

JOSH STEIN • Governor

DEVDUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

## **VIA EMAIL ONLY**

July 8, 2025

Kimberly Randolph krandolph@bakerdonelson.com

**Exempt from Review – Replacement Equipment** 

Record #: 4829

Date of Request: June 19, 2025 Facility Name: Mission Hospital

FID #: 943349

Business Name: MH Mission Hospital, LLLP

Business #: 3045

Project Description: Replace hybrid operating room equipment

County: Buncombe

Dear Ms. Randolph:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Philips Azurion 7 M20 FlexArm hybrid operating room equipment to replace the Siemens Axiom Artis Zeego, Model #07555283, Serial # 4603, hybrid operating room equipment,. This includes renovating the space that will house the replacement equipment. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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

Sincerely,

Ena Lightbourne Project Analyst

Micheala Mitchell Chief

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

Construction Section, DHSR

Micheala Mitchell

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603

MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704

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www.bakerdonelson.com

KIMBERLY RANDOLPH Direct Dial: 984-844-7903 Cell: 919-614-9124

E-Mail Address: krandolph@bakerdonelson.com

June 17, 2025

#### **VIA E-MAIL**

Micheala Mitchell, Chief Ena Lightbourne, Project Analyst N.C. Department of Health and Human Services Division of Health Service Regulation Certificate of Need Section 809 Ruggles Drive, Raleigh, N.C. 27603

RE: Notice of Exemption for Replacement Equipment, CVOR 24 Hybrid Room, at MH Mission Hospital, LLLP (Buncombe County)

#### Dear Micheala:

I am writing on behalf of our client MH Mission Hospital, LLLP ("Mission") to provide the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section ("the CON Section" or "the Agency") with prior written notice of Mission's plan to modernize its Hybrid OR space and replace its Hybrid OR equipment, since this equipment has now exceeded it useful life, on Mission's main campus, located at 509 Biltmore Avenue, Asheville, NC (the "Project"). For the reasons set forth below, we do not believe that the Project is subject to review by the Agency or that Mission is required to obtain a certificate of need ("CON") before proceeding with the Project because the Project qualifies for an exemption pursuant to N.C. Gen. Stat. § 131E-184(f).

# **Background**

Mission is planning to modernize the space housing the existing Hybrid OR equipment ("Existing Equipment") and will physically replace the Existing Equipment located on the main campus of Mission Hospital, with new Hybrid OR equipment ("Replacement Equipment"), since the Existing Equipment has reached the end of its useful life. This modernization Project involves the renovation of Room E234 in the E (Heart) Tower at 509 Biltmore Avenue (Mission's main campus), on the second floor, the current location of the Existing Equipment. The Existing Equipment will be replaced with the Replacement Equipment in the space currently occupied by the Existing Equipment.

The Existing Equipment is currently in use and the total capital cost for the modernization of the existing space and installation of the Replacement Equipment exceeds three million dollars (\$3,000,000.00).

Michaela Mitchell June 17, 2025 Page 2

The sole purpose of the Project is to replace the existing Hybrid OR equipment, that was acquired by a CON with an effective date of August 24, 2010. The scope of work for the Project includes but is not limited to: replacing and mounting the new equipment, replacing the lighting and booms, replacing existing finishings and refreshing the existing space for the installation of the new Hybrid OR equipment. The construction estimate total is \$1,215,000.00 and the equipment cost estimate total is \$1,707,670.38, for a cost estimate, including construction and equipment, in the amount of \$2,922,670.38. See Attachment 1 (construction estimate) and Attachment 2 (equipment estimate). Including, as required, all essential costs for acquiring and making the equipment operational, such as taxes, shipping, studies, and planning, the Project's total costs are projected to exceed \$3,100,000.00.

When the Replacement Equipment is ready to be used, Mission will dispose of the Existing Equipment. The Existing Equipment will not be used again without CON approval. For the reasons stated below, this modernization and replacement of the Hybrid OR equipment is exempt from CON Section review and thus does not require that Mission obtain a CON, pursuant to N.C. Gen. Stat. § 131E-184(f).

# **Applicable Legal Authorities**

The CON Law precludes any person from offering or developing a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178(a). The definition of "new institutional health service" includes, *inter alia*, the following:

• The acquisition by purchase, donation, lease, transfer, or comparable arrangement by any person of major medical equipment.

N.C. Gen. Stat. § 131E-176(16)(p). The General Assembly has chosen to exempt certain, otherwise reviewable, events from CON review. Among the exemptions is a specific exemption for the purchase of any replacement equipment that exceeds the monetary threshold set forth in G.S. 131E-176(22a) if all of the following conditions are met:

- (1) The equipment being replaced is located on the main campus.
- (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
- (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criterion of this subdivision.

N.C. Gen. Stat. § 131E-184(f). Replacement equipment is defined in N.C. Gen. Stat. § 131E176(22a) as follows:

Replacement equipment" means equipment that costs less than three million dollars (\$3,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. In determining whether the replacement equipment costs less than three million dollars (\$3,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and

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making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Beginning September 30, 2023, and on September 30 each year thereafter, the cost threshold amount in this subdivision shall be adjusted using the Medical Care Index component of the Consumer Price Index published by the U.S. Department of Labor for the 12-month period preceding the previous September 1.<sup>1</sup>

The exemption at N.C. Gen. Stat. § 131E-184(f), where applicable, eliminates the need to obtain a CON before incurring the capital expenditure. The Project, which is the subject of this Exemption Notice, involves a capital expenditure of more than \$3,000,000.00, since the total projected capital cost for the Project is \$3,100,000.00. However, the Project is exempt from CON Section review since it meets the three conditions required for application of the exemption at N.C. Gen. Stat. § 131E-184(f), as shown below:

# The equipment being replaced is located on the main campus.

The Project qualifies for the statutory exemption at N.C. Gen. Stat. § 131E-184(f) because the equipment being replaced is located on the main campus. The sole purpose of the project and related expenditure is to renovate Mission's Hybrid OR room and replace its existing Hybrid OR equipment on the second floor of Mission's E Tower on the main campus.

The term "campus" is defined at N.C. Gen. Stat. § 131E-176(2c) as "the adjacent grounds and buildings, or grounds and buildings not separated by more than a public right-of-way, of a health service facility and related health care entities." For the purposes of the exemption at N.C. Gen. Stat. § 131E-184(f), "main campus" is defined as:

- a. The site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building; and
- b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

N.C. Gen. Stat. § 131E-176(14n).

# The Department has previously issued a certificate of need for the equipment being replaced.

The CON for the existing Hybrid OR was issued in 2010 with an effective date of August 24, 2010.

# Mission has provided prior written notice along with supporting documentation to the Department.

This exemption notice is prior written notice regarding the replacement of the Hybrid OR equipment at Mission's main campus. Supporting documentation related to projected construction and equipment costs is attached.

<sup>&</sup>lt;sup>1</sup> The cost threshold amount for Replacement Equipment is \$3,089,400

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# Conclusion

For the reasons recited herein, the Project qualifies under the exemption from CON Section review set forth at N.C. Gen. Stat. § 131E-184(f). Please allow this letter to serve as the advance written notice required by N.C. Gen. Stat. § 131E-184(f). We would appreciate the CON Section acknowledging, at its earliest opportunity, that Mission's Project, as described herein, is not subject to CON Section Review and that Mission may proceed with the project without first obtaining a CON.

Please let me know if you have questions or need further information regarding this notice.

Sincerely yours,

/s/Kimberly Randolph Kimberly Randolph

cc: Wyatt Chocklett

Attachments



# **FEE PROPOSAL**

April 28, 2025

**Charles Wegner** 

**Project Manager** 

Facility Planning, Design & Construction

MH Mission Hospital, LLLP

CVOR 24 Hybrid Room Replacement

**Design Fee Proposal** 

LS3P Project Number: 8401-250220

Dear Mr. Wegner:

LS3P ASSOCIATES LTD. and our design team are pleased to present our proposal for the design and construction administration services on the **CVOR 24 Hybrid Room Replacement**. We are excited about the opportunity to be a part of this project and look forward to partnering with you.

# **SCOPE**

This project will consist of renovations to replace all of the existing medical equipment and finishes in an existing Hybrid Operating Room on the second floor of the Heart Center. The existing imaging equipment will be replaced with equipment that is either floor or ceiling mounted. For the purposes of this proposal LS3P assumes that the existing structure is adequate to support the new equipment and only new attachments need to be designed. The existing operating lights and booms will all be replaced. Equipment will be selected and purchased by the hospital and all installation requirements will be provided by the equipment vendor. All of the existing finishes will be replaced. The renovations will need to be performed in a manner that supports the ongoing operations of the rest of the surgery area. LS3P will need to design temporary interim life safety measures that permit both the continuation of life safety compliance and also satisfy DHSR regulations for ongoing operations, including access to all the support spaces behind the red line, including access to support spaces including anesthesia, clean supply and dirty support spaces.

The fees are based upon an a construction budget of \$1,215.00. This fee assumes **May 15, 2025** start date. The team we have selected for the work is as follows.

Structural Engineering: Fama Structural Engineering P.O. Box 304, Hazelwood, NC 28738



Mechanical, Electrical, Plumbing, Fire Protection, IT and Security: McKim & Creed
35 N. Market Street, Asheville, NC 28801

#### **BASIC SERVICES**

The scope of work included in this proposal is based on the AIA B101 LS3P which describes each phase of the project. In addition, this proposal includes the following conditions:

- All of the medical equipment selections will need to be provided by MH Mission Hospital, LLLP in order for LS3P to begin design work.
- LS3P will provide three deliverables during the design phases of the project.
  - Schematic Design for program and scope confirmation
  - o 90% Construction Documents for review by the Owner (MH Mission Hospital, LLLP)
  - o 100% Construction Documents for permit and contract acquisition
- LS3P will make one (1) round of drawing revisions to the Schematic Design documents based on the Owner (MH Mission Hospital, LLLP)'s comments.
- LS3p will make one (1) round of drawing revisions to the 90% Construction Documents based on the Owner (MH Mission Hospital, LLLP)'s comments and prepare 100% Construction Documents on the basis of these review comments.
- LS3P will submit the Schematic Design and 100% Construction Documents to NC DHSR for review and approval. LS3P will respond to the written review comments make one (1) round of revisions to the construction documents in compliance with the review comments from NC DHSR.
- The Design Development and Construction Document phases will be combined into a single phase.
- LS3P will prepare Division 1 and Technical Specifications for the project. Alternatively, the Owner (MH Mission Hospital, LLLP) may provide LS3P with their own Division 1 specification requirements.
- During the design phases, LS3P will participate in three (3) total design meetings:
  - o one (1) in-person meeting, and
  - o two (2) virtual meetings.
- During construction administration, LS3P will participate in:
  - Eight (8) virtual biweekly OAC meetings
  - o Four (4) on-site project progress reviews, including the punch list review
  - o Two (2) on-site DHSR inspections

#### **PRODUCTION SCHEDULE**

The estimate is based upon the project schedule below.

Start of Design: May 15, 2025

Schematic Design Submittal: June 12, 2025 (4 weeks) 90% Construction Documents Augst 7, 2025 (8 weeks)



Anticipated Release for Bidding (Dependent on Reviews): September 4, 2025 (or 2 weeks after

receiving Owner (MH Mission Hospital, LLLP) review comments)

Permitting 1 month
Construction 4 months

#### **PROPOSED FEES:**

	SD	DD/CD	Permitting	CA	Proposed Fee
Architectural Fee (LS3P)	\$ 21,988	\$ 38,605	\$ 6,780	\$ 32,410	\$ 99,783
MEP Fee (McKim & Creed)	\$ 6,600	\$ 25,500	n/a	\$ 13,900	\$ 46,000
Structural (Paul Fama)	n/a	\$ 5,200	n/a	\$ 1,300	\$ 6,500
Total Estimated Fee					\$ 152,283

Reimbursable Expense Allowance NTE \$ 4,700

Construction Budget \$ 1,215,000

# **ADDITIONAL SERVICES (FUTURE):**

Additional services not covered in the above scope of work but found to be necessary in final design production or construction administration services shall be recoverable. Revisions to the Construction Drawings because of "Value Engineering" or other Owner (MH Mission Hospital, LLLP) or Tenant requested changes shall be considered an additional service. Additional site visits will also be considered as additional service. The client shall be advised of additional costs and shall approve the same before Architect proceeds with additional work.

Additional services for consultants are billed at 1.1 times the consultant's direct invoice to the Architect.

# **REIMBURSABLE EXPENSES:**

In addition to our compensation, we would ask that we be reimbursed for expenditures incurred by LS3P ASSOCIATES LTD. and our consultants specifically for this project. These expenses can include travel, postage, handling and delivery, renderings, etc.). These expenses will be monthly at our and our consultant's actual cost times a multiple of 1.1 for administrative fees. LS3P proposes a reimbursable expense allowance not to exceed \$4,700.

#### **EXCLUSIONS**

The following services have been excluded from this proposal, but can be included if desired at any point during the project:

- Owner (MH Mission Hospital, LLLP) to provide ALTA survey.
- Owner (MH Mission Hospital, LLLP) to provide geotechnical report.
- Civil, Landscape
- Experiential Graphic Design
- Art, or Exhibit Design Consultation and/or Coordination.
- Site Lighting and photometrics.



- Energy Modeling.
- WELL or LEED certification.
- Project delays (both design and construction) longer than 4 weeks or which will result in a change of work will be considered Additional Services.
- Value Engineering changes to the drawings.
- Specialty consultants including acoustical, security, audio-visual and theatrical lighting, food service, signage, or other specialized consultants not listed or otherwise outside of normal design criteria.
- Construction cost estimating.
- Representation or design beyond the described scope of design services as made part of this proposal.
- Computer three-dimensional models, physical paper models, photo realistic renderings and fly through movies.
- Furniture procurement and bidding services.
- Exterior building signage and site monument signage.
- Wetland or Stream investigation
- Smoke control modeling for atrium design (not anticipated).
- Physical models, other than those used by the design team to convey design ideas.
- Renderings beyond those used by the design team for design purposes or those required for design presentations.
- 3D Acoustical Modeling, Construction Noise Control, and Electronic Variable Acoustic Systems
- City, County, and State Review and Permit fees.
- Special Inspections Observations during construction.
- Hazardous Materials Abatement Monitoring during construction.
- Medical Equipment Planning or Selection
- Additional exclusions and additional services as outlined in the enclosed proposals from our consulting engineers

We appreciate this opportunity to continue working with MH Mission Hospital, LLLP on this important project! Please let us know if you have any questions or comments about this proposal.

Sincerely,

LS3P ASSOCIATES LTD.		MH Mission Hospital, LLLP			
Ci	- ERO				
Chris R	oberts, AIA	Laurie Haynes			
	•	Eddire Hayries			
Principal   Raleigh Office Leader		Chief Financial Officer			
Date: 04/28/2025		Date:			
Encl:	l: Exhibit 1: Standard Terms and Standard Billing Provisions, dated July 1, 2023				
	Fee Proposal from Fama Structural Engineering, dated March 20, 2025				

Fee Proposal from McKim & Creed Engineers, dated March 25, 2025



PLANNERS

March 28, 2025

Mr. Jeff Mural, AIA, EDAC, NCARB 421 N. Harrington Street, Suite 700 Raleigh, NC 27603

Subject: HCA/Mission Hybrid CVOR-24 Renovation-Design Services Fee Proposal (McKim & Creed File Number 251415)

#### Dear Jeff:

McKim & Creed is pleased to present this proposal to provide Mechanical, Plumbing, Electrical, and Fire Protection Engineering (MEP,FP) services for the HCA/MHS Hybrid CVOR-24 Renovation. (The Project).

# A. BASIS OF PROPOSAL AND UNDERSTANDING OF THE PROJECT

- 1. LS3P will be providing traditional architectural and engineering services for The Project. Generally, the project includes replacement of existing CVOR equipment. The existing surgical equipment is Siemens equipment and will be replaced with either floor mounted GE or ceiling mounted Phillips equipment. The floor-to-floor height within this room is approximately 14 ft. The existing CVOR-24 is located within an existing surgical suite on the 2<sup>nd</sup> floor of the Heart Center at HCA/Mission Main Campus in Asheville NC.
- This proposal is for McKim & Creed to support LS3P by providing MEP/FP engineering design services for the project consisting of design/construction documents (CDs), bidding, basic construction administration (CA) and closeout.
- 3. It is McKim & Creeds understanding that there will be no changes to the current FGI space classification/programming.
- 4. Based on owner input the estimated construction budget for the project is approximately \$1,215,000 Dollars.
- 5. The project will require NC-DHSR review and approval.

35 N. Market St.

Asheville, NC 28801

828.252.8181

www.mckimcreed.com

# B. Scope of Services – Design Process

- Design of HVAC, plumbing, fire protection and electrical systems required to support the Hybrid CVOR-24 renovation/upfit. Owner and owner's vendors will provide design input for the design of low voltage and special systems. Owner's vendors will provide final equipment drawings for engineering system coordination.
- 2. Attendance at four design review meetings to confirm design requirements. Meeting may be a combination of virtual and in person.
- 3. Review existing drawings and field investigation of existing conditions.
- 4. Provide mechanical, plumbing, fire protection, electrical code review for this project.
- 5. Provide coordination with the Architect and other consultants.
- 6. Generally, MEP,FP deliverables include Appendix-B support, required calculations, as well as drawings describing the required construction work for complete and operable systems.
- 7. Construction document specifications will be in book spec form.
- 8. MEP,FP Phases and deliverables are as follows:
  - a. Schematic Design (SD) deliverables include:
    - 1) A basic design narrative to define project scope based on engineering judgment given the constraints of the Project.
  - b. Upon approval of Schematic Design, Construction Documents Phase (CD) deliverables include:
    - 1) MEP/FP construction documents will be provided for each discipline.
    - 2) The Engineer will provide 95% CD for Review set for Owner/Client review and approval.
    - 3) Final signed/sealed construction documents with Owner/Client comments incorporated.

### C. Scope of Services – DHSR Construction Administration

- 1. The Engineer will aid the Client/Architect in submitting construction documents and functional program to NC DHSR in accordance with the NC DHSR requirements. The Engineer will support the review by answering/responding to review comments for project approval. The functional program will be created under the Architect's direction.
- 2. Two (2) DHSR related site visits are included. Upon project completion, the Engineer will conduct one (1) pre-final inspection and will provide a punch list noting items needing correction prior to the final DHSR inspection. One (1) final on-site walkthrough with DHSR included to assist project closeout. Additional DHSR pre-final and/or final inspections if required for project phasing will be considered additional services.



# D. SCOPE OF SERVICES - BID SUPPORT

1. Bid support shall include supporting one (1) pre-bid conference, answering contractor RFIs, and providing general bid review.

#### E. Scope of Services –Bim Modeling

- 1. Building information models will be provided at a minimum level of LOD 300 for coordination purposes.
- 2. Trade contractors are responsible for detailed coordination, clash detection, and fabrication level shop drawings.

#### F. Scope of Services – Basic Construction Administration

- 1. Provide construction support services consisting of review of shop drawings, answering RFIs and a maximum of two intermediate inspections.
- 2. Reference DHSR CA section for additional inspections
- 3. The Engineer will attend virtual monthly OAC meeting during the active construction phase.
- 4. Project Closeout Services: The Engineer will provide as-built record drawings, as required by the Client based off contractor mark-ups.

#### G. ADDITIONAL SERVICES

- 1. Any services not reflected in the Scope of Services section of this Agreement, including but not limited to the following, are not included in this Agreement. Engineer may elect to provide or coordinate these services, if requested, but they will be considered additional services. These additional services can be performed as mutually agreed upon by the Client and Engineer and documented by a written addendum to this Agreement. They are as follows:
  - a. Upgrades or expansion to existing facility central M,E,P, FP systems including but not limited to central air handlers, central exhaust systems, medical gas systems and electrical systems.
  - b. Value Engineering resulting from the bidding process.
  - c. Code related upgrades outside of specified scope of work.
  - d. Construction Scheduling, or Cost estimating.
  - e. Special studies and cost analysis of various systems and options.
  - f. Design modifications due to Owner modifications/preferences after final drawing issuance.
  - g. Additional site visits outside of the quantities specifically noted within this proposal.
  - h. Equipment Commissioning



# H. CLARIFICATIONS

- 1. McKim & Creed will provide site survey(s) to confirm existing conditions. Facility provided as-built drawings and observable site conditions for the areas of work will be used as the basis for determining the existing conditions. No destructive testing and/or selective demolition will be performed by the Engineer to observe concealed conditions.
- 2. We have assumed that there is sufficient electrical system capacity at the site to accommodate renovation and equipment being installed. Should parts of the system need replaced or upgraded due to lack of capacity, the scope of services will be defined, and an additional design fee established based on the proposed solution.
- 3. We have assumed that there is sufficient capacity from the existing HVAC unit serving the areas of work. Should the system need to be replaced, upgraded, and/or a new standard-alone system be desired, the scope of services will be defined, and an additional design fee established based on the proposed solution.
- 4. Scope of design analysis within the existing facilities is limited to the area of the work. The impact on the overall building systems beyond the project area is not within the scope of the project.
- 5. McKim & Creed will not employ invasive methods to reveal unexposed, concealed conditions.
- 6. Where required, the Owner will provide panel board metering for a minimum 30 days on panel board(s) identified by the Engineer to verify existing conditions.

#### I. COMPENSATION & BILLING – BASIC SERVICES

1. McKim & Creed proposes a total base lump sum fee of \$46,000 to provide the design and construction administration services outlined above with a breakdown as follows. Billings will be made monthly based on percent complete of each phase outlined below.

Schematic Design Phase	\$ 6,600
DD/CD Design Phase	\$ 25,500
Bid & Construction Administration	\$ 9,300
DHSR Support / Closeout	\$ 4,600
<b>Total Base Services Fee</b>	\$ 46,000



# J. INVOICING

1. Invoicing will be made monthly in accordance with an approved payment schedule.

#### K. EXPENSES

1. Included in the above fee are normal reimbursable expenses including phone, fax, postage, copies, and local travel.

# L. SCHEDULE OF SERVICES

1. We will perform the work described in the above Scope of Services as expeditiously as practical to meet a mutually agreed upon schedule after receipt of your written authorization to proceed.

#### M. Proposal Validity

- 1. This proposal is valid for 30 days from the date of this letter.
- 2. If this proposal is acceptable, please sign on the acceptance line below and return to our office or issue your standard Purchase Order or Contract.

# N. TERMS AND CONDITIONS

- 1. McKim & Creed is required to have a contract, purchase order, or other written authorization to proceed before starting work on any project.
- 2. Incorporated herein by reference are the McKim & Creed, Inc. Engineering Division General Conditions.

We thank you for the opportunity to submit this proposal and look forward to working with you on this project.

If you have any questions or require additional information, please call. Sincerely,



Senior Project Manager

Jame S. Cam



Marc	h 28, 2025	
Page	6 of 6	
I her	eby authorize McKim & Creed, Inc. to p	proceed with the work described
abov	-	
D		D. I
By: _		Date:
	(Print or Type Name)	
	(Signatura)	<del></del>
	(Signature)	

HCA/Mission Hybrid CVOR-24 Renovation





March 20, 2024

#### LS3P

14 O'Henry Avenue, Suite 210 Asheville, NC 28801

Attention: Mr. Jeff Mural

jeffmural@ls3p.com

Reference: Proposal for Structural Engineering Services

Mission Hospital - New Renovation Projects

509 Biltmore Avenue Asheville, North Carolina FSE Proposal No. 2025-025

Dear Mr. Mural:

Thank you for requesting Fama Structural Engineering PC (FSE) to provide a proposal for the subject project. Our proposal is based on the information you provided. We understand that you are requesting a proposal for the following renovation projects at Mission Hospital.



# **CVOR 24 Hybrid Room Replacement – Heart Center**

- o Renovation of an existing cardiovascular hybrid OR.
- o Equipment selection in pending but will be either GE floor mounted or Philips ceiling mounted.
- o Includes replacement of all existing Skytron OR Lights and booms with new STERIS equipment.

# **Proposed Scope of Work**

Our scope of work will include the following Structural Engineering Services:

Analysis & Construction Document Phase

1. Perform a preliminary site visit to observe the existing structures at the proposed renovation locations. An owner representative or contractor may be required to assist with ceiling removal and ladder to access the areas above ceiling. One preliminary site visit has been included for each project.



- 2. Review the existing as-built drawings at each project location. As built drawings will be provided by the client if documents are available.
- 3. Review the provided new equipment specifications, structural support requirements and weights.
- 4. Review the proposed new architectural room and equipment layouts for each new project location.
- 5. Perform a structural analysis of the existing structural framing to confirm if the structure can safely support the new equipment. Our analysis will be solely based on the provided as-built structural drawings. (If as built drawings are not available, then additional testing services to confirm the reinforcing and concrete strength may be required but are not included in the scope of this proposal.)
- 6. Provide a written report of our analysis findings along with our opinions and recommendations if required.
- 7. Provide structural design and drawings for new equipment supports as required. (*Design of structural reinforcement of the existing structure, if required, is not included in the scope of this proposal. FSE is unable to determine if the existing structure requires reinforcement until after the structural analysis is completed.*)

#### Construction Contract Administration Phase

- 8. Review contractor's shop drawings for new equipment support framing.
- 9. Respond to reasonable requests for information by the contractor during construction.
- 10. Visit the site during construction to observe work in progress. One site visit during construction has been included for each project.

# **SPECIAL & GENERAL CONDITIONS OF SERVICES:**

The following limitations and exclusions apply to our proposed scope of design services:

- 1. All drawings produced by FSE will be in AutoCAD format.
- 2. If the final scope of work changes, FSE reserves the right to revise the final fees based on the final scope of work.
- 3. Structural analysis of the existing structures will be performed at the permanent installed locations only. Structural analysis of the existing structures at equipment travel paths was not requested and is not included in the scope of this proposal.



- 4. Testing services to confirm the existing reinforcing and material strength are not included in the scope of this proposal.
- 5. Load testing services are not included in the scope of this proposal.
- 6. Design of structural reinforcement of the existing structure, if required, is not included in the scope of this proposal. FSE is unable to determine if the existing structure requires reinforcement, or what the scope of the reinforcement might be, until after the structural analysis is completed.
- 7. This proposal includes the design of structural framing supports to attach the proposed new equipment to the existing building only. Design of non-load bearing framing systems, such as interior partition wall framing, is not included.
- 8. Additional service fees apply to changes in the scope for work or terms of this agreement and may include, but are not necessarily limited to, the following conditions:
  - a. Studies of the proposed changes to scope of work, whether they are accepted or not.
  - b. Alternate designs in addition to those that may be included in the scope of work.
  - c. Concealed or unknown conditions discovered after the date of agreement, which result in additional costs to FSE.
  - d. Resolution of contractor errors and non-compliant construction.
  - e. Changes after design work is complete for reasons beyond our control, including cost cutting, code changes, etc.
  - f. Value engineering to reduce costs of project items that are not included within FSE scope and which results in additional costs to FSE.

#### **FEE & PAYMENTS:**

Fama Engineering PC proposes to bill for the above scope of work for the following lump sum fees:

CVOR 24 Hybrid Room Replacement \$6,500.00

These fees will be billed based on the percentage of completion for each project phase, as follows:

Analysis & CD Phase (80%)

Construction Administration (20%)

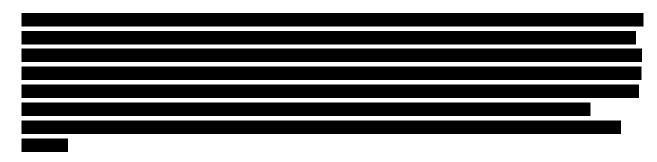
Total Fee (100%)

The proposed fees are valid for 90 days from the date of this proposal.

## **LIMITS OF LIABILITY**

FSE will carry workers compensation, general liability, umbrella, and professional liability insurance with industry standards for firms our size with our average project sizes and annual billings. FSE will furnish appropriate insurance certificates to Client upon request. Client agrees that FSE's normal coverage types and amounts are acceptable to Client.





Fama Structural Engineering PC appreciates this opportunity to submit a proposal for engineering services on this project. If you have any questions about this proposal, or if the scope of work is not as expected, please do not hesitate to call. If you find this proposal acceptable, please return one signed copy. We look forward to working with you.

Sincerely,

**Fama Structural Engineering PC** 

Paul Fama, P.E.

President

PO Box #304

Hazelwood, NC 28738

dpf@fse-pc.com



# **ACCEPTANCE**

By signing below wh	nere indicated, LS3P, agrees with	h the terms of FSE Prop	osal No. 2025-025.
Respectfully,			
Fama Structural Eng			
Signature:	Sfran	Date:	3/20/2025
Printed Name:	Paul Fama	Title:	President
LS3P			
Signature:		Date:	
Printed Name:		Title:	
Please return one sig	gned copy of this Agreement to o	our office at PO Box #304	4 Hazelwood, NC 28738 oi

email to dpf@fse-pc.com



#### Sold to:

Mh Mission Hospital LLLP 509 Biltmore Ave Asheville, NC 28801-4601

#### Ship to:

Mh Mission Hospital LLLP 509 Biltmore Ave Asheville, NC 28801-4601

#### **Presented By**

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

Quote #: Q-00493003 Customer #: 94090104 Quote Date: 04/23/25 Valid Until: 07/01/25

# Hybrid OR - Azurion 7 FlexArm - Siemens Replacement

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
- Complete the information on the quote Signature Page

Thank you again for considering Philips.

Regards, Michael Noland

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.

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	\$ 1,528,057.79
2	797403	INTRASIGHT	1	\$ 114,023.25
3	SP059Q	Flex Account	1	\$ 30,000.00
4	100133	CV Third Party Products	1	\$ 35,589.34

Total Net Price \$ 1,707,670.38

**Total Net Price** 

# (Optional Items)

Line	Article No.	Description	Qty	Net Price	Customer Initials
1	722234	Azurion 7 M20			
	989801256034	(Opt) iXR Full Travel Pkg OffSite	2	\$ 4,716.00	
	NCVA197	(Opt) pedestal	1	\$ 9,113.96	
	NCVC199	(Opt) Wireless footswitch: mono-plane version	1	\$ 7,109.06	
	NCVD080	(Opt) 3rd touch screen module	1	\$ 9,026.40	
	NCVD081	(Opt) Touch Screen Module Pro	1	\$ 25,385.12	
	NCVD084	(Opt) addl control module ER	1	\$ 4,465.05	
	NCVC546	(Opt) HeartNavigator R3	1	\$ 40,618.82	



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# 2. Quote Summary

Line	Article No.	Description	Qty	Net Price
1	722234	Azurion 7 M20		
1.1	NNAT329	Azurion 7 C20 FlexArm	1	\$ 645,946.00
1.2	NNAT129	Ceiling Rails FlexArm 4300 mm	1	\$ 4,443.70
1.3	NNAE709	Low Load Fluoro (LLF) UPS - 5	1	\$ 0.00
1.4	989806130836	480V - IGT Compact Low Load Fluoro - Modulys 75KVA	1	\$ 38,850.00
1.5	NNAE732	No, not ordering IntraSight 7	1	\$ 0.00
1.6	NNAT254	Yes new to Azurion FlexArm	1	\$ 0.00
1.7	NNAT251	New to Philips Azurion FlexArm	1	\$ 10,034.40
1.8	FNA2912	Number of users at this site?	4	\$ 0.00
1.9	NNAE278	Heart Navigator OnSite Educ	1	\$ 0.00
1.10	NNAE503	ClinEd_VesselNavigator	1	\$ 0.00
1.11	NNAT060	SmartCT Angio Ent	1	\$ 0.00
1.12	NNAE676	Azurion FlexArm/Flexmove Educ Pkg	1	\$ 0.00
1.13	NCVD069	ClarityIQ.	1	\$ 102,675.00
1.14	NCVD226	Hybrid kit for FlexArm	1	\$ 26,520.75
1.15	NCVD034	FlexVision XL HD, 3rd p MCS	1	\$ 81,170.49
1.16	NCVD051	addl FlexVision XLHD 3rd p MCS	1	\$ 53,383.60
1.17	FCV0974	3rd party video cloning (2 output)	2	\$ 16,405.80
1.18	NCVD490	FlexSpot	1	\$ 50,186.80
1.19	NCVD491	FlexSpot secondary monitor	1	\$ 8,202.90
1.20	NCVD061	optional ref monoplane	1	\$ 4,199.72
1.21	NCVD064	Extension to FlexVision Pro	1	\$ 31,825.66
1.22	FCV0981	Video input WCB on 1st MCS	2	\$ 10,552.40
1.23	FCV0985	Video input WCB outside the MCS	8	\$ 17,905.60
1.24	NCVD097	DVD writer	1	\$ 362.04
1.25	NCVA694	Subtracted Bolus Chase	1	\$ 17,153.20
1.26	NCVA695	FD Rotational Angio	1	\$ 16,890.35
1.27	NCVD072	SmartMask Monoplane	1	\$ 9,424.61
1.28	NCVD076	30 frame per second extension for monoplane systems	1	\$ 12,824.02
1.29	NCVD078	FD Dual Fluoro monoplane	1	\$ 15,472.66
1.30	NCVD128	storage extension	1	\$ 4,569.39
1.31	NCVA258	CO2 VIEW TRACE	1	\$ 2,519.07



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1.32	NCVD606	Premium Table (Pivot, APC, Volcano)	1	\$ 29,495.71
1.33	NCVA101	Peripheral X-ray filter	1	\$ 1,855.95
1.34	FCV0510	Long mattress cardio	1	\$ 807.93
1.35	FCV0815	add. table access. rail (US)	1	\$ 3,144.08
1.36	NCVD092	height-adjustable arm support	1	\$ 777.44
1.37	NCVC265	Prep table for Table Mount inj	1	\$ 6,189.06
1.38	NCVC846	SmartCT Angio	1	\$ 36,770.60
1.39	NCVC847	SmartCT Roadmap	1	\$ 30,643.40
1.40	NCVC852	SmartCT Vessel Analysis	1	\$ 4,377.10
1.41	NCVC465	VesselNavigator	1	\$ 35,362.27
1.42	NCVD177	IW Hardware (FlexSpot)	1	\$ 16,669.31
1.43	722351	EchoNavigator		
1.44	NNAE405	IGT EchoNavigator Education Pkg	1	\$ 0.00
1.45	NNAE672	IGT EchoNavigator Ext 1	1	\$ 0.00
1.46	NCVD181	EPIQ CVxi integration kit	1	\$ 13,262.28
1.47	NCVC654	AVIDIS Smart Cable	1	\$ 9,725.67
1.48	NCVD551	EchoNav R4 license	1	\$ 113,745.40
1.49	722367	DoseAware		
1.50	NCVC149	Yes, for new system	1	\$ 0.00
1.51	FCV0854	DoseAware Xtend pack	1	\$ 37,130.57
1.52	722240	Remote Service IGT		
1.53	459801079651	Cabinet Rear Cover	1	\$ 400.16
1.54	459801613311	Cabinet Rear Cover Deep	2	\$ 3,270.80
1.55	989600213943	Patient table adaptation plate	1	\$ 2,911.90
				\$ 1,528,057.79
2	797403	INTRASIGHT		
2.1	NNAW510	IntraSight 5	1	\$ 114,023.25
				\$ 114,023.25
3	SP059Q	Flex Account	1	\$ 30,000.00
4	100133	CV Third Party Products		
4.1	989806101012	MD/ Mark7 Arterion Table Mount Injector	1	\$ 18,647.87
4.2	989806101063	MD/ VFlow Hand Controller	1	\$ 1,050.80
4.3	989806100588	MD/Lowerbody UT70-145cm width	1	\$ 1,822.32
4.4	989806105835	Vitaling Communication System	1	\$ 14,068.35
				\$ 35,589.34



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# **Total Net Price**

Total Net Price \$ 1,707,670.38

# (Optional Items)

Line	Article No.	Description	Qty	Net Price
1 722234		Azurion 7 M20		
	989801256034	(Opt) iXR Full Travel Pkg OffSite	2	\$ 4,716.00
	NCVA197	(Opt) pedestal	1	\$ 9,113.96
	NCVC199	(Opt) Wireless footswitch: mono-plane version	1	\$ 7,109.06
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	NCVD084	(Opt) addl control module ER	1	\$ 4,465.05
	NCVC546	(Opt) HeartNavigator R3	1	\$ 40,618.82



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# 3. Quote Details

Line	Description	Qty
1	Azurion 7 M20 Article No. 722234	
1.1	Azurion 7 C20 FlexArm Article No. NNAT329 Azurion 7 C20 FlexArm	1

The Azurion 7 M20 Monoplane Ceiling Mounted with FlexArm Image Guided Therapy system 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")
- Rotates on no less than eight axes to create virtually unlimited flexibility to perform imaging, from head to toe on the left and right side for 2D and 3D visualizations
- The Image Beam Rotation technology enables patient-oriented images in every angulation avoiding the need to pivot the table or reposition the patient
- 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.

FlexArm rotates on no less than eight axes to create virtually unlimited flexibility to perform imaging, from head to toe on the left and right side for 2D and 3D visualizations. The image beam remains aligned with the patient, allowing better visualization of anatomies during rotations or angulations. 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 with FlexArm system perfectly exemplifies our EcoVision program. We drastically reduced the product's environmental impact by examining every aspect of the Azurion 7 M20 with FlexArm design and development with a green eye.

#### **System Geometry**

#### **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

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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.

#### **Workflow and dose management**

#### **ProcedureCards**

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

#### **Parallel Working**

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

#### Dose management and awareness

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

#### **Zero Dose Positioning**

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

# **Monitor solutions**

## Monitor concept (control room)

The default control room configuration consists of two 24 color monitors (acquisition and review) for patient administration and X-ray image display/review. The acquisition monitor features a status bar, which replicates the same system information shown in the exam room (incl. dose values, system positioning, and system messages). The review monitor can be used to review any acquired images with

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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



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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**

PHILIPS

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# Monitor concept (control room) Amount of monitors delivered

2 x 24" color monitors

#### Ceiling-mounted stand

**C-arm Z rotation** 

-135° to +135°

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** 

285 cm (112.2"), 460 cm (181.1") rail type 1 and 635 cm (250.0") rail type 2

**Lateral movement** 

150 cm (59.1")

C-arm depth

90 cm (35.4")

Focal spot to isocenter

81 cm (31.9")

#### Fluoroscopy modes

**Pulse rates** 

0.5 -30 images/sec

Fluoroscopy storage

enabled with FluoroStore button on imaging module

Fluoroscopy storage capacity

up to 2000 images

Ceiling-mounted stand

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")

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

# Monitor concept (exam room)

#### Height movement of monitor frame

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

#### X-ray tube MRC 200+ GS 0407

#### Focal spot size

0.4/0.7 nominal focal spot values

#### Loadability

max. 30 kW and 65 kW on small and large focal spot

#### Fluoro power for 10 min

4,500 W

# Fluoro power for 20 min

4,000 W

#### Anode heat dissipation

21,000 W

#### Max. assembly continuous heat dissipation

4,000 W

#### Anode target angle

11°

#### Extra pre-filtration

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

#### 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"

#### Pixel pitch

154 micrometer x 154 micrometer

#### **DQE (0)**

77% at 0 lp/mm

# **Detector dimension**

47.2 x 36.0 cm (18.6 x 14 .2")

# Monitor concept (exam room)

Rotation range of monitor frame

360°

#### **Resolution of monitors**

1,920 x 1,080 Full HD



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# Flat detector MTF at 1 lp/mm 59% (typical)

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

Flat detector

Detector bit depth

16 bits

Size of detector housing

67 cm (26") diagonal, including BodyGuard

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

Monitor concept (exam room) Amount of monitors delivered 1 x 27" color monitors

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

Fluoroscopy modes 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



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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



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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. **Azurion 7 C20 FlexArm** 

1.2 Ceiling Rails FlexArm 4300 mm
Article No. NNAT129

1

Ceiling Rails FlexArm 4300 mm

**CEILING RAILS FLEXARM 4300** 

CEILING RAIL FLEXARM INTERFACE SET 4300

1.3 Low Load Fluoro (LLF) UPS - 5
Article No. NNAE709

1

1.4 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.

1.5 No, not ordering IntraSight 7
Article No. NNAE732

1



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Yes new to Azurion FlexArm
Article No. NNAT254

1

# 1.7 New to Philips Azurion FlexArm Article No. NNAT251

1

#### **New to Philips Azurion FlexArm**

#### Education Package for New Philips Azurion FlexArm/FlexMove System Users:

**Site/User Assessment:** A Philips Clinical Specialist will provide a four (4) hour assessment of the comfort, confidence, and knowledge of the Customers 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 workflow of the cardiovascular imaging system. In order to provide trainees with the ability to apply all fundamental functioning on their system, and to achieve maximum effectiveness, this class should be attended no earlier than two weeks prior to system installation. This twenty-eight (28) hour class is located in Cleveland, Ohio, and is scheduled based on your equipment configuration and availability. 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.

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

# 1.8 Number of users at this site? Article No. FNA2912

4

### 1.9 Heart Navigator OnSite Educ Article No. NNAE278

1

### **Key Benefits**

This training is provided only with the purchase of Heart Navigator.



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

#### **Details**

Clinical Education Program for iXR Heart Navigator:

iXR Heart Navigator OnSite Education: Philips Education specialist will provide sixteen (16) hours of education for up to (4) students selected by the customer. The Physicians performing the procedures are required to be part of the training session. CEU credits may be available for each participant that meet 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 the equipment during the educations sessions except to demonstrate proper equipment operation. iXR Heart Navigator OnSite Live Case Follow Up Education: Philips Education Specialist will provide twenty -four (24) hours of education for Physicians and staff for live case use of the Heart Navigator software. This will be a follow up visit to the initial training of the Heart Navigator software. It is required that Live Valve implantation studies be performed during this education session. No CEU credits will be available for this session. 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 the equipment during the educations sessions except to demonstrate proper equipment operation. Education expires one (1) year from equipment installation date (or purchase date if sold separately).

1.10 ClinEd\_VesselNavigator
Article No. NNAE503

1

#### **Details**

Vessel Navigator Clinical Education Program:

Philips Imaging Systems Clinical Education Specialist will provide 1 consecutive sixteen (16) hour session 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).

1.11 SmartCT Angio Ent Article No. NNAT060

1

#### **Details**

Clinical Education Program for SmartCT Angio



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IGT SmartCT Angio Handover OnSite Education: Philips Education Specialists will provide 1 consecutive sixteen (16) hour session of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. 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.

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 Azurion FlexArm/Flexmove Educ Pkg Article No. NNAE676

Azurion FlexArm/Flexmove Educ Pkg

#### Clinical Education Program for Azurion FlexArm C-Arm System:

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

Essentials Offsite Education: Philips will provide 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.

**Pre-Training Onsite Education:** Philips Education Specialists will provide one consectutive session of twenty -four (24) hours of pre-training applications for up to (8) students selected by customer,

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including technologists from night/weekend shifts if necessary. This training will be coordinated to provide instruction on the operation of the FlexArm C-Arm prior to the Go Live handover date of the entire Azurion Imaging System. In the event that a Maquet OR table with 24 hours of pre training has also been purchased this FlexArm 24 hour training will be used as a post-handover follow up session. No CEU credits will be available for this session. Please refer to guidelines for more information. Note: The equipment must be entirely operational. Philips personnel are not responsible for actual patient contact or operation of the equipment during the education sessions except to demonstrate proper equipment operation. 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-four (24) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. Students should attend all 24 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 (IGT Addl 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.

# 1.13 ClarityIQ. 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

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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

# 1.14 Hybrid kit for FlexArm Article No. NCVD226

The Hybrid OR Ceiling kit is a set of materials and adaptations to cope with the stricter cleaning and sterility requirements in modern Hybrid OR environments. It supports undisturbed laminar airflow.

#### **Key benefits**

- Supports sterility and easy cleanability of moving ceiling parts
- Height adjustable carriage top cover to improve air flow and eliminate air jet effects

The ceiling mounted FlexArm supports optimal utilization of your lab by allowing procedure-based workflow. To support the high sterility and cleanability standards in the Hybrid OR, the top of the moving parts of the ceiling rails has been specially designed to cope with the higher sterility and laminar airflow compatibility requirements in modern Hybrid ORs.

#### **Specifications**

The Hybrid OR ceiling kit for FlexArm includes a closed cable duct and a carriage cover.

#### Cable duct

- Closed duct to keep out dust
- Easy to clean stainless steel belt
- Seal strip affixed to duct maintains a tight seal
- High quality, specially designed rail guide materials, result in low friction and no/low noise

#### Carriage cover

- Carriage cover for top of ceiling rails prevents jet air effects to eliminate laminar airflow disturbances
- Closes off top of rail carriage
- · Cover can also be added after installation of stand

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## 1.15 FlexVision XL HD, 3rd p MCS Article No. NCVD034

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

This FlexVision XL is mounted on 3rd party Monitor Ceiling Suspension.

#### **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

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- 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.

# 1.16 addl FlexVision XLHD 3rd p MCS Article No. NCVD051

1

Additional FlexVision XL HD Philips 58 inch monitor, for 3rd party MCS. The content is a slave of the 1st FlexVision XL HD screen.

# 1.17 3rd party video cloning (2 output) Article No. FCV0974

2

### 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.

### 1.18 FlexSpot

1

Article No. NCVD490



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#### Introduction

One 27-inch monitor capable of connecting up to 20 video sources from multiple modalities in the lab enabling the user to control and manipulate, in full HD, up to 4 sources at the same time.

#### **Details**

The Azurion FlexSpot is an integrated user-centric workplace that gives you seamless access to video sources to significantly reduce clutter and simplify workflow. Team members can perform different tasks separately, without interrupting each other, to reduce gaps between cases. While fluoroscopy/exposure is being done, you can review previous images from the same or a different patient, prepare for the next exam or finish reporting on another patient. With ProcedureCards it's possible to set up custom screen layouts for every procedure and/or clinical user. The workplace enables full flexibility of screen layouts (live resize, drag and drop) and Video integration of 3rd party applications with a full HD display for an optimized control room.

# 1.19 FlexSpot secondary monitor Article No. NCVD491

#### 1

#### **Details**

A 27-inch monitor connected to the primary FlexSpot capable of displaying up to 4 video sources at the same time. Controlled by the same mouse and keyboard as the FlexSpot.

# 1.20 optional ref monoplane Article No. NCVD061

1

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 Extension to FlexVision Pro Article No. NCVD064

1

### 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



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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

# 1.22 Video input WCB on 1st MCS Article No. FCV0981

2

#### 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)

# 1.23 Video input WCB outside the MCS Article No. FCV0985

8

#### **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



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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.

1.24 **DVD writer** 

Article No. NCVD097

#### **Key benefits**

• Store images and information on DVDs for easy sharing

#### Store images and information on DVDs for easy sharing

To provide flexible storage options, a DVD writer is available with the Philips X-ray system. Procedural images and information can be stored on DVDs and used for archiving, training and presentations.

#### Specifications

Export and import of X-ray images and X-ray runs to DVD and/or from DVD

# 1.25 Subtracted Bolus Chase Article No. NCVA694

1

1

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.



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### 1.26 FD Rotational Angio Article No. NCVA695

1

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.

# 1.27 SmartMask Monoplane Article No. NCVD072

1

#### **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.



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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.

# 1.28 **30** frame per second extension for monoplane systems Article No. NCVD076

1

#### 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

# 1.29 FD Dual Fluoro monoplane Article No. NCVD078

1

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.



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## 1.30 storage extension Article No. NCVD128

1

#### Extends image storage capacity on your X-ray system

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

#### **Specifications**

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

# 1.31 CO2 VIEW TRACE Article No. NCVA258

1

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.

## 1.32 Premium Table (Pivot, APC, Volcano) Article No. NCVD606

1

#### 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.



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

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

#### **Specifications**

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

#### **Includes**

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

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

### **Additional Information**

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

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

# 1.33 Peripheral X-ray filter Article No. NCVA101

1

• Obtain uniform density of lower peripheral areas

**Enhance consistency of lower peripheral images** 



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# **PHILIPS**

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

# 1.34 Long mattress cardio Article No. FCV0510

1

- 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 add. table access. rail (US) Article No. FCV0815

1

- Position operating modules and/or accessories conveniently
- Work comfortably at the head end of the table

#### Work comfortably at the head end of the table

To provide more flexibility when working at the head end of the table, the auxiliary OP (operation profile) rail can be used to position operating modules and/or accessories closer to the head end of the tabletop. This allows the user to work comfortably when performing pacemaker implantations, venous jugular catheter insertions, and other procedures near the patient's head. This version of the OP rail is designed for use in the US only.

# 1.36 height-adjustable arm support Article No. NCVD092

1

• Enhance patient comfort during catheter usage

#### Enhance patient comfort during catheter usage

To support the patient's arm when a catheter is used for brachial catheterization and digital imaging techniques, the arm support can be attached to the tabletop. The support is made of X-ray transparent material and includes a mattress pad for increased patient comfort. The fixation clamp and pivot mechanism are not made of X-ray transparent material.



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## 1.37 Prep table for Table Mount inj Article No. NCVC265

1

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

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

# 1.38 SmartCT Angio Article No. NCVC846

1

NCVC846 SmartCT Angio

SmartCT Angio offers a 3D Rotational Angiography (3D RA) acquisition technique augmented with step-by-step guidance, advanced 3D visualization and measurement tools all accessible on the touch screen module at table side. To support you perform a fast and first-time-right\* 3D-RA acquisition and streamline your workflow, you are guided though 4 key steps.

- 1- Room setup
- 2- Proper 3D protocol with corresponding suggested injection protocol (when applicable)
- 3- Collision free Zero dose table iso-centring
- 4- When to press and release the acquisition button

Once the 3D rotational scan is successfully performed, the acquired 3D image is automatically displayed in the SmartCT 3D visualization tools with the adequate rendering settings and the 3D measurement tools tailored for the selected 3D protocol.

### **Key Benefits**

- Provides 3D imaging in the interventional suite to enhance decision making and guidance
- Supports accurate assessment of vascular pathologies by providing high-resolution 3D reconstructions of small vessels and lesions
- Enhances understanding of vascular anatomy for interventional treatment planning and procedural outcome verification.

### **Enhancing 3D functionality**

Visualizing the complex spatial relationship between critical and branching vessels often involves several sequential 2D (DSA) acquisitions and radiation dose for the patient. SmartCT Angio offers a 3D-RA (3D Rotational Angiography) acquisition protocol that provides extensive 3D visualization of anatomy and vessels based on a single contrast-enhanced rotational angiogram. Its high-resolution 3D reconstructions provide critical information about depth and the relationship of one vessel to another to support the accurate assessment of anatomy and vasculature.

With SmartCT Angio, complex anatomy such as aneurysms, complex anatomy, or tortuous vessel structures can be assessed in three dimensions. This enhances the chances of delineating the neck of



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aneurysms, for example, and its shape and relationship to adjacent arteries. It also enhances the assessment of complex congenital heart disease anatomy and its relationship to adjacent structures.

Combined with the unique whole body coverage of the X-ray system, specifically designed for 3D imaging, SmartCT Angio can cover cerebral, abdominal, cardiac, and peripheral vasculature as well as other anatomy.

#### **Specifications**

4 step Guidance.

- 1. Room setup
- 2. Proper 3D protocol with corresponding suggestion of injection protocol (when applicable)
- 3. Collision free Zero dose table iso-centring
- 4. When to press and release the acquisition button

#### Image Acquisition

Image acquisition is performed with the Rotational Angiography feature of the X-ray system with the flexibility to position the C-arm in either head or side (not F12) position.

C-arm in head position: scan range of 240 degrees with a rotation speed up to 55 degrees/sec. C-arm in side position: scan range of 180 degrees with a rotation speed up to 30 degrees/sec.

#### 3D Vessel Reconstruction

The rotational run is automatically transferred and displayed as a 3D vessel model: with the Real-Time digital link (option) 125 images are reconstructed into a 3-dimensional model within seconds. Additional reconstructions, using the Reconstructive Zooming Technique, can be performed as well.

#### Workflow

Step by step acquisition guidance

Automated 3D-RA process from 3D acquisition to 3D Viewing,

3D at touch screen module,

3D Automatic Position Control (3D-APC),

3D Follow C-arc.

#### Calibration

3D-RA calibrations are performed by Philips Customer Support.

3D-RA calibration data are stable over at least 6 months' time.

#### Viewing

Real Time user interface.

Philips' CRM (Contrast Resolution Management) Technology.

Image rendering:

Volume/Surface Rendering,

MIP,

Average

Gradient rendering,

MPR (Multi-Planar Reformatting),

unlimited distance measurements calculated in the same volume, including "Quick measurement".

Volume calculation

Lesion segmentation,

Annotation,

Reconstructive Zooming Technique,





Subtraction of reconstructed volumes, Set grey values WW/WL, Store/Recall of user defined projections.

Archiving

Transfer to:

Optional Hard Copy unit (DICOM Print),
DICOM compatible device, supported are DICOM XA, DICOM SC, DICOM CT and DICOM 3D,
Any PC in a standard PC compatible format (JPEG, AVI),
One or multiple DVD's, CD-ROM(s),

one or multiple DVD's, C

USB device.

\*Evaluated with clinical users in a simulated lab environment with a total of 17 teams consisting of a physician and a radio-tech, with different levels of experience

# 1.39 SmartCT Roadmap Article No. NCVC847

NCVC847 SmartCT Roadmap

SmartCT Roadmap facilitates complex interventions by providing live 3D image guidance that can be segmented to emphasize the targeted vessel and lesions, supporting fast and accurate treatment planning. All controlled via the touch screen module at the table. The SmartCT Roadmap overlays a 3D reconstruction of the vessel tree, acquired with a SmartCT 3D acquisition mode (3D RA or CBCT) on your interventional X-ray system, with live fluoro images. Previous projection positions, including the gantry position, table position and field of view, can be easily recalled at the press of a button on the touch screen module to save time. To enhance visibility for different guidewires and anatomy, you can choose your preferred 3D rendering mode, adapt its transparency and contrast, and display the vessel path, segmentation, markings and measurements of the 3D volume on the SmartCT Roadmap.

#### **Key benefits**

- Provides full 3D view to enhance navigation of guide wire, catheter, or other devices through complex vascular structures
- Helps to overcome the limitations of 2D roadmaps in visualizing overlapping vessels
- Offers a high level of precision thanks to real-time compensation for gantry, table, and small patient movements
- · Accessible via the touch screen module to enhance efficiency during procedures
- Perform a 3D-RA scan without leaving the exam room

### Live 3D image guidance

Diagnosing and treating vascular diseases without a clear picture of the relationships between overlapping vessels is a daily challenge for interventionists. SmartCT Roadmap was developed to overcome the inherent limitations of 2D versus 3D in visualizing overlapping vessels and therefore eliminate the need to perform multiple 2D(DSA) runs. 3D Roadmap provides a 3D real-time roadmap that overcomes this challenge by providing dynamic 3D guidance for navigating through vascular structures anywhere in the body.

### **Specifications**

1

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SmartCT Roadmap is based on the visualization of the vessel tree from a SmartCT 3D acquisitions (3D RA, CBCT) activated with one touch of a button on the touch screen module at tableside.

#### Viewing:

Table side control: bidirectional link between the X-ray system and 3D Roadmap,

3D Automatic Position Control,

3D Follow C-arc,

The 3D roadmap provides the freedom to change:

The angulation of the C-arc,

The rotation of the C-arc,

The Field of View,

The Source to Image Distance,

Landmarking,

Overlay opacity,

WW/WL settings,

Store and review runs,

Store snapshots and movies. Transfer/ export to:

Optional Hard Copy unit (DICOM Print)

DICOM compatible device, supported are DICOM XA, DICOM SC, DICOM CT and DICOM 3D

Any PC in a standard PC compatible format (JPEG,AVI)

One or multiple DVD's, CD-ROM(s)

USB device.

## 1.40 SmartCT Vessel Analysis Article No. NCVC852

NCVC852 SmartCT Vessel Analysis

SmartCT Vessel Analysis allows easy inspection of the vessel and device positioning with straightened, curved and cross-section reformats to support treatment planning. The curved MPR view allows you to see the whole vessel segment on one plane. The straightened reformat view of the vessel segment, where the curvature is extracted from the vessel, while preserving the longitudinal and angular position, contains a graph showing the vessel diameter along the segment. The straightened cross-section view displays an indication of the minimum and maximum diameters at the pointer location as you move it over the curved, reformat or straightened reformat view. You can choose your preferred rendering to enhance visibility of guidewires and the stretched vessel view allows you to measure the diameter of the vessel/lumen and the length of the segment/stenosis at three locations. Ring landmarks can be used to mark feeder vessels to aid navigation.

# 1.41 VesselNavigator Article No. NCVC465

1

1

#### Introduction

VesselNavigator allows reuse of 3D vascular anatomical information from existing CTA and MRA datasets as a 3D roadmap overlay on a live X-ray image.



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#### **Key Benefits**

- Supports navigation through complex vessel structures
- Reusing a pre-acquired CTA or MRA reduces the need for contrast enhanced runs
- Philips CTA Image Fusion Guidance may lead to shorter procedure times
- Intuitive and easy to use by providing step-by-step workflow guidance
- VesselNavigator is a Medical Device as defined in Regulation (EU) 2017/745 (EU-MDR)

#### **Details**

Vessel Navigator essential components are: - 3D roadmap navigation with a personalized visualization of a CT or MR overlay of the selected vasculature on live fluoro; - Both 2D and 3D registration for CT or MR image fusion, allowing to choose the registration method for the user's workflow; - Easy, intuitive four step workflow, with one click vessel segmentation; - Ring markers to easily indicate the ostia and landing zones.

VesselNavigator provides the following functions: - One click vessel segmentation; - 3D landmarks, - Plan angles, - 2D registration; - 3D registration; - Live image guidance; Real-time overlay of the 3D Vessel segmentation on the live 2D X-ray images from the Philips Azurion X-ray system of the same anatomy; - Table tracking; - Table side control.

VesselNavigator movies and snapshots can be stored/archived on: - A PACS systems as DICOM Secondary Capture images or movies; - USB device; - One or multiple DVD's, CD-ROM(s) for easy archiving; - Hard copy via the (DICOM Print) protocol.

#### **Includes**

Reduce your need for contrast medium When delicately navigating a guidewire or inserting a stent in challenging endovasculature, seeing the full perspective of anatomy is crucial. Using X-ray and contrast medium efficiently is also very important, especially for vulnerable patients. VesselNavigator allows reuse of 3D vascular anatomical information from existing CTA and MRA datasets as a 3D roadmap overlay on a live X-ray image. With its excellent visualization, VesselNavigator provides an intuitive and continuous 3D roadmap to guide you through vasculature during the entire procedure. This reduces the need for a contrast enhanced run to create a conventional roadmap. Unlike 2D angiography images which can be limited by vessel superpositioning or foreshortening, VesselNavigator provides three dimensional views of vasculature that allow you to easily define the right projection angle2 for navigation and stent placement. With the use of ring markers you can easily indicate the ostia and landing zones.

# 1.42 IW Hardware (FlexSpot) Article No. NCVD177

#### 1

### Introduction

Hardware for the 3D interventional tools combined with FlexSpot.

### **Key Benefits**

- Facilitates multimodality viewing in exam room and control room
- Supports DICOM compatible data from CT and MR imaging modalities



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Provides real-time access to images to support fast results

#### **Details**

Conditionally: FD Calibration Tool Kit for 3D-RA

Interventional Workspot is a Medical Device as defined in Regulation (EU) 2017/745 (EU-MDR)Key benefits:

#### **Includes**

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

Specifications: The Interventional hardware is the hardware for the 3D interventional tools that included Real Time Link. It enables import and viewing of DICOM compatible data from other imaging modalities. The Interventional Hardware comprises at least: - Computer Workstation; - Internal/external CD-ROM / DVD writer; - Mouse tablet to interact with all the interventional tools at the table side.

1.43 EchoNavigator
Article No. 722351

### **Details**

Configured offering

1.44 IGT EchoNavigator Education Pkg
Article No. NNAE405

#### Introduction

Philips Education Pkg for EchoNavigator

#### **Details**

Philips Imaging Systems Clinical Education Specialist will provide one consecutive sixteen (16) hour education session for up to four (4) students, as selected by customer, including technologists from weekend/night shifts as necessary. CE 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.

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

# 1.45 IGT EchoNavigator Ext 1 Article No. NNAE672

1

# 1.46 EPIQ CVxi integration kit Article No. NCVD181

1

#### **EPIQ CVxi integration kit**

This integration kit is required to connect the EPIQ CVxi and EchoNavigator fusion imaging to an Allura or Azurion system.

#### **Key benefits**

- Easy single cable connection between EPIQ CVxi and Allura or Azurion system.
- Enables EchoNavigator workspot on the EPIQ CVxi, which allows the Echo cardiologist to operate the EchoNavigator fusion imaging from theEPIQ CVxi console.
- Enables EchoNavigator fusion imaging for intuitive Structural Heart Disease guidance.

The EPIQ CVxi integration kit enables the connection of the EPIQ CVxi with EchoNavigator (Note: the EPIQ CVxi is a separate product that is not included with the EchoNavigator).

The EPIQ CVxi with EchoNavigator is a real time imaging product that supports the procedure by combining both X-ray and 3D TEE echo in an interactive, intuitive, and procedurally relevant way. It is designed to help you intuitively guide your device in the 3D space more quickly.

#### **Specifications**

The EPIQ CVxi integration kit provides:

- Cables to connect the EPIQ CVxi to the cath lab.
- Hardware, software, and license.
- Interventional Echo Link which provides a high speed live 2D and 3D digital connection between the Echo unit and the EchoNavigator imaging platform.
- A mouse and mouse tablet (with table attachment) is included to operate the EchoNavigator functionality from the X-ray system table side.
- A Wall Connection Box is included, in case the maximum number of Wall Connection Boxes for the X-ray system is not reached and/or no free Wall Connection Box is available. Note: when the maximum of Wall Connection Boxes is reached, a Wall Connection Box needs to be freed up.
- Creates two visual outputs (with 1920\*1080 display resolution), one for the Control Room and
  one for the Examination Room. The visual output for the Control Room is connected to a
  dedicated color 24"wide screen LCD display and is part of the solution (unless it is connected to
  an Azurion system with FlexSpot control room option).

#### **EPIQ CVxi integration kit requires**

- Compatible Echo unit (i.e. EPIQ CVxi and X8-2t transducer).
- For Allura systems: FlexVision XL.
- One available Wall Connection Box in the Control Room (to connect the EchoNavigator system).



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#### 1.47 **AVIDIS Smart Cable** Article No. NCVC654

**AVIDIS Smart Cable** 

The AVIDIS Smart Cable connects the "EPIQ CVxi" with the "EPIQ CVxi integration kit" of the Allura or Azurion system.

### **Key benefits**

Easy single cable connection between EPIQ and Allura or Azurion system which have the EPIQ CVxi integration kit installed

#### **Enhance workflow**

Connecting peripheral equipment in the cath-lab can require multiple cables which can be a hassle and can be prone to failure.

With the AVIDIS Smart Cable the hospital staff can easily connect the echo unit. It is possible to use the echo unit equipped with the Smart Cable EPIQ in any room which has the EPIQ CVxi integration kit.

#### **Specifications**

The AVIDIS Smart Cable connects the video, network and USB interfaces of EPIQ CVxi and Azurion or Allura systems via a single cable.

### **AVIDIS Smart Cable requires:**

EPIQ CVxi Integration Kit

"EPIQ CVxi" with the "EPIQ CVxi integration kit" of the Allura or Azurion system.

#### 1.48 EchoNav R4 license

**Article No. NCVD551** 

#### **EchoNav R4 license**

EchoNavigator R4 with Dynamic Heart Models fuses in real-time 3D TEE Echo images (from a X8-2t probe) with X-ray images.

### **Key benefits**

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- Assists heart teams with intuitive live fusion of X-ray and ultrasound imaging
- Simultaneously visualize devices and soft tissue using 3D imaging
- Navigate device in challenging cases with automated anatomical insights
- Improve communication and facilitate efficient interaction throughout the heart team
- Perform interventional procedures with confidence and clarity, giving quick understanding of Echo anatomy

#### Advanced fusion that advances with you

Structural heart procedures often rely on X-ray imaging to visualize the devices, while also using TEE echo imaging to visualize soft tissue and anatomical structures. These images, however, are

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# **PHILIPS**

represented differently, so valuable time and effort was often channeled into mentally aligning them. But not any more...

EchoNavigator is a real time imaging product that supports the procedure by combining both X-ray and 3D TEE echo in an interactive, intuitive, and procedurally relevant way. The SmartFusion facilitates/provides an easy understanding of 3D anatomical heart structures and how they relate to the X-ray image. It is designed to help you intuitively guide your device in the 3D space more quickly.

#### **Specifications**

EchoNavigator includes the Integrated workspot that can display and operate from the EPIQ CVxi console. It allows for multiple views of Live 3D TEE, segmented heart structures, X-ray, EchoNavigator fusion, and localization of the echo target on X-ray.

EchoNavigator R4 requires a EPIQ CVxi 9.0 or higher release.

### Features EchoNavigator:

- EchoNavigator allows for multiple user-defined live views of Echo data, showing relevant anatomical structures from different angles simultaneously in real time.
- The EchoNavigator user interface is integrated in intuitive touchscreen on the EPIQ CVxi system and optimized for use from the table side and from EPIQ touch screen
- Multiple annotations can be placed on soft tissue anatomical structures in the Echo image and these markers automatically appear in the X-ray image to provide context and help guidance.
- EchoNavigator allows to segment heart structures on the fly, based on the 3D Echo data. It projects this anatomical model into the X-ray view.
- Create 3D segmentation models of the heart, including the optimal transseptal area and enhanced mitral valve anatomical modeling with mitral valve leaflets
- Follow easy step-by-step guidance to create annotations of the optimal transseptal area, based on the distance of the transseptal area to the mitral valve
- The Echo viewpoint is adjusted as the gantry is repositioned (follow C-arc).
- SmartFusion projects the ultrasound field of view into the X-ray view.
- Auto MPR's automatically set the MPR planes based on 3D heart models. You can select the clinical view from the MPR preset gallery, including presets for e.g. the aortic, LAA ormitral valve or
- MultiVue integration allows for 3D echo cropping and catheter alignmentduring image fusion
- DICOM export of fused X-ray and Echo images via the EPIQ archiving functionality
- EchoNavigator projects the ultrasound field of view (Ultrasound cone) as an outline into the X-ray view.
- An elliptical shape, in addition to single point markers, can be selected as annotation to mark anatomical regions of interest.
- A movie of the main display area can be recorded to capture interesting events and sequences during the intervention.
- Prospective (whole case) recordings are supported.

1.49 **DoseAware**Article No. 722367

**Details** 

Configured offering



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## 1.50 Yes, for new system Article No. NCVC149

1

## 1.51 **DoseAware Xtend pack Article No. FCV0854**

1

#### Key benefits:

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

With all the information DoseAware Xtends provide, the individual can understand, act and change behavior to manage the received dose.

The DoseAware Xtend combines individual dose information from the PDM with modality procedure data from the Philips X-ray system and integrates this into real time feedback.

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

**Specifications:** The following elements are included in this bundle.

- 6 Personal Dose Meters (1 for use as reference PDM)
- 1 Personal Dose Meter rack
- 1 Dosimetry hub
- Dose view software

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

It includes a cable for connecting the PDM with the PC (not included). The Dose view software uses a USB connection for installation on a PC (not included), with following PC requirements:

- Windows XP, -7,- 8.1 or -10.NET 3.5 onwards
- At least 2 GB system memory
- At least one available USB port
- At least 1GB free disk space

# 1.52 Remote Service IGT Article No. 722240

#### **Details**

Configured offering



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# 1.53 Cabinet Rear Cover Article No. 459801079651

1

Cabinet Rear Cover

# 1.54 Cabinet Rear Cover Deep Article No. 459801613311

2

#### 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.

# 1.55 Patient table adaptation plate Article No. 989600213943

1

#### Introduction

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

#### **Details**

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

#### **Includes**

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

# (Opt) 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.



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

(Opt) pedestal
Article No. NCVA197

1

The pedestal creates an additional work spot to operate the system in the examination room.

#### **Key Benefits**

Easy system control from different locations

#### Full control where you need it

To help your interventional suite work as efficiently as possible, no matter what layout or case mix it has, you can add this additional work spot to easily control the system from various locations in the Examination Room.

### **Specifications**

The pedestal is provided with additional geometry and imaging modules. It offers the possibility to hold the X-ray footswitch. Optionally an additional touch screen module can be mounted on the pedestal, creating a work spot with full system control. The pedestal is connected to the system by means of a wall connection box. A cable length of 8 meter allows the user to position the pedestal freely around the patient table. The pedestal has been designed with stability and ease of use in mind and can be moved towards the wall connection box when not in use.

(Opt) Wireless footswitch: mono-plane version Article No. NCVC199

1

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.



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- 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.

# (Opt) 3rd touch screen module Article No. NCVD080

1

#### **Key benefits**

• Control system operations with a third 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, table-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 third 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

### (Opt) Touch Screen Module Pro Article No. NCVD081

1

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

#### **Key benefits**



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- 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) addl control module ER Article No. NCVD084

Extension of the control facility for imaging functionality for the Exam Room

#### **Key benefits**

- An additional control for imaging functionality at table side
- Intuitive operation thanks to streamlined design

#### Full control where you need it

To help your interventional suite work as efficiently as possible, no matter what layout or case mix it has, you can choose extra imaging control modules to easily control the system from a different location in the Examination Room. Each control module works according to the Philips workflow concept, allowing intuitive operation of the system thanks to the streamlined design.

### **Specifications**

The imaging control module can also be positioned at three sides of the patient table. It provides the following functionality:

- Fluoroscopy Flavor selection defined per setting
- Shutters and Wedge positioning (for both frontal and lateral plane)
- Manual or automatic semi-transparent wedge filter
- Fluoro Storage
- Selection of the Detector field size
- Reset of the fluoroscopy buzzer
- Roadmap Pro activation if function is available

1



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

(Opt) HeartNavigator R3
Article No. NCVC546

1

#### Introduction

HeartNavigator R3 automatically segments anatomical structures, anatomical landmark points and anatomical planes from previously acquired DICOM compliant CT datasets. Key benefits: - Deeper anatomical understanding to plan and perform TAVR/TAVI, mitral valve replacement and LAAC procedures; - Immersive user experience and fully automated tasks simplify planning, measurement, device selection and choice of X-ray viewing angle; - Enhanced insight into calcification distribution.

### **Key Benefits**

HeartNavigator R3 is a Medical Device as defined in Regulation (EU) 2017/745 (EU-MDR)

#### **Details**

Different visualization tools, including anatomical landmarks, virtual devices, viewing planes and measurements are available to support precise planning.

Specifications: - Automatic segmentation of tissue, anatomical structures, landmarks, calcium, anatomical planes and viewing angles within the cardiac CT data for TAVI/TAVR; - Automatic distance, diameter, area and perimeter measurements for TAVI/TAVR; - Automatic Free centerline measurement along the ascending aorta for TAVI/TAVR; - Segmentation, measurements and viewing angles for other SHD procedures, e.g. mitral valve replacement and left atrial appendage closure; - Up to date virtual device library for TAVI/TAVR procedures; - Report with all relevant measurements, viewing angles and selected device as print for use in exam room or stored on the PACS; - Live guidance with CT overlay and automatic viewing angles; - Highly automated intuitive workflow; - Enhanced anatomy visualization

Contact your local sales person for any CT compatibility details.

#### **Includes**

When planning a structural heart disease (SHD) procedure, an objective assessment on vascular anatomy can help you work with greater confidence and avoid complications. Understanding the patient's individual anatomy when planning a transcatheter aortic valve replacement or implantation (TAVR/TAVI), mitral valve replacement, left atrial appendage closure (LAAC) or other procedure helps you select the appropriate approach, and size and type of a device. In addition, safely navigating the valve delivery devices through anatomy and deploying the valve in the correct position are recognized as technical challenges when performing TAVR/TAVI procedures.

HeartNavigator Release 3 automatically segments anatomical structures, anatomical landmark points and anatomical planes from previously acquired DICOM compliant CT datasets to support a wide variety of structural heart disease procedures.

Line

Description

Qty

)

INTRASIGHT Article No. 797403



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#### INTRASIGHT

# 2.1 IntraSight 5 Article No. NNAW510

#### IntraSight 5

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

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

Imaging (IVUS) License.Includes IntraSight IVUS Software package: Digital (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.

M-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.

Line	Description	Qty
3	Flex Account Article No. SP059Q	1
Line	Description	Qty
4	CV Third Party Products Article No. 100133	
	Details	
	Configured offering	
4.1	MD/ Mark7 Arterion Table Mount Injector Article No. 989806101012	1

#### 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

PHILIPS

1

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Cable length / Interface cable type specified on order

#### **Includes**

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

Automated delivery of contrast with parameters you set

Ability to manually control flow similar to hand injection with VFlow™\* hand controller option Flexibility to monitor and control the injector from multiple locations

ISI connectivity to enable injection control from injector or imaging equipment

Our quality care comes in customized solutions, including on-site clinical training, service and emergency technical support

\*add to quote via separate 12NC

# 4.2 MD/ VFlow Hand Controller Article No. 989806101063

1

#### 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.

# 4.3 MD/Lowerbody UT70-145cm width Article No. 989806100588

1

#### **Details**

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

# 4.4 Vitaling Communication System Article No. 989806105835

1

#### **Vitaling Communication System**

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

Each Vitaling 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



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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



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### 4. Local Sales Terms and Conditions

Line	Product Code	Contract Name	Contract No.	Invoice Schedule
1	722234 Azurion 7 M20	HEALTHTRUST PURCHASING GROUP HPG81970	HPG81970	0/80/20
2	797403 INTRASIGHT	HEALTHTRUST PURCHASING GROUP HPG7415	HPG7415	0/80/20
3	SP059Q Flex Account	NONE	NONE	0/80/20
4	100133 CV Third Party Products	HEALTHTRUST PURCHASING GROUP HPG81970	HPG81970	0/80/20

Payment Terms US: Net 45 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

#### Additional Terms US:

Cancellation: Order(s) are cancellable with written notice to Philips. Cancellation is subject to a 10% penalty unless one of the following is true: 1. Non-installable products, consumables, off-the-self software, and infringing products, not shipped; or, 2. Services not commenced; or 3. Force Majeure; or, 4. Philips receives notice 5 days prior to the start of SOW or project; 5. Products failing to comply with the HealthTrust Agreement or applicable law or regulation or subject to a recall; or, 6. Philips' breach of Warranty exclusions in section 14.9 of HealthTrust Agreement.



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### 5. Signature Page

Invoice to:

Mh Mission Hospital LLLP 509 Biltmore Ave Asheville, NC 28801-4601 Ship to:

Mh Mission Hospital LLLP 509 Biltmore Ave Asheville, NC 28801-4601

Total Net Price

Total Net Price \$ 1,707,670.38

### 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 <a href="https://www.usa.philips.com/healthcare/support/terms-and-conditions">https://www.usa.philips.com/healthcare/support/terms-and-conditions</a>. 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: \_\_\_ 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 PHILIPS SIGNATURE** by its authorized representative by its authorized representative Signature: Signature: Print Name: Print Name: Title: Title: Date: Date:



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 From:
 Mitchell, Micheala L

 To:
 Stancil, Tiffany C

 Cc:
 Lightbourne, Ena

Subject: FW: [External] Exemption Request

Date: Wednesday, June 18, 2025 9:48:43 AM

Attachments: Exemption Request -Hybrid OR Equipment Replacement with Attachments.docx.pdf

Morning Tiffany,

Would you mind logging this as an exemption and assigning to Ena? She'll be back in tomorrow.

Micheala Mitchell, JD

NC Department of Health and Human Services

**Division of Health Service Regulation** 

Section Chief, Healthcare Planning and CON Section

809 Ruggles Drive, Edgerton Building

2704 Mail Service Center Raleigh, NC 27699-2704

Office: 919 855 3879 Micheala.Mitchell@dhhs.nc.gov

**Sent:** Tuesday, June 17, 2025 5:55 PM

To: Mitchell, Micheala L < Micheala. Mitchell@dhhs.nc.gov>

**From:** Randolph, Kim <krandolph@bakerdonelson.com>

Cc: Stauffer, Iain <istauffer@bakerdonelson.com>; Lightbourne, Ena

<ena.lightbourne@dhhs.nc.gov>

Subject: [External] Exemption Request

**CAUTION:** External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Hey Micheala,

I hope you are doing well.

Attached please find an exemption request for Hybrid OR replacement equipment on the Mission main campus. Please let me know if you have any questions.

Thanks so much!

#### Kim Randolph

Attorney

Baker, Donelson, Bearman, Caldwell & Berkowitz, PC 2235 Gateway Access Point, Suite 220 Raleigh, NC 27607 Direct: 984-844-7903

Cell: 919-614-9124

krandolph@bakerdonelson.com

Baker, Donelson, Bearman, Caldwell & Berkowitz, PC represents clients across the U.S. and abroad from offices in Alabama, Florida, Georgia, Louisiana, Maryland, Mississippi, New Jersey, North Carolina, South Carolina, Tennessee, Texas, Virginia, and Washington, D.C.

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