NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

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

VIA EMAIL ONLY

July 29, 2025

Brighid Humber
Brighid.Huber@advocatehealth.org

Exempt from Review – Replacement Equipment

Record #:	**4840**
Date of Request:	July 10, 2025
Facility Name:	Carolinas Medical Center
FID #:	944734
Business Name:	The Charlotte-Mecklenburg Hospital Authority
Business #:	1770
Project Description:	Replace pediatric cardiac catheterization equipment in Lab #2
County:	Mecklenburg

Dear Brighid Huber:

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(a)(7). Therefore, you may proceed to acquire without a certificate of need the seeks to acquire Canon Alphenix Bi-Plane cardiac catheterization equipment ("Replacement Equipment") to replace existing Canon (Toshiba) Infinix Bi-Plane cardiac catheterization equipment ("Existing Equipment")This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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

Sincerely,

Chalice L. Moore, Project Analyst

Micheala Mitchell, Chief

cc: Radiation Protection Section, DHSR
Construction Section, DHSR

July 9, 2025

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

RE: Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center ("CMC") to Replace Pediatric Cardiac Catheterization Equipment

Dear Ms. Mitchell:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center ("CMC") seeks to acquire Canon Alphenix Bi-Plane cardiac catheterization equipment ("Replacement Equipment") to replace existing Canon (Toshiba) Infinix Bi-Plane cardiac catheterization equipment ("Existing Equipment") that was acquired in 2017 and is at the end of its useful life. The Existing Equipment is currently housed in Pediatric Cardiac Catheterization Lab #2 on the sixth floor of CMC's main hospital building located at 1000 Blythe Boulevard, Charlotte, NC 28203.

The purpose of this letter is to provide the Agency with notice and to request a determination that CMC's purchase of the Replacement Equipment is exempt from Certificate of Need ("CON") review. The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of "replacement equipment," defined in NCGS § 131E-176(22a) as follows in the CON law:

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

CMC's proposal qualifies for this exemption.

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

The purchase price of the Replacement Equipment is $1,723,527 ($1,607,018 Canon Alphenix Bi-Plane + $116,509 sales tax). The projected total cost of this project is $2,461,117 and includes the cost to acquire, install and make operational the Replacement Equipment.

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

Attachment A provides the quote for the Replacement Equipment. The total capital cost worksheet is provided in Attachment B.

B. Comparable Equipment

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

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

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

For further equipment comparison, please refer to Attachment D, which contains the Equipment Comparison Chart.

The Existing Equipment in Pediatric Cardiac Catheterization Lab #2 has been and is currently in use. In the previous 12 months, 248 cases were performed using the Existing Equipment in Pediatric Cardiac Catheterization Lab #2.

C. Existing Equipment

The Existing Equipment will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate CON approval.

CONCLUSION:

Based on the foregoing information, CMC hereby requests that the Agency provide a written response confirming that the acquisition of the Replacement Equipment described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please let us know.

Thank you for your consideration of this notice.

Sincerely,

Elizabeth V. Kirkman

Elizabeth V. Kirkman
Assistant Vice President
Core Market Growth Business Development

Attachments

Attachment A

CANON MEDICAL SYSTEMS USA, INC.

Made For life

QUOTATION/ORDER SUMMARY

DATE: 3/27/2025
SID #: 30065956
QUOTE #: 178467-8

PRESENTED TO:

LEVINE CHILDRENS HOSPITAL PEDIATRIC
1001 BLYTHE BLVD
CHARLOTTE, NC. 28203

VL/ALPH/BP/3.000
[V9.5] ALPHENIX BIPLANE VASCULAR SYSTEM

SPECIAL INFORMATION & TERMS

- This quote includes the Canon Medical Systems Encore Plus Loyalty Upgrade program. With Encore Plus, current Canon Medical installed-base customers can transform their aging system to the latest technology while maintaining some existing components where possible. This program provides access to the most recent technological advancements and offers training and warranty equal to a completely new system.

  Note: In case of a power outage, only a three-phase full-system UPS will be compatible with the Alphenix system. Please contact a Canon sales representative if you want to include a three-phase full-system UPS to the quote.

- This quotation includes deinstallation and removal of Customer's existing system.

- If this quotation is not accepted by July 31, 2025, Canon Medical Systems USA, Inc. reserves the right to cancel this quotation.

- The parties acknowledge and agree the Canon terms and conditions exclusively govern this transaction and that the sole purpose of referencing the OSR shall be for Customer's own internal tracking purposes.

- OSR # 23000006717

This quotation shall remain valid until July 31, 2025.

All prices are F.O.B. destination.
Payment terms are: Cash - 0% down payment, 80% upon delivery, 20% net 45 days upon completion of installation and/or availability for first use, whichever is earlier.

This quotation/order will be subject to and governed by the Agreement for Vascular equipment products between Premier Healthcare Alliance, L.P. and Canon Medical Systems USA, Inc. Reference contract no. PP-IM-288, effective October 1, 2015.

Please return signed quotation to Canon Medical Systems USA, Inc. by email OrderAdmin@us.medical.canon or fax 714-441-9320.

ACCEPTED AGREED AND ORDERED:

PURCHASER'S SIGNATURE/TITLE	DATE	CANON MEDICAL SYSTEMS REP	DATE

EQUIPMENT SUMMARY:

VL/ALPH/BP/3.000 **[V9.5] ALPHENIX BIPLANE VASCULAR SYSTEM**

PART NUMBER	QTY	DESCRIPTION
	1	PEDIATRIC LAB
ALPH-BP/HDSR/12.100	1	SYSTEM KIT: ALPHENIX BIPLANE HI-DEF 12"X12" FPD SYSTEM WITH SPOT ROI
	1	MAIN UNIT: ALPHENIX BIPLANE HI-DEF 12"X12" FPD SYSTEM WITH SPOT ROI
	1	6 METER CEILING RAILS FOR CAS-830B AND CAS-930A SERIES
CAT-880B-AL2.100	1	[KIT] CATHETERIZATION TABLE (TILT/CRADLE)
	1	CATHETERIZATION TABLE
	1	INTERFACE CAT-880B/870B TO CAS-880A
	1	MUSHROOM HANDLE FOR CAT-850B/B1, CAT-880B/B1
	1	OVER HEAD HANDGRIPS / ARMREST FOR CAT-880B/B1
	1	SUPPORT ARM LOCK KIT
	1	SINGLE ARM BOARD
	1	HEAD-END DRAPE HOLDER FOR CAT-880B
	1	2" TABLE PAD FOR CAT-880B
	1	STANDARD APPLICATIONS TRAINING
	1	CABINET SIDE COVER
	1	[KIT] 21" COLOR MONITOR KIT
	1	21" MONITOR, LCD COLOR (BASE PLATE INCLUDED)
	1	SUPINE POSITION SCOOP ARM SUPPORT
	1	ANTI-FATIGUE FLOOR MAT
	1	SERVICE INSTALLATION COMPONENTS
	1	MAVIG TABLE MOUNTED RADIATION SHIELD
	2	COPPER PHANTOM FOR WAKE UP PROGRAM FOR ALPHENIX
	1	WAKEUP CHECK PROCEDURE BOOKLET
	12	COOLANT - 1 GALLON
	2	19" COLOR MONITOR
	1	ENCOREPLUS LOYALTY DISCOUNT FOR CANON INSTALLED BASE

PART NUMBER	QTY	DESCRIPTION
XIDF-STA801/A1	1	DYNAMIC DEVICE STABILIZER FOR AWS PRO WITH 3D VIEWER OR GPU KIT
BTL SVC LABOR	1	BTL SVC LABOR
BTL 3RD PARTY DEINSTALL	1	DE-INSTALLATION AND TRADE IN OF CUSTOMER'S EXISTING SYSTEM
UNISPOT-BP.100	1	[KIT] CONTROL ROOM UNISPOT FOR BIPLANE SYSTEMS
	2	UNISPOT DISPLAY KIT WITH 32" 4K MONITOR
	2	UNISPOT DISPLAY KIT WITH LICENSE AND DECODER
	2	MONITOR INTEGRATION SYSTEM ACCESSORY KIT
BARCO-58/2.100	1	[KIT] BARCO 58" V7 LARGE MONITOR WITH BUILT-IN PROTECTIVE GLASS NIVR58-T7 G KIT
	1	BARCO 58" V7 NIVR58-T7 G KIT (COMPOSITOR, 4 ENCODERS, NETWORK SWITCH AND CABLES)
	3	100FT CAT5E BLUE PATCH CABLE CABL CAT5 SNAGLESS MOLDED M/M RJ45 350MHZ
	3	6FT CAT5 CAT5E BLUE PATCH CABLE CABL SNAGLESS MOLDED M/M RJ45 350MHZ
	1	BACKUP MONITOR INTERFACE KIT FOR BARCO 58" MONITOR
	1	CABINET FOR LARGE LCD COLOR DISPLAY MONITOR
	1	TRIPP LITE WALL MOUNT CABINET
	2	TRIPPLITE 6 OUTLET RACKMOUNT POWER STRIP PERP 1U REAR FACING
	1	TRIPPLITE 1U RACK ENCLOSURE FIXED SHELF
	2	TRIPPLITE WALL MOUNT RACK ROOF FAN KIT FAN
	1	BLACKBOX 10 PORT GIGABIT WEB SMART
BARCO-58-GUESTPORT.100	2	[KIT] BARCO V7 GUEST PORT INPUT DISPLAY
	2	K9303320 MNA-420 ENC HDMI INCLUDES: MNA-420 ENC, 2XHDMI-DVI 10FT CABLE AND 10GSFP+
	2	MNA-120 ENC ANA AUDIO TMS WITH EXTRA SFP+
	2	DVI EXTENDER AND RECEIVER CABLE
	2	CANON LOGO PLATE
	4	1M FIBER MMF LC-LC OM3 DX 2MM CABLE CUSTOM
	2	DVI TO HDMI ADAPTOR (2 PCS 8" ADAPTORS INCLUDED)
BARCO-58-HDMI-INPUT.100	2	[KIT] HDMI VIDEO INPUT HD ENCODER FOR BARCO V7
	2	K9303320 MNA-420 ENC HDMI INCLUDES: MNA-420 ENC, 2XHDMI-DVI 10FT CABLE AND 10GSFP+

PART NUMBER	QTY	DESCRIPTION
	2	1M FIBER MMF LC-LC OM3 DX 2MM CABLE CUSTOM
	2	30M LC-LC OM3 MM DX 2MM CABLE CUSTOM
BARCO-58-ANALOG-INPUT.100	1	[KIT] ANALOG INPUT ON BARCO MONITOR
	1	MNA-120 ENC ANA AUDIO TMS WITH EXTRA SFP+
	1	1M FIBER MMF LC-LC OM3 DX 2MM CABLE CUSTOM
	1	30M LC-LC OM3 MM DX 2MM CABLE CUSTOM
BARCO-FHD-OUTPUT.100	3	[KIT] FHD-VIDEO READY OUTPUT DECODER KIT FOR DIAGNOSTIC MONITOR INTERFACE
	3	MNA-420 DEC V2 HD DUAL CHANNEL DECODER 2X HDMI OUTPUT ADDITIONAL 10G SFP+
	3	DVI TO HDMI ADAPTOR (2 PCS 8" ADAPTORS INCLUDED)
	3	ONE KIT 36M OPTIC FIBER CABLE TMS
	3	NO MONITOR
2-LS2R/3.100	1	[KIT] ONDAL LARGE MONITOR SUSPENSION CEILING MOUNT OPTION KIT
	1	ONDAL LARGE MONITOR SUSPENSION CEILING MOUNT (2900+MM CEILING HEIGHT) - INSTALLATION & EQUIPMENT RENTAL INCLUDED. A SECOND INSTALLATION VISIT IS INCLUDED IF NECESSARY
1944547	1	CEILING COVER H50, MEDIBOOM, 222, 9010 (CENTER MOUNT)
XGCP-882AA/B1	1	JOYSTICK CONTROL UNIT WITH STAND (BIPLANE)
XACP-001BA/C1	1	TABLE SIDE TABLET CONSOLE (4M CABLE)
XIDF-QCA850/B1.100	1	BASIC KIT FOR CLINICAL ANALYSIS APPLICATION
	1	CAAS BASIC KIT FOR CLINICAL ANALYSIS APPLICATION
XIDF-QCA851/B1	1	QUANTITATIVE CORONARY VESSEL ANALYSIS - 9MM OR LESS
XIDF-QCA852/B1	1	QUANTITATIVE VESSEL ANALYSIS - 9MM OR ABOVE
XIDF-QCA854/B1.100	1	LEFT VENTRICULAR ANALYSIS (BIPLANE) KIT
	1	LEFT VENTRICULAR ANALYSIS (BIPLANE)
	1	LEFT VENTRICULAR ANALYSIS (SINGLE PLANE)
XIDF-AWS801/CA2/3.100	1	[KIT] ALPHENIX ANGIO WORKSTATION (AWS PRO) AND MONITOR
	1	ALPHENIX ANGIO WORKSTATION (AWS PRO)
	1	ROCKET LINK CONNECTION KIT

PART NUMBER	QTY	DESCRIPTION
	1	21" MONITOR, LCD COLOR (BASE PLATE INCLUDED)
	2	DISPLAY PORT TO DVI-D ADAPTER/VIDEO CONVERTER 1080P
3D-ANGIO-SW-KIT/AL.100	1	BASE 3D ACQUISITION SOFTWARE
	1	3-D ANGIO SOFTWARE
APPS-ONSITE-32	1	ON-SITE APPLICATIONS TRAINING - 32 HOURS
XIDF-PVG801/A1.100	1	3D VIEWER KIT
	1	3D VIEWER KIT
XIDF-3DP802/C1.100	1	3D ROADMAP WITH NEEDLE GUIDANCE KIT ON AWS
	1	3D ROADMAP WITH NEEDLE GUIDANCE KIT ON AWS
XIDF-3DP804	1	MULTI-MODALITY ROADMAP KIT (CT & MR)
XIDF-ROT801	1	ROTATIONAL DSA KIT
XIDF-LCI801	1	LOW CONTRAST IMAGING (ALPHA CT/CBCT) (REQUIRES AWS)
XBER-001A	1	TABLE SIDE CONTROL EXTENSION RAIL SET (PAIR)
XBET-001A	1	FOOT-END TABLE EXTENSION (REQUIRES XBER-001A)
9445	1	FOOT END TABLE CONTROL MOUNTING RAIL FOR EXTENSION RAIL OPTION
9412	1	2" TABLE FOOT-END EXTENSION PAD FOR PART # XBET-001A
PX17-36730-2	1	I/V POLE FOR ALPHENIX SERIES
FOOTSWITCH/W/BP/880.100	1	WIRELESS FOOTSWITCH FOR CAT-880B BIPLANE
PQUBE-CANON-FM-01	1	POWER QUALITY AND ENVIRONMENTAL MONITORING PACKAGE (FLUSH MOUNT)
XIDF-DTS802/C1.100	1	[KIT] DOSE TRACKING SYSTEM WITH MONITOR FOR ALPHENIX
	1	DOSE TRACKING SYSTEM FOR ALPHENIX
	1	21" MONITOR, LCD COLOR (BASE PLATE INCLUDED)

TOTAL QUOTE PRICE **$1,607,018.00**

Applicable Sales Tax Additional

FINANCE OPTIONS:
Finance options are available through Canon Medical Finance USA, a program of Canon Medical Systems USA, Inc.

CANON MEDICAL FINANCE USA OFFERINGS:

- Fair Market Value, $1.00 Buy Out (Lease to Own), and Loan structures
- Finance terms ranging from 12 months to 84 months
- Financing for 3rd party assets (including, but not limited to leasehold improvements & I.T.)

CANON MEDICAL FINANCE USA BENEFITS:

- No progress payments. Payments begin after delivery and installation
- Upgrades to the current technology platform can be financed.
- Flexible finance structures, such as deferred payments, tiered repayments, and bridge financing, to meet cash flow needs

Finance options are subject to credit underwriting, approval, and a fully executed contract.

For more information, please contact Trish Malone, Sr. Dir. Financial Programs at: tmalone@us.medical.canon or visit us at https://us.medical.canon/service-and-support/financial-programs/

COMPONENT SUMMARY:

PART NUMBER	QTY	DESCRIPTION
	1	**PEDIATRIC LAB** Optimized for Pediatric facilities, the Canon family of angiography systems Combines industry-leading dose management technologies, enhanced workflow and a new set of features. Canon Medical is commited to supporting you and your mission to provide patients with safe, accurate and fast imaging. **WorkRite Technology:** WorkRite technologies help you optimize workflow and provide an unprecedented range of patient access and coverage. The unique flexibility and design of the C-arm, combined with low-profile FPD housing, offers optimal ergonomic orientation enabling "line of sight" over the system and patient to view the display monitors. Our feature-rich workstation enhances productivity and integrates applications to help you plan, analyze and perform interventional procedures. **ImagingRite:** ImagingRite technologies Offers A full complement of advanced imaging tools that can be customized based on the clinical application. **DoseRite:** DoseRite technologies provide a comprehensive dose management suite of tools designed to minimize patient X-ray exposure while maintaining optimum image quality, enabling you to prioritize safe operating conditions for patients and clinical staff. A redesigned imaging platform with 8th generation Advanced Image Processing (AIP) and noise reduction technology Even standard system configurations offer many dose management features to help you provide benefits for everyone, from patients to clinical staff.
ALPH-BP/HDSR/12.100	1	**SYSTEM KIT: ALPHENIX BIPLANE HI-DEF 12"X12" FPD SYSTEM WITH SPOT ROI** **STANDARD SYSTEM COMPONENTS** • CAS-820B/B1 — C-arm, Ceiling-Mounted (Omega-Arm) • CAS-880A/B2 — Multi-Axis C-arm, Floor Mounted • DSRX-T7735GFS — High Capacity X-ray Tube (Qty 2) • BLA-900A/R1 — Automatic Rotating Collimator (Qty 2) with Spot ROI • TFP-1200C/A1 — 12" x 12" HD Flat Panel Detector (Qty 2) • XGCP-882BA/B1 — Tableside Control (Hyper Handle) • XBFS-880B — Standard Biplane Footswitch • XTP-8100XG — High-Frequency X-ray Generator 100 kW (Qty 2)

• DFP-8000C/A2	Multitasking Digital Fluoroscopy Processor
• XIDF-MIC802	Microphone Kit
• XIDF-MCC80B	Main Console
• XIDF-FS801B	Control Room Footswitch
• XJDK-002A/V9	Dose Meter Controller
• XJDC-016A	Dose Chambers (Qty 2)

C-ARM, CEILING-MOUNTED (OMEGA-ARM) CAS-820B/B1

The unique, ceiling mounted omega-arm provides clinical angles for fluoroscopy, radiography and digital fluorography.

Specifications:

- Variable rotation speeds up to 15 degrees per second for fast C-arm angulation
- Stroke of flat panel detector movement (SID): 380 mm, motor-driven
- Isocenter height: 111 cm (43.7")

Variable Height Imaging Plane

Canon Medical Systems exclusive feature provides 70 mm of synchronized x-ray tube and flat panel detector vertical travel. Enhancing patient safety and physician comfort, adjusting the height of the lateral imaging plane enables table height to be adjusted for physician height and provides the ability to maintain table height and patient position while adjusting vertical imaging plane with the lateral arm.

C-arm Flip

Canon Medical Systems exclusive feature enables the lateral c-arm to reverse the side of the x-ray tube and flat panel, mid procedure. As scatter radiation exposures are higher on the x-ray tube side by up to 50%, the Alphenix BiPlane provides flexibility for procedures on either side of the patient table while minimizing dose exposure to the operator.

Positioning Features to Enhance Workflow

The floor-mounted C-arm is designed to enhance workflow. Features include:

- C-Arm Movement: Flexible positioner that, combined with low-profile housing of the X-ray tube and FPD, optimizes imaging angles. Enables variable-speed axial rotations and isocentric fluoroscopy and fluorography with rotations from:
  - Omega Arm Rotation**:**
    - CRA 45 degrees to CAU 45 degrees (left lateral setting)
    - CRA 45 degrees to CAU 45 degrees (right lateral setting)
  - Omega Arm sliding:
    - LAO 120 degrees to LAO 0 degrees (left lateral setting)
    - RAO 120 degrees to RAO 0 degrees (right lateral setting)

- Auto-Positioning/Auto-Set Functions: Allows Specific auto-positioning settings sequentially for each study protocol. Enables fast initiation of C-arm positioning and system settings for the desired imaging requirements. Records and reproduces over 64 programs of: Angulations and SID, Initial Field of View (FOV), Table height, Compensation-filter position
- Auto-Angle: For acquired images, auto-angle stores the following for one-touch recall (can be customized to site): C-arm angle, SID, Compensation filter position, Table height, Magnification size, FOV, Live Zoom

MULTI-AXIS C-ARM, FLOOR MOUNTED - CAS-880A/B2

Unique, floor-mounted C-arm provides clinical angles for fluoroscopy, radiography and digital fluorography. It provides all clinical angles for diagnostic and interventional procedures with 6'6" head-to-toe and 6' fingertip-to-fingertip access for maximum patient coverage.

Specifications:

- Variable rotation speeds up to 50 degrees per second for fast C-arm angulation
- Stroke of flat panel detector movement (SID): 350 mm, motor-driven
- Isocenter height: 111 cm (43.7")

Positioning Features to Enhance Workflow

The floor-mounted five-axis C-arm is designed to enhance workflow. Features include:

- C-Arm Movement: Flexible positioner that, combined with low-profile housing of the X-ray tube and FPD, optimizes imaging angles. Enables variable-speed axial rotations and isocentric fluoroscopy and fluorography with rotations from:
  - Rotation angle: RAO 120 degrees to LAO 120 degrees
  - Sliding angle: CRA 50 degrees to CAU 90 degrees (head-end position)
- Auto-Positioning/Auto-Set Functions: Specify auto-positioning settings sequentially for each study protocol. Quickly initiate C-arm positioning and system settings for the desired imaging requirements. Record and reproduce over 64 programs of: Angulations and SID, Initial Field of View (FOV), Table height, Compensation-filter position
- Auto-Angle: For acquired images, auto-angle stores the following for one-touch recall (can be customized to site): C-arm angle, SID, Compensation filter position, Table height, Magnification size, FOV, Live Zoom

HIGH-CAPACITY X-RAY TUBE WITH LIQUID METAL BEARING DSRX-T7735GFS (QTY 2)

Includes a standard 36-month, non-prorated tube warranty. Triple-focus design provides small-focal-spot redundancy. Highly efficient, pulsed fluoroscopy with built-in, beam-hardening aluminum and copper filters

reduces dose. Continuous, high-speed (9000 rpm) anode rotation provides immediate display of fluoroscopic and fluorographic images. Other features include:

- Grid switch
- Maximum kV: 125 kV
- Focal spot: 0.4/0.6/1.0 mm
- Maximum ratings: 28/48/100 kW
- Target angle: 11 degrees
- Maximum anode heat storage: 3800 kHU
- Maximum anode cooling rate: 9240 HU/s

AUTOMATIC ROTATING COLLIMATOR - BLA-900A/R1 (QTY 2)

- For Spot ROI fluoroscopy which has the dedicated filter with a rectangular hole making a normal exposure area and filter-attenuated area
- Four dose adjustment filters, with rotating collimator using industry-standard filtration materials, including: Aluminum 1.8 mm, Copper 0.2 mm, 0.3 mm, 0.5 mm
- Automatic or manual rotating collimator keeps a heads-up alignment
- Automatic selection of appropriate filter is possible when registered in the fluorographic program
- Additional Compensation filters are provided with: Fe 1.2 mm
- Two left/right filters (heart shaped or straight filters available)

12″X12″ CANON EXCLUSIVE HIGH DEFINITION FLAT PANEL DETECTOR - TFP-1200C/A1 (Qty 2)

Canon exclusive new High Definition panel consists of a 12″ x 12″ (Standard) Amorphous panel that is combined with a 3.5″ x 3.5″ (High Definition) CMOS panel. This results in resolutions of 2.6 lp/mm (Standard) and 6.6 lp/mm (High Definition). The High Definition (3.5″ x 3.5″) small pixel detector panel contains a novel proprietary architecture that utilizes 76 × 76 µm in addition to the standard architecture of 194 × 194 µm.

- Multiple fields-of-view:
  12″x12″, 10″x10″, 8″x8″, 6″x6″ (Standard)
  3″x3″, 2.3″x2.3″, 1.5″x1.5″ (High Definition)

TABLESIDE CONSOLE (HYPER HANDLE)- XGCP-882BA/B1

Adjustable, rail-mounted, tableside control provides functional control of component movement and interface with digital console. Control features a slim profile and ergonomic design with tactile control buttons, enhancing the user experience.

STANDARD BIPLANE FOOTSWITCH - XBFS-880B

Provides various image acquisition and other programmable functions via foot pedals and buttons, freeing the clinician's hands and allowing more focus on the patient and image display.

HIGH-FREQUENCY X-RAY GENERATOR 100 KW - XTP-8100XG

Uses dual-inverter method for increased reliability with redundant inverter. Operates in normal/standard mode, low-dose mode and high-dose mode fluoroscopy.
Includes: Control console, Control cabinet, Power cabinet with high-speed starter, Fluoroscopy control cabinet, System power source cabinet.

Fluorographic Ratings

- 125 kV, 800 mA (0.1 s)
- 100 kV, 1000 mA (0.1 s)

Pulsed Fluoroscopy Function

- Fluoroscopic tube voltage range: 50 kV to 120 kV
- Fluoroscopic tube current range: 200 mA peak
- Pulse width: 1.0 ms to 13.3 ms
- Repetition pulse rate: 30, 20, 15, 10, 7.5, 5, 3, 2, 1 exp/s (can be selected at the time of installation)
- ABC (auto brightness control) function: provides the automatic adjustment of the tube voltage or the tube voltage and tube current to maintain uniform monitor brightness

Digital Subtraction Angiography (DSA) Functions

- Tube voltage range: 50 kV to 125 kV
- Tube current range: maximum 1000 mA (may be restricted depending on the rating of the X-ray tube assembly)
- Pulse width: 1.0 ms to 100 ms

Digital Angiography (DA) Functions

- Tube voltage range: 50 kV to 125 kV
- Tube current range: maximum 1000 mA (may be restricted depending on the rating of the X-ray tube assembly)

MULTITASKING DIGITAL FLUOROSCOPY PROCESSOR - DFP-8000C/A2

Canon Medical Systems' digital processor provides a variety of features to enhance workflow and image processing.

Fluoro and Acquisition Modes

- Fluoro:
  - Matrix: 1024^2, 16 bits
  - Pulse rate: Continuous or 1, 2, 3, 5, 7.5, 10, 15, 20, 30 exp/s

- DA Acquisitions: (selected at the time of installation)
  - Matrix of 1024^2: 16 bits at 1, 2, 3, 5, 7.5, 10, 15, 30 fps
  - Matrix of 512^2: 16 bits at 60 fps (only available for less than 8" input size other than high definition mode)

- DSA Acquisitions: (selected at the time of installation)
  - Matrix of 1024^2:16 bits at 1/3, 1/2, 1, 2, 3, 6, 10, 15, 30 fps

Common Graphic User Interface
The new digital platform comes with a graphic user interface that is common across modalities on all Canon Medical Systems devices for more intuitive operation of all systems.

Advanced Image Processor (AIP)
Canon Medical Systems' exclusive imaging technology – AIP (advanced image processing) – is a combination of software, filters and proprietary hardware. AIP enables enhanced visualization of small devices and structures while providing real-time response to optimize the collection of critical imaging information during the most demanding procedures.

Advantages Over Conventional Imaging
- Virtually instant-on fluoroscopy helps to capture critical information at fluoro initiation. Noise and anti-blooming suppression technology is designed to provide a more uniform, high-resolution presentation of the image during fluoroscopy. Virtually zero lag during fluoroscopic imaging helps to further enhance visualization during movement and while manipulating wires.

Proprietary Technology
AIP proprietary computing technology brings a new dimension to the overall performance of the system, adding specific functions for either targeted or general anatomical imaging to advance treatment planning and intervention. This includes:
- Dynamic Pattern Recognition Filter (DPRF): enhances visibility with digital recognition of devices to differentiate devices from anatomy.
- Dynamic Digital Compensation Filter (DDCF): improves exam efficiency and decreases dose by reducing the need for acrylic filters.
- Super Noise Reduction Filters (SNRF): allows for better visualization of anatomy and device by reducing noise, even with acute angulations. These enhancements reduce the amount of noise and lag in digital imaging for both digital angiography (DA) and fluoroscopy.

Dynamic Trace
Use of a panning mode while imaging the lower extremities, and for Bolus Chase examinations, for a more uniform image display and background compression. This provides greater vessel detail even when vessels overlap bone.

Guideview Subtracted 2-D Roadmap Fluoro
Canon Medical Systems' proprietary Guideview technology is particularly useful during roadmap imaging. Guideview provides the ability to combine features to better distinguish and visualize guide wires within the vessel. These features include:

- Fade vessel or background, adjust brightness and contrast real-time, and reverse blacks and whites
- Provide boney Landmark
- Create Roadmap using LIH or an acquired image;
  - Peak Pixel Roadmap – provides the optimal, live, peak, fluoroscopic-subtracted roadmap image.
  - Add Subtracted Fluoroscopy – provides a completely subtracted display to better visualize live contrast injections or embolic materials.
  - CO_2 DSA – provides the optimal, live, CO_2 (low-density pixel), fluoroscopic subtracted roadmap image without the use of iodinated contrast media.

Fluoro Record and Fluoro Store
Enables the easy use of fluoro store and playback to further study regions of interest, potentially reducing overall radiation dose. Ideal for pediatric imaging.
- Tableside, one button control
- Maximum: 90 seconds or 1020 frames of prospective recording
- Maximum: 60 seconds or 900 frames of retrospective recording

Digital Live Zoom
Live zoom digitally enlarges images in real time during both fluoroscopy and digital acquisition (DA) and offers the capability to provide a dose savings alternative compared to traditional field of view (FOV) magnifications.

Virtual Collimation using Last Image Hold
Provides an electronic outline to position the collimator and acrylic filter without fluoroscopy, with no additional dose.

Virtual ROI
Virtual ROI displays an outline of the last image hold with a center point on the Live monitor which may be used as a reference to reposition the patient

without the use of fluoroscopy. The outline and the center point moves during panning of the table to indicate the next area of exposure.

DA and DSA
The user-friendly, icon-driven platform provides intuitive, rapid, tableside control over image processing and data management.

Radiographic "One Shot" Mode
Allows the capture of a single image at radiographic technique level. Image can be used as a mask for functions such as "Guideview" subtracted roadmap fluoro.

Simultaneity
True multi-tasking including: Image retrieval, Image acquisition, Post processing, Archiving , Printing.

Prevision
Enables retrieval and display of previously acquired Alphenix series images as reference during follow-up procedures.

Post-Processing Software
- Auto-window, Pan and zoom, Distance measurement and stenosis ratio measurement, Spatial filtering (edge enhancement), Brightness/contrast control, Landmarking percent, Peak trace, CO2 trace, Shutter control, Annotation, Image rotation, Pixel shift, Panoramic view (available with S-DSA).

Image Recording Unit
High-capacity, high-speed disk (RAID Level 3):
- Maximum recording number: 10242 16-bits: 206,400; 5122 16 bits: 820,800
- Online recording
- DVD-R and CD-R Recording
- DICOM 3.0, 5122 or 10242 8/10/12-bits, JPEG loss-less compression
- Up to 4,800 frames at 5122 x 8 bits
- Recording operation: Manual or automatic background recording can be performed after examination

DICOM Conformance and Dose Reporting
- DICOM Store/Store Commitment, Query/Retrieve
- DICOM MWM and MPPS
- DICOM Structured Dose Reporting provides a comprehensive data set of procedural dose information that is available for output to further analyze and track dose information

MICROPHONE KIT - XIDF-MIC802

- Includes noise-reduction transformer
- Remote operator activates microphone/speaker with footswitch
- In-room microphone/speaker mounts on monitor support

MAIN CONSOLE - XIDF-MCC80B

Control room console with similar functions as exam room console, which enhances workflow due to a more intuitive use of the system. From inside the control room a user can:

- Operate the ring menu
- Use pre-programmed functions
- Control collimator and filters
- Review and manipulate images

FOOTSWITCH FOR CONTROL ROOM - XIDF-FS801B

Footswitch that enables fluoroscopy to be initiated from inside the control room.

DOSE METER CONTROLLER FOR BI-PLANE - XJDK-002A/V9

Manages dose when combined with a dose chamber (part XJDC-009A or XJDC-016A) on the front of the beam-limiting device. Sends the following data to the digital fluoroscopy processor**:**

- Exposure time
- Dose area product (DAP) in µGycm²
- Dose area product rate (DAP) in µGycm²/s
- Calculated surface dose in mGy and in mGy/s

DOSE CHAMBERS - XJDC-016A (QTY 2)

For cardiovascular tube. Mounted on top of the collimator to enables dose data for real-time display.

CUSTOMER CARE SERVICES

Developed with customer input, Canon Medical Systems' innovative support programs have resulted in increased customer satisfaction. The following support programs are available to customers covered under warranty:

InTouch Center®

This centralized service facility provides applications and service support 24 hours a day, seven days a week.

InnerVision™ Plus

Remote system diagnostics are available around the clock to help identify problems and provide potential solutions before care is interrupted.

Technical Assistance

Customer support specialists are available 24/7 to help resolve technical issues in real time.

Local Customer Teams
A single call mobilizes a local team of Canon Medical Systems customer engineers. With an average of over 10 years of Canon Medical Systems experience and more than 100 hours of specialized training, they can resolve any performance issue.

Parts Support
A complete inventory of product parts maintained in 34 parts depot locations throughout the country for shipment when and where they are needed, any time of day or night.

INTOUCH SERVICE MAINTENANCE AGREEMENTS
Canon Medical Systems offers a variety of customizable service plans ranging from shared risk to full security maintenance agreements that provide complete system coverage.

The Alphenix Bi Plane is the INFX-8000V/BM (BP)

The operating system is based on Microsoft Windows 10 IoT Enterprise ***2019 LTSC.***

	1	**MAIN UNIT: ALPHENIX BIPLANE HI-DEF 12"X12" FPD SYSTEM WITH SPOT ROI**
	1	**6 METER CEILING RAILS FOR CAS-830B AND CAS-930A SERIES** XGCR-060B – 6 meter ceiling rails for CAS-830B and CAS-930A: • Provides longitudinal system movement of 3,100 mm (122.0”)
CAT-880B-AL2.100	1	**[KIT] CATHETERIZATION TABLE (TILT/CRADLE)** **CATHETERIZATION (TILTING) TABLE - CAT-880B/B1** Facilitates catheterization of cardiac, cerebral, abdominal and peripheral areas. As a hybrid catheterization table, can also support some open surgical procedures. Micro-processor-controlled longitudinal movement enables table to be used for numerous radiographic techniques. Flat surface eases movement of patient on and off the table. **Specifications** • Sliding movements (manual): o Longitudinal stroke: 1350 mm (53.1") o Lateral stroke: ±200 mm (±7.9") • Vertical movement (motor-driven): 754 mm to 1054 mm (29.7" to 41.5") (from floor level) • Tilt: 16 degrees head up and 16 degrees head down (motor drive for longitudinal shift when tilted)

- Lateral tilt: 16 degrees left and 16 degrees right (manual lateral panning is possible, even when tilted laterally)
- Tabletop rotation range (manual pivot): +90 to -90 degrees
- Maximum patient weight:
  - 551 lbs. (250 kg) at maximum table extension
  - Can support additional loading of up to 220 lbs. (100 kg) for cardiopulmonary resuscitation (CPR)

1 CATHETERIZATION TABLE

1 INTERFACE CAT-880B/870B TO CAS-880A

1 MUSHROOM HANDLE FOR CAT-850B/B1, CAT-880B/B1

1 OVER HEAD HANDGRIPS / ARMREST FOR CAT-880B/B1
This armrest allows the patient's arms to rest comfortably when they are positioned above the patient's head.

For use with CAT-880B/B1 Table

1 SUPPORT ARM LOCK KIT

1 SINGLE ARM BOARD
Carbon fiber arm rest for the right or left side. One is included standard with CAT-850B table.

1 HEAD-END DRAPE HOLDER FOR CAT-880B
Mounted on the edge of catheterization table to keep the drape away from the patient's face.

1 2" TABLE PAD FOR CAT-880B
Two-inch thick table pad to increase patient comfort during long procedures.
- Made with a combination of dense foam and memory foam.
- Has a black, stretch cover.

Fits CAT-880B tabletop.

1 STANDARD APPLICATIONS TRAINING
Each system includes a three-phase education program and the industry exclusive Performance Pro Guarantee.

Performance Pro is a unique approach to education utilizing blended learning with the goal of achieving technical proficiency and optimal productivity. If for any reason the customer is not satisfied with any portion of the onsite training, Canon Medical Systems, USA will conduct that portion of the training again. This is only valid during the warranty period and does not include training new technologists.

Phase I: Two attendance vouchers for a four-day technologist-focused course held at the Canon Academy. This course provides the fundamentals of operating Canon Medical Systems' Alphenix interventional XR system, including a variety of interventional XR system exams performed with the latest dose reduction techniques. This course includes in-depth lectures and hands-on training. At the completion of the course, the attendee will be proficient in the following applications and operations: basic to advanced interventional XR system imaging console operation, system menus, system default protocols, post-processing image data, and basic troubleshooting. This course is all-inclusive of the following: tuition, airfare (booked by Canon Medical Systems), lodging, and meals. Accredited for CE credits by the ASRT Education Foundation. Training at the Canon Academy **i**s dependent upon facility availability. If not available, alternative training will be provided.

Phase II: An initial 32 hours of on-site education will be provided at the customer facility during system go-live. This training is provided for up to four imaging professionals, including the two who attended Phase I training, to focus on maximizing imaging techniques, protocols and system operation. Training is scheduled consecutively, Monday through Friday, with Monday mornings and Friday afternoons scheduled as travel time for the applications specialist. CE credits are earned by participants who attend the Phase II training event in its entirety.

Phase III: An additional 16 hours of on-site education will be provided for the same four imaging professionals who participated in Phase II training. Timing is approximately 6-8 weeks following installation, to optimize staff proficiency and system productivity.

Note: *Canon Medical Systems personnel are not responsible for imaging patients, patient safety, any actual patient contact, or operation of equipment during education sessions. Canon Medical Systems will only demonstrate proper equipment operation.*

The training is offered to the customer at no charge, providing that it is completed no later than one year after the warranty start date.

Additional classroom and on-site training is available for purchase.

Applications support is available by phone on the toll-free ASSIST line, 1-800-521-1968.

1 CABINET SIDE COVER

This side cabinet cover is required in select installations due to site limitations in the Equipment Room, such as a floor-to-ceiling support beam causing separation of cabinets. This part provides for both left and right side cover needs.

Note: Only for DFP-8000B and later versions.

1 [KIT] 21" COLOR MONITOR KIT

1 21" MONITOR, LCD COLOR (BASE PLATE INCLUDED)

1 SUPINE POSITION SCOOP ARM SUPPORT

- Patient weighted arm boards hold weight of patient's arm alongside the torso at the Infinix table edge
- Set of two

1 ANTI-FATIGUE FLOOR MAT

1 SERVICE INSTALLATION COMPONENTS

1 MAVIG TABLE MOUNTED RADIATION SHIELD

Provides additional radiation protection from direct and scatter X-ray exposure.

- Mounts on Canon Medical Systems tableside rails, reversible for right or left side mounting
- Three-piece radiation shield assembly:

Main shield: 181 mm x 645 mm
Angled side shield: 700 mm x 645 mm
Tabletop scatter shield: 700 mm x 700 mm (removes to facilitate patient loading)

- Wall storage holders:

Upper shield: 600 mm
Lower shield: 460 mm

- Includes mini-rail for mounting table-function controls, if desired.

2 COPPER PHANTOM FOR WAKE UP PROGRAM FOR ALPHENIX

Wake Up Check test phantom for daily QA.

Includes 2 mm copper and instructions to be used for the Wakeup Check protocol, which checks the imaging conditions for DA, DSA and One Shot acquisition.

1 WAKEUP CHECK PROCEDURE BOOKLET

12 COOLANT - 1 GALLON

2 19" COLOR MONITOR

1 ENCOREPLUS LOYALTY DISCOUNT FOR CANON INSTALLED BASE

XIDF-STA801/A1	**1**	**DYNAMIC DEVICE STABILIZER FOR AWS PRO WITH 3D VIEWER OR GPU KIT** Real-time multi-frame image display which makes a stent appear stationary is provided even with cardiac motion. Available not only for digital acquisition but also for fluoroscopy thanks to a robust algorithm powered by deep learning technology. The automated layout of the large display provides enhanced images without requiring extra operation for replacement or changes of image, allowing for a significantly streamlined allin-one clinician viewing experience. Prerequisites: XIDF-AWS801/B4 (AWS PRO) and either XIDF-GPU801 (GPU Kit) or XIDF-PVG801/A1 (3D Viewer) is required. XIDF-GPU801 (GPU Kit) is not required if the system includes XIDF-PVG801/A1 (3D Viewer)
	1	**BTL SVC LABOR**
	1	**DE-INSTALLATION AND TRADE IN OF CUSTOMER'S EXISTING SYSTEM**
UNISPOT-BP.100	**1**	**[KIT] CONTROL ROOM UNISPOT FOR BIPLANE SYSTEMS** The Control Room UniSpot for Biplane offers one view of all information including flexible layouts. The UniSpot has been designed to improve teamwork and reduce clutter and complexity in the interventional control room. It brings together all imaging sources on a single display, managed by a single keyboard and mouse. The software enables clinical staff to manage up to 6 sources or applications from one integrated display. No need for separate displays or keyboards and mice. The intuitive interface allows to manage source selection and define preset configurations. With the MDSC-8532 surgical display, you'll experience excellence in surgical precision on one of the most versatile displays in the operating room. Providing you with our recognized image quality, this 4K UHD display offers exceptional brightness and crisp contrast. The MDSC-8532 has been designed for endoscopy imaging and the integrated operating room. The display has a wide color gamut and offers advanced color calibration algorithms. This results in accurate color reproduction, making it the preferred choice for real-time imaging.

The dual user interface is user friendly – there is one at the front as well as at the back – makes it easy to operate the display. The intuitive user interface allows you to easily set up the screen or change the display's layout configurations to fit the procedure. On top of that, dedicated shortcut buttons further enable fluent configuration of the display.

The 32" screen is designed in an stylish and sleek industrial style, envisioned to assure a professional, purposeful, and elegant fit for the surgical suite. Moreover, the MDSC-8532 SSTP is fanless, which contributes to its low weight.

In the MDSC-8532, our automated failover feature has been further improved with a faster switching time and the possibility to have a 4K UHD image as backup. The display is easy to disinfect thanks to the smooth surface and splash-proof housing. The integrated cable cover combined with the rubber joystick ensure optimal hygiene. Approved for use in patient vicinity area.

The MNA-240 decoder converts RAW IP packets into DVI video signals and other signals such as audio and USB. End-to-end latency is short and is guaranteed not to exceed a single frame (< 15 ms). The video streams that are distributed over the Nexxis network can go up to a resolution of 4K.

Includes:

- Two Color LCD Displays (MDSC-8532, mfg. part #K9352530) – a 32" 4K display with DP (DisplayPort) input for UniSpot
- Two Power extension cables (5 meter, mfg. part # K3495079)
- Two Display desk stands (mfg. part # K9350821)
- Two MNA 240 Decoders (mfg. part # K9303275A)
- Two Power extension cables for MNA-240 DEC (10 meter, mfg. part # C9826127)
- Two UniSpot licenses (also known as Barco Nexxis WorkSpot Software license, mfg. part # K9350219)
- Two 36m Optic Fiber Cables (mfg. part # C9826172)
- Two accessory kits, which includes one key board, one mouse, and one attachment plate (CMSC part # XIDF-MISAA2)

Note: All product Designed and Manufactured by Barco Corporation, with the exception of the accessory kit (part # XIDF-MISA/A2), which is from Canon Medical Systems Corporation Japan.

2 UNISPOT DISPLAY KIT WITH 32" 4K MONITOR

2 UNISPOT DISPLAY KIT WITH LICENSE AND DECODER

2 MONITOR INTEGRATION SYSTEM ACCESSORY KIT

BARCO-58/2.100 **1** **[KIT] BARCO 58" V7 LARGE MONITOR WITH BUILT-IN PROTECTIVE GLASS NIVR58-T7 G KIT**

A Barco large-screen surgical display with LED backlight, provides the opportunity to have all relevant clinical data to display within customizable layouts. It features a 58-inch LCD panel (16:9), Ultra-HD (UHD) resolution (3840x2160), a maximum luminance of 700 cd/m^2 and 4000:1 contrast ratio.

Video input signals:

- DVI Dual link (full screen image 2 x DVI inputs)
- DVI Signal link (full screen image 4 x DVI inputs or 4 Quadrant Drive from 4 independent sources)
- DP 1.2 SST (full screen image; 4k native or 2k upscale)

Kit includes:

- Built-in glass protective cover with non-reflective coating
- Compositor, 4x encoders, 8 inputs, 13-inch touchscreen monitor manager, and associated cables

Note: designed and manufactured by Barco, Inc.

1 **BARCO 58" V7 NIVR58-T7 G KIT (COMPOSITOR, 4 ENCODERS, NETWORK SWITCH AND CABLES)**

3 **100FT CAT5E BLUE PATCH CABLE CABL CAT5 SNAGLESS MOLDED M/M RJ45 350MHZ**

3 **6FT CAT5 CAT5E BLUE PATCH CABLE CABL SNAGLESS MOLDED M/M RJ45 350MHZ**

1 **BACKUP MONITOR INTERFACE KIT FOR BARCO 58" MONITOR**

1 **CABINET FOR LARGE LCD COLOR DISPLAY MONITOR**
Wall or floor mounted storage unit to house large LCD monitor electronic components.

1 **TRIPP LITE WALL MOUNT CABINET**

2 **TRIPPLITE 6 OUTLET RACKMOUNT POWER STRIP PERP 1U REAR FACING**

1 **TRIPPLITE 1U RACK ENCLOSURE FIXED SHELF**

2 **TRIPPLITE WALL MOUNT RACK ROOF FAN KIT FAN**

1 **BLACKBOX 10 PORT GIGABIT WEB SMART**

BARCO-58-GUESTPORT.100	**2**	**[KIT] BARCO V7 GUEST PORT INPUT DISPLAY**
	2	**K9303320 MNA-420 ENC HDMI INCLUDES: MNA-420 ENC, 2XHDMI-DVI 10FT CABLE AND 10GSFP+**
	2	**MNA-120 ENC ANA AUDIO TMS WITH EXTRA SFP+**
	2	**DVI EXTENDER AND RECEIVER CABLE**
	2	**CANON LOGO PLATE**
	4	**1M FIBER MMF LC-LC OM3 DX 2MM CABLE CUSTOM**
	2	**DVI TO HDMI ADAPTOR (2 PCS 8" ADAPTORS INCLUDED)**
BARCO-58-HDMI-INPUT.100	**2**	**[KIT] HDMI VIDEO INPUT HD ENCODER FOR BARCO V7**
	2	**K9303320 MNA-420 ENC HDMI INCLUDES: MNA-420 ENC, 2XHDMI-DVI 10FT CABLE AND 10GSFP+**
	2	**1M FIBER MMF LC-LC OM3 DX 2MM CABLE CUSTOM**
	2	**30M LC-LC OM3 MM DX 2MM CABLE CUSTOM**
BARCO-58-ANALOG-INPUT.100	**1**	**[KIT] ANALOG INPUT ON BARCO MONITOR**
	1	**MNA-120 ENC ANA AUDIO TMS WITH EXTRA SFP+**
	1	**1M FIBER MMF LC-LC OM3 DX 2MM CABLE CUSTOM**
	1	**30M LC-LC OM3 MM DX 2MM CABLE CUSTOM**
BARCO-FHD-OUTPUT.100	**3**	**[KIT] FHD-VIDEO READY OUTPUT DECODER KIT FOR DIAGNOSTIC MONITOR INTERFACE**
	3	**MNA-420 DEC V2 HD DUAL CHANNEL DECODER 2X HDMI OUTPUT ADDITIONAL 10G SFP+**
	3	**DVI TO HDMI ADAPTOR (2 PCS 8" ADAPTORS INCLUDED)**
	3	**ONE KIT 36M OPTIC FIBER CABLE TMS**

	3	**NO MONITOR**
2-LS2R/3.100	1	**[KIT] ONDAL LARGE MONITOR SUSPENSION CEILING MOUNT OPTION KIT**
	1	**ONDAL LARGE MONITOR SUSPENSION CEILING MOUNT (2900+MM CEILING HEIGHT) - INSTALLATION & EQUIPMENT RENTAL INCLUDED. A SECOND INSTALLATION VISIT IS INCLUDED IF NECESSARY** 2-LS2R/3 ONDAL LARGE MONITOR SUSPENSION CEILING MOUNT Monitor Carrier – Large Screen monitor suspension with mounts for two rear-mounted monitors. System includes: • Side and rear brake buttons • Monitor Carrier – For Large Screen Display with up to 2 Rear Monitors (LS2R) • Arm System 2600mm – 1600x1000mm arm lengths, • Medilift XL, Spring 120-180kg capacity • 2900+ ceiling height, • 300mm ceiling tube, ceiling cover & interface plate. Installation & Equipment Rent included 1-LS2R/3 is manufactured, installed, and serviced by Ondal Medical Systems
1944547	1	**CEILING COVER H50, MEDIBOOM, 222, 9010 (CENTER MOUNT)**
XGCP-882AA/B1	1	**JOYSTICK CONTROL UNIT WITH STAND (BIPLANE)**
XACP-001BA/C1	1	**TABLE SIDE TABLET CONSOLE (4M CABLE)** This tablet console is mounted tableside to the existing table rails and includes a 4-meter cable. The tablet console is used in addition to or in place of the standard system controls to select the following functions in the examination room. • Select the desired acquisition program • Select the desired auto-positioning number • Select the desired function • Provide assistance in angiographic workstation operation • Play back, stop, and frame advance cine images • Switch between a cine image file and a map image file • Select specific hemodynamic functions if available
XIDF-QCA850/B1.100	1	**BASIC KIT FOR CLINICAL ANALYSIS APPLICATION**

	1	**CAAS BASIC KIT FOR CLINICAL ANALYSIS APPLICATION** **Application** This is platform software for running the clinical analysis applications such as QCA, QVA, LVA, LVA-BP, RVA, QCA3D, and Stent Enhancer. **Features** Table side operation is available.
XIDF-QCA851/B1	1	**QUANTITATIVE CORONARY VESSEL ANALYSIS - 9MM OR LESS** **Application** XIDF-QCA850/B1 is required. XIDF-QCA851/B1 is a QCA (quantitative coronary analysis) software package for use in clinical practice and research. This software features automatic contour detection of the coronary artery of interest and analysis of its dimensions. **Features** • Automatic contour detection is supported for QCA. • Various calibration methods such as catheter calibration, sphere calibration, and distance calibration are available. • Report files of QCA can be transferred to the PACS server and can be referred to in the examination room and control room. • Table side operation is available.
XIDF-QCA852/B1	1	**QUANTITATIVE VESSEL ANALYSIS - 9MM OR ABOVE** **Application** XIDF-QCA850/B1 is required. XIDF-QCA852/B1 is a QVA (quantitative vessel analysis) software package for use in clinical practice and research. The QVA software is used for quantitative analysis of blood vessels such as the aorta, iliac arteries, renal arteries, etc. QVA supports automatic contour detection for vessels up to 50 mm in diameter. **Features** • Automatic contour detection is supported for QVA. • Various calibration methods such as catheter calibration, sphere calibration, and distance calibration are available. • Report files of QVA can be transferred to the PACS server and can be referred to in the examination room and control room. • Table side operation is available.
XIDF-QCA854/B1.100	1	**LEFT VENTRICULAR ANALYSIS (BIPLANE) KIT**
	1	**LEFT VENTRICULAR ANALYSIS (BIPLANE)** **Application** XIDF-QCA850/B1 and XIDF-QCA853/B1 are required.

XIDFQCA854/B1 is an LVA-BP (left ventricular analysis, biplane analysis) software package for use in clinical practice and research. LVA-BP can be applied to images acquired during left ventricular diagnosis with biplane imaging. This software supports automatic contour detection of the left ventricle, volume calculation, and wall motion analysis.

Features

- Automatic contour detection is performed for LVA using frontal and lateral images.
- Various calibration methods such as catheter calibration, sphere calibration, and distance calibration are available.
- Report files of LVA-BP can be transferred to the PACS server and can be referred to in the examination room and control room.
- Table side operation is available.

1 **LEFT VENTRICULAR ANALYSIS (SINGLE PLANE)**

Application

XIDF-QCA850/B1 is required. XIDF-QCA853/B1 is an LVA (left ventricular analysis) software package for use in clinical practice and research. This software supports automatic contour detection of the left ventricle, volume calculation, and wall motion analysis. LVA can be applied to images acquired during left ventricular diagnosis.

Features

- Automatic contour detection is supported for LVA.
- Various calibration methods such as catheter calibration, sphere calibration, and distance calibration are available.
- Report files of LVA can be transferred to the PACS server and can be referred to in the examination room and control room.
- Table side operation is available.

XIDF-AWS801/CA2/3.100 1 **[KIT] ALPHENIX ANGIO WORKSTATION (AWS PRO) AND MONITOR**

1 **ALPHENIX ANGIO WORKSTATION (AWS PRO)**

Alphenix Workstation Pro-(Software Version 9.5.)
Angio Workstation (Alphenix Workstation Pro) (XIDF-AWS801/B4)

This general-purpose workstation is used in combination with an interventional angiography system (Alphenix series system) for performing selective catheterization and angiography of the heart, head, abdomen, and lower extremities. It provides the image information and measurement results that are required when performing IVR procedures such as PCI and embolization procedures.
Note: This unit is intended for use with existing imaging from the cleared device. The unit is not intended for stand-alone use or diagnosis

- Supports Analysis and Planning Software.
- Supports 3D-DA/DSA applications.
- Supports 3-D Roadmap and Multi-Modality Roadmap.
- Supports Alpha CT (Low Contrast Imaging) Display
- Supports Dose Tracking System Option (DTS)
- Supports Dynamic Device Stabilizer
- Supports Emboliztion Plan
- Supports Cerebral Aneurysm Analysis
- Supports Parametric Imaging.
- Supports TAVR.
- Supports Dose Tracking System (DTS)

Hardware Specification
Angio Workstation (Alphenix Workstation) (XIDF-AWS801/B4)
• System software plus image storage total capacity: 1.7 TB (SSD)
• Total image storage capacity for all installed applications: 1.2 TB
• CPU: Intel® Xeon® Silver 4215 2.5GHz (2 CPUs)
• RAM: 32 GB (16 GB x 2)

Parametric Imaging (PI) Functions*
- Displays an entire image sequence as a single composite DSA image that is color coded in order to characterize the contrast media dynamics and to allow easier visual evaluation
- Color Coded Circulation (CCC) can create movies by shifting color scale gradually so that it is easy to understand vessel flow

**Parametric Imaging Software is not intended for stand-alone use or diagnosis*

Note: All advance 3D and Analysis software is optional.
If it is desired to extend viewing and control of advanced imaging applications into the exam room the extension kit must be selected as an option and possibly other components dependent on current monitor configuration.

AWS Pro is not backward compatible with Alphenix version 8.3 or prior versions.

	1	**ROCKET LINK CONNECTION KIT**
	1	**21" MONITOR, LCD COLOR (BASE PLATE INCLUDED)**
	2	**DISPLAY PORT TO DVI-D ADAPTER/VIDEO CONVERTER 1080P**
3D-ANGIO-SW-KIT/AL.100	1	**BASE 3D ACQUISITION SOFTWARE**

This option for Alphenix systems provides the necessary software for acquisition, reconstruction and display of 3-Dimensional Angiographic

image data. From the head-end approach to the patient table, the c-arm can be programmed to acquire a serial acquisition over a 200-degree arc around the target area. A special high-speed reconstruction workstation provides fast transfer and display of the 3-D images on the AWS with 3D Viewer software option.

This option is integral and a prerequisite for the optional Low Contrast Imaging (CT-like data) and Roadmapping options.
Onsite Applications Training Included

Note: Requires XIDF-ROT801 and Angio Workstation (v9.0 or greater).

1 **3-D ANGIO SOFTWARE**

APPS-ONSITE-32 **1** **ON-SITE APPLICATIONS TRAINING - 32 HOURS**
Four (4) days, thirty-two (32) hours, of additional onsite applications support. Training is scheduled consecutively, Monday through Friday, with Monday mornings and Friday afternoons scheduled as travel time for the applications specialist.

Note: Canon Medical Systems personnel are not responsible for scanning patients, patient safety, any actual patient contact, or operation of equipment during education sessions. Canon Medical Systems will only demonstrate proper equipment operation.

Education expires two (2) years from the later of purchase date or warranty start date.

XIDF-PVG801/A1.100 **1** **3D VIEWER KIT**

This kit enables users to operate 3D viewers on AWS.
Graphical user interface (GUI) and faster 3D volume rendering with graphics processing unit (GPU) maximize operation and workflow efficiencies. A series of tools such as Edge enhancement and Ellipse drawing can be used for 3D Roadmap to highlight anatomical landmarks for treatment.

1 **3D VIEWER KIT**
This kit allows the operator of the XIDF-AWS801/B3 to apply the study list image storage, 3D Viewer, and 3D reconstruction function used at the Vitrea™ workstation. This kit includes Viewer and GPU.

Prerequisite: 3D-ANGIO

XIDF-3DP802/C1.100 **1** **3D ROADMAP WITH NEEDLE GUIDANCE KIT ON AWS**

1 **3D ROADMAP WITH NEEDLE GUIDANCE KIT ON AWS**

Alphenix software option to provide 3-D Angio image super-imposed over live fluoroscopy

- Superimposed 3-D image is linked to all system mechanical movements to maintain accurate alignment of 3-D image with fluoroscopy projection as c-arm or table position changes
- Device enhance processing improves visualization of fine metallic interventional devices
- Simple, convenient user interface for manual adjustment, if desired
- Multiple display modes, solid or hollow vessel with transparency adjustment
- Needle Guidance

Included as standard with Canon Medical Systems' Volume Navigation 3-D Roadmap is a Needle Guidance application, which provides pathway planning and real-time guidance for percutaneous interventions

Prerequisite:

- *3-D Angio, including XIDF-3DI801,XIDF-ROT801 Rotational DSA Kit, XIDF-PVG801/A1 3D Viewer Kit and XIDF-AWS801/B3 software and hardware.*
- *Modality image which the Needle Guidance application can fuse:*

3D-Angio (3D-DA, 3D-DSA) included as standard
Alpha CT, Requires option XIDF-LCI801
CT/MR fusion with fluoro requires option XIDF-3DP804

XIDF-3DP804 **1** **MULTI-MODALITY ROADMAP KIT (CT & MR)**

3-D Multi-Modality Fusion Roadmap is a software application that enables overlay of live 2-D fluoro images, with previously acquired 3-D image data sets, to enhance 3-D anatomical reference. The previously acquired 3-D data sets can be rendered from either a CT or MR scanner or the Canon Medical Systems Cardiovascular systems using CT-like imaging or 3-D DSA.

3-D volumes are reconstructed using the Angio Work Station PC, then projected on the exam room monitor where it is overlaid by live 2-D fluoro images. This functionality enables real-time integration of 3-D anatomical information to better aid clinical guidance and procedure planning. Automated c-arm positioning is integrated with the 3-D anatomical reference image for enhanced clinical workflow.

Requires DFP-8000B/B2 and XIDF-AWS801/B1 or later, 3D-ANGIOKIT and 3D Roadmap software. LCI software is required when customer desires to perform tableside CT-like imaging for creating a 3D model of the LA for ablations as well as using previously acquired CT datasets.

XIDF-ROT801 **1** **ROTATIONAL DSA KIT**

The system has integrated multiple forms of rotation technology to include high-speed C-arm rotation for 3-D acquisition and 2-D rotational capabilities. High-speed rotation provides acquisition frame rates ideal for high-resolution 3-D reconstructions.

Specifications

- Image size: 1024x1024; 16-bit
- Image rate (FPS): Up to 25 FPS at 1024x1024 matrix
- Acquires images throughout and up to a 200-degree C-arm arc
- X-ray exposure timing: angle trigger method
- Provides 3-D color image display for enhanced diagnosis, treatment planning and interventional procedures.

Rotational DSA

- Programmable single-axis rotation (manual or auto) to optimize display area

Mask - Return - Contrast acquisition (MRC method)
Mask - Contrast acquisition (MC method)
Mask - Return - Contrast - Contrast acquisition
(MRCC method)
Mask - Contrast - Contrast acquisition (MCC method)

Data acquisition range: RAO 100° to LAO 100°

C-arm rotation speed: 50°/s or 30°/s

Fluorography techniques: 3D-DSA
Reconstruction image type:
• Blood vessel display in 3D from rotational DSA images
• Blood vessel display in 3D from rotational DSA images/ visualization of interventional device images from mask images/Interventional device display in 3D (Depending on the functions of the workstation used in combination, blood vessel interventional device images can be fused after acquisition (device fusion).)

3D-DSA acquisition mode:
·10242 16 bits: 2°/frame: C-arm rotation speed 50°/s
1°/frame: C-arm rotation speed 30°/s*

* (When the C-arm rotation speed of 30°/s is selected,
acquisition is performed at intervals of 1.2°/frame.)
·512² 16 bits: 1°/frame: C-arm rotation speed 50°/s*

* (Only for TFP-1216A/C1, TFP-1200A/C1 and TFP-1200C/A1)
– Time for image transfer and Angio Workstation: When this Angio Workstation PC is used in combination, the reconstruction time is less than 5s in the fastest mode.

XIDF-LCI801 **1** **LOW CONTRAST IMAGING (ALPHA CT/CBCT) (REQUIRES AWS)**
(Alpha CT)
CBCT for Low contrast imaging can be performed from the control or examination room .

Low Contrast Imaging Kit (XIDF-LCI801) (Alpha CT)
CBCT for Low contrast imaging can be performed from the control or examination room.

- CAS-830B/B1: Only when the C-arm is set to the head-end position.
- CAS-930A/F1: When the C-arm is set to the head-end, patient left or right side.
- Data acquisition range
  - CAS-830B/B1: RAO 100° to LAO 100°
  - CAS-930A/F1: RAO 115° to LAO 85° LAO 115° to RAO 85°
- Rotation speed:
  - CAS-830B/B1: Max. 25°/s or Max. 50°/s
  - CAS-930A/F1: Max. 50°/s or Max. 80°/s
- Acquisition technique: Alpha CT
- 3D reconstruction image type: Alpha CT (MPR etc.) Fine Voxel image
- Alpha CT acquisition mode
  - Vessel acquisition: 1024 x 1024, 16 bits Approx. 100 frames C-arm rotation speed is 50°/s.
  - Fast acquisition: 1024 × 1024, 16 bits Approx. 250 frames C-arm rotation speed is 25°/s.
  - Mid acquisition: 1024 × 1024, 16 bits Approx. 400 frames C-arm rotation speed is 15°/s.
  - High acquisition: 1024 × 1024, 16 bits Approx. 600 frames C-arm rotation speed is 10°/s.
  - HS-Fast acquisition*1: 512 × 512, 16 bits Approx. 220 frames C-arm rotation speed is 50°/s.
  - HS- Mid acquisition*1: 512 × 512, 16 bits Approx. 380 frames C-arm rotation speed is 30°/s.
  - HS-High acquisition*1: 512 × 512, 16 bits Approx. 580 frames C-arm rotation speed is 20°/s.

(*1: Only for TFP-1200A/C1, TFP-1200C/A1, TFP-1216A/C1 and TFP-1216C/A1)

- High resolution reconstruction mode: The following acquired data before the reconstruction is selectable.
  - Data of the center area (512 × 512) extracted from 1024 × 1024 acquired data acquisition.
  - Data reduced from 1024 × 1024 acquired data to 512 × 512
- Metal artifact reduction Metal artifacts can be reduced
- Pulse Width Modulation makes acquired 2D images brightness almost flat and S/N is improved. Based on these better 2D images, better IQ Alpha CT will be reconstructed.
- Multiphase CBCT allows Alpha CT scans to be performed continuously over multiple phases. Early-phase and late-phase contrast images of the portal veins and hepatic arteries can be acquired. Such images are useful for identifying the feeding vessels of hepatocellular carcinomas.

Prerequisite: 3D-ANGIO

XBER-001A	**1**	**TABLE SIDE CONTROL EXTENSION RAIL SET (PAIR)** • Designed for application with the CAT-850B, CAT-860B or CAT-880B tables only • Tableside rail set (2), one for each side • Designed to accommodate Infinix table controls and common accessories (*e.g.,* I.V. pole)
XBET-001A	**1**	**FOOT-END TABLE EXTENSION (REQUIRES XBER-001A)** Auxiliary table extension installed at the foot end of the table. Easily folds over on to the foot end of the table when not in use.
9445	**1**	**FOOT END TABLE CONTROL MOUNTING RAIL FOR EXTENSION RAIL OPTION** Clamp and rail system that attaches to the extended side rails at the foot end of CAT-850B/CAT-860B/CAT-880B catheterization tables. This provides a rail across the foot end of the Alphenix table, for foot end mounting of system controls. Designed and manufactured by Domico. ***Prerequisite: XBER-001A, Table Side Control Extension Rail Set (Pair) for CAT-850B, CAT-860B or CAT-880B.***
9412	**1**	**2" TABLE FOOT-END EXTENSION PAD FOR PART # XBET-001A** 2" x 27.6" x 29.5" pad for foot end of Infinix table used as a work station. Coordinates with 9409 Table pad, elevates work area to flush level with patient pad area. Black stretch vinyl cover.
PX17-36730-2	**1**	**I/V POLE FOR ALPHENIX SERIES**
FOOTSWITCH/W/ BP/880.100	**1**	**WIRELESS FOOTSWITCH FOR CAT-880B BIPLANE** The wireless footswitch provides cable-free operation. More flexibility for the customer, and easy maintenance. This kit requires a Table Modification Kit XBFM-880A in accordance with the combined table. **Key Product Features:** • Charging time: 4.5 hours • Standby mode time: 48 hours • Continuous use: 20 hours • Battery needs to be replaced after 500 hours or 1 year • 5M max distance from transmitter • AC Charger • System Cable to direct connect footswitch to table • LED indicators for charged, charging, needs charge • LED indicators also indicates errors

Prerequisite – requires software version 6.1 or above

PQUBE-CANON-FM-01 1 **POWER QUALITY AND ENVIRONMENTAL MONITORING PACKAGE (FLUSH MOUNT)**

XIDF-DTS802/C1.100 1 **[KIT] DOSE TRACKING SYSTEM WITH MONITOR FOR ALPHENIX**

DTS provides a virtual patient dose map with real time tracking of estimated peak and accumulated skin dose during an interventional procedure.

- Color-coded and easy to read 3D spatial visualization of radiation exposure to the patient and clear indication of radiation distribution.
- Automatically activated when examination starts with patient information obtained through Modality Worklist Management (MWM) allowing for smooth workflow.
- Total of 8 target positions are available, meeting every clinical situation including:
  Heads up/Upside down images for supine and prone positions, left lateral decubitus position and right lateral decubitus position
- Real time feedback enables the clinician to make procedural adjustments and thus limit exposure in any area for prolonged periods.
- Estimation of peak skin dose available on cardiovascular/neurovascular procedures.

Please note: Dose Tracking System for Alphenix requires AWS for Alphenix (XIDF-AWS801/B4). Additional monitors for exam room viewing may be required depending on current configuration and are not included.

1 **DOSE TRACKING SYSTEM FOR ALPHENIX**

DTS provides a virtual patient dose map with real time tracking of estimated peak and accumulated skin dose during an interventional procedure.

- Color-coded and easy to read 3D spatial visualization of radiation exposure to the patient and clear indication of radiation distribution.
- Real time feedback enables the clinician to make procedural adjustments and thus limit exposure in any area for prolonged periods.
- Estimation of peak skin dose available on cardiovascular/neurovascular procedures.

Please note: Dose Tracking System for Alphenix requires AWS for Alphenix (XIDF-AWS801/B4). Additional monitors for exam room viewing may be required depending on current configuration and are not included.

1 **21" MONITOR, LCD COLOR (BASE PLATE INCLUDED)**

PRODUCT WARRANTY AND SERVICE COVERAGE

SYSTEM WARRANTY TERMS

Canon Medical Systems warrants that the Equipment will be free from defects in material and workmanship, for the duration and subject to the terms and conditions stated below. Any part furnished to Customer during the warranty period (stated in the table below) to correct a warranty failure will be warranted to the extent of the unexpired term of the warranty applicable to the Equipment.

The warranty period will commence on the date the installation of the product is complete. Notwithstanding the foregoing, in the event that the installation of the product is delayed for a total of thirty (30) days or more from the date of delivery for any reason or reasons for which Canon Medical Systems is not responsible, the warranty period for such product may, at Canon Medical Systems' option, commence on the thirtieth (30th) day from the date such product is delivered to Customer.

WARRANTY EXCLUSIONS

Warranty coverage does not include any defect which results, in whole or in part, from (1) negligent storage or handling of the product by Customer, its employees, agents, or contractors, (2) failure of Customer to prepare the site or provide power requirements or operating environmental conditions in compliance with any applicable instructions or recommendations of Canon Medical Systems, (3) absence of any product, component, or accessory recommended by Canon Medical Systems but omitted at Customer's direction, (4) any design, specification or instruction furnished by Customer, its employees, agents, or contractors, (5) any alteration of the product by persons other than Canon Medical Systems, (6) combining Canon Medical Systems' product with any product furnished by others that is not approved by Canon Medical Systems, (7) combining incompatible products of Canon Medical Systems, without Canon Medical Systems' prior approval, (8) improper use of the product, improper maintenance of the product by a party other than Canon Medical Systems, or failure to comply with any applicable instructions or recommendations of Canon Medical Systems, or (9) acts of God, fires, floods, strikes or other labor disturbances, or other causes beyond the reasonable control of Canon Medical Systems.

Canon Medical Systems does not warrant any products not manufactured by Canon Medical Systems such as, without limitation, monitors, cameras, computer equipment, injectors, and lasers. Such items will be furnished subject only to the manufacturer's warranty, if any, and without any warranty whatsoever by Canon Medical Systems.

Warranty coverage also excludes consumables, including but not limited batteries, storage media, positioning pads, table pads, cassettes, magazines, printer consumables, and power units.

GLASSWARE WARRANTY

X-ray Vascular tubes are covered under a separate warranty. X-ray Vascular tubes included with the purchase of a new system is governed by the glassware warranty, described below, not the system warranty.

Tube Type	Time-Based Warranty
Liquid Bearing Tubes (DSRX-TXXXX)	36 months, non-prorated

Tubes with Non-Prorated, Time-Based Warranty:

Tubes with a non-prorated warranty will be replaced during the initial warranty period at no charge to the customer. The replacement tube carries the remainder of the original warranty on the system. For example, a tube with a 12-month non-prorated warranty fails at month eleven (11), the tube is replaced at no charge and carries a one (1) month of warranty.

REMEDIES

If Canon Medical Systems determines that any product fails to meet the above-mentioned warranty during the applicable warranty period, Canon Medical Systems will correct any such failure by either, at its option, repairing, adjusting, or replacing without charge to Customer any defective or nonconforming parts of the product. Canon Medical Systems will have the option to furnish either new or remanufactured replacement parts or assemblies. However, remanufactured parts will meet the manufacturer's specifications for new components as of the date of completion of installation. All defective parts replaced by Canon Medical Systems will become the property of Canon Medical Systems.

SOFTWARE UPDATES

Canon Medical Systems will furnish to Customer, free of charge for the life of the Equipment, all Canon Medical Systems software or hardware upgrades to the Equipment purchased by Customer, which are intended to correct a safety risk. Software updates offering enhancements to previously purchased software features will be provided during the term of the warranty, if they do not require hardware modifications or additions. Software upgrades providing new features or capabilities not originally purchased, will be made available for purchase by Customer upon request when compatible with the originally purchased hardware. Canon Medical Systems retains the sole right to determine whether a software release is considered an update or an upgrade for which Customer will be charged. The above items will be performed only during the Covered Hours stated in the warranty. Service required outside these hours will be billed at Canon Medical Systems' differential rates in effect at the time such items are provided to Customer.

WARRANTY SERVICE

Warranty service during the applicable warranty period will be performed without charge to Customer during Canon Medical Systems' normal business hours, Monday through Friday, excluding Canon Medical Systems holidays. Subject to the availability of personnel, after-hours service is available upon request at an additional charge.

Customer must promptly notify Canon Medical Systems within the applicable warranty period of any defect that is covered by the warranty, and make the Equipment promptly available for repair and maintenance.

DISCLAIMERS AND LIMITATIONS ON LIABILITY

Canon Medical Systems' obligations stated above will be Customer's sole and exclusive remedy for a breach of the warranty set forth above. SUCH WARRANTY WILL BE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Canon Medical Systems does not warrant that the operation of the Equipment will be uninterrupted.

WARRANTIES BY PRODUCT LINE

ITEM TYPE	X-RAY VASCULAR
EQUIPMENT	12 Months
ACCESSORY OPTIONS	6 Months
REPLACEMENT & OPTIONAL PARTS*	90 Days
UPGRADE COMPONENTS	6 Months

* The above 90-day period applies only to parts that are not furnished pursuant to a warranty repair for the Equipment. Any part furnished to Customer during the warranty period to correct a warranty failure will be warranted to the extent of the unexpired term of the warranty applicable to the System.

TERMS AND CONDITIONS OF SALE

1. TITLE AND RISK OF LOSS. Title and risk of loss to the Equipment purchased under this Agreement will pass to Customer: (a) if Canon Medical Systems is to provide installation, upon Canon Medical Systems' completion of installation, or (b) if Canon Medical Systems will not provide installation, upon delivery by Canon Medical Systems to Customer.

2. TERMS OF PAYMENT. Prices stated are F.O.B. Customer's facility. All taxes which are payable by Canon Medical Systems in connection with the sale, use, or possession of the Equipment (excluding income taxes), will be paid by Customer in addition to the quoted price. Terms of payment will be as stated in the first page of this Quotation. All invoices paid after due date will be assessed a late payment charge of the lesser of 1 1/2% per month or the maximum rate permitted by law.

3. DELAYS. If Customer changes the scheduled delivery date during the period of 120 days preceding the delivery date, Customer will nevertheless pay the installment of the purchase price which would have been payable upon delivery, on the Scheduled Delivery Date as if delivery had been made on such date. In addition, Customer will pay all extra costs incurred by Canon Medical Systems as a result of such delay, including, without limitation, storage and transportation. Storage fees will be charged at commercially comparable rates for storage on Canon Medical Systems' site. If delivery is delayed by 12 months or more from the Scheduled Delivery Date, except through the fault of Canon Medical Systems, the price set forth in this Agreement may be increased by Canon Medical Systems to a level equal to the prevailing price in effect at the time of the revised delivery date.

4. EQUIPMENT INSTALLATION. Canon Medical Systems will provide, at no additional cost, standard labor and rigging services to unload the Product from the transport vehicle and move to the final position. The shoring of floors, the widening of doorways, and other nonstandard rigging requirements will be negotiated between the Canon Medical Systems and Customer separately if it is determined they are required. Canon Medical Systems will install all Equipment purchased under this Agreement and connect them to existing power and/or plumbing lines at no additional charge to Customer. Customer will be responsible for electrical wiring, plumbing, carpentry, plastering, painting, or all other site preparation required prior to installation and connection of the Equipment by Canon Medical Systems. Customer will provide space at the installation site for the safe storage of Canon Medical Systems' tools, test equipment and other materials used for installation at no charge to Canon Medical Systems. Customer shall, at its cost, obtain all permits and licenses required by governmental authorities in connection with the installation and operation of the Equipment. Customer acknowledges that the System and Software are designed to operate within certain power, temperature, airborne contamination, and humidity ranges. Customer will be responsible for, without limitation: (i) preparing and maintaining the Customer facility in conformance with the Site Preparation Guide; (ii) maintaining its network infrastructure; (iii) providing Canon Medical Systems, access to a network connection in or near the area of the System being serviced by the equipment service staff; and (iv) supplying computer grade AC power. The Equipment relies upon a stable grounded connection to the main power grid in order to function effectively. Customer acknowledges that AC power supply quality may be a problem in old facilities or in those facilities receiving poor quality utility service and that power conditioning may be necessary in such cases.

5. EQUIPMENT OPERATION. Customer agrees that all Equipment purchased under this Agreement will be operated exclusively by duly qualified technicians and/or medical doctors in a safe and reasonable manner in accordance with Canon Medical Systems' written instructions, applicable laws and regulations, and for the purposes for which such Equipment was intended.

6. LIMITED WARRANTY AND REMEDY. A. For the warranty period described below by product, Canon Medical Systems, as its only obligation, will replace or repair, without charge to Customer during Canon Medical Systems' normal working hours (if Customer requests warranty service outside such hours, Customer will pay overtime premium for labor), any component of the Equipment that is defective in materials or workmanship, provided such defect is reported to Canon Medical Systems within the warranty period. Canon Medical Systems' warranty period is as follows: (a) Systems and Major Components – one year from date of completion of installation; (b) Accessories/Options (except glassware) – six months from date of completion of installation. Components not manufactured by Canon Medical Systems will be furnished subject only to the manufacturer's warranty, if any, and without any warranty whatsoever by Canon Medical Systems. During the warranty period, Canon Medical Systems will furnish free of charge any parts, including software required to correct any defect in the Equipment or as required under applicable laws.

B. Canon Medical Systems does not warrant that the operation of the Equipment of the System will be uninterrupted. All defective parts replaced by Canon Medical Systems will become the property of Canon Medical Systems. Replacement parts may be re-manufactured. However, such parts will meet the manufacturer's specifications for new components as of the date of completion of installation. CANON MEDICAL SYSTEMS' OBLIGATION TO REPAIR OR REPLACE DEFECTIVE PARTS OR SOFTWARE WILL BE CUSTOMER'S SOLE AND EXCLUSIVE REMEDY FOR A BREACH OF THE WARRANTY SET FORTH IN THIS AGREEMENT. SUCH WARRANTY WILL BE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. The warranty set forth in this Agreement will not apply to, and Canon Medical Systems will not be liable for any defects resulting from misuse, repairs performed by unauthorized third parties, accidents, acts of God, or neglect of anyone other than Canon Medical Systems.

7. LATEST HARDWARE AND SOFTWARE AT TIME OF DELIVERY. Canon Medical Systems agrees that the Equipment ordered by Customer will, at the time of delivery to Customer, contain, at no additional charge to Customer, the latest hardware and software manufactured by Canon Medical Systems for such Equipment that are commercially available in the United States and which are provided as part of Canon Medical Systems' standard configuration for such Equipment at the time of delivery. This commitment applies only to components and not an upgrade to the entire system. Furthermore, it is limited to hardware and software that (a) have been ordered by Customer, and not any optional or other items that were not ordered by Customer, and (b) are cleared by the FDA as of the date of delivery of the Equipment. This clause does not apply to Assure, Demonstration or Used Equipment.

8. LIMITATION OF LIABILITY. A. NEITHER CANON MEDICAL SYSTEMS NOR CUSTOMER WILL UNDER ANY CIRCUMSTANCES BE LIABLE FOR CONSEQUENTIAL, SPECIAL, INCIDENTAL, OR EXEMPLARY DAMAGES OR ECONOMIC LOSS ARISING OUT OF OR RELATED TO THE TRANSACTIONS CONTEMPLATED IN THIS AGREEMENT, EVEN IF EITHER PARTY IS APPRISED OF THE LIKELIHOOD OF SUCH DAMAGES OCCURRING.

B. IN NO EVENT WILL CANON MEDICAL SYSTEMS' LIABILITY TO THE CUSTOMER (WHETHER BASED ON AN ACTION OR CLAIM IN CONTRACT, TORT, INCLUDING NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE) ARISING OUT OF OR RELATING TO THE TRANSACTIONS CONTEMPLATED IN THIS AGREEMENT EXCEED THE AGGREGATE AMOUNT ACTUALLY PAID BY CUSTOMER TO CANON MEDICAL SYSTEMS UNDER THIS AGREEMENT. THE LIMITATION OF LIABILITY SET FORTH ABOVE WILL NOT APPLY TO CLAIMS FOR PERSONAL INJURY OR PROPERTY DAMAGE CAUSED BY EQUIPMENT DEFECTS.

9. SECURITY INTEREST. Canon Medical Systems hereby reserves and Customer grants to Canon Medical Systems a security interest pursuant to the Uniform Commercial Code, in and to the Equipment (and all products and proceeds of it) until full payment of the purchase price is received. In the event that Customer finances its acquisition of the Equipment through a lease, conditional sale contract, secured loan agreement or other financing agreement (collectively, "Lease") with Canon Medical Systems, then the security interest in the Equipment (and all products and proceeds thereof) shall secure all obligations of Customer due and to become due under the Lease.

10. REMOVAL OF EQUIPMENT. Until Canon Medical Systems has received full payment of the purchase price, Customer will not remove all or any part of the Equipment from Customer's premises, nor will Customer sell, lease, transfer or otherwise part with the possession of, or permit any lien or encumbrance to be placed on all or any part of the Equipment.

11. TRADE-IN. If this quotation includes the trade-in of Customer's existing equipment and the removal date of the trade-in equipment is delayed due to no fault of Canon Medical Systems or if the trade-in equipment is damaged or its condition deteriorates from the date of this quotation through the date of removal, Canon Medical Systems reserves the right to increase the pricing of the new equipment in an amount equal to the reduction in the resale price of the trade-in equipment. Customer must convey free and clear title to the trade-in equipment. If there are any liens or encumbrances on the trade-in equipment, Canon Medical Systems cannot accept the trade-in. Canon reserves the right to adjust trade-in values for equipment not removed by the agreed upon date. The trade-in equipment shall include any associated parts or accessories, included but not be limited to: backup software, manuals, service dongles, positioning pads, straps, CD's, chillers, coils, transducers, UPS systems, and other ancillary items. The trade-in equipment needs to be maintained to OEM specifications up until the time of removal and is subject to inspection by Canon or a Canon designated third party. Equipment must be available for inspection at least 30 days prior to removal. Customer is responsible for a clear removal path to include removal of any walls or doorways, if necessary, as well as responsible for removal of all patient information from the system prior to the removal date. HARD DRIVES MUST BE INCLUDED, INTACT, FUNCTIONAL, AND IRREVERSABLY WIPED OF ALL DATA. For CT system trade-ins: if the CT tube is replaced prior to removal of the CT system, the tube must either be documented as a new tube or documented used tube and less than 100k scan seconds, 40 million mAs, or 100k slices each. For MR system trade-ins: MRI cryogen level must be at a minimum of 70% at the time of removal. Equipment found to be performing below OEM specifications will be subject to a reduced trade-in amount.

12. REMEDIES OF CANON MEDICAL SYSTEMS. If Customer fails to make any payment when due under this Agreement, or becomes insolvent or makes an assignment for the benefit of creditors, or if a petition in Bankruptcy is filed by or against Customer, or if the financial responsibility of Customer becomes impaired, or if Customer otherwise breaches any of the terms and conditions of this Agreement, then Canon Medical Systems may, without prior notice or demand, defer shipments, cancel the balance of the order, suspend performance of any obligation (including without limitation, all obligations set forth under Limited Warranty And Remedy above), and/or take immediate possession of the Equipment delivered, until the full purchase price of the Equipment is paid by Customer or, at Canon Medical Systems' discretion, until security satisfactory to Canon Medical Systems is given by Customer. Any costs incurred by Canon Medical Systems as a result of suspending performance or repossession or collection will be payable by Customer. Canon Medical Systems may sell repossessed Equipment with proceeds to be applied to unpaid balance and expenses incurred in sale, repossession and collection. Customer will pay any remaining deficiency. Canon Medical Systems may exercise any other rights available to it by law.

13. **EXCUSED PERFORMANCES.** Except for Customer's payment obligations hereunder, neither party will be liable to the other for non-performance or delay in performance resulting directly or indirectly from any occurrences beyond such party's control, including without limitation, strikes or other labor troubles, acts of God, war, accidents, fires, floods, other catastrophes, inclement weather, transportation, delays caused by suppliers, or laws, regulations, or acts of any governmental agency.

14. **SOFTWARE.** All rights and interest in any software that may be furnished under this Agreement, and any updates and enhancements to it, will remain the property of Canon Medical Systems. Such software is being furnished to Customer under a non-exclusive license. Customer will not, or allow others to decompile, modify, copy, reproduce, or transcribe the software nor allow third parties to use the same without Canon Medical Systems' prior written consent. In the event a third party's software is furnished to Customer, Customer may be required to execute a software license agreement as requested by such third party as a condition to delivery and/or purchase of the third party's product. Canon Medical Systems will furnish Customer with a copy of such license agreement for its review and execution. In the event Customer sells the Equipment to a third party, the purchaser thereof will have the same rights and obligations with respect to any Canon Medical Systems software as Customer. Customer will need to make its own determination whether it needs to obtain any consent from a third party for non-Canon Medical Systems software. Any Canon Medical Informatics, Inc. products quoted herein are conditioned on and subject to the Software License located: https://us.medical.canon/download/CMI-Capital-License-Agreement. Any Dell, Inc. software, which may be imbedded in Canon products are conditioned and subject to the Software License located: https://i.dell.com/sites/csdocuments/Legal_Docs/en/us/reseller-terms-of-sale.pdf. Both the CMI and Dell licenses are incorporated herein by reference.

15. **CANCELLATION.** Customer may not cancel the order subject to this Agreement except with Canon Medical Systems' prior written consent. Canon Medical Systems will allow Customer to modify the product one time, as long as such request is approved by Canon Medical Systems in accordance with timeline below:
a. CT: No later than 120 days before scheduled delivery date:
b. MR: No later than 150 days before scheduled delivery date:
c. VL: No later than 150 days before scheduled delivery date:
d. XR (excluding Mobile XR): No later than 120 days before scheduled delivery date:

In the event of cancellation without Canon Medical Systems' written consent, Canon Medical Systems will be entitled to recover liquidated damages in an amount equal to twenty percent (20%) of the purchase price of the Equipment

16. **ASSIGNMENT.** Neither party may assign any of its obligations under this Agreement without the prior written consent of the other party However, some of the obligations stated in this Agreement, such as the ones relating to installation of items not manufactured by Canon Medical Systems and the warranty thereof may be performed by Canon Medical Systems' contractors or suppliers.

17. **EXPORT REGULATIONS.** This Agreement involves products, and/or technical data that may be controlled under the U.S. Export Administration Regulations and may be subject to the approval of the U.S. Department of Commerce prior to export. Any export or re-export by Customer, directly or indirectly, in contravention of such Regulations is prohibited.

18. **ATTORNEY'S FEES AND COSTS.** In the event of any legal proceeding involving any party to this Agreement against the other relating to the subject matter of this Agreement, the prevailing party in such proceeding will be entitled to recover reasonable attorney's fees, expert fees, and court costs against the non-prevailing party

19. **ACCEPTANCE BY CANON MEDICAL SYSTEMS.** This Quotation/Order will not be binding on Canon Medical Systems even if signed by a Canon Medical Systems' employee, until Customer's order for the Equipment is booked by Canon Medical Systems' Headquarter office.

20. **END USER CERTIFICATION.** Purchaser represents, warrants and covenants that it is acquiring the Products for its own end use and not for reselling, leasing or transferring to a third party (except for leaseback financing).

21. **CONFIDENTIALITY.** The parties agree that the use of the Equipment purchased and any associated output (including but not limited to binary data files) shall remain confidential between the parties and shall not be shared externally with any third party without the express written permission of Canon Medical Systems.

22. **ENTIRE AGREEMENT.** This quotation contains the entire agreement between the parties and supersedes all prior and contemporaneous agreements between the parties, whether oral or written, relating to its subject matter, including, without limitation, all different or additional terms and conditions which may be contained in Customer's bid documents, purchase order or any other documents furnished by Customer. The provisions of this Agreement may not be modified unless in writing and executed by both parties.

Attachment B

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project name: CMC/LCH Pediatric Cardiac Catheterization Lab #2

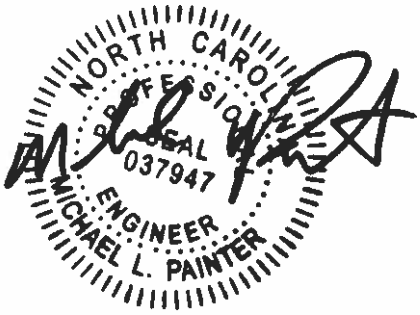
Provider/Company: Atrium Health

(1)	Purchase price of land	n/a
(2)	Closing costs	n/a
(3)	Site Preparation	n/a
(4)	Construction/Renovation Contract	650,000
(5)	Landscaping	n/a
(6)	Architect/Engineering Fees	77,000
(7)	Medical Equipment	1,723,526.80
(8)	Non Medical Equipment	0
(9)	Furniture	0
(10)	Consultant Fees (CON Fees and Legal Fees)	1,750
(11)	Financing Costs	n/a
(12)	Interest During Construction	n/a
(13)	Other (IS, Security, Internal Allocation)	88,400
(14)	**Total Capital Cost**	2,461,116.80

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

7.7.25

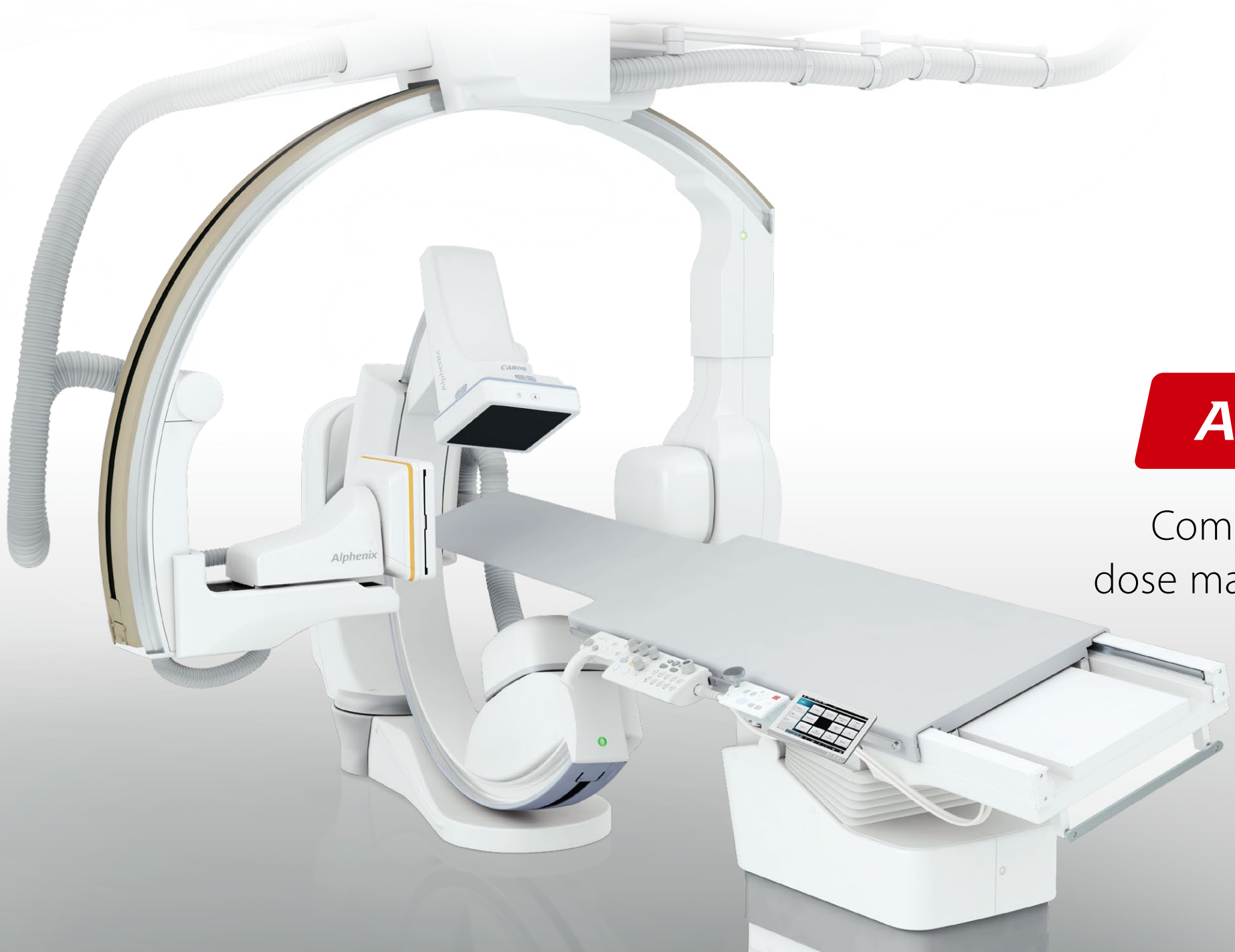
(Signature of Licensed Architect or Engineer) *DATE*



Sales taxes have been included in these equipment costs. However, because Atrium Health is entitled to a sales tax refund under N.C. Gen. Stat. § 105-164.14(b) and 105-467, the sales tax that Atrium Health initially incurs for this medical equipment purchase will be refunded to Atrium Health, and thus will reduce the capital costs that Atrium Health actually incurs for the equipment by $116,508.80.

Attachment C

Canon



Alphenix

Comprehensive
dose management
solutions

Your concerns, are our concerns

In general, medical radiation is known to possibly cause a variety of diseases. There has been increased concern by clinical staff and those in the healthcare industry, to better manage or minimize the amount of radiation necessary for diagnosis and treatment.

A study*[1] showing radiation effects on patient hair and skin has shown radiobiology effects of the skin and the relationship between radiation dose and skin effects in interventional fluoroscopy. Residual effects from radiation therapy and from previous procedures influence the skin response and subcutaneous tissues to subsequent procedures.

Ionizing radiation is a very serious threat to patients, as well as clinical staff. One study*[2] has shown radiological technologists who assisted with fluoroscopically-guided interventional procedures (FGIP) were of increased risk for cataract diagnosis compared to technologists who never assisted with FGIP*[2].

For both patients and clinical staff, radiation dose does induce effects on them. Proper dose management to prevent unnecessary exposure is essential.

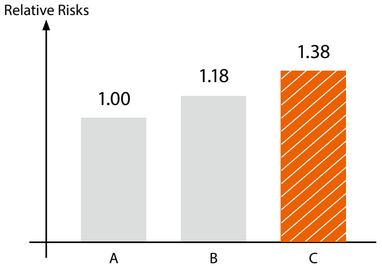


Fig. Radiation exposure-related work history and Relative Risk of cataract*[2]

A: Radiologic technologists who never assisted with FGIP
B: Radiologic technologists who assisted with FGIP
C: Radiologic technologists who assisted with >5,000 cumulative FGIP

Solutions for you

DoseRite

DoseRite technologies provide a comprehensive dose management suite of tools designed to help you minimize patient X-ray exposure while maintaining optimum image quality, enabling you to prioritize safe operating conditions for patients and clinical staff.

PF

Dose Adjustment Filter

F-Rec

F-Store

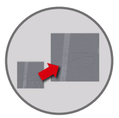
Live Zoom

Virtual Filter/
Virtual Collimator

Position

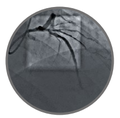
Reverse Geometry

Auto Pixel Shift

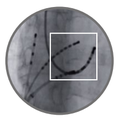


3D Road Map

Spot ROI

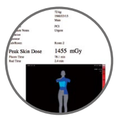


Spot Fluoro



DTS

Report



A unique level of flexibility

Reverse geometry of the ceiling-suspended Ω-arm

The biplane system's ceiling-suspended Ω-arm makes it easier for you to minimize scatter radiation with its left/right inversion capabilities. Both positions can be registered to the auto-positioning function, and the X-ray source can be positioned either side of the patient with simple table-side operation.

Normal position

Position that minimizes exposure for the operator

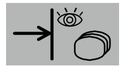
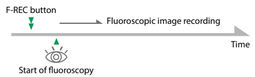
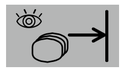
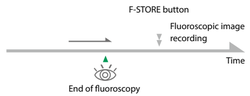
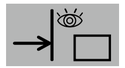
Lateral and vertical motion

While the system's lateral motion lets you place the detector as close as possible to your patient, the vertical motion helps you adjust the detector position without changing the table height. This would help to decrease unnecessary exposure risk and to increase efficiency.

Advanced dose management tools.

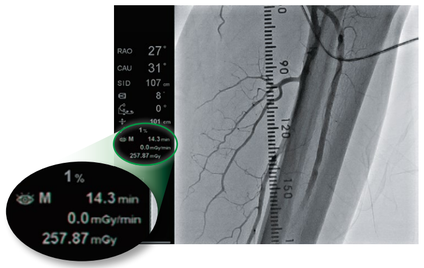
Fluoroscopic acquisition

Using the footswitch, the operator can capture still and dynamic images for future reference.

F-REC		Fluoroscopic images acquired after pressing the fluoroscopy start button are recorded. Images can be recorded for up to 90 seconds or 1020 frames. (Dynamic image recording) 
F-STORE		Fluoroscopic images acquired in the last 10 seconds are recorded. Press the F-STORE button after fluoroscopy is completed to save the run as part of the patient file. (Dynamic image recording) 
F-REC (S)		The single image acquired in fluoroscopy is recorded. (Still image recording) 

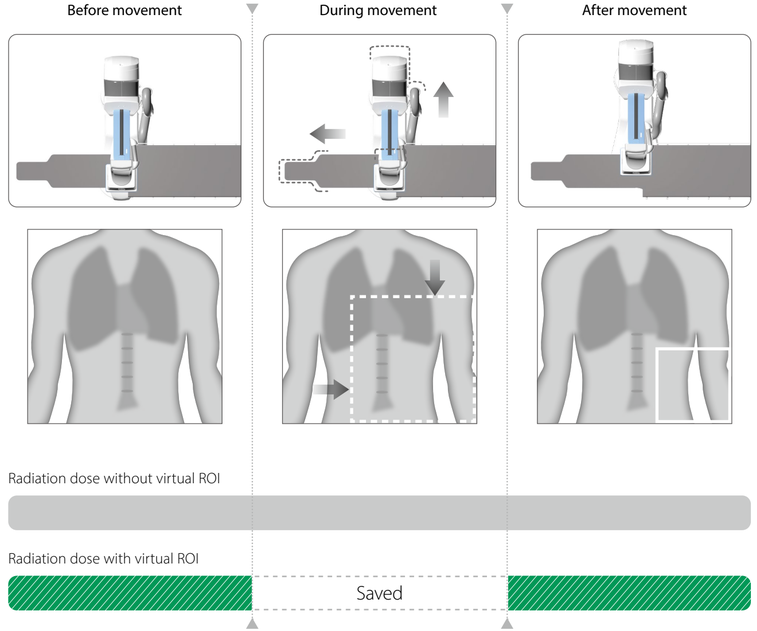
Real time display of exposure dose

The operator can observe real time dose levels on a digital display in the examination and control rooms.



Virtual position

By applying a graphical outline to the LIH image, virtual regions of interest (ROI) can help you accurately position your patient after the c-arm or tabletop is moved. This can also help minimize unnecessary exposure dose before, during, and after c-arm or tabletop movement.



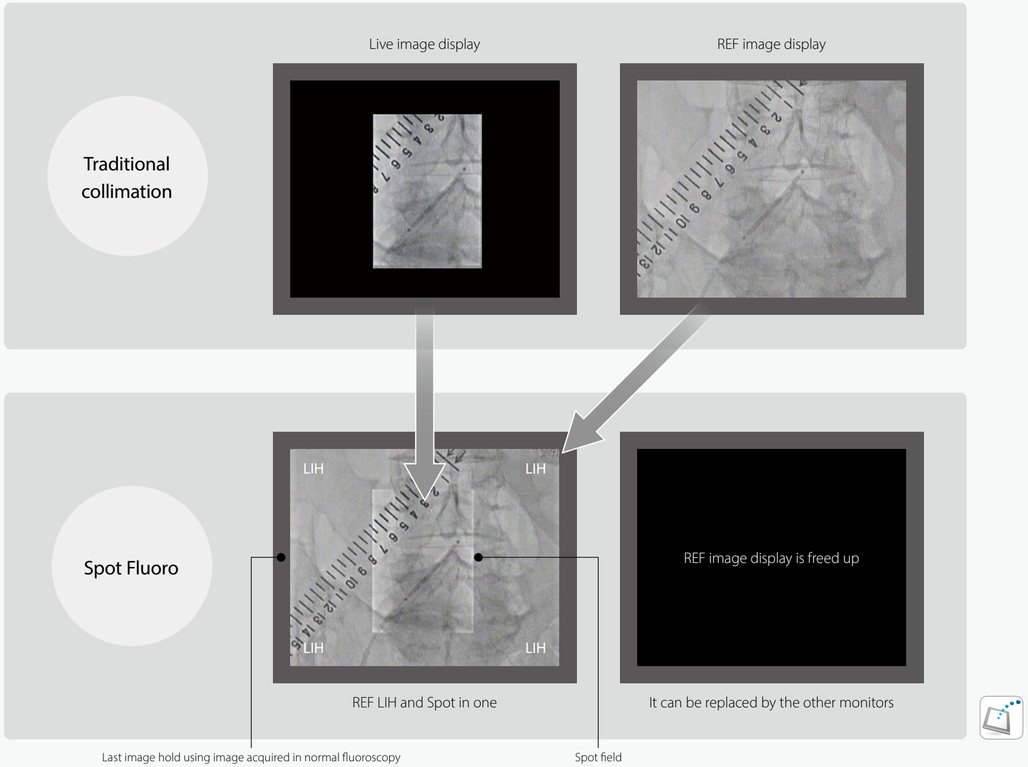
Asymmetric collimation for additional reductions in radiation dose

Leading-edge spot fluoroscopy

Canon Medical's spot fluoroscopy technology can reduce the cumulative dose area product by up to 50%*[3].
What's more, scatter radiation can also be reduced by more than 50%*[3], enabling a safer procedure for both you and your patient.

What is Spot Fluoro?

Spot Fluoro, enables the operator to collimate a rectangular or square region of interest anywhere within the general field of view. The collimated, rectangular area can be resized and/or repositioned easily and as often as necessary to obtain an optimal FOV. This has potential advantages over conventional collimation, which is limited to symmetric collimation centered over the field of view.



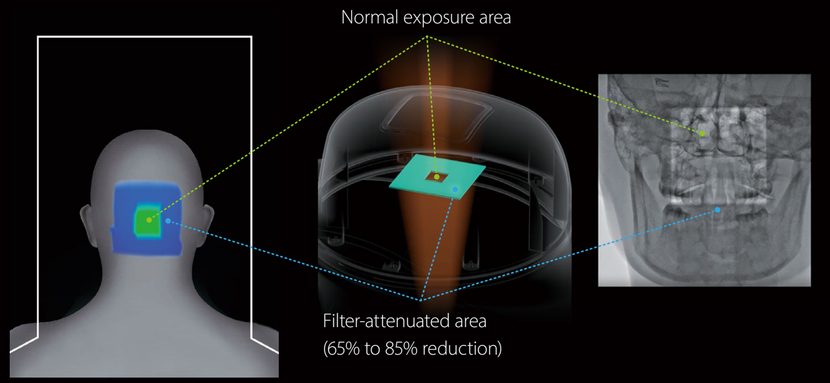
See more of interest, with less exposure

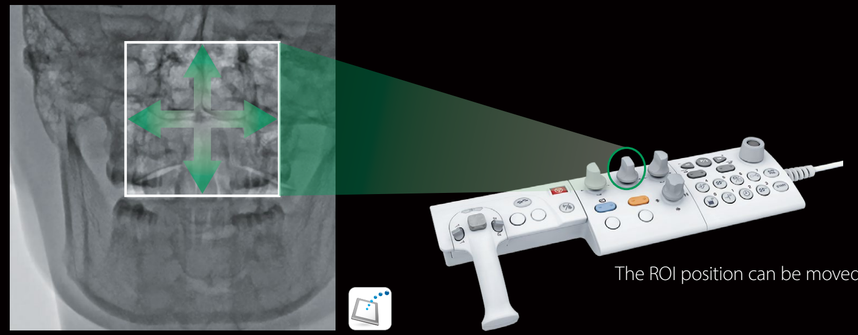
What is Spot ROI?

Spot region of interest (Spot ROI) is a novel functionality that has been developed for reduction of radiation dose during interventional procedures. The feature, as well as Spot fluoro is integrated into the commercially available Alphenix angiographic system*. Spot ROI permits a ROI exposure with normal dose, while the dose to the surrounding anatomy is significantly reduced thanks to the higher attenuation of the additional copper filter. This enables the operator to conveniently position the ROI always over the vascular structure of interest, independently of its location within the FOV selected.

A promising dose-saving technology

Spot ROI's greatest benefit is its ability to always keep the entire Field of View (FOV) information visible. Spot ROI is a promising dose-saving technology as it can be applied in fluoroscopy, DSA and digital angiography acquisition. A combination of using Spot fluoro and Spot ROI is potentially useful for obtaining an visual information while reducing radiation dose.





* Only for Alphenix Core+ and Alphenix Biplane

Visualize estimated peak skin dose in realtime

Dose Tracking System* (DTS)

Enhanced dose tracking tools allow realtime peak skin dose monitoring and archiving. Displayed as a 3D color map, on a realistic patient graphic, this data can be used to avoid regions of previous high exposure during subsequent procedures.

Guide the procedure safely

Each patient's estimated peak skin dose is represented on a 3D color map. Realtime estimated skin dose is displayed live. It allows you to avoid regions of previous high exposure. During long procedures, such as PCO, CTO, EP and cerebral aneurysm coiling, you can choose alternative approaches to optimize patient radiation dose while continuing treatment.

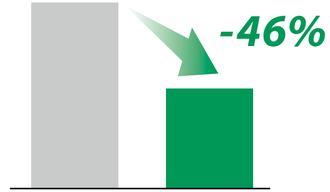
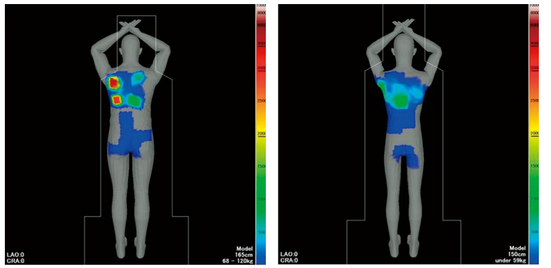


Fig. DTS reduced peak skin dose almost half (46%) in PCI patients[#4]

Multiple 3D patient models based on patient's height and weight are defined in advance and a patient model is selected for each study.

Operator blinded to DTS

Operator with informed DTS



With DTS, the operator can chose different angulations during long procedures, such as CTO, to avoid over exposure to various anatomy. Visualize the accumulated estimated peak skin dose on the patient's model.

* option

References

*1: Stephen B, John W. H, Donald L. M, et al. Fluoroscopically Guided Interventional Procedures: A Review of Radiation Effects on Patients' Skin and Hair. Radiology 2010; 254(2)

*2: Raquel V, David B, Ethel S. G, et al. Cataract risk in US radiologic technologists assisting with fluoroscopically-guided interventional procedures: a retrospective cohort study. Occup Environ Med. 2019; 56(5); 317-325.

*3: Wilson S, Prasan AM, Virdi A, et al. Real- time colour pictorial radiation monitoring during coronary angiography: effect on patient peak skin and total dose during coronary angiography. EuroIntervention 2016;12:939–47

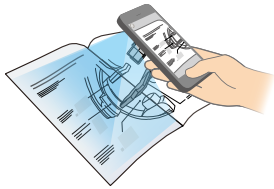
*4: Borota L, Jangland L, Åslund PE, et al. Spot fluoroscopy: a novel innovative approach to reduce radiation dose in neurointerventional procedures. Acta Radiol. 2017;58(5):600-608.

How to Use the medicalAR App

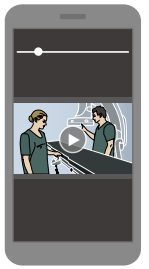
Images with the icon can be viewed in motion.

To download the app, scan the QR code or visit our website:
https://global.medical.canon/about/medicalAR

① Launch the app and start AR Camera.



② Scan a page that includes image with the icon.



③ When a trigger image is captured, linked content will be displayed.

Canon
CANON MEDICAL SYSTEMS CORPORATION
https://global.medical.canon

Model number: INFX-8000V MCAVL0010EA 2020-11 CMSC/xx/Printed in Japan

Canon Medical Systems Corporation meets internationally recognized standards for Quality Management System ISO 9001, ISO 13485. Canon Medical Systems Corporation meets the Environmental Management System standard ISO 14001.

Disclaimer: Some features presented in this brochure may not be commercially available on all systems shown or may require the purchase of additional options. Please contact your local representative from Canon Medical Systems for details.

Made For life

Attachment D

EQUIPMENT COMPARISON – Pediatric Cardiac Catheterization Lab #2 Replacement

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, etc.)	Cardiac Catheterization Equipment	Cardiac Catheterization Equipment
Manufacturer	Canon (Toshiba)	Canon
Model name/number	Infinix Bi-Plane	Alphenix Bi-Plane
Other method of identifying the equipment (e.g., Serial Number, VIN #)	A7B16Y2001	Not Available Until Installed
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2017	2025
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project	$4,024,000	$2,461,117
Total cost of the equipment	$1,387,377	$1,607,018
Location of the equipment	Pediatric Cardiac Catheterization Lab #2	Pediatric Cardiac Catheterization Lab #2
Document that the existing equipment is currently in use	Existing equipment performed 248 cases in the most recent 12 months	N/A
Will the replacement equipment result in any increase in the **average charge per procedure**?	N/A	No
If so, provide the increase as a percent of the current average charge per procedure	N/A	N/A
Will the replacement equipment result in any increase in the **average operating expense per procedure**?	N/A	No
If so, provide the increase as a percent of the current average operating expense per procedure	N/A	N/A
Type of procedures performed on the existing equipment	Cardiac Catheterization/EP Procedures	N/A
Type of procedures the replacement equipment will perform	N/A	Cardiac Catheterization/EP Procedures

From: Huber, Brighid K
To: Stancil, Tiffany C; Moore, Chalice L
Subject: [External] Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center
Date: Wednesday, July 9, 2025 5:47:48 PM
Attachments: 2025 CMC Pediatric Cardiac Cath Lab #2 Equip Rplcmt Exemption.pdf

Good afternoon,

Please find attached an exemption request submitted by The Charlotte-Mecklenburg Hospital Authority (“CMHA”) d/b/a Carolinas Medical Center ("CMC") to replace existing pediatric cardiac catheterization equipment.

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

Best,

Brighid

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

Atrium Health