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

July 9, 2021

Lisa L. Griffin
llgriffin@novanthealth.org

Exempt from Review – Replacement Equipment

Record #:	**3604**
Date of Request:	July 2, 2021
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(f). Therefore, you may proceed to acquire without a certificate of need the Philips Azurion 7 F20 cardiac catheterization equipment to replace the GE Innova 3100 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

Julie M. Faenza
Project Analyst

Lisa Pitt

Lisa Pittman
Acting Chief, Certificate of Need

cc: Radiation Protection Section, DHSR
Construction Section, DHSR
Acute & Home Care Licensure & Certification Section, DHSR

Faenza, Julie M

From: Griffin, Lisa L <llgriffin@novanthealth.org>
Sent: Friday, July 2, 2021 1:47 PM
To: Faenza, Julie M
Cc: Waller, Martha K
Subject: [External] NH Presbyterian Cath Lab Equipment Replacement Exemption Letter
Attachments: PMC CathLab2 REER to Agency 7.2.21.pdf

Julie,

Attached is an exemption letter regarding the replacement of an existing cardiac cath lab located at Novant Health Presbyterian Medical Center in Charlotte, NC. Please let me know if you have any questions or need additional information.

Have a nice Independence Day holiday!

Lisa Griffin
Manager, Operational Planning
Novant Health, Inc.
(704) 351 – 1132

NOVANT HEALTH

2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

July 2, 2021

Via Email

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

Re: Novant Health Presbyterian Medical Center
Replacement of Cardiac Catheterization Lab
Charlotte, North Carolina (FID # 943501; Mecklenburg County)

Dear Ms. Inman:

Novant Health Presbyterian Medical Center ("NH Presbyterian") intends to replace an existing cardiac catheterization (cath) lab located at the hospital in Charlotte, North Carolina pursuant to N.C. Gen. Stat. 131E-184(f). The existing cath lab is over twelve years old and is past its useful life. It is located on the fifth floor of the hospital in the Cardiac Catheterization/Cardiovascular Services Department. NH Presbyterian will acquire a new Philips Azurion system to replace the existing lab system. See **Attachment A** for the equipment quote. As part of the equipment cost, the vendor will provide onsite clinical training for the equipment. The existing equipment will be traded in and will be removed by the vendor and not used within North Carolina without appropriate CON notice. See page 32 of the equipment quote for information regarding the removal and tread-in. The total capital cost for the proposed replacement equipment project is estimated to be $2,297,020[1]. See **Attachment B** for the signed Projected Capital Cost form.

NH Presbyterian's project meets the requirements set forth in N.C. Gen. Stat. 131E-184(f) for "replacement equipment" that exceeds two million ($2,000,000) threshold in the following ways:

Main Campus:

The existing and replacement cath lab is and will be located in the Cardiac Catheterization/Cardiovascular Services Department at NH Presbyterian, which is located at 200 Hawthorne Lane, Charlotte, North Carolina. At this location, NH Presbyterian's President and COO, Saad Ehtisham's office is located in Administration on the Main Floor. This location provides clinical patient services and exercises financial and administrative control over the entire campus. See **Attachment C** for a campus map. The existing equipment is one of two operating cath labs at NH Presbyterian and is still in service as reported on the most recent annual License Renewal Application ("LRA") which is excerpted in **Attachment D**.

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

Previous Certificate of Need:

We are unable to locate documentation regarding the cath lab's original acquisition. The existing cath lab equipment dates from 2008 and has been in use and reported on NH Presbyterian's annual LRA for many years. NH Presbyterian has been approved for two cath labs and this lab is one of those approved cath labs.

Replacement Equipment:

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) NH Presbyterian will replace the existing cath lab equipment 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.

See Attachment E for the Equipment Comparison of the existing and planned new equipment.

In support of our request, please find attached:

Attachment A – Vendor Equipment Quote
Attachment B – Projected Capital Costs
Attachment C – Main Campus Map
Attachment D - LRA Excerpt
Attachment E – Equipment Comparison Form

NH Presbyterian'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 $2,297,020. 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 NH Presbyterian's replacement equipment exemption 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

Lisa Griffin
Manager, Operational Planning
Novant Health, Inc.

Attachments

ATTACHMENT A

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

PHILIPS

Quotation #: 1-2FNTCI0	**Rev:** 1	**Effective From:** 09-Mar-21	**To:** 08-Aug-21

Presented To:

NOVANT HEALTH PRESBYTERIAN MEDICAL CENTER
200 HAWTHORNE LN
CHARLOTTE, NC 28204-2515

Tel:

Alternate Address:

Presented By:

Christopher Starnes
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Fax:

Date Printed: 01-May-21

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
	100237 Azurion 7 M20	1	$1,124,981.20
		Equipment Total:	$1,124,981.20

Solution Summary Detail

Product	Qty	Each	Monthly	Price
100237 Azurion 7 M20	1	$1,124,981.20		$1,124,981.20

Buying Group: **VIZIENT SUPPLY LLC** **Contract #:** **XR0312 CV**

Addt'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

100237 Azurion 7 M20

Qty	Product
1	NNAT022 Azurion 7 F20.
1	NNAT135 Intrasight 5
2	FCV0824 video WCB on rear side 1st MCS
1	FCV0812 live/ref slaving for ER
8	FCV0588 Isolated Wall Connection Box
1	NCVD069 ClarityIQ.
1	NCVA101 peripheral X-ray filter
1	NCVA694 Subtracted Bolus Chase
1	NCVD099 Quantitative Coronary Analysis
1	NCVA851 Swivel for table base.
1	NCVD072 SmartMask Monoplane
1	NCVD078 FD Dual Fluoro monoplane
1	NCVD128 storage extension
1	NCVD030 FlexVision XL HD
1	NCVA258 CO2 VIEW TRACE
1	FCV0510 Long mattress cardio
1	989801229902 Low Load Fluoro (LLF) UPS - 5
1	980406041009 Rad Shield w/ Arm (Contoured) 61X76
1	989801220012 Cable Spooler
1	989801220273 Ceiling Track w/Column & Handle Ext
1	989801220388 Lower Body Protection
1	989801220397 Lamp Y LED 1F
1	NNAE159 30Fr/sec Extension
1	SP019 Trade in Allowance

Options

Qty	Product
1	NCVD064 extension to FlexVision Pro
1	NCVD081 Touch Screen Module Pro
1	NCVD178 IW Hardware
1	NCVC465 VesselNavigator
1	989801220158 Mark 7 Arterion, Table Mount
1	NNAE503 Clinical Education Program for Vessel Navigation

100237 Azurion 7 M20

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	**NNAT022 Azurion 7 F20	Azurion 7 F20.	1	$651,966.00	$651,966.00

Versatile solution for diagnostic and interventional vascular and cardio cases.

Key benefits

- Optimized utilization of your lab by procedure based workflow
- Flexibility in work spots allowing multi-modality control where you need it
- Intuitive user interaction delivering an easy to use, easy to learn system

Enhance confidence for vascular and cardio interventions

With our Live Image Guidance we aim to remove barriers to safer, effective and reproducible treatments, delivering relevant 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 for diagnostic and interventional vascular and cardio applications. Get high-resolution imaging support and extra flexibility for mixed-use and dedicated procedures like PTCA. 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 open 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 F20 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.

100237 Azurion 7 M20

Line #	Part #	Description	Qty	Each	Price

The Philips Azurion 7 F20 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:

• 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 F20 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 F20 stand

100237 Azurion 7 M20

Line #	Part #	Description	Qty	Each	Price

The X- Philips Azurion F20 stand is a stable assembly of a C-arm and a floor mounted base. The X-ray tube and the flat detector are integrated into the C-arm. This provides a compact assembly with positioning flexibility and easy access to the patient. The robust design ensures excellent reproducibility of projections, needed in for example subtracted imaging procedures and advanced 3D imaging. The base can be rotated allowing a three-sided patient approach.

• Base rotation around the patient table: +90, 0, -90 degrees.

Philips Azurion F20 stand allows a very wide range of projections, including PA and AP imaging.

In the head position (0 degrees position, Base parallel to patient table):

• C-arm rotation range (degrees): 120 LAO to 185 RAO

• C-arm angulation range (degrees): 90 CA to 90 CR (Full angulation capability determined by patient position)

In the side position (+90 / -90 degrees position, base perpendicular to patient table):

• C-arm rotation range (degrees): 90 LAO to 90 RAO

• C-arm angulation range (degrees): 185 CA to 120 CR or 120 CA to 185 CR (Full angulation capability determined by patient position)

The stand provides fully motorized movements with variable and configurable maximum speed. Coupled to the BodyGuard detection system, it allows high patient throughput.

• Variable C-arm rotation speed, up to 25 degrees/s

• Variable C-arm angulation speed, up to 25 degrees/s

Base rotation is motorized and can also be performed manual.

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 F20 adapts to the actual size of the patient and allows taking full advantage of the high speed movements.

Philips Azurion F20 features Xper Access to position the Flat Detector in portrait and landscape imaging modes. The motorized variable source image distance (SID) between focus and

Dynamic Flat Detector input screen can be adjusted from 895 to 1195 mm. This allows for excellent patient accessibility, imaging coverage and projection flexibility.

B. Patient Support

The patient support 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 endovascular tools. On customer request, the standard table top can be replaced by a table top for neuro procedures. This table top has a smaller width at the head end for better imaging results in neuro procedures.

• Table top length of 319 cm including OR rails (316 cm excluding OR rails), width of 50 cm (neuro table top is 45cm at head end)

• Metal-free cantilever 125 cm

• Floating table-top movement of 120 cm longitudinal and +/- 18 cm transversal

• Motorized height adjustment range is 74 -102 cm cm for a table without swivel nor cradle/tilt.
• Maximum cantilever of 223 cm, for full patient coverage

• Table tilt +17 /-17 degrees (optional)

• Table cradle +15 / -15 degrees (optional)

• Pivot range 270 degrees (-90 to +180 or +90 to -180 degrees), table can be locked at any position and has stops at 0, +/-13, +/- 90 and +/- 180 (optional)

• Table swivel, 78.2 cm longitudinal displacement, motorized (optional).

• 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

The UIM modules are not accessories; make consistent with "AD7 accessories Cardiac"

The Philips Azurion system can be fitted with a comprehensive set of accessories to help you perform your procedures as conveniently as possible. Included are:

• Cerebral filter

• Drip stand

• Rail accessory clamp

- Set of cable holders
- Patient straps
- Arm Support Board
- Set of Elbow Supports
- Head Support
- Lower Body Protection
- Black anti-fatigue floor mat w/logo
- Mattress

The mattress is a slow recovery foam mattress with a density of 58 kg/m3. The mattress has a thickness of 7 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.

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 7 F20 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 (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

• Pulsed X-ray for (subtracted) acquisition up to 12 frames/s for vascular applications

B. X-ray tube

The 7 F20 system has the Maximus ROTALIX Ceramic grid switch tube assembly MRF200+ GS 0407 integrated.

The MRC 200+ GS 04 07 tube assembly and cooling unit CU 3101 for cardiovascular systems comprises:

• 0.4/0.7 mm nominal focal spot values maximal 30 and 65 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 is oil cooled with thermal safety switch

• Maximum anode cooling rate of 1820 kHU/min

• Anode heat storage capacity of 6.4 [MHUeff]

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, and adaptive harmonization)

• Built-in SpectraBeam filtering of low energy radiation to improve image quality and dose efficiency with MRF200+ 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 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, and adaptive harmonization).

Roadmap Pro can be selected from the control module.

In the first Roadmap phase a vessel map is created by live fluoroscopy or by selecting an exposure image (SmartMask) with a vessel map which, in the second Roadmap phase, is superimposed with subtracted live fluoroscopy.

Roadmap Pro features Smart Settings in special clinical modes that are optimized to visualize special materials such as coils and glue.

- Acquisition runs can be done without losing the vessel map of Roadmap Pro.
- Live processing of the vessel map, the device map and the landmark map can be done on the touch screen module.
- Field of View (FoV) can be altered during the second phase.

- Xres for vascular procedures is standard part of Roadmap Pro.

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 Re port

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 system has a 20 inch flat panel image detector. This detector can be rotated over 90 degrees from portrait to landscape and vice versa.

The image chain with the 20 inch flat panel image detector comprises the following:

• A 30 cm by 40 cm (20 in.) diagonal 8 mode Dynamic Flat Detector subsystem for fluoroscopy and cine-fluorography.

• 8 modes 30*38/30*30/26*26/22*22/19*19/16*16/13.5*13.5/11*11 cm, Dynamic Flat Detector

48, 42, 37, 31, 27, 22, 19, 15 cm (19, 17, 14.4, 13, 10.5, 8, 7, 6 inch) diagonal formats

• The outer detector physical housing is 36 x 47.2 cm
• The digital output of the Flat detector is 1904*2586 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 offers a storage capacity of (optionally extendable) of 50,000 images at matrix size of 1024 x 1024, in 8 or 10 bit depth. With a matrix size of 2048 x 2048 this is 12,500 images. 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 thefull 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.

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 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)

• Quantitative Analysis (optional) User can only start QA from the touch screen module. No controls

Viewpad

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

• Run and image selection

• File and run cycle

• File overview

• Store to Reference image file

• Copy image to photo file

• Digital (fixed) zoom and panning

• Recall reference images, which means switching control of Viewpad function from 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

• Subtraction on/off

• Remasking

• Landmarking

• Access flat detector rotation

100237 Azurion 7 M20

Line #	Part #	Description	Qty	Each	Price

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-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
- 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. A printed paper instructions for use can also be ordered at no additional cost.

5. Viewing

A. Viewing in Examination room

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

The On-Screen Display provides status information on stand rotation-angulation, table height, display of system messages, X-ray tube load status, selected fluoroscopy mode, selected detector Field of View, and both the rate and accumulation of the dose area product and Air Kerma dose.

The main characteristics are:

- 27 inch high brightness color TFT-LCD display

- Native format 1920x1080 Full HD
- 10 bit gray-scale resolution with gray-scale correction
- Wide viewing angle (approx. 178 degrees)
- High brightness (max 650 Cd/m2, default 400 Cd/m2)
- Long term luminance stability through backlight stabilization circuit
- Automatic brightness control with backlight sensor
- Control functions on side
- User programmable and standard reference setting
- On-Screen Display
- Internal selectable lookup table for gray-scale transfer function, including DICOM
- Internal power supply (100-240 VAC)
- Integrated LCD protection screen

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

B. Viewing in Control room

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

The main characteristics for color monitor are:

- 24 inch color TFT-LCD display
- Native format 1920x1080 Full HD
- High brightness (max 400 Cd/m2, default 350 Cd/m2)
- Wide viewing angle (approx. 178 degrees)

- Long term luminance stability through backlight stabilization circuit
- Automatic brightness control with backlight sensor
- Control functions on side
- User programmable and standard reference setting
- On-Screen Display
- Internal selectable lookup table for gray-scale transfer function, including DICOM
- Internal power supply (100-240 VAC)
- Integrated USB hub

A Philips Azurion system includes the DICOM Image Interface which enables the export of clinical images to a DICOM destination like a CD-Medical station or a PACS server. The export formats are based on DICOM 3.0 protocols. The system exports clinical studies in Cardiac DICOM XA Multi-Frame or DICOM Secondary Capture formats.

The DICOM Image Interface transfers through its fast Ethernet link, making images available on-line within seconds. The archive process can be configured by X-ray settings. The images are sent out either in the background, or manually upon completion of the examination. The export format is configurable in 512x512 or 1024x1024 matrix in 8 or 12 bit depth. The examination can be sent to multiple destinations for archiving and reviewing purposes. The DICOM Image Interface provides DICOM Storage and DICOM Storage Commitment Services. The DICOM Query/Retrieve function allows older DICOM XA MF and DICOM SC studies to be uploaded in the system. Furthermore, additional information can be appended to a study while keeping the patient identification the same.

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 7 F20 system is a perfect example of our EcoVision program. By examining every aspect of the 7 F20 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 Vascular Analysis

Key benefits

- Allows quantitative assessment of different size vessels such as aortic and peripheral
- 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 aortic and peripheral vasculature

To support decision-making and allow quantitative assessment of vasculature during vascular interventions, the 2D quantitative vascular analysis option supports quantification such as aortic and peripheral artery dimensions of about 5 to 50 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 vessel segmentation
- Diameter measurement along 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

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.

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

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.

Marker tool

Marker tool allows you to easily mark areas of interest on a 2D image. Clear and precise markings on the image as the marking scales with the image when it's zoomed or panned

Key benefits

- Allows you to mark areas of interest to on a image during your procedure (e.g. to indicate where to put stent/grafts)

Enhance functionality on the touch screen module
This option extends the functionality of the touch screen module, allowing markings on images. Affordable alternative vs expensive 3rd party applications

Specifications
- Enhance functionality on the TSM
- Provides intuitive zooming an panning functionality (also during fluoroscopy)
- Turns the touchscreen into the marking device in order to improve communication during the procedure

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.

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.

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Line #	Part #	Description	Qty	Each	Price

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	**NNAT135	**Intrasight 5**	**1**	**$115,364.70**	**$115,364.70**

IntraSight 5

IntraSight 5 is a scalable, applications-based platform designed to meet the evolving needs of your lab. This platform provides best-in-class physiology and imaging tools. In addition to providing these leading technologies, the IntraSight platform also optimizes lab performance with efficient data management and user controls, remote service diagnostics, and advanced cybersecurity protection while minimizing the learning curve with a modern, intuitive interface that is fast to learn & easy to use.

IntraSight interventional applications platform. Includes IntraSight CPU, CPU Base, Operator's Manual, Power Transformer, Cable Pre-Install Kit, Power Supply, Connection Box, Mouse, Keyboard, 19" Monitor Kit, DICOM Network Connection.

Imaging (IVUS) License. Includes IntraSight IVUS Software package: Digital, Rotational, and ChromaFlo IVUS.

Digital PIM. Includes PIM, Cabling, and PIM holder.

Physiology (iFR/FFR) License. Includes IntraSight Physiology Software Package: iFR Hyperemia Free Lesion Assessment Modality, FFR Modality, iFR Option Manual FFR 2.5.

M-PIM. Cabling, FM-PIM holder, and FM-PIM to Verrata Wire Adapter.

3	**FCV0824	**video WCB on rear side 1st MCS**	**2**	**$5,452.40**	**$10,904.80**

Line #	Part #	Description	Qty	Each	Price

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	$5,486.80	$5,486.80

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 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.
- If the customer chooses for FlexSpot, then the total amount of live/ref slaving that can be selected is max 3, 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	$1,414.70	$11,317.60

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.

Line #	Part #	Description	Qty	Each	Price

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 **NCVD069 **ClarityIQ.** 1 $119,325.00 $119,325.00

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

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

7 **NCVA101 **peripheral X-ray filter** 1 $1,251.30 $1,251.30

• Obtain uniform density of lower peripheral areas

Enhance consistency of lower peripheral images
To help clinicians obtain consistent images of lower peripheral anatomy, this option provides a set of flexible X-ray filters. They provide uniform density in angiographic examinations of the lower peripheral area.

8 **NCVA694 **Subtracted Bolus Chase** 1 $19,934.80 $19,934.80

Helps to visualize vessel structures when blood flow is difficult to estimate.

Key benefits
• Bolus Chase improves results in case of challenging step movements, a mismatch between blood flow and selected program, or lack of real-time image information.

During digital acquisition in non-subtracted mode with uninterrupted real-time image display, the contrast bolus is followed (chased) interactively by a motorized table scan movement using a

Line #	Part #	Description	Qty	Each	Price

hanbd-hold speed controller to adapt the speed of the table scan to the contrast flow. With biplane systems, this Bolus Chase is applied with the lateral channel.

Specifications
- Framespeed can be adapted.
- Bolusrun is followed with a maskrun, using the same speed curve and framespeed that was generated during the bolusrun.
- Viewing is possible in the subtracted and non-subtracted mode. If subtracted viewing is not required, the maskrun can be skipped.
- Subtracted Bolus Chase gives fast, accurate results high patient throughput and efficient patient management.
- Automated exposure control and precise speed control generate high quality images and excellent subtraction cases.

9	**NCVD099	**Quantitative Coronary Analysis**	1	$6,966.00	$6,966.00

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.

10	**NCVA851	**Swivel for table base.**	1	$16,615.20	$16,615.20

- Simplifies patient positioning
- Easy patient transfer

Simplifies patient positioning
The swivel option with pivot movement allows you to easily move the table to reach upper and lower peripherals for angiographic and interventional procedures. Swivel the table from side-to-side or pivot the table on its vertical axis. The table moves with less friction, making it easier to move larger patients. A secure mechanism locks the tabletop in place to prevent it from moving.

11	**NCVD072	**SmartMask Monoplane**	1	$10,633.90	$10,633.90

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Line #	Part #	Description	Qty	Each	Price

Key benefits

- Simplifies roadmap procedures by overlaying fluoroscopy with a selected acquired image.
- Enables roadmap procedures to manage radiation dose and contrast media by selecting an image from an acquired series as a mask image.

Supports navigation during interventions without the need of additional contrast media.
SmartMask simplifies roadmap procedures by overlaying fluoroscopy with a selected acquired image in the Live X-ray window.

Specifications
The reference image can be faded in/out with variable intensity, controlled from tableside.
SmartMask uses the reference image displayed on the reference monitor. Any previously acquired image can be used as reference. SmartMask facilitates pre- and post- intervention comparisons to assess treatment results.

12	**NCVD078	FD Dual Fluoro monoplane	1	$17,458.00	$17,458.00

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.

13	**NCVD128	storage extension	1	$5,155.70	$5,155.70

Extends image storage capacity on your X-ray system
As imaging data becomes larger, you can quickly reach the limit of the storage capacity on your interventional X-ray system. The Storage extension extends the storage capacity of your interventional X-ray system.

Specifications
By default 50.000 images are available, this option will give 100.000 images (this is for 1K2 image size).

14	**NCVD030	FlexVision XL HD	1	$96,754.30	$96,754.30

FlexVision XL HD is an integrated viewing solution designed to give you full control over your viewing environment which brings High Definition viewing.

Key benefits

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

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Line #	**Part #**	**Description**	**Qty**	**Each**	**Price**

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 HD. You can display multiple images in a variety of custom layouts on a large, high-definition 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
FlexVision XL HD offers:
• Native resolution of FD20 can be displayed.
• Sharp images at full size without zoom
• High Definition display at native resolution for ultimate detail
• Up to 2k*2k image display fully integrated
• Enhanced small vessel visualization

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

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 HD as a photo image to the current acquisition patient study.

15	****NCVA258**	**CO2 VIEW TRACE**	**1**	**$2,842.30**	**$2,842.30**

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Line #	Part #	Description	Qty	Each	Price
		Software package enabling tracing (stacking) of images acquired with CO2 injections. This function can be used during postprocessing next to view trace of images acquired with CO2 injections.			
16	**FCV0510	**Long mattress cardio**	1	$533.20	$533.20
		• Enhances patient comfort • Adapts to the shape of the patient's body **Enhance patient comfort during cardio exams** To enhance patient comfort during cardio exams, the inflatable, latex free mattress can be used. It is extra-long to accommodate the patient on the tabletop, and adapts to the shape of the patient's body. The pressure within the mattress is evenly distributed so that it recovers its original shape quickly. Dimensions of the mattress: Length: 3165mm Width: 500mm Height: 70mm Radius: 150mm			
17	**989801229902	**Low Load Fluoro (LLF) UPS - 5**	1	$38,334.50	$38,334.50
		Tested and approved 3-phase double conversion Low Load UPS enables the system to be used normally with the exception of the exposure functionality, Run time 5 mins (Typical 8 min)			
18	**980406041009	**Rad Shield w/ Arm (Contoured) 61X76**	1	$2,528.40	$2,528.40
		Contoured Rad Shield with Arm rest. 61X76			
19	**989801220012	**Cable Spooler**	1	$348.30	$348.30
20	**989801220273	**Ceiling Track w/Column & Handle Ext**	1	$3,792.60	$3,792.60
		Mavig 2.5m Ceiling Track with Ceiling trolley, 360 degree column, and brake handle extension.			
21	**989801220388	**Lower Body Protection**	1	$1,487.80	$1,487.80
		UT70-10WS Lower body protection, width 1410 mm incl. wide extension Lower body protection of the model series UT70 with a modular design to provide a maximized protective zone for the physician and staff.			
22	**989801220397	**Lamp Y LED 1F**	1	$2,580.00	$2,580.00
		LE7017100 Lamp YLED-1F with Portegra2 extension/spring arm 750/910 mm Technical Data and Specifications 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			

100237 Azurion 7 M20

Line #	Part #	Description	Qty	Each	Price

–
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

23 ****NNAE159** **30Fr/sec Extension** **1**

24 **SP019** **Trade in Allowance** **1** **($16,600.00)** **($16,600.00)**

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

Product: GE INNOVA 3100
Serial Number: 20033300884
Manufacturer: GE MEDICAL SYSTEMS CAPITAL

Trade-In authorization number:	117330
Trade-In Value:	$16,600.00
De-install Date:	7/19/2021

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

1. Customer represents and warrants that Customer has good and marketable title to the Trade-In as of the date of this Quotation and will have good and marketable title when Philips removes the Trade-In from Customer's site (the "Removal Date");
2. Title to the Trade-In shall pass from Customer to Philips on the Removal Date, unless otherwise agreed by Philips and the Customer;
3. Notwithstanding anything to the contrary in any Business Associate Addendum, Customer represents and warrants that as of the Removal Date all Protected Health Information will have been de-identified or removed from the Trade-In;
4. Philips may test and inspect the Trade-In prior to de-installation. If the condition of the Trade-In is not substantially the same on the Removal Date (ordinary wear and tear excepted) as it is identified on the System Disclosure Form, then Philips may reduce the price quoted for the Trade-In;
5. If the removal date is delayed until after the De-Install Date, unless Philips causes the delay, then Philips may reduce the price quoted for the Trade-In by six percent (6%) per month.
6. Philips is responsible for normal de-installation costs of the Trade-In.

100237 Azurion 7 M20

Line #	Part #	Description	Qty	Each	Price

7. The trade-in value will not include costs associated for any facility modifications and/or rigging required for de-installation and must be accounted for separately.
8. Customer is responsible for all plumbing necessary to properly drain coolant from chiller system and cap the lines.
9. Prior to the Removal Date, Customer shall remove from the room all equipment that is not being de-installed.

100237 Azurion 7 M20

NET PRICE **$1,124,981.20** **(+ Trade-In $16,600 = $1,141,581)**

Buying Group: VIZIENT SUPPLY LLC Contract #: XR0312 CV

Addt'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),

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.

ATTACHMENT B

Projected Capital Cost Form

NH Presbyterian Medical Center Cath Lab #2 Replacement

Building Purchase Price		
Purchase Price of Land		
Closing Costs		
Site Preparation		
Construction/Renovation Contract(s)	$	702,173
Landscaping		
Architect / Engineering Fees	$	69,500
Medical Equipment	$	1,141,581
Other Equipment	$	284,257
Furniture	$	-
Removal of Existing Equipment	$	-
Financing Costs		
Interest during Construction		
Other: Contingency	$	99,509
Total Capital Cost	**$**	**2,297,020**

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: June 23, 2021

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 Stiene ______ Date Signed: 06/30/2021 | 10:14:57 EDT

Signature of Officer/Agent

Senior Vice President, Real Estate & Construction, Novant Health, Inc.

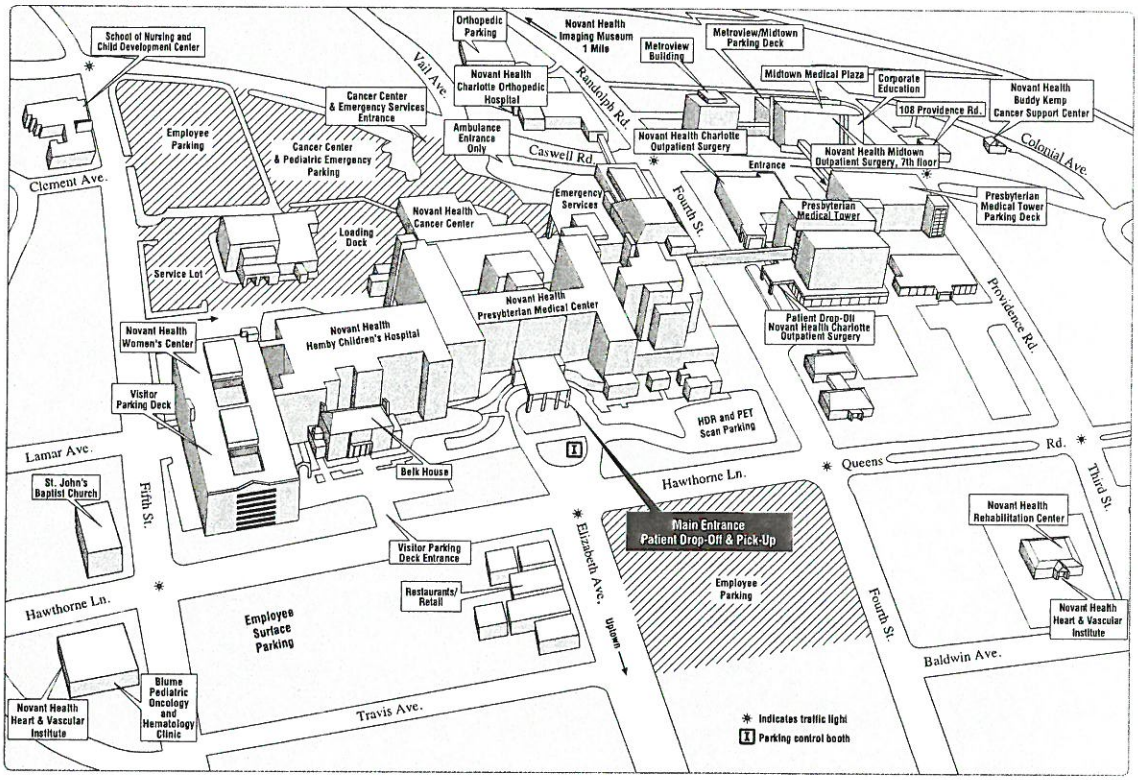
Title of Officer/Agent

ATTACHMENT C

Campus map

Presbyterian Medical Center

For more information about Novant Health Presbyterian Medical Center, call 704-384-4000 or visit our website at NovantHealth.org.



NOVANT HEALTH

ATTACHMENT D

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	Ø	Ø
3. Number of Procedures* Performed in Fixed Units on Patients Age 15 and older	933	738
4. Number of Procedures* Performed in Mobile Units	Ø	Ø
Dedicated Electrophysiology (EP) Equipment		
5. Number of Units of Fixed Equipment	3	
6. Number of Procedures on Dedicated EP Equipment	1243	

*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)

ATTACHMENT E

EQUIPMENT COMPARISON

NH Presbyterian Cath Lab Room 2	**EXISTING EQUIPMENT**	**REPLACEMENT EQUIPMENT**
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	Cardiac Cath	Cardiac Cath
Manufacturer	GE	Philips
Model number	Innova 3100 IQ	Azurion 7 F20
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	Serial #: 553070BU4 Fixed Assets #: 190356	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2/1/2008	TBD
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <Attach a signed Projected Capital Cost form for New Equipment>	NA	$2,297,020
Total cost of the equipment	$1,075,896	$1,141,581
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Cath Lab #2	Cath Lab #2
Document that the existing equipment is currently in use	See LRA Excerpt	NA
Will the replacement equipment result in any increase in the **average charge per procedure**?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the **average operating expense per procedure**?	NA	No
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/Peripheral Procedures	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	Cardiac Cath/Peripheral Procedures

Date of last revision: 5/17/19