply dragging them into position. A pointer is also available on screen to improve communication in and between the exam room and control room.

**Specifications**

- enhance image navigation on the TSM
- intuitive control of shutters and wedges by simply dragging the lines shown on top of the image
- provides intuitive zooming an panning functionality (also during fluoroscopy)
- turns the touchscreen into the pointing device in order to improve communication in ER/CR: when activated the pointer is shown on corresponding monitor

!!! Note: Touchpad and Keyboard control from the TSM is NOT part of this option but 'FlexVision Pro' option.

!!! Note: Images shown on the TSM are not meant for diagnostic purposes (image is downscaled, compressed and latency during live/replay maybe higher than on the live monitor)

19	**NCVD031	<b>FlexVision XL + 2 LCD's</b>	1	<b>\$118,391.40</b>	<b>\$118,391.40</b>
----	-----------	--------------------------------	---	---------------------	---------------------

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
--------	--------	-------------	-----	------	-------

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

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
		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.			
		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.			
20	**NCVD137	<b>CardiacSwing</b> CardiacSwing allows dual-axis rotational coronary angiography	1	\$14,198.40	\$14,198.40

**Key benefits**

- Provides uncommon angiography views to capture a more complete view of the coronary tree
- Reduces vessel foreshortening effect

**Less risk, more information for coronary artery diagnosis**

The goal of a coronary angiogram is to obtain as much information to assess lesions with a minimum of vessel foreshortening. The challenge is to do this without losing any of the information or views required and to use as little radiation and contrast as possible. CardiacSwing was designed to meet these goals by reducing the acquisition runs to typically 3 separate runs using 24-26 cc of contrast in total. It also significantly reduces the total procedure time.

CardiacSwing replaces two single axis runs with one dual axis run for the left and right coronary artery. Unlike typical coronary angio which acquires multiple stationary views, a CardiacSwing rotation can begin in the left anterior oblique (LAO), caudal orientation and end in the right anterior oblique (RAO), cranial orientation in one acquisition run. Unexpected angles are presented in a CardiacSwing. These views of the coronary tree provide additional support for lesion assessment and can expose views of vascular anatomy that might be hidden in a normal 2D X-ray angiogram.

**Specifications**

In total seven pre-programmed trajectories are available:

- Three for Left coronary imaging
- Two for Right Coronary imaging,
- Two generic trajectories.

The choice depends on size and weight of the patient. These trajectories are designed to fully cover all conventional projections for a diagnostic coronary angiography. Rotation and angulation movements are combined in one complete scan trajectory, using the maximum rotation and angulation speed of the X-ray system. (55 resp 30 degr/sec). CardiacSwing is possible in the side position (ceiling mounted systems) and in the head position.

CardiacSwing functionality includes, but is not limited to

- 15 frames per seconds acquisition to allows using of less contrast.
- Wide rotation range provides a complete evaluation of the anatomy.
- Precise positioning and high reproducibility.
- Set up and executed in a matter of seconds.
- Set of dedicated acquisition programs with the trajectories available on the touch screen module
- The rotation end- and start-positions can be selected.
- Acquisition procedure is controlled from the exposure hand or footswitch.

21	**NCVD139	<b>rotational scan</b> Realtime 3D impressions of complex vasculature	1	\$15,442.80	\$15,442.80
----	-----------	--	---	-------------	-------------

**Key benefits**

- Use 3D imaging to quickly determine the projection angle for treatment in complex vascular interventions, surgery and radiotherapy
- Supports assessment of vascular pathologies for diagnostic and therapeutic decisions.

**100233 Azurion 7 M12**

Line #	Part #	Description	Qty	Each	Price
		<p><b>Revealing hidden structures</b>                      The complexity of interventional procedures lies in the fact that every person's pathology is unique. Visualization in three dimensions is therefore vital to aid decision making by the clinician. Rotational Scan provides real-time 3D impressions of complex vasculature and the coronary artery tree. Rotational Angio can be used to quickly determine the projection angle for treatment.</p> <p><b>Specifications</b>                      Rotational Scan is possible with the X-ray systems in the side position (ceiling mounted systems) and in the head position which provides the flexibility to perform procedures virtually from head to toe.</p> <p>With FD20 C-arm in side position:                      Max. rotation speed: 30°                      Max. rotation angle: 180°</p> <p>C-arm in head position:                      Max. rotation Speed: 55°                      Max. rotation Angle: 305°</p> <p>With FD12:                      Poly G in side position (ceiling version):                      Max. rotation Speed: 30°                      Max. rotation Angle: 90°</p> <p>Poly G in head position:                      Max. rotation Speed: 55°                      Max. rotation Angle: 240°</p> <p>Maximum speeds are given by the frame speed specifications of the system configuration. The high speed allows using less contrast whereas the wide rotation range provides a complete evaluation of the anatomy.</p> <p>The stand is designed for very high mechanical stability. It offers precise positioning and high reproducibility assuring you of high quality images and excellent studies. These images can be used at the 3D workstation.</p> <p>Operation of Rotational Scan is straight forward: the procedure is selected, set up, and executed, virtually within a matter of seconds supporting high patient throughput.</p> <p>A set of dedicated acquisition programs is available on the touch screen module and can be selected at the touch of a button. The Rotational Scan is controlled from the exposure hand or foot-switch.</p>			
22	**989801220012	<b>Cable Spooler</b>	1	\$413.10	\$413.10
23	**989801220037	<b>M LED 3MC Light</b> MAVIG M3 MC LED - Multi Color / power Supply Included Includes Portegra2 Ext Spring Arm 75/90cm	1	\$12,224.70	\$12,224.70
24	**989801220273	<b>Ceiling Track w/Column &amp; Handle Ext</b> Mavig 2.5m Ceiling Track with Ceiling trolley, 360 degree column, and brake handle extension.	1	\$4,498.20	\$4,498.20
25	SP059D	<b>System Admin</b> Additional sales purchased 6 months of warranty	1	\$36,536.50	\$36,536.50
26	SP003	<b>Installation Labor</b> Weekend delivery Charges	1	\$5,000.00	\$5,000.00

**100233 Azurion 7 M12**

\*\*\*\*\*PROMOTIONS\*\*\*\*\*

<b>Promotion Name</b>	<b>Description</b>
ClarityIQ New and Refurbished System Promo 2018Q1	Philips is pleased to offer this special \$55,000 discount for customers purchasing systems with ClarityIQ. To take advantage of this promotion, customer orders must be placed prior to March 31, 2018.

**100233 Azurion 7 M12**

LIST PRICE	\$2,641,676.50
DISCOUNT	\$1,329,068.60
	\$0.00
NET PRICE	\$1,312,607.90

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.

**100233 Azurion 7 M12**

**OPTIONS**

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial
1	**FCV0807	live/ref slaving for CR	1	\$6,507.60	\$6,507.60	_____

Live/ref slaving for Control Room

**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.

Live/ref slaving will enable the option to slave the Live and Ref video source from the X-ray system. The total amount of live/ref slaving that can be selected is max 3.

**Specifications**

Live/ref slaving for CR is possible:

- In Control Room in combination with FCV00806 (Addl 24" LCD Control Room)
- In Examination Room in combination with FCV0806 (Addl 24" LCD Control Room) as a standalone option and not on MCS or boom. For live/ref slaving to monitors on MCS or boom use FCV0812 Live/ref slaving for ER.

2	**NCVD061	optional ref monoplane	1	\$5,620.20	\$5,620.20	_____
---	-----------	------------------------	---	------------	------------	-------

Additional Ref2 and Ref3 viewport

**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. 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.

3	**NCVC199	Wireless footswitch: mono-plane version	1	\$8,277.30	\$8,277.30	_____
---	-----------	---	---	------------	------------	-------

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



**100233 Azurion 7 M12**

**OPTIONS**

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial
		customers preferred lay-out.				
		<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>• The wireless footswitch has high water ingress protection standard (IPX8), it can easily be cleaned in water.</li> </ul> <p>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.</p>				

<b>4</b>	<b>**NCVB266</b>	<b>3D-RA Complete</b>	<b>1</b>	<b>\$72,669.90</b>	<b>\$72,669.90</b>	<b>_____</b>
<p>The combination of Allura 3D-RA with 3D dynamic roadmap offers a real time registration of "live" 2D fluoro and a 3D-RA angiography volume (3D roadmap) or a previous acquired CT or MR data set (CT/MR roadmap). With the roadmap a better understanding of the anatomy can be obtained for procedure planning or risk assessment</p>						

Allura 3D-RA assists physicians in decision making for treatment strategy in endovascular procedures, neuro or vascular surgery or even radiotherapy.  
 Allura 3D-RA reduces the number of DSA acquisitions and fluoroscopy time needed to perform an examination. This means less X-Ray dose for the patient and the medical staff and a reduced quantity of dye, leading to reduced procedure costs.  
 Allura 3D-RA provides a unique assessment after treatment due to the use of non-subtracted images that allows to shows devices stents, coils, clips and provide the optimal stand projection for endovascular treatment.  
 Allura 3D-RA provides a wide range of communication facilities to export 3D images.

**1 Image Acquisition**

Image acquisition is performed with the Rotational Angiography feature of the Allura Xper FD series with the flexibility to position the C-arm in either head or side position.  
 C-arm in Head position: the Rotational Angiography run is performed over a scan range of 240 degrees with a rotation speed up to 55 degrees/sec.  
 C-arm in Side position: the Rotational Angiography run is performed over a scan range of 180 degrees with a rotation speed up to 30 degrees/sec.

**2 3D Vessel Reconstruction**

The rotational run is automatically transferred and displayed as a 3D vessel model: with the Real-Time digital link (option) 120 images are reconstructed into a 3 dimensional model within seconds. Additional reconstructions, using the Reconstructive Zooming Technique, can be performed as well.

**3 Workflow:**

Allura 3D-RA in combination with the Allura Xper FD series will provide an optimal workflow via the following workflow enhancers:  
 Complete automated 3D-RA process from 3D acquisition to 3D Viewing: no user interaction needed.  
 3D Automatic Position Control (3D-APC); When the optimal working position has been chosen via the Allura 3D-RA interventional tool, the C-arc will automatically steer to this position.

**100233 Azurion 7 M12**

**OPTIONS**

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial
--------	--------	-------------	-----	------	-------	---------

3D Follow C-arc; When the position of the C-arc (not using any X-ray) is changed, the 3D volume will automatically follow the position of the C-arc. This means the position of the C-arc (and therefore the 2D projection) and the 3D volume are always aligned. As last seen; when the user leaves the patient in the model and later selects that patient again, the Allura 3D-RA interventional tool will return to the image last used by the user.

Mouse over: When moving the mouse cursor over a button the mouse over text will show up to explain the function of that specific button.

**4 Calibration**

Allura 3D-RA calibrations are performed by Philips Healthcare Customer Support. Allura 3D-RA calibration data are stable over at least 6 months time.

**5 Viewing**

A Real Time user interface is available with 3D-RA, providing 3D object viewing in any space direction. A graphical display of (C-arm) stand position including angulation/rotation for any projection.

Philips' CRM (Contrast Resolution Management) Technology for a considerable increase in contrast resolution in all volumes.

Various Image Rendering possibilities: Volume/Surface Rendering, MIP, Endoscopy, SUM (pseudo x-ray image) Gradient rendering; the possibility to display the vessel structure transparently.

Cut-plane function to get a precise insight of the shape of the pathology

Orthoviewer providing a multi-planar visualization of objects using the different Image Rendering possibilities.

MPR (Multi-Planar Reformatting): enables visualization of the volume in all three standard projections (coronal, sagittal and axial) Especially useful for optimal viewing of spine procedures (e.g. Vertebroplasty)

SpineView: special acquisition protocol for optimal viewing of the spine, especially osteoporotic vertebrae

CalciView: allows visualization of Hyper dense plaque in 3D, separately or in relation to the lumen. 5 different distance measurements calculated in the same volume, including "Quick measurement" feature

Volume calculation

Automated Vessel Analysis (AVA), provides information on vessel segment diameter, area and length with only three mouse-clicks. Endoscopic and cross sectional views are available.

Computer Assisted Aneurysm Analysis (CAAA), providing information on Aneurysms, like volume, neck size etc..

Catheter tip shape simulation, providing information on how to shape the catheter tip.

Virtual stenting; Ability to simulate a stent placement in a selected vessel segment for proper stent sizing. All relevant data of the simulated stent are displayed

Annotation: text can be added to a volume to capture comments.

Interpolative Zoom

Reconstructive Zooming Technique, 2 additional user defined reconstructions focused on the Volume Of Interest (VOI) using different cube size and voxel resolution.

Subtraction of reconstructed volumes, allowing to visualize vessels without embolization devices (stents, coils, clips,..) to assess the outcomes of treatment

Automatic Voxelshift: compensates for movement when rendering subtracted or superimposed volumes

Set the grey values WW/WL

Store/Recall of user defined projections.

**6 3D-RA on Xper Module**

The 3D-RA on XPER MODULE integrates the off-line 3D-RA application in the Allura Xper system.

**100233 Azurion 7 M12**

**OPTIONS**

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial
--------	--------	-------------	-----	------	-------	---------

It allows operation of 3D-RA with the Xper module in the examination room during an examination. Display of 3D-RA imaging in the examination room has to be arranged for the monitor ceiling suspension with an additional monitor or with MultiVision (sharing an existing monitor). Following 3D-RA functions are available on the Xper module:

- Image rotation
- Image translation
- Start mouse mode
- Snapshot
- Segmentation (window-width/window-level control)
- 3D zoom control
- Store/recall views
- Recall Anterior-Posterior view
- Select 3D APC / Follow stand mode

**7 3D and MR/CT Roadmap**

3D Roadmap extends the capabilities of the integrated 3D product by providing a sustainable 3D roadmap to support interventional procedures. The 3D Roadmap option matches the real-time 2D fluoro images with the 3D-RA reconstruction or a previous acquired CT or MR data of the vessel tree. It provides a 3D real time insight of the advancement of the guide wire, catheter and coils through complex vessel structures.

**Image Acquisition**

The 3D Roadmap is based on the visualization of the vessel tree out of 3D-RA. THE MR/CT roadmap is based on visualization of the anatomy on previous acquired CT or MR data sets which are match with the X-ray unit by registration of the CT or MR data sets with a low dose 3D-RA scan. The roadmap is activated with one button touch at tableside (Xper Module). Select the roadmap function on the touch screen module, activate fluoroscopy and the roadmap is activated. The "live" 2D fluoroscopy image is overlaid with the 3D volume of the vessel tree and is automatically displayed on the roadmap monitor in both the examination and control room.

**Table side control**

The bidirectional link between the X-ray system and the roadmap allows the user to select the optimal stand position for the procedure in two ways. 3D Automatic Position Control allows the gantry to automatically move to the best interventional projection as shown on the roadmap monitor. 3D Follow C-arc allows the roadmap to remain in sync with the 2D projection, automatically adjusting viewpoint as the gantry is repositioned

The roadmap is dynamic, providing the freedom to change:

- The angulation of the C-arc;
- The rotation of the C-arc;
- The Field of View;
- The Source to Image Distance.

i.e. if the geometry system is changed, the image angle changes accordingly, real-time.

Intuitive, fully controlled from tableside:

- Landmarking to adjust the intensity of the anatomical reference surrounding the vessels;
- 3D blending to fade in/out the 3D view;

**100233 Azurion 7 M12**

**OPTIONS**

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial
--------	--------	-------------	-----	------	-------	---------

- WW/WL settings to control the contrast/brightness;
- Store and review runs for reporting and archive purposes;
- Store snapshots and movies

**8 Archiving**

Transfer to:

Optional Hard Copy unit (DICOM Print)

Any optional DICOM compatible device (e.g. PACS/ViewForum/Xcelera), supported are DICOM XA, DICOM SC, DICOM CT and DICOM 3D

Any PC in a standard PC compatible format (JPEG,AVI)

One or multiple DVD's, CD-ROM(s) for easy archiving

Store a subset of exportable objects (snapshots and AVI Movies) to a USB removable memory device.

**CV 3DRA Handover 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. 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. Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref# 222-100615

5	**NCVD074	60Fr/sec extension (mono)	1	\$18,400.80	\$18,400.80	_____
---	-----------	---------------------------	---	-------------	-------------	-------

Frame rate extension to 60 frames per second.

**Designed to enhance visualization of complex and pediatric interventions**

Frame rate extension to 60Fr/sec increases the system acquisition speed up to 60 frames per second for cardio-vascular studies requiring high speed imaging allowing, for example, high speed pediatric applications.

**Specifications**

Up to 60 frames per second acquisition speed is achieved with 512x512 matrix.

6	**NCVD138	table tilt option	1	\$21,552.60	\$21,552.60	_____
---	-----------	-------------------	---	-------------	-------------	-------

Table tilt option provides precise imaging of contrast medium, blood, or objects in the body.

**Key benefits**

- Tilts the table to support gravity oriented and puncture procedures
- Keeps the region of interest in the isocenter of rotation and angulation
- Allows more precise imaging of contrast medium, blood, or objects in the body

**Precise imaging during gravity oriented and puncture procedures**

To obtain high quality results and avoid re-takes during gravity oriented or puncture procedures, it's important to keep the region of interest centered at all times. The tilt option allows you to tilt the table. As the table tilts, the X-ray beam automatically adapts to the movement to keep the region of interest in the isocenter of rotation and angulation of the stand. As a result, your region of interest always remains centered to allow more precise imaging of contrast medium, blood, or objects in the body.

The table floats even when tilted, and the region of interest can be followed by panning the tabletop. When combined with the Bolus Chase option, the table tilt option enables phlebography to be performed with a head-up tilted patient.

**100233 Azurion 7 M12**

**OPTIONS**

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial
--------	--------	-------------	-----	------	-------	---------

**Specifications**

- Motorized table height from 78.5 - 103.5 cm
- Maximum tilt range: -17 degrees (head down) to +17 degrees (head up).
- Tilt speed: 2 degrees/sec
- Automatic safeguarding system with manual override
- Panning range in tilted plane: equal to the standard tabletop specifications (longitudinal 120cm, lateral 36cm)
- Easy to use controls

7	**NCVD078	FD Dual Fluoro monoplane	1	\$20,706.00	\$20,706.00	
---	-----------	--------------------------	---	-------------	-------------	--

An additional fluoro channel in parallel to the standard fluoro channel

**Key benefits**

- View the subtracted fluoroscopy next to the default non subtracted fluoroscopy
- View a digitally zoomed fluoroscopy image next to the default fluoroscopy image

**Second fluoro image to support complex interventions**

For complex interventions, it can be useful to view the subtracted fluoroscopy image next to the normal fluoroscopy image. The Dual Fluoro option provides an additional fluoro channel in parallel to the default fluoro channel. The dual fluoro option allows to view live digitally zoomed fluoroscopy next to non-zoomed fluoroscopy.

**Specifications**

The Dual fluoroscopy mode is selected via the touch screen module.

The trace subtracted fluoro image will be displayed on the live viewport, the non-subtracted fluoro image is displayed on the reference 3 viewport.

In Dual Fluoro mode, the live fluoroscopy image can be zoomed digitally, providing a larger view of the region of interest for complex interventions. The zoomed live fluoroscopy image will be shown on the live viewport, while the entire non zoomed image will be shown on the reference 3 viewport. The fluoro zoom function is controlled via the touch screen module.

8	**FCV0604	DoseAware Bundle	1	\$24,689.10	\$24,689.10	
---	-----------	------------------	---	-------------	-------------	--

DoseAware is a unique solution providing staff working in an X-Ray environment with direct, real time dose feedback, enabling them to optimize their behaviour and reduce exposure to scattered dose. The DoseAware bundle comprises:

- 1 BaseStation Package
- 10 PDMs
- DoseManager
- 2 PDM racks.

**Base Station Package**

The Base Station is the heart of the DoseAware system. It offers Online View, which displays real time dose rate and immediate dose data for any Personal Dose Meter (PDM) in range. The Walk-Up View enables easy access to personal dose history and PDM settings.

The Base Station has a touch screen interface and wireless communication with the PDM. The PDM dose information is stored within the Base Station and can be retrieved by the DoseAware Dose Manager software via a standard network interface to complete the DoseAware system with archiving and reporting functions.

The Base Station package includes also:

## 100233 Azurion 7 M12

### OPTIONS

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line #	Part #	Description	Qty	Each	Price	Initial
		<ul style="list-style-type: none"><li>a cradle and the DoseView software package that can be installed on a local PC (not included), which has Windows XP or Vista as operating system.</li><li>Mounting material for the Base Station, facilitating mounting on a wall or on a Philips Monitor Ceiling Suspension or a Philips mobile C-arm system.</li></ul>				

#### 10 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 (868.3 Mhz for Europe version, 915 Mhz for USA version) 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, DoseView, and Dose Manager Software.

#### Dose Manager Package

The Dose Manager is a software program that serves as archive and reporting facility for all dose data of the DoseAware system. It allows tracking of multiple PDM's at a location.

Core functionality is:

- Store and manage dose history for multiple PDM's
- Collect all dose history from connected Base Stations via the network
- Browse dose history of PDM's as graph or table
- Export dose data for personal analysis with other software tools, like Windows Excel
- Create and print reports of dose history

# PHILIPS PRODUCT WARRANTY

## CARDIOVASCULAR SYSTEMS (CV)

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 Cardio Vascular 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 A.M. and 5:00 P.M. 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: (a) upon termination of the initial twelve (12) month warranty period for the System on which the option or accessory is installed, b) 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 tube 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 Exclusion**

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

5.2 Customer's 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 loss, or damage in transit; improper site preparation; unauthorized maintenance or Philips applicable System specifications and written instructions; abuse, negligence, accident, 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 flat detectors 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 (a) is to be installed by authorized Philips representatives (or is to be installed in accordance with all Philips installation instructions by personnel trained by Philips); (b) is to be operated exclusively by duly qualified personnel in a safe and reasonable manner in accordance with Philips written instructions and for the purpose for which the products were intended; and (c) 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 and in the applicable product-specific warranty document 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. Remote Services Network ("RSN")**

10.1 Customer will (a) 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 (b) 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 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 FROM 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:

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

(b) 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;

(c) 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;

(d) 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



Carolinas Medical Center  
Charlotte, North Carolina  
January 12, 2018

This letter is to confirm that all components of the Philips Allura Xper FD10 Cardiovascular system, located at Carolinas Medical Center in Charlotte, North Carolina, will be taken as a trade-in (TI 47578) by Philips Healthcare. The system 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](mailto:michael.vitagliano@philips.com)

# Attachment E

**PROPOSED TOTAL CAPITAL COST OF PROJECT**

**Project name:** OSR#3141111 CMC Main Cardiac Cath Labs 4 Renovation  
**Provider/Company:** Carolinas HealthCare System

(1) Purchase price of land	NA
(2) Closing costs	NA
(3) Site Preparation	NA
(4) Construction/Renovation Contract	\$377,300.00
(5) Landscaping	NA
(6) Architect/Engineering Fees	\$71,000.00
(7) Medical Equipment	\$1,411,053.00
(8) Non Medical Equipment	NA
(9) Furniture	\$6,500.00
(10) Consultant Fees (CON Fees, Legal Fees, Design Fees)	NA
(11) Financing Costs	NA
(12) Interest During Construction	NA
(13) Other (IS, CSG Internal Allocation)	\$95,959.00
(14) <b>Total Capital Cost</b>	<b>\$1,961,812.00</b>

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



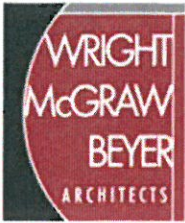
License # 3963

2/6/18

*(Signature of Licensed Architect or Engineer)*

*DATE*

Sales taxes have been included in these equipment costs. However, because CHS is entitled to a sales tax refund under N.C. Gen. Stat. § 105-164.14(b) and 105-467, the sales tax that CHS initially incurs for this medical equipment purchase will be refunded to CHS, and thus will reduce the capital costs that CHS actually incurs for the equipment by \$83,129.93.



February 5, 2018

Ms. Martha Frisone, Chief, Certificate of Need  
Healthcare Planning and Certificate of Need Section  
Division of Health Services Regulation  
2704 Mail Service Center  
Raleigh, NC 27699-2704

Re: CMC Main Cardiac Cath Lab 4 Renovation  
Charlotte, NC  
OSR #:3141111

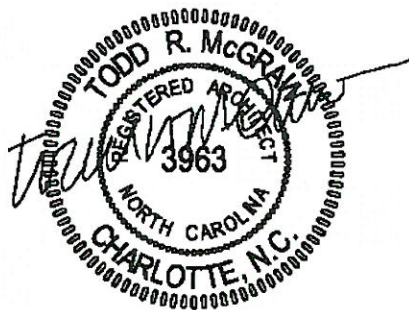
Ms. Frisone,

Having worked with Carolinas HealthCare System to develop the design of the reference project, Wright McGraw Beyer Architects, p.a., is pleased to provide this Construction Cost Certification Letter. The probable cost is based on the drawings included with the CON Submittal. The estimated Construction Cost reflects our experience with similar healthcare projects and the expertise of Rodgers Builders. Wright McGraw Beyer Architects, p.a. certifies to the best of our knowledge the construction cost of \$377,300.00.

Sincerely,  
Wright McGraw Beyer Architects, p.a.

Todd R. McGraw, AIA, NCARB, LEED AP  
Managing Principal  
North Carolina License # 3963

TRM/hh



H:\3125 CMC Main Cath Lab IV Fluoro Replacement\01-Predesign\I.B - Statements of Probable Cost\2018 02 05 MFrison CMC Main Cardiac Cath Lab 4 Renovation CON Letter.docx

2105 Water Ridge  
Parkway Suite 450  
Charlotte, NC  
28217  
704.535.6374  
www.wmba.net