NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

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

August 29, 2019

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

Exempt from Review – Replacement Equipment

Record #:	**3030**
Facility Name:	Carolinas Medical Center
FID #:	943070
Business Name:	The Charlotte-Mecklenburg Hospital Authority
Business #:	1770
Project Description:	Replace existing cardiac catheterization equipment in CMC's Cardiac Catheterization Lab #8 in Room 04H104 and renovate cardiac catheterization suite
County:	Mecklenburg

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of August 23, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Philips Azurion 3 M15 to replace the Toshiba Infinix Bi-plane (serial #99E08Y2974). 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, Radiation Protection, and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

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

Sincerely,

Julie M. Faenza
Project Analyst

Martha J. Frisone
Chief

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

Atrium Health

August 23, 2019

Ms. Martha Frisone, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health & Human Services
809 Ruggles Drive
Raleigh, NC 27603

RE: Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center ("CMC") to Replace Cardiac Catheterization Equipment and Renovate the Cardiac Catheterization Suite on the Fourth Floor of CMC

Dear Ms. Frisone:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center ("CMC"), seeks to acquire a Philips Azurion 3 M15 ("Replacement Equipment"). Please see Attachment A for a copy of CMC's current hospital license. The Replacement Equipment will replace CMC's current Toshiba Infinix Bi-Plane ("Existing Equipment") which is near the end of its useful life and is at risk for service interruptions due to downtime. The Existing Equipment is currently housed in Cardiac Catheterization Lab #8 in room 04H104 on the fourth floor of the main hospital building on CMC's main campus located at 1000 Blythe Boulevard in Charlotte, NC 28203 (see Attachment B).

The proposed project also includes the replacement of the existing Carto 2 3D mapping system that is currently located in Cardiac Catheterization Lab #8 with a Carto 3 3D mapping system. The existing Carto 2 3D mapping system has not been upgraded since 2012 and is no longer suitable to support advanced, complex ablation procedures in Cardiac Catheterization Lab #8. Quotes for the Replacement Equipment and Carto 3 3D mapping system are provided in Attachment C.

As part of this project, CMC also plans to renovate Cardiac Catheterization Lab #8 and the surrounding suite located on the fourth floor. Cardiac Catheterization Lab #8 will undergo several infrastructure and aesthetic upgrades, including reconfiguring the walls within the cardiac catherization lab, relocating power panels and medical gas, replacing existing cabinetry with stainless steel cabinetry, and installing additional framing to the existing overhead support structure. The proposed project also involves renovations to the area surrounding Cardiac Catheterization Lab #8, including installing a new door between the cardiac catheterization lab and the control room for infection prevention, adding controlled access doorways at the two entrance points into the cardiac catheterization suite, converting an existing environmental services closet into a soiled utility room, and converting unused holding bays into a rated storage room for equipment.

The purpose of this letter is to provide the Agency with notice and to request a determination that CMC's purchase of the Replacement Equipment is exempt from Certificate of Need ("CON") review under the replacement equipment exemption provisions contained in Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6 (which are codified at N.C. Gen. Stat. 131E-184(f)(1)-(3)).

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of "replacement equipment," defined as follows in the CON law:

> "Replacement equipment" means equipment that costs less than two million dollars ($2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

See N.C. Gen. Stat. 131E-176(22a). Under the new provisions found at N.C. Gen. Stat. 131E-184(f)(1)-(3), the CON law provides:

> (f) The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the two million dollar ($2,000,000) threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:
>
> (1) The equipment being replaced is located on the main campus.
> (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
> (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

See Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6. The term "main campus" was defined in Session Law 2013-360, Section 13G.3(a) (codified N.C. Gen. Stat. 131E-176(14n)) as follows:

> (14n) "Main campus" means all of the following for the purposes of G.S. 131E-184(f) and (g) only:
>
> a. The site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building.
> b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

The Existing Equipment is currently located on the fourth floor of CMC's main hospital building located at 1000 Blythe Boulevard, Charlotte, NC 28203, which is the site from which CMC provides clinical patient services and exercises financial and administrative control over the entire facility (see Attachment B). CMC's President's office is located on the second floor of the main hospital building. Please see a copy of CMC's license in Attachment A.

In addition to the foregoing, to qualify for this exemption, the replacement equipment must be "comparable" to the equipment it replaces and the equipment being replaced must be "sold or otherwise disposed of when replaced." CMC's proposal qualifies for this exemption.

A. Cost of the Replacement Equipment

The purchase price of the Replacement Equipment is $1,136,105 ($1,057,258 Cardiac Catheterization Equipment & Carto 3 3D Mapping System + $78,847 Tax). Quotes for the Replacement Equipment and Carto 3 3D mapping system are provided in Attachment C. The projected total capital cost of the project is $2,310,617 (including taxes and freight) and includes the removal of the existing equipment and installation of the Replacement Equipment. The projected total capital cost of the project also includes the infrastructure and aesthetic renovations to Cardiac Catheterization Lab #8 and the surrounding suite. The total capital cost schedule for the installation of the new equipment as well as the renovations to Cardiac Catheterization Lab #8 and the surrounding suite is provided in Attachment D.

B. Equipment Being Replaced is Located on the Main Campus

The Existing Equipment is currently located in room 04H104 on the fourth floor of the main hospital building on CMC's main campus (see Attachment B). The Replacement Equipment will be located in the same location as the Existing Equipment (see Attachment B).

C. Certificate of Need Issued for Equipment Being Replaced

This proposal also fits within the exemption criterion in Section 131E-184(f)(2) because the Agency previously issued an exemption request for the Existing Equipment (see Attachment E). The Existing Equipment was originally purchased in 2009. In 2015, the Agency approved a subsequent exemption request ('The 2015 Exemption Request') submitted by CMHA d/b/a CMC to replace the equipment in Cardiac Catheterization Lab #8 (room 04H104) and relocate it to Pediatric Cardiac Catheterization Lab #2 on the sixth floor (see Attachment F). As part of the 2015 Exemption Request, the Existing Equipment was sold to the vendor then repurchased by CMHA for less than $750,000 and reinstalled in room 04H104. Once reinstalled, the Existing Equipment was no longer licensed cardiac catheterization equipment and was therefore only used to perform EP procedures; not cardiac catheterization. In 2017, the Agency approved a material compliance request that transferred the CON rights from Atrium Health University City's one cardiac catheterization lab to the Existing Equipment located in room 04H104 at CMC, once again making it a licensed cardiac

catheterization lab. Please see Attachment G for the Agency's approval of the material compliance request.

D. Comparable Equipment

The CON rule codified as 10A N.C.A.C. 14C.0303 (the "Regulation") defines "comparable medical equipment" in subsection (c) as follows:

> "Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

CMC intends to use the Replacement Equipment for substantially the same cardiac catheterization procedures for which it currently uses the Existing Equipment. The Existing Equipment is a Toshiba Infinix Bi-Plane that was installed new in 2009. Since 2009, the Existing Equipment has been used for cardiac catheterization procedures during the time periods for which it held the CON rights to do so.

The Replacement Equipment will perform all procedures currently performed on the Existing Equipment. Although it possesses some expanded capabilities due to technological improvements, the Replacement Equipment will perform the same cardiac catheterization procedures (see Attachment H for the Equipment Brochure). The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c).

Furthermore, CMC does not intend to increase patient charges or per procedure operating expenses within the first 12 months after equipment acquisition. For further equipment comparison, please refer to Attachment I, the Equipment Comparison Chart.

Subsection (d) of the regulation further provides:

(1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
(2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
(3) the acquisition of the equipment does not result in more than a 10.0 percent increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

The Replacement Equipment will meet all three of tests set out in Subsection (d). The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Chart (Attachment I). Moreover, CMC represents the use of the Replacement Equipment will not result in the types of expense or charge increases described in Subsection (d)(3).

Documentation provided in Attachment J indicates that 399 procedures were performed from August 2018 to July 2019 on the Existing Equipment.

E. Disposition of Equipment

Please see Attachment I for a letter documenting the Existing Equipment will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate certificate of need approval.

CONCLUSION:

Based on the foregoing information, CMC hereby requests that the Agency provide a written response confirming that the acquisition of the Replacement Equipment and the infrastructure and aesthetic renovations to Cardiac Catheterization Lab #8 and the surrounding suite described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please let us know.

Thank you for your consideration of this notice.

Sincerely,

Elizabeth V. Kirkman
Assistant Vice President
Atrium Health Strategic Services Group

Attachments

cc: Vicki Block, Senior Vice President, Market President – Central Division

Attachment A

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Effective January 01, 2019, this license is issued to

The Charlotte-Mecklenburg Hospital Authority

to operate a hospital known as

Carolinas Medical Center/Center for Mental Health

located in Charlotte, North Carolina, Mecklenburg County.

This license is issued subject to the statutes of the State of North Carolina, is not transferable and shall remain in effect until amended by the issuing agency.

Facility ID: 943070

License Number: H0071

Bed Capacity: *1211*

General Acute 1055, Rehabilitation 13 , Psych 132, Substance Abuse 11,

Dedicated Inpatient Surgical Operating Rooms: 10
Dedicated Ambulatory Surgical Operating Rooms: 11
Shared Surgical Operating Rooms: 41
Dedicated Endoscopy Rooms: 12

Authorized by:

Secretary, N.C. Department of Health and Human Services

Director, Division of Health Service Regulation

Attachment B

COLOR KEY

- EXISTING BUILDING
- CARDIAC CATH - 752 SF
- RENOVATION - 768 SF
- UNDERGROUND WALKWAY

SITE PLAN

ATRIUM HEALTH

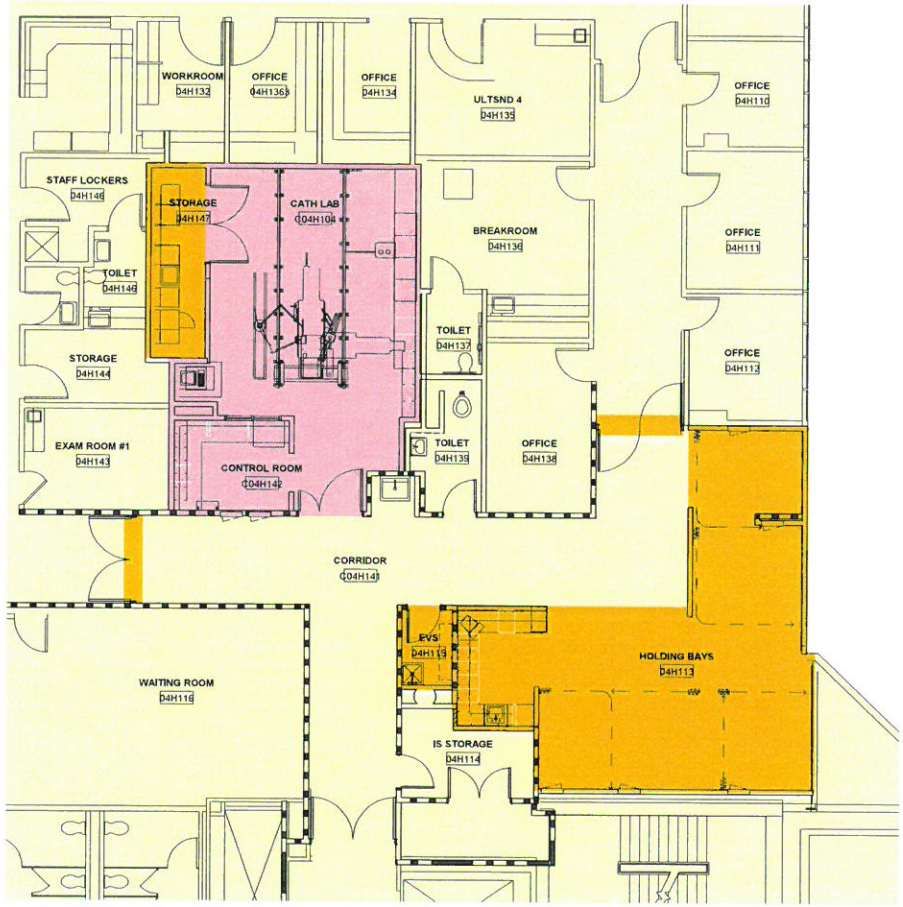
08/19/2019

Cardiac Cath Lab 8 & Additional Scope

Carolinas Medical Center

CON COLOR KEY

- EXISTING BUILDING
- CARDIAC CATH - 752 SF
- RENOVATION - 768 SF



ENLARGED EXISTING LEVEL 04 PLAN

Cardiac Cath Lab 8 & Additional Scope

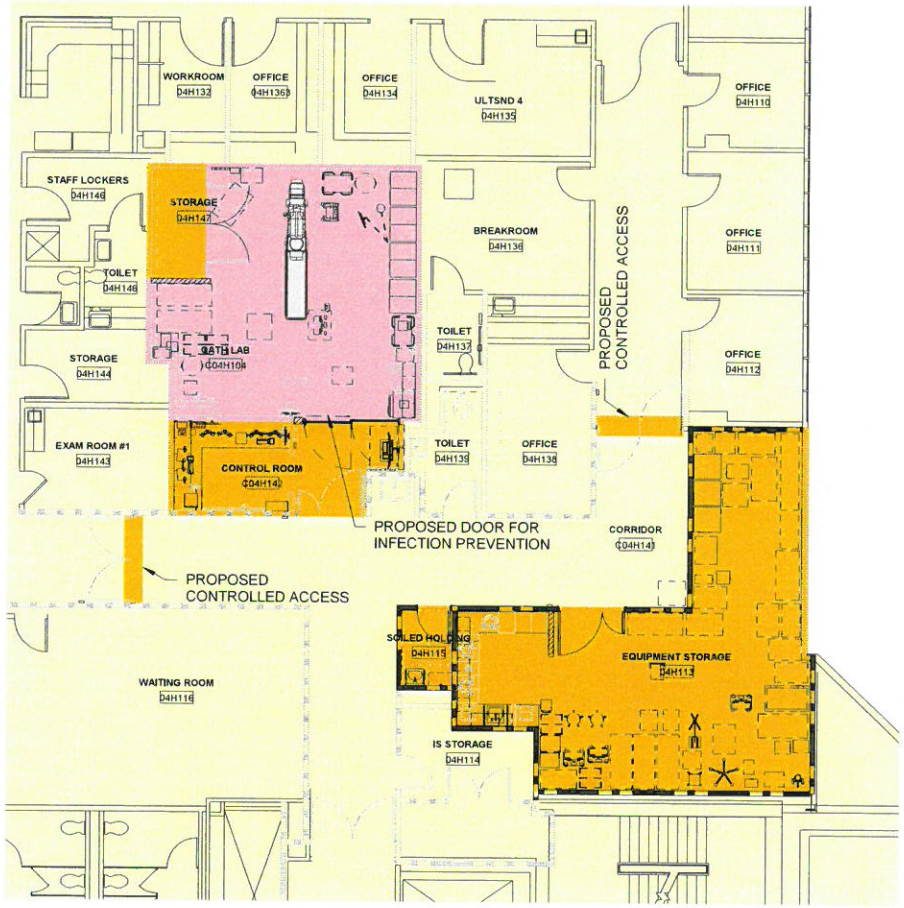
ATRIUM HEALTH

08/19/2019

Carolinas Medical Center

CON COLOR KEY

- EXISTING BUILDING
- CARDIAC CATH - 752 SF
- RENOVATION - 768 SF



ENLARGED PROPOSED LEVEL 04 PLAN

ATRIUM HEALTH

08/19/2019

Cardiac Cath Lab 8 & Additional Scope

Carolinas Medical Center

Attachment C

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

PHILIPS

Quotation #: 1-210BNAT	**Rev:** 5	**Effective From:** 15-Jul-19	**To:** 13-Sep-19

Presented To:

ATRIUM HEALTH'S CAROLINAS MEDICAL CENTER
1000 BLYTHE BLVD
CHARLOTTE, NC 28203-5871

Tel:

Alternate Address:

Presented By:

Kimberly Bates
Account Manager
Tel: (704) 577-2484
Fax:

John Hill
Regional Manager
Tel: (800) 722-7900 x6806
Fax:

Date Printed: 15-Jul-19

Submit Orders To:

22100 BOTHELL EVERETT HWY
BOTHELL WA 98021

Tel: (888) 564-8643 Fax: (425) 458-0390

IMPORTANT NOTICE: Health care providers are reminded that if the transactions herein include or involve a loan or discount (including a rebate or other price reduction), they must fully and accurately report such loan or discount on cost reports or other applicable reports or claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, such as may be required by state or federal law, including but not limited to 42 CFR 1001.952(h).

Quote Solution Summary

Line #	Product	Qty	Price
	100232 Azurion 3 M15	1	$856,099.20
		Equipment Total:	$856,099.20

Solution Summary Detail

Product	Qty	Each	Monthly	Price
100232 Azurion 3 M15	1	$856,099.20		$856,099.20

Buying Group: **CAROLINAS HEALTHCARE SYSTEM SCA** **Contract #:** **CAA0013200**

Addt'l Terms:

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

Payment Terms: 0% Down, 80% Upon Delivery, 20% Due When the Product is Available for First Patient Use, Net due 30 days from date of invoice

Quote Summary

100232 Azurion 3 M15

Qty	Product
1	NNAE762 Azurion 3 F15
2	FCV0812 live/ref slaving for ER
3	FCV0809 addl 27" LCD Exam Room
10	FCV0588 Isolated Wall Connection Box
2	FCV0824 video WCB on rear side 1st MCS
1	NCVA089 RIS / CIS DICOM interface
1	NCVD067 ClarityIQ
1	NCVD099 Quantitative Coronary Analysis
1	NCVD095 checklists & protocols
1	NCVA780 Digital subtracted Angio
1	NCVD029 FlexVision XL
1	NCVD052 addl integr. for 2F 3rd p boom
1	NCVD138 table tilt option
1	NCVD078 FD Dual Fluoro monoplane
1	NCVA258 CO2 VIEW TRACE
1	NCVD128 storage extension
1	NCVA851 Swivel for table base.
1	NCVD072 SmartMask Monoplane
1	NCVD088 system & table APC
1	NCVD089 Zero Dose Positioning
1	FCV0248 Set of arm supports
2	FCV0589 Legacy Video Convertor
1	FCV0833 DVI splitter
1	459800938361 Clip rails for MCC (390cm)
1	459800706722 MONITOR CEILING CARRIAGE
1	FCV0510 Long mattress cardio
1	980406041009 Rad Shield w/ Arm (Contoured) 61X76
1	989801220012 Cable Spooler
1	989801220068 10 Meter DVI Cable Set
1	989801220273 Ceiling Track w/Column & Handle Ext
4	989801220375 Black Anti-fatigue Floor Mat w/logo.
1	989801220385 Mavig Fixed Column
1	989801220388 Lower Body Protection

Quote Summary

100232 Azurion 3 M15

Qty	Product
1	NCVC005 Equipment Rack DVI
1	989600207421 Equipment rack Predelivery set
1	NCVC413 Electrical Accessory kit OSC
1	NCVC414 Pre-Install Bracket
1	SP003 Installation Labor
1	SP059R Service Items
1	SP059R Service Items
1	Third Party Item Additional ceiling mounted monitor
1	SP019 Trade in Allowance

100232 Azurion 3 M15

System Type: New
Freight Terms: FOB Destination
Warranty Terms: Part numbers beginning with two (2) asterisks (**) are covered by a System 12 Months Warranty. All other part numbers are third (3rd) party items.
Special Notations: Contingencies must be removed 120 days before scheduled shipment to assure delivery on specified date. Any rigging costs are the responsibility of the Purchaser.
Additional Terms:

Line #	Part #	Description	Qty	Each	Price
1	**NNAE762	Azurion 3 F15	1	$489,856.00	$489,856.00

Multipurpose interventional X-ray suite for cardiac, electrophysiology, neuro and vascular procedures

Key benefits

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

Proven versatility and productivity

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

This robust multipurpose interventional X-ray suite is designed to handle a variety of procedures at an excellent pace. The system with 15 inch detector is developed for mixed use. This future proof solution is designed around a single, standardized hardware and software platform that can be upgraded and expanded as new needs arise or requirements change. Its architecture is made to easily integrate with third party applications and devices. A new workflow approach aims to support interventional teams in carrying out procedures for their patients, consistently and efficiently with great ease of use.

The Philips Azurion 3 Series uses a range of Procedure Cards to help optimize and standardize system set-up for your cases, from routine to mixed procedures.

Procedure Cards can increase the consistency of exams by offering presets (e.g. most-frequently used, default protocols and user-specified settings) on procedure-, physician- or departmental level.

The Philips Azurion 3 Series interventional X-ray suite has been specifically designed to save time by enabling the interventional team to work on all activities in the exam room at the same time - without interrupting each other. This leads to higher throughput and faster exam turnover help to minimize preparation errors.

Specifications

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 3 F15 system comprises five functional building blocks:

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

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

1. Geometry

A. 3 F15 stand

The Philips Azurion F15 stand is a stable assembly of a C-arm and a floor mounted base. The X-ray tube and the flat detector are integrated into the C-arm. This provides a compact assembly with positioning flexibility and easy access to the patient. The robust design ensures excellent reproducibility of projections, needed in for example subtracted imaging procedures and advanced 3D imaging. The base can be rotated allowing a three-sided patient approach.

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

Philips Azurion F15 stand allows a very wide range of projections, including PA and AP imaging.

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

- C-arm rotation range (degrees): 120 LAO to 185 RAO
- C-arm angulation range (degrees): 90 CA to 90 CR (Full angulation capability determined by patient position)

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

- C-arm rotation range (degrees): 90 LAO to 90 RAO
- C-arm angulation range (degrees): 185 CA to 120 CR or 120 CA to 185 CR (Full angulation capability determined by patient position)

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

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

Base rotation movement is motorized and can also be performed manual.

The BodyGuard is a detection system for automatic safeguarding of patient and equipment. This detection system senses objects close to the detector and subsequently limits system movements. Therefore the Philips Azurion F15 adapts to the actual size of the patient and allows taking full advantage of the high speed movements.

The motorized variable source image distance (SID) between focus and Dynamic Flat Detector input screen can be adjusted from 895 to 1195 mm. This allows for excellent patient accessibility, imaging coverage and projection flexibility.

B. Patient Support

The patient support provides very light manual float movement, even for heavy patients, thanks to the mono-bearing technology. The long flat carbon fiber tabletop provides ample space to place e.g. catheters and endovascular tools. On customer request, the standard table top can be replaced by a table top for neuro procedures. This table top has a smaller width at the head end for better imaging results in neuro procedures.

- Table top length of 319 cm, 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 +/- 18 cm transversal
- Motorized height adjustment range is 74 -102 cm cm for a table without swivel nor cradle/tilt.
- Maximum cantilever of 223 cm , for full patient coverage
- Table tilt +17 /-17 degrees (optional)
- Table cradle +15 / -15 degrees (optional)
- Pivot range 270 degrees (-90 to +180 or +90 to -180 degrees), table can be locked at any position and has stops at 0, +/-13, +/- 90 and +/- 180 (optional)
- Table swivel, 78.2 cm longitudinal displacement, motorized (optional).
- Maximum load: 275 kg (up to 250 kg patient weight plus 25kg accessories or 225kg patient weight plus 50kg accessories) plus 500 N for CPR in any longitudinal position of the table top

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

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

- 1 cerebral filter
- 3 rail accessory clamps
- 1 drip stand
- 1 mattress
- Arm Support Board
- Set of Elbow Supports

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.

2. X-ray Generation

A. Generator

100232 Azurion 3 M15

Line #	Part #	Description	Qty	Each	Price

The 3 F15 system comprises an integrated, micro-processor controlled Certeray generator based on high frequency converter technique. The user interface control of this X-ray Generator is incorporated in the touch screen module, review module, and the on-screen displays. The Certeray generator comprises:

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

Program selection:

- Pulsed X-ray up to 3.75 , 7.5 , 15 , 30, 60(optional) frames/s for digital dynamic exposures
- Pulsed X-ray for pulsed fluoroscopy (3.75 , 7.5 , 15 , 25, 30 frames/s).
- Minimum exposure time of 1 ms
- ECG triggered acquisition: allows acquiring one exposure for each QRS peak with selectable delay time
- Automatic kV and mA control for excellent image quality prior to run to save dose
- X-ray tube load incorporated in the Certeray generator

C. X-ray tube

The 3 F15 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:

- 0.4/0.7 mm nominal focal spot values maximal 30 and 65 kW short time load
- Grid switching at pulsed fluoroscopy and low load exposure (to eliminate soft radiation and improve image quality)
- Continuous loadability: 3400 W (at 21 degrees C room temperature) / 4000 W (= Max assembly continuous heat dissipation)
- Application of SpectraBeam dose management
- Tube housing is oil cooled with thermal safety switch
- Maximum anode cooling rate of 1820 kHU/min
- Anode heat storage capacity of 6.4 [MHUeff]

C. System intrinsic

- Fully digital imaging chain in maximizing the utilization and technology of the x-ray generator, x-ray tube, flat detector and image processing.
- Customizable EPX protocols to each application according to user preferences for different composition of dose rate, pulse speed, filter setting, and image processing (noise reduction, adaptive contour enhancement, and adaptive harmonization)
- Built-in SpectraBeam filtering of low energy radiation to improve image quality and dose efficiency with MRC200+ X-ray tubes.
- Pre-filters of 0.2, 0.5 and 1.0 mm CU equivalent
- Automatic cardiac wedge positioning

- X-ray depth collimator with single semi-transparent wedge filter with manual and automatic positioning.
- Xper Beam Shaping, which means that both shutters and wedges can be positioned on the Last image Hold without the need for X-ray radiation.
- Xper Fluoro Storage, a grab function allows storage and archiving of both a fluoro image or the last 20 seconds of fluoroscopy run. These images or runs can be archived and reviewed as a regular run.

D. User selections

- Removable anti-scatter grid to lower x-ray dose for pediatrics (grid ratio 13:1)
- ECG triggered acquisition, offering the possibility to acquire images at the same phase of the heart cycle. This applies to the low dose fluoro and exposure program for EP applications. This allows patient dose reduction by lowering the pulse rate to 1 pulse per heart and let the physician still focus on relevant items
- Three programmable fluoroscopy modes can be selected from the control module. Each mode has a different composition of dose rate, pulse speed, filter setting, and image processing (noise reduction, adaptive contour enhancement, and adaptive harmonization)

Secondary Capture Dose Report

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

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

3. Image Detection

The image chain with the 15 inch flat panel image detector comprises the following:

- A 39 cm (15 in.), 26x33 cm, diagonal 7 mode Dynamic Flat Detector subsystem for fluoroscopy and cine-fluorography.
- 7 modes 11*11/13.5*13.5/16*16/19*19/22*22/26*26/29*26 [cm] Dynamic Flat Detector
- The outer detector physical housing is 39.2 * 33.8 [cm]
- The digital output of the Flat detector is 1420*1560 pixels at 16 bit depth.
- The pixel pitch is 184 micron by 184 micron
- The DQE (0) is 70% providing high conversion of X-ray into a digital image, while maintaining a high MTF.

Philips Azurion offers a storage capacity of (optionally extendable) of 50,000 images at matrix size of 1024 x 1024, in 8 or 10 bit depth. With a matrix size of 2048 x 2048 this is 12,500 images. Maximum number of examinations is 999, with no limit to the maximum number of images per examination.

Xres is a multi-resolution spatial temporal noise reduction and edge enhancement filter for interventional applications. Xres exploits 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
- Detector field size display
- General System messages ()
- Selected Frame speed ()
- Fluoroscopy mode ()
- Integrated fluoroscopy time ()
- Skin Dose: dose rate during X-ray, cumulated dose when no X-ray ()
- Dose Area Product: dose rate during X-ray, cumulated dose when no X-ray ()
- Graphical bars for Body Zone specific dose-rate and accumulated skin dose levels, related to the 2 Gy level (for cardiac applications)
- Stopwatch

Touch screen module

The touch screen module is provided for use at either the tableside or in the control room. The touch screen module has a touch screen, which can be operated when covered with sterile covers. The touch screen module allows control of (depending on configuration):

- 3rd party equipment (e.g. CX50, Interventional Tools, EchoNav, DoseAware)
- -Monitor layout (FlexVision, switchable viewing)
- X-Ray settings (Collimation, Projections, Table, Series and Processing

Viewpad

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

- Run and image selection
- File and run cycle
- File overview
- Store to Reference image file
- Copy image to photo file
- Digital (fixed) zoom and panning

- Recall reference images, which means switching control of Viewpad function from life to reference monitor
- Laser pointer, intended to point at regions of interest on the image monitors
- LED indication of laser pointer on/off and battery low

Control module.

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

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

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

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

Key benefits

- Flexible positioning during cardio and neuro procedures
- Flexible positioning during cardio and neuro procedures

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

Pan handle with cable and connector

Table-top attachment clamp

Accessory-rail attachment clamp

User Interface in Control Room

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

- Power on/off
- File and run cycle
- File, Run, and Image stepping
- Run and file overview
- Reset fluoroscopy timer
- Enable/disable X-ray
- Geo disable

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

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

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

Scheduling

In the scheduling page it is possible to add new patients (either querying from RIS/CIS or by creating patient locally). The patients can be listed and selected per date, physician, and intervention type. Previous DICOM patient studies can be uploaded with the DICOM Query Retrieve function in the Philips Azurion system. Patient management protocols are flexible and allow for multiple studies to be selected under one patient identification number. This means that new studies can be appended to an earlier patient file. Furthermore, each study can contain multiple examinations to allow for split administrative purposes. Each examination contains multiple files, like acquisition file, reference file, and QA results file.

Procedure Cards

Procedure Cards provide the information of room and patient preparation for each individual physician. Procedure Cards are customizable per setting and allow each physician to provide their

own room protocols. Procedure Cards is intended to make hard copies of the protocol instructions redundant.

Acquisition

The acquisition page contains information on the currently selected patient.

Reviewing

The review page allows for reviewing of patients:

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

Archiving

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

With Philips Azurion the control room comprises of an acquisition monitor and a review monitor. The review monitor is a 24 inch color TFT-LCD medical grade monitor.
The Graphical User Interface on the Review monitor has the following features and possibilities:

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

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

5. Viewing

A. Viewing in Examination room

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

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

The main characteristics are:

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

If applicable included is a flat monitor ceiling suspension for 2 monitors (2F MCS). MCS includes motorized height adjustment. The ceiling suspension allows flexible monitor positioning over a range of about 360 x 300 cm.

B. Viewing in Control room

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

The main characteristics for color monitor are:

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

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

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

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

Uninterruptable Power System (UPS)

Ensures data integrity

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

Specifications

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

Remote service

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

Environmental

At Philips Healthcare, we feel the responsibility towards society and the environment. The latest 3 F15 system is a perfect example of our EcoVision program. By examining every aspect of the 3 F15 design and development through a green eye, we drastically reduced the products environmental impact.

Clinical Education Program for Azurion System:

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

Essentials OffSite Education: Philips will provide up to two (2) Cardiovascular Technologists, Registered Technologists, Registered Nurses, or other system operator as selected by customer, with in-depth didactic, tutorial, and hands-on training covering basic functionality and work-flow of the cardiovascular imaging system. In order to provide trainees with the ability to apply all fundamental functioning on their system, and to achieve maximum effectiveness, this class should be attended no earlier than two weeks prior to system installation. This twenty-eight (28) hour

Line #	Part #	Description	Qty	Each	Price

class is located in Cleveland, Ohio, and is scheduled based on your equipment configuration and availability. Due to program updates, the number of class hours is subject to change without notice. Customer will be notified of current, total class hours at the time of registration. This class is a prerequisite to your equipment handover OnSite Education. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. In the event that an EP Navigator workstation has also been ordered, the offsite training course will be tailored to focus on the electrophysiology functionality of the FD system and the EPN workstation. Travel and lodging are not included, but may be purchased through Philips. It is highly recommended that 989801292102 (CV Full Travel Pkg OffSite) is purchased with all OffSite courses

Initial Handover OnSite Education: The primary Philips Education Specialists will provide twenty-eight (28) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. Students should attend all 28 hours, and must include the two OffSite education attendees. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Site must be patient-ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. It is highly recommended for systems that are fully loaded or for customers with a large number of staff members to also purchase 989801292099 (CV Add OnSite Clin Educ 24h).

FollowUp OnSite Education: Philips Education Specialists will provide sixteen (16) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. Students should attend all 16 hours, and must include the two OffSite education attendees. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Site must be patient-ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation.

Assessment OnSite Year 1: The primary Philips Education Specialist will perform a two day onsite assessment at the customer site on or close to the first anniversary of the Initial Handover. The Specialist will assess through various means not limited to; physical observation of procedure workflow, tool usage data analysis and staff interviews. The Specialist will then review findings with department head and make recommendations thereof. The Specialist may perform refresher training if required.

Education expires one (1) year from installation date (or purchase date if sold separately).
Ref#29633929634029634129634 2-20170209

2	**FCV0812	**live/ref slaving for ER**	**2**	**$5,678.20**	**$11,356.40**

Live/ref slaving for Exam Room.

Key benefits

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

Simplify workflow with flexible viewing control

Having patient data and clinical information easily available on screen can enhance decision making and efficiency during interventions. The live/ref slaving will enable the option to slave the Live and Ref video source from the X-ray system. The total amount of live/ref slaving that can be selected is max 5, minus the number of FCV0807 Live/ref slaving for CR.

Specifications

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

100232 Azurion 3 M15

Line #	Part #	Description	Qty	Each	Price
3	**FCV0809	addl 27" LCD Exam Room	3	$3,057.15	$9,171.45

Additional 27 inch high brightness color medical grade LCD monitor.

Key benefits

• Enhance visibility for a variety of procedures

Get a wider view of the situation

Mix and match the widescreen monitors to make efficient use of your lab space. Each monitor can display input from different sources so you can see just what you need for different phases and types of procedures. The high definition color widescreen monitors enhance the visibility of fine details and vital signs.

Specifications

This LCD monitor is intended for viewing in the Examination Room and is designed for medical applications.

The main characteristics are:
- 27 inch high brightness color TFT-LCD display
- Native format 1920x1080 Full HD
- Two DVI inputs to display one or two channels (dual view)
- 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 projection screen

Line #	Part #	Description	Qty	Each	Price
4	**FCV0588	Isolated Wall Connection Box	10	$1,464.05	$14,640.50

Isolated Wall Connection box to support the display of an external video source on a monitor in the examination room.

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

Easily stream video to other locations

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

Specifications

The quantity of the VWCB's has to be calculated as follows:
For each video signal via MultiVision: 1 VWCB (max = 4)
For each video signal to FlexVision XL on Cardio System: 1 VWCB (max = 9)
For each video signal to FlexVision XL on Vascular System: 1 VWCB (max = 8)
For each 3rd party video signal directly connected to an LCD in the MCS: 1x VWCB.

Line #	Part #	Description	Qty	Each	Price

Note:
No VWCB is required in case a video signal is connected directly to a dedicated LCD from the following sources:
1) Live/ref Slaving
2) Interventional HW (XtraVision), IntelliSpace Portal, Philips Xcelera (only if workstations are powered by Philips X-ray system)
3)XperIM

5	**FCV0824	**video WCB on rear side 1st MCS**	2	$5,642.60	$11,285.20

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.

6	**NCVA089	**RIS / CIS DICOM interface**	1	$3,924.90	$3,924.90

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

Key benefits
• Reduce errors in patient information
• Facilitate X-ray dose management

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

If a hospital has an X-ray system and an information system it can receive patient and examination request information from the information system and report examination results to:
• Eliminate the need for retyping patient information on the X-ray system
• Prevent errors in typing patient names and registration numbers (ensuring consistency with IS information to prevent problems in archive clusters or to search for a name in case of later retrieval)
• Inform the information system about the acquired images and radiation dose for each examination

Specifications
Upon request from the X-ray system the complete worklist with all relevant patient and examination data is returned from the IS to the X-ray system. For each patient the following information will be shown on the -ray system after it has been retrieved from the IS:
• Patient Identification: Patient name, Patient ID, Birth date, Sex
• Examination/Request Information: Accession number, Scheduled procedure step start time, scheduled performing physician's name

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

Line #	Part #	Description	Qty	Each	Price

On request of the clinical user the X-ray system will report the following information about the selected patient to the IS:
• Patient Identification: Patient name, Patient ID, Birth date, Sex
• Examination/Request Information: Accession number, Performed procedure step status start/end date and time, Performing physician's name, Referenced image sequence
• Radiation dose: Total time of fluoroscopy, Accumulated fluoroscopy dose, Accumulated exposure dose, Total dose, Total number of exposures, Total number of frames

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

7	**NCVD067	ClarityIQ	1	$88,021.00	$88,021.00

Significantly lower dose- across clinical areas, patients and operators.

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

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

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

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

8	**NCVD099	Quantitative Coronary Analysis	1	$7,209.00	$7,209.00

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

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

Specifications
• Automated segmentation of selected coronary

Line #	Part #	Description	Qty	Each	Price

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

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

9	**NCVD095	checklists & protocols	1	$10,324.00	$10,324.00

Key benefits

- Standardize workflow in the interventional lab to help safeguard the consistency of procedures and help to minimize preparation errors
- Access hospital specific protocols and checklists via the Procedure Cards in the exam and/or control room
- Improve efficiency and quality by importing best practice protocols and checklists from other institutions

Increase consistency of procedures

Interventional workflow can vary greatly between different teams, shifts and types of procedures, leading to errors and potential risk situations. To help standardize working practices in the interventional lab, hospital checklists and/or protocols can be added to the Procedure Cards on the X-ray system and display in the exam and/or control room. These can include hospital specific clinical protocols, room preparation protocols and other checklists. They can be defined by procedure, physician or other criteria, and can include best practice protocols and checklists from other institutions.

Specifications

The user can upload from the USB storage device up to 100MB of own protocols and help files in XPS (Microsoft XML Paper Specification File) format, preview them and link to the procedure cards as so called 'bookmarks'. During the procedure files linked with the selected Procedure card can be viewed on the Review monitor.

10	**NCVA780	Digital subtracted Angio	1	$15,588.35	$15,588.35

Key benefits

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

Supports navigation without the need to use additional contrast

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

Specifications

This option will comprise following functionality:

- Roadmap Pro can be selected from the imaging module and touch screen module. A vessel map is created and superimposed with live fluoroscopy. Acquisition runs can be done during Roadmap without losing the vessel map.
- Roadmap Pro features Smart Settings in special clinical modes that are intended to visualize

Line #	Part #	Description	Qty	Each	Price

special materials such as coil and glue.
- Live Processing of the vessel map, the device map and the landmark map can be done on the touch screen module.
Automatic Motion Compensation" (AMC) functionality; during roadmapping small movements of the patient can lead to subtraction artifacts. These artifacts might conceal important clinical information. Automatic Motion Compensation compensates for rigid uniform (skeletal/table) translations and is therefore very effective in interventional (Neurology) applications where subtraction imaging is applied.
- Exposure subtract on individual image or run basis
- Mask selection
- Average masking during acquisition as additional subtracted IQ improvement
- Landmarking
- Pixel shift

11 ****NCVD029** **FlexVision XL** **1** **$97,188.00** **$97,188.00**

FlexVision XL is an integrated viewing solution designed to give you full control over your viewing environment.

Key benefits

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

Diagnostic information easily made available at table side

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

Specifications

1. DVI video composition unit.

The DVI video composition unit allows the user to direct and switch the video output of all connected medical equipment to specific sub windows of the Philips 58-inch color LCD with LED backlight in the Examination Room.
• The DVI video composition unit is operated from the touch screen module.
• The DVI video composition unit supports a wide variety of display formats (up to 1920x1200)
• Up to 11 external inputs are connected to the DVI video composition unit via wall connection box or boxes.

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

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

Main characteristics are:
- 58-inch, 8 Megapixel color LCD
- Native resolution: 3840x2160
- Brightness: Max: 700 Cd/m2 (typical) stabilized: 400 Cd/m2
- Contrast ratio: 1:4000 (typical)
- Wide viewing angle (approx. 176 degrees)
- Constant brightness stabilization control

Line #	Part #	Description	Qty	Each	Price

- Lookup tables for gray-scale, color and DICOM transfer function
- Full protective screen Ingress Protection: IP-21

3. Large color LCD control (touch screen module)

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

4. Monitor ceiling suspension

Monitor ceiling suspension for use in the Examination Room carries the 58-inch color LCD, providing highly flexible viewing capabilities. The monitor ceiling suspension is height-adjustable and moveable along ceiling rails. It can be positioned on either side of the table.

5. Snapshot

The snapshot function allows the user to store/save a screen-capture of any image on the FlexVision XL as a photo image to the current acquisition patient study.

12	**NCVD052	**addl integr. for 2F 3rd p boom**	1	$6,995.40	$6,995.40

Integration kit to connect 2 monitors in additional 2F 3rd party boom.
Philips does not provide monitor suspension for this option.

13	**NCVD138	**table tilt option**	1	$18,805.70	$18,805.70

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

Key benefits

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

Precise imaging during gravity oriented and puncture procedures

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

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

Specifications

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

14	**NCVD078	**FD Dual Fluoro monoplane**	1	$18,067.00	$18,067.00

Line #	Part #	Description	Qty	Each	Price

An additional fluoro channel in parallel to the standard fluoro channel

Key benefits

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

Second fluoro image to support complex interventions

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

Specifications

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

15	**NCVA258	CO2 VIEW TRACE	1	$2,941.45	$2,941.45

Software package enabling tracing (stacking) of images acquired with CO2 injections. This function can be used during postprocessing next to view trace of images acquired with CO2 injections.

16	**NCVD128	storage extension	1	$5,335.55	$5,335.55

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).

17	**NCVA851	Swivel for table base.	1	$17,194.80	$17,194.80

- Simplifies patient positioning
- Easy patient transfer

Simplifies patient positioning

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

18	**NCVD072	SmartMask Monoplane	1	$11,004.85	$11,004.85

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Line #	Part #	Description	Qty	Each	Price

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

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

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

19	**NCVD088	system & table APC	1	$10,221.65	$10,221.65

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

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

20	**NCVD089	Zero Dose Positioning	1	$8,259.20	$8,259.20

Key benefits
• Manage radiation usage by moving to region of interest on Last Image Hold without fluoro.

ROI positioning without using fluoroscopy
To manage radiation dose, you can move the stand and table to the region of interest shown on the last recorded clinical image before a new acquisition is started, without any radiation.

Specifications
Before a new acquisition is started the operator can move the stand and table to visualize the part of the image that will be irradiated when the next X-ray starts.

21	**FCV0248	Set of arm supports	1	$0.00	$0.00

• Enhances comfort for patient's arms

Comfortable support for patient's arms
These arm supports are designed to support the patient's arms comfortably during examinations and also prevent the patient's arms from hanging over the side of the table.

22	**FCV0589	Legacy Video Convertor	2	$1,459.60	$2,919.20

The Legacy Video Convertor enables conversion from PAL/NTSC towards DVI.

The Legacy Video Convertor enables conversion from VGA towards DVI for supported input resolutions, as listed in the table below.
Signal type Native resolution Image Aspect Ratio
VGA 640x480 4:3
SVGA 800x600 4:3
XGA 1024x768 4:3
SXGA 1280x1024 5:4
SXGA+1400x10504:3
UXGA 1600x1200 4:3

Line #	Part #	Description	Qty	Each	Price
		WXGA 1280x800 16:10 (8:5) WSXGA 1440x900 16:10 (8:5) WSXGA+ 1680x105016:10 (8:5) WUXGA 1920x1200 16:10 (8:5) 2K 2048x1080 19:10 TV1080I/P 1920x1080 16:9 TV 480I 720x480 4:3 TV 480P 704x480 4:3 TV 576I 720x576 4:3 TV 576P 704x576 4:3 TV 720P 1280x720 16:9			
23	**FCV0833	**DVI splitter** The DVI splitter is used to split the video signal coming from a 3rd Party system into two video signals. One video signal will then appear on a monitor and the other signal appears on the large screen. The combination with FCV0832 Bracket DVI splitter SAM is part of the Corindus Kit but an option on the XperIM/FC kit. If XperIM/FC is used with an X-ray system and desires display of Haemo signals both on monitor and large screen, FCV0832 and FCV0833 need to be ordered.	1	$1,717.70	$1,717.70
24	**459800938361	**Clip rails for MCC (390cm)** Comprising: • 2 clip rails length 390 cm. • Mounting material for 200 cm track pitch.	1	$1,286.05	$1,286.05
25	**459800706722	**MONITOR CEILING CARRIAGE** Monitor ceiling carriage	1	$6,710.60	$6,710.60
26	**FCV0510	**Long mattress cardio** • Enhances patient comfort • Adapts to the shape of the patient's body **Enhance patient comfort during cardio exams** To enhance patient comfort during cardio exams, the inflatable, latex free mattress can be used. It is extra-long to accommodate the patient on the tabletop, and adapts to the shape of the patient's body. The pressure within the mattress is evenly distributed so that it recovers its original shape quickly. Dimensions of the mattress: Length: 3165mm Width: 500mm Height: 70mm Radius: 150mm	1	$551.80	$551.80
27	**980406041009	**Rad Shield w/ Arm (Contoured) 61X76** Contoured Rad Shield with Arm rest. 61X76	1	$2,616.60	$2,616.60
28	**989801220012	**Cable Spooler**	1	$360.45	$360.45
29	**989801220068	**10 Meter DVI Cable Set** 10 meter DVI cable set with zipper hose cover.	1	$489.50	$489.50
30	**989801220273	**Ceiling Track w/Column & Handle Ext**	1	$3,924.90	$3,924.90

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Line #	Part #	Description	Qty	Each	Price
		Mavig 2.5m Ceiling Track with Ceiling trolley, 360 degree column, and brake handle extension.			
31	**989801220375	**Black Anti-fatigue Floor Mat w/logo.**	4	$178.00	$712.00
		Black Anti-fatigue Floor Mat with Philips Logo 36" x 60"			
32	**989801220385	**Mavig Fixed Column**	1	$885.55	$885.55
		Mavig Fixed Column 360°Column Stationary: - 360 ° MAVIG column for stationary fix mounting - total height 850 mm* - 360 ° rotation of the lower pin - electrified upper pin with a 240 ° rotation - max. load weight of each pin is 18kg or 15 kg for longer 950 mm extension arm - for fixed ceiling installation			
33	**989801220388	**Lower Body Protection**	1	$1,539.70	$1,539.70
		UT70-10WS Lower body protection, width 1410 mm incl. wide extension Lower body protection of the model series UT70 with a modular design to provide a maximized protective zone for the physician and staff.			
34	**NCVC005	**Equipment Rack DVI**	1	$16,278.10	$16,278.10
		The Equipment Rack for EP cockpit allows users of the Philips Allura Xper[Clarity] system to organize all the equipment used in an EP Lab on one moveable rack and removes cable clutter through a cable conduit. This provides a much "cleaner" organized look for the busy EP Lab. The ceiling-mounted Equipment Rack, located in the Exam Room, can support 3rd party equipment. Cabling for this equipment is guided up through the ceiling mounted suspension. It can be moved by swiveling the ceiling mounted boom. The Equipment Rack can be positioned within a circular range of 1.6 meters. The Equipment Rack consists of: • 5 shelves and 1 drawer with flexible mounting position and can support 150kg of equipment weight. • An infusion extension rod • An extension arm with a standard VESA mounting plate, on which different types of equipment can be mounted • A Wall Connection Box (1 of the standard EP cockpit Wall Connection Boxes) with Power (230V, 50Hz), Grounding, Network (RJ45), Keyboard/mouse (USB) and Video (DVI) connections • 10 country-specific power connectors Note: For USA/Canada 16 country specific power connectors • 4 Ethernet network connectors • Ergonomically operating handles with electric brakes • Standard gas outlets for O2, NO2, and Vacuum Notes: • Life-supporting equipment cannot be connected to the Equipment Rack. • Medical equipment with dedicated keyboards or displays should not be connected without consent of the manufacturer. Please contact your 3rd party equipment vendor for information and clearance. • Please contact 3rd party equipment vendor for information and clearance in case of cable routing through equipment rack. • The Wall Connection Box can be used to connect 3rd party equipment that complies with the			

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Line #	Part #	Description	Qty	Each	Price
		following requirements: • Qualified medical electrical equipment [IEC 60601-1] • IEC 950 only if connected to an EP cockpit Wall Connection Box mains (230V) connection in the Control Room or otherwise isolated from hospital mains according IEC60601-1. • Connected to the same earth as the Philips Protective Conductor Bar (PPCB). • Can be operated with a standard AT 101-key US English keyboard connected through a USB connection. • Provide video-output that matches the display range of the Color monitor that is used for display. Standard VESA video formats up to 1920x1200 are supported			
35	****989600207421**	**Equipment rack Predelivery set** Pre-delivery for Equipment Rack.	**1**	**$1,379.50**	**$1,379.50**
36	****NCVC413**	**Electrical Accessory kit OSC**	**1**	**$311.50**	**$311.50**
37	****NCVC414**	**Pre-Install Bracket**	**1**	**$75.65**	**$75.65**
38	**SP003**	**Installation Labor** Weekend labor included for Saturday delivery	**1**	**$5,000.00**	**$5,000.00**
39	**SP059R**	**Service Items** Monitor Brackets for additional 27" Exam Room monitors	**1**	**$3,000.00**	**$3,000.00**
40	**SP059R**	**Service Items** Mavig vertical Post for Center Mount room layout. P/N 453580496865	**1**	**$1,900.00**	**$1,900.00**
41	**Third Party Item**	**Additional ceiling mounted monitor** Additional ceiling mounted mounitor for displaying live flouroscopy image.	**1**	**$2,750.00**	**$2,750.00**
42	**SP019**	**Trade in Allowance** 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: Toshiba INFINIX Serial Number: 99E08Y2974 Manufacturer: TOSHIBA AMERICA MEDICAL SYSTEMS I	**1**	**($5,700.00)**	**($5,700.00)**

Trade-In authorization number: 107054

Trade-In Value: $5,700.00

De-install Date: 10/9/2019

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:

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Line #	Part #	Description	Qty	Each	Price

1. Customer represents and warrants that Customer has good and marketable title to the Trade-In as of the date of this Quotation and will have good and marketable title when Philips removes the Trade-In from Customer's site (the "Removal Date");
2. Title to the Trade-In shall pass from Customer to Philips on the Removal Date, unless otherwise agreed by Philips and the Customer;
3. Notwithstanding anything to the contrary in any Business Associate Addendum, Customer represents and warrants that as of the Removal Date all Protected Health Information will have been de-identified or removed from the Trade-In;
4. Philips may test and inspect the Trade-In prior to de-installation. If the condition of the Trade-In is not substantially the same on the Removal Date (ordinary wear and tear excepted) as it is identified on the System Disclosure Form, then Philips may reduce the price quoted for the Trade-In;
5. If the removal date is delayed until after the De-Install Date, unless Philips causes the delay, then Philips may reduce the price quoted for the Trade-In by six percent (6%) per month.
6. Philips is responsible for normal de-installation costs of the Trade-In.
7. The trade-in value will not include costs associated for any facility modifications and/or rigging required for de-installation and must be accounted for separately.
8. Customer is responsible for all plumbing necessary to properly drain coolant from chiller system and cap the lines.
9. Prior to the Removal Date, Customer shall remove from the room all equipment that is not being de-installed.

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

Promotion Name	Description
Azurion Floor Mount ClarityIQ Promo Q3 2019	For a limited time, customers purchasing Azurion Floor-Mounted systems are eligible to receive a $50,000 discount when the order includes ClarityIQ. Promotion expires September 30, 2019.

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NET PRICE $856,099.20

Buying Group: CAROLINAS HEALTHCARE SYSTEM SCA Contract #: CAA0013200

Addt'l Terms:

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid.

Price above does not include any applicable sales taxes.

The preliminary delivery request date for this equipment is:_____.

If you do not issue formal purchase orders indicate by initialing here_____.

Tax Status:

Taxable_____ Tax Exempt_____

If Exempt, please indicate the Exemption Certification Number:_____, and attach a copy of the certificate.

Delivery/Installation Address:

_____

_____

_____

Invoice Address:

_____

_____

_____

Contact Phone #:

_____

Contact Phone #:

_____

Purchaser approval as quoted:

_____

Date:

_____

Title:

_____

This quotation is signed and accepted by an authorized representative in acknowledgement of the system configuration, terms and conditions stated herein.

PHILIPS PRODUCT WARRANTY

Interventional X-RAY (IXR) Systems
Product Warranty

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

1. Twelve (12) Month System Warranty

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

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

2. Planned Maintenance.

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

3. System Options, Upgrades or Accessories.

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

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

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

4. MRC X-Ray Tubes

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

4.2 The warranty period for MRC Tubes provided with Customer's purchase of a new or refurbished X-Ray system shall be the shorter of thirty-six (36) months after installation or thirty-eight (38) months after date of shipment from Philips.

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

5. MRC Tube Warranty Exclusions

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

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

6. MRC Tube Warranty Remedies

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

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

7. Dynamic Flat Detectors

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

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

7.3 If a detector fails to meet this warranty, as Customer's sole and exclusive remedy, upon return of the detector, Philips will provide Customer a replacement detector at no additional charge.

8. System Software and Software Updates

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

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

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

8.4 Use of the software is subject to the terms of a separate software license agreement. Customer must sign all such license agreements prior to or upon the delivery of the product.

8.5 No license or other right is granted to Customer or to any other party to use the software except as set forth in the license agreements.

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

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

9. Warranty Limitations

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

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

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

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

9.4.1 is to be installed by authorized Philips' 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).

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

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

11. Transfer of System

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

11.2 Upon any transfer or relocation, the System must be inspected and certified by Philips as being free from all defects in material, software and workmanship and as being in compliance with all technical and performance specifications.

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

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

12. Limitation of Liability

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

12.2 THIS LIMITATION SHALL NOT APPLY TO:

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

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

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

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

13. Disclaimer

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

14. FORCE MAJEURE

14.1 Philips and Customer shall each be excused from performing its obligations arising from any delay or default caused by events beyond its reasonable control including, but not limited to: acts of God, acts of third parties, acts of the other party, acts of any civil or military authority, fire, floods, war, embargoes, labor disputes, acts of sabotage, riots, accidents, delays of carriers, subcontractors or suppliers, voluntary or mandatory compliance with any government act, regulation or request, shortage of labor, materials or manufacturing facilities.

Philips' system specifications are subject to change without notice

Biosense Webster
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CARTO® 3 System
Summary of Proposed Pricing
Name: CAROLINAS MEDCL CTR
Account Number: 77102/57891
Prepared: 7/30/2019 11:03:17 AM
Valid Through Date: 10/28/2019
List Pricing as of: 7/30/2019

Qty.	Cat No.	Description	List Price	Contract Pricing
1	C3CNFDRPLY	CARTO® 3 CONFIDENSE + REPLAY Bundle: CARTO® 3 System CONFIDENSE™ Mapping Module: This module provides rapid acquisition of mapping points based on physician standards. Included are the capability to continuously acquire MEM points, indicators of tissue proximity for MEM-enabled catheters, advanced electrogram annotation algorithms, and advanced map integrity algorithms. AND CARTO® 3 REPLAY™ Module: This module provides detailed electrogram recording and review for the duration of each case, with the ability to add points from any time in the case to a map, review catheter placement for any acquired point and edit maps with data from review tools.	$55,000.00	$35,200.00
1	C3PASO	PASO™ Module is a modular software package to be used with the Carto® 3 System. Software allows user to automate pace mapping for ventricular tachycardia cases and integrates the results into the Carto® 3 System maps for streamlined navigation.	$27,500.00	$26,400.00
1	C3SOUND	CartoSound® Image Integration Software Module is a modular software package to be used with the Carto® 3 System, Serial Number that allows for the integration of real time Intracardiac echo in an integrated and a side by side manner on the Carto® 3 System screen. This CartoSound® software is compatible with the Biosense Webster SoundStar® 10F and Siemens 10F and 8F AcuNav™ Catheters. This software module includes a Dell 390 or higher workstation. On-site training for technicians included. If needed, includes two 24" wide screen monitors.	$82,500.00	$46,200.00
1	MA5402201	Carto® 3 Workstation Cart Dual Monitor Arm	$4,300.00	$2,900.00
1	KT5400170	CARTO® CONFIDENSE® Module with Ripple Mapping: is a module software package to be used with the Carto® 3 System. This software is designed to help physicians better understand the arrhythmia mechanism through a unique simultaneous dynamic display of voltage and tissue activation.	$25,000.00	$12,500.00
1	KT5400165	FAM Dx Expansion Pack (for Carto 3 v6 base software) Enables catheter visualization, point acquisition and Fast Anatomical Mapping (FAM) without first connecting a therapeutic catheter.	$1,000.00	$1,000.00
			GRAND TOTAL	**$124,200.00**

*** The information in this Summary of Proposed Pricing is not complete and may be changed. A legally binding obligation between the parties will exist only upon the execution of a definitive agreement. This document is being delivered for discussion purposes only.**

Biosense Webster

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This is not an offer to sell the products or a solicitation of an offer to buy the products. No party shall have any obligation or liability arising from this document. Either party may cease negotiations regarding the purchase of the products at any time without further obligation or liability. The pricing for the products in this Summary of Proposed Pricing may include discounts. If a definitive agreement is executed by the parties, the document will include additional disclosure related to the discounts. The information in this document is confidential and may not be discussed with any other party without Biosense Webster's prior written consent. To request an Agreement or for any questions, please contact your Biosense Webster Representative, Andrew Leventis at aleventi@its.jnj.com.

Attachment D

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project name: CMC Main Cardiac Invasive Cath Lab 8 Renovation

Provider/Company: Atrium Health

(1)	Purchase price of land	0
(2)	Closing costs	0
(3)	Site Preparation	0
(4)	Construction/Renovation Contract	750,350.00
(5)	Landscaping	0
(6)	Architect/Engineering Fees	162,207.00
(7)	Medical Equipment	1,136,105.00
(8)	Non Medical Equipment	
(9)	Furniture	10,905.00
(10)	Consultant Fees (CON Fees, Legal Fees)	
(11)	Financing Costs	
(12)	Interest During Construction	
(13)	Other (IS, Security, Internal Allocation)	251,050.00
(14)	**Total Capital Cost**	2,310,617.00

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

(Signature of Licensed Architect or Engineer) 8/20/19 *DATE*

TODD R. McGRADY REGISTERED ARCHITECT 3963 NORTH CAROLINA CHARLOTTE, N. C.

Sales taxes have been included in these equipment costs. However, because Atrium Health is entitled to a sales tax refund under N.C. Gen. Stat. § 105-164.14(b) and 105-467, the sales tax that Atrium Health initially incurs for this medical equipment purchase will be refunded to Atrium Health, and thus will reduce the capital costs that Atrium Health actually incurs for the equipment by $ 78,847.00 .

Attachment E

STATE OF NORTH CAROLINA

COUNTY OF MECKLENBURG

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS
11 DHR 0360

THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a CAROLINAS HEALTHCARE SYSTEM,

Petitioner,

v.

N.C. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION,

Respondent.

STATE OF NORTH CAROLINA

COUNTY OF MECKLENBURG

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS
11 DHR 0698

THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a CAROLINAS HEALTHCARE SYSTEM,

Petitioner,

v.

N.C. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION,

Respondent.

SETTLEMENT AGREEMENT

This Settlement Agreement (the "Agreement") is entered into by The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System ("CMHA") and the North Carolina Department of Health and Human Services, Division of Health Service Regulation,

Certificate of Need Section (the "Agency" or the "CON Section") (collectively referred to hereinafter as "the Parties" and individually as "a Party").

RECITALS

September 5, 2008 Replacement Equipment Notice

WHEREAS, on or September 5, 2008 CMHA submitted a letter containing an Exemption Notice to replace a nine year old Phillips Vascular Imaging System with a Toshiba Bi-Plane X-Ray System (hereinafter referred to as the "September 2008 Replacement Equipment") at Carolinas Medical Center ("CMC") without a Certificate of Need ("CON") pursuant to the exemption provisions in N.C. Gen. Stat. § 131E-184(a)(8) of the CON law.

WHEREAS, on April 1, 2010 and October 19, 2010, pursuant to requests for additional information from the Agency, CMHA submitted additional information regarding the September 2008 Replacement Equipment.

WHEREAS, by letter dated December 14, 2010, the Agency notified CMHA that it had denied its Exemption Notice, asserting that the replacement equipment proposed is not comparable to the existing medical equipment currently in use, and therefore, does not allegedly meet the definition of replacement equipment exempt from review in accordance with N.C. Gen. Stat. § 131E-184(a)(7). In addition, the Agency denied CMHA's Exemption Notice on the basis that the 2010 State Medical Facility Plan only identified seven (7) cardiac catheterization labs rather than eight (8) labs at CMC.

WHEREAS, on January 13, 2011, Petitioner filed a Petition for a Contested Case Hearing initiating the above-captioned contested case, identified as 11 DHR 0360, challenging the Agency's decision to deny Petitioner's Exemption Notice for the September 2008 Replacement Equipment ("September 2008 Contested Case").

November 2008 Replacement Equipment Notice

WHEREAS, on or November 20, 2008 CMHA submitted a letter containing an Exemption Notice to replace a nine year old Trexx Cardiac Imaging System with a Toshiba Infinix VF-I Vascular X-Ray System (hereinafter referred to as the "November 2008 Replacement Equipment") at CMC without a CON, pursuant to the exemption provisions in N.C. Gen. Stat. § 131E-184(a)(8) of the CON law.

WHEREAS, on April 1, 2010 and October 19, 2010, pursuant to requests for additional information from the Agency, CMHA submitted additional information regarding the November 2008 Replacement Equipment.

WHEREAS, by letter dated December 23, 2010, the Agency notified CMHA that it had denied its Exemption Notice, asserting that the replacement equipment proposed is not comparable to the existing medical equipment currently in use, and therefore, does not allegedly meet the definition of replacement equipment exempt from review in accordance with N.C. Gen. Stat. § 131E-184(a)(7).

WHEREAS, on January 24, 2011, Petitioner filed a Petition for a Contested Case Hearing initiating the above-captioned contested case, identified as 11 DHR 0698, challenging the Agency's decision to deny Petitioner's Exemption Notice for the November 2008 Replacement Equipment ("November 2008 Contested Case").

WHEREAS, Petitioner's September 2008 and November 2008 Exemption Notices are collectively referred to as the Exemption Notices and the projects referenced therein are collectively referred to as the Replacement Equipment Projects.

WHEREAS, there are no known intervenors that have an interest in either of the above-captioned Contested Cases (collectively "the Contested Cases").

WHEREAS, pursuant to N.C. Gen. Stat. § 150B-22, it is the policy of the State to settle disputes between State agencies and other persons whenever possible.

WHEREAS, pursuant to this policy, the Parties have discussed settlement of these contested cases.

WHEREAS, in the context of settlement negotiations, Petitioner has submitted additional information to the Agency since the filing of the Contested Case petitions, allowing the Agency to determine that Petitioner's Proposed Projects are exempt from Agency review, such that the Agency may approve Petitioner's Replacement Equipment Projects.

WHEREAS, the execution of this Settlement Agreement does not constitute an admission of error by any Party and does not constitute a concession by any Party regarding any issue in the Contested Cases.

WHEREAS, for and in consideration of the mutual promises and agreements contained herein, which the Parties agree constitute good and satisfactory consideration to resolve all issues among the Parties involving the Contested Cases; and to resolve other issues, disputes, and potential disputes described herein.

NOW THEREFORE, pursuant to N.C. Gen. Stat. §§ 150B-22 and 31(b), and subject to the approval of the Director of the Division of Health Service Regulation (the "Director"), the Parties agree to resolve these Contested Cases in the manner set forth below.

AGREEMENT

1. Petitioner's Voluntary Dismissal with Prejudice. Within five (5) business days after the Director approves this Settlement Agreement, CMHA shall file notices of voluntary dismissal ("the Voluntary Dismissal"), with prejudice, in the Office of Administrative Hearings in the Contested Cases, 11 DHR 0360 and 11 DHR 0698.

2. Replacement Equipment. The Agency authorizes CMHA to replace, without a CON, a nine year old Phillips Vascular Imaging System with a Toshiba Infinix VF-I Vascular X-Ray System located at CMC and a nine year old Trexx Cardiac Imaging System with a Toshiba Bi-Planc X-Ray Systcm located at CMC, as the equipment is described in CMHA's September 5, 2008 and November 20, 2008 Exemption Notices. The Agency further authorizes CMHA to locate the Toshiba Infinix VF-I Vascular X-Ray System at the location of the nine year old Trexx Cardiac Imaging System and to locate the Toshiba Bi-Plane X-Ray System at the location of the nine year old Trcxx Cardiac Imaging System without a CON.

3. Release. Each Party hereby releases all other Parties, their officials, employees, and representatives, from any and all liability or claims that have arisen or might arise out of: (a) the Agency's review of the Exemption Notices; or (b) the Contested Cases.

4. Expenses. The Parties agree that each shall bear its own expenses, including attorneys' fees, and that no claim for such costs or expenses shall be made by one Party against the other.

5. Effect of Approval. If approved by the Director, this Agreement shall resolve all issues involved in, or arising out of, the Contested Cases.

6. Effect of Disapproval. If this Agreement is not approved by the Director, it shall be null and void and the Parties shall be entitled to proceed with the Contested Cases. In that event, the Director's review of this Agreement as provided herein shall not prejudice his authority to render the final Agency decision following the hearing in this matter in accordance with Article 3 of Chapter 150B of the North Carolina General Statutes. In addition, if this Agrccmcnt is not approvcd by the Director, the Parties agree that it shall be inadmissible at the hearing in the Contested Cases for any purpose.

7. Waiver of Right to Appeal Agreement. The Parties irrevocably waive any right to initiate an appeal from this Agreement, assuming that any such right exists; provided that nothing in this Agreement shall be construed to waive any claim for enforcement or breach of this Agreement. The Parties reserve the right to intervene in any appeal of this Agreement that might be filed by any third parties.

8. Merger. The Parties further agree and acknowledge that this written Agreement sets forth all of the terms and conditions among all of them concerning the subject matter of this Agreement, superseding all prior oral and written statements and representations and that there are no terms and conditions among the Parties, except as specifically set forth in this Agreement.

9. Modification or Waiver. No modification or waiver of any provision of this Agreement shall be effective unless it is in writing. Any modification or waiver must be signed by authorized representatives of the Parties and must be adopted and approved by the Director.

10. No Strict Interpretation Against Drafter. Each of the Parties has participated in the drafting of this Agreement and has had the opportunity to consult with counsel concerning its terms. This Agreement shall not be interpreted strictly against any one Party on the ground that it drafted the Agreement.

11. Recitals and Headings. All parts and provisions of this Agreement, including the recitals and paragraph headings, are intended to be material parts of the Agreement.

12. Authority to Settle. The undersigned represent and warrant that they are authorized to enter into this Agreement on behalf of the Parties to this Agreement.

13. *Ex Parte* Presentation. Petitioner authorizes counsel for the Agency to present this

Agreement to the Director, *ex parte*.

14. Effective Date. This Agreement shall be effective as of the day and year on which it is adopted and approved by the Director of the Division of Health Service Regulation.

15. Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective legal representatives, successors, and assigns.

IN WITNESS WHEREOF, the Parties have executed two originals of this Settlement Agreement, with one original copy being retained by each Party.

THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a CAROLINAS HEALTHCARE SYSTEM

F. Del Murphy, Jr.
Vice President, CHS Management Company

Date

K&L GATES LLP

By: Colleen M. Crowley

4-19-11
Date

Gary S. Qualls
Colleen M. Crowley
Susan K. Hackney
430 Davis Drive, Suite 400
Morrisville, NC 27560
Telephone: (919) 466-1182

ATTORNEYS FOR PETITIONER

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION

By: Craig R. Smith
Craig R. Smith, Chief

Date: 4.28.11
CRS

ROY COOPER
Attorney General

By: Stephanie A Brennan
Stephanie Brennan
Assistant Attorney General
N.C. Department of Justice
P.O. Box 629
Raleigh, NC 27602-0629

Date: 4-19-11

COUNSEL FOR THE NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION

APPROVAL AND ADOPTION

The foregoing Settlement Agreement is hereby APPROVED AND ADOPTED this the 21st day of April, 2011.

Drexdall Pratt, Director
Division of Health Service Regulation

Attachment F

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Drexdal Pratt
Division Director

September 15, 2015

Elizabeth V. Kirkman
Assistant Vice President
CHS Management Company
2709 Water Ridge Parkway, Suite 200
Charlotte, North Carolina 28217

Exempt from Review – Replacement Equipment

Record #:	**1720**
Facility Name:	Carolinas Medical Center (CMC)
FID #:	943070
Business Name:	Charlotte-Mecklenburg Hospital Authority
Business #:	1772
Project Description:	Replace cardiac catheterization lab located in CMC's Cath Lab Room #04H104
County:	Mecklenburg

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of September 9, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(f). Therefore, you may proceed to replace the existing Toshiba Biplane Cath Lab System, Model #DFP-8000A/W1, located in Cath Lab Room #04H104 of CMC's main campus in Charlotte, with a comparable cardiac catheterization lab. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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

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

Office of the Director
http://www.ncdhhs.gov/dhsr/
Phone: 919-855-3750 / Fax: 919-733-2757
Location: 809 Ruggles Drive, Dorothea Dix Hospital Campus, Raleigh, N.C. 27603
Mailing Address: 2701 Mail Service Center • Raleigh, North Carolina 27699-2701
An Equal Opportunity / Affirmative Action Employer

Sincerely,

Gloria C. Hale

Gloria C. Hale
Project Analyst

Martha J. Frisone

Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Assistant Chief, Healthcare Planning

Attachment G

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

September 29, 2017

Gary S. Qualls
K&L Gates
430 Davis Drive, Suite 400
Morrisville, NC 27560

Material Compliance Approval

Project ID #:	F-6384-01
Facility:	Carolinas HealthCare System (CHS) University
Project Description:	Change site of one unit of cardiac catheterization equipment from CHS University to Carolinas Medical Center (CMC)
County:	Mecklenburg
FID #:	923516

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the change proposed in your letter of September 7, 2017 is in material compliance with representations made in the application. This change includes changing the site of one unit of cardiac catheterization equipment from CHS University to CMC where it will be located in Cardiology Room 8. The EP unit located in that room will become a cardiac catheterization unit. Upon completion, CHS University will have zero cardiac catheterization units and CMC will have nine cardiac catheterization units on its license. However, you should contact the Agency's Construction Section to determine if they have any requirements pertinent to the proposed change.

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. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

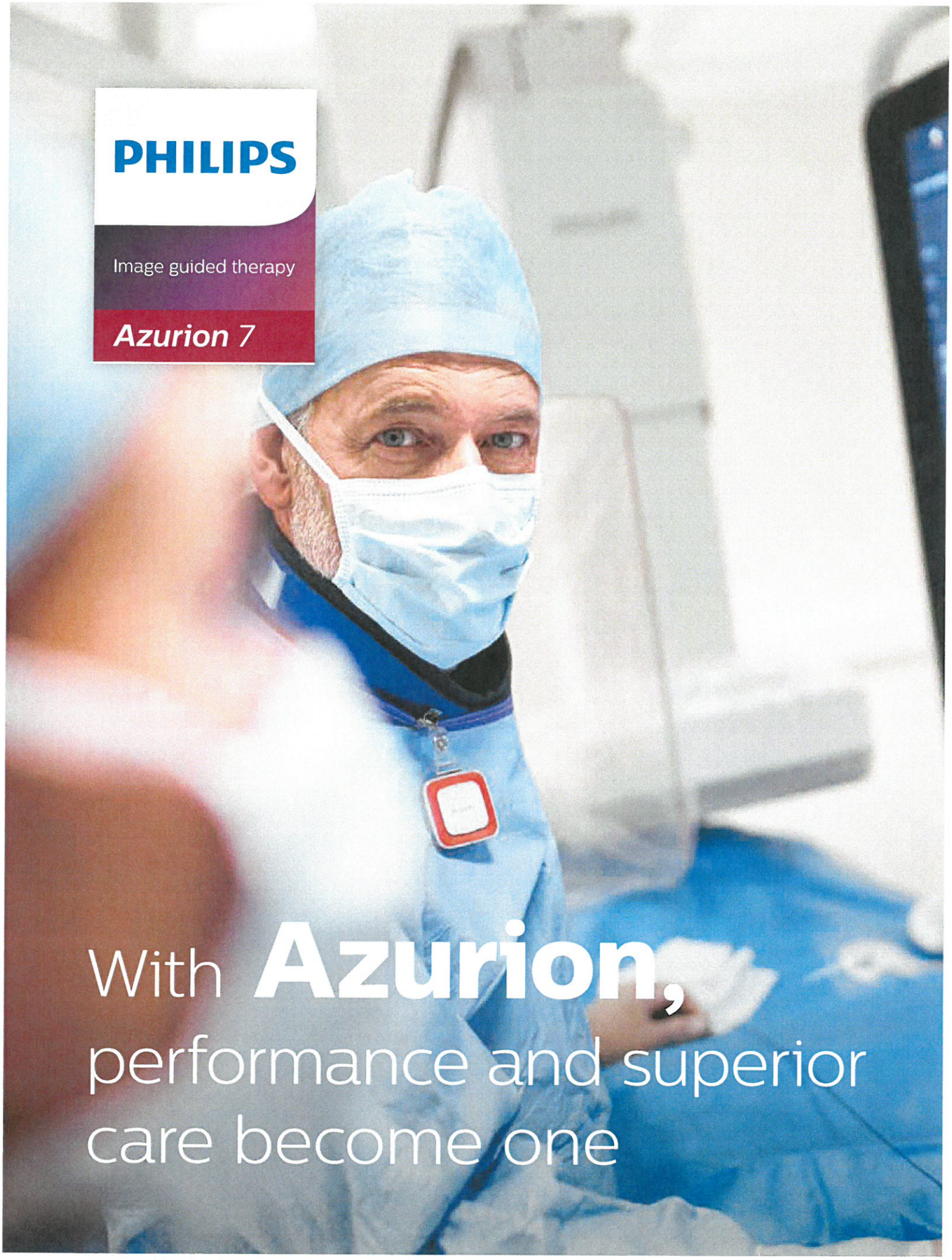
Sincerely,

Gloria C. Hale
Gloria C. Hale
Project Analyst

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

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

Attachment H


PHILIPS
Image guided therapy
Azurion 7
With Azurion,
performance and superior
care become one

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

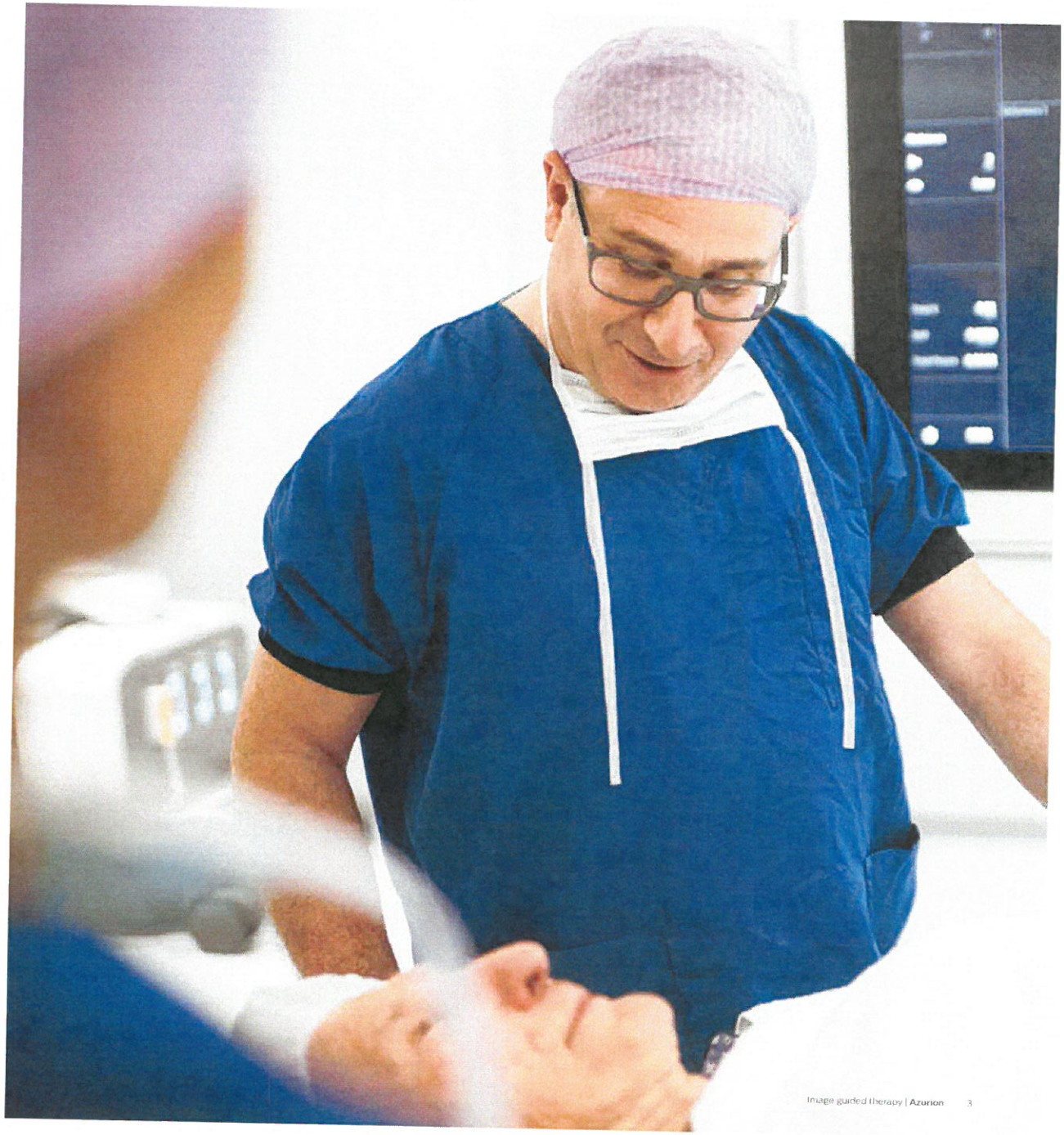
Azurion enables you to provide superior care

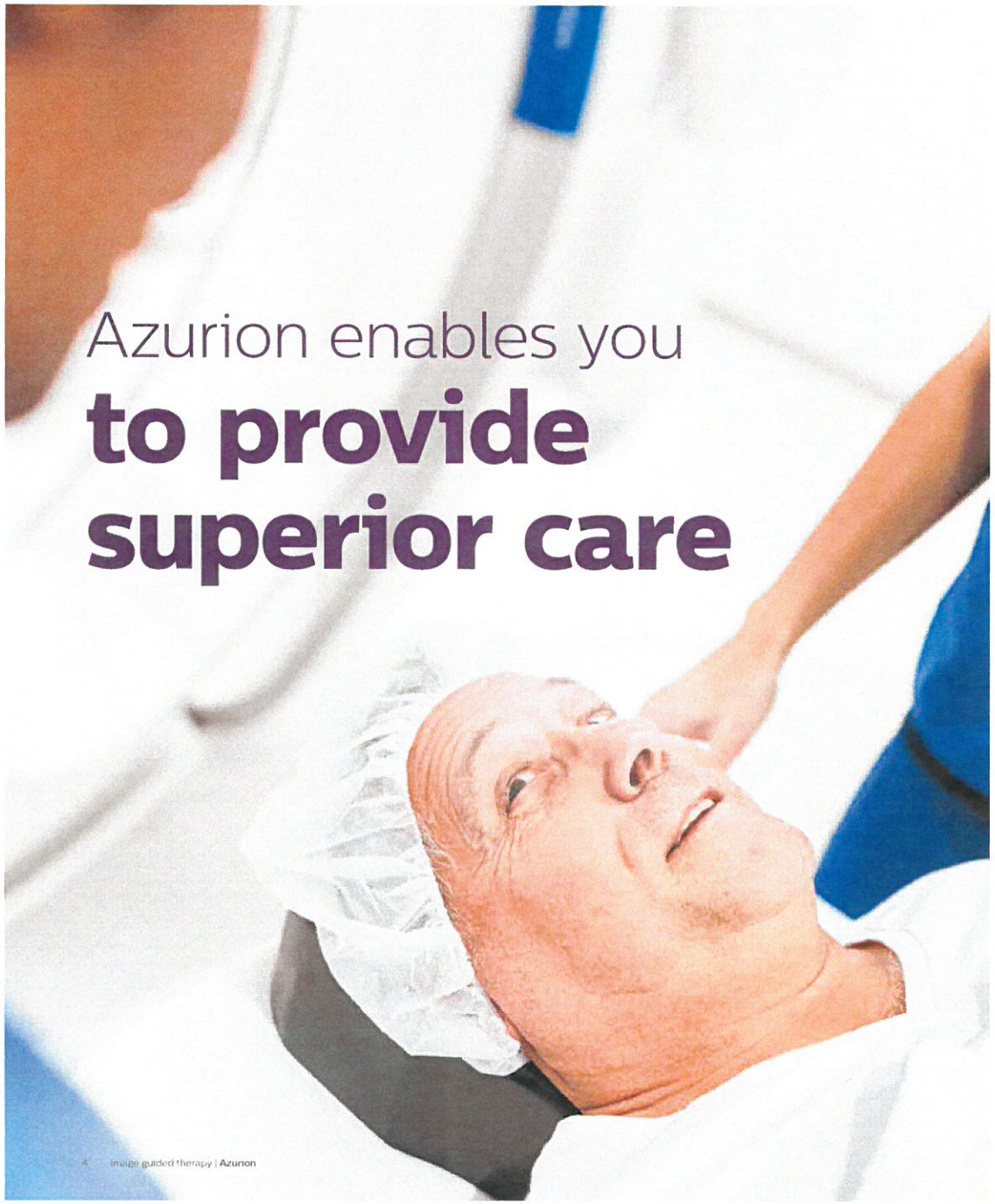
Azurion helps you optimize your lab performance

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

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

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





Azurion enables you **to provide superior care**

In a simulation study with over 60 users globally,

100% believe that the possibility to display Checklists & Protocols on the system will help minimize preparation errors[1]

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

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

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

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

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

> “The FlexVision Pro is fantastic! I can **control everything** from table side without sterility breaks.”
>
> Marco van Strijen, MD

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

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

Managing dose efficiently

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

High quality images at a low x-ray dose

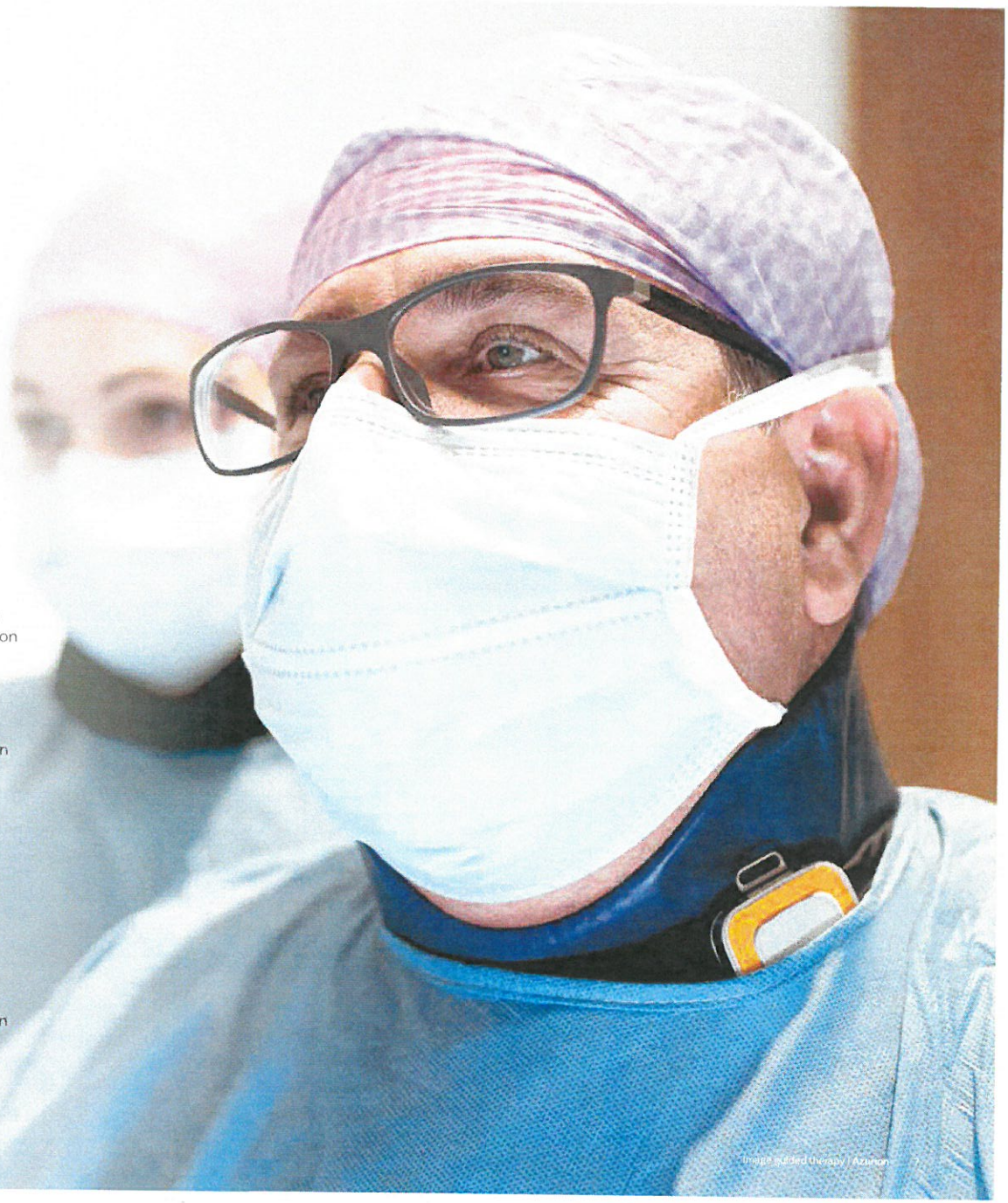
ClarityIQ technology that provides high quality imaging for a comprehensive range of clinical procedures, achieving excellent visibility at low X-ray dose levels for patients of all sizes.

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

Managing dose across your organization

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

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



With Azurion we help you to

optimize your lab performance

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

Save time through Instant Parallel Working

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

Imagine an easier work day

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

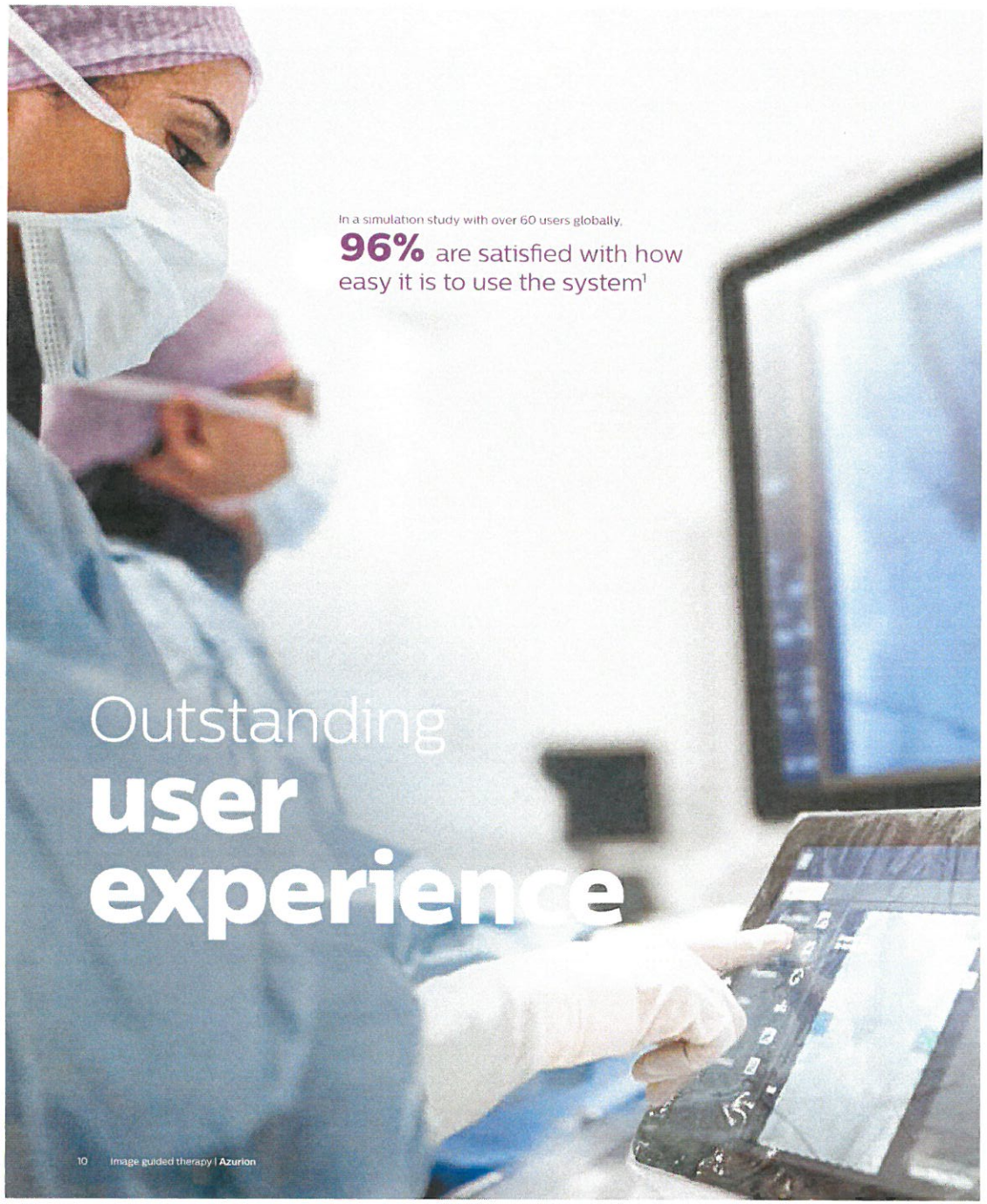
In a simulation study with over 60 users globally,

91% believe that the system will help reduce procedure time[1]

Touch screen module Pro

FlexSpot

FlexVision Pro



In a simulation study with over 60 users globally,

96% are satisfied with how easy it is to use the system[1]

Outstanding **user experience**

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

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

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

The next step in ease of use
All controls feature the latest advances in ease of use. On screen, you can see easily information against the distinctive black background where active applications are highlighted. Backlit icons and distinctly shaped buttons on the Control Module promote intuitive operation. The touch screen module Pro[3] offers tablet-like control at table side – select, zoom and pan with your fingertips and display X-ray images on its screen. All controls are designed for easy cleaning to meet stringent sterility requirements.

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

The next-generation

image guided therapy platform

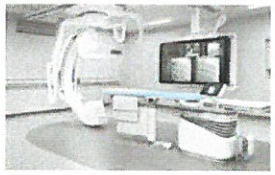
Azurion is the next-generation Image Guided Therapy platform that provides a foundation for today and the innovations of tomorrow. It is backed by innovative services and support that offer a lifetime of benefits, reinforcing our commitment to you and your patients.

Enjoy a lifetime of benefits

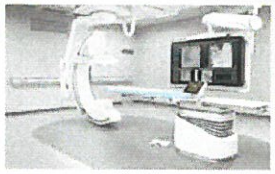
The entire Azurion family is designed around a single, standardized hardware and software platform. New solutions and innovations are added as they evolve. And as your requirements change you can easily integrate additional functionality and third-party applications.

Azurion 7

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



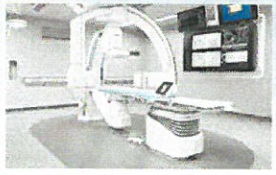
Azurion 7 C12



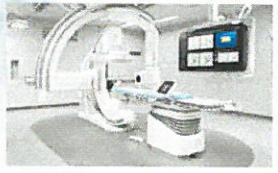
Azurion 7 C20

Azurion 7 biplane

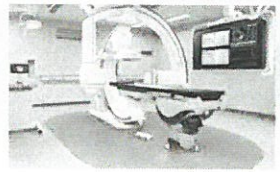
The Azurion 7 biplane is available in different configurations to support neuro, congenital heart, structural heart, electrophysiology and other complex cardiac and vascular interventions. The biplane system with two 12" Flat Detectors provides high-resolution imaging and positioning flexibility to reveal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



Azurion 7 B12/12



Azurion 7 B20/15



Azurion 7 B20/12 with OR table

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

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

Increase your return on investment

To help you fully leverage your financial, technological and staffing resources and realize a high return on your investment, we offer professional support through our experienced network of over 7.000 field service engineers, as well as a flexible service offering that includes innovative financing solutions tailored for the healthcare community. Our broad range of healthcare consulting and education programs can help you further enhance the efficiency and efficacy of your care delivery process.

Make the most of every day

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

Unlock your potential

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

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

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

4522 991 28911 * JUL 2017

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

Attachment I

EQUIPMENT COMPARISON – Carolinas Medical Center Cardiac Catheterization Lab #8 Replacement

Type of Equipment (List each component)	Existing Equipment	Replacement Equipment
Manufacturer of Equipment	Cardiac Catheterization Lab	Cardiac Catheterization Lab
Tesla Rating for MRIs	Toshiba	Philips
Model Number	N/A	N/A
Serial Number	Infinix Bi-plane	Azurion 3 M15
Provider's Method of Identifying Equipment	99E08Y2974	Not Available Until Installed
Specify if Mobile or Fixed	Internal Asset # / Serial #	Internal Asset # / Serial #
Mobile Trailer Serial Number/VIN #	Fixed	Fixed
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	N/A	N/A
Does Provider Hold Title to Equipment or Have a Capital Lease?	September 2015	September 2019
Specify if Equipment Was/Is New or Used When Acquired	Title	Title
Total Capital Cost of Project (Including Construction, etc.)	New	New
Total Cost of Equipment	$145,000	$2,310,617
Fair Market Value of Equipment	$145,000	$1,136,105
Net Purchase Price of Equipment	$145,000	N/A
Locations Where Operated	$145,000	$1,136,105
Number Days in Use/To Be Used in N.C. per Year	CMC 4th Floor, Room 04H104	CMC 4th Floor, Room 04H104
Percent of Change in Patient Charges (by procedure)	365 days/year	365 days/year
Percent of Change in Per Procedure Operating Expenses (by procedure)	0%	0%
Type of Procedures Currently Performed on Existing Equipment	0%	0%
Type of Procedures New Equipment is Capable of Performing	Cardiac Catheterization	N/A
	N/A	Cardiac Catheterization

Attachment J

CMC Cardiac Catheterization Lab #8 Volumes

Month	Volume
Aug-18	24
Sep-18	22
Oct-18	32
Nov-18	19
Dec-18	30
Jan-19	44
Feb-19	37
Mar-19	34
Apr-19	42
May-19	48
Jun-19	47
Jul-19	20
Total	399

Attachment K

Kim Bates

June 14, 2019

Philips Healthcare Cardiology/Radiology Account Manager

24133 NC Hwy 24-27

Albemarle NC 28001

RE: Toshiba Bi Plane serial number 99E08Y2974

Atrium Health

1000 Blythe Blvd,

Charlotte, NC 28203Atrium Health

To Whom It May Concern: The above mentioned system will be traded in and sold to a third party vendor. Philips Healthcare will not reinstall the system in NC.

Sincerely,

Kim Bates