

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

September 24, 2020

James Roskelly Jim.roskelly@conehealth.com

Exempt from Review – Replacement Equipment				
Record #:	3365			
Facility Name:	Alamance Regional Medical Center			
FID #:	954565			
Business Name:	Alamance Regional Medical Center, Inc.			
Business #:	49			
Project Description:	Replace existing cardiovascular equipment			
County:	Alamance			

Dear Mr. Roskelly:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of September 23, 2020, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Philips Azurion 7 M20 Ceiling shared cardiovascular equipment to replace the Siemens Artis Z Floor cardiovascular equipment, identified as 2E176. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you need to contact the Agency's Construction Section to determine if they have any requirements for development of the proposed project.

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

Sincerely,

Celia C. Unman

Celia C. Inman, Project Analyst

Martha J. Fresone

Martha J. Frisone, Chief

cc: 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

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Strategy and Planning 1200 North Elm Street Greensboro, NC 27401-1020 336.663.5600 www.conehealth.com

September 23, 2020

Ms. Martha Frisone, Chief Ms. Celia C. Inman, Project Analyst Healthcare Planning and Certificate of Need Section Division of Health Service Regulation, NC DHHS 2704 Mail Service Center Raleigh, NC 27699-2704

Re: Vascular Lab Equipment Replacement at Alamance Regional Medical Center (Lic# H0272/FID# 954565)

Dear Ms. Frisone and Ms. Inman:

I am writing to you pursuant to NCGS § 131E-184(a)(7) to inform you of Cone Health's plans to replace equipment currently used in the shared vascular and interventional radiology lab located at Alamance Regional Medical Center. Attachment 1 contains a comparison of the existing equipment and the planned replacement equipment. The replacement equipment, an Azurion 7 M20 Ceiling Mount vascular and nonvascular embolization system will cost \$1,036,006. The new equipment will be functionally similar to the existing equipment but will provide greater flexibility for more detailed imaging due to its ceiling placement. Minor renovations to the existing space will add \$918,000 to the cost along with Architect and Engineering fees of \$42,000. These costs were estimated by CPL (Clark Patterson Lee) based on their knowledge and expertise with similar projects. The total proposed capital cost for this equipment replacement is \$1,996,005. A detailed capital budget signed by a licensed architect and an officer of the corporation is included in Attachment 2.

As detailed on page 32 of the vendor quote in Attachment 3, Philips Healthcare will accept the existing equipment for trade in at a value of \$7,000 and will remove the existing equipment from the campus. The equipment being replaced was purchased by Alamance Regional Medical Center in 2009 and has reached the end of its usable life.

Please let me know if you have any questions regarding this equipment replacement project.

Sincerely,

in K.Sum

Melissa K. Shearer Executive Director Strategy and Planning

Attachment 1

Equipment Comparison Form

EQUIPMENT COMPARISON

EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Cardiovascular Lab	Cardiovascular Lab
Siemens	Philips
Artis Z floor	Azurion 7 M20
2E176	2E176
Floor fixed	Ceiling fixed
2009	2020
New	New
NA	\$1,996,006
\$905,000	\$1,036,006
Vascular/Interventional Radiology Lab	Vascular/Interventional Radiology Lab
See Attachment 4	NA
NA	No
NA	N/A
NA	No
NA	N/A
See Next Page	NA
NA	See Next Page
	EQUIPMENTCardiovascular LabSiemensArtis Z floorArtis Z floorPloor fixed2009NewNANA\$905,000Vascular/Interventional Radiology LabSee Attachment 4NANANASee Next Page

Date of last revision: 5/17/19

Case type

A/V Fistulagram Lower extremity angiography/interventions Upper extremity angiography/interventions Portacath Insertion Portacath Removal Renal angiograms/interventions Shuntogram Embolization Carotid angiography/interventions Perm catheter Insertion Perm catheter Removal **IVC** Insertion IVC Removal Pulmonary Thrombectomy Central Line AV shunt/intervention Pelvic angiography Visceral angiography Endovascular Aortic Aneurysm Repair

Attachment 2 Capital Cost Worksheet

	auc
Building Purchase Price	N/A
Purchase Price of Land	N/A
Closing Costs	N/A
Site Preparation	N/A
Construction/Renovation Contract(s)	\$918,000
Landscaping	N/A
Architect / Engineering Fees	\$42,000.00
Medical Equipment	\$1,036,005.52
Non-Medical Equipment	N/A
Furniture	N/A
Consultant Fees (specify)	Included in Arch/Eng. Fees
Financing Costs	N/A
Interest during Construction	N/A
Other (specify)	N /A
Total Capital Cost	\$1,996,005.32

Projected Capital Cost Form- Alamance Regional Medical Center Vascular Lab Upgrade

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

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

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 it is our intent to carry out the proposed project as described.

James Rockelly

r

Date Signed: 9/23/2020

Date Signed: **<u>8</u>/20/2020**

Signature of Officer/Agent

Executive Vice President, Strategic Development Title of Officer/Agent Attachment 3 Equipment Quote



Quotation #: 1-2A2T9UW	Rev: 2	Effective From: 31-Jul-20	To: 29-Sep-20
Presented To:		Presented By:	
ALAMANCE REGIONAL MEDICAL CE 1240 HUFFMAN MILL RD	INTER	Christopher Starnes Account Manager	Tel: (803) 504-1412 Fax: (855) 890-2822
BURLINGTON, NC 27215-8700		John Hill Regional Manager	Tel: (800) 722-7900 x6806 Fax:
Tel:			
Alternate Address:			
Date Printed: 31-Jul-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			
100237 Azurion 7 M20			1		\$1,036,005.52	
			Equipment Total:		\$1,036,005.52	
	Solution Summary Detail					
Product		<u>Qty</u>	<u>Each</u>	<u>Monthly</u>	<u>Price</u>	
100237 Az	urion 7 M20	1	\$1,036,005.52		\$1,036,005.52	
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 (sult to such Contract), applicable to the purchase of any Product identified as part of this quoted Solution.				ns of Sale (subject		

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 NNAT023 Azurion 7 C20.
- 8 FCV0588 Isolated Wall Connection Box
- 2 FCV0824 video WCB on rear side 1st MCS
- 1 FCV0812 live/ref slaving for ER
- 1 NCVD069 ClarityIQ.
- 1 NCVD099 Quantitative Coronary Analysis
- 1 NCVD061 optional ref monoplane
- 1 NCVA783 table pivot option
- 1 NCVD072 SmartMask Monoplane
- 1 NCVD081 Touch Screen Module Pro
- 1 NCVD030 FlexVision XL HD
- 1 NCVD128 storage extension
- 1 NCVD178 IW Hardware
- 1 FCV0510 Long mattress cardio
- 1 NCVC664 SmartPerfusion
- 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 NNAE957 Clinical Education Program for SmartPerfusion
- 1 NNAE159 30Fr/sec Extension
- 1 989600213942 AD5 TO XPER TABLE ADAPT. PLATE
- 1 989801229902 Low Load Fluoro (LLF) UPS 5
- 1 SP019 Trade in Allowance

Options

- Qty Product
- 1 989801220158 Mark 7 Arterion, Table Mount

	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	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 Philip fees and any specific terms and conditions, including the Vendor's Terms and Conditions of Sale (s				5		
Line # Part #	Description	Qty	Each	Price		
1 **NNA Azur	F023 Azurion 7 C20. ion 7 C20	1	\$666,310.40	\$666,310.40		

Advanced solution for vascular, non-vascular, embolization to interventional oncology procedures.

Key benefits

- Optimized utilization of your lab by procedure based workflow
- Superb image quality to evaluate small details and vessels with clarity.
- Intuitive user interaction delivering an easy to use, easy to learn system.

Changing interventions

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

The 7 series C20 ceiling system is designed to enhance all the different procedures your interventional lab faces, from vascular, non-vascular and embolization to interventional oncology procedures. 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 7C20 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 Philins	Azurion 7 C20 interventional X-	rav suite has been specific	ally designed to save tim	he

The Philips Azurion 7 C20 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 C20 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 C20 stand

100237 Azurion 7 M20

Line #	Part #	Description	Qty	Each	Price
The Philips Azurion 7 C20 stand is a stable assembly of a C-arm and a ceiling suspended L-a The X-ray tube and the flat detector are integrated into the C-arm. This provides a compact assembly completely free from the floor, with maximal positioning flexibility and unrestricted access to the patient. The robust design ensures excellent reproducibility of projections, need for example subtracted imaging procedures and advanced 3D imaging. The L-arm can be rota and moved in longitudinal direction allowing a three-sided patient approach and total body coverage.					
	• L-arm	rotation around the patient table: +90), 0, -90 degrees.		
	• L-arm	longitudinal movement: 300 cm			

This movement features auto-stops at the parking position, cardio/neuro position and lower peripheral position.

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 50 cm (neuro table top is 45cm at head end)

- Metal-free cantilever 125 cm
- Floating table-top movement of 120 cm longitudinal and 36 cm lateral float range
- Motorized height adjustment range is 74 -102 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: 250 kg (up to 250 kg patient weight plus 25kg accessories) plus 500 N for CPR in any longitudinal position of the table top

100237 Azurion 7 M20					
Line # Part #	Description	Qty	Each	Price	
The UIM m	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

100237 Azurion 7 M20						
Line # Part #	Description	Qty	Each	Price		

2. X-ray Generation

A. Generator

The 7 C20 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 C20 system has the Maximus ROTALIX Ceramic grid switch tube assembly MRC200+ GS 0407 integrated.

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

	100237 Azurion 7 M20						
e #	Part #	Description	Qty	Each	Price		
	• 0.4/0.7	mm nominal focal spot values ma	aximal 30 and 65 kW short tir	ne load			

• Grid switching at pulsed fluoroscopy and low load exposure (to eliminate soft radiation and improve image quality)

• Continuous loadability: 3500 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 1750 kHU/min
- Anode heat storage capacity of 6.4 [MHUeff]
- C. System intrinsic

Line

• 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 MRC200+ X-ray tubes.

- Pre-filters of 0.2, 0.5 and 1.0 mm CU equivalent
- Automatic cardiac wedge positioning

• X-ray depth collimator with single semi-transparent wedge filter with manual and automatic positioning.

• Xper Beam Shaping, which means that both shutters and wedges can be positioned on the Last image Hold without the need for X-ray radiation.

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

D. User selections

• Removable anti-scatter grid to lower x-ray dose for pediatrics (grid ratio 12:1).

	100237 Azurion 7 M20						
Line #	Part #	Description	Qty	Each	Price		
	• ECG triggered acquisition offering the possibility to acquire images at the same phase of the						

• 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.

100237 Azurion 7 M20					
Line # Part #	Description	Qty	Each	Price	
Radiation Dose Structured Report					

Collection of dose relevant parameters and settings and export to a DICOM database (e.g. PACS) (dose information is sent in MPPS message not as Radiation Dose Structure report), according IEC60601-2-43, 2nd Edition. The reported data can be used for, for example:

• Quality improvement: evaluating trends in X-ray dose performance per facility, system and operator. RDSR enables analysis of average dose levels & variance for routinely performed exams and procedures. Also, typical system usage can be extracted from the data, helping to identify root causes behind deviations and measures to improve.

• Analysis of individual patient cases: using dose levels and system usage per procedure

• Alerting for high dose cases, timely identifying patients at risk or deterministic effects, for proper follow-up.

Secondary Capture Dose Report

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

The dose report will be stored in the related patient image folder.

3. Image Detection

The 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

100237	Azurion	7	M20
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Line #	Part #	Description

Qty

Each

Price

• The digital output of the Flat detector is 2480*1920 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 examinat ion.

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.

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

100237 Azurion 7 M20

Line # Part

• Detector field size display

Description

Qty

Price

- General System messagesSelected 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

100237 Azurion 7 M20 Line # Part # Description Qty Each Price

- 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

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

100237 Azurion 7 M20

Line # Part

Qty

Price

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

Description

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.

	10023	7 Azurion 7 M20		
Line # Part #	Description	Qty	Each	Price

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

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.

100237 Azurion 7 M20 Line # Part # Description Qty Each Price

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:

100237 Azurion 7 M20

Qty

Each

Price

Line # Part

- 24 inch color TFT-LCD display
- Native format 1920x1080 Full HD
- High brightness (max 400 Cd/m2, default 350 Cd/m2)

Description

- 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 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.

Security

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

Remote service

100237 Azurion 7 M20				
Line # Part #	Description	Qty	Each	Price

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 C20 system is a perfect example of our EcoVision program. By examining every aspect of the 7 C20 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 isocenter and recall this table position.

Quantitative Vascular Analysis

100237 Azurion 7 M20				
Line # Part #	Description	Qty	Each	Price
Key benefits				

- 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

		10023	7 Azurion 7 M20		
Line #	Part #	Description	Qty	Each	Price
	Reduce dat	a errors and facilitate X-ray do	se management		
	exam workf allows your interface us	the X-ray system with your loc low and promote radiation mar X-ray system to communicate ses the DICOM Worklist Manag Step (DICOM MPPS) standard	nagement. The RIS/CIS DIC with a local CIS or RIS info jement (DICOM WLM) and I	COM interface package mation system. The	
	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:				
	 Prevent er information retrieval) 	the need for retyping patient in rrors in typing patient names an to prevent problems in archive information system about the	nd registration numbers (en- clusters or to search for a r	suring consistency with IS name in case of later	3
	Specificatio	ns			
	examination	est from the X-ray system the c n data is returned from the IS to will be shown on the -ray syste	o the X-ray system. For eac	h patient the following	
	 Examination 	entification: Patient name, Patie on/Request Information: Acces performing physician's name		ocedure step start time,	
	It is possible	e at all times to enter patient de	emographics information ma	anually within the X-ray	

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

system in case of an emergency or in case the local Information System connection is down.

• 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

100237 Azurion 7 M20				
Line # Part #	Description	Qty	Each	Price

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.

100237 Azurion 7 M20				
Line # Part #	Description	Qty	Each	Price

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:

100237 Azurion 7 M20				
Line # Part #	Description	Qty	Each	Price

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 twentyeight (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 may perform refresher training if required.

Education expires one (1) year from installation date (or purchase date if sold separately).

2	**FCV0588	Isolated Wall Connection Box	8	\$1,408.12	\$11,264.96

	10023	37 Azurion 7 M20		
Line # Part #	Description	Qty	Each	Price

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

3 **FCV0824 video WCB on rear side 1st 2 \$5,427.04 \$10,854.08 MCS

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	\$5,461.28	\$5,461.28
		·			

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

		100237	7 Azurion 7 M2	0			
ine #	Part #	Description	Qty		Each	Price	
	Live and Ref video source from the X-ray system. The total amount of live/ref slaving that can be selected is max 5, minus the number of FCV0807 Live/ref slaving for CR.						
	- On Philips	ns ng for ER is possible: MCS (additional monitor exclud tion with FCV0519 1 or 2 MCS					
5	**NCVD069	ClarityIQ.	1		\$118,770.00	\$118,770.00	
	Significantly	lower dose- across clinical are	as, patients and op	perators.			
	 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						
6	**NCVD099	Quantitative Coronary	Analysis 1		\$6,933.60	\$6,933.60	
	 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

		100237 Azu					
ine #		Description eter, stenosis length	Qty	Each	Price		
		ameter, % stenosis area d manual calibration routines age					
	the mouse on o	targeted vessel segment has been r close to the stenotic area and cliv ows the obstruction, healthy vesse	ck once to detect	the relevant segment.	The		
	**NCVD061	optional ref monoplane	1	\$4,716.56	\$4,716.5		
	Additional Ref2	and Ref3 viewport					
	Simplify workf Having patient of making and effit output of the X- Combined with	any data or clinical information ne low with flexible viewing contro data and clinical information easily ciency during interventions. Option ray system offering an additional F the Dual Fluoro license this enable of Dual Fluoro image visible on the	available on scre nal ref monoplan Ref2 and Ref3 vie as users to zoom	een can enhance decisi e offers an additional vio wport on one LCD mon	deo itor.		
	**NCVA783	table pivot option	1	\$4,408.40	\$4,408.40		
	Flexible positionEasy patient to	oning for upper extremity angiogra	phy		• ,		
	Transradial acc with our optiona moves with less	oning and transfers ess, upper extremity angiography, al Pivot feature. One finger push-to s friction, making it easier to move e to prevent it from moving.	-pivot allows effo	rtless patient positioning	g. It		
1	**NCVD072	SmartMask Monoplane	1	\$10,584.44	\$10,584.4 ₄		
	 Enables roadr 	dmap procedures by overlaying flu nap procedures to manage radiation 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.						
0	**NCVD081	Touch Screen Module Pro	1	\$24,819.72	\$24,819.72		
	Extension of To	uch Screen Module for easy contro	ol of X-Ray image	•			
		neters can be quickly and easily a are shown to support easy naviga			one		

finger. Pinch, zoom, pan and flag images for processing. Position shutters and wedges by simply

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.

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

Pro' option.

**NCVD030

11

control room. **Specifications**

 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

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.

100237 Azurion 7 M20

- All X-ray settings can be easily adjusted to help you effectively manage patient and staff dose

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

- intuitive control of shutters and wedges by simply dragging the lines shown on top of the image

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

!!! Note: Images shown on the TSM are not meant for diagnostic purposes (image is downscaled,

1

- turns the touchscreen into the pointing device in order to improve communication in ER/CR:

Qty

Line # Part # Description

swiping the image on screen.

- enhance image navigation on the TSM

- provides intuitive zooming an panning functionality (also during fluoroscopy)

compressed and latency during live/replay maybe higher than on the live monitor)

Enhance image navigation on the touch screen module

when activated the pointer is shown on corresponding monitor

FlexVision XL HD

Each

\$96,304.28

\$96,304.28
Qty

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:

Line # Part #

- 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

Description

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.

12 **NCVD128 storage extension

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).

13 **NCVD178 IW Hardware

1

1

\$20,278.64

\$5,131.72

\$20,278.64

\$5,131.72

Key benefits

• Facilitates the interventional tools and multimodality viewing in exam room and control room

• Supports import and viewing of DICOM compatible data from CT and MR imaging modalities

View multimodality images in exam room and control room

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

Specifications

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

Price

		100237 A	zurion 7 M20		
Line #	Part #	Description	Qty	Each	Price
	 Computer W Control Roor 16 GB memory 	n 24" display ory			
	 Internal CD-I 	or the operating system, applica ROM / DVD writer to interact with all the interventi			
	FD Calibration	Tool Kit for 3D-RA			
14	**FCV0510	Long mattress cardio	1	\$530.72	\$530.72
	 Enhances pa Adapts to the 	atient comfort shape of the patient's body			
	To enhance pa is extra-long to	ent comfort during cardio exa atient comfort during cardio exar o accommodate the patient on the ssure within the mattress is ever	ns, the inflatable, late ne tabletop, and adapt	s to the shape of the p	patient's
	Dimensions of Length: 3165n Width: 500mm Height: 70mm Radius: 150m	nm I			

When trying to restore vessel patency during an endovascular intervention or evaluate remaining blood perfusion during tumor embolization, getting feedback on tissue perfusion before and after treatment can provide essential information to guide decision-making. SmartPerfusion image analysis software helps clinicians identify and quantify the change in perfusion due to an intervention to support determination of treatment endpoint* of procedures.

SmartPerfusion requires only one contrast enhanced DSA run for each perfusion image, and provides rich information of vessel perfusion in the interventional lab. By comparing pre- and post-procedure images, clinicians can easily identify perfusion differences in the color images and timedensity curves and consequently verify if the required level of perfusion has been achieved. Perfusion characteristics in multiple regions of interest can be compared on one screen to quantify the effects of revascularization during and immediately after the procedure.

The software provides step-by-step guidance to aid standardization of pre- and post-comparison runs. The catheter position of the pre-run is stored and the fluoro overlay is aligned with the previous position to support accurate comparisons. The footrest stabilizes the lower leg and foot to maintain a consistent imaging position. Advanced and automated guidance supports standardized comparisons to simplify clinical adoption.

Key benefits

- Supports determination of treatment endpoint*
- Supports physicians in assessing treatment efficacy by instantly showing changes in perfusion parameters
- Provides seamless and automated guidance
- Standardizes pre- and post-comparison runs through guided positioning

*Determination of treatment endpoint is the conclusion reached by the physician, based on qualitative information together with other relevant clinical data.

16	**980406041009	Rad Shield w/ Arm (Contoured)	1	\$2,516.64	\$2,516.64
		61X76			

		100237 Az	urion 7 M20			
Line #	Part #	Description	Qty	Each	Price	
	Contoured Rad S	Shield with Arm rest. 61X76				
17	**989801220012	Cable Spooler	1	\$346.68	\$346.68	
18	**989801220273	Ceiling Track w/Column & Handle Ext	1	\$3,774.96	\$3,774.96	
	Mavig 2.5m Ceili	ng Track with Ceiling trolley, 360) degree column, a	ind brake handle extens	sion.	
19	**989801220397	Lamp Y LED 1F	1	\$2,568.00	\$2,568.00	
		p YLED-1F with Portegra2 exter	nsion/spring arm 7	· ·		
	Technical Data a	nd Specifications				
	Technical Data a					
	Colour temperatu Colour rendering Focusable light fi Electronic brightr Sterilisable hand	nsity (at 1 m distance) 70,000 lx ure 4100 ± 200 K i index at 4100 Kelvin (CRI) Ra s ield size 140 – 250 mm ness control 50% – 100% le Yes rease 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 r Lifetime of LEDs Working area 70 Height adjustmer Lamp dimension Housing colour F	50,000 h – 140 cm nt (on Portegra2 spring arm) 117 s 28 x 36 cm	7 cm			
	Housing – Protec Fire protection cl Medical Products	s Directive 93/42/EEC Yes DIN VDE 0100-710 Yes				
20	**989801220388	Lower Body Protection	1	\$1,480.88	\$1,480.88	
		ver body protection, width 1410	mm incl. wide exte		÷ -, -00100	
	Lower body prote	ection of the model series UT70 or the physician and staff.			nized	
21	**NNAE957	Clinical Education Program SmartPerfusion	for 1			

			100237 Azurio	n 7 M20		
Line #	Part #	Description		Qty	Each	Price
	of education for unight/weekend should be guidelines problem be patient-ready. equipment during	up to four (4) stude nifts if necessary. ovided by Philips. Philips personnel g education sessio	ents, selected by cu CEU credits may b Please refer to guid are not responsible ons except to demo	istomer, includ e available fo delines for mo e for actual pa nstrate proper	vill provide sixteen (16 ding technologists from r each participant that ore information. Note: S atient contact or operat r equipment operation. purchase date if sold	n meets Site must tion of
		# 6034-20131218 uires the purchase				
22	**NNAE159	30Fr/sec Exten	sion	1		
23	**989600213942	AD5 TO XPER ⁻ PLATE	TABLE ADAPT.	1	\$1,844.68	\$1,844.68
24	**989801229902	Low Load Fluo	ro (LLF) UPS - 5	1	\$38,156.20	\$38,156.20
			ble conversion Low exposure functional		nables the system to b	e used
	Run time 5 mins	(Typical 8 min)				
25	SP019Trade in Allowance1(\$7,000.00)(\$7,000.00)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: Artis zeego C-Arm Artis zeego C-Arm Serial Number: 135746 Manufacturer: SIEMENS MEDICAL SOLUTIONS USA INC					
	Trade-In authorizat	ion number:	113251			
	Trade-In Value:		\$7,000.00			

De-install Date:

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 deidentified 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.

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 deinstalled.

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

Promotion Name	Description
IGTS Non-Philips Trade-in Promo Q3 2020	Philips is pleased to offer this special, one-time \$25,000 promotional discount on purchases of new Azurion systems for customers trading in a non-Philips interventional x-ray system. To receive this discount, orders must be received by September 30, 2020.

	NET PRICE		\$1,036,005.52	
Buying Group:	VIZIENT SUPPLY LLC	Contract #:	XR0312 CV	
and any specific	The specific Contract # referenced above re and any specific terms and conditions, inclu solution will reference a specific Buying Grou terms and conditions which will apply to that d Conditions of Sale will apply to the quoted	ding the Vendor's Terms a p/Contract Number repressingle quoted solution. If r	and Conditions of Sale (subj enting an agreement contai	ect to such Contract), ining discounts, fees
	system listed on purchase order/orders repre- is to be individually billed and paid.	esents a separate and dis	inct financial transaction. V	Ve understand and agree that
Price above of	loes not include any applicable sale	s taxes.		
The prelimina	ry delivery request date for this equ	ipment is:		
If you do not	issue formal purchase orders indica	te by initialing here_	·	
Tax Status:				
Taxable	Tax Exempt			
If Exempt, ple the certificate	ease indicate the Exemption Certifica.	ation Number:		, and attach a copy of
Delivery/Insta	Illation Address:	Invoice Ad	dress:	
Contact Phor		Contact Pt	ione #:	
Purchaser ap	proval 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.

OPTIONS

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

Line # Part #	Description	Qtv	Each	Price	Initial
	Description	ary	Luon	11100	minuai

1 **989801220158 Mark 7 Arterion, Table Mount 1 \$24,396.00 \$24,396.00 ____

The Mark 7 Arterion Injection System is the latest in MEDRAD's "Mark" series of angiographic injectors. Compared to earlier systems, the Mark 7 Arterion injector head is lighter and easier to use so you can focus more on the patient.

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

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

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

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

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

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

System Specifications:

- Flow Rate 0.1-45.0 ml/s in 0.1 ml increments
- 0.1-59.9 ml/m in 0.1 ml increments
- Volume 1-150 ml in 1 ml increments
- Pressure Limit 100-1200 psi in 1 psi increments
- (150ml syringe) 689-8273 kPa in 1 kPa increments
- Rise Time 0.0-9.9 seconds in 0.1 increments
- Delay Time 0.0-99.9 seconds in 0.1 increments
- Fill Speed 1-20 ml/s
- Fill Volume 1-150 ml
- Syringe Size 150 ml
- Syringe Heat Maintainer 35 °C (95 °F) ± 5 °C (9 °F)
- Protocol Memory 40 Protocols
- Injection Memory History

PHILIPS PRODUCT WARRANTY

Interventional X-RAY (IXR) Systems Product Warranty

This product warranty document is an addition to the terms and conditions set forth in the quotation to which this warranty document is attached. Unless specifically listed below, this warranty does not apply to replacement parts. The terms and conditions of the quotation are incorporated into this warranty document. The capitalized terms herein have the same meaning as set forth in the quotation.

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

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

Planned Maintenance.

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

3. System Options, Upgrades or Accessories.

3.1 Any Philips' authorized options, upgrades, or accessories for the System which are delivered and/or installed on the System during the original term of the System warranty shall be subject to the same warranty terms contained in the first paragraph of this warranty, except that such warranty shall expire on the later of 3.1.1 upon termination of the initial twelve (12) month warranty period for the System on which the option or accessory is installed,

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

4. MRC X-Ray Tubes

4.1 Philips warrants to Customer, for the warranty periods further specified in this section, that the Philips' X-Ray tubes (tubes) will be substantially free from defects in material and manufacturing workmanship, which impair performance under normal use as specified in Philips' System descriptions and specifications. 4.2 The warranty period for MRC Tubes provided with Customer's purchase of a new or refurbished X-Ray system shall be the shorter of thirty-six (36) months after installation or

thirty-eight (38) months after date of shipment from Philips.

4.3 The warranty period for purchases of replacement tubes shall be the shorter of twelve (12) months after installation or fourteen (14) months after date of shipment from Philips.

5. MRC Tube Warranty Exclusions

5.1 The above warranty shall not apply to X-Ray Tubes outside the United States and Canada. 5.2 Philips' obligations under the System warranty do not apply to any System defects resulting from: improper or inadequate maintenance or calibration by Customer or its agents; Customer or third party supplied software, interfaces, or supplies; use or operation of the System other than in accordance with Philips' applicable System specifications and written instructions; improper site preparation; abuse, negligence, accident, loss or damage in transit, unauthorized maintenance or modifications to the System; or, to viruses or similar software interference resulting from the connection of the System to a network.

6. MRC Tube Warranty Remedies

6.1 If a tube is found to fail during the warranty period, and if, in the best judgment of Philips, the failure is not due to neglect, accident, improper installation, use contrary to instructions, or the exclusions stated above, Philips' tube warranty liability hereunder is limited to, at Philips' option, the repair or replacement of the tube.

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

7. Dynamic Flat Detectors

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

7.2 Claims must be made within twelve (12) months after installation or fifteen (15) months after date of shipment from Philips, whichever occurs first. 7.3 If a detector fails to meet this warranty, as Customer's sole and exclusive remedy, upon return of the detector, Philips will provide Customer a replacement detector at no additional charge.

8. <u>System Software and Software Updates</u> 8.1 The software provided with the System will be the latest version of the standard software available for that System as of the ninetieth (90th) day prior to the date the System is delivered to Customer.

8.2 Updates to standard software for the System that do not require additional hardware or equipment modifications will be performed as a part of normal warranty service during the term of the warranty.

8.3 All software is and shall remain the sole property of Philips or its software suppliers.8.4 Use of the software is subject to the terms of a separate software license agreement. Customer must sign all such license agreements prior to or upon the delivery of the product. 8.5 No license or other right is granted to Customer or to any other party to use the software except as set forth in the license agreements.

8.6 Any Philips maintenance or service software and documentation provided with the System and/or located at Customer's premises is intended solely to assist Philips and its authorized agents to install and to test the System, to assist Philips and its authorized agents to maintain and to service the System under a separate support agreement with Customer, or to permit Customer to maintain and service the System.

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

9. <u>Warranty Limitations</u> 9.1 Philips' sole obligations and Customer's exclusive remedy under any product warranty are limited, at Philips option, to the repair or the replacement of the product or a portion thereof, within thirty (30) days after receipt of written notice of such material breach from Customer (Product Warranty Cure Period) or, upon expiration of the Product Warranty Cure Period, to a refund of a portion of the purchase price paid by the Customer upon Customer's request. 9.2 Any refund will be paid, to the Customer when the product is returned to Philips.

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

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

9.4.1 is to be installed by authorized Philips' representitives (or is to be installed in accordance with all Philips' installation instructions by personnel trained by Philips); 9.4.2 is to be operated exclusively by duly qualified personnel in a safe and reasonable manner in accordance with Philips' written instructions and for the purpose for which the products were intended; and

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

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

9.6 Philips does not provide a warranty for any third party products furnished to Customer by Philips under this quotation; however, Philips shall use reasonable efforts to extend to Customer the third party warranty for the product. 9.7 The obligations of Philips described herein are Philips' only obligations and Customer's sole and exclusive remedy for a breach of a warranty.

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

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

10. Philips' Remote Services Network (RSN) 10.1 Customer will

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

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

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

1.2. Customer's failure to provide such access will constitute Customer's waiver of the scheduled planned maintenance service and will void support or warranty coverage of product malfunctions until such time as planned maintenance service is completed or RSN access is provided. 10.3 Customer agrees to pay Philips at the prevailing demand service rates for all time spent by Philips' service personnel waiting for extended coverage.

11. Transfer of System

11.1 In the event Customer transfers or relocates the System, all obligations under this warranty will terminate unless Customer receives the prior written consent of Philips for the transfer or relocation.

11.2 Upon any transfer or relocation, the System must be inspected and certified by Philips as being free from all defects in material, software and workmanship and as being in compliance with all technical and performance specifications. 11.3 Customer will compensate Philips for these services at the prevailing service rates in effect as of the date the inspection is performed.

11.4 Any System which is transported intact to pre-approved locations and is maintained as originally installed in mobile configurations will remain covered by this warranty.

12. Limitation of Liability 12.1 THE TOTAL LIABILITY, IF ANY, OF PHILIPS AND ITS AFFILIATES FOR ALL DAMAGES AND BASED ON ALL CLAIMS, WHETHER ARISING OR RELATING TO BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING FROM A PRODUCT, LICENSED SOFTWARE, AND/OR SERVICE IS LIMITED TO THE PRICE PAID HEREUNDER FOR THE PRODUCT, LICENSED SOFTWARE, OR SERVICE GIVING RISE TO THE LIABILITY. 12.2 THIS LIMITATION SHALL NOT APPLY TO:

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

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

12.2.3 OUT OF POCKET COSTS INCURRED BY CUSTOMER TO PROVIDE PATIENT NOTIFICATIONS, REQUIRED BY LAW, TO THE EXTENT SUCH NOTICES ARE CAUSED BY PHILIPS' UNAUTHORIZED DISCLOSURE OF PHI; and; 12.2.4 FINES/PENALTIES LEVIED AGAINST CUSTOMER BY GOVERNMENT AGENCIES CITING PHILIPS' UNAUTHORIZED DISCLOSURE OF PHI AS THE BASIS OF

THE FINE/PENALTY, ANY SUCH FINES OR PENALTIES SHALL CONSTITUTE DIRECT DAMAGES,

13. Disclaimer

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

14. FORCE MAJEURE

14.1 Philips and Customer shall each be excused from performing its obligations (except for payment obligations) arising from any delay or default caused by events beyond its reasonable control including, but not limited to: acts of God, acts of third parties, acts of any civil or military authority, fire, floods, war, embargoes, labor disputes, acts of sabotage, riots, accidents, delays of carriers, subcontractors or suppliers, voluntary or mandatory compliance with any government act, regulation or mandatory direction, request, shortage of labor, materials or manufacturing facilities. For clarity, Customer requests shall not be considered 'government' under this section.

Philips' system specifications are subject to change without notice

Non Disclosure Agreement for Philips Confidential Pricing Information

The parties specified below agree to the following terms:

A. Philips

Β.

Name Philips Healthcare, a division of Philips North America LLC					
	Address	22100 Bothell-Everett Highway, Bothell, WA 98021 United States of America			
3.	Company				

Name ALAMANCE REGIONAL MEDICAL CENTER		ALAMANCE REGIONAL MEDICAL CENTER
	Address	1240 HUFFMAN MILL RD BURLINGTON, NC 27215-8700
l		

C. Confidential Information

Authorized Purpose To evaluate Philips' confidential information relating to pricing for imaging equipment ("Pricing") in connection v		
	the potential purchase of such imaging equipment.	
Period	Begins on the date Pricing is first disclosed and continues for 5 years from date Pricing is last disclosed.	

D.

Philips Contact		Company Contact
Name	Christopher Starnes	Name
Title		Title
Telephone	(803) 504-1412	Telephone
Fax	(855) 890-2822	Fax
e-mail		e-mail
Signature		Signature

1. The following terms and conditions (the "Agreement") apply to Pricing disclosed by Philips and its Affiliates ("Philips") to Company and its Affiliates ("Company"), in connection with the Authorized Purpose.

(a) Subject to Philips' prior written consent, Company may disclose, or request that Philips disclose, Pricing to Company's Affiliates that need to know the Pricing for carrying out the Authorized Purpose, provided they are advised of and agree to be bound by this Agreement. Company is responsible for any breach of this Agreement by its Affiliates.

(b) An Affiliate is any corporation, company, or other entity, that: (i) is under the Control of a party hereto; or (ii) has Control of a party hereto; or (iii) is under common Control with a party hereto. For this purpose "Control" means that more than fifty percent (50%) of the controlled entity's shares or ownership interest representing the right to make decisions for such are owned or controlled, directly or indirectly, by the controlling entity.

- 2. Philips may disclose Pricing to Company with respect to the Authorized Purpose in writing, orally, or otherwise. All information is assumed to be Pricing, and confidential, if the confidential or proprietary nature is reasonable under the circumstances.
- 3.All Pricing disclosed by Philips shall remain Philips' the property. Company does not, by implication, estoppel, or otherwise, acquire any intellectual property right, title, or ownership, nor a license to any such intellectual property right, with respect to any Pricing disclosed by Philips hereunder.

ALL PRICING IS PROVIDED ON AN "AS IS" BASIS, WITHOUT ANY WARRANTY WHATSOEVER. PHILIPS SHALL HAVE NO LIABILITY WHATSOEVER RESULTING FROM THE USE OF THE INFORMATION PROVIDED.

Company shall:

- (a) not use the Pricing for any purpose other than the Authorized Purpose;
- (b) not disclose the Pricing to any third party;
- protect the Pricing against disclosure in the same manner and with the same degree of care with which Company protects its own (c) confidential information but not less than a reasonable degree of care; and

(d) limit circulation of the Pricing to Company's employees as have a need to know in connection with the Authorized Purpose. These obligations shall survive the termination of this Agreement. Philips may terminate this Agreement at any time by means of a written notice to Company. Company shall return to Philips, or certify destruction of, all Pricing, immediately upon termination or expiration of this Agreement.

- 5. Information disclosed by Philips to Company pursuant to this Agreement shall not be confidential to the extent that the information:
 - (a) is or becomes part of the public domain without violation of this Agreement or any other obligation of confidentiality;
 - (b) is known by Company prior to disclosure by Philips;
 - (c) is lawfully obtained by Company from a third party without any breach of confidentiality or violation of law; or
 - (d) is developed by Company completely independently of any such disclosure by Philips.
- 6. If Company is required, pursuant to administrative or judicial action or subpoena, to disclose the Pricing, Company shall use its best efforts to maintain the confidentiality of the Pricing, e.g. by asserting in such action any applicable privileges. Immediately after gaining knowledge or receiving notice of such action or subpoena, Company shall notify Philips and give Philips the opportunity to seek any other legal remedies so as to maintain such Pricing in confidence, including a reasonable protective order.
- 7. Company may not transfer or assign any or all of its rights and/or obligations or delegate the performance of any or all of its obligations under this Agreement, directly or indirectly, through acquisition, merger or otherwise, without the prior written consent of Philips. Any transfer, assignment or delegation in contravention of the foregoing shall be void.

8. Company shall not disclose, export or release the Pricing in contravention of any applicable laws or regulations.

- 9. This Agreement shall be governed and construed in accordance with the laws of the State of New York, without giving effect to its conflict of laws provisions.
- 10. This Agreement contains the entire understanding of the parties and supersedes any previous understandings or agreements with respect to the subject matter hereof. This Agreement may be amended only in writing signed by authorized representatives of each party.

Pricing NDA ver1 - 8/9/07

Attachment 4 Documentation of Use North Carolina Department of Health and Human Services Division of Health Service Regulation Acute and Home Care Licensure and Certification Section Regular Mail: 1205 Umstead Drive 2712 Mail Service Center Raleigh, North Carolina 27699-2712 Overnight UPS and FedEx only: 1205 Umstead Drive Raleigh, North Carolina 27603 Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use On	ly		
License # H0272		Medicare #	340070
FID #: 954565			
PC	Date _		

License Fee:

\$4,715.00

2020 HOSPITAL LICENSE RENEWAL APPLICATION

Legal Identity of Applicant: <u>Alamance Regional Medical Center, Inc.</u> (Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As

(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

	lamance Regional Medical Center
Other:	
Other:	
Facility Mailing Add	ess: PO Box 202
	Burlington, NC 27216-0202
Facility Site Address	1240 Huffman Mill Rd
Country	Burlington, NC27215 Alamance
County:	(336)538-7450
Telephone: Fax:	(336)538-7425
Administrator/Dir	ector: Preston Hammock- Vicki Moran
Title: <u>President</u>	Interim President
	vidual) responsible to the governing body (owner) for the management of the licensed facility)
Chief Executive O	ficer: Terrence B. Akin Title: CEO
	ridual) responsible to the governing body (owner) for the management of the licensed facility)
Name of the person t	contact for any questions regarding this form:
Name: Melissa K.	Shearer Telephone: 336.663.5600

E-Mail: melissa.shearer@conehealth.com

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

g. Positron Emission Tomography (PET). Campus - if multiple sites: Alamance Regional Medical Center - Main Campus

	Number	Number of Procedures*		
	of Units	Inpatient	Outpatient	Total
Dedicated Fixed PET Scanner	1	16	828	844
Mobile PET Scanner	0			
PET pursuant to Policy AC-3	0			
Other PET Scanners used for Human Research only	0			

* PET procedure means a single discrete study of one patient involving one or more PET scans. PET scan means an imagescanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. The number of PET procedures in this table should match the number of patients reported on the PET Patient Origin Table on page 31.

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

CON Project ID numbers for all non-grandfathered fixed PET scanners on this campus: G-7738-06

Does the hospital own a mobile PET scanner that performed procedures on this campus? Yes X No

If Yes, enter the CON Project ID number(s) for the mobile scanner(s):

If No, name of Mobile PET Provider, if any:

h. Other Imaging Equipment. Campus - if multiple sites: Alamance Regional Medical Center - Main Campus

	Number of	Number of Procedures		
	Units	Inpatient	Outpatient	Total
Ultrasound equipment	6	2,719	10,689	13,408
Mammography equipment	3	9	32,109	32,118
Bone Density Equipment	1	0	1,517	1,517
Fixed X-ray Equipment (excluding fluoroscopic)	3	14,080	33,868	47,948
Fixed Fluoroscopic X-ray Equipment	3	1,051	6,103	7,154
Special Procedures/ Angiography Equipment (neuro & vascular, but not including cardiac cath.)	1	1,525	2,737	<mark>4,262</mark>
Coincidence Camera				
Mobile Coincidence Camera. Vendor:				
SPECT	2	61	633	694
Mobile SPECT. Vendor:				
Gamma Camera	2	121	688	809
Mobile Gamma Camera. Vendor:				
Proton Therapy equipment				

i. Lithotripsy. Campus – if multiple sites: Alamance Regional Medical Center – Main Campus

Number		Number of Procedures		
of Units	Inpatient	Outpatient	Total	
Fixed	0			
Mobile	1	7	101	108

Lithotripsy Vendor/Owner Piedmont Stone Center

From:	Flores, Disraeliza
To:	Waller, Martha K
Subject:	FW: [External] CON Exemption Letter for Alamance Regional Medical Center Vascular Lab
Date:	Wednesday, September 23, 2020 12:02:06 PM
Attachments:	ARMC Vascular Lab Exemption Request.pdf
Importance:	High

Disraeliza Flores Adminstrative Assistantant Division of Health Service Regulation North Carolina Department of Health and Human Services

919-855-3872 office disraeliza.flores@dhhs.nc.gov

809 Ruggles Drive Raleigh NC, 27603

2704 Mail Service Center Raleigh, NC 27699-2704

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From: Sanders, Frederick <frederick.sanders@conehealth.com>
Sent: Wednesday, September 23, 2020 11:44 AM
To: Flores, Disraeliza <Disraeliza.Flores@dhhs.nc.gov>
Subject: [External] CON Exemption Letter for Alamance Regional Medical Center Vascular Lab
Importance: High

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Good morning, Lisa:

Please find attached a Certificate of Need Exemption Request for an equipment replacement in the Vascular Lab at Alamance Regional Medical Center. Feel free to contact me should you have any questions.

Warmest Regards,

Fred Sanders

Frederick L. Sanders, MBA Cone Health | Strategy & Planning Planning Manager Direct Dial: 336.663.5607 | Fax: 336.663.5611 Website: conehealth.com

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