NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

JOSH STEIN • Governor
DEVDUTTA SANGVAI • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

June 9, 2025

Murray Gilgo
mgilgo@carolinaeasthealth.com

No Review

Record #:	**4798**
Date of Request:	May 23, 2025
Facility Name:	CarolinaEast Medical Center
FID #:	923126
Business Name:	CarolinaEast Health System
Business #:	2722
Project Description:	Perform cardiac catheterization procedures in hybrid operating room
County:	Craven

Dear Mr. Gilgo:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the representation in your request and the CON law **in effect on the date of this response to your request,** the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. **As a reminder, it is unlawful to offer or develop a new institutional health service without first obtaining a certificate of need. The Department reserves the right to impose sanctions, including civil penalties and the revocation of a license, upon any entity that offers or develops a new institutional health service without first obtaining a certificate of need.**

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Gregory F. Yakaboski
Project Analyst

Micheala Mitchell
Chief

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

From: Kim Meymandi
To: Yakaboski, Greg
Subject: [External] CarolinaEast Letter of Exemption
Date: Thursday, May 29, 2025 11:12:17 AM
Attachments: image001.png

Hi Greg-

To clarify and summarize our discussion regarding the Exemption letter from CarolinaEast:

- CarolinaEast is licensed for three fixed cardiac caths.
- CarolinaEast has a CON approved hybrid OR that because of its set-up and functionality is capable of performing cardiac cath procedures.
- CarolinaEast does a high volume of EP procedures and is utilizing one fixed cardiac cath exclusively for EP procedures.
- CarolinaEast seeks to utilize the hybrid OR as the third unit cardiac cath equipment when the third cath unit is unavailable and/or while the unit of cath equipment is being replaced.
- CarolinaEast attests that at no time will more than three cardiac cath procedures be performed simultaneously.

Please advise if you need any additional information and thank you for your assistance.

Kim

Kim Meymandi | MANAGER

kimmeymandi@ascendient.com | 919.226.1712 | linkedin | www.ascendient.com

May 23, 2025

Ms. Micheala Mitchell, Chief
Mr. Greg Yakaboski, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation, NC DHHS
2704 Mail Service Center
Raleigh, NC 27699-2704
Micheala.Mitchell@dhhs.nc.gov
Greg.yakaboski@dhhs.nc.gov

RE: Request for Exemption from Review to Replace Cardiac Catheterization Lab and Confirmation of Ability to Use Hybrid OR Occasionally for Cardiac Catheterization Procedures
Facility Name: CarolinaEast Medical Center
County: Craven

Dear Ms. Mitchell and Mr. Yakaboski:

Replacement Equipment Exemption

Please accept this letter as notification of the intent of CarolinaEast Medical Center (CEMC) to replace one unit of existing cardiac catheterization equipment for a total cost less than $3,089,400[1] pursuant to N.C. Gen. Stat. § 131E-184(a)(7) and 10A NCAC 14C .0303.

Under N.C. Gen. Stat. § 131E-184(a)(7), the CON law provides that an applicant's proposal "[t]o provide replacement equipment" is exempt from Certificate of Need review if the Department receives prior written notice from the entity proposing the new institutional health service, including an explanation of why the new institutional health service is required. Replacement equipment is defined in the CON law under N.C. Gen. Stat. § 131E-176(22a)[2] as:

> "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

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1 On October 1, 2024, the cost threshold amount for replacement equipment was increased to $3,089,400 based on the change in the Medical Care Index (MCI) of the Consumer Price Index published by the US Department of Labor on September 30, 2024 for the 12-month period preceding September 1.

2 Please note that the text cited below is as amended by Session Law 2023-7, which was enacted March 27, 2023, with the cited portion effective immediately.

> 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."

As set forth below, CEMC's proposed cardiac catheterization equipment replacement meets the definition of replacement equipment and is exempt from Certificate of Need review.

CEMC seeks to acquire a Philips Azurion 7 M20 (Replacement Equipment) to replace CEMC's existing cardiac catheterization equipment (Existing Equipment). The proposed replacement is needed as the Existing Equipment is beyond its useful life. The Replacement Equipment is functionally similar to the Existing Equipment and will be used for the same treatment purposes, although the Replacement Equipment will possess expanded capabilities given technological advancements. The proposed Replacement Equipment will not be used to provide a new health service and will not result in more than a 10 percent increase in patient charges or per procedure operating expenses within the first 12 months after it is acquired. Further, as documented in Attachment 1, once the Replacement Equipment has been installed and is operational, the Existing Equipment will be sold or otherwise disposed of by CEMC and will not be otherwise utilized in the state without permission.

Specifically, the total capital cost for the proposed equipment replacement, including all costs associated with equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making the Replacement Equipment operational is $1,933,223. Attachment 2 contains a projected capital cost form for the project and all associated construction and engineering fees as well as vendor quotes for the proposed Replacement Equipment and all associated systems and tools. Attachment 3 provides the vendor quote for the Replacement Equipment. As documented in Attachment 1, the Existing Equipment will be removed from North Carolina by the vendor and will not be used again without Agency approval.

As outlined above and illustrated in the Attachments, the proposed Replacement Equipment qualifies as replacement equipment pursuant to regulatory and statutory definitions (N.C. Gen. Stat. § 131E-176(22a) and 10A NCAC 14C .0303). As such, the proposed project is exempt from Certificate of Need review pursuant to N.C. Gen. Stat. § 131E-184(a)(7).

Confirmation of Ability to Use Hybrid OR Occasionally for Cardiac Catheterization Procedures

CEMC currently holds three Certificates of Need (CONs) for fixed cardiac catheterization equipment and operates one unit of dedicated electrophysiology (EP) equipment. Due to CEMC's high volume of electrophysiology procedures, the third cardiac catheterization lab is being utilized exclusively for EP procedures, reducing the total number of regularly active cardiac catheterization labs at CEMC to a total of two. At present, CEMC is able to regularly accommodate its scheduled cardiac catheterization procedures in two labs; however, occasionally a third lab is needed for urgent or emergent cases when the two labs are already being used for scheduled patients. Of note, CEMC also holds a CON for a hybrid OR, which involves the same type of equipment used in performing cardiac catheterization procedures. In order to ensure that sufficient cardiac catheterization capacity is available for both scheduled and emergency patients, both during the catheterization lab replacement process and moving forward, CEMC also seeks confirmation that it may occasionally utilize its hybrid OR to perform cardiac catheterization procedures when its third cardiac catheterization lab is not being used for those procedures. CEMC attests that at no time will more than three cardiac catheterization procedures be performed simultaneously.

Ms. Micheala Mitchell, Chief
Mr. Greg Yakaboski, Project Analyst
May 23, 2025

Since CEMC currently provides cardiac catheterization services and does not propose to develop any additional services, and because CEMC seeks to utilize existing equipment capable of performing cardiac procedures when its primary cardiac catheterization lab is unavailable rather than acquire new equipment, CEMC believes the definitions of "new institutional health service" in NC General Statute § 131E-176(16) do not apply in this case.

Furthermore, CEMC believes that this request is analogous to other providers that have requested confirmation that they can utilize an existing unit of non-cardiac catheterization equipment for cardiac catheterization procedures during replacement or other downtimes of the cardiac catheterization equipment. See, e.g., UNC Health Wayne's request at https://info.ncdhhs.gov/dhsr/coneed/reviews/2017/nov/1219_wayne_wmh_cc.pdf and Novant Health Matthews Medical Center's request at https://info.ncdhhs.gov/dhsr/coneed/reviews/2015/aug/0914_mecklenburg_nhmmccc.pdf. The request is also comparable to facilities requesting to use dedicated research MRI equipment for radiation oncology treatment planning during installation of replacement equipment. See, e.g., Duke University Hospital's request at https://info.ncdhhs.gov/dhsr/coneed/reviews/2016/jun/0718_durham_duh.pdf.

Thank you in advance for your consideration of these requests. If you have any additional questions, please do not hesitate to contact me. CEMC hopes to commence work on this project in the near future, so please let me know if I can provide any additional information to expedite our request.

Sincerely,

Murray Gilgo
Vice President, Physician Practice Management
CarolinaEast Medical Center

Attachment 1 – Letter Re: Continuous Historical Use and Future Disposition of Existing Equipment
Attachment 2 – Projected Capital Costs
Attachment 3 –Vendor quote

May 23, 2025

Ms. Micheala Mitchell, Chief
Greg Yakaboski, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation, NC DHHS
2704 Mail Service Center
Raleigh, NC 27699-2704
Micheala.Mitchell@dhhs.nc.gov
greg.yakaboski@dhhs.nc.gov

Dear Ms. Mitchell and Mr. Yakaboski:

CarolinaEast currently owns and operates a unit of fixed cardiac catheterization (Existing Equipment) that has been in operation continuously on the main campus of CarolinaEast since it was acquired. The Existing Equipment has not been taken out of service since originally acquired, except on a temporary basis as needed for updates or repairs. Additionally, the Existing Equipment has been used at least 10 times in the past 12 months.

CarolinaEast proposes to replace the Existing Equipment with new fixed cardiac catheterization equipment to be located in the same space as the Existing Equipment. CarolinaEast understands that the Existing Equipment will be removed from North Carolina by the vendor. CarolinaEast will not own or use the Existing Equipment after its replacement.

Please contact me with any questions regarding this matter.

Sincerely,

Patti Hudson
Executive Director
CarolinaEast Health System

Projected Capital Cost Form

Building Purchase Price	N/A
Purchase Price of Land	N/A
Closing Costs	N/A
Site Preparation	N/A
Construction/Renovation Contract(s)	425,000
Landscaping	N/A
Architect / Engineering Fees	10,000
Medical Equipment	1,480,223
Non-Medical Equipment	28,000
Furniture	N/A
Financing Costs	N/A
Interest during Construction	N/A
Other (specify)	N/A
Total Capital Cost	1,933,223

CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

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

Patti Hudson

_____ Date Signed: 5.7.25_____

Signature of Officer/Agent

Executive Director_____

Title of Officer/Agent

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Sold to:
CarolinaEast Medical Center
2000 Neuse Blvd
New Bern, NC 28560-3449

Presented By
Hunter Pfister
Philips Healthcare a division of Philips North America LLC
414 Union Street
Nashville, Tennessee 37219
Email: hunter.pfister@philips.com

Ship to:
CarolinaEast Medical Center
2000 Neuse Blvd
New Bern, NC 28560-3449

Quote #: Q-00474112
Customer #: 94017567
Quote Date: 03/24/25
Valid Until: 06/25/25

Replace Allura Cath Lab- Site ID 49325440

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

Pricing contained in this proposal is contingent on receiving the PO for Q-00473083 concurrently with this proposal.

Thank you again for considering Philips.

Regards,

Hunter Pfister

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

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1. Financial Overview

Line	Article No.	Description	Qty	Net Price
1	722234	Azurion 7 M20	1	$ 967,648.92
2	797403	INTRASIGHT	1	$ 185,000.00
3	100133	CV Third Party Products	1	$ 67,573.43
4	846001	Philips Laser System	1	$ 230,000.00
5	SP059Q	FlexAccount	1	$ 30,000.00

Total Net Price

Total Net Price
$ 1,480,222.35

(Optional Items)

Line	Article No.	Description	Qty	Net Price	Customer Initials
1	**722234**	**Azurion 7 M20**			
	NCVD064	(Opt) Extension to FlexVision Pro	*1*	*$ 45,978.95*	_____
	NCVD072	(Opt) SmartMask Monoplane	*1*	*$ 13,614.87*	_____
	NCVD078	(Opt) FD Dual Fluoro monoplane	*1*	*$ 22,355.99*	_____
	NCVD081	(Opt) Touch Screen Module Pro	*1*	*$ 31,929.83*	_____
	NCVC542	(Opt) Dynamic Coronary Roadmap	*1*	*$ 36,876.85*	_____

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2. Quote Summary

Line	Article No.	Description	Qty	Net Price
1	**722234**	**Azurion 7 M20**		
1.1	NNAT308	Conv. Azurion 7 C20	1	$ 424,729.65
1.2	NNAE709	Low Load Fluoro (LLF) UPS - 5	1	$ 0.00
1.3	989806130836	480V - IGT Compact Low Load Fluoro - Modulys 75KVA	1	$ 40,845.00
1.4	NNAT194	Yes, ordering Standalone IS7	1	$ 0.00
1.5	NNAE737	No, live/ref is not present	1	$ 0.00
1.6	NNAE738	Yes, SBL is needed	1	$ 0.00
1.7	NNAT134	Stentboost Live bundle	1	$ 0.00
1.8	NNAT253	Yes new to Philips Azurion Sys	1	$ 0.00
1.9	NNAT252	New to Philips Azurion System	1	$ 17,922.55
1.10	FNA2912	Number of users at this site?	4	$ 0.00
1.11	989801256034	iXR Full Travel Pkg OffSite	2	$ 4,716.00
1.12	NNAE596	StentBoost Live_ClinEd	1	$ 0.00
1.13	NNAE597	Coronary RoadMap ClinEd	1	$ 0.00
1.14	NNAE675	Azurion Clinical Education Pkg	1	$ 0.00
1.15	NCVD069	ClarityIQ.	1	$ 107,948.00
1.16	NCVD220	MRC200+ GS 04/07	1	$ 54,486.52
1.17	NCVD032	FlexVision XL HD + 2 LCD's	1	$ 106,533.40
1.18	FCV0974	3rd party video cloning (2 output)	1	$ 8,798.01
1.19	NCVD487	MultiSwitch	1	$ 6,237.26
1.20	NCVD061	optional ref monoplane	1	$ 4,916.52
1.21	FCV0981	Video input WCB on 1st MCS	2	$ 11,317.32
1.22	FCV0985	Video input WCB outside the MCS	8	$ 19,202.48
1.23	NCVA093	Physio Viewing	1	$ 5,136.99
1.24	NCVA694	Subtracted Bolus Chase	1	$ 20,696.00
1.25	NCVA695	FD Rotational Angio	1	$ 19,774.79
1.26	NCVD076	30 frame per second extension for monoplane systems	1	$ 15,015.59
1.27	NCVD137	CardiacSwing	1	$ 12,420.70
1.28	NCVA258	CO2 VIEW TRACE	1	$ 2,948.88
1.29	NCVD099	Quantitative Coronary Analysis	1	$ 7,228.85
1.30	NCVD100	Left Ventricular Analysis	1	$ 10,314.36
1.31	NCVA082	Intercom	1	$ 1,971.78
1.32	NCVC199	Wireless footswitch: mono-plane version	1	$ 7,245.41

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1.33	NCVD606	Premium Table (Pivot, APC, Volcano)	1	$ 31,010.35
1.34	FCV0510	Long mattress cardio	1	$ 1,992.49
1.35	NCVD379	StentBoost Subtract	1	$ 7,762.93
1.36	**722240**	**Remote Service IGT**		
1.37	459801079651	Cabinet Rear Cover	1	$ 468.88
1.38	459801613311	Cabinet Rear Cover Deep	2	$ 3,684.80
1.39	989600205302	FLOORPLATE AD5/AD7(NONSWIVEL)	1	$ 863.24
1.40	459800660501	Clip rail 390 cm G-Stand	1	$ 3,185.91
1.41	459800938361	Clip rails for Monitor Ceiling Carriage (390cm, 153.5")	1	$ 1,546.38
1.42	459800706722	MONITOR CEILING CARRIAGE	1	$ 6,727.88
				$ 967,648.92
2	**797403**	**INTRASIGHT**		
2.1	NNAW511	IntraSight 7	1	$ 185,000.00
				$ 185,000.00
3	**100133**	**CV Third Party Products**		
3.1	989806101012	MD/ Mark7 Arterion Table Mount Injector	1	$ 27,203.95
3.2	989806101063	MD/ VFlow Hand Controller	1	$ 1,532.94
3.3	989806100590	Port2 Lamp Yled 70K-lux focus&arm	1	$ 4,204.51
3.4	989806100465	Port2 Track250cm&Trolley column 57cm	1	$ 3,817.99
3.5	989804306796	Port2 cable spooler 250CM	1	$ 655.09
3.6	989806100414	MD/Portegra2 LeadShield OT54001	1	$ 6,977.27
3.7	989806100588	MD/Lowerbody UT70-145cm width	1	$ 2,658.44
3.8	989806105835	Vitalinq Communication System	1	$ 20,523.24
				$ 67,573.43
4	**846001**	**Philips Laser System**		
4.1	NVRA001	Philips Laser System	1	$ 230,000.00
				$ 230,000.00
5	**SP059Q**	**FlexAccount**	1	$ 30,000.00

Total Net Price

Total Net Price
$ 1,480,222.35

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(Optional Items)

Line	Article No.	Description	Qty	Net Price
1	**722234**	**Azurion 7 M20**		
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	NCVD081	(Opt) Touch Screen Module Pro	*1*	*$ 31,929.83*
	NCVC542	(Opt) Dynamic Coronary Roadmap	*1*	*$ 36,876.85*

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3. Quote Details

Line	Description	Qty
1	**Azurion 7 M20** **Article No. 722234**	
1.1	**Conv. Azurion 7 C20** **Article No. NNAT308** **Conv. Azurion 7 C20** The Philips Catalyst program converts the currently installed system into an Azurion 7 M20 Monoplane Ceiling Mounted. The Azurion 7 M20 Monoplane Ceiling Mounted image-guided therapy is designed to enhance treatment and provide high-quality image guidance during minimally invasive interventions. Key benefits : • A detector that delivers high-resolution imaging over a large field of view (20”) • Extensive C-arm angulation and rotation for excellent patient access • Stand, monitor suspension, and operating modules can be freely positioned for full flexibility • Display, access, and control up to 20 multimodality video sources **Details :** Experience outstanding interventional performance on the Azurion 7 Series with a 20”flat detector. This industry-leading image-guided therapy platform allows you to perform procedures easily and confidently with a unique user experience, helping you optimize your lab performance and provide superior care. Seamlessly control all relevant applications from a single touch screen at the table side, to help make fast, informed decisions in the sterile field. With Azurion, you are future-ready. At Philips Healthcare, we feel a responsibility towards society and the environment. The latest Azurion 7 M20 Monoplane Ceiling Mounted system perfectly exemplifies our EcoVision program. We drastically reduced the product's environmental impact by examining every aspect of the Azurion 7 M20 design and development with a green eye. **<u>System Geometry</u>** **Ceiling Mounted stand** The Philips Azurion M20 stand is a stable assembly of a C-arm and a ceiling-mounted base. The X-ray tube and the flat detector are integrated into the C-arm. This provides a compact assembly with positioning flexibility and easy access to the patient. 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 C-arm contains the high-performance grid-switch MRC200 0407 X-ray tube to enable high image quality in every stand position. **<u>Workflow and dose management</u>** **ProcedureCards**	1

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.

Technology Maximizer Essential

Technology Maximizer Essential program keeps your technology up to date to maximize its operational performance

This program is included in your Azurion release 3 system purchase, for 5 years from the system installation date, Philips will provide the following if and when available during the coverage term:

- Core system software release upgrade
- Operating system (OS) update
- Safety and security updates as approved and communicated by Philips for the system and as part of the core system software release
- Clinical/technical training is not included unless operational workflows are modified due to a core release upgrade
- A computer hardware upgrade is provided to support a core system software upgrade
- Does not include upgrades to clinical applications

Specifications

X-ray tube MRC 200+ GS 0407
Anode heat dissipation
21,000 W

Ceiling-mounted stand
C-arm Z rotation
-90° to +90°
C-arm Z rotation speed

12°/sec
C-arm rotation in head-end position
120° LAO, 185° RAO
C-arm rotation in side position
90° LAO, 90° RAO
C-arm angulation head-end position
90°cranial, 90° caudal
C-arm angulation in side position
185° cranial, 120° caudal
C-arm rotation/angulation speed
up to 25°/sec
Longitudinal movement
260 cm (102.4”) or 410 cm (161.4”) with an extended rail of 150 cm (59.1”)

Fluoroscopy modes
Pulse rates
0.5 –30 images/sec

Ceiling-mounted stand
C-arm depth
90 cm (35.4“)

X-ray generator
Nominal power
100 kW
Minimum switching time
1 ms
Voltage range
40 - 125 kV
Maximum current
1000 mA at 100 kV
Maximum continuous power
2.5 kW for 15 minutes, 1.5 kW for 8 hours

Ceiling-mounted stand
Focal spot to isocenter
81 cm (31.9“)
Isocenter-to-floor distance
106.5 cm (41.9“)

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
motorized 32 cm (12.6“) or 52 cm (20.5“)

Monitor concept (control room)
Amount of monitors delivered

2 x 24”color monitors

X-ray tube MRC 200+ GS 0407
Focal spot size
0.4/0.7 nominal focal spot values
Loadability
max. 30 kW resp. 65 kW on small resp. large focal spot
Fluoro power for 10 min
4,500 W
Fluoro power for 20 min
4,000 W

Flat detector
Maximum field of view
48 cm (19“) diagonal
X-ray sensitive area
1,904 x 2,586 pixels
Detector zoom fields
48, 42, 37, 31, 27, 22, 19, 15 cm 19, 16.5, 14.6, 12.2, 10.6, 8.7, 7.5, 5.9“

Monitor concept (exam room)
Rotation range of monitor frame
360°

Ceiling-mounted stand
Source-to-image distance
89.5 cm to 119.5 cm (35.2”to 47.0“)

Monitor concept (exam room)
Amount of monitors delivered
1 x 27”color monitors
Resolution of monitors
1,920 x 1,080 Full HD

Monitor concept (control room)
Resolution of monitors
1,920 x 1,080 Full HD

X-ray tube MRC 200+ GS 0407
Max. assembly continuous heat dissipation
4,000 W
Anode target angle
11°

Flat detector
DQE (0)
77% at 0 lp/mm

X-ray tube MRC 200+ GS 0407
Extra pre-filtration

SpectraBeam filters with 0.1, 0.4, 0.9 mm Cu and 1 mm Al backing

Flat detector
Pixel pitch
154 micrometer x 154 micrometer
MTF at 1 lp/mm
59% (typical)
Detector bit depth
16 bits
Size of detector housing
67 cm (26“) diagonal, including BodyGuard
Detector dimension
47.2 x 36.0 cm (18.6 x 14 .2“)

Digital acquisition X-ray protocols
DSA frame rates
0.5 to 6 images/sec.
Image storage
50,000 images (based on 1,024 matrix)
Cardio and cine mode
3.75 to 10 images/sec

Fluoroscopy modes
Fluoroscopy storage
enabled with FluoroStore button on imaging module
Fluoroscopy storage capacity
up to 2000 images
Grid-switched pulsed fluoroscopy
Yes

Ceiling-mounted stand
Longitudinal/Lateral speed
15 cm/sec (5.9”/sec)

Quantitative Vascular Analysis

Key benefits

- Allows quantitative assessment of different size vessels such as aortic and peripheral
- Aids confident decision making for device selection, approach angles and follow-up
- Designed for efficiency with single click functions and fast results

Easily obtain objective assessment of aortic and peripheral vasculature

To support decision-making and allow quantitative assessment of vasculature during vascular interventions, the 2D quantitative vascular analysis option supports quantification such as aortic and peripheral artery dimensions of about 5 to 50 mm from 2D angiographic images. With one click, the relevant segment is detected and a visualization of the obstruction, healthy vessel, reference diameter, stenosis diameter and plaque area is created.

Specifications:

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

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

2nd touch screen module

Key Benefits

- Control system operations with a second touch screen module

Tablet-like touch screen control
During an intervention flexible control of applications and system operations can support fast decisions and communication with team members. The touch screen module provides fast, tablet-like touch response to control system operations. Up to three touch screen modules can be connected to the X-ray system: on the table, on the pedestal and in the control room.

Specifications
The second touch screen module is similar to the standard touch screen module and provides touch screen control of displayed functionality. The following functions can be made available providing the relevant commercial options have been selected:

- Acquisition settings
- Image processing controls
- Channel selection for MultiVision
- Automatic position control (optional)
- Quantitative Analysis controls (optional)
- Xcelera and IntelliSpace Portal viewing (optional)
- Interventional tool controls (optional)
- 3D-RA, Dynamic 3D Roadmap (optional)
- StentBoost, 3D-CA (optional)
- XperCT, XperGuide (optional)
- XIM physio monitoring controls (optional)

Connectivity:
A maximum of 3 touch screen modules can be connected to the X-ray system:

- one touch screen module on the table
- one touch screen module in the Control Room
- one touch screen module on the pedestal

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, and head support.

Disclaimers

The Philips Azurion 7 M20 is a Medical Device as defined in Regulation (EU) 2017/745 (EU-MDR). The Philips Azurion 7 C20 is a commercial package and represents a base configuration within the Azurion 7 M20 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.
Conv. Azurion 7 C20

1.2	**Low Load Fluoro (LLF) UPS - 5** **Article No. NNAE709**	1
1.3	**480V - IGT Compact Low Load Fluoro - Modulys 75KVA** **Article No. 989806130836**	1

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.

1.4	**Yes, ordering Standalone IS7** **Article No. NNAT194**	1
1.5	**No, live/ref is not present** **Article No. NNAE737**	1
1.6	**Yes, SBL is needed** **Article No. NNAE738**	1
1.7	**Stentboost Live bundle** **Article No. NNAT134**	1

StentBoost Live

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

1.8	**Yes new to Philips Azurion Sys** **Article No. NNAT253**	1
1.9	**New to Philips Azurion System** **Article No. NNAT252**	1

New to Philips Azurion Systems
Education Package for New Philips Azurion System Users:
Site/User Assessment: A Philips Clinical Specialist will provide a four (4) hour assessment of the comfort, confidence, and knowledge of the Customer's clinical staff. An assessment can be scheduled upon the mutual agreement of the parties and may consist of observation of workflow and interviews of staff. Delivery will be remotely conducted.
Essentials Offsite with Travel: Philips will provide one (1) Cardiovascular Technologist, Registered Technologist, 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. Package includes tuition, meals and transportation, plus modest airfare and lodging which are coordinated through a Philips Travel Service partner. 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.

Follow Up Training Onsite: Philips Education Specialists will provide sixteen (16) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. Students should attend all 16 hours, and must include the two OffSite education attendees. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Site must be patient-ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation.
Year End Assessment Onsite: The primary Philips Education Specialist will perform a sixteen (16) hour onsite assessment at the customer site on or close to the first anniversary of the Initial Handover. The Specialist will assess through various means not limited to; physical observation of procedure workflow, tool usage data analysis and staff interviews. The Specialist will then review findings with department head and make recommendations thereof. The Specialist may perform refresher training if required. Education expires one (1) year from installation date (or purchase date if sold separately).

1.10	**Number of users at this site?** **Article No. FNA2912**	4
1.11	**iXR Full Travel Pkg OffSite** **Article No. 989801256034**	2

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).

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

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).

1.13 **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).

1.14 **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).

1.15 **ClarityIQ.** 1
Article No. NCVD069

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

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

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

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

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

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

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

1.16 **MRC200+ GS 04/07** 1
Article No. NCVD220

Maximus ROTALIX Ceramic grid switch tube assembly MRC200+ GS 0407

The MRC 200+ GS 04 07 tube assembly and cooling unit CU 3101 for cardiovascular systems comprises:
- 0.4/0.7 mm nominal focal spot values maximal 30 and 65 kW short time load
- Grid switching at pulsed fluoroscopy and low load exposure (to eliminate soft radiation and improve image quality)
- Continuous loadability: 3400 W (at 21 degrees C room temperature) / 4000 W (= Max assembly continuous heat dissipation)
- Application of SpectraBeam dose management
- Tube housing is oil cooled with thermal safety switch
- Maximum anode cooling rate of 1820 kHU/min
- Anode heat storage capacity of 6.4 [MHUeff]

1.17 **FlexVision XL HD + 2 LCD's** 1
Article No. NCVD032

FlexVision XL HD is an integrated viewing solution designed to give you full control over your viewing environment which brings High Definition viewing.
This FlexVision XL HD 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 access multiple, up to 8, video inputs (including third party systems) video inputs to inform decision making during procedures
• Create custom display templates to support diverse procedures
• The screen layout of the FlexVision XL HD can also be changed from the control room
• Enlarge images to reveal more details and support comfortable working positions

Diagnostic information easily made available at table side
In today's interventional setting, as you perform more complex procedures with smaller devices in complex anatomy, you rely on various types of diagnostic information to guide you. To inform decision making in the exam room, Philips offers an advanced digital workspace called FlexVision HD. You can display multiple images in a variety of custom layouts on a large, high-definition LCD screen. Zoom in

and out to enhance fine details, while maintaining an overview of all information. Create custom display templates for specific procedures/physician preferences to easily support diverse procedures.

Specifications
FlexVision XL HD offers:
• Native resolution of FD20 can be displayed.
• Sharp images at full size without zoom
• High Definition display at native resolution for ultimate detail
• Up to 2k*2k image display fully integrated
• Enhanced small vessel visualization

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

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

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

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

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

PHILIPS

1.18 **3rd party video cloning (2 output)** 1
Article No. FCV0974

Introduction

A video cloning license to a 3rd party system.

Details

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

Includes

The Live/Ref license is part of this video option.

1.19 **MultiSwitch** 1
Article No. NCVD487

Details

The MultiSwitch option for IP-based video infrastructure allows you to view and control a selection of 8 video sources on the review monitor in the control room. The Azurion review application and up to 7 other video sources can be configured from all available Azurion and auxiliary video sources.

1.20 **optional ref monoplane** 1
Article No. NCVD061

Additional Ref2 and Ref3 viewport

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

Simplify workflow with flexible viewing control
Having patient data and clinical information easily available on screen can enhance decision making and efficiency during interventions. Optional ref monoplane offers an additional video output of the X-ray system offering an additional Ref2 and Ref3 viewport on one LCD monitor.
Combined with the Dual Fluoro license this enables users to zoom live images during acquisition, while having the Dual Fluoro image visible on the Ref3 viewport.

1.21 **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)

1.22 **Video input WCB outside the MCS** 8
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.

1.23 **Physio Viewing** 1
Article No. NCVA093

Physio Viewing is an extension for acquisition storage and display of up to four physiological signals in the X-ray system.

The operator can select one of the recorded physio signals for display together with the acquired image.
It allows ECG-triggered acquisition: allows acquiring one exposure for each QRS peak with a selectable delay time.

Specifications
-Acquisition and storage of a maximum 4 channels of physio data together with the X-ray images
-Setting determined storage on/off of all inputs; recording only in parallel with X-ray acquisition
-Operator can select one recorded physio channel for display

1.24 **Subtracted Bolus Chase** 1
Article No. NCVA694

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

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

During digital acquisition in non-subtracted mode with uninterrupted real-time image display, the contrast bolus is followed (chased) interactively by a motorized table scan movement using a hanbd-hold speed controller to adapt the speed of the table scan to the contrast flow. With biplane systems, this Bolus Chase is applied with the lateral channel.

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

1.25 **FD Rotational Angio** 1
Article No. NCVA695

Realtime 3D impressions of complex vasculature

Key benefits
• Use 3D imaging to quickly determine the projection angle for treatment in complex vascular interventions, surgery and radiotherapy
• Supports assessment of vascular pathologies for diagnostic and therapeutic decisions.

Revealing hidden structures
The complexity of interventional procedures lies in the fact that every person’s pathology is unique. Visualization in three dimensions is therefore vital to aid decision making by the clinician. Rotational angiography provides real-time 3D impressions of complex vasculature and the coronary artery tree. Rotational Angio can be used to quickly determine the projection angle for treatment.

Specifications
Rotational Angio acquires multiple projections with just one contrast injection via a fast rotational scan of the region of interest. A rotational scan is possible both with the X-ray systems in the side position (ceiling mounted systems) and in the head position, providing the flexibility to perform procedures virtually from head to toe.
C-arm in side position:
Max. rotation Speed: 30 degrees/s
Max. rotation Angle: 180 degrees
C-arm in head position:

Max. rotation Speed: 55 degrees/s
Max. rotation Angle: 240 degrees
Max. Frame speeds are given by the frame speed specifications of the system configuration.
The very high movement speed allows using less contrast, whereas the very wide rotation range provides a complete evaluation of the anatomy.
A contrast run can be followed up with a mask run, to allow image/run subtraction.
The stand is designed for a very high mechanical stability. It offers precise positioning and high reproducibility, assuring you of high quality images and excellent subtraction studies. Rotational Angio results are available on the X-ray system.
Operation of Rotational Angiography is straight forward: the procedure is selected, set up and executed virtually in a matter of seconds, supporting high patient throughput.
A set of dedicated acquisition programs is available on the touch screen module and can be selected at the touch of a button. The Rotational Angio is controlled from the exposure hand- or footswitch.

1.26 **30 frame per second extension for monoplane systems** 1
Article No. NCVD076

Introduction

The frame rate extension increases the monoplane system acquisition speed up to 30 frames per second for cardio studies requiring high-speed imaging.

Key Benefits

- Designed to enhance visualization of complex and pediatric interventions
- Up to 15 fr/sec and 30 fr/sec acquisition speed is achieved with a 1024 x 1024 matrix
- Up to 25 frames per second when using ClarityIQ

1.27 **CardiacSwing** 1
Article No. NCVD137

CardiacSwing allows dual-axis rotational coronary angiography

Key benefits
• Provides uncommon angiography views to capture a more complete view of the coronary tree
• Reduces vessel foreshortening effect

Less risk, more information for coronary artery diagnosis
The goal of a coronary angiogram is to obtain as much information to assess lesions with a minimum of vessel foreshortening. The challenge is to do this without losing any of the information or views required and to use as little radiation and contrast as possible. CardiacSwing was designed to meet these goals by reducing the acquisition runs to typically 3 separate runs using 24-26 cc of contrast in total. It also significantly reduces the total procedure time.

CardiacSwing replaces two single axis runs with one dual axis run for the left and right coronary artery. Unlike typical coronary angio which acquires multiple stationary views, a CardiacSwing rotation can begin in the left anterior oblique (LAO), caudal orientation and end in the right anterior oblique (RAO), cranial orientation in one acquisition run. Unexpected angles are presented in a CardiacSwing. These

views of the coronary tree provide additional support for lesion assessment and can expose views of vascular anatomy that might be hidden in a normal 2D X-ray angiogram.

Specifications
In total seven pre-programmed trajectories are available:
• Three for Left coronary imaging
• Two for Right Coronary imaging,
• Two generic trajectories.
The choice depends on size and weight of the patient. These trajectories are designed to fully cover all conventional projections for a diagnostic coronary angiography. Rotation and angulation movements are combined in one complete scan trajectory, using the maximum rotation and angulation speed of the X-ray system. (55 resp 30 degr/sec). CardiacSwing is possible in the side position (ceiling mounted systems) and in the head position.

CardiacSwing functionality includes, but is not limited to
• 15 frames per seconds acquisition to allows using of less contrast.
• Wide rotation range provides a complete evaluation of the anatomy.
• Precise positioning and high reproducibility.
• Set up and executed in a matter of seconds.
• Set of dedicated acquisition programs with the trajectories available on the touch screen module
• The rotation end- and start-positions can be selected.
• Acquisition procedure is controlled from the exposure hand or footswitch.

1.28 **CO2 VIEW TRACE** 1
Article No. NCVA258

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

1.29 **Quantitative Coronary Analysis** 1
Article No. NCVD099

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.

1.30 **Left Ventricular Analysis** 1
Article No. NCVD100

Key benefits
• Allows quantitative quantification of left ventricular volumes
• Designed for efficiency with single click functions and fast results

Easily obtain objective assessment of coronary artery
To support decision making and allow quantitative assessment of anatomy during cardiac interventions, the 2D Left Ventricular Analysis option supports quantification of left ventricular volumes and local wall motion from angiographic series. It calculates the ejection fraction and local wall motion parameters in different formats. Wall contours can be easily drawn both automatically and manually.

Specifications
• Various LV-volumes: ED, ES, Stroke Volume
• Ejection Fraction
• Cardiac Output
• Centerline Wall Motion
• Slager Wall Motion
• Automated and manual calibration routines
• ECG visualization facilitates image selection for analysis
• Store result pages

1.31 **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.

1.32 **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.

1.33 **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.

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1.34 **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

1.35 **StentBoost Subtract** 1
Article No. NCVD379

StentBoost is a simple, quick, and cost-effective tool to enhance stent visualization in the coronary arteries.

Enhanced visualization software
When inserting a stent in complex cardiac vasculature, inexact positioning and under deployment are always a challenge. StentBoost is a simple, quick, and cost-effective tool to enhance stent visualization in the coronary arteries. With the StentBoost Subtract feature, you can even see the stent in relation to the vessel wall as you are working.

StentBoost automatically detects the stent delivery markers image after image. In each image StentBoost aligns the markers with the markers of the previous image. By doing this all radiopaque material in the close proximity of the markers will be enhanced resulting in enhanced stent visualization.

Specifications
StentBoost can be used with and without contrast. Without contrast the images are acquired with only a short cine run of 1 to 2 sec (recommended with 40 frames out).
With contrast the images are acquired with a cine run of 5 to 6 sec. Contrast media is required only for the last 3 to 5 sec. A contrast enhanced image run results in a dynamic representation of the enhanced stent in relation with the vessel wall.

The StentBoost Subtract functionality includes, but is not limited to:
• Review of StentBoost runs
• Store image snapshot
• Automatic pre-defined Region of Interest to indicate the location of the stent/balloon markers
• Fading in/out of contrast vessel and StentBoost image
• Viewing selection of StentBoost with and without contrast
• Manual correction possibility, boost phase and contrast image identification
• Automatically or manually create and store as movie to PACS

Stentboost Substract data can be exported to:
Any optional DICOM compatible device, supported only by DICOM SC

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

Details

Configured offering

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

Cabinet Rear Cover

1.38 **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.

1.39 **FLOORPLATE AD5/AD7(NONSWIVEL)** 1
Article No. 989600205302

This unit is a prerequisite for the installation of the table. This item can be ordered in advance in order to perform hospital room preparations in advance for the installations of the table.

Compatible with:

- Patient table, both without and with pivot

1.40 **Clip rail 390 cm G-Stand** 1
Article No. 459800660501

Ceiling rails with clip mounting and isolation parts length 390 cm.

1.41 **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.

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

Monitor ceiling carriage

(Opt) **Extension to FlexVision Pro** 1
Article No. NCVD064

Introduction

With FlexVision Pro license the user can control the monitor and video sources on displayed on the FlexVision through a wireless mouse as well as virtual keyboard and touchpad on the touch screen module (TSM) in the Examination Room. An operator can resize images and adjust the screen layout during the procedure without going into configuration.

Key Benefits

- Define and manage the layout of the preset and alter the displayed content
- Display a downscaled version of the FlexVision content in a new monitor
- Captured screenshots with a single click
- Live resize the video window and adjust the screen layout during the procedure without going into configuration
- Operate all the video sources displayed on the monitor using the wireless mouse at tableside

Includes

- Mouse and keyboard function on the touch screen module to control external sources
- Includes the license to downscale FlexVision to a 3rd party full HD monitor

(Opt) **SmartMask Monoplane** 1
Article No. NCVD072

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

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

Specifications
The reference image can be faded in/out with variable intensity, controlled from tableside.

SmartMask uses the reference image displayed on the reference monitor. Any previously acquired image can be used as reference. SmartMask facilitates pre- and post- intervention comparisons to assess treatment results.

(Opt) **FD Dual Fluoro monoplane** 1
Article No. NCVD078

An additional fluoro channel in parallel to the standard fluoro channel

Key benefits
• View the subtracted fluoroscopy next to the default non subtracted fluoroscopy
• View a digitally zoomed fluoroscopy image next to the default fluoroscopy image

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

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

(Opt) **Touch Screen Module Pro** 1
Article No. NCVD081

Extension of Touch Screen Module for easy control of X-Ray images at table site

Key benefits
- Imaging parameters can be quickly and easily adjusted at tableside
- Clinical image are shown to support easy navigation. Collimate on the clinical image with one finger. Pinch, zoom, pan and flag images for processing. Position shutters and wedges by simply swiping the image on screen.
- All X-ray settings can be easily adjusted to help you effectively manage patient and staff dose

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

Specifications
- enhance image navigation on the TSM

- intuitive control of shutters and wedges by simply dragging the lines shown on top of the image
- provides intuitive zooming an panning functionality (also during fluoroscopy)
- turns the touchscreen into the pointing device in order to improve communication in ER/CR: when activated the pointer is shown on corresponding monitor
!!! Note: Touchpad and Keyboard control from the TSM is NOT part of this option but 'FlexVision Pro' option.
!!! Note: Images shown on the TSM are not meant for diagnostic purposes (image is downscaled, compressed and latency during live/replay maybe higher than on the live monitor)

(Opt) **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.

Line	Description	Qty
2	**INTRASIGHT** **Article No. 797403** INTRASIGHT	
2.1	**IntraSight 7** **Article No. NNAW511** **IntraSight 7**	1

IntraSight 7 is a scalable, applications-based platform designed to meet the evolving needs of your lab. Included within IntraSight 7 are best-in-class physiology and imaging tools such as iFR co-registration & IVUS co-registration. In addition to providing these leading technologies, the IntraSight platform also optimizes lab performance with efficient data management and user controls, remote service diagnostics, and advanced cybersecurity protection while minimizing the learning curve with a modern, intuitive interface that is fast to learn & easy to use.
IntraSight interventional applications platform.Includes IntraSight CPU, CPU Base, Operator's Manual, Power Transformer, Cable Pre-Install Kit, Power Supply, Connection Box, Mouse, Keyboard, 19"Monitor Kit, DICOM Network Connection.
Imaging (IVUS) License.Includes IntraSight IVUS Software package: Digital (requires PIM hardware, included), Rotational (requires SpinVision/PIMr, hardware optional), and ChromaFlo IVUS.
Digital PIM. Includes PIM, Cabling and PIM holder.
Physiology (iFR/FFR) License (requires FM-PIM hardware, included).Includes IntraSight Physiology Software Package: iFR Hyperemia Free Lesion Assessment Modality, FFR Modality, iFR Option Manual FFR 2.5.
FM-PIM.Cabling, FM-PIM holder, and FM-PIM to Verrata Wire Adapter.
Touch Screen Module (TSM).Table side touch screen controller and articulating bedrail mount.
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.

Line	Description	Qty
3	**CV Third Party Products** **Article No. 100133** **Details** Configured offering	
3.1	**MD/ Mark7 Arterion Table Mount Injector** **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	1

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

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

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.

3.3 **Port2 Lamp Yled 70K-lux focus&arm** 1
Article No. 989806100590

Details

Yled Lamp, 70.000 Lux focusable LED examination Lamp, incl sterilizable handle, power supply unit build in,
incl. an electrical portegra2 extension spring arm 75/91cm

3.4 **Port2 Track250cm&Trolley column 57cm** 1
Article No. 989806100465

Details

Portegra2 360 System, ceiling track 250cm with 360 degrees trolley with column 57cm long with brake handle extension

3.5 **Port2 cable spooler 250CM** 1
Article No. 989804306796

Details

Cable spooler fitting kit for track length = 2500 mm

3.6 **MD/Portegra2 LeadShield OT54001** 1
Article No. 989806100414

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Details

Model OT54 (Patient right side) dimensions 780 x 900 mm, Pb 0.50 mm, Lead acrylic shield, with a special contour cut out and Lead curtain for radial and lateral procedures,
Incl. a Portegra2 suspension arm, 750/910 mm, Comes with 50 sterile covers

3.7 **MD/Lowerbody UT70-145cm width** 1
Article No. 989806100588

Details

UT70 Lower body protection, 0.50mm Pb, width 1450mm, inlcuding upper shields

3.8 **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
1 Year Warranty

Line	Description	Qty
4	**Philips Laser System** **Article No. 846001**	
4.1	**Philips Laser System** **Article No. NVRA001** The Philips Laser System has a broad range of clinical applications including peripheral atherectomy, coronary atherectomy, lead extraction and IVC filter retrieval, allowing the physician to treat a variety of disease states. Using low temperature pulsed bursts of 308 nm UV light, physicians can modify a wide range of lesion morphologies safely and effectively. Features such as 30 seconds start-up time, guided workflow touch screen and 360-degree maneuverability simplifies set up.Initial placement of a laser system includes: Philips Laser System, operator’s manual, power cord, keys (2), footswitch, reference catheter, danger signs (2), safety glasses (10).	1

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Line	Description	Qty
5	**FlexAccount** **Article No. SP059Q**	1

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4. Local Sales Terms and Conditions

Line	Product Code	Contract Name	Contract No.	Invoice Schedule
1	722234 Azurion 7 M20	Vizient Supply LLC XR0703	XR0703	0/80/20
2	797403 INTRASIGHT	Vizient Supply LLC XR0703	XR0703	0/80/20
3	100133 CV Third Party Products	Vizient Supply LLC XR0703	XR0703	0/80/20
4	846001 Philips Laser System	Vizient Supply LLC XR0703	XR0703	0/80/20
5	SP059Q FlexAccount	NONE	NONE	0/80/20

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 Invoice Schedule 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

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5. Signature Page

Invoice to:
CarolinaEast Medical Center
2000 Neuse Blvd
New Bern, NC 28560-3449

Ship to:
CarolinaEast Medical Center
2000 Neuse Blvd
New Bern, NC 28560-3449

	Total Net Price
Total Net Price	$ 1,480,222.35

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 24)

1. **Initial Provisions**.

1.1 The Products (equipment, service, and software) offered on the quotation ("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 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 Customer's purchase order or otherwise issued by 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 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 Customer by mandatory law.

2.4.1 If Customer cancels the order prior to the order being sent to the factory for manufacturing, then Customer shall pay fifteen percent (15%) of the net selling price of the Product(s).

2.4.2 If 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).

2.4.3 If Customer has not taken delivery for each Product contained in Quotation and Customer's purchase order (or in-lieu of purchase order) within twenty-four (24) months from Philips' receipt of Customer's purchase order (or in-lieu of purchase order) then the Product shall be deemed cancelled. In such event, if the order is deemed cancelled prior to being sent to the factory for manufacturing, then the requirements under Section 2.4.1 apply; if the order is deemed cancelled after being sent to the factory for manufacturing, then the requirements under Section 2.4.2 apply.

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 two percent (2%), which is not greater than its 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 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 Customer desires to convert the purchase of any Products to a lease, Customer shall, within ninety (90) days prior to the delivery of the Products, provide all relevant rental documents for review and approval by Philips. 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 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:

5.1.1 Customer guarantees the payment of all monies due or that may become due under these Conditions of Sale;

5.1.2 Philips may convert the lease back to a purchase and invoice Customer; accordingly, and

5.1.3 Customer will pay all such invoiced amounts per the invoice terms. In the event that there are multiple Products on one Quotation, 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"), 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 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. However, in all cases and notwithstanding the foregoing, Customer shall bear the costs of any reduction in trade-in value arising due to a delay by Customer in connection with equipment delivery, installation, and go-live dates 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 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 In the event the condition of the trade-in is not in good working order or physically damaged, Customer's trade-in credit may be reduced, in whole or in part by Philips, at Philips' discretion.

5.3.5 Customer undertakes to

5.3.5.1 clean and sanitize all components that may be infected and all biological fluids from the Trade-In;

5.3.5.2 drain any applicable chiller lines and cap any associated plumbing and

5.3.5.3 delete all personal data in the Trade-In. Customer agrees to reimburse Philips for 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 Customer agree to any other terms of delivery, additional costs shall be for the account of Customer. Title (subject to Section 3 entitled Philips Security Interest) to any Product (excluding software), and risk of loss shall pass to 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. If 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 eighty percent (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 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, 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. 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. 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 Customer's premises to the installation site. 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, 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 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:
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 Customer shall return the Products. Each returned Product shall be packed in its original packaging.

9. Product Warranty.

9.1 The Product warranties for Philips products sold hereunder are set forth on https://www.usa.philips.com/healthcare/about/terms-conditions. The terms set forth on such webpage are incorporated herein. Customer's signature of the Quotation or issuance of purchase order in connection with the Quotation will be deemed agreement that such terms apply to Customer's purchase.

9.2 In the event a Product warranty is not listed on the webpage referenced above under Section 9.1 for a Product set forth on the Quotation, Sections 9.3-9.10 of these terms and conditions shall apply to the Product.

9.3 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 (1) 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 Customer will be of good quality until the expiration date applicable to such Product.

9.4 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 Customer. "Stand-alone Licensed Software" means Licensed Software sold without a contemporaneous purchase of a server for the Licensed Software.

9.5 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.

9.6 Customer shall only be entitled to make a Product warranty claim if Philips receives written notice of the defect during the warranty period within a reasonable period after Customer discovering such 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.

9.7 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 Customer solely after a reasonable cure period is given to Philips.

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

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

9.8.2 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.

9.8.3 abuse, negligence, accident, or damages (including damage in transit) caused by Customer.

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

9.8.5 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.

9.9 Philips is not responsible for the warranty for the third-party product provided by Philips to 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 Customer the third-party warranty and service solutions for such Products.

9.10 During the term of the warranty and any customer service arrangement, 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:

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

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

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

9.10.4 maintaining the established connection throughout the applicable period.

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

9.10.6 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.

9.10.7 THE WARRANTIES SET FORTH IN THESE 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 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 that 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:

11.3.1 procure for Customer the right to continue using the Product;

11.3.2 replace it with an equivalent non-infringing Product;

11.3.3 modify the Product so it becomes non-infringing; or

11.3.4 refund to 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 Section 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); or

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:

13.1.1 exported or re-exported directly or indirectly in violation of Export Laws; or

13.1.2 used for any purposes prohibited by the Export Laws, including military end-use, human rights abuses, nuclear, or chemical or biological weapons proliferation.

13.2 Customer represents that:

13.2.1 Customer is not located in a country that is subject to a UN, US, or EU embargo and trade restriction; and

13.2.2 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. Licensed 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 software (as specified on the Quotation, whether embedded or stand-alone) ("Licensed Software") in Products and the permitted use (as referenced in the instructions for use/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 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, 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 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 HIPAA on behalf and by instruction of 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 Customer or otherwise performing any obligation arising out of the sale, Philips shall not be liable to 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 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, 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 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. Customer shall not, without the prior written consent of Philips, transfer or assign any of its rights or obligations.

18.7 Customer's obligations do not depend on any other obligations it may have under any other agreement or arrangement with Philips. 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 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 in Customer's country or state, Philips and Customer shall comply with the Omnibus Reconciliation Act of 1980 (P.L. 96-499) and its 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, and 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 prior to a date of exclusion.

18.12 To the extent applicable in Customer's 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 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. **Product-specific terms**.

19.1 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 expressly set forth in the Product specific schedule shall govern in such instance.

PHILIPS

Schedule 1
Imaging Systems Portfolio (IS) (Rev 24)

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.

1.1.3 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 is provided at no additional cost.

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

2.3 For Catalyst systems, warranty is included and starts when installation is completed, and system is accepted by Customer.

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 the proposed 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 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 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 dust from 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 Licensed Software 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. Customer agrees that Philips may use and disclose Mandatory Data for Philips' own business purposes (including, but not limited to, for data analytics activities to determine trends of usage of Philips' or its affiliates' devices and services, 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.

PHILIPS

Schedule 14

ADDITIONAL TERMS AND CONDITIONS FOR TECHNOLOGY MAXIMIZER (Rev 24)

1. Services.

If Philips Technology Maximizer ("Technology Maximizer") is purchased under this Agreement for a specific piece of Equipment identified by its serial number, and the requirements of the Agreement are satisfied, then Philips will make available upgrade(s) during term of agreement for the Equipment as outlined below and according to the Technology Maximizer version listed on the Quotation. Technology Maximizer is available in the following versions, subject to modality and market variations:

1.1 Technology Maximizer Essential

1.1.1 Maintain Equipment at latest configuration as follows:

1.1.1.1 Major release upgrades to the core system Licensed Software which is designed to run the system's hardware and essential application programs ("Core System Software");

1.1.1.2 Third party operating system (OS) updates;

1.1.1.3 Any available safety and security updates which are included in a major release;

1.1.1.4 If operational workflows are modified in the latest upgrade, Philips will provide clinical training for new or enhanced functionality of that upgrade; and

1.1.1.5 Hardware replacement to support software upgrades is not included unless specifically included in the Quotation.

1.2 Technology Maximizer Plus

1.2.1 Maintain Equipment at latest configuration as follows:

1.2.1.1 All Technology Maximizer Essential deliverables listed above;

1.2.1.2 Software upgrades to previously purchased Philips Licensed Software on the Equipment other than the Core System Software such as ancillary applications which accomplish specialized clinical functions on the Equipment;

1.2.1.3 Application training for new or enhanced functionality included in upgrades to Licensed Software noted in 1.2.1.2; and

1.2.1.4 Computer hardware replacement necessary to support software upgrade, as/if needed. This entitlement is limited to one replacement unless specifically included otherwise in the Quotation.

1.3 Technology Maximizer Pro

1.3.1 Selected access to future clinical innovation released during term of agreement as follows:

1.3.1.1 All Technology Maximizer Plus deliverables listed above; and

1.3.1.2 New features and/or applications within selected clinical area, as specified in the Quotation determined by Philips as eligible in the Technology Maximizer Pro program.

1.3.1.3 Advanced training for new features and/or applications provided under 1.3.1.2.

1.4 Technology Maximizer Premium

1.4.1 Full access to future clinical innovation across selected clinical domains released during term of agreement as follows:

1.4.1.1 All Technology Maximizer Pro deliverables listed above; and

1.4.1.2 New future clinical features and/or applications across selected Philips clinical domain on the Equipment as specified in Quotation determined by Philips as eligible in the Technology Maximizer Premium program.

2. Terms and Conditions of Technology Maximizer.

2.1 Technology Maximizer does not include basic Equipment preventive maintenance which is purchased separately.

2.2 Licensing. All Philips Licensed Software upgrades are subject to the Licensed Software terms and conditions agreed to at purchase of the Equipment or Licensed Software sale (as applicable), including but not limited to usage and license limitations.

2.3 Software Warranty. All Philips Licensed Software upgrades issued under this Agreement are subject to the warranty terms and conditions agreed to at purchase of the Equipment or Licensed Software sale (as applicable) for a warranty period of 90 days.

2.4 Upgrade preconditions. All upgrades and new software features and/or applications may be delivered, if and when:

2.4.1 made commercially available by Philips after the Start Date and before the End Date specified in the Quotation;

2.4.2 supported by the Equipment hardware and configuration; and

2.4.3 intended for use in the "clinical domain" identified in the Quotation or otherwise as explicitly specified in the Quotation.

2.5 Term of Technology Maximizer. If purchased with the sale of Equipment Technology Maximizer service coverage begins one day following the first year of the warranty period or as specified on Quotation. Technology Maximizer purchased after sale of Equipment shall begin on the Start Date listed on the Quotation.

2.6 Upgrade Delivery Process. Philips will notify Customer of an upgrade that is included in Customer's Technology Maximizer entitlement. Customer must provide written notice (email acceptance is sufficient) of intent to receive the upgrade within the term of the Technology Maximizer Agreement. If Customer does not provide written notice of intent to receive the upgrade within term of the Technology Maximizer Agreement, then Philips is under no obligation to provide such upgrade. If the Technology Maximizer Agreement term expires after Customer has provided written notice to receive the upgrade, but before it is delivered, then Customer is entitled to receive it within year following such expiration and must schedule the installation within this one-year period.

2.7 Upgrade Limitations. The upgrades provided under Technology Maximizer:

2.7.1 are available only for the designated Equipment specified on the Quotation;

2.7.2 unless explicitly described otherwise in the Quotation and except in case of Technology Maximizer Pro and Premium, do not include new applications, options or the like that were not purchased with the Equipment, or purchased separately from Philips for the Equipment;

2.7.3 may not be sold, transferred, or assigned to any third party; and

2.7.4 are subject to the terms and conditions of the Agreement and any licensing terms and conditions included in the purchase of the Equipment from Philips.

2.7.5 Parts removed for the purpose of an upgrade become the property of Philips on an exchange basis as defined in the Agreement.

2.8 Availability limitation. In case Customer refuses the installation of an upgrade, or in case no upgrade is provided by Philips (for any reason, e.g., not made available commercially) during the Term of the Technology Maximizer entitlement, no credit for any already paid amounts is carried forward or eligible for refund. Philips makes no representations in number of Core System Software, OS, ancillary or other Licensed Software upgrades or enhancements that shall be made available to Customer during the term of this Agreement. The release of all 3rd party software publishers' upgrades is at the sole discretion of the software publisher and only to the extent made available to Philips. All such 3rd party software is subject to prior validation by Philips for use with the Equipment. Philips validation of 3rd party software includes without limitation screening for safety issues, processing delays, or image distortion. Any

upgrades/updates or enhancements to the Philips application software is subject to regulatory clearance and commercial availability, solely at Philips' discretion.

2.9 Termination**.** If the Agreement is terminated due to the fault of Customer or Customer defaults under the Agreement after any upgrades under this Technology Maximizer have been provided by Philips, then Customer shall pay Philips the list price of the so provided upgrades within thirty (30) days of such termination or default. No paid amount is eligible for refund.

PHILIPS

7. Warranty

IMAGE-GUIDED THERAPY (IGT) FIXED SYSTEMS
PRODUCT WARRANTY

This product warranty document is an addition to the terms and conditions set forth in the Quotation. 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 For Catalyst systems, full warranty is included and starts when installation is completed, and system is accepted by the Customer.

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

5.1 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).
- **10.1.3** 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.
- **10.1.4** 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.

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.

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.
IGT Fixed System Product Warranty Rev 24

May 23, 2025

Ms. Micheala Mitchell, Chief
Mr. Greg Yakaboski, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation, NC DHHS
2704 Mail Service Center
Raleigh, NC 27699-2704
Micheala.Mitchell@dhhs.nc.gov
Greg.yakaboski@dhhs.nc.gov

RE: Request for Exemption from Review to Replace Cardiac Catheterization Lab and Confirmation of Ability to Use Hybrid OR Occasionally for Cardiac Catheterization Procedures
Facility Name: CarolinaEast Medical Center
County: Craven

Dear Ms. Mitchell and Mr. Yakaboski:

Replacement Equipment Exemption

Please accept this letter as notification of the intent of CarolinaEast Medical Center (CEMC) to replace one unit of existing cardiac catheterization equipment for a total cost less than $3,089,400[1] pursuant to N.C. Gen. Stat. § 131E-184(a)(7) and 10A NCAC 14C .0303.

Under N.C. Gen. Stat. § 131E-184(a)(7), the CON law provides that an applicant's proposal "[t]o provide replacement equipment" is exempt from Certificate of Need review if the Department receives prior written notice from the entity proposing the new institutional health service, including an explanation of why the new institutional health service is required. Replacement equipment is defined in the CON law under N.C. Gen. Stat. § 131E-176(22a)[2] as:

> "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

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1 On October 1, 2024, the cost threshold amount for replacement equipment was increased to $3,089,400 based on the change in the Medical Care Index (MCI) of the Consumer Price Index published by the US Department of Labor on September 30, 2024 for the 12-month period preceding September 1.

2 Please note that the text cited below is as amended by Session Law 2023-7, which was enacted March 27, 2023, with the cited portion effective immediately.

> 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."

As set forth below, CEMC's proposed cardiac catheterization equipment replacement meets the definition of replacement equipment and is exempt from Certificate of Need review.

CEMC seeks to acquire a Philips Azurion 7 M20 (Replacement Equipment) to replace CEMC's existing cardiac catheterization equipment (Existing Equipment). The proposed replacement is needed as the Existing Equipment is beyond its useful life. The Replacement Equipment is functionally similar to the Existing Equipment and will be used for the same treatment purposes, although the Replacement Equipment will possess expanded capabilities given technological advancements. The proposed Replacement Equipment will not be used to provide a new health service and will not result in more than a 10 percent increase in patient charges or per procedure operating expenses within the first 12 months after it is acquired. Further, as documented in Attachment 1, once the Replacement Equipment has been installed and is operational, the Existing Equipment will be sold or otherwise disposed of by CEMC and will not be otherwise utilized in the state without permission.

Specifically, the total capital cost for the proposed equipment replacement, including all costs associated with equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making the Replacement Equipment operational is $1,933,223. Attachment 2 contains a projected capital cost form for the project and all associated construction and engineering fees as well as vendor quotes for the proposed Replacement Equipment and all associated systems and tools. Attachment 3 provides the vendor quote for the Replacement Equipment. As documented in Attachment 1, the Existing Equipment will be removed from North Carolina by the vendor and will not be used again without Agency approval.

As outlined above and illustrated in the Attachments, the proposed Replacement Equipment qualifies as replacement equipment pursuant to regulatory and statutory definitions (N.C. Gen. Stat. § 131E-176(22a) and 10A NCAC 14C .0303). As such, the proposed project is exempt from Certificate of Need review pursuant to N.C. Gen. Stat. § 131E-184(a)(7).

Confirmation of Ability to Use Hybrid OR Occasionally for Cardiac Catheterization Procedures

CEMC currently holds three Certificates of Need (CONs) for fixed cardiac catheterization equipment and operates one unit of dedicated electrophysiology (EP) equipment. Due to CEMC's high volume of electrophysiology procedures, the third cardiac catheterization lab is being utilized exclusively for EP procedures, reducing the total number of regularly active cardiac catheterization labs at CEMC to a total of two. At present, CEMC is able to regularly accommodate its scheduled cardiac catheterization procedures in two labs; however, occasionally a third lab is needed for urgent or emergent cases when the two labs are already being used for scheduled patients. Of note, CEMC also holds a CON for a hybrid OR, which involves the same type of equipment used in performing cardiac catheterization procedures. In order to ensure that sufficient cardiac catheterization capacity is available for both scheduled and emergency patients, both during the catheterization lab replacement process and moving forward, CEMC also seeks confirmation that it may occasionally utilize its hybrid OR to perform cardiac catheterization procedures when its third cardiac catheterization lab is not being used for those procedures. CEMC attests that at no time will more than three cardiac catheterization procedures be performed simultaneously.

Ms. Micheala Mitchell, Chief
Mr. Greg Yakaboski, Project Analyst
May 23, 2025

Since CEMC currently provides cardiac catheterization services and does not propose to develop any additional services, and because CEMC seeks to utilize existing equipment capable of performing cardiac procedures when its primary cardiac catheterization lab is unavailable rather than acquire new equipment, CEMC believes the definitions of "new institutional health service" in NC General Statute § 131E-176(16) do not apply in this case.

Furthermore, CEMC believes that this request is analogous to other providers that have requested confirmation that they can utilize an existing unit of non-cardiac catheterization equipment for cardiac catheterization procedures during replacement or other downtimes of the cardiac catheterization equipment. See, e.g., UNC Health Wayne's request at https://info.ncdhhs.gov/dhsr/coneed/reviews/2017/nov/1219_wayne_wmh_cc.pdf and Novant Health Matthews Medical Center's request at https://info.ncdhhs.gov/dhsr/coneed/reviews/2015/aug/0914_mecklenburg_nhmmccc.pdf. The request is also comparable to facilities requesting to use dedicated research MRI equipment for radiation oncology treatment planning during installation of replacement equipment. See, e.g., Duke University Hospital's request at https://info.ncdhhs.gov/dhsr/coneed/reviews/2016/jun/0718_durham_duh.pdf.

Thank you in advance for your consideration of these requests. If you have any additional questions, please do not hesitate to contact me. CEMC hopes to commence work on this project in the near future, so please let me know if I can provide any additional information to expedite our request.

Sincerely,

Murray Gilgo
Vice President, Physician Practice Management
CarolinaEast Medical Center

Attachment 1 – Letter Re: Continuous Historical Use and Future Disposition of Existing Equipment
Attachment 2 – Projected Capital Costs
Attachment 3 –Vendor quote

From: Kim Meymandi
To: Mitchell, Micheala L; Yakaboski, Greg
Cc: Stancil, Tiffany C
Subject: [External] CarolinaEast Exemption Request
Date: Friday, May 23, 2025 9:56:59 AM
Attachments: image001.png
CarolinaEast Cath Lab Exemption Signed.pdf

Good Morning and Happy Friday!

Hope you all are doing well and have fun plans for the long weekend. Please see the attached for an Exemption letter submitted on behalf of our client, CarolinaEast. If you would please confirm receipt and let us know if you have any questions.

Thank you!
Kim

Kim Meymandi | Manager
kimmeymandi@ascendient.com | 919.226.1712 | linkedin | www.ascendient.com

Our Higher Thinking here