NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

January 21, 2025

Elizabeth Kirkman, Assistant Vice President
Elizabeth.Kirkman@atriumhealth.org

Exempt from Review – Replacement Equipment

Record #:	**4678**
Date of Request:	December 19, 2024
Facility Name:	Atrium Health Pineville
FID #:	110878
Business Name:	The Charlotte-Mecklenburg Hospital Authority
Business #:	1770
Project Description:	Replace cardiac catheterization equipment
County:	Mecklenburg

Dear Elizabeth Kirkman:

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

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

Sincerely,

Chalice L. Moore
Project Analyst

Micheala Mitchell
Chief

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

December 17, 2024

Ms. Micheala Mitchell, 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 Atrium Health Pineville ("AH Pineville") to Replace Cardiac Catheterization Equipment

Dear Ms. Mitchell:

The Charlotte-Mecklenburg Hospital Authority d/b/a Atrium Health Pineville ("AH Pineville"), seeks to acquire Philips Azurion 7 F12 cardiac catheterization equipment ("Replacement Equipment") to replace existing GE Innova 3100 cardiac catheterization equipment ("Existing Equipment") that was acquired in 2009 and is at the end of its useful life. The Existing Equipment is currently housed in Cardiac Catheterization Lab #1 in room #1103 on the first floor of AH Pineville's main hospital building located at 10628 Park Road, Charlotte, NC 28203. The Replacement Equipment will be installed in the same room that currently houses the Existing Equipment (see Attachment A).

The purpose of this letter is to provide the Agency with notice and to request a determination that AH Pineville'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 in NCGS § 131E-176(22a) as follows in the CON law:

> "Replacement equipment" means equipment that costs less than three million dollars ($3,000,000) 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. In determining whether the replacement equipment costs less than three million dollars ($3,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Beginning September 30, 2023, and on September 30 each year thereafter, the cost threshold amount in this subdivision shall be adjusted using the Medical Care Index component of the Consumer Price Index published by the U.S. Department of Labor for the 12-month period preceding the previous September 1.[1]

Under the provisions found at NCGS § 131E-184(f)(1)-(3), the CON law provides:

[1]The current monetary threshold for replacement equipment is $3,089,400.

(f) The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the monetary threshold set forth in G.S. 131E-176(22a) 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.

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 in in Cardiac Catheterization Lab #1 in room #1103 on the first floor of AH Pineville's main hospital building (see Attachment A). The main hospital building, located at 10628 Park Road in Charlotte, is the site from which AH Pineville exercises financial and administrative control over the entire facility. AH Pineville's Facility Executive's office is located on the ground floor of the main hospital building. Please see a copy of AH Pineville's hospital license in Attachment B.

In addition to the foregoing, AH Pineville's proposal qualifies for this exemption based on the following information:

A. <u>Cost of the Replacement Equipment</u>

The purchase price of the Replacement Equipment is $1,377,938 ($1,159,379 Philips Azurion 7 F12 + $46,145 ancillary equipment + $172,414 freight/storage/sales tax). The projected total cost of this project is $4,177,938 and includes the cost to acquire, install and make operational the Replacement Equipment. Attachment C provides the quote for the Replacement Equipment. The total capital cost worksheet is provided in Attachment D.

B. <u>Equipment Being Replaced is Located on the Main Campus</u>

The Existing Equipment is currently located in in Cardiac Catheterization Lab #1 in room #1103 on the first floor of on the first floor of AH Pineville's main hospital building. The

Replacement Equipment will also be located in in Cardiac Catheterization Lab #1 in room #1103 (see Attachment A).

C. Certificate of Need Issued for Equipment Being Replaced

This proposal also fits within the exemption criterion in Section 131E-184(f)(2). Atrium Health Pineville currently has three units of cardiac catheterization equipment: one unit of "legacy" or "grandfathered" cardiac catheterization equipment that was acquired before a CON was required and two units of cardiac catheterization equipment that were acquired pursuant to CON Project ID #F-7979-07. The two units that were acquired pursuant to CON Project ID #F-7979-07 were relocated from AH Mercy to AH Pineville. Please see Attachment E for an excerpt of AH Pineville's 2024 hospital license renewal application that identifies the three units of cardiac catheterization equipment. As identified in the application for CON Project ID #F-7979-07, as part of that project, AH Pineville was approved to purchase three new pieces of cardiac catheterization equipment – these three units would replace the one existing, grandfathered cardiac catheterization lab at AH Pineville as well as the two cardiac catheterization labs that were being relocated from AH Mercy to AH Pineville. The Existing Equipment identified in this exemption request is the equipment that was purchased pursuant to CON Project ID #F-7979-07 to replace AH Pineville's one unit of grandfathered cardiac catheterization equipment. Please see Attachment F for a copy of the certificate for CON Project ID #F-7979-07 as well as relevant excerpts from the application.

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.

Although it possesses some expanded capabilities due to technological improvements, AH Pineville intends to use the Replacement Equipment for substantially the same cardiac catheterization procedures for which it currently uses the Existing Equipment (see Attachment G for the Equipment Brochure). The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c).

Furthermore, AH Pineville 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 H, 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 H). Moreover, AH Pineville 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 I indicates that 716 procedures were performed from November 2023 to October 2024 on the Existing Equipment.

E. Existing Equipment

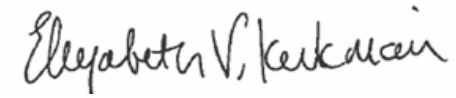
The Existing Equipment will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate CON approval. Please see the equipment quote contained in Attachment C which identifies that Philips will be de-installing the Existing Equipment.

CONCLUSION:

Based on the foregoing information, AH Pineville hereby requests that the Agency provide a written response confirming that the acquisition of the Replacement Equipment 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
Core Market Growth Business Development
Atrium Health

Attachments

Attachment A

SITE PLAN COLOR KEY

- EXISTING BUILDING
- RENOVATION
- CATH LAB

Site Plan

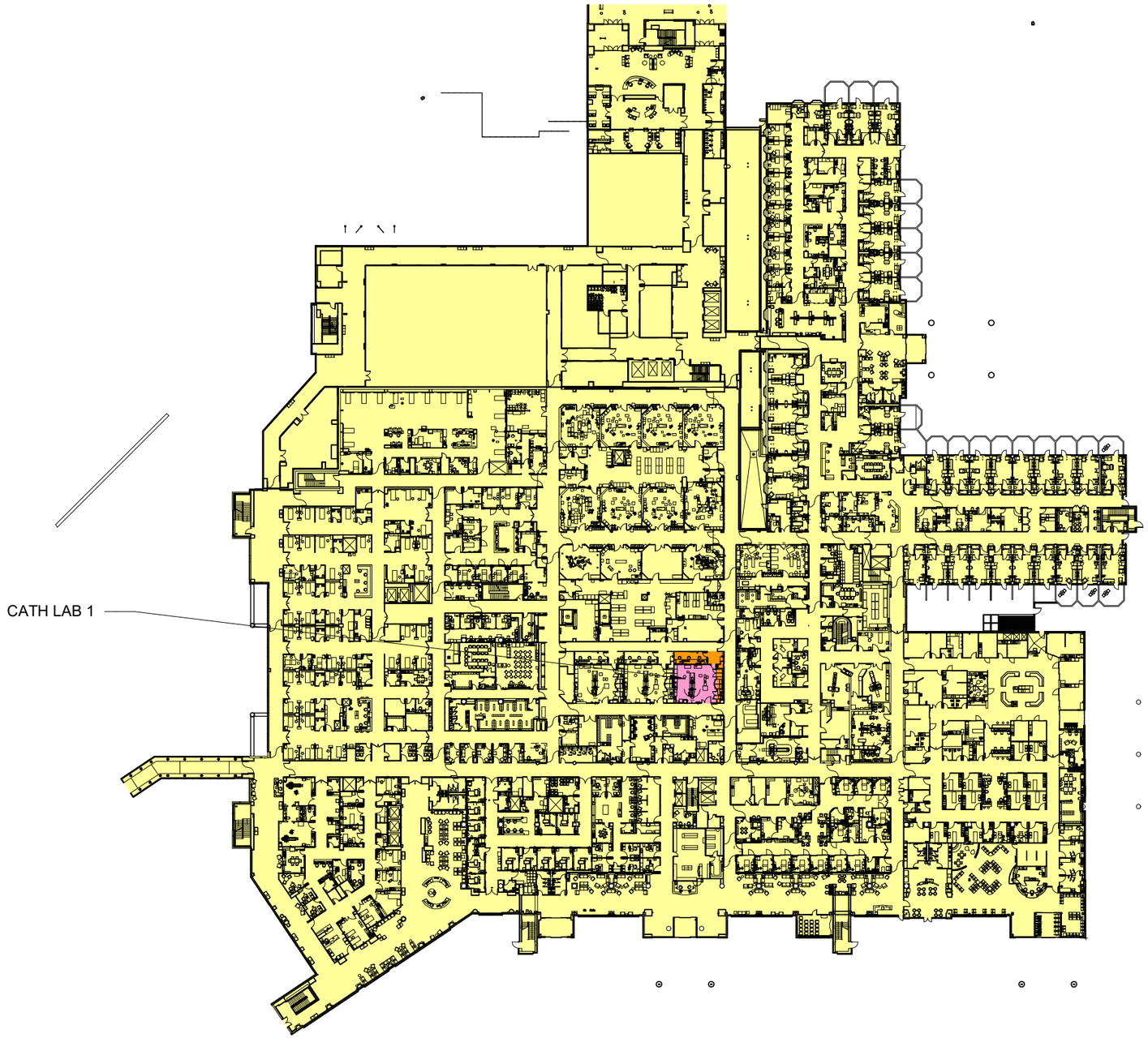
Cath Lab 1 Replacement

Atrium Health

Atrium Health Pineville

Color Key

- EXISTING BUILDING
- RENOVATION
- CATH LAB



Existing Overall Floor Plan - Level 01

Cath Lab 1 Replacement

Atrium Health

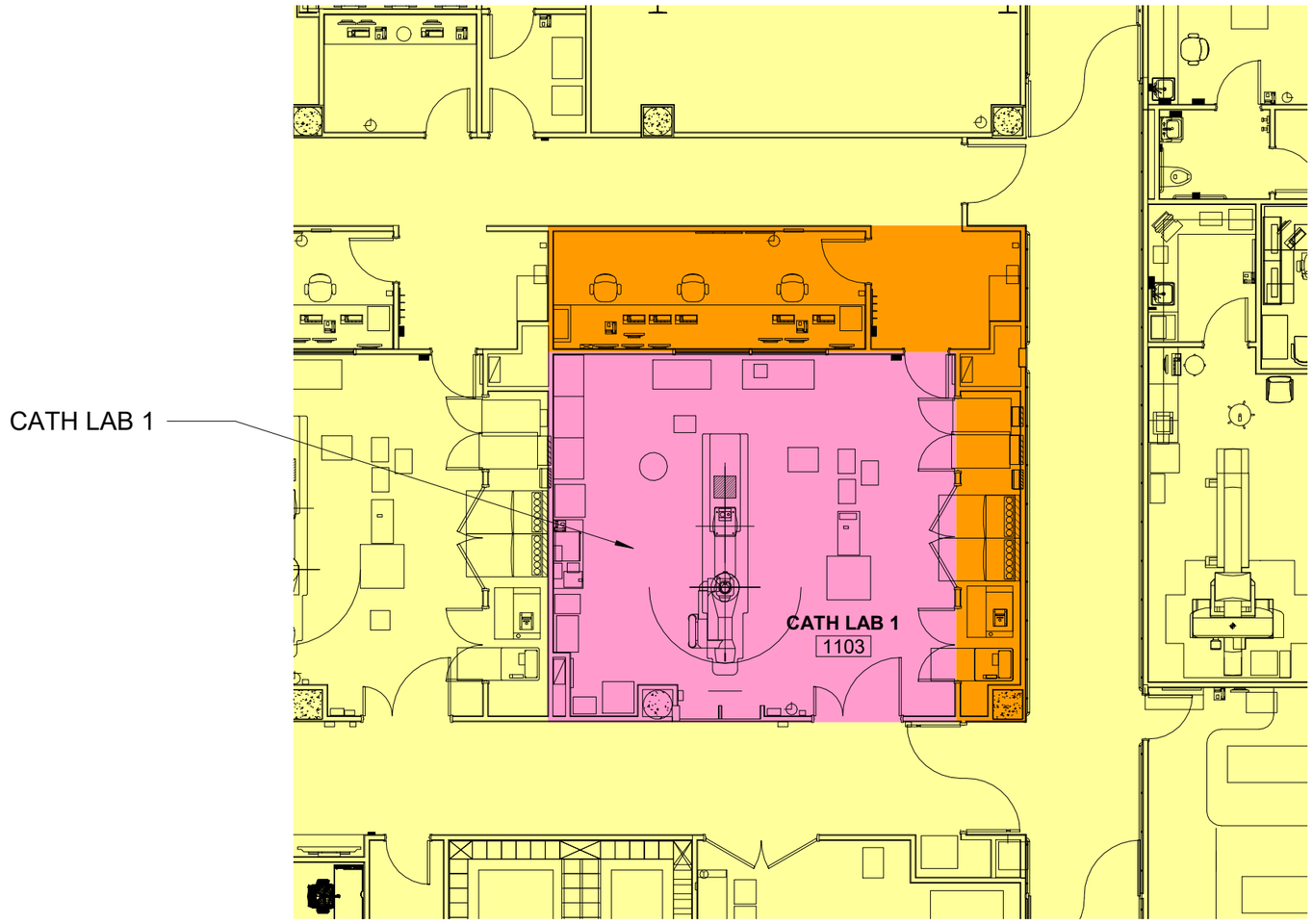
Atrium Health Pineville

Color Key

EXISTING BUILDING

RENOVATION

CATH LAB



Existing Enlarged Floor Plan - Level 01 - Cath Lab

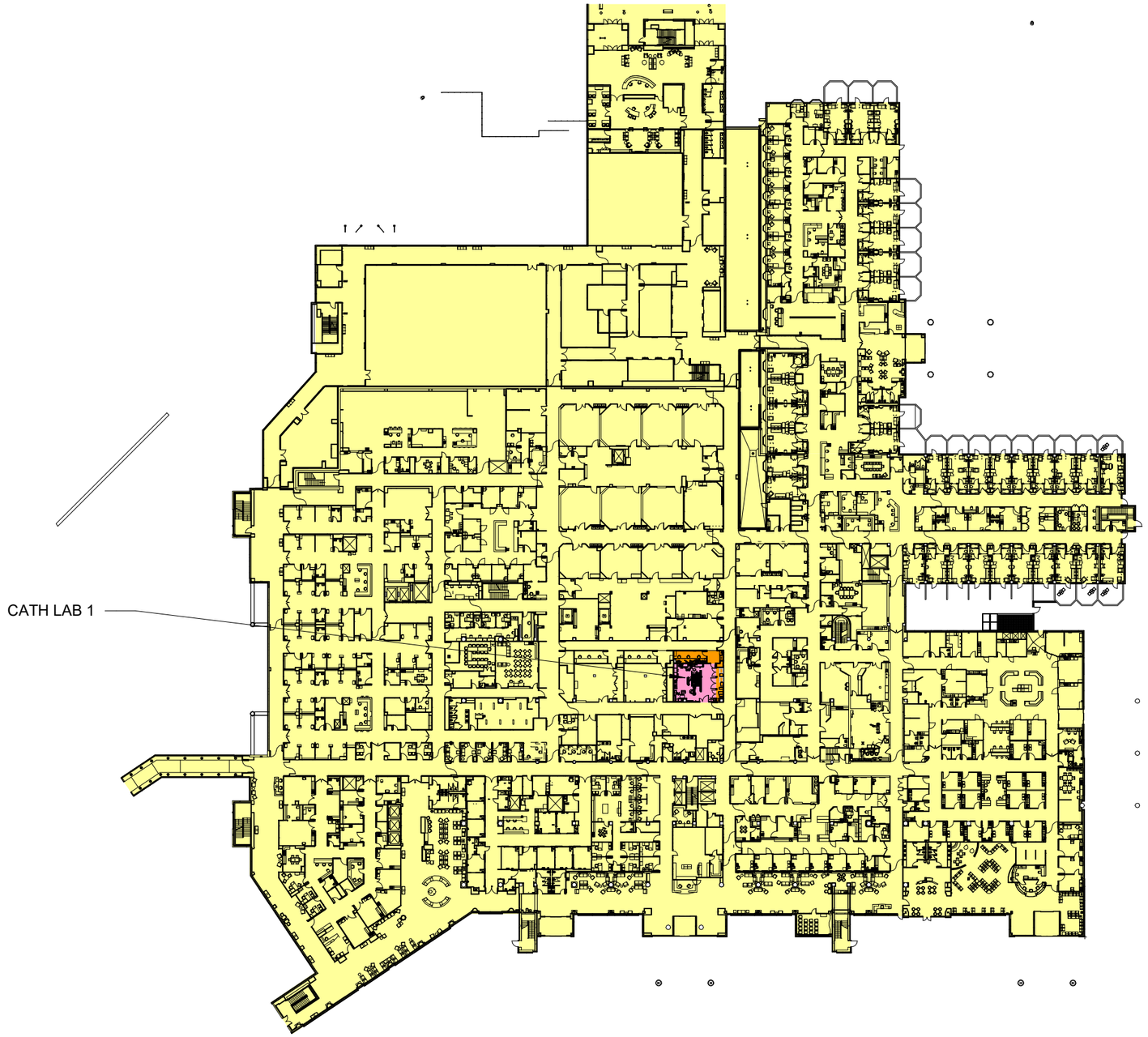
Cath Lab 1 Replacement

Atrium Health

Atrium Health Pineville

Color Key

- EXISTING BUILDING
- RENOVATION
- CATH LAB



Proposed Overall Floor Plan - Level 01

Cath Lab 1 Replacement

Atrium Health

Atrium Health Pineville

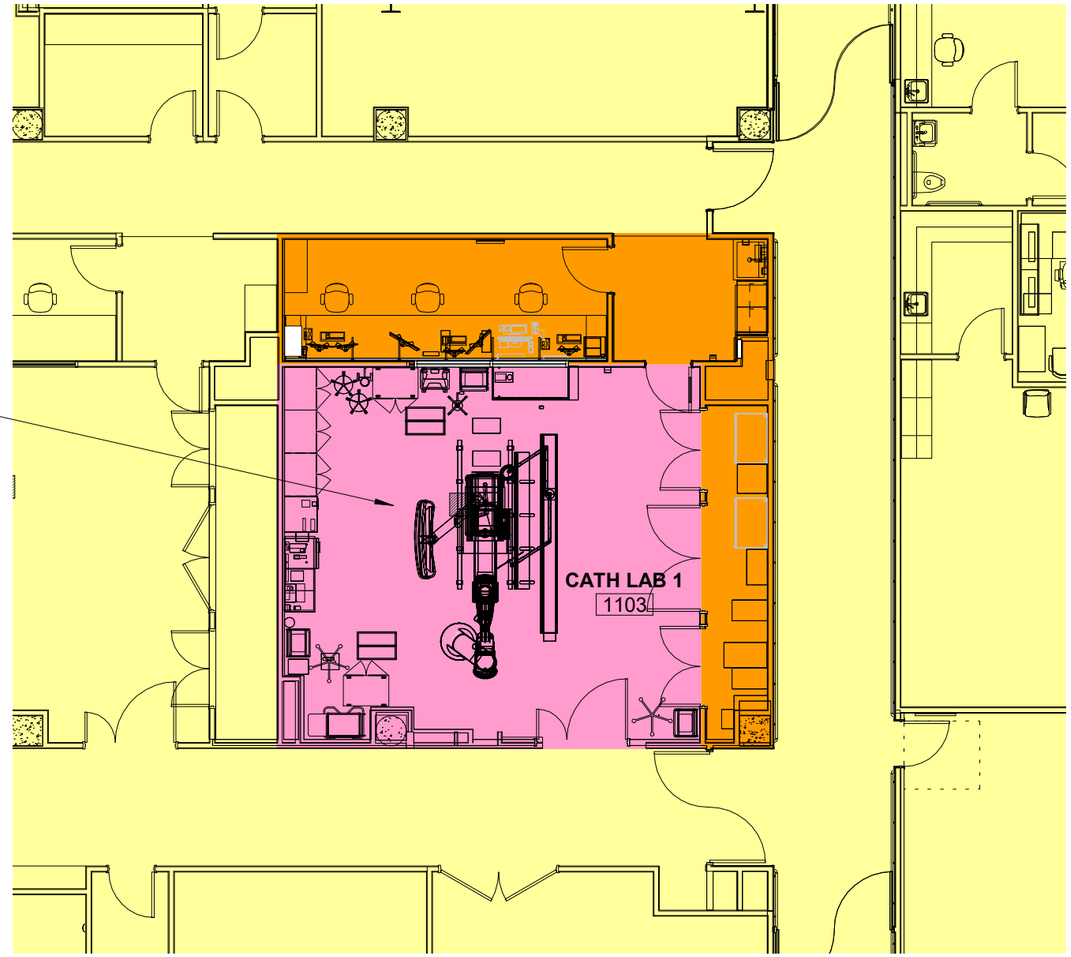
Color Key

EXISTING BUILDING

RENOVATION

CATH LAB

CATH LAB 1



Enlarged Proposed Plan - Level 01 - Cath Lab

Cath Lab 1 Replacement

Atrium Health

Atrium Health Pineville

Attachment B

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Effective May 24, 2024, this license is issued to

The Charlotte Mecklenburg Hospital Authority

to operate a hospital known as

Atrium Health Pineville

Atrium Health Steele Creek, Atrium Health Providence

located at Charlotte, NC, 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: 110878 ***License Number: H0042***

*Bed Capacity:**337***

General Acute: **308** Rehabilitation: **29**

*Dedicated Inpatient Surgical Operating Rooms: **3***

*Shared Surgical Operating Rooms: **12***

*Dedicated Ambulatory Surgical Operating Rooms:**0***

*Dedicated Endoscopy Rooms: **2***

License Categories:

Authorized by:

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

Director, Division of Health Service Regulation

Attachment C

PHILIPS

Sold to:

Charlotte-Mecklenburg Hospital Authority DBA Atrium Health
10628 Park Rd
Charlotte, NC 28210-8407

Ship to:

Charlotte-Mecklenburg Hospital Authority DBA Atrium Health
10628 Park Rd
Charlotte, NC 28210-8407

Presented By

Michael Noland
Philips Healthcare a division of Philips North America LLC
414 Union Street
Nashville, Tennessee 37219
Email: michael.noland@philips.com

Quote #: Q-00374554
Customer #: 94097071
Quote Date: 10/03/24
Valid Until: 12/20/24

Atrium Health Pineville Cath lab 1 Replacement - Azurion 7 F12

Thank you for investing your trust in Philips; we know that there were many options out there for you to choose from. As the industry leader in Healthcare, we also pride ourselves on providing great Customer Service.
I am pleased to submit the attached proposal for your consideration.
I trust this meets your expectation, however, should you have any queries or require further information or clarification, please do not hesitate to contact me.
To ensure a smooth purchasing experience here are a few helpful tips to keep in mind when submitting your purchase order.

- Please specify any specific delivery date requirements or shipping/delivery needs
- Ensure your purchase order references the Philips quote number
- Purchase orders must be signed digitally or physically

  or
- Complete the information on the quote Signature Page

Thank you again for considering Philips.

Regards,
Michael Noland

PHILIPS

Table of Content

PHILIPS

1. Financial Overview

Line	Article No.	Description	Qty	Net Price
1	722233	Azurion 7 M12	1	$ 988,489.41
2	100133	CV Third Party Products	1	$ 61,244.61
3	797406	SYNCVISION	1	$ 98,301.00
4	SP059R	Intrasight De-install	1	$ 11,344.00

	Total Price
Total Net Price	**$ 1,159,379.02**

PHILIPS

2. Quote Summary

Line	Article No.	Description	Qty	Net Price
1	**722233**	**Azurion 7 M12**		
1.1	NNAT320	Azurion 7 F12	1	$ 583,320.00
1.2	989806130836	480V - IGT Compact Low Load Fluoro - Modulys 75KVA	1	$ 39,375.00
1.3	989801256034	iXR Full Travel Pkg OffSite	2	$ 4,660.00
1.4	NNAE597	Coronary RoadMap ClinEd	1	$ 0.00
1.5	NNAE596	StentBoost Live_ClinEd	1	$ 0.00
1.6	NNAE675	Azurion Clinical Education Pkg	1	$ 0.00
1.7	NCVD067	ClarityIQ	1	$ 74,175.00
1.8	NCVD031	FlexVision XL + 2 LCD's	1	$ 87,052.50
1.9	FCV0974	3rd party video cloning (2 output)	1	$ 8,313.75
1.10	FCV0981	Video input WCB on 1st MCS	2	$ 10,695.66
1.11	FCV0985	Video input WCB outside the MCS	14	$ 31,758.30
1.12	NCVA780	Digital subtraction angiography (DSA)	1	$ 13,136.25
1.13	NCVA082	Intercom	1	$ 1,657.50
1.14	NCVC199	Wireless footswitch: mono-plane version	1	$ 6,086.25
1.15	NCVD606	Premium Table (Pivot, APC, Volcano)	1	$ 29,894.30
1.16	FCV0510	Long mattress cardio	1	$ 465.00
1.17	NCVC265	Prep table for Table Mount inj	1	$ 5,036.25
1.18	NCVC542	Dynamic Coronary Roadmap	1	$ 23,190.00
1.19	NCVC544	StentBoost Live	1	$ 19,571.25
1.20	**722367**	**DoseAware**		
1.21	FCV0854	DoseAware Xtend pack	1	$ 36,536.25
1.22	**722240**	**Remote Service IGT**		
1.23	459801079651	Cabinet Rear Cover	1	$ 393.75
1.24	459801613311	Cabinet Rear Cover Deep	2	$ 3,482.40
1.25	989600213943	Patient table adaptation plate	1	$ 2,951.25
1.26	459800938361	Clip rails for Monitor Ceiling Carriage (390cm, 153.5")	1	$ 1,083.75
1.27	459800706722	MONITOR CEILING CARRIAGE	1	$ 5,655.00
				$ 988,489.41
2	**100133**	**CV Third Party Products**		

PHILIPS

2.1	989806101012	MD/ Mark7 Arterion Table Mount Injector	1	$ 20,183.58
2.2	989806101063	MD/ VFlow Hand Controller	1	$ 1,137.34
2.3	989801220012	Cable Spooler	2	$ 745.20
2.4	989801220397	Lamp Y LED 1F	2	$ 5,520.00
2.5	989801229910	RAD SHIELD W/ARM (CONTOURED) 61X76	1	$ 2,704.80
2.6	989801220388	Lower Body Protection	1	$ 1,591.60
2.7	989801220273	Ceiling Track w/Column & Handle Ext	2	$ 8,114.40
2.8	989604354501	MD/ STARSystem	1	$ 6,020.77
2.9	989806105835	Vitalinq Communication System	1	$ 15,226.92
				$ 61,244.61
3	**797406**	**SYNCVISION**		
3.1	NVLV010	SyncVision	1	$ 98,301.00
				$ 98,301.00
4	**SP059R**	**Intrasight De-install**	1	$ 11,344.00

Total Price

Total Net Price **$ 1,159,379.02**

PHILIPS

3. Quote Details

Line	Description	Qty
1	**Azurion 7 M12** **Article No. 722233**	
1.1	**Azurion 7 F12** **Article No. NNAT320** **Azurion 7 F12** The Philips Azurion 7 M12 Monoplane Floor Mounted Image Guided Therapy system is designed to enhance treatment and provide high-quality image guidance during a wide range of routine and complex cardiovascular interventions. The intuitive Azurion user interface and its seamless integration of data and compatible applications help you optimize lab performance and provide superior care. Key benefits : • Powerful imaging chain with a high resolution 30 cm detector (12 ”) and high-power MRC 200+ x-ray tube with grid-switch functionality • Excellent patient access with unique G-shaped stand, which is designed to reach patient ’s groin with system positioned at head-end • Centralized controls with Azurion Touch Screen Module (TSM) at table side, reducing clutter and avoiding sterility breaks • Azurion ProcedureCards allow creation of customizable system presets to drive for procedure efficiency and standardization of care • New video infrastructure allows to display, access, and control up to 20 multimodality video sources across the lab **Details :** With Azurion’s industry leading image guided therapy platform, 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. As the interventional space evolves, we continuously enhance our Azurion platform capabilities based on our close collaboration with clinical users all over the world to strive for a better user experience. The latest release of our Philips Azurion platform offers a redesigned network video infrastructure streamlining integration and distribution of video signals across your interventional lab. The key concept of seamless integration has been further enhanced by integrating compatible applications on the Azurion Touch Screen module such as IVUS imaging and physiologic iFR measurements with Philips IntraSight or hemodynamic measurements with the Philips Interventional Hemodynamic system. New remote secure network capabilities improve our capability to discover system issues before they become apparent to you so that you can achieve the high lab uptime, that lets you treat more patients. At Philips, we feel a responsibility towards society and the environment. The latest Azurion 7 M12 Monoplane Floor Mounted system perfectly exemplifies our EcoVision program. We drastically reduced the product's environmental impact by examining every aspect of the Azurion 7 M12 design and development with a green eye. **<u>System Geometry</u>**	1

Floor-mounted stand

The fully motorized system geometry with high-end motor drives enables fast system positioning, excellent repositioning accuracy and covers the full range of cardiac projection possibilities. The unique G-shaped stand is designed to reach the patients groin area with the image beam from the head-end of the patient. Further, the gantry can be rotated to position the image-beam off-center, which supports imaging of an outstretched patient arm for endovascular access. C-arc rotations and angulations as well as gantry rotations can also be executed manually for better patient access in case of a power outage situation. Collision prevention technology (BodyGuard) is in place to protect the patient by slowing down system movement speeds when an object is detected within a certain safety distance. The incorporated 30 cm detector (12") provides a significantly larger field of view and higher resolution, compared to previous 25cm (10") technology, while its compact design still allows for steep projections.

Workflow and dose management

ProcedureCards

The Azurion ProcedureCards for system setup can be customized based on user, procedure, or department workflow preferences. Further, it is possible to upload hospital checklists and/or protocols into the ProcedureCards to help safeguard the consistency of interventional procedures and help minimize preparation errors. The ProcedureCards can be coupled to hospital RIS codes to automatically select the right system settings once the procedure is started.

Parallel Working

The Azurion Parallel Working concept allows the review of acquired images from current or previous exams in the control room simultaneously with an ongoing live intervention. This allows the physician in the exam room to carry with the intervention, while the supporting staff can run image processing, vessel analysis, or flag images for PACS export. The concept provides a flexible workflow, leading to higher throughput and faster exam turnover without compromising on the quality of care.

Dose management and awareness

DoseWise comprises a set of technologies to actively manage dose. The X-ray tube copper filtration will permanently remain in the X-ray beam for a chosen X-ray protocol, independent of projection angle or patient thickness. Grid-switch controlled fluoroscopy and collimation on the last-image-hold help to avoid unnecessary radiation. The high-resolution flat detector features high X-ray-to-signal conversion rates to support brilliant image quality. Advanced image processing further enhances high image quality through automatic noise reduction and edge enhancement algorithms. After the procedure is finished, a DICOM radiation dose structured report provides an overview of all dose-relevant parameters, which can be automatically exported with the patient images to a DICOM database (e.g. PACS).

Zero Dose Positioning

Zero Dose Positioning function lets you move the stand, pan the table, and change table height or field-of-view on your Last Image Hold (LIH) image. This means you can already see the effect of changing the gantry position or field-of-view format on your region of interest to prepare for your next acquisition without using additional fluoroscopy.

Monitor solutions

Monitor concept (control room)

The default control room configuration consists of two 24 color monitors (acquisition and review) for patient administration and X-ray image display/review. The acquisition monitor features a status bar, which replicates the same system information shown in the exam room (incl. dose values, system positioning, and system messages). The review monitor can be used to review any acquired images with Parallel Working, perform measurements, and access general system settings e.g. for the creation and adjustment of Procedure Cards or to open the electronic Instruction for Use (IFU).

Monitor concept (exam room)

Unless otherwise stated, the default monitor solution in the exam room is a ceiling-suspended rail system, which holds a monitor carriage for 2 widescreen monitors (2F MCS) and is delivered with one 27 monitor. The rail system enables both longitudinal and transversal movements so that the monitors can be flexibly positioned on both table sides and from foot-end to head-end. This ensures access to relevant information during the procedure, independently of the user position. The 27 monitor is used to display the Live/Reference images. The Live image view contains a status bar, which displays all relevant system values such as geometry positioning, select X-ray settings, current dose values, and general system messages.

System controls & user interface

Touch screen module (exam room)

The Azurion touch screen module (TSM) is positioned at the table side in the exam room and is the backbone of the system. The unique aspect of the Azurion TSM is its multi-modality readiness, which means that it allows access and control of other compatible applications. The TSM can be clamped to any of the OR rails, which are located on three sides of the patient table. It comes with a protective frame which is designed to reduce collisions with other equipment in the room.

Azurion control modules (exam room)

One system control module and a viewpad are delivered as standard. The control module provides the controls required to adjust the position of the table and stand, and to perform imaging functions during the acquisition. It has a protection bar that prevents unintended system activation. The orientation of the Azurion control module can be adjusted so that system control remains intuitive and any system movements remain predictable independent of which table rail the control module is clamped to. The viewpad is a handheld remote control that is usually stored in a respective holder next to the TSM. It can be used to control the viewing of acquired images or to allocate acquired images to the reference windows from anywhere in the examination room.

Azurion review module (control room)

The review module is used to switch the Azurion system on or off and offers further buttons to control the basic review functions for the control room acquisition monitor.

Footswitch (exam room)

The function allows the user to perform exposure, fluoroscopy, single-shot exposure, and switch the room light on and off (if connected to the electronic infrastructure of the room light).

Connectivity and security

DICOM compatibility

The Azurion system includes a DICOM image interface, which enables the transfer of DICOM data/clinical images from and to a DICOM destination such as RIS/CIS, PACS or Medical DVD station. The export formats are based on DICOM 3.0 protocols with a fast Ethernet link to make images available within seconds. The DICOM archiving process can be configured in the system settings: images can either be sent automatically or manually upon completion of the examination. The export format is configurable in 512x512 or 1024x1024 matrix in 8- or 10-bit depth. Examination data can be sent to multiple destinations for archiving and reviewing purposes. The DICOM image interface provides DICOM Storage and DICOM Storage Commitment Services. With DICOM Query/Retrieve historic DICOM XA MF and DICOM SC studies can be uploaded to the system.

Security

The Philips Azurion system is based on an embedded Windows 10 Operating system, which offers features such as OS Hardening, AppLocker, and BitLocker functionality. The Azurion is further protected by a firewall, which primary function is to avoid unsolicited and unnecessary traffic from the interventional lab toward the Hospital Network such as multicast (mDNS, SSDP), internal proprietary Azurion broadcast (IST, CWIS), and internal proprietary Azurion traffic for IANA ephemeral ports (TCP/UDP 49152-65535).

Proactive remote services

The Philips 24/7 remote support keeps your lab up and running smoothly and helps you treat more patients. Our remote services make use of proactive model-based analytics to identify issues and enable our service team to have them resolved before you are even aware that there has been an issue. Having your Azurion system connected to our secure VPN based remote network not only enables us to implement operating system security patches timely but also increases our first-time-right fix rate due to continuous system log filing. Philips is committed to ensuring the safety and security of patients, operators, and customers and operates with an ISO/IEC 27001 certified security infrastructure and under its binding corporate rules to ensure that data privacy is always addressed.

Specifications
X-ray generator
Minimum switching time
1 ms

X-ray tube (MRC 200+ GS 0508)
Focal spot size
0.5/0.8 nominal focal spot values
Loadability
max. 45 kW resp. 85 kW on small resp. large focal spot
Fluoro power for 10 min
4,500 W
Fluoro power for 20 min
4,000 W
Anode heat dissipation
21,000 W
Max. assembly continuous heat dissipation
4,000 W
Anode target angle
9°
Extra pre-filtration
0.1, 0.4, 0.9 mm Cu and 1 mm Al backing

Floor stand
Floor stand Z rotation
-105° to +105°
C-arm rotation in head-end position
120° LAO, 120° RAO
C-arm angulation in head-end position
45° cranial, 45° caudal
C-arm rotation/angulation speed
up to 25°/sec
C-arm depth
105 cm (41.3")
Focal spot to isocenter distance
76.5 cm (30.1“)
Isocenter to floor distance
106.5 cm (41.9“)
Source-to-image distance (SID)
89 - 123.5 cm (35 - 48.6")

Monitor concept (control room)
Amount of monitors delivered
2 x 24”color monitors
Resolution of monitors
1,920 x 1,080 Full HD

X-ray generator
Voltage range
40 - 125 kV
Maximum current
1000 mA at 100 kV

Digital acquisition X-ray protocols
Image storage

100,000 images (based on 1,024 matrix)
Cardio and cine mode
3.75 to 30 images/sec

Fluoroscopy modes
Pulse rates
0.5 -30 images/sec
Fluoroscopy storage
enabled with FluoroStore button on control module
Fluoroscopy storage capacity
up to 2000 images
Grid-switched pulsed fluoroscopy
Yes

X-ray generator
Maximum continuous power
2.5 kW for 15 minutes, 1.5 kW for 8 hours

Monitor concept (exam room)
Longitudinal movement of monitor rail
max. 330 cm (129.9“)
Transversal movement of monitor rail
max. 293 cm (115.4“)
Height movement of monitor frame
32 cm (12.6“) or 52 cm (20.5“), depending on ceiling height
Rotation range of monitor frame
360°
Amount of monitors delivered
1 x 27”color monitor
Resolution of monitors
1,920 x 1,080 Full HD

X-ray generator
Nominal power
100 kW

Floor stand
Foor stand Z rotation speed
12°/sec

Quantitative Coronary Analysis

Key benefits

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

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

Specifications

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

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

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

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

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

Specifications

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

Black Anti-fatigue Floor Mat w/logo.
36"x60"

Advanced Room Solutions Plus

Details
Advanced Room Solutions Plus facilitates an interactive 3D lab visualization of 2D site plans allowing for a more intuitive understanding of the entire solution before it is installed. It enables an interactive lab design that allows viewing of standard room templates, interaction with systems and models, and creation of 3D customized room layouts and site plans, and configuration of multiple rooms.

Includes
The Azurion is delivered with the following patient table accessories: lower body protection UT70-10WS, pan handle, set of elbow supports and arm support board.

Disclaimers
The Philips Azurion 7 M12 is a Medical Device as defined in Regulation (EU) 2017/745 (EU-MDR). The Philips Azurion 7 F12 is a commercial package and represents a base configuration of the Azurion 7 M12 medical product.
The content and specifications of the base configuration can be altered by adding additional options to the system configuration. Typical examples are the amount and characteristics of viewing monitors in the exam and control room, enabled X-ray protocols, or table specifications. If altered specifications apply, this will be listed in the respective option article.
The Azurion system delivered can deviate from the product image shown depending on options selected as part of the overall configuration.
The compatible applications Philips SmartCT, Philips IntraSight and Philips Hemo System are independent medical products, which have to be purchased separately. Their commercial availability depends on local clearance. Please reach out to your local sales representative for further information.

1.2 **480V - IGT Compact Low Load Fluoro - Modulys 75KVA** 1
Article No. 989806130836

Details

Low Load Fluoro (LLF) UPS - 5
75kva Socomec Low Load Fluoro (LLF) UPS - 5:
Enough battery to perform fluoro for five minutes (assumes batteries are in good condition) (1 cabinet plus remote display panel).
Tested and approved 3-phase double conversion Low Load UPS enables the system to be used normally with low load fluoro and the exception of the exposure functionality.
Run time 5 mins (typical 8 min)
UPS has a compatibility statement with Philips Imaging Systems.

1.3 **iXR Full Travel Pkg OffSite** 2
Article No. 989801256034

Details

Includes one (1) participant's modest airfare from North American customer location to Cleveland, Ohio, with lodging, ground transportation, and meal expenses. Breakfast/dinner provided by the hotel,

and lunch/breaks are catered by Philips. All other expenses will be the responsibility of the attendee. Details are provided during the scheduling process.

Philips Clinical Services cancellation policies strictly enforced; policy provided during scheduling process.

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

1.4 **Coronary RoadMap ClinEd** 1
Article No. NNAE597

Details

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

Philips Clinical Services cancellation policies strictly enforced; policy provided during scheduling process.

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

1.5 **StentBoost Live_ClinEd** 1
Article No. NNAE596

Details

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

Philips Clinical Services cancellation policies strictly enforced; policy provided during scheduling process.

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

1.6 **Azurion Clinical Education Pkg** 1
Article No. NNAE675

Azurion Clinical Education Pkg

Clinical Education Program for Azurion System:

Essentials Offsite Education : Philips will provide two (2) Cardiovascular Technologists, Registered Technologists, Registered Nurse, or other system operators as selected by customer, with in-depth didactic, tutorial, and hands-on training covering basic functionality and work-flow of the cardiovascular imaging system. In order to provide trainees with the ability to apply all fundamental functioning on their system, and to achieve maximum effectiveness, this class should be attended no earlier than two weeks prior to system installation. This twenty-eight (28) hour class is located in Cleveland, Ohio, and is scheduled based on your equipment configuration and availability. Due to program updates, the number of class hours is subject to change without notice. Customer will be notified of current, total class hours at the time of registration. This class is a prerequisite to your equipment handover OnSite Education. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. **In the event that an EP Navigator workstation has also been ordered, the offsite training course will be tailored to focus on the electrophysiology functionality of the Azurion 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.** Clinical Services cancellation policies apply and will be provided during scheduling process.

Introductory e-Learning: Introductory electronic learnings are provided on the Philips Learning Center educational portal. These courses introduce the Philips IGT systems. Course topics include system startup and shutdown, system functionalities, helpful quick-steps and more. The modules will provide the technologist familiarity with the workflow and software prior to onsite training. It is recommended that this online self-paced learning be completed prior to the onsite applications training. The eLearning modules can be accessed by technologists as needed for reference and refresher. Clinical Services cancellation policies apply and will be provided during scheduling process.

Initial Handover OnSite Education: The primary Philips Education Specialists will provide one consecutive session of 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).** Clinical Services cancellation policies apply and will be provided during scheduling process.

FollowUp OnSite Education: Philips Education Specialists will provide one consecutive session of 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. Clinical Services cancellation policies apply and will be provided during scheduling process.

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

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1.7 **ClarityIQ** 1
Article No. NCVD067

Introduction

Low 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

Details

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

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

Includes

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 Azurion.

1.8 **FlexVision XL + 2 LCD's** 1
Article No. NCVD031

FlexVision XL is an integrated viewing solution designed to give you full control over your viewing environment.
This FlexVision XL is delivered with two 27 inch high brightness color medical grade LCD monitors. The monitors can be mounted on top side or on rear side of the MCS.

Key benefits

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

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

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

2. Medical grade, high resolution color LCD in the Examination Room
This display supports the image quality requirements for monochrome X-ray images as well as color images and replaces all displays normally delivered with the system for the Examination Room.
Main characteristics are:
- 58-inch, 8 Megapixel color LCD
- Native resolution: 3840x2160
- Brightness: Max: 700 Cd/m2 (typical) stabilized: 400 Cd/m2
- Contrast ratio: 1:4000 (typical)
- Wide viewing angle (approx. 176 degrees)
- Constant brightness stabilization control
- Lookup tables for gray-scale, color and DICOM transfer function
- Full protective screen Ingress Protection: IP-21

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

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.

1.9 **3rd party video cloning (2 output)** 1
Article No. FCV0974

Details

Replicate up to two full HD video signals to a 3rd party system.

1.10 **Video input WCB on 1st MCS** 2
Article No. FCV0981

Introduction

A wall connection box attached to the mounting ceiling suspension platform, providing one connection point, DVI or Display Port, to the Azurion system.

Details

The wall connection box attached to the mounting ceiling suspension platform (MCS) provides one connection point, DVI or Display Port, to the Azurion system for Ethernet, video, and USB (Universal Serial Bus). The system powers it and can be installed in the examination room. Once the connection is established it is possible to display a video source (up to FHD resolution) on a monitor and control the connected system.

Includes

1. One cable 3 m DVI-I to DVI-I (3m) and one cable DisplayPort to DisplayPort (3m)

2. A wall connection box, supporting resolutions up to 1920 x 1200 x 60 Hz (WUXGA)

1.11 **Video input WCB outside the MCS** 14
Article No. FCV0985

Key Benefits

- Cable length: 3 m DVI-I to DVI-I cable and 3 m DP to DP cable
- Supported resolutions: up to 1920 x 1200 x 60 Hz (WUXGA)
- Supported features: EDID (Extended Display Identification Data) / DDC2, Hot Plug Detect optionally
- If required, an HDMI-DVI cable can be ordered separately

Details

The wall connection box provides one connection point, DVI or Display Port, to the Azurion system for Ethernet, video, and USB (User Service Bus). It can be installed in the control room, the examination

room, and the technical room and is powered by the hospital mains. Once the connection is established it's possible to display a video source on a monitor and control the connected system.

1.12 **Digital subtraction angiography (DSA)** 1
Article No. NCVA780

Introduction

Digital image subtraction to enable the visualization of blood vessels. The digital image subtraction option can be performed during vascular studies, enabling uncompromised image quality of the subtracted images. The option features a real-time digital subtraction at low frame speeds of 0.5, 1, 2, 3, or 6 frames per second.

Key Benefits

- Allows subtraction on individual image or run basis (run-subtract), which can be applied in the Rotational Scan and Bolus Chase Subtract options.
- Enables 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.
- A lower frame speed will occurs when using ClarityIQ.
- Possible to have mask selection, average masking during acquisition as additional subtracted IQ improvement, landmarking, and pixel shift.
- Live Processing of the vessel map, the device map and the landmark map can be done on the touch screen module.

1.13 **Intercom** 1
Article No. NCVA082

• Enhance communication between exam room and control room

Enhance communication
The remote intercom is used to communicate between the examination and control room. A separate intercom can be connected to the system and placed in the preferred working position in the control room or examination room. The listen function can be selected separately on each intercom. Activating the talk function on a selected intercom automatically disables this function on the other intercom.

1.14 **Wireless footswitch: mono-plane version** 1
Article No. NCVC199

One wireless footswitch in the examination room.

Key benefits
• Reduces clutter around the examination table
• Simplifies preparation and cleanup
• Streamlines workflow in the interventional suite

Reduce clutter and streamline workflow

The wireless footswitch option streamlines workflow, reduces clutter, and simplifies preparation and cleanup in the interventional suite. Clinicians can use the footswitch to wirelessly control the X-ray system in the examination room, from any convenient position around the table. No sterile covers are needed with the IPX8 certified waterproof design.

Specifications

• The mono-plane wireless footswitch is a 3 pedal version; one pedal for fluoroscopy, one for exposure and one to control the room light/single shot. The pedals can be configured according customers preferred lay-out.
• The wireless footswitch is working via RF technology and is fully tested and released for medical use. It has an active range up to 10 meters, depending on structures within this range.
• The wireless footswitch has a lithium battery which only needs to be recharged once per week. During recharging the footswitch still can be used and is fully functional. In parallel, a wired footswitch can also be used.
• The status of the battery is indicated by an LED-indication on the footswitch itself, so that the user can decide when the footswitch needs to be recharged.
• The wireless footswitch has high water ingress protection standard (IPX8), it can easily be cleaned in water.
The wireless footswitch has an on/off switch. It can be switched off when not in use. When the footswitch is active, but not in use, it will go into a sleep-mode. It will be re-activated when touched or when one of the pedals is pressed.

1.15 **Premium Table (Pivot, APC, Volcano)** 1
Article No. NCVD606

Introduction

The Azurion premium patient table is designed to support a full range of interventional procedures. It enables automated positioning, clinical flexibility and is ready to support IVUS and physiology imaging at table side.

Key Benefits

- Remarkably high patient load ability, while enabling effortless table panning
- Allows for emergency CPR in any table position
- Excellent patient positioning with remarkable flexibility and easy patient transfer
- Save time and manage X-ray dose with automatic positioning
- Prepared for IVUS and physiology integration at table side with a Philips IntraSight system

Details

The Azurion premium patient table supports a wide range of routine and complex interventional procedures. The table is equipped with a feather-light free floating table top for remarkably high patient load ability, whilst enabling effortless table panning. It is also designed to allow for emergency cardiopulmonary resuscitation (CPR) in any table position.

The table is equipped with our pivot feature simplifying transradial access, upper extremity angiography and patient transfer. One finger push-to-pivot allows effortless patient positioning. The table moves with minimal friction, making it even easier to move larger patients. A secure mechanism locks the tabletop in place to prevent it from moving.

The included full system Automatic Position Control (APC) functionality is designed to save time and manage X-ray dose. Reproducing precise coordinates (height, longitudinal and lateral positions) is critical for obtaining accurate visualizations. Therefore, the table features an easy way to recall and store stand and table positions, to help manage x-ray dose and improve efficiency. The integrated tabletop brake kit also prevents the tabletop from floating when power goes off.

The table comes with the required cabling pre-installed to connect a Philips IntraSight system that allows for easy control of your IVUS and physiology imaging at table side. The cabling is neatly routed through the table base, reducing clutter and supporting a clean work environment.

Specifications

Patient table

Table height (min./max.)	74 -104 cm (29.1 inch - 40.9 inch)	**Tabletop length (incl. OR rail)**	319 cm (125.6 inch)
Tabletop width	50 cm (19.7 inch)	**Max. table load**	275 kg (606 lbs) + 500 N additional force max. tabletop extension in case of CPR
Max. patient weight	250 kg (551 lbs)	**Table up/down the speed**	30 mm/s (1.2 inch/s)
Pivot range	-90°/+180° or -180°/+90°	**Detent positions for pivot movement**	0°, 13°, 90° and 180° or -180° (+/- 0.5°)

Includes

The Azurion premium patient table includes: Pivot, Full-system auto-position control (APC), Prep table for IntraSight.

The patient table is delivered with the following accessories: a patient mattress, patient straps, drip stand, OP rail accessory clamps and cable holders (15 pieces). It also includes an additional OR rail at the Azurion table base to mount the Bedside Utility Box (BUB) of Philips IntraSight or Philips Core.

Additional Information

The Azurion premium patient table can be extended with the prepared for table mount injection option and subtracted bolus chase option.

The table height range can change due to other options. If altered specifications apply, this will be listed in the respective option article.

1.16 **Long mattress cardio** 1
Article No. FCV0510

- 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

1.17 **Prep table for Table Mount inj** 1
Article No. NCVC265

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

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

1.18 **Dynamic Coronary Roadmap** 1
Article No. NCVC542

Introduction

When advancing guidewires and devices through the vasculature during percutaneous coronary interventions, it's important to understand the relationship between the device and the anatomy. Navigation is based on the physician's knowledge of the patient's anatomy, shown on angiograms and live fluoroscopic images. As the physician works, small shots of contrast agent are applied to check the device position, on the live fluoro image with the anatomical reference provided by the previously acquired angiogram.

Details

Note: when ordering Dynamic Coronary Roadmap and/or StentBoost Live for a non-FlexVision system a single dedicated color monitor must be added to the MCS.

Dynamic Coronary Roadmap is a Medical Device as defined in Regulation (EU) 2017/745 (EU-MDR)

Includes

Dynamic Coronary Roadmap combines the live fluoro and angiogram image into a single adaptive roadmap image, which provides immediate feedback on the position of the device and its relationship to the anatomy to guide navigation. Dynamic Coronary Roadmap features include: - Automatic creation and storage of a dynamic roadmap from each acquired coronary angiogram. Only one roadmap per projection is stored; - Automatic overlay of the dynamic roadmap on live fluoroscopy; - Automatic

guidance to reach projections for which a roadmap is available; - The Dynamic Coronary Roadmap functionality is fully integrated in the interventional X-ray system; - Image snapshots or movies can be archived to any DICOM compatible PACS. These include DICOM XA and DICOM SC.

1.19 **StentBoost Live** 1
Article No. NCVC544

Introduction

When inserting a stent in complex cardiac vasculature, inexact positioning and under deployment are always a challenge.

Key Benefits

- StentBoost Live is a Medical Device as defined in Regulation (EU) 2017/745 (EU-MDR)

Details

StentBoost Live features include: - Automatic marker detection; - Real-time image enhancement during the StentBoost Live run; - Immediately after acquiring the StentBoost Live run, the run is automatically looped three times to allow for further review; - StentBoost Live functionality is fully integrated in the interventional X-ray system; - Image snapshots or movies can be archived to any DICOM compatible PACS. These include DICOM XA and DICOM SC.

Note: when ordering Dynamic Coronary Roadmap and/or StentBoost Live for a non-FlexVision system a single dedicated color monitor must be added to the MCS.

Includes

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

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

StentBoost Live can be applied to any cine run acquisition and at least four frames of images are required.

1.20 **DoseAware**
Article No. 722367

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Details

Configured offering

1.21	**DoseAware Xtend pack** **Article No. FCV0854**	1

Key benefits:
- DoseAware Xtend, providing staff working in an X-Ray environment with direct, real time dose feedback.
- Enabling pro-actively to optimize behavior and manage exposure to scattered dose.
- DoseAware Xtend provides smarter read out with the DoseAware data per procedure by sharing information from the Philips X-ray system:
o An advisory when user is advised to take more radiation protection measures, like using lead curtain or lead shielding between themselves and the X-ray Tube
o Accumulative dose data per procedure
o A relative value as behavior indicator (Relative dose in %) per procedure (normalized data by reference PDM on C-Arm)

With all the information DoseAware Xtends provide, the individual can understand, act and change behavior to manage the received dose.
The DoseAware Xtend combines individual dose information from the PDM with modality procedure data from the Philips X-ray system and integrates this into real time feedback.

The DoseAware Xtend screen will be displayed either on the FlexVision monitor, which allows for flexible real-time display close to live view or any other preferred position or other dedicated monitor

Specifications: The following elements are included in this bundle.
• 6 Personal Dose Meters (1 for use as reference PDM)
• 1 Personal Dose Meter rack
• 1 Dosimetry hub
• Dose view software

The Dose Manager package includes a cable for connecting the PDM with the PC (not included) and

It includes a cable for connecting the PDM with the PC (not included).The Dose view software uses a USB connection for installation on a PC (not included), with following PC requirements:
• Windows XP, -7,- 8.1 or -10.NET 3.5 onwards
• At least 2 GB system memory
• At least one available USB port
• At least 1GB free disk space

1.22	**Remote Service IGT** **Article No. 722240**	

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Details

Configured offering

1.23 **Cabinet Rear Cover** 1
Article No. 459801079651

Cabinet Rear Cover

1.24 **Cabinet Rear Cover Deep** 2
Article No. 459801613311

Introduction

The Cabinet Rear Cover Deep is part of the Azurion technical cabinets and, depending on country of delivery, can be delivered before the actual system delivery to support a more efficient installation process.

1.25 **Patient table adaptation plate** 1
Article No. 989600213943

Introduction

The patient table adaptation plate is designed to simplify the installation process of the Azurion patient table. As the adaptation plate can be installed on top of the room floor, it is not necessary to carry out extensive floor construction works, which is usually required in case the floorplate is embedded into the floor.

Details

This option increases the minimum table height, specified in the default configuration, by 3cm (1.2 inch).

Includes

The patient table adaptation plate is backwards compatible. This means that a new Philips Azurion patient table can be mounted on top of an existing floorplate of predecessor tables, which were used in the previous Philips Allura platform (AD5 patient table).

1.26 **Clip rails for Monitor Ceiling Carriage (390cm, 153.5")** 1
Article No. 459800938361

Introduction

The clip rails for the Monitor Ceiling Carriage (MCC) are part of the ceiling rail construction, which holds the exam room monitors. Depending on country of delivery, these rails can be delivered and installed

before the actual delivery of the Philips Azurion IGT system to support a more efficient installation process.

1.27 **MONITOR CEILING CARRIAGE** 1
Article No. 459800706722

Monitor ceiling carriage

Line	Description	Qty

2 **CV Third Party Products**
Article No. 100133

Details

Configured offering

2.1 **MD/ Mark7 Arterion Table Mount Injector** 1
Article No. 989806101012

Introduction

ART700 TABL - Easy-to-use functionality, simple set-up, and use for single-patient injections, the MEDRAD® Arterion offers solutions for a range of procedures
Automated and manual control of your injections, including VFlow to deliver hand injections with high accuracy
Connectivity with imaging equipment, flexible configurations and automated contrast delivery to enhance workflow efficiency
Table mount to match room configuration
Cable length / Interface cable type specified on order

Includes

Bayer Medical Care B.V. - MEDRAD® Mark 7 Arterion is an established contrast injection system to support your clinical success in angiographic diagnostic and interventional procedures including endovascular aortic repair (EVAR), transarterial embolization (TAE), and cerebral angiography

Automated delivery of contrast with parameters you set
Ability to manually control flow similar to hand injection with VFlow™* hand controller option
Flexibility to monitor and control the injector from multiple locations
ISI connectivity to enable injection control from injector or imaging equipment
Our quality care comes in customized solutions, including on-site clinical training, service and emergency technical support
*add to quote via separate 12NC

2.2 **MD/ VFlow Hand Controller** 1
Article No. 989806101063

PHILIPS

Introduction

ART 700 VFL - Bayer Medical Care B.V. - Medrad® VFlow Software and Sterile Hand Controller provide the flexibility to deliver injections with the accuracy of an injector to enable consistent contrast delivery. Low flow and small volume selective injection of 1.0-10.0 mL/s in 0.1 mL/s increments. Puffing to localize catheter tip. Automatic re-arm to rapidly repeat injections.

2.3	**Cable Spooler** **Article No. 989801220012**	2
2.4	**Lamp Y LED 1F** **Article No. 989801220397**	2

LE7017100 Lamp YLED-1F with Portegra2 extension/spring arm 750/910 mm

Technical Data and Specifications

Model YLED-1F
Central light intensity (at 1 m distance) 70,000 lx
Colour temperature 4100 ± 200 K
Colour rendering index at 4100 Kelvin (CRI) Ra 95
Focusable light field size 140 250 mm
Electronic brightness control 50% 100%
Sterilisable handle Yes
Temperature increase in head area 0.5 K

Power consumption (total) 24 VA
Mains voltage
and frequency 100 240 VAC
at 50 60 Hz

Number of LED modules 17
Lifetime of LEDs 50,000 h
Working area 70 140 cm
Height adjustment (on Portegra2 spring arm) 117 cm
Lamp dimensions 28 x 36 cm
Housing colour RAL 9002

Hazardous substances (EU Directive 2011/65/65) RoHs compliant
Housing Protected against splashed water IP44
Fire protection class V0
Medical Products Directive 93/42/EEC Yes
Use according to DIN VDE 0100-710 Yes
Approvals CE / NRTL

2.5	**RAD SHIELD W/ARM (CONTOURED) 61X76** **Article No. 989801229910**	1

Contoured Rad Shield with Arm rest. 61X76

2.6 **Lower Body Protection** 1
Article No. 989801220388

Details

"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."

2.7 **Ceiling Track w/Column & Handle Ext** 2
Article No. 989801220273

Mavig 2.5m Ceiling Track with Ceiling trolley, 360 degree column, and brake handle extension.

2.8 **MD/ STARSystem** 1
Article No. 989604354501

Introduction

The Adept Medical STARSystem (AM0160) is a combination of the STARBoard, STARSupport and STARTable, an ultimate solution for radial access procedures. The STARBoard is designed to presenting the wrist in hyper-extension for access then relaxation. The STARSupport clips onto the STARBoard, facilitating left arm radial procedures. The STARTable contains 0.5mm lead (Pb) enclosed in the vertical surface for additional scatter radiation protection.

2.9 **Vitalinq Communication System** 1
Article No. 989806105835

Vitalinq Communication System

The Vitalinq Model 94A-07 Communication System is an intercom system designed for use in Cath, EP and IR labs.

Each Vitalinq intercom and music system is provided with everything needed for installation, including:
Six speakers (one communication and two music speakers per room)
Procedure room microphone
Control room desk microphone
Control room corded headset with mute switch
Pre-terminated color-coded cables
Speakers “daisy chain”together using color-coded Ethernet cables, thereby minimizing the number of cables required and simplifying installation.
Console Dimensions (Working Surface Footprint): 8.5”x 9”x 4.5”
Console Weight: 5.5 lbs
System Weight 60 lbs

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1 Year Warranty

Line	Description	Qty
3	**SYNCVISION** **Article No. 797406** SYNCVISION	
3.1	**SyncVision** **Article No. NVLV010** SyncVision IVUS Co-registration System SyncVision IVUS and IFR Co-registration System SyncVision Workstation CPU, Power Supply, Isolation Transformer Medical Grade, Joystick Controller, Optical USB Mouse and Keyboard, LCD Monitor 19" Philips, Cable Kit, SyncVision System Operator's Guide. End User License Agreement Customer agrees that use of the SyncVision software is subject to the terms of the End User License Agreement, as it may be updated by VOLCANO from the time to time ("EULA"). A copy of the EULA is also available online at www.volcanocorp.com/products/pdf-files/end-user.pdf. The terms of the EULA are incorporated herein by reference. Three (3) Year Software Support Agreement Customer agrees that the initial term of the Software Support Agreement (SSA) is three (3) years, which term shall automatically commence upon installation of SyncVision, This three-year term may be extended upon mutual agreement of the parties and is subject to earlier termination as provided in the SSA. The SSA provides for unspecified updates to the SyncVision software released during the Term of the SSA at no additional cost (should any be commercially released). In the absence of an SSA, future Updates will be made available at additional cost to be determined by VOLCANO). A copy of of the SSA is available from your Volcano Sales Representative on online at www.volcanocorp.com/products/pdf-files/software-support.pdf. The terns of the SSA are incorporated herein by reference.	1

Line	Description	Qty
4	**Intrasight De-install/Re-install** **Article No. SP059R** Quote Number: LS - 144603 Quote Number: LS - 144603	1

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4. Local Sales Terms and Conditions

Line	Product Code	Contract Name	Contract No.	Billing Plan
1	722233 Azurion 7 M12	Premier Healthcare Alliance PP-IM-280	PP-IM-280	0/80/20
2	100133 CV Third Party Products	Premier Healthcare Alliance PP-IM-280	PP-IM-280	0/80/20
3	797406 SYNCVISION	Premier Healthcare Alliance PP-IM-280	PP-IM-280	0/80/20
4	SP059R Intrasight De-install/Re-install	NONE	NONE	0/0/100

Payment Terms US: Net 30 Days

INCO Terms: Carriage and Insurance Paid To Destination

This is a cash price quote, which includes ACH, check, and wire transfer. Any other form of payment will result in different price, which may be higher.

Billing Terms: Are as displayed under the Billing Plan table above. For each item, X/Y/Z milestones are defined as follows (unless an Agreement specifying alternative payment terms has been negotiated between the parties):

X is the percentage invoiced upon signed acceptance of quotation or upon receipt of Customer Purchase Order
Y is the percentage invoiced upon delivery of major components to Customer designated location or Philips warehouse.
Z is the percentage invoiced upon completion of installation or product available for first patient use, whichever occurs first.

If DEMO Equipment is included in this quotation it is sold under the Contact No. Contract Name/Contract Number ("Contract") of the products/solution included in this quotation.

All amounts in this quote are in USD

Additional Terms US:

The specific Premier Contract # referenced above represents the applicable Premier agreement with Philips containing discounts, fees and any specific terms and conditions applying to any Product identified as part of this quoted Solution. Philips Standard Terms and Conditions of Sale attached to the Quote Solution will also apply to the extent they do not expressly conflict with the terms and conditions of the referenced Premier Contract

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5. Signature Page

Invoice to:
Charlotte-Mecklenburg Hospital Authority DBA Atrium Health
920 Church St N
Concord, NC 28025-2927

Ship to:
Charlotte-Mecklenburg Hospital Authority DBA Atrium Health
10628 Park Rd
Charlotte, NC 28210-8407

	Total Price
Total Net Price	$ 1,159,379.02

Acceptance by Parties

Each Quotation solution is issued pursuant to and will reference a specific Contract Name/Contract Number ("Contract") representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. Philips Standard Terms and Conditions for Value Added Services (VAS) and Connected Care Warranty is located at http://www.usa.philips.com/healthcare/about/terms-conditions. Any PO for the items herein will be accepted subject to the terms of that Contract. If no Contract is shown, Philips Terms and Conditions of Sale including applicable product warranty or Philips Terms of Service ("Philips Terms") located in the Philips Standard Terms and Conditions of the quotation shall solely apply to the quoted solution. **Issuance by customer of a non-contingent signed purchase order(s) referencing the quote and master agreement (as applicable) expressly represents customer's acceptance of the quotation and the associated terms in lieu of the customer signature on this quotation**. Each equipment system and/or service 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. This quotation contains confidential and proprietary information of Philips Healthcare, a division of Philips North America LLC ("Philips") and is intended for use only by the customer whose name appears on this quotation. Except as otherwise required by state or federal law after strict compliance with any applicable notification and procedural requirements therein, it may not be disclosed to third parties without the prior written consent of Philips. This quotation provides contract agreement discounts and does not reflect rebates that may be earned by Customer, under separate written rebate agreements, from cumulative volume purchases beyond the individual quantity being ordered under this quote. Customer is reminded that rebates constitute discounts under government laws which are reportable by Customers.

The price above does not include sales tax.

Please fill in the below if applicable:

1. Tax Status: Taxable _____ Tax Exempt _____
   If Exempt, please indicate the Exemption Certification Number: _____, and attach a copy of the certificate.
2. Requested equipment delivery date _____
3. If you do not issue formal purchase orders indicate by initialing here: _____
4. For Recurring Maintenance Service & Support Agreements with New Equipment Purchases: Our facility does issue formal purchase orders; however, due to our business/system limitation, we cannot issue a formal purchase order for the service agreement until 90 days prior to standard warranty expiration. Our facility agrees to submit the service agreement purchase order at such time. Initialed: _____

CUSTOMER SIGNATURE
by its authorized representative

Signature: _____
Print Name: _____
Title: _____
Date: _____

PHILIPS SIGNATURE
by its authorized representative

Signature: _____
Print Name: _____
Title: _____
Date: _____

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6. Philips Standard Terms and Conditions

GENERAL TERMS AND CONDITIONS OF SALE AND SOFTWARE LICENSE ("Conditions of Sale") Rev 23

1. Initial Provisions.

1.1 The Products (equipment, service, and software) offered on the quotation by the Philips legal entity identified thereon are subject to these Conditions of Sale.

1.2 The purchase prices set out on the quotation excludes all taxes. All taxes on the Products will be borne by the Customer unless Customer provides a tax exemption certification reasonably in advance of the date the Order is invoiced, otherwise, Philips will invoice Customer for those taxes and Customer shall pay those taxes in accordance with the terms of the invoice.

2. Quotation, Order and Payment.

2.1 Any quotation on the Products will be open for acceptance within the period indicated therein and may be amended or revoked by Philips prior to Customer's acceptance. Any purchase orders shall be subject to Philips' confirmation. Any terms and conditions set forth on the Customer's purchase order or otherwise issued by the Customer shall not apply to the Products.

2.2 The prices and payment terms are set out on the quotation. Orders are subject to Philips' ongoing credit review and approval.

2.3 Interest will apply to any late payments. Customer shall pay interest on any overdue amount not actively disputed paid at the annual rate of twelve percent (12%) which may be billed monthly. If the Customer fails to pay any amounts due or breaches these Conditions of Sale, Philips will be entitled to suspend the performance of its obligations and deduct the unpaid amount from any amounts otherwise owed to Customer by Philips, in addition to any other rights or remedies available to Philips. Philips shall be entitled to recover all costs and expenses, including reasonable attorneys' fees related to the enforcement of its rights or remedies.

2.4 Customer has no right to cancel an order, unless such cancellation right is granted to the Customer by mandatory law.

2.4.1 If the Customer cancels the order prior to the order being sent to the factor for manufacturing, then the Customer shall pay the costs incurred by Philips up to the date of cancellation or 15% of the net selling price of the product(s), whichever is less.

2.4.2 If the Customer cancels the order after the order is sent to the factory for manufacturing, then Customer shall pay the full net selling price of the product(s) ordered.

2.4.3 If Customer has not taken delivery date for each product contained in Philips quotation and Customer's purchase order, or in-lieu of purchase order, within 30 months from Philips' receipt of Customer's purchase order, or in-lieu of purchase order, then the product shall be deemed cancelled and Customer shall be subject to the cancellation fee in section 2.4.1.

2.5 Philips may make partial or early shipments and Customer will pay such invoice based on the date of invoice for each product in accordance with the payment terms set forth in the quotation

2.6 Payments may be made by check, ACH or wire. Philips does not accept transaction fees for any electronic fund transfers or any other payment method; Philips imposes a surcharge on credit cards of 2%, which is not greater than our cost of acceptance. All check payments over $50,000 USD must be paid via eCheck or via Philips prepaid FedEx account with tracking to secure against fraud and misappropriation.

3. Philips Security Interest until Full Payment.

3.1 Philips is entitled to retain a security interest in the Philips products, until Philips receives full payment.

4. Technical Changes

4.1 Philips shall be entitled to make changes to the design or specifications of the Products at any time, provided such change does not adversely affect the performance of the Products.

5. Lease and Trade In

5.1 If the Customer desires to convert the purchase of any Products to a lease the Customer shall within ninety (90) prior to the delivery of the Products provide all relevant rental documents for review and approval by Philips. The Customer is responsible for converting the transaction to a lease and is required to secure the leasing company's approval of all these Conditions of Sale. No product will be delivered to the Customer until Philips has received copies of the fully executed lease documents and has approved the same. For any lease, if the lease does not fund then: (i) Customer guarantees the payment of all monies due or that may become due under these Conditions of Sale; (ii) Philips may convert the lease back to a purchase and invoice Customer accordingly; and (iii) Customer will pay all such invoiced amounts per the invoice terms. In the event that there are multiple Products on one quote, the Product with the longest period for converting the transaction to a lease shall prevail.

5.2 Philips may provide a rental agreement at its discretion.

5.3 In the event Customer will be trading-in equipment ("Trade-In"), the Customer will provide the following:

5.3.1 Customer undertakes to possess good and marketable title to the Trade-In as of the date of the quotation and when Philips takes possession of

the Trade-in from Customer's site. In the event Customer is in breach of this undertaking, Customer shall not be entitled to keep a trade-in credit for such Trade-In and shall promptly refund Philips such credited amounts upon receipt of an invoice from Philips.

5.3.2 The trade-in value set forth on the Philips quotation is conditioned upon Customer providing Trade-In no later than the date Philips makes the new Product listed on such quotation available for first patient use. Customer shall bear the costs of any reduction in trade-in value arising due to a delay by the Customer causing the trade-in not to occur by the expected date and promptly pay the revised invoice.

5.3.3 In the event Philips receives a Trade-In having a different configuration (including software version) or model number than the Trade-In described on the Philips quotation, Philips reserves the right to adjust the trade-in value and revise the invoice accordingly and Customer shall pay such revised invoice promptly upon receipt.

5.3.4 Customer undertakes to (i) clean and sanitize all components that may be infected and all biological fluids from the Trade-In; (ii) drain any applicable chiller lines and cap any associated plumbing and (iii) delete all personal data in the Trade-In. Customer agrees to reimburse Philips against any out- of-pocket costs incurred by Philips arising from Customer's breach of its obligations herein.

6. Shipment and Delivery Date.

6.1 Philips shall deliver the Products in accordance with the Incoterms set forth on the quotation. If Philips and the Customer agree to any other terms of delivery, additional costs shall be for the account of the Customer. Title (subject to Section 3 entitled Philips Security Interest) to any product (excluding software), and risk of loss shall pass to the Customer upon delivery to the shipping carrier. However, Philips shall pay the cost of freight and risk insurance (during transport to destination). Customer shall obtain and pay for insurance covering such risks at destination.

6.2 Philips will make reasonable efforts to meet delivery dates quoted or acknowledged. Failure to deliver by the specified date will not be a sufficient cause for cancellation nor will Philips be liable for any penalty, loss, or expense due to delay in delivery. If the Customer causes the delay, any reasonable expenses incurred by Philips will be paid for by Customer, including all storage fees, transportation expenses, and related costs. Customer shall pay the 80% installment payment upon delivery to Customer site or Philips warehouse. For the purposes of clarification, "Delay" in this section shall mean a date later than the Customer agreed delivery date identified via confirmation of the delivery date with Customer prior to releasing the Product for production.

7. Installation.

7.1 If Philips has undertaken installation of the Products, the Customer shall be responsible for the following at its sole expense and risk:

7.1.1 The provision of adequate and lockable storage for the Products on or near the installation site. Additionally, Customers shall consider the manufacturing labeling requirements for environmental and storge conditions. The Customer will repair or replace any lost or damaged item during the storage period.

7.1.2 Philips or its affiliate's representative shall have access to the installation site without obstacle or hindrance in due time to start the installation work at the scheduled date.

7.1.3 The timely execution and completion of the preparatory works, in conformity with Philips' installation requirements. The Customer shall ensure the prepared site shall comply with all safety, electrical and building codes relevant to the Products and installation thereof.

7.1.4 The proper removal and disposal of any hazardous material at the installation site prior to installation by Philips.

7.1.5 The timely provision of all visa, entry, exit, residence, work or any other permits and licenses necessary for Philips' or Philips' representatives' personnel and for the import and export of tools, equipment, Products, and materials necessary for the installation works and subsequent testing.

7.1.6 The assistance to Philips or Philips' representative for moving the Products from the entrance of the Customer's premises to the installation site. The Customer shall be responsible, at its expense, for rigging, the removal of partitions or other obstacles, and restoration work.

7.2 If Products are connected to a computer network, the Customer shall be responsible for network security, including but not limited to, using secure administrative passwords, installing the latest validated security updates of operating software and web browsers, running a Customer firewall as well as maintaining up-to-date drivers, and validated anti-virus and anti-spyware software. Unauthorized Updates, as defined in the Product Schedules, may adversely affect the functionality and performance of the Licensed Software.

7.3 If any of the above conditions are not complied with, Philips or Philips' representative may interrupt the installation and subsequent testing for reasons not attributable to Philips and the parties shall extend the period for completing the installation. Any additional costs shall be for the Customer's account and Philips shall have no liability for any damage resulting from or in connection with the delayed installation.

7.4 Philips shall have no liability for the fitness or adequacy of the premises or the utilities available at the premises for installation or storage of the Products.

8. Product Damages and Returns.

8.1 The following shall apply solely to medical consumables:
The Customer shall notify Philips in writing substantiating its complaints within ten (10) days from its receipt of the Products. If Philips accepts the claim as valid, Philips shall issue a return authorization notice and the Customer shall return the Products. Each returned Product shall be packed in its original packaging.

9. Product Warranty.

9.1 In the absence of any specific Product warranty attached to the quotation, the following warranty provisions will apply to the Product.

9.2 Hardware Products. Philips warrants to Customer that the Product shall materially comply with its product specification on the quotation and the user documentation accompanying the shipment of such Product for a period of one year from the date of acceptance or first clinical use, whichever occurs first, but under any circumstances, no more than fifteen (15) months from the date of shipment, provided the Product has been subject to proper use and maintenance. Any disposable Product intended for single use supplied by Philips to the Customer will be of good quality until the expiration date applicable to such Product.

9.3 Stand-alone Licensed Software Products. Philips warrants that the Stand-alone Licensed Software shall substantially conform to the technical specification for a period of ninety (90) days from the date Philips makes such Stand-alone Licensed Software available to the Customer. "Stand-alone Licensed Software" means Licensed Software sold without a contemporaneous purchase of a server for the Licensed Software.

9.4 Service. Philips warrants that all services will be carried out with reasonable care and skill. Philips' sole liability and Customer's sole remedy for breach of this warranty shall be, at its option, to give credit for or re-perform the services in question. This warranty shall only extend for a period of ninety (90) days after the completion of the services.

9.5 Customer shall only be entitled to make a Product warranty claim if Philips receives written notice of the defect during the warranty period within ten (10) days from the Customer discovering the defect and, if required, the Product or the defective parts shall be returned to an address stated by Philips. Such defective parts shall be the property of Philips after their replacement.

9.6 Philips' warranty obligations and Customer's sole remedy for the Product shall be limited, at Philips' option, to the repair or replacement of the Product or any part thereof, in which case the spare parts shall be new or equivalent to new in performance, or to the refund of a pro rata portion of the purchase price paid by the Customer solely after a reasonable cure period is given to Philips.

9.7 Philips' warranty obligations shall not apply to any defects resulting from:

9.7.1 improper or unsuitable maintenance, configuration or calibration by the Customer or its agents.

9.7.2 use, operation, modification, or maintenance of the Product not in accordance with the Product specification and the applicable written instructions of Philips or performed prior to the completion of Philips' validation process.

9.7.3 abuse, negligence, accident, damages (including damage in transit) caused by the Customer.

9.7.4 improper site preparation, including corrosion to Product caused by Customer.

9.7.5 any damage to the Product or any medical data or other data stored, caused by an external source (including viruses or similar software interference) resulting from the connection of the Product to a Customer network, Customer client devices, a third-party product or use of removable devices.

9.8 Philips is not responsible for the warranty for the third-party product provided by Philips to the Customer and Customer shall make any warranty claims directly with such vendors. However, if Philips, under its license agreement or purchase agreement with such third party, has right to warranties and service solutions, Philips shall make reasonable efforts to extend to the Customer the third-party warranty and service solutions for such Products.

9.9 During the term of the warranty and any customer service arrangement the Customer shall provide Philips with a dedicated high-speed broadband internet connection suitable to establish a remote connection to the Products in order for Philips to provide remote servicing of the Products by:

9.9.1 supporting the installation of a Philips approved router (or a Customer-owned router acceptable for Philips) for connection to the Products and Customer network (which router remains Philips property if provided by Philips and is only provided during the warranty term.

9.9.2 maintaining a secure location for hardware to connect the Products to the Philips Remote Service Data Center (PRSDC).

9.9.3 providing and maintaining a free IP address within the site network to be used to connect the Products to the Customer's network.

9.9.4 maintaining the established connection throughout the applicable period.

9.9.5 facilitating the reconnection to Philips in case any temporary disconnection occurs.

9.9.6 If Customer fails to provide the access described in this section and the Product is not connected to the PRSDC (including any temporary disconnection), Customer accepts any related impact on Products availability, additional cost, and speed of resolution.

9.9.7 THE WARRANTIES SET FORTH IN THESE TERMS AND CONDITIONS OF SALE AND QUOTATION ARE THE SOLE WARRANTIES MADE BY PHILIPS IN CONNECTION WITH THE PRODUCT, ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, WHETHER WRITTEN, ORAL, STATUTORY, EXPRESS, OR IMPLIED, INCLUDING ANY WARRANTY OF NON-INFRINGEMENT, QUIET ENJOYMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. PHILIPS EXPRESSLY DISCLAIMS THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. MOREOVER, PHILIPS DOES NOT WARRANT ANY PRODUCT USING THE CLOUD TO BE UNINTERRUPTED OR ERROR FREE.

10. Limitation of Liability.

10.1 THE TOTAL LIABILITY OF PHILIPS ARISING UNDER OR IN CONNECTION WITH THE PRODUCT FOR ANY BREACH OF CONTRACTUAL OBLIGATIONS, WARRANTY, NEGLIGENCE, UNLAWFUL ACT OR OTHERWISE IN CONNECTION WITH THE PRODUCT IS LIMITED TO THE ACTUAL PURCHASE PRICE RECEIVED FOR THE PRODUCT THAT GAVE RISE TO THE CLAIM.

10.2 PHILIPS SHALL NOT BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, EXEMPLARY, SPECIAL OR CONSEQUENTIAL DAMAGES AND/OR FOR ANY DAMAGES INCLUDING LOSS OF DATA, PROFITS, REVENUE, BUSINESS INTERRUPTION OR USE IN CONNECTION WITH OR ARISING OUT OF THESE CONDITIONS OF SALE, REGARDLESS OF WHETHER THEY ARE FORESEEABLE OR NOT AND WHETHER THE CLAIM IS MADE IN TORT (INCLUDING

NEGLIGENCE), BREACH OF CONTRACT, INDEMNITY, AT LAW OR IN EQUITY. NEITHER PHILIPS NOR PHILIPS' SUPPLIERS SHALL BE LIABLE FOR ANY LOSS OR INABILITY TO USE MEDICAL OR OTHER DATA STORED ON OR BY THE PRODUCT.

10.3 THE EXCLUSION OF LIABILITY IN THESE CONDITIONS OF SALE SHALL ONLY APPLY TO THE EXTENT ALLOWED UNDER THE APPLICABLE LAW.

10.4 FOR US CUSTOMERS, THE FOLLOWING ARE NOT SUBJECT TO THE LIMITATIONS OF LIABILITY UNDER SECTION 10.1:

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

10.4.2 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.

10.4.3 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 PROTECTED HEALTH INFORMATION.

10.4.4 FINES/PENALTIES LEVIED AGAINST CUSTOMER BY GOVERNMENT AGENCIES CITING PHILIPS' UNAUTHORIZED DISCLOSURE OF PROTECTED HEALTH INFORMATION AS THE BASIS OF THE FINE/PENALTY. ANY SUCH FINES OR PENALTIES SHALL CONSTITUTE DIRECT DAMAGES.

11. Infringement of Intellectual Property Rights to the Products.

11.1 Philips will, at its option and expense, defend or settle any suit or proceeding brought against Customer based on any third-party claim that any Product or use thereof for its intended purpose constitutes an infringement of any intellectual property rights in the country where the Product is delivered by Philips.

11.2 Customer will promptly give Philips written notice of such claim and the authority, information and assistance needed to defend such claim. Philips shall have the full and exclusive authority to defend and settle such claim. Customer shall not make any admission which might be prejudicial to Philips and shall not enter a settlement without Philips' prior written consent.

11.3 If the Product is held to constitute infringement of any intellectual property right and its use by Customer is enjoined, Philips will, at its option and expense, either: (i) procure for Customer the right to continue using the Product; (ii) replace it with an equivalent non-infringing Product; (iii) modify the Product so it becomes non-infringing; or (iv) refund to the Customer a pro rata portion of the Products' purchase price upon the return of the original Products.

11.4 Philips will have no duty or obligation under this clause 11 if the infringement is caused by a Product being:

11.4.1 supplied in accordance with Customer's design, specifications or instructions and compliance therewith has caused Philips to deviate from its normal course of performance.

11.4.2 modified by Customer or its contractors after delivery.

11.4.3 not updated by Customer in accordance with instructions provided by Philips (e.g. software updates).

11.4.4 combined by Customer or its contractors with devices, software, methods, systems, or processes not furnished hereunder and the third-party claim is based on such modification or combination.

The above states Philips' sole liability and Customer's exclusive remedy in respect of third-party intellectual property claims.

12. Use and exclusivity of Product documents.

12.1 All documents and manuals, including technical information related to the Products and its maintenance, as delivered by Philips is the proprietary information of Philips, covered by Philips' copyright, and remains the property of Philips, and as such, it shall not be copied, reproduced, transmitted, or disclosed to or used by third parties without the prior written consent of Philips.

13. Export Control and Product Resale.

13.1 Customer agrees to comply with relevant export control and sanction laws and regulations, including the UN, EU or US ("Export Laws"), to ensure that the Products are not (i) exported or re-exported directly or indirectly in violation of Export Laws; or (ii) used for any purposes prohibited by the Export Laws, including military end-use, human rights abuses, nuclear, chemical or biological weapons proliferation.

13.2 Customer represents that (i) Customer is not located in a country that is subject to a UN, US or EU embargo and trade restriction; and (ii) Customer is not listed on any UN, EU, US export and sanctions list of prohibited or restricted parties.

13.3 Philips may suspend its obligation to fulfil any order or subsequent service if the delivery is restricted under Export Laws or an export/import license is not granted by relevant authorities.

14. License Software Terms.

14.1 Subject to any usage limitations set forth on the quotation, Philips grants to Customer a non-exclusive, non-transferable license, without the right to grant sub-licenses, to incorporate and use the Licensed Software (as specified on the quotation, whether embedded or stand-alone) in Licensed Products and the permitted use (as referenced in the quotation) in accordance with these Conditions of Sale.

14.2 The Licensed Software is licensed and not sold. All intellectual property rights in the Licensed Software shall remain with Philips.

14.3 Customer may make one copy of the Licensed Software in machine-readable form solely for backup purposes. Philips reserves the right to charge for backup copies created by Philips. Customer may not reproduce, sell, assign, transfer or sublicense the Licensed Software. Customer shall preserve the confidential nature of the Licensed Software and shall not disclose or transfer any portion of the Licensed Software to any third party.

14.4 Customer shall maintain Philips' copyright notice or other proprietary legends on any copies of the Licensed Software. Customer shall not (and shall not allow any third party to) decompile, disassemble, or reverse engineer the Licensed Software.

14.5 The Licensed Software may only be used in relation to Licensed Products or systems certified by Philips. If Customer modifies the Licensed Software in any manner, all warranties associated with the Licensed Software and the Products shall become null and void. Customer installation of Philips' issued patches or updates shall not be deemed to be a modification.

14.6 Philips and its affiliates shall be free to use any feedback or suggestions for modification or enhancement of the Licensed Software provided by Customer for the purpose of modifying or enhancing the Licensed Software, as well as for licensing such enhancements to third parties.

14.7 With respect to any third-party licensed software, the Customer agrees to comply with the terms applicable to such licensed software. Customer shall indemnify Philips for any damage arising from its failure to comply with such terms. If the third-party licensor terminates the third party license, Philips shall be entitled to terminate the third party license with the Customer and make reasonable effort to procure a solution.

15. Confidentiality.

15.1 If any of the parties have access to confidential information of the other party, it shall keep this information confidential. Such information shall only be used if and to the extent that it is necessary to carry out the concerned transactions. This obligation does not extend to public domain information and/or information that is disclosed by operation of law or court order.

16. Compliance with Laws and Privacy.

16.1 Each party shall comply with all laws, rules, and regulations applicable to the party in connection with the performance of its obligations in connection with the transactions contemplated by the quotation, including, but not limited to, those relating to employment practices federal and state anti-discrimination laws (including Title VII of the Civil Rights Act of 1964 as amended, the Rehabilitation Act of 1973 as amended and the Veterans Readjustment ACT of 1972 as amended), E-Verify, FDA, Medicare fraud and abuse, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Health care providers are reminded that if the purchase includes a discount or loan, they must fully and accurately report such discount or loan on cost reports or other applicable claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, as required by federal law (see 42 CFR 1001.952[h]).

16.2 Processing of personal data: In relation to the provision of services, Philips may process information, in any form, that can relate to identified or identifiable individuals, which may qualify as personal data. Philips and/or its affiliates will: a) process any protected health information (PHI) as defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) on behalf and by instruction of the Customer, the terms, rights and responsibilities of the Parties for such processing of PHI are set forth in a Business Associate Agreement between the parties and b) process information such as log files or device parameters (which may contain personal data), to provide the services and to enable its compliance with and performance of its task as manufacturer of (medical) devices under the applicable regulations and standards (including but not limited to the performance of vigilance, post market surveillance and clinical evaluation related activities).

16.3 Customer agrees that Philips and/or its affiliates may use any data, other than personal data, generated by a Product and/or otherwise provided by Customer to Philips for Philips' own legitimate business purposes including, but not limited to, for data analytics activities to determine trends of usage and advise on the use of products and services, for research, product and service development and improvement (including the development of new offerings), substantiation of marketing claims and for benchmarking purposes.

17. Force Majeure.

17.1 Each party shall not be liable in respect of the non-performance of any of its obligations to the extent such performance is prevented by any circumstances beyond its reasonable control, including, but not limited to, acts of God, war, civil war, insurrection, fire, flood, labor disputes, epidemics, pandemic, cyber- attack, act of terrorism, governmental regulations and/or similar acts, embargoes, export control sanctions or restrictions, Philips' unavailability regarding any required permits, licenses and/or authorizations, default or force majeure of suppliers or subcontractors.

17.2 If force majeure prevents Philips from fulfilling any order from the Customer or otherwise performing any obligation arising out of the sale, Philips shall not be liable to the Customer for any compensation, reimbursement, or damages.

18. Miscellaneous.

18.1 Any newly manufactured Product provided may contain selected remanufactured parts equivalent to new in terms of performance.

18.2 If the Customer becomes insolvent, unable to pay its debts as they fall due, files for bankruptcy or is subject to it, has appointed a recipient, is subject to a late fee on payments (temporary or permanent), or has its assets assigned or frozen, Philips may cancel any unfulfilled obligations or suspend its performance; provided that, however, the Customer's financial obligations to Philips shall remain in full force and effect.

18.3 If any provision of these Conditions of Sale is found to be unlawful, unenforceable, or invalid, in whole or in part, the validity and enforceability of the remaining provisions shall remain in full force and effect. In lieu of any provision deemed to be unlawful, unenforceable, or invalid, in whole or in part, a provision reflecting the original intent of these Conditions of Sale, to the extent permitted by the applicable law, shall be deemed to be a substitute for that provision.

18.4 Notices or other communications shall be given in writing and shall be deemed effective if they are delivered in person or if they are sent by courier or mail to the relevant party.

18.5 The failure by the Customer or Philips at any time to require compliance with any obligation shall not affect the right to require its enforcement at any time thereafter.

18.6 Philips may assign or novate its rights and obligations in whole or in part, to any of its affiliates or may assign any of its accounts receivable to any party without Customer's consent. Customer agrees to execute any documents that may be necessary to complete Philips' assignment or novation. The Customer shall not, without the prior written consent of Philips, transfer or assign any of its rights or obligations.

18.7 The Customer's obligations do not depend on any other obligations it may have under any other agreement or arrangement with Philips. The Customer shall not exercise any offset right in the quotation or sale in relation to any other agreement or arrangement with Philips.

18.8 These Conditions of Sale shall be governed by the laws of the country or state wherein the Philips legal entity identified in the quotation is situated, and the parties submit to the exclusive jurisdiction of the courts of that country or state, provided that Philips will be entitled to start legal proceedings against the Customer in any other court of competent jurisdiction. The United Nations Convention on Contracts for the International Sale of Goods and the Uniform Computer Information Transactions Act (UCITA), in any form, is expressly excluded.

18.9 Customer will report immediately to Philips any event of which Customer becomes aware that suggests that any Products provided by Philips, for any reason:

18.9.1 may have caused or contributed to a death or serious injury, or

18.9.2 have malfunctioned where such malfunctions would likely cause or contribute to a death or serious injury if the malfunction were to occur again. Additionally, Customer will also report to Philips complaints it receives from its personnel and patients or any other person regarding the identity, quality, performance, reliability, safety, effectiveness, labels, or instructions for use of the Products provided by Philips. Philips shall be solely responsible for submitting any filings or reports to any governmental authorities with respect to the Products provided by Philips hereunder, unless otherwise required by law.

18.10 To the extent applicable to your country or state, Philips and Customer shall comply with the Omnibus Reconciliation Act of 1980 (P.L. 96-499) and it's implementing regulations (42 CFR, Part 420). Philips agrees that until the expiration of four (4) years after furnishing Products pursuant to these Conditions of Sale, Philips shall make available, upon written request of the Secretary of the Department of Health and Human Services, or upon request of the Comptroller General, or any of their duly authorized representatives, these Conditions of Sale and the books, documents and records of Philips that are necessary to verify the nature and extent of the costs charged to Customer hereunder. Philips further agrees that if Philips carries out any of the duties of these Conditions of Sale through a subcontract with a value or cost of ten-thousand U.S. dollars ($10,000.00) or more over a twelve (12) month period, with a related organization, such subcontract shall contain a clause to the effect that until the expiration of four (4) years after the furnishing of such Products pursuant to such subcontract, the related organization shall make available, upon written request to the Secretary, or upon request to the Comptroller General, or any of their duly authorized representatives the subcontract, and books and documents and records of such organization that are necessary to verify the nature and extent of such costs. This paragraph relating to the retention and production of documents is included because of possible application of Section 1861(v) (1) (1) of the Social Security Act (42 U.S.C. 1395x (v) (1) (I) (1989)), as amended from to time to these Conditions of Sale. If Section 1861(v) (1) (1) should be found to be inapplicable, then this paragraph shall be deemed inoperative and without force and effect.

18.11 As of the date of the sale of this Product, Philips represents and warrants that Philips, its employees and subcontractors, are not debarred, excluded, suspended or otherwise ineligible to participate in a federal or state health care program, nor have they been convicted of any health care related crime for Products provided under these Conditions of Sale (an "Excluded Provider"). Philips shall promptly notify Customer if it becomes aware that Philips or any of its employees or subcontractors providing Products hereunder have become an Excluded Provider under a federal or state healthcare program, whereupon Customer shall provide Philips with a reasonable opportunity to discuss and attempt to resolve in good faith with Customer any Customer related concerns in relation thereto, and/or will give Philips a reasonable opportunity to dispute its, or its employee's or subcontractor's, designation as an Excluded Provider. In the event that the parties are unable to resolve any such Customer concerns of the applicable party's designation as an Excluded Provider, then Customer may terminate this order by express written notice for Products not yet shipped or rendered prior to a date of exclusion.

18.12 To the extent applicable to your country or state, it is Customer's responsibility to notify Philips if any portion of the order is funded under the American Reinvestment and Recovery Act (ARRA). To ensure compliance with the ARRA regulation, Customer shall include a clause stating that the order is funded under ARRA on its purchase order or other document issued by Customer.

18.13 To the extent applicable, Customer acknowledges it shall comply with all Medicare. Medicaid or state cost reporting requirements, including discounts afforded to Customer under these Conditions of Sale, for any Products purchased hereunder.

18.14 Entire Agreement. These Terms and Conditions of Sale, the terms and conditions set forth in the quotation and the applicable Philips' product-specific warranty constitute the entire understanding and agreement by and between the parties with respect to the transactions contemplated by the quotation and supersede any previous understandings or agreements between the parties, whether written or oral, regarding the transactions contemplated by the quotation. The pricing in the quotation is based upon the terms and conditions in the quotation. No additional terms, conditions, consents, waivers, alterations, or modifications shall be binding unless in writing and signed by the parties. Customer's additional or different terms and conditions, whether stated in a purchase order or other document issued by Customer, are specifically rejected and shall not apply to the transactions contemplated by the quotation.

19. <u>Product specific terms.</u>

Product specific schedules are incorporated herein as they apply to the Products listed in the quotation and their additional terms shall apply solely to the Products specified therein. If any terms set forth in the Product specific schedules conflict with terms expressly set forth in these Conditions of Sale, the terms set forth in the Product specific schedule shall govern in such instance.

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Schedule 1
Imaging Systems Portfolio (IS) Rev 23

Product Category	Products
Image Guided Therapy (IGT)	Interventional X-Ray (iXR)
	Mobile C-Arms (Surg)
	Philips Image Guided Therapy Corporation (IGTD)fka Volcano (Capital only)
Imaging Clinical Applications (ICAP)	IntelliSpace Portal (ISP)
Diagnostic Imaging	Digital X-Ray (DXR)
	Computed Tomography (CT)
	Magnetic Resonance (MR)
	OEM Imaging Components (Coils)
	Positron Emission Tomography (PET/CT)
	Advanced Molecular Imaging (SPECT & SPECT/CT)
	Radiation Oncology (PROS)

1. Payment Terms.

Unless otherwise specified in the quotation, Philips will invoice Customer and Customer will pay such invoice based on the date of the invoice for each of the products and integration services as follows:

1.1 For Imaging Systems Portfolio:

1.1.1 0% of the purchase price shall be due with Customer's submission of its purchase order.

1.1.2 80% of the purchase price shall be due on delivery of the major components of the Product to Customer designated location or Philips warehouse. Product installation will not begin until Customer has paid this portion of the purchase price.

Subject to Section 6.2 of the Conditions of Sale, 20% of the purchase price shall be due net thirty (30) days from the invoice date based on Product(s) availability for first patient use. Available for first patient use means the product has been installed and substantially meets Philips' systems verification functionality set forth in the installation manual.

2. For IGT Fixed Systems.

2.1 Project management support to enable delivery and installation is provided at no additional cost. Consulting and other turnkey room preparation services are not included.

2.2 Delivery and Installation are included in the purchase of the system.

3. Additional Customer Installation Obligations for Magnetic Resonance (MR).

3.1 Customer shall provide any and all site preparation and shall be in compliance with all radio frequency (RF) or magnetic shielding and acoustical suppression and building codes relevant to the Product and its installation and use.

3.2 If applicable, Customer's contractor or Customer's architect is required to provide detailed information on theproposed Helium Exhaust Pipe for their MRI system prior to installation to ensure safety specifications are being met.

Required Details include:

3.2.1 Architectural drawing or sketch with complete dimensions including lengths, bending radii, bending angles, and pipe diameters for entire Helium Exhaust Pipe run from RF enclosure to discharge location.

3.2.2 Completed Helium Exhaust Pipe Verification Checklist (Provided by Local Philips Project Manager)

3.2.3 Picture showing the area where the Helium Exhaust Pipe will discharge.

3.3 If applicable, Magnets will not be released for delivery unless and until Helium Exhaust Pipe details are provided for verification and have been confirmed to meet all life safety specifications.

3.4 Costs of equipment preservation, to ensure a high-quality system, will be passed to the Customer if the installation site is not ready due to delays not caused by Philips. Additionally, climate control costs during and after equipment installation are also the responsibility of the Customer. Preservation of equipment is required to prevent exposing equipment to the negative effects of a non-climate-controlled construction environment, where there is dust or high humidity. Climate control could include costs associated with ensuring a climate- controlled environment. Activities and expenses required for preservation may include time, materials, and transportation to package and seal, and transport the equipment to a controlled environment to prevent dustfrom entering the equipment. For MR, as may be applicable, this includes the consumption of Helium for life support.

4 Further use of System Data.

4.1 Mandatory Data. Customer acknowledges and agrees that by executing this Agreement and using the Licensed Software, it has agreed that product inventory and crash signature data generated by the LicensedSoftware shall be delivered into the custody of Philips, or of systems maintained on Philips' behalf, without notice to Customer. Such data is referred to herein as "Mandatory Data" and such data is described in the Licensed Software's documentation

for each Licensed Software release; the data comprising Mandatory Data is subject to change with each release of upgrades, updates, patches and modifications to the Licensed Software.

4.2 Customer agrees that any Mandatory Data will be the property of Philips. Part of the Mandatory Data might constitute (non-sensitive) Personal Data, which is anonymized data or aggregate log files, device parameters and other signals collected from the equipment used by Customer and associated with Customer. Customeragrees that Philips may use and disclose Mandatory Data for Philips' own business purposes (including, butnot limited to, for data analytics activities to determine trends of usage of Philips' or its affiliates' devices andservices, to facilitate and advise on continued and sustained use of Philips' or its affiliates' products and services, for product and service development and improvement (including the development of new offerings), substantiation of marketing claims and for benchmarking purposes). In connection with any disclosure of Mandatory Data, Philips will not associate such data with the Personal Data of Customer's patients, consumers, or employees.

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7. 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 and availability for first patient use.

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

3. System Options, Upgrades or Accessories.

3.1 Any Philips' authorized upgrades, options 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:

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

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 (tube) will be substantially free from defects in material and manufacturing workmanship, which impair performance under normal use as specified in Philips' System descriptions and specifications.

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

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

5. MRC Tube Warranty 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; improper site preparation; 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 Dynamic 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.

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 its 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. 8:00am - 5:00pm in the time zone where the Customer is located, 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' representatives (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 recommended and scheduled maintenance instructions provided with the product and Customer is to notify Philips immediately if the product at any time fails to meet its printed performance specifications.

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

9.6 Philips does not provide a warranty for any third-party products furnished to Customer by Philips under the 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 product warranty.

9.8 THE WARRANTIES SET FORTH HEREIN 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 products.

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 or access to the products.

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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 OF PHILIPS ARISING UNDER OR IN CONNECTION WITH THE PRODUCT FOR ANY BREACH OF CONTRACTUAL OBLIGATIONS, WARRANTY, NEGLIGENCE, UNLAWFUL ACT OR OTHERWISE IN CONNECTION WITH THE PRODUCT IS LIMITED TO THE ACTUAL PURCHASE PRICE RECEIVED FOR THE PRODUCT THAT GAVE RISE TO THE CLAIM.

12.2 PHILIPS SHALL NOT BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, EXEMPLARY, SPECIAL OR CONSEQUENTIAL DAMAGES AND/OR FOR ANY DAMAGES INCLUDING, LOSS OF DATA, PROFITS, REVENUE, BUSINESS INTERRUPTION OR USE IN CONNECTION WITH OR ARISING OUT OF THESE CONDITIONS OF SALE, REGARDLESS OF WHETHER THEY ARE FORESEEABLE OR NOT AND WHETHER THE CLAIM IS MADE IN TORT (INCLUDING NEGLIGENCE), BREACH OF CONTRACT, INDEMNITY, AT LAW OR IN EQUITY. NEITHER PHILIPS NOR PHILIPS' SUPPLIERS SHALL BE LIABLE FOR ANY LOSS OR INABILITY TO USE MEDICAL OR OTHER DATA STORED ON OR BY THE PRODUCT.

12.3 THE EXCLUSION OF LIABILITY IN THESE CONDITIONS OF SALE SHALL ONLY APPLY TO THE EXTENT ALLOWED UNDER THE APPLICABLE LAW.

12.4 FOR US CUSTOMERS, THE FOLLOWING ARE NOT SUBJECT TO THE LIMITATIONS OF LIABILITY UNDER SECTION 12.1:

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

12.4.2 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.

12.4.3 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 PROTECTED HEALTH INFORMATION.

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

13. Force Majeure.

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

Philips' system specifications are subject to change without notice.

iXR Product Warranty Rev 23

Attachment D

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project name: AH Pineville Cath Lab #1 Replacement

Provider/Company: Atrium Health

(1)	Purchase price of land	-
(2)	Closing costs	-
(3)	Site Preparation	-
(4)	Construction/Renovation Contract	$1,757,000
(5)	Landscaping	-
(6)	Architect/Engineering Fees	$495,000
(7)	Medical Equipment	$1,377,938
(8)	Non Medical Equipment	$2,000
(9)	Furniture	$4,000
(10)	Consultant Fees (CON Fees and Legal Fees)	-
(11)	Financing Costs	-
(12)	Interest During Construction	-
-(13)	Other (IS, Security, Internal Allocation)	$542,000
(14)	**Total Capital Cost**	$4,177,938

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

December 17, 2024

(Signature of Licensed Architect or Engineer) *DATE*

HEATHER CAROLINE BEARD
REGISTERED ARCHITECT
13583
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 $90,414.

Attachment E

j. Heart/Kidney	0	k. Kidney	0	l. Lung	0
m. Pancreas	0	n. Pancreas/Kidney	0	o. Pancreas/Liver	0
p. Other	0				

Do you perform living donor transplants? No

7. Telehealth/Telemedicine

Telehealth/telemedicine is defined by the U.S. Health Resources & Services Administration as "the use of electronic information and telecommunication technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health, and health administration. Technologies include video conferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications."

Check the appropriate box for each service this facility provides or receives via telehealth/telemedicine. A service may apply to more than one category. **Check all that apply.**

Service	Provide service to other facilities via telemedicine	Receive service from other facilities via telemedicine
Emergency Department	☐	☑
Imaging	☑	☑
Psychiatric	☐	☑
Alcohol and/or substance use disorder (other than tobacco cessation) services	☐	☐
Stroke	☐	☑
Other services	☐	☑

8. Specialized Cardiac Services

8-a. Open Heart Surgery

Open Heart Surgery	Number of Machines/Procedures
1. Number of heart-lung bypass machines	3
2. Total annual number of open heart surgery procedures utilizing heart-lung bypass machine	344
3. Total annual number of open heart surgery procedures done without utilizing a heart-lung bypass machine	20

* For questions on this section, contact Healthcare Planning at 919-855-3865.

8-b. Cardiac Catheterization and Electrophysiology

1. Does this facility provide cardiac catheterization on fixed units or electrophysiology services? Yes

* Cardiac Catheterization procedures (as defined in G.S. § 131E-176 (2g))

Number of units of fixed cardiac catheterization equipment with a CON: 3

* CON Project IDs for fixed equipment:

F-7979-07 covers relocation of 2 units from AH Mercy.

* Number of units of legacy fixed cardiac catheterization equipment (i.e., equipment obtained before a CON was required): 1

	Diagnostic Cardiac Catheterization**	Interventional Cardiac Catheterization***
Number of Procedures* Performed in Fixed Units on Patients Age 14 and younger:	0	0
Number of procedures* performed in fixed units on patients age 15 and older:	1281	844

- Electrophysiology procedures on dedicated electrophysiology equipment

* Number of units of fixed dedicated electrophysiology equipment: 1

* Number of procedures* performed on dedicated electrophysiology equipment: 1014

2. Does this facility provide cardiac catheterization on mobile equipment? No

* A procedure is defined as one visit or trip by a patient to a catheterization laboratory for a single or multiple catheterizations. If the visit includes both diagnostic and interventional procedures, count the interventional procedures only. For example, if a patient has both a diagnostic and an interventional procedure in one visit, Count all EP procedures separately.

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

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

Number of fixed or mobile units of legacy cardiac catheterization equipment owned by hospital (i.e., equipment obtained before a CON was required): 0

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

Name of Mobile Vendor, if not owned by hospital:

Number of 8-hour days per week the mobile unit is onsite *(Examples: Monday through Friday for 8 hours per day is 5 8-hour days per week. Monday, Wednesday, & Friday for 4 hours per day is 1.5 8-hour days per week):* 0

9-a. Does this facility provide any of the following services?

Attachment F

STATE OF NORTH CAROLINA

Department of Health and Human Services
Division of Health Service Regulation

CERTIFICATE OF NEED

for
Project Identification Number #F-7979-07
FID# 923352

ISSUED TO: **Mercy Hospital, Inc. d/b/a Carolinas Medical Center – Pineville and Carolinas Medical Center - Mercy and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center – University and CS Center, LLC d/b/a Carolinas Surgery Center - Randolph**

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: **Expand CMC-Pineville by constructing an 8-story bed tower, renovating several hospital departments, and relocating 50 acute care beds from CMC-Mercy, 36 acute care beds from CMC-University , two operating rooms from Carolinas Surgery Center- Randolph, and two heart-lung bypass machines and two cardiac catheterization labs from CMC – Mercy. Upon completion of this project and Project I. D. #F-7313-05, CMC-Pineville shall have no more than 206 licensed acute care beds and 12 operating rooms/Mecklenburg County**

CONDITIONS: **See Reverse Side**

PHYSICAL LOCATION: **Carolinas Medical Center – Pineville**
10628 Park Road
Pineville, NC 28210

MAXIMUM CAPITAL EXPENDITURE: $174,000,000
TIMETABLE: **See Reverse Side**
FIRST PROGRESS REPORT DUE: September 1, 2008

This certificate is effective as of the 2nd day of April, 2008.

Lee B. Hoffman by CRSAC

Chief, Certificate of Need Section
Division of Health Service Regulation

CONDITIONS:

1. Mercy Hospital, Inc. d/b/a Carolinas Medical Center-Pineville and Carolinas Medical Center-Mercy and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-University and CS Center, LLC d/b/a Carolinas Surgery Center-Randolph shall materially comply with all representations made in the certificate of need application, except as specifically amended by the conditions of approval.

2. Mercy Hospital, Inc., d/b/a Carolinas Medical Center-Pineville [CMC-Pineville] and the Carolinas Medical Center-Mercy [CMC-Mercy] and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center – University [CMC-University] and CS Center, LLC d/b/a Carolinas Surgery Center – Randolph shall relocate no more than 36 acute care beds from CMC-University and 50 acute care beds from CMC-Mercy to increase the number of licensed acute care beds at CMC-Pineville to 206 upon completion of this project and Project I. D. #F-7313-05. CMC-University shall be licensed for no more than 94 acute care beds and CMC-Mercy shall be licensed for no more than 124 acute care beds, upon completion of this project and Project I. D. #F-7313-05.

3. Of the 86 acute care beds to be relocated to CMC-Pineville, six acute care beds shall be developed as labor-delivery-recovery-postpartum (LDRP) beds for a total of 34 LDRP beds, 20 acute care beds shall de developed as intensive care unit (ICU) beds for a total of 30 ICU beds, and 60 acute care beds shall be developed as medical/surgery beds for a total of 132 medical/surgical beds, in addition to the ten existing neonatal Level III beds.

4. Mercy Hospital, Inc., d/b/a Carolinas Medical Center-Pineville [CMC-Pineville] and Carolinas Medical Center-Mercy [CMC-Mercy] and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-University and CS Center, LLC d/b/a Carolinas Surgery Center-Randolph [CSC-Randolph] shall relocate no more than two existing operating rooms from CSC-Randolph to CMC-Pineville, for a total of nine shared operating rooms and three inpatient operating rooms, which includes two dedicated C-Section operating rooms, upon completion of this project and Project I., D. #F-7313-05. CSC-Randolph shall be licensed for no more than six operating rooms following completion of this project.

5. Mercy Hospital, Inc., d/b/a Carolinas Medical Center-Pineville [CMC-Pineville] and Carolinas Medical Center-Mercy [CMC-Mercy] and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-University and CS Center, LLC d/b/a Carolinas Surgery Center-Randolph [CSC-Randolph] shall convert the existing inpatient operating room to a shared operating room, for a

total of no more than 11 shared operating rooms at CMC-Mercy upon completion of this project and Project I. D. #F-7313-05.

6. Mercy Hospital, Inc., d/b/a Carolinas Medical Center-Pineville [CMC-Pineville] and Carolinas Medical Center-Mercy [CMC-Mercy] and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-University and CS Center, LLC d/b/a Carolinas Surgery Center-Randolph [CSC-Randolph] shall relocate no more than two existing units of cardiac catheterization equipment from CMC-Mercy to CMC-Pineville, for a total of three units of cardiac catheterization equipment at CMC-Pineville and one unit of cardiac catheterization equipment at CMC-Mercy.

7. Mercy Hospital, Inc., d/b/a Carolinas Medical Center-Pineville [CMC-Pineville] and Carolinas Medical Center-Mercy [CMC-Mercy] and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-University and CS Center, LLC d/b/a Carolinas Surgery Center-Randolph [CSC-Randolph] shall relocate no more than two existing heart-lung bypass machines from CMC-Mercy to CMC-Pineville. One of the two machines shall be used for emergency back-up only and in no instance shall both heart-lung bypass machines at CMC-Pineville be scheduled simultaneously. CMC-Mercy shall remove one existing heart-lung bypass machine from service, and terminate open heart surgery services on the CMC-Mercy campus following completion of the project.

8. Mercy Hospital, Inc., d/b/a Carolinas Medical Center-Pineville [CMC-Pineville] and Carolinas Medical Center-Mercy [CMC-Mercy] and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-University and CS Center, LLC d/b/a Carolinas Surgery Center-Randolph [CSC-Randolph] shall add no more than twenty-two unlicensed observation beds, of which ten beds shall be used for general observation for a total of 16 general observation beds, two shall be used for obstetrical observation, and ten shall be used in the clinical decision unit (CDU) in the emergency department. CMC-Pineville shall have a total of no more than 28 observation beds upon completion of this project and Project I. D. #F-7313-05.

9. Mercy Hospital, Inc., d/b/a Carolinas Medical Center-Pineville [CMC-Pineville] and Carolinas Medical Center-Mercy [CMC-Mercy] and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-University and CS Center, LLC d/b/a Carolinas Surgery Center-Randolph [CSC-Randolph] shall develop at CMC-Pineville no more than three acute dialysis units to be used for inpatients only.

10. Mercy Hospital, Inc., d/b/a Carolinas Medical Center-Pineville [CMC-Pineville] and Carolinas Medical Center-Mercy [CMC-Mercy] and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center-University and CS Center, LLC d/b/a Carolinas Surgery Center-Randolph [CSC-Randolph] shall not acquire, as part of this project, any equipment that is not included in the

project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.

11. Mercy Hospital, Inc., d/b/a Carolinas Medical Center-Pineville and Carolinas Medical Center-Mercy and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center – University and CS Center, LLC d/b/a Carolinas Surgery Center – Randolph shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

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TIMETABLE:

50% Completion of construction ----------September 30, 2010
75% Completion of construction ---------- August 2, 2011
Completion of construction ---------- May 2, 2012
Occupancy/offering of service(s) ---------- July 1, 2013

equipment of a similar nature does the applicant own in other states?

Not applicable. The proposed project does not involve the acquisition of major medical equipment as defined by NCGS 131E-176 (14o) or 16 (f1). The equipment list in Exhibit II-28 does include the purchase of three new cardiac catheterization labs and one gamma camera, each of which is valued at more than $750,000. This equipment will be replacement of existing equipment (including replacing the two cardiac cath labs relocated from CMC-Mercy). By the completion date of the proposed project, normal wear and aging of the equipment listed will necessitate replacement.

(b) List by name and location all similar medical equipment in North Carolina currently managed/operated by the company or person(s) that will be managing this facility.

Not applicable. The proposed project does not involve the acquisition of major medical equipment as defined by NCGS 131E-176 (14o) or 16 (f1). The equipment list in Exhibit II-28 does include the purchase of three new cardiac catheterization labs and one gamma camera, each of which is valued at more than $750,000. This equipment will be replacement of existing equipment (including replacing the two cardiac cath labs relocated from CMC-Mercy). By the completion date of the proposed project, normal wear and aging of the equipment listed will necessitate replacement.

(c) Describe specific experience of the applicant in providing the proposed service(s).

Not applicable. The proposed project does not involve the acquisition of major medical equipment as defined by NCGS 131E-176 (14o) or 16 (f1). The equipment list in Exhibit II-28 does include the purchase of three new cardiac catheterization labs and one gamma camera, each of which is valued at more than $750,000. This equipment will be replacement of existing equipment (including

replacing the two cardiac cath labs relocated from CMC-Mercy). By the completion date of the proposed project, normal wear and aging of the equipment listed will necessitate replacement.

Attachment G

PHILIPS

Image Guided Therapy System

Azurion 7

With Azurion, performance and superior care become one

17% reduction of procedure time with Philips Azurion at St. Antonius Hospital.[1]

The ability to treat one more patient per day today, or in the future

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 Image Guided Therapy System - Azurion 7. It 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 image guided therapy platform.

As the interventional space evolves, we continue to integrate essential lab systems and tools onto the Azurion platform for a better user experience. The Azurion integrated lab offers a seamless user experience that gives you control of all compatible applications from a single touch screen at table side, to help make fast and informed decisions without breaking sterility.

With Azurion's industry leading image guided therapy platform, 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.

Outstanding user experience

At Philips, we are guided by you. With Azurion, we've brought the user experience and simplicity of touch screen controls right where it's needed to make a difference to lab workflow.

Full control at table side to enhance decision making
You can now control all compatible applications in the interventional lab via the central touch screen module and FlexVision Pro. 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.

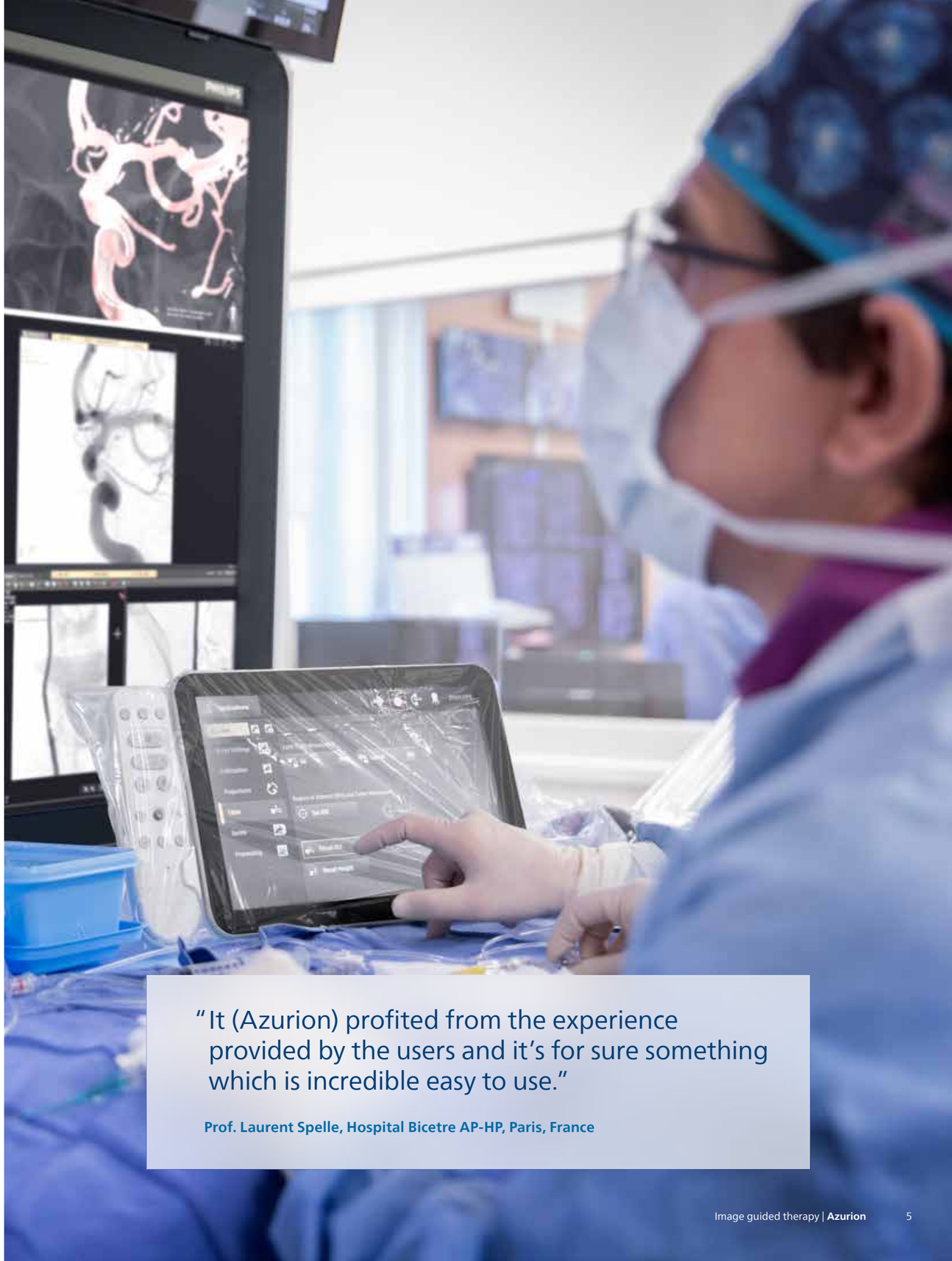
Gain advanced physiologic guidance to help improve treatment outcomes
You can access IntraSight, a comprehensive suite of clinically proven[2-6] imaging, physiology and co-registration[7] tools, via the central touch screen module. These tools allow you to go beyond the angiogram and complete your view of the target vessel, to help you make fast, informed clinical decisions.

Azurion with FlexArm – more independent control for physicians
The FlexArm option further evolves Azurion's table side control with the intuitive Axsys controller to make procedures flow naturally and easily. When changes or complications occur, the physician can quickly and easily take action. This can also reduce the need to move in and out of the sterile field during a procedure.

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.

Clear and simple to use
On screen, information clearly stands out against the distinctive black background where active applications are highlighted. Backlit icons and distinctly shaped buttons on the Control Module promote intuitive operation. All controls are designed for easy cleaning to meet stringent sterility requirements.

Less clutter and faster workflow
With the Azurion integrated lab, controlling all compatible applications at the touch screen module can reduce extra interfaces and controls table side.
The FlexSpot works according to the same principle.
It gives you access to all compatible applications in one compact, customizable workplace that can be placed in the control room or exam room where needed.
Save time by setting the display to re-arrange and re-size as applications are opened and closed.



"It (Azurion) profited from the experience provided by the users and it's for sure something which is incredible easy to use."

Prof. Laurent Spelle, Hospital Bicetre AP-HP, Paris, France

With Azurion we help you to optimize your lab performance

"The new integrated system saves us time, because we can control all applications via one user interface."

Dr. med. Peter Ong, Robert Bosch Hospital, Stuttgart, Germany.

Azurion's integrated approach can help you achieve measurable improvements in throughput, cost reduction and staff satisfaction.

Do more at table side

With our enhanced touch screen module, you will experience simpler, smoother procedures, based on familiar tablet interactions. For example, you can now easily mark relevant details on 2D images on the touch screen with your fingertip.

Azurion allows you to run an entire case without breaking sterility

The touch screen module offers total control within the sterile field. Run an entire case table side as you quickly diagnose, navigate, annotate and measure to your exact specifications, even when wearing gloves and under a sterile drape. Table side control saves you from having to go to the control room to access applications.

Save time through Instant Parallel Working

The Azurion 7 image guided therapy system 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.

Simplify workflow

Enter patient information once and it is automatically transferred to connected applications to reduce data entry errors. To save time, IntelliSpace Cardiovascular[8] and IntelliSpace Portal launch automatically with the specific patient on the exam room monitor.

Azurion's full system automatic position control (APC) gives you more flexibility to recall the stored position of the C-arm, table and other parameters for a particular image to simplify positioning.

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. At these workspots you can co-register[9] iFR or IVUS data with the angiogram, 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.

Safeguard clinical performance and enhance lab security over time with Windows 10 platform

The standard Windows 10 platform can help support compliance with the latest security and standards to protect patient data. It can also accommodate new software options to extend your system's clinical relevance over time.

Touch screen module Pro

FlexSpot

FlexVision Pro

Azurion enables you to provide superior care

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

Clinical demands are getting more specific. So are we.

Our clinical suites are tailored to meet your specific challenges, while offering you the flexibility to carry out procedures in the easiest, most efficient way.
We have a flexible portfolio of integrated technologies and services to support the full interventional spectrum. We also offer Hybrid OR solutions that create an innovative care environment for performing open and minimally invasive surgical procedures.

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. The system will automatically select the appropriate ProcedureCard(s) based on the (CIS/RIS/HIS) code of the scheduled procedure from the information system.

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.

Enhance patient care with continuous monitoring

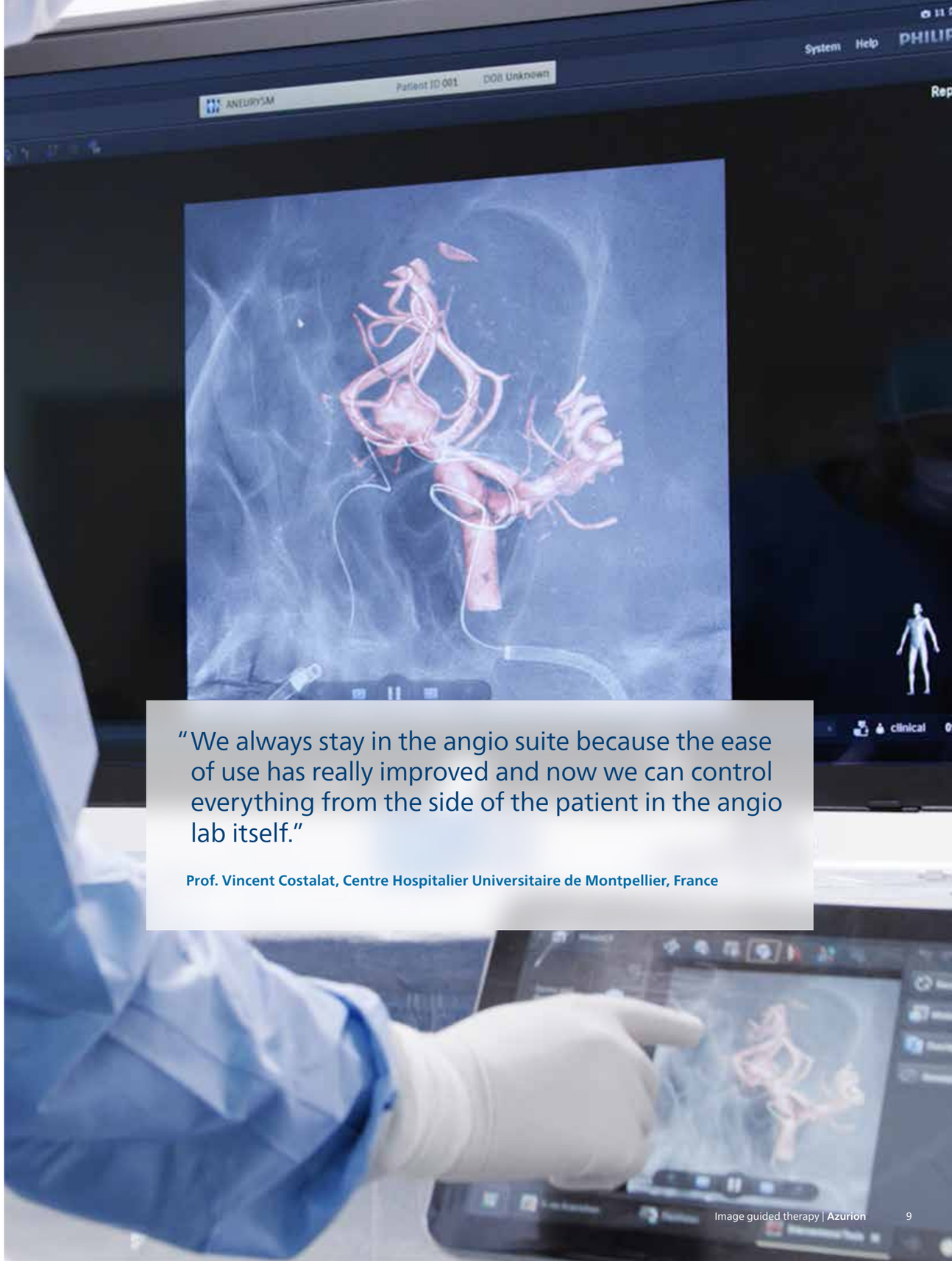
The Philips Interventional Hemodynamic System is integrated with the IntelliVue X3 patient monitor, allowing continuous patient monitoring throughout procedures in the interventional workflow. There is no need to change cables, minimizing disruption to vulnerable patients and giving you more time to focus on them. Continuous patient monitoring also results in a gap-free patient record.

Increase clinical confidence with 3D imaging

The clinical application software SmartCT enriches our exceptional 3D interventional tools for interventional procedures with step-by-step guidance that is designed to remove the barriers to acquiring 3D images in the interventional lab.

Easily control advanced 3D visualization and measurements at table side on the touch screen module. Studies have shown that 3D CT-like imaging can enhance diagnostic accuracy [9,10,11] and support improved patient outcomes.

Clinical suites



"We always stay in the angio suite because the ease of use has really improved and now we can control everything from the side of the patient in the angio lab itself."

Prof. Vincent Costalat, Centre Hospitalier Universitaire de Montpellier, France

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.

High quality images at low X-ray dose

Our ClarityIQ imaging technology provides significantly lower dose across clinical areas, patients, and operators.[12] In routine coronary procedures[13], ClarityIQ technology reduces patient dose by 67% without affecting procedural performance while maintaining equivalent image quality, compared to a system without ClarityIQ.[14,15] In interventional Neuro procedures, ClarityIQ technology reduces patient dose by 65%, compared to a system without ClarityIQ.[16]

Managing dose efficiently

DoseWise is integrated across the Philips image-guided therapy Azurion portfolio. DoseWise consists of a comprehensive range of radiation dose management tools, training, and integrated product technologies that aim to help you take control over patient care, staff safety, and regulatory compliance. Another feature is the Zero Dose Positioning function. It lets you pan the table, change table height or field-of-view on your Last Image Hold (LIH) image. This enables positioning without the use of radiation on previously recorded last image.

Managing dose across your organization

Philips DoseAware provides real-time feedback in the exam room It displays the invisible nature of radiation in real time, so that you and your staff can see it promptly, easily and simply – and rapidly understand the effect of behavior changes and work patterns.

DoseAware Xtend is a dedicated solution for treatment rooms that builds on the capabilities of DoseAware and interfaces seamlessly with the Azurion image-guided therapy system. Thanks to this seamless integration, DoseAware Xtend can provide live individual dose rates (live screen) during procedures, and summarized procedure doses (review screen). It also reminds staff to better protect themselves by providing a warning symbol when the lead protection screen is not being used properly.

Perform standardized quality assurance verifications in just 5 minutes[17]

To make it easier for you to routinely perform consistent verification tests of radiation dose and image quality, only Philips offers the User Quality Control Mode (UQCM) tool on its Azurion system.
With this option, you can independently verify and audit the radiation and image quality related factors of your Azurion system in a standardized way in just 5 minutes, as well as carry out a range of validation and quality assurance tests.

Azurion – a comprehensive image guided therapy platform

The Azurion 7 integrated lab brings together a range of sophisticated interventional tools, including clinically proven[2-6] imaging and physiology tools, advanced hemodynamic measurements and cardiac informatics to support clinical excellence during procedures.

Cybersecurity woven into every layer of your interventional suite

Philips Image Guided Therapy recognizes the importance of securing medical devices and protecting your patient data. Together we can maintain a secure environment by remaining vigilant and identifying the ever-changing cybersecurity threat landscape. We are committed to meeting the needs and requirements of our customers. Our security plans encompass your people, processes, and technology with the goal of ensuring the confidentiality, integrity and availability of critical data - whether at rest or in transit. For more information, please contact your sales representative or send an email to: productsecurity@philips.com

Azurion 7 C/F12

With its 12" Flat Detector, the 7 Series provides high-resolution imaging over a large field-of-view with flexible projection capabilities, making it ideal for cardiac interventions. The entire coronary tree can be visualized in a single view with minimal table panning.

Azurion 7 C/F20

Enhance visibility for diverse cardiac and vascular procedures with the excellent image quality and broad coverage of the next generation 20" Flat Detector. This system supports head-to-toe imaging and patient access from all sides.

Azurion 7 C20 with FlexArm

Create a Hybrid OR that provides unlimited imaging flexibility for diverse procedures and exceptional positioning freedom for medical teams with the Azurion 7 and the next generation 20" Flat Detector, combined with the ceiling-mounted FlexArm option. You get a highly cost-effective environment that is ready for the procedures of the future.

Azurion 7 C20 with FlexMove

Move to a Hybrid OR with confidence, with the Azurion 7 and the next generation 20" Flat Detector, combined with the ceiling-mounted FlexMove option. FlexMove offers exceptional workflow flexibility to perform open and minimally invasive procedures in the same room.

Azurion 7 B12/12

The Azurion 7 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.

Azurion 7 B20/12

The Azurion 7 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 B20/15

Enhance insight and certainty during neuro interventions with the Azurion 7 biplane system. It pairs a 20" frontal with a 15" lateral detector.

High productivity combined with low cost of ownership

With Philips, you get the best service performance which enables you to treat more patients, and professional support to help you deliver cost-efficient care.

Best service performance[18] enables you to treat more patients[19]

Staying on top of today's complex healthcare environment is challenging enough without a constant concern of keeping your systems up and running smoothly. With Philips, your operations are protected by the best overall service engineer performance for imaging systems according to IMV ServiceTrak for 5 years in a row. Philips remotely connected systems provide 135 more hours of operational availability per year, enabling you to treat more patients.

Professional support helps you deliver cost-efficient care

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 to meet the needs of healthcare organizations
- A broad range of healthcare consulting programs to help your organization further enhance the efficiency and efficacy of your care delivery process
- 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.

Cost-effectively manage future upgrades with the Technology Maximizer program

Technology Maximizer is a program that runs in tandem with your Philips Service Agreement.[20] When you opt into the program, you receive the latest available software and hardware[21] technology releases for a fraction of the cost of purchasing them individually. The Technology Maximizer Plus allows you to further tailor upgrades to reduce costs. No need to wait for budget approval.
No need to buy individual upgrades. Just a cost-effective way to manage ongoing technology upgrades through your operational budget.

Doing business responsibly and sustainably

When you choose Philips, you are choosing a partner committed to meet sustainability and circular economy ambitions. As a leading health technology company, our purpose is to improve people's health and well-being through meaningful innovation, positively impacting 2.5 billion lives per year by 2030.

The Azurion is the result of our EcoDesign process and offers significant environmental improvements:

- 100% product take-back after customers' acceptance of our trade-in offer.
- 100% repurposing of the equipment that is returned to Philips
- Up to 90% of material weight is reused during refurbishing, depending on type and age of product
- At least 10% lower energy consumption over total product life usage[22]

Read more about our Environmental, Social and Corporate Governance (ESG) commitments here: https://www.philips.com/a-w/about/sustainability.html

Philips remotely connected systems provide

135 more hours of operational availability on average, per year, enabling you to treat more patients.[19]

References

1. Philips whitepaper 12nc 4522 991 30501; Reduction of procedure time by 17% with Philips Azurion in independently verified study; https://www.philips.com.au/healthcare/resources/landing/ azurion/lab-performance-study-results. Results are specific to the institution where they were obtained and may not reflect the results achievable at other institutions.
2. Davies JE, et al. DEFINE-FLAIR: A Multi- Centre, Prospective, International, Randomized, Blinded Comparison of Clinical Outcomes and Cost Efficiencies of iFR and FFR Decision-Making for Physiological Guided Coronary Revascularization. New England Journal of Medicine, epub March 18, 2017.
3. Gotberg M, et al., Instantaneous Wave-Free Ratio Versus Fractional Flow Reserve Guided Intervention (IFR-SWEDEHEART): A Multicenter, Prospective, Registry-Based Randomized Clinical Trial. New England Journal of Medicine, epub March 18, 2017.
4. Patel M. "Cost-effectiveness of instantaneous wave-Free Ratio (iFR) compared with Fractional Flow Reserve (FFR) to guide coronary revascularization decision-making." Late-breaking Clinical Trial presentation at ACC on March 10, 2018.
5. Maehara A, Matsumura M, Ali ZA, Mintz GS, Stone GW. IVUS-guided versus OCT-guided coronary stent implantation. J Am Coll Cardiol Img. 2017;10:1487-1503.
6. Choi K, et al. Impact of Intravascular Ultrasound-Guided Percutaneous Coronary Intervention on Long-Term Clinical Outcomes in Patients Undergoing Complex Procedures. JACC: Cardivascular Interventions. Mar 2019, 4281; DOI: 10.1016/j.jcin.2019.01.227.
7. Co-registration tools available within IntraSight 7 configuration via SyncVision
8. It is the user's responsibility to ensure that Philips network requirements (such as performance, VPN) for IntelliSpace Cardiovascular are met. Note: Automatic same patient launch feature is available only with specific versions of ISCV and ISP.
9. Loffroy R et al. Comparing the Detectability of Hepatocellular Carcinoma by C-arm Dual-Phase Cone-Beam Computed Tomography During Hepatic Arteriography With Conventional Contrast- Enhanced Magnetic Resonance Imaging Cardiovasc Intervent Radiol. 2012, 35 (1), 97-104,
10. Berman et al. ,The use of threedimensional rotational angiography to assess the pulmonary circulation following cavopulmonary connection in patients with single ventricle. https:// www.ncbi.nlm.nih.gov/pubmed/22419358 Catheter Cardiovasc Interv. 2012 Nov 15;80(6):922-30.
11. https://pubmed.ncbi.nlm.nih.gov/?term=Schernthaner+RE&cauthor_id=25476872 Schernthaner et al., Delayed-Phase Cone-Beam CT Improves Detectability of Intrahepatic Cholangiocarcinoma During Conventional Transarterial Chemoembolization Cardiovasc Intervent Radiol , 38 (4), 929-36, 2015
12. In 28 individual comparative studies, Philips ClarityIQ was associated with reductions in patient radiation exposure. All 28 studies can be found online: www.philips.com/clinicallyproven
13. Routine coronary interventions comprise of fluoroscopy and exposure usage.
14. Buytaert, D., et al., Evaluation of patient and staff exposure with state of the art x ray technology in cardiac catheterization: A randomized controlled trial. Journal of Interventional Cardiology, 2018. 31(6): p. 807-814.

    (95% CI of 53%, 77% for all diagnostic and interventional coronary procedures). The results of the application of dose reduction techniques will vary depending on the clinical task, patient size, anatomical location and clinical practice. The interventional cardiologist assisted by a physicist as necessary has to determine the appropriate settings for each specific clinical task.
15. Results based on total dose area product from a single center prospective controlled randomized study (University Hospital Gent, Belgium) on 122 patients (42 for Allura Xper and 80 for AlluraClarity) undergoing coronary procedures. Of the 122 patients, 102 (83.6%) had a diagnostic procedure without intervention and 51 (41.8%) resulted in a diagnosis of no coronary disease. Patient radiation exposure was quantified using cumulative dose area product as collected from Radiation Dose Structured Reports and/or Allura Reports. Baseline dose was maintained by configuring both systems to power up with the lowest dose settings as default and default procedure settings for cardio were used. Exam duration and fluoro time was consistent between the systems and an increase in number of exposure images and runs with the AlluraClarity was attributed to the biplane configuration compared to the monoplane configuration of the Allura Xper.
16. Söderman, M., et al., Radiation dose in neuroangiography using image noise reduction technology: a population study based on 614 patients. Neuroradiology, 2013. 55(11): p. 1365-1372.

    Routine neuro interventions comprise of DSA and fluoroscopy usage.

    (95% CI 56%, 68% for routine diagnostic neuroendovascular procedures, 95% CI 58%, 71% forroutine interventional neuroendovascular procedures). The results of the application of dose reduction techniques will vary depending on the clinical task, patient size, anatomical location and clinical practice. The interventional radiologist assisted by a physicistas necessary has to determine the appropriatesettings for each specific clinical task. Results based on total dose area product from a single center retrospective historically controlled cohortstudy (Karolinska Hospital - Solna, Sweden) on 614patients (302 for Allura Xper and 312 for AlluraClarity) undergoing neuro endovascular procedures.
17. The related tests were performed by 3 users with different background and experience level. The test timings were performed using a frontal plane of an Azurion biplane R2.1 system (FD20/15N, STM-1713 (Dick Bruna), location QL-1).
18. IMV ServiceTrak 2018 X-ray Cardiovascular Systems.
19. Data shown is an average, based on the comparison between remotely connected and non-remotely connected systems. Data sample from 2018 for Allura FD and Azurion systems (n=9955).
20. Eligible RightFit Service Agreements are available with Technology Maximizer.
21. Not currently available for ultrasound hardware.
22. Determined via the COCIR SRI method. Compared to predecessor Allura Xper platform. Exact energy reduction depends on configuration

4522 991 74251 * JAN 2022

How to reach us
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healthcare@philips.com

Attachment H

EQUIPMENT COMPARISON – AH Pineville Cardiac Catheterization Lab #1 Replacement

	EXISTING EQUIPMENT	**REPLACEMENT EQUIPMENT**
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, etc.)	Cardiac Catheterization Equipment	Cardiac Catheterization Equipment
Manufacturer	GE	Philips
Model name/number	Innova 3100	Azurion 7 F12
Other method of identifying the equipment (e.g., Serial Number, VIN #)	55423	Not Available Until Installed
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2009	2024
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project	Not available due to system transition	$4,177,938
Total cost of the equipment	Not available due to system transition	$1,377,938
Location of the equipment	AH Pineville Room #1103	AH Pineville Room #1103
Document that the existing equipment is currently in use	Existing equipment performed 716 procedures from Nov 2023 to Oct 2024	N/A
Will the replacement equipment result in any increase in the **average charge per procedure**?	N/A	No
If so, provide the increase as a percent of the current average charge per procedure	N/A	N/A
Will the replacement equipment result in any increase in the **average operating expense per procedure**?	N/A	No
If so, provide the increase as a percent of the current average operating expense per procedure	N/A	N/A
Type of procedures performed on the existing equipment	Cardiac Catheterization Procedures	N/A
Type of procedures the replacement equipment will perform	N/A	Cardiac Catheterization Procedures

Attachment I

AH Pineville Cardiac Catheterization Lab #1	
Month	**Volume**
Nov-23	60
Dec-23	40
Jan-24	55
Feb-24	62
Mar-24	71
Apr-24	56
May-24	52
Jun-24	54
Jul-24	49
Aug-24	66
Sep-24	71
Oct-24	80
Total	**716**

From: Huber, Brighid K
To: Stancil, Tiffany C; Moore, Chalice L
Subject: [External] Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Atrium Health Pineville
Date: Tuesday, December 17, 2024 4:00:24 PM
Attachments: 2024 CMHA dba AH Pineville Exemption Request to Replace Cath Lab #1.pdf

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Good afternoon,

I hope this email finds you well! Please find attached an exemption request submitted by The Charlotte-Mecklenburg Hospital Authority ("CMHA") d/b/a Atrium Health Pineville to replace existing cardiac catheterization equipment.

Thank you, and please let me know if you have any questions.

Best,

Brighid

Brighid Knoll Huber, MHA, ATC
Core Market Growth Business Development
Mobile: 724-986-6214

Atrium Health
