



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

December 22, 2020

Lisa L. Griffin
llgriffin@novanthealth.org

Exempt from Review – Replacement Equipment

Record #: 3450
Date of Request: 12/8/2020
Facility Name: Novant Health Presbyterian Medical Center
FID #: 943501
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Replace existing cardiac catheterization equipment
County: Mecklenburg

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Philips Azurion 3 M12 cardiac catheterization equipment to replace the GE Innova 2100 IQ cardiac catheterization equipment. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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

Sincerely,

Julie M. Faenza
Project Analyst

Lisa Pittman
Assistant Chief, Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR
Construction Section, DHSR

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

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

December 8, 2020



Via Email

Julie Faenza, Project Analyst, Certificate of Need
N.C. Department of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

Re: Novant Health Presbyterian Medical Center
Replacement of Cardiac Catheterization Equipment Charlotte, NC (FID: 943501;
Mecklenburg County)

Dear Ms. Faenza:

Novant Health Presbyterian Medical Center (“NHPMC”) intends to replace an existing cardiac catheterization equipment currently located at the main campus of NHPMC in Charlotte, North Carolina. The existing cardiac catheterization equipment is past its useful life having been acquired in 2008 as an equipment replacement. Therefore, NHPMC will acquire a new Philips Azurion 3 system. See **Attachment A** for the Equipment Quote and a quote regarding the removal of the existing equipment. As part of the equipment cost, the vendor will provide onsite clinical training for the equipment. The total capital cost for the proposed replacement equipment project is estimated to be \$1,955,245¹. See **Attachment B** – Projected Capital Cost Form.

The proposed project meets the definition of “replacement equipment” found in G.S. 131E-176(22a) and 10A N.C.A.C 14C.0303 for the following reasons:

- (1) NHPMC will replace the existing cardiac catheterization with the proposed equipment that is functionally similar and will be used for the same diagnostic purposes, although it possesses expanded capabilities due to technological improvements.
- (2) The proposed equipment will not be used to provide a new health service.
- (3) The acquisition of the proposed equipment will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.
- (4) NHPMC seeks to replace comparable medical equipment currently in use at project cost less than \$2 million.
- (5) The existing equipment was not purchased second-hand nor was the existing equipment leased.
- (6) The existing equipment will be removed from North Carolina.

In support of our request, please find attached:

- Attachment A** – Vendor Equipment Quote & Removal Quote
- Attachment B** – Project Capital Costs & Certified Architects Letter
- Attachment C** – NC CON Equipment Comparison chart
- Attachment D** - Excerpt of 2020 License Renewal Application

¹ The project cost does not include sales, property or excise taxes as NHPMC is not subject to these taxes as a non-profit, tax-exempt organization.

Ms. Julie Faenza
Re: NHPMC Replacement of Cardiac Catheterization Room 3
December 8, 2020
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The Equipment Comparison is included as **Attachment C**. The most recent License Renewal Application is attached as **Attachment D** to document that this cardiac catheterization lab is still in use. It is one of two CON-approved cardiac catheterization labs located at NHPMC.

NHPMC's acquisition of the replacement equipment does not require a certificate of need because none of the definitions of "new institutional health services" set forth in N.C.G.S. Section 131E-176(16) apply to the proposed project. As outlined above, the total cost for the project is \$1,955,245. The proposed capital cost includes equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation and other activities essential to making the equipment operational.

Based on the information provided, please confirm that NHPMC's replacement equipment request does not constitute a new institutional health service and is exempt from certificate of need review.

If you need additional information, please do not hesitate to contact me.

Sincerely,



Lisa Griffin
Manager, Operational Planning
Novant Health, Inc.

Enclosures

ATTACHMENT A –

- **Equipment Quote**
- **Removal Quote**

PHILIPS HEALTHCARE
A division of Philips North America LLC
414 Union St, 2nd Floor
Nashville, TN 37219



Quotation #: 1-21HT3N8	Rev: 6	Effective From: 20-Oct-20	To: 19-Dec-20
Presented To: NOVANT HEALTH PRESBYTERIAN MEDICAL CENTER 200 HAWTHORNE LN CHARLOTTE, NC 28204-2515 Tel: Alternate Address:	Presented By: William Haynes <i>Account Manager</i> John Hill <i>Regional Manager</i>	Tel: (919) 949-4747 Fax: Tel: (800) 722-7900 x6806 Fax:	
Date Printed: 20-Oct-20			

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
	100231 Azurion 3 M12	1	\$653,520.42
Equipment Total:			\$653,520.42

Solution Summary Detail

Product	Qty	Each	Monthly	Price
100231 Azurion 3 M12	1	\$653,520.42		\$653,520.42

Buying Group: VIZIENT SUPPLY LLC

Contract #: XR0312 CV

Add'l Terms: The specific Contract # referenced above represents the Novation or Vizient agreement with Philips containing discounts, fees and any specific terms and conditions, including the Vendor's Terms and Conditions of Sale (subject to such Contract), applicable to the purchase of any Product identified as part of this quoted Solution.

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

100231 Azurion 3 M12

Qty	Product
1	NNAT007 Azurion 3 F12.
1	NCVD067 ClarityIQ
2	FCV0824 video WCB on rear side 1st MCS
1	FCV0812 live/ref slaving for ER
8	FCV0588 Isolated Wall Connection Box
1	NCVD100 Left Ventricular Analysis
1	NCVA783 table pivot option
1	NCVD029 FlexVision XL
1	NCVD089 Zero Dose Positioning
1	FCV0510 Long mattress cardio
1	459800706722 MONITOR CEILING CARRIAGE
1	459800938361 Clip rails for MCC (390cm)
1	980406041009 Rad Shield w/ Arm (Contoured) 61X76
1	989801220012 Cable Spooler
1	989801220273 Ceiling Track w/Column & Handle Ext
1	989801220397 Lamp Y LED 1F
1	989801220388 Lower Body Protection
1	NNAE597 IXR Dynamic Coronary Roadmap OnSite Education
1	989801220514 - Compact Low Load Fluoro UPS - Standard
1	989600213942 AD5 TO XPER TABLE ADAPT. PLATE
1	SEBLRSVNP1 Customer Note

Options

Qty	Product
1	NNAE751 Intrasight Interventional 5
1	NCVC542 Dynamic Coronary Roadmap
1	989801220158 Mark 7 Arterion, Table Mount

100231 Azurion 3 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: The specific Contract # referenced above represents the Novation or Vizient agreement with Philips containing discounts, fees and any specific terms and conditions, including the Vendor's Terms and Conditions of Sale (subject to such

Line #	Part #	Description	Qty	Each	Price
1	**NNAT007	Azurion 3 F12.	1	\$406,194.48	\$406,194.48
		Azurion 3 F12			

Multipurpose interventional X-ray lab 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
- Upgradeable platform to grow your service line over time
- Intuitive user interaction delivering an easy to use, easy to learn system
- Optimized utilization of your lab by procedure based workflow

Expanding reach

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 is a highly versatile yet compact X-ray suite designed to handle a variety of cardiovascular procedures at an excellent pace. This system combines ease-of-use and reliability with essential functionality for diagnostics and interventions for cardiovascular diseases. This future proof solution is designed around a single, standardized hardware and software platform that can be upgraded and expanded as new needs arise or requirements change. Its architecture is made to easily integrate with third party applications and devices. 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 3 Series 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.

The Philips Azurion 3 Series 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 at the same time - without interrupting each other. This leads to higher throughput and faster exam turnover help to minimize preparation errors.

Specifications

100231 Azurion 3 M12

Line #	Part #	Description	Qty	Each	Price
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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) is intended for use to perform:

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

The Philips Azurion 3 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. 3 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

100231 Azurion 3 M12

Line #	Part #	Description	Qty	Each	Price
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Motorized stand movements with variable speed and configurable max speed, allowing:

- Rotation up to 25 degrees
- Angulation up to 18 degrees

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 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 including OR rails (316 cm excluding OR rails), 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/m³. The mattress has a thickness of 5 cm and adapts to the body shape of the patient. It divides the pressure equally and 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

Line #	Part #	Description	Qty	Each	Price
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- Patient straps
- Arm Support Board
- Set of Elbow Supports
- Lower Body Protection
- Black anti-fatigue floor mat w/logo

Prep Table for Volcano

Prep Table for Volcano prepares the table with the cabling needed for an integrated version of the Volcano IntraSight system. This preparation will facilitate the installation of the integrated system and reduce the cable clutter around the table. The user interface can be placed on the table OP rails, while the Volcano IntraSight unit is typically placed in the control room. The Volcano IntraSight Bedside Utility Box (BUB) that is used to connect the IVUS and FFR PIM cables can be stored on the Auxiliary OP-Rail mounted at the foot of the table base.

The Prep Table for Volcano option cannot be purchased in combination with Swivel AND Prep Table for Table Mount Injector.

Content:

- OP rail at table foot
- Cables

2. X-ray Generation

A. Generator

The 3 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:

100231 Azurion 3 M12

Line #	Part #	Description	Qty	Each	Price
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- 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 (30 | 15 | 7.5 | 3.75 | 1.875 | 1.0 | 0.5 img/s (non Clarity settings))
 - Minimum exposure time of 1 ms
 - ECG triggered acquisition: allows acquiring one exposure for each QRS peak with selectable delay time (optional)
 - 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 3 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

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Line #	Part #	Description	Qty	Each	Price
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- 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 12:1)
 - 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 (optional)
 - Three programmable fluoroscopy modes can be selected from the control module. Each mode has a different composition of dose rate, pulse speed, filter setting, and image processing (noise reduction, adaptive contour enhancement, adaptive harmonization)
- E. User dose 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.
- 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. As an example, the reported data can be used for:

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Line #	Part #	Description	Qty	Each	Price
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- 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
 - 30, 27, 22, 19, 15 cm (12, 11, 8, 7, 6 inch) diagonal square formats
- 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 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.

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Line #	Part #	Description	Qty	Each	Price
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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 either at the tableside or in the control room. The touch screen module has a touch screen, which can be operated when covered with sterile covers. The touch screen module includes Multi-modality function that allows control of (depending on configuration):

- Compatible other equipment (e.g. IntraSight, CX50, Interventional Tools, EchoNav, DoseAware, Philips Hemo system)
- Monitor layout (Flexvision, switchable viewing)
- X-Ray settings (Collimation, Projections, Table, Series and Processing)

Viewpad

The Viewpad contains the preprogrammed function settings. The system is provided with two Viewpads. The following functions are provided:

- Run and image selection

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Line #	Part #	Description	Qty	Each	Price
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- File and run cycle
- File overview
- Store to Reference image file
- Copy image to photo file
- Digital (fixed) zoom and panning
- Recall reference images, which means switching control of Viewpad function from 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

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Line #	Part #	Description	Qty	Each	Price
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- Manual or automatic semi-transparent wedge filter
 - Xper Fluoro Storage
 - Selection of the Detector field size
 - Reset of the fluoroscopy buzzer
 - Roadmap Pro activation if function is available
- The control module is provided with a protection bar. This removable bar protects the buttons from unintended control.

Pan Handle

An optional 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
- Accessory-rail attachment clamp

User Interface in Control Room

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

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

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Line #	Part #	Description	Qty	Each	Price
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- Run and file overview

- Reset fluoroscopy timer

- Enable/disable X-ray

- Geo disable

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

- Stopwatch and Time

- System guidance information

- Dose Area Product (DAP) and Skin Dose, as dose rate during X-ray and cumulative dose at no X-ray

- Frame speed settings, fluoroscopy mode, and accumulated Fluoroscopy time

- Exposure and fluoroscopy settings as Voltage (kV), Current (mA) and time (ms)

- Geometry information as rotation, angulation, and SID

The acquisition monitor is designed for standard workflow based on scheduling, preparation, acquisition, review, report, and archive.

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

100231 Azurion 3 M12

Line #	Part #	Description	Qty	Each	Price
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- Review of other DICOM XA or DICOM SC studies.

Archiving

Clinical studies 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. The printed paper instructions for use can also be ordered at no additional cost.

5. Viewing

A. Viewing in Examination room

Philips Azurion systems come with one 27 inch high brightness color medical grade LCD monitor for clinical image display in the Examination room. This LCD monitor is intended for viewing in the examination room and is designed for medical applications. The monitor 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

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Line #	Part #	Description	Qty	Each	Price
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- 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.

B. Viewing in Control room

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

The main characteristics for color monitor are:

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

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Line #	Part #	Description	Qty	Each	Price
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- 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 online 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.

Intercom

Enhance communication between exam room and control room

The remote intercom is used to communicate between the examination and control room. A separate intercom can be connected to the system and placed in the preferred working position in the control room or examination room. The listen function can be selected separately 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/required.

Security

The Philips Azurion system runs on the Windows 10 Operating system and offers features such as OS Hardening, AppLocker, & BitLocker functionality

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 3 F12 system is a perfect example of our EcoVision program. By examining every aspect of the 3

Line #	Part #	Description	Qty	Each	Price
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F12 design and development through a green eye, we drastically reduced the products environmental impact.

Full System APC

Store and recall stand-related positions

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 & table related positions. Operators can select a sequence from a pre-defined list or from positions stored during a procedure or use an image to define the position to be recalled.

Specifications

Different modes of Automatic Positioning Control for system are defined:

- * Sequence: for recalling a list of user customizable positions of the stand
- * Store / Recall: for storing and recalling stand positions during system use.
- * Image Reference: an image is used to determine the stand & table position that has to be recalled
- * Image Reference 3D: an image from a 3D work spot is used to recall.
- * The operator can define a new point of the table (longitudinal, lateral and height) as the new iso-center and recall this table position.

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

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Line #	Part #	Description	Qty	Each	Price
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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.

RIS/CIS Interface

This package allows communication of the X-ray system with a local information system (CIS or RIS).

Key benefits

- Reduce errors in patient information
- Facilitate X-ray dose management

Reduce data errors and facilitate X-ray dose management

Connecting the X-ray system with your local information system (CIS or RIS) helps streamline exam workflow and promote radiation management. The RIS/CIS DICOM interface package allows your X-ray system to communicate with a local CIS or RIS information system. The interface uses the DICOM Worklist Management (DICOM WLM) and Modality Performed Procedure Step (DICOM MPPS) standards.

If a hospital has an X-ray system and an information system it can receive patient and examination request information from the information system and report examination results to:

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

Line #	Part #	Description	Qty	Each	Price
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Specifications

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

- Patient Identification: Patient name, Patient ID, Birth date, Sex
- Examination/Request Information: Accession number, Scheduled procedure step start time, scheduled performing physician's name

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

On request of the clinical user the X-ray system will report the following information about the selected patient to the IS:

- Patient Identification: Patient name, Patient ID, Birth date, Sex
- Examination/Request Information: Accession number, Performed procedure step status start/end date and time, Performing physician's name, Referenced image sequence
- Radiation dose: Total time of fluoroscopy, Accumulated fluoroscopy dose, Accumulated exposure dose, Total dose, Total number of exposures, Total number of frames

Further detailed information can be found in the X-ray system DICOM Conformance Statement. The interface requires an EasyLink (hardware and software) if the RIS/CIS is not compliant with DICOM WLM and DICOM MPPS.

Contrast Injector Interface

Simplify contrast injection timing and enhance imaging results.

The Contrast Injector Interface allows the injection of contrast to be coupled to the start of X-ray acquisition. This simplifies contrast injection timing during interventions.

Specifications

The Contrast Injector Interface allows injection of contrast coupled to the start of X-ray acquisition, controlled by the X-ray ON button. The timing of the X-ray start related to the contrast injection is programmable.

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Line #	Part #	Description	Qty	Each	Price
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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 workflow 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 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).

2	**NCVD067	ClarityIQ	1	\$72,988.20	\$72,988.20
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Line #	Part #	Description	Qty	Each	Price
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Significantly lower dose- across clinical areas, patients and operators.

Key benefits

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

See with confidence every time

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

AlluraClarity with its unique ClarityIQ technology gives you exceptional live image guidance during treatment. What's more, you can confidently manage low X-ray dose levels without changing your way of working. In short, you can see what you have to regardless of patient size.

Specifications

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

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

Pulsed X-ray for pulsed fluoroscopy
25 | 12.5 | 6.25 | 3.125 | 2.5 | 1.25 | 0.625 img/s

3	**FCV0824	video WCB on rear side 1st MCS	2	\$4,678.92	\$9,357.84
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Isolated Wall Connection box on the rear side of the monitor ceiling suspension to support the display of an external video source on a monitor in the examination room.

Key benefits

- Easily connect external video in the exam room

Specifications

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

4	**FCV0812	live/ref slaving for ER	1	\$4,708.44	\$4,708.44
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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

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Line #	Part #	Description	Qty	Each	Price
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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

5	**FCV0588	Isolated Wall Connection Box	8	\$1,214.01	\$9,712.08
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Isolated Wall Connection box to support the display of an external video source on a monitor in the examination room.

Key benefits

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

Easily stream video to other locations

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

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

6	**NCVD100	Left Ventricular Analysis	1	\$8,531.28	\$8,531.28
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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 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

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Line #	Part #	Description	Qty	Each	Price
		<ul style="list-style-type: none"> • 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 			
7	**NCVA783	table pivot option	1	\$3,800.70	\$3,800.70
		<ul style="list-style-type: none"> • Flexible positioning for upper extremity angiography • Easy patient transfer 			

Flexible positioning and transfers

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

8	**NCVD029	FlexVision XL	1	\$80,589.60	\$80,589.60
		<p>FlexVision XL is an integrated viewing solution designed to give you full control over your viewing environment.</p> <p>Key benefits</p> <ul style="list-style-type: none"> • 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)

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Line #	Part #	Description	Qty	Each	Price
		<ul style="list-style-type: none"> - Constant brightness stabilization control - Lookup tables for gray-scale, color and DICOM transfer function - Full protective screen Ingress Protection: IP-21 <p>3. Large color LCD control (touch screen module)</p> <ul style="list-style-type: none"> • 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 <p>4. Monitor ceiling suspension</p> <p>Monitor ceiling suspension for use in the Examination Room carries the 58-inch color LCD, providing highly flexible viewing capabilities. The monitor ceiling suspension is height-adjustable and moveable along ceiling rails. It can be positioned on either side of the table.</p> <p>5. Snapshot</p> <p>The snapshot function allows the user to store/save a screen-capture of any image on the FlexVision XL as a photo image to the current acquisition patient study.</p>			
9	**NCVD089	Zero Dose Positioning	1	\$6,848.64	\$6,848.64
		<p>Key benefits</p> <ul style="list-style-type: none"> • Manage radiation usage by moving to region of interest on Last Image Hold without fluoro. <p>ROI positioning without using fluoroscopy</p> <p>To manage radiation dose, you can move the stand and table to the region of interest shown on the last recorded clinical image before a new acquisition is started, without any radiation.</p> <p>Specifications</p> <p>Before a new acquisition is started the operator can move the stand and table to visualize the part of the image that will be irradiated when the next X-ray starts.</p>			
10	**FCV0510	Long mattress cardio	1	\$457.56	\$457.56
		<ul style="list-style-type: none"> • Enhances patient comfort • Adapts to the shape of the patient's body <p>Enhance patient comfort during cardio exams</p> <p>To enhance patient comfort during cardio exams, the inflatable, latex free mattress can be used. It is extra-long to accommodate the patient on the tabletop, and adapts to the shape of the patient's body. The pressure within the mattress is evenly distributed so that it recovers its original shape quickly.</p> <p>Dimensions of the mattress:</p> <p>Length: 3165mm Width: 500mm Height: 70mm Radius: 150mm</p>			
11	**459800706722	MONITOR CEILING CARRIAGE	1	\$5,564.52	\$5,564.52
		Monitor ceiling carriage			
12	**459800938361	Clip rails for MCC (390cm)	1	\$1,066.41	\$1,066.41
		<p>Comprising:</p> <ul style="list-style-type: none"> • 2 clip rails length 390 cm. • Mounting material for 200 cm track pitch. 			

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Line #	Part #	Description	Qty	Each	Price
13	**980406041009	Rad Shield w/ Arm (Contoured) 61X76 Contoured Rad Shield with Arm rest. 61X76	1	\$2,169.72	\$2,169.72
14	**989801220012	Cable Spooler	1	\$298.89	\$298.89
15	**989801220273	Ceiling Track w/Column & Handle Ext Mavig 2.5m Ceiling Track with Ceiling trolley, 360 degree column, and brake handle extension.	1	\$3,254.58	\$3,254.58
16	**989801220397	Lamp Y LED 1F LE7017100 Lamp YLED-1F with Portegra2 extension/spring arm 750/910 mm	1	\$2,214.00	\$2,214.00
<p>Technical Data and Specifications</p> <p>Model YLED-1F Central light intensity (at 1 m distance) 70,000 lx Colour temperature 4100 ± 200 K Colour rendering index at 4100 Kelvin (CRI) Ra 95 Focusable light field size 140 – 250 mm Electronic brightness control 50% – 100% Sterilisable handle Yes Temperature increase in head area 0.5 K – Power consumption (total) 24 VA Mains voltage and frequency 100 – 240 VAC at 50 – 60 Hz – Number of LED modules 17 Lifetime of LEDs 50,000 h Working area 70 – 140 cm. Height adjustment (on Portegra2 spring arm) 117 cm Lamp dimensions 28 x 36 cm Housing colour RAL 9002 – Hazardous substances (EU Directive 2011/65/65) RoHs compliant Housing – Protected against splashed water IP44 Fire protection class V0 Medical Products Directive 93/42/EEC Yes Use according to DIN VDE 0100-710 Yes Approvals CE / NRTL</p>					
17	**989801220388	Lower Body Protection UT70-10WS Lower body protection, width 1410 mm incl. wide extension	1	\$1,276.74	\$1,276.74
<p>Lower body protection of the model series UT70 with a modular design to provide a maximized protective zone for the physician and staff.</p>					
18	**NNAE597	IXR Dynamic Coronary Roadmap OnSite Education	1		

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Line #	Part #	Description	Qty	Each	Price
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Philips Imaging Systems Clinical Education Specialist will provide eight (8) hours of education for up to four (4) students, as selected by customer, including technologists from weekend/night shifts as necessary. CEU credits are not available for this portion of training. Please refer to guidelines for more information. Note: Site must be patient ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation.

Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref#296309-20170315

This training requires the purchase of Dynamic Coronary Roadmap.

19	**989801220514	• Compact Low Load Fluoro UPS – Standard	1	\$32,896.35	\$32,896.35
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- Custom designed Schneider UPS for Philips
- Compatible with Allura 8.2 and Azurion IGT imaging systems
- 20kVA (80kVA Peak) Capacity UPS with integrated input 20kVA 480v/400v isolation transformer
- Input Breaker Panel with integrated EPO switch
- Output Switch rated at 80 amp
- Remote Alarm Status Panel (RASP) – Touch screen for UPS monitoring with Dry contact cards for UPS
- Network Management Cards with external Triple Chassis for Optional Network Management
- Factory Start-Up Service (5x8, Normal business Hours) and 2nd year of warranty service (next business day response)

Compatible with Allura R8.2 and Azurion R1.1 and R1.2 IGT imaging systems

20	**989600213942	AD5 TO XPER TABLE ADAPT. PLATE	1	\$1,590.39	\$1,590.39
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21	SEBLRSVNP1	Customer Note	1		
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OpenMarkets - The net price in the configured solution contained in this quotation is reflective of an additional OpenMarkets special discount.

Avante | Health Solutions

Avante Health Solutions agrees to purchase the equipment listed below for a total price of \$10,000.

2008 GE Innova 2100 with 2016 MX160 X-ray tube.

This offer is based on inspection of the unit and assumes the equipment is fully functional. Upon inspection and verification that the system is fully functional, Avante will send payment prior to the deinstallation of the equipment.

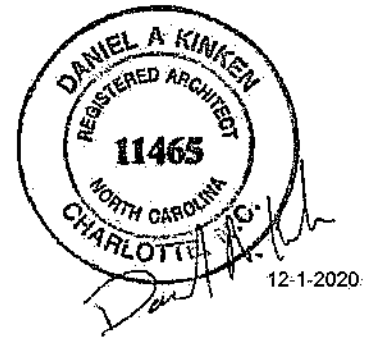
Customer Acceptance: _____ Date: _____

Avante Health Solutions: _____ Date: _____

**ATTACHMENT B –
Projected Capital Cost Form**

Projected Capital Cost Form
NH Presbyterian Medical Center Cath Lab #3 Replacement

Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction/Renovation Contract(s)	\$ 686,890
Landscaping	
Architect / Engineering Fees	\$ 69,500
Medical Equipment	\$ 653,520
Non-Medical Equipment	\$ 435,826
Furniture	\$ -
Removal of Existing Equipment	\$ 10,000
Financing Costs	
Interest during Construction	
Other: Contingency	\$ 99,509
Total Capital Cost	\$ 1,955,245



CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

I certify that, to the best of my knowledge, the projected construction costs for the proposed project is complete and correct.

Daniel A. Kinken

Date Signed: 12-1-2020

Signature of Licensed Architect or Engineer

CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that is our intent to carry out the proposed project as described.

DocuSigned by:
Matthew Stone
0BCEA0893518459

Date Signed: 12/02/2020 | 10:12:1

Signature of Officer/Agent

Vice President, Construction & Engineering, Novant Health

Title of Officer/Agent

**ATTACHMENT C –
NC Equipment Comparison Form**

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
NH Presbyterian Cath Lab Room 3	Cardiac Cath	Cardiac Cath
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	GE	Philips
Manufacturer	Innova 2100 IQ	Azurion 3 F12
Model number	Cath Lab #3, Serial # (001771)	TBD
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	Fixed	Fixed
Is the equipment mobile or fixed?	3/1/2008	TBD
Date of acquisition	New	New
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	n/a	\$1,955,245
Total projected capital cost of the project <Attach a signed Projected Capital Cost form for New Equipment>	n/a	\$653,520
Total cost of the equipment	Cath Lab #3	Cath Lab #3
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	<i>See LRA</i>	NA
Document that the existing equipment is currently in use	NA	No
Will the replacement equipment result in any increase in the average charge per procedure ?	NA	NA
If so, provide the increase as a percent of the current average charge per procedure	NA	No
Will the replacement equipment result in any increase in the average operating expense per procedure ?	NA	NA
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	Cardiac Cath Procedures	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	Cardiac Cath Procedures

Date of last revision: 5/17/19

**ATTACHMENT D –
2020 License Renewal Excerpt**

All responses should pertain to **October 1, 2018 through September 30, 2019.**

8. Specialized Cardiac Services *continued* (for questions, call Healthcare Planning at 919-855-3865)

b. Cardiac Catheterization and Electrophysiology

Cardiac Catheterization, as defined in NCGS 131E-176(2g)	Diagnostic Cardiac Catheterization**	Interventional Cardiac Catheterization***
1. Number of Units of Fixed Equipment	2	
2. Number of Procedures* Performed in Fixed Units on Patients Age 14 and younger	∅	∅
3. Number of Procedures* Performed in Fixed Units on Patients Age 15 and older	1178	830
4. Number of Procedures* Performed in Mobile Units	∅	∅
Dedicated Electrophysiology (EP) Equipment		
5. Number of Units of Fixed Equipment	3	
6. Number of Procedures on Dedicated EP Equipment	1245	

*A **procedure** is defined as one visit or trip by a patient to a catheterization laboratory for a single or multiple catheterizations. Count each visit only once, regardless of the number of diagnostic, interventional, and/or EP catheterizations performed during that visit. For example, if a patient has both a diagnostic and an interventional procedure in one visit, count it as one interventional procedure.

** "a cardiac catheterization procedure performed for the purpose of detecting and identifying defects or diseases in the coronary arteries or veins of the heart, or abnormalities in the heart structure, but not the pulmonary artery." 10A NCAC 14C .1601(9)

*** "a cardiac catheterization procedure performed for the purpose of treating or resolving anatomical or physiological conditions which have been determined to exist in the heart or coronary arteries or veins of the heart, but not the pulmonary artery." 10A NCAC 14C .1601(16)

Number of fixed or mobile units of grandfathered cardiac catheterization equipment owned by hospital (i.e., equipment obtained before a CON was required):

N/A

For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.

CON Project ID numbers for all non-grandfathered fixed or mobile units of cardiac catheterization equipment owned by hospital:

F-3472-98

F-5975-99

Name of Mobile Vendor, if not owned by hospital: N/A

Number of 8-hour days per week the mobile unit is onsite: N/A 8-hour days per week.

(Examples: Monday through Friday for 8 hours per day is 5 8-hour days per week. Monday, Wednesday, & Friday for 4 hours per day is 1.5 8-hour days per week)

From: [Faenza, Julie M](#)
To: [Waller, Martha K](#)
Subject: FW: [External] Replacement Equipment Exemption Notice for NH PMC Cardiac Cath Lab
Date: Tuesday, December 8, 2020 12:28:03 PM
Attachments: [PMC Cath Lab Rm 3 REER to Agency 12.08.2020.pdf](#)

Julie M. Faenza, Esq.

Project Analyst, Certificate of Need

[Division of Health Service Regulation](#), [Healthcare Planning and Certificate of Need Section](#)
[NC Department of Health and Human Services](#)

Office: 919-855-3873

Julie.Faenza@dhhs.nc.gov

Pronouns: She/her/hers

Help protect your family and neighbors from COVID-19.

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From: Griffin, Lisa L <lgriffin@novanthealth.org>
Sent: Tuesday, December 8, 2020 12:25 PM
To: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Cc: Flores, Disraeliza <Disraeliza.Flores@dhhs.nc.gov>
Subject: [External] Replacement Equipment Exemption Notice for NH PMC Cardiac Cath Lab

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Hi Julie,

Please find attached an exemption notice related to the replacement of cardiac catheterization equipment at NH Presbyterian Medical Center.

Let me know if you have questions or need more information.

Thank you,

Lisa Griffin

Manager, Operational Planning

Novant Health, Inc.

(704) 351 - 1132

We are here to help you get the care you need. Visit [Novant Health](#) or [Novant Health UVA](#) for up-to-date information.

Estamos aquí para ayudarle con el cuidado que usted necesita. Visite [Novant Health](#) o [Novant Health UVA](#) para información actualizada.

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