

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

VIA EMAIL ONLY

January 25, 2023

Lisa Griffin <u>llgriffin@novanthealth.org</u>

Exempt from Review – Replacement Equipment				
4117				
January 17, 2023				
Novant Health Rowan Medical Center				
933436				
Novant Health Rowan Medical Center				
2561				
Replace cardiac catheterization equipment				
Rowan				

Dear Ms. Griffin,

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above-referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Canon Alphenix Core cardiac catheterization system to replace the Toshiba Infinix cardiac catheterization system (Serial # 03462). 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,

Donna Donihi, Project Analyst

Micheala Mitrael

Micheala Mitchell, Chief

cc: Radiation Protection Section, DHSR

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

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603 MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704 https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873 January 17, 2023

<u>Via Email</u>

2085 Frontis Plaza Boulevard

Winston-Salem, NC 27103

N HEALTH

Donna Donihi, Project Analyst, Certificate of Need N.C. Department of Health Service Regulation 809 Ruggles Drive Raleigh, North Carolina 27603

Re: Novant Health Rowan Medical Center Replacement of Cardiac Catheterization Lab Salisbury, North Carolina (FID # 933436; Rowan County)

Dear Ms. Donihi:

Novant Health Rowan Medical Center ("NH Presbyterian") intends to replace an existing cardiac catheterization (cath) lab located at the hospital in Salisbury, North Carolina pursuant to N.C. Gen. Stat. 131E-184(f). The existing cath lab is over ten years and is past its useful life. It is located on the first floor in the Novant Health Smith Heart & Vascular Institute. NH Rowan plans to acquire a new Canon Alphenix Core+ Vascular System to replace the existing lab system. See **Attachment A** for the equipment quote. As part of the equipment cost, the vendor will provide onsite clinical training for the equipment. Also included as part of the equipment costs is a GE MacLab and a Stryker equipment boom. Included in **Attachment A** is an email from the vendor indicating that Canon will remove the existing cath lab equipment. The total capital cost for the proposed replacement equipment project is estimated to be \$2,377,458¹. See **Attachment B** for the signed Projected Capital Cost form.

NH Rowan's project meets the requirements set forth in N.C. Gen. Stat. 131E-184(f) for "replacement equipment" that exceeds two million (\$2,000,000) threshold in the following ways:

Main Campus:

The existing and replacement cath lab is and will be located in the Novant Health Smith Heart & Vascular Institute at NH Rowan, which is located at 612 Mocksville Avenue, Salisbury, Charlotte, North Carolina. At this location, NH Rowan's President and COO, Gary Babon's office is located in Administration on the Main Floor. This location provides clinical patient services and exercises financial and administrative control over the entire campus. See **Attachment C** for a campus map. The existing equipment is still in service as reported on the most recent annual License Renewal Application ("LRA") which is excerpted in **Attachment D**.

¹ The project cost does not include sales, property or excise taxes as NH Rowan is not subject to these taxes as a non-profit, tax-exempt organization.

Re: NH Rowan Replacement of Cardiac Catheterization Equipment January 17, 2023 Page 2

Previous Certificate of Need:

We are unable to locate documentation regarding the cath lab's original acquisition. The current cath lab equipment dates from 2012 and was last replaced per an April 2011 replacement equipment exemption request. A copy of the Agency's replacement equipment exemption determination is included in **Exhibit D**. The cardiac catheterization lab is reported on NH Rowan's annual LRA and an excerpt of the latest is included as **Exhibit E** in the State Medical Facilities Plan (SMFP) for many years.

Replacement Equipment:

The proposed project meets the definition of "replacement equipment" found in G.S. 131E-176(22a) and 10A N.C.A.C 14C.0303 for the following reasons:

- (1) NH Rowan intends to replace the existing cath lab equipment with the proposed equipment that is functionally similar and will be used for the same diagnostic purposes, although it possesses expanded capabilities due to technological improvements.
- (2) The proposed equipment will not be used to provide a new health service.
- (3) The acquisition of the proposed equipment will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

See Attachment E for the Equipment Comparison of the existing and planned new equipment.

In support of our request, please find attached:

Attachment A – Vendor Equipment Quotes Attachment B – Project Capital Costs Attachment C – Main Campus Map Attachment D – Last Agency Replacement Equipment Exemption Determination Attachment E - In Use Documentation (LRA Excerpt) Attachment F – Equipment Comparison Form

NH Rowan's acquisition of the replacement equipment does not require a certificate of need because none of the definitions of "new institutional health services" set forth in N.C.G.S. Section 131E-176(16) apply to the proposed project. As outlined above, the total cost for the project is \$2,377,458. The proposed capital cost includes equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation and other activities essential to making the equipment operational.

Based on the information provided, please confirm that NH Rowan's replacement equipment exemption request does not constitute a new institutional health service and is exempt from certificate of need review.

Re: NH Rowan Replacement of Cardiac Catheterization Equipment January 17, 2023 Page 3

If you need additional information, please do not hesitate to contact me.

Sincerely,

Lisa Griffin

Lisa Griffin Manager, Operational Planning Novant Health, Inc.

Attachments

ATTACHMENT A

CANON MEDICAL SYSTEMS USA, INC.

QUOTATION/ORDER SUMMARY

DATE: 12/16/2022 SID #: 30075111 QUOTE #: 159717-3

PRESENTED TO: NOVANT HEALTH ROWAN MEDICAL CENTER 612 MOCKSVILLE AVE SALISBURY, NC. 28144

VL/ALPH/COREPLUS/2.000

ALPHENIX CORE+ VASCULAR SYSTEM

SPECIAL INFORMATION & TERMS

- Included in this quote is the Canon Medical Systems Encore Plus Upgrade program. With Encore Plus, installed-base customers get the benefit of upgrading their aging system to new technology. This gives you access to latest clinical capabilities and offers training and warranty equal to a completely new system.
- If this quotation is not accepted by March 31, 2023, Canon Medical Systems USA, Inc. reserves the right to cancel this quotation.

This quotation shall remain valid until March 31, 2023.

All prices are F.O.B. destination.

Payment terms are: Cash - 0% down payment, 80% upon shipment net 45 days, 20% net 30 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 Vizient Supply, LLC and Canon Medical Systems USA, Inc. Reference contract no. XR0701, effective September 1, 2021.

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

ACCEPTED AGREED AND ORDERED:

PURCHASER'S SIGNATURE/TITLE

DATE

CANON MEDICAL SYSTEMS REP DATE

EQUIPMENT SUMMARY:

All information contained in this quotation is confidential and may not be disclosed to any third party without Canon Medical Systems' prior written consent.

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VL/ALPH/COREPLUS/2.000		ALPHENIX CORE+ VASCULAR SYSTEM
PART NUMBER	<u>QTY</u>	DESCRIPTION
	1	SHARED LAB
ALPH-SPOTROI/HD/FM12- 880/3.100	1	SYSTEM KIT: ALPHENIX CORE + HI-DEF (FLOOR MOUNT) 12"X12" FPD SYSTEM WITH CAT-880B/B1 HYBRID TABLE WITH SPOT ROI, AWS AND DOSE TRACKING SYSTEM
	1	MAIN UNIT: ALPHENIX CORE + HI-DEF (FLOOR MOUNT) 12"X12" FPD SYSTEM WITH SPOT ROI
	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	SINGLE ARM BOARD
	1	HEAD-END DRAPE HOLDER FOR CAT-880B
	1	SUPPORT ARM LOCK KIT
	1	2" TABLE PAD FOR CAT-880B
	1	[KIT] ALPHENIX ANGIO WORKSTATION (AWS PRO) AND MONITOR
	1	ALPHENIX ANGIO WORKSTATION (AWS PRO)
	1	ROCKET LINK CONNECTION KIT
	1	21" MONITOR, LCD COLOR (BASE PLATE INCLUDED)
	2	DISPLAY PORT TO DVI-D ADAPTER/VIDEO CONVERTER 1080P
	1	[KIT] DOSE TRACKING SYSTEM WITH MONITOR FOR ALPHENIX
	1	DOSE TRACKING SYSTEM FOR ALPHENIX
	1	21" MONITOR, LCD COLOR (BASE PLATE INCLUDED)
VL-FM-HD/SPOTROI- PROMO-PR	1	HI-DEF AND SPOT ROI PROMOTION FOR CORE+ HI-DEF WITH SPOT ROI FPD SYSTEM
	1	STANDARD APPLICATIONS TRAINING
	1	CABINET SIDE COVER
	1	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

Made For life

PART NUMBER	<u>QTY</u>	DESCRIPTION
	1	MAVIG TABLE MOUNTED RADIATION SHIELD
	1	COPPER PHANTOM FOR WAKE UP PROGRAM FOR ALPHENIX
	1	WAKEUP CHECK PROCEDURE BOOKLET
	6	COOLANT - 1 GALLON
	1	BACKUP MONITOR INTERFACE KIT FOR BARCO 58" MONITOR
	1	19" COLOR MONITOR
DIGITAL-SERVICES-PR.100	1	[KIT] DIGITAL SERVICES PROMOTION
	1	VASCULAR OPTIONS FOR ALPHENIX DFP-8000C/A2 V9 WINDOWS 10 SERIES
INTV-DASH/SP30/2.100	1	30" CONTROL ROOM MONITOR - SP/DP
	1	4 MEGA PIXEL (2560 X 1600), 30 INCH WIDE, COLOR LCD DISPLAY
	4	USB CABLE, 2M
	1	HP USB KEYBOARD/MOUSE/MOUSEPAD KIT
	1	TRIPPLITE 6 OUTLET RACKMOUNT POWER STRIP PERP 1U REAR FACING
	1	19" RACKMOUNT SHELF
BARCO-58.100	1	[KIT] BARCO 58" V5 LARGE MONITOR WITH BUILT-IN PROTECTIVE GLASS NIVR58-T5 G KIT
	1	BARCO 58" V5 NIVR58-T5 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	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	1	[KIT] BARCO V5 GUEST PORT INPUT DISPLAY
	1	MNA-420 ENC HDMI INCLUDES: MNA-420 ENC, 2XHDMI- DVI 10FT CABLE AND 10GSFP+

PART NUMBER	<u>QTY</u>	DESCRIPTION
	1	MNA-120 ENC ANA AUDIO TMS WITH EXTRA SFP+
	1	DVI EXTENDER AND RECEIVER CABLE
	1	CANON LOGO PLATE
	2	1M FIBER MMF LC-LC OM3 DX 2MM CABLE CUSTOM
	1	DVI TO HDMI ADAPTOR (2 PCS 8" ADAPTORS INCLUDED)
BARCO-58-HDMI-INPUT.100	1	[KIT] HDMI VIDEO INPUT ON BARCO V5 MONITOR
	1	MNA-420 ENC HDMI INCLUDES: MNA-420 ENC, 2XHDMI- DVI 10FT CABLE AND 10GSFP+
	1	1M FIBER MMF LC-LC OM3 DX 2MM CABLE CUSTOM
	1	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	1	[KIT] GRAPHIC INTERFACE/DIAGNOSTIC MONITORS FHD VIDEO READY OUTPUT KIT WITHOUT MOUNTING SOLUTION
	1	MNA-420 DEC V2 HD DUAL CHANNEL DECODER 2X HDMI OUTPUT ADDITIONAL 10G SFP+
	1	DVI TO HDMI ADAPTOR (2 PCS 8" ADAPTORS INCLUDED)
	1	ONE KIT 36M OPTIC FIBER CABLE TMS
A240-1087A	1	IDI MONITOR MOUNT BRACKET ASSEMBLY
1000F1H-IDI-03-17.8/2.100	1	LARGE LCD MONITOR SUSPENSION FOR IDI RAILS FOR FLOOR SYSTEMS
	1	LARGE LCD MONITOR SUSPENSION FOR IDI RAILS FOR FLOOR SYSTEMS
	1	IDI MONITOR MOUNT BRACKET ASSEMBLY
XGCP-880AA/B1	1	JOYSTICK CONTROL UNIT WITH STAND (CORE + SKY)
XACP-001BA/C1	1	TABLE SIDE TABLET CONSOLE (4M CABLE)
XIDF-STP801/KIT.100	1	DSA STEPPING + FI-09 COMPENSATION FILTER SET
	1	DSA STEPPING
	1	COMPENSATION FILTER SET FOR PERIPHERAL STUDIES
XIDF-QCA850/A1.100	1	BASIC KIT FOR CLINICAL ANALYSIS APPLICATION
	1	CAAS BASIC KIT FOR CLINICAL ANALYSIS APPLICATION

PART NUMBER	<u>QTY</u>	DESCRIPTION
XIDF-QCA851/A1	1	QUANTITATIVE CORONARY VESSEL ANALYSIS - 9MM OR LESS
XIDF-QCA852/A1	1	QUANTITATIVE VESSEL ANALYSIS - 9MM OR ABOVE
XIDF-QCA853/A1	1	LEFT VENTRICULAR ANALYSIS (SINGLE PLANE)
3D-ANGIO-SW-KIT/CA2.100	1	BASE 3D ACQUISITION SOFTWARE
APPS-ONSITE-32	1	ADDITIONAL ON-SITE APPLICATIONS TRAINING - 32 HOURS
XIDF-PVG801/A1.100	1	3-D 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 (REQUIRES AWS)
MIAB-880	1	PRONE POSITION ARMBOARD FOR CAT-880B
XBAR-001A	1	SINGLE ARM BOARD
XBER-001A	1	TABLE SIDE CONTROL EXTENSION RAIL SET (PAIR)
XBET-001A	1	FOOT-END TABLE EXTENSION (REQUIRES XBER-001A)
XBAM-001A	1	HEAD-END ACCESSORY RAIL FOR CAT-880B
9407	1	KNEE SUPPORT PAD
PX17-36730-2	1	I/V POLE FOR ALPHENIX SERIES
FOOTSWITCH/W/SP/880.100	1	WIRELESS FOOTSWITCH FOR CAT-880B SINGLE AND DUAL PLANE
TS1006-US	1	MAVIG TRACK 4.0 M LENGTH / 335 MM WIDTH WITH SPOOLER
57CM-COLUMN- TROLLEY.100	1	MAVIG CEILING 360 COLUMN WITH TROLLEY (57 CM) WITH BRAKE STRAP
OT90001-US	1	MAVIG PORTEGRA2 (95/90 CM) EXTENSION SPRING ARM WITH CENTER MOUNTED CONTOUR CUT-OUT SHIELD (61X76 CM)
LE9017100	1	MAVIG PORTEGRA2 (95/90 CM) EXTENSION SPRING ARM WITH YLED-1F LED LAMP
93PM-100/2	1	EATON 93PM-100 UPS
PQUBE-CANON-WM-01	1	POWER QUALITY MONITORING PACKAGE (WALL MOUNT)

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PART NUMBER

MARK7-TABLE/2.100

QTY DESCRIPTION

- 1 [KIT] MEDRAD / BAYER MARK 7 ARTERION INJECTOR, INSTALL INCLUDED (TABLE MOUNT)
- 1 MEDRAD / BAYER MARK 7 ARTERION INJECTOR, INSTALL INCLUDED (TABLE MOUNT)

TOTAL QUOTE PRICE

Applicable Sales Tax Additional

\$934,798.00

CANON MEDICAL SYSTEMS USA, INC.

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: <u>tmalone@us.medical.canon</u> or visit us at <u>https://us.medical.canon/service-and-support/financial-programs/</u>

VL/ALPH/COREPLUS/2.000

ALPHENIX CORE+ VASCULAR SYSTEM

The new Alphenix family of angiography systems Combines industryleading dose management technologies, enhanced workflow and a new set of features. Alphenix continues Canon Medical's commitment to supporting you and your mission to provide patients with safe, accurate and fast imaging.

WorkRite:

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.

CANON MEDICAL SYSTEMS USA, INC.

COMPONENT SUMMARY:

PART NUMBER QTY DESCRIPTION

1 SHARED LAB

Optimized for systems shared by Cardiology, Radiology, and/or other physicians, the Canon family of angiography systems Combines industryleading 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:

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-SPOTROI/HD/FM1 2-880/3.100

1

SYSTEM KIT: ALPHENIX CORE + HI-DEF (FLOOR MOUNT) 12"X12" FPD SYSTEM WITH CAT-880B/B1 HYBRID TABLE WITH SPOT ROI, AWS AND DOSE TRACKING SYSTEM

Note: In order to reduce the risk of unnecessary radiation exposure when the system is configured with TFP-1200C High Definition Detector the XIDF-DTS802 Dose Tracking System is incorporated in the configuration. Additionally, Live Zoom is not allowed in HD mode and requires an FOV of 6" or greater.

Note: Optional TFP-1200C High Definition Detector available with the INFX-8000V Single-Plane and Biplane systems only.

STANDARD SYSTEM COMPONENTS

- CAS-880A/B2
 - Five-Axis C-arm, Floor Mounted High Capacity X-ray Tube DSRX-T7445GFS
 - Automatic Rotating Collimator with Spot ROI
 - BLA-900A/R1 TFP-1200C/A1
- CAT-880B/B1
- XGCP-880BA/B1
- XBFS-880S •

•

- XTP-8100XG
- DFP-8000C/A2 ٠
- XIDF-MIC802
- XIDF-MCC80S •
- XIDF-FS801S •
- XJDK-001A/V9
- XJDC-016A

- 12" x 12" HD Flat Panel Detector Catheterization (Tilting) Table
- Tableside Console HyperHandle
 - Standard Footswitch
- High-Frequency X-ray Generator 100 kW
- Multitasking Digital Fluoroscopy Processor
 - Microphone Kit
- Main Console
- Control Room Footswitch
- Dose Meter Controller
- Dose Chamber

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

The AlphenixCore+ floor-mounted C-arm provides clinical angles for fluoroscopy, radiography and digital fluorography. This flexible design allows superb access to the patient and enables the steep angulation required for complex cardiac catheterization procedures.

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") •
- ±135 degree column rotation •

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:
 - RAO 120 degrees to LAO 120 degrees
 - 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

• <u>Auto-Angle</u>: 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-T7445GFS

Includes a standard 36 month non-prorated tube warranty. Triple-focus design provides small-focal-spot redundancy for uninterrupted procedure in the event of fluoro filament failure. Highly efficient, pulsed fluoroscopy with built-in, beam-hardening filters reduces dose. Continuous, high-speed (9000 rpm) anode rotation provides immediate display of fluoroscopic and fluorographic images. Other features include:

- Grid switched
- Maximum kV: 125 kV; Focal spot: 0.4/0.6/0.9 mm; Maximum ratings: 30/50/100 kW; Target angle: 9 degrees Maximum anode heat storage: 3000 kHU;
- Maximum cooling rate anode: 7700 HU/min

AUTOMATIC ROTATING COLLIMATOR - BLA-900A/R1

- 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 industrystandard filtration materials, including: Aluminum 1.8 mm, Copper 0.2mm, 0.3mm, 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)

<u>12"X12" CANON EXCLUSIVE NEW HIGH DEFINITION FLAT PANEL</u> <u>DETECTOR - TFP-1200C/A1</u>

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)

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

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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):
- Longitudinal stroke: 1,350 mm (53.1")
- 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 s
- Maximum patient weight:
- 551 lbs. (250 kg IEC) at maximum table extension
- Can support additional loading of up to 220 lbs. (100 kg) for cardiopulmonary resuscitation (CPR)

TABLESIDE CONSOLE (HYPERHANDLE) - XGCP-880BA/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 FOOTSWITCH - XBFS-880S

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
- Flouroscopic time setting range (timer): Maximum 5 minutes

- 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)
- Pulse width: 1.0 ms to 25 ms

MULTITASKING DIGITAL FLUOROSCOPY PROCESSOR - DFP-8000B/C/A2

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

Fluoro and Acquisition Modes

- Fluoro:
 - Matrix of 1024²: 16 bits
 - o 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 1024²: 16 bits at 1, 2, 3, 5, 7.5, 10, 15, 30 FPS
 - Matrix of 512²: 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 1024²: 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

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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 ablity 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, fluoroscopicsubtracted roadmap image.
- Add Subtracted Fluoroscopy provides a completely subtracted display to better visualize live contrast injections or embolic materials.
- CO₂ DSA provides the optimal, live, CO₂ (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 Position

Virtual Position 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.

Virtual Collimation using Last Image Hold

Provides an electronic outline to position the collimator and acrylic filter without fluoroscopy, with no additional dose.

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

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- 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-MCC80S

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-FS801S

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

DOSE METER CONTROLLER - XJDK-001A/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 CHAMBER - XJDC-016A

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

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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 AlphenixCore + is the INFX-8000V/B (SP)

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

1 MAIN UNIT: ALPHENIX CORE + HI-DEF (FLOOR MOUNT) 12"X12" FPD SYSTEM WITH SPOT ROI

- **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 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 SUPPORT ARM LOCK KIT

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 [KIT] ALPHENIX ANGIO WORKSTATION (AWS PRO) AND MONITOR

1 ALPHENIX ANGIO WORKSTATION (AWS PRO)

Alphenix Workstation Pro-(Software Version 9.3) 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 Parametric Imaging.
- Supports TAVR.
- Supports Dose Tracking System (DTS)

Parametric Imaging (PI) Functions*

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- 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.

This AWS is not backwards compatible.

- **1 ROCKET LINK CONNECTION KIT**
- 1 21" MONITOR, LCD COLOR (BASE PLATE INCLUDED)
- 2 DISPLAY PORT TO DVI-D ADAPTER/VIDEO CONVERTER 1080P
- 1 [KIT] DOSE TRACKING SYSTEM WITH MONITOR FOR ALPHENIX

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)

1 HI-DEF AND SPOT ROI PROMOTION FOR CORE+ HI-DEF WITH SPOT ROI FPD SYSTEM

1 STANDARD APPLICATIONS TRAINING

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

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Performance Pro is a unique approach to education utilizing blended learning with the promise of technical proficiency and optimal productivity. If for any reason the customer is not satisfied with any portion of the training, Canon Medical Systems will conduct that portion of the training again, during the warranty period at no charge.

Phase I: Two attendance vouchers for a four-day technologist-focused course held at the Canon Medical Systems Institute of Advanced Imaging in Irvine, California. 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, postprocessing 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.

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



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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 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 Infinix-i 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.

1 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

6 COOLANT - 1 GALLON



1 BACKUP MONITOR INTERFACE KIT FOR BARCO 58" MONITOR

1 19" COLOR MONITOR

DIGITAL- 1 [KIT] DIGITAL SERVICES PROMOTION

Canon Medical Systems' Gateway Platinum Cybersecurity Kit is a state-ofthe-art, integrated cybersecurity solution that creates an ultra-protective shield around your imaging assets and patients' most valuable personal data. This next-generation, deny-all firewall isolates the imaging system from the hospital network – enabling multilayered protection that alerts to malicious activity. The package includes a one-year subscription to Firewall Insights reporting, Canon Medical Systems' Rapid Incident Response coverage, Intrusion Prevention System (monitoring, blocking, and alerting), with full audit trail and SIEM (Security Information and Event Management) integration. Gateway Platinum kit also includes InnerVision Plus services (remote system diagnostics, power and environmental monitoring).

Utilization Analytics Plus Package provides visibility to the utilization of your Canon Medical Systems' diagnostic imagining devices, with tools to help you maximize throughput. The Plus Package includes the Asset Inventory and Asset Utilization dashboards – giving you access to near-real time reporting on the number and types of exams being performed across your Canon Medical Systems' assets, as well as access to historical data to identify trends and track throughput improvements.

The Analytics Plus Package is included in your Canon Medical Systems' imaging equipment during the warranty period and for systems under any Canon Medical Systems' service agreements. For post-warranty subscription of Gateway Platinum and Utilization

Analytics including analytical performance metrics and insights -- Referral Analysis, Operator Utilization, Turn Around Time, Change over Time, Dose Analysis, and Benchmarking – contact your Canon Medical Systems' Service Representative for details.

1 VASCULAR OPTIONS FOR ALPHENIX DFP-8000C/A2 V9 WINDOWS 10 SERIES

INTV-DASH/SP30/2.100

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SERVICES-PR.100

30" CONTROL ROOM MONITOR - SP/DP

The Interventional Dashboard brings your important computer based tools to your fingertips. Up to eight (8) different systems can be interfaced into the Interventional Dashboard, providing a single collaborative workstation with one keyboard and one mouse.

Easily modify screen inputs and video sizes for optimal customization based on clinical need or preference. One system can be controlled at a time so you

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can update patient charts while viewing the information you need at the same workstation.

Includes:

- One Color LCD Display
- Interface module
- Cabling to connect Live and Reference x-ray images
- Cabling to connect four external sources
- Keyboard and Mouse

Note: Display of mammography images for diagnosis is not supported Designed and Manufactured by Eizo Corporation.

1 4 MEGA PIXEL (2560 X 1600), 30 INCH WIDE, COLOR LCD DISPLAY

Color LED Display for use with the Interventional Dashboard 30" monitor solution. This monitor supports 4 megapixel (2560 x 1600) resolution and is suitable for displaying and viewing large volumes of information on just one screen, improving workflow efficiency and saving time.

- 30 inch diagonal (76 mm)
- 1500:1 Contrast Ratio (typical)
- 500 cd/m² brightness rating (typical)
- Weight (including stand) 14.2 kg (31.3 lb.
 - С

Note: This product is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis. Designed and manufactured by Eizo Corporation.

4 USB CABLE, 2M

1 HP USB KEYBOARD/MOUSE/MOUSEPAD KIT

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

1 19" RACKMOUNT SHELF

BARCO-58.100 1 [KIT] BARCO 58" V5 LARGE MONITOR WITH BUILT-IN PROTECTIVE GLASS NIVR58-T5 G KIT

58" High Bright, Ultra-HD Surgical display (3840x2160) with LED, Backlight for use in Interventional Imaging. Brightness: 600 cd/m2 with 4000:1 contrast. Connectivity: 1x DP1.2 SST, 4x DVI-SL or 2x DV-DL. Integrated Nexxis 4K IP Decoder and scratch-resistant front-glass.

1 BARCO 58" V5 NIVR58-T5 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	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	1	[KIT] BARCO V5 GUEST PORT INPUT DISPLAY
	1	MNA-420 ENC HDMI INCLUDES: MNA-420 ENC, 2XHDMI-DVI 10FT CABLE AND 10GSFP+
	1	MNA-120 ENC ANA AUDIO TMS WITH EXTRA SFP+
	1	DVI EXTENDER AND RECEIVER CABLE
	1	CANON LOGO PLATE
	2	1M FIBER MMF LC-LC OM3 DX 2MM CABLE CUSTOM
	1	DVI TO HDMI ADAPTOR (2 PCS 8" ADAPTORS INCLUDED)
BARCO-58-HDMI- INPUT.100	1	[KIT] HDMI VIDEO INPUT ON BARCO V5 MONITOR
	1	MNA-420 ENC HDMI INCLUDES: MNA-420 ENC, 2XHDMI-DVI 10FT CABLE AND 10GSFP+
	1	1M FIBER MMF LC-LC OM3 DX 2MM CABLE CUSTOM
	1	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	1	[KIT] GRAPHIC INTERFACE/DIAGNOSTIC MONITORS FHD VIDEO READY OUTPUT KIT WITHOUT MOUNTING SOLUTION
	1	MNA-420 DEC V2 HD DUAL CHANNEL DECODER 2X HDMI OUTPUT ADDITIONAL 10G SFP+
	1	DVI TO HDMI ADAPTOR (2 PCS 8" ADAPTORS INCLUDED)
	1	ONE KIT 36M OPTIC FIBER CABLE TMS
A240-1087A	1	IDI MONITOR MOUNT BRACKET ASSEMBLY Mounts one smaller monitor, typically 19", on the rear of a large LCD monitor suspension unit.
		 Bracket holds one smaller monitor (typically non-fluoro) with a 100 VESA mount
		• Mounts to rear on either side of the large LCD suspension assembly to provide additional location for alternate monitor (maximum of two monitors, one for each side)
		Note: Total weight of each monitor must not exceed 20 lbs each. Maximum weight of combined optional items may not exceed 155 lbs. Consult with your Canon Medical Systems representative to determine total weight payload.
		Alternate monitor sold separately.
1000F1H-IDI-03- 17.8/2.100	1	LARGE LCD MONITOR SUSPENSION FOR IDI RAILS FOR FLOOR SYSTEMS
	1	LARGE LCD MONITOR SUSPENSION FOR IDI RAILS FOR FLOOR SYSTEMS
		Optimizes monitor positioning around the patient table with an articulating arm for vertical height adjustments and a column that allows virtually 360 degree rotation. The transverse provides ample side-to-side positioning with a 60-inch movement range.

- Holds one large LCD monitor with a VESA 400 mount
- Total weight payload: 155 lbs (70.45 kg)
- Complete assembly included:
 - o Bridge
 - Interface
 - IDI rails: 17' 8"
 - Rail assembly: 17' 8"
- Accommodates up to two monitor mount bracket assemblies or mounting brackets for monochrome monitors to rear-mount smaller monitors (typically 19")
- Includes attachments and grounding hardware including a 100-foot AC power cable

Other optional devices will add payload weight. Please consult with a Canon Medical Systems representative regarding adding items to this assembly.

1 IDI MONITOR MOUNT BRACKET ASSEMBLY

Mounts one smaller monitor, typically 19", on the rear of a large LCD monitor suspension unit.

- Bracket holds one smaller monitor (typically non-fluoro) with a 100 VESA mount
- Mounts to rear on either side of the large LCD suspension assembly to provide additional location for alternate monitor (maximum of two monitors, one for each side)

Note: Total weight of each monitor must not exceed 20 lbs each. Maximum weight of combined optional items may not exceed 155 lbs. Consult with your Canon Medical Systems representative to determine total weight payload.

Alternate monitor sold separately.

XGCP-880AA/B1 1 JOYSTICK CONTROL UNIT WITH STAND (CORE + SKY)

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

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• Select specific hemodynamic functions if available

DSA STEPPING + FI-09 COMPENSATION FILTER SET

XIDF-

STP801/KIT.100

1 DSA STEPPING

Software that provides micro processor control of stepping functions, and real-time display of DSA images. Stepping is user controlled. Ideal for use during lower-extremity contrast-injected examination.

Specifications

- Image size: 1024x1024; 12-bit
- Image rate (FPS): 15, 10, 6, 3, 2, 1 can be selected at the time of installation
- Stages: 8 (7 steps)
- Speed: 1.7 sec/step
- Stroke:
 - 120 mm (4.7") minimum
 - 220 mm (8.6") maximum
- Maximum sweep: 1350 mm (53.1")
- Three sweeps:
 - Set up exposures at fluoro dose levels (abdomen to feet)
 - Mask acquisition (feet to abdomen)
 - DSA exposures (abdomen to feet)

1 COMPENSATION FILTER SET FOR PERIPHERAL STUDIES

Set of six silicone rubber compensating filters for digital subtraction arteriography of the lower extremities.

- Can be used for unilateral or bilateral examinations.
- Can be used with or without subtraction (DSA and DA).
- Two opaque rulers are incorporated in the midline filters.
- Can be used for venography.

1 BASIC KIT FOR CLINICAL ANALYSIS APPLICATION

XIDF-QCA850/A1.100

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/A1 1 QUANTITATIVE CORONARY VESSEL ANALYSIS - 9MM OR LESS Application

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XIDF-QCA850/A1 is required. XIDF-QCA851/A1 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.

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XIDF-QCA852/A1

QUANTITATIVE VESSEL ANALYSIS - 9MM OR ABOVE 1 Application

XIDF-QCA850 is required. XIDF-QCA852 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-QCA853/A1

1 LEFT VENTRICULAR ANALYSIS (SINGLE PLANE) Application

XIDF-QCA850/A1 is required. XIDF-QCA853/A1 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.

3D-ANGIO-SW- KIT/CA2.100	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 Vitrea VL 3-D software.
		This option is integral and a prerequisite for the optional Low Contrast Imaging (CT-like data) and Roadmapping options.
		Note: Requires XIDF-ROT801 and AWS.
APPS-ONSITE-32	1	ADDITIONAL 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- PVC801/A1 100	1	3-D VIEWER KIT
1 1 000 / 11.100		This kit allows the operator of the XIDF-AWS801 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
	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:
 - o 3D-Angio (3D-DA, 3D-DSA) included as standard
 - Alpha CT, Requires option XIDF-LCI801
 - o CT/MR fusion with fluoro requires option XIDF-3DP804

XIDF-3DP804

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

1

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; 12-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

1 LOW CONTRAST IMAGING (REQUIRES AWS)

(Alpha CT)

CBCT for Low contrast imaging can be performed from the control or examination room (only when the C-arm is set to the head-end position).

- Data acquisition range: RAO 100° to LAO 100°
- Rotation speed: Max. 25°/s or Max. 50°/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

XIDF-LCI801

		 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. <i>Prerequisite: 3D-ANGIO</i>
MIAB-880	1	 PRONE POSITION ARMBOARD FOR CAT-880B Provides arm support when patient is in the prone position on the angiographic table. Allows comfortable arm support with patient in prone position Mounts easily onto the table without clamps or belts Compatible with CAT-880B table only Made of radiolucent material that is easy to clean
XBAR-001A	1	SINGLE ARM BOARD Carbon fiber arm rest for the right or left side. One is included standard with CAT-850B table.
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 (<i>e.g.</i>, 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.
XBAM-001A	1	 HEAD-END ACCESSORY RAIL FOR CAT-880B Clamps to the edge of CAT-880B table: Head-end 14.5" down each side of tabletop An I.V. drip holder can be mounted to this rail.
9407	1	KNEE SUPPORT PAD White coated pad for below the waist elevation of the upper leg via support behind the knee.
PX17-36730-2	1	I/V POLE FOR ALPHENIX SERIES

FOOTSWITCH/W/S P/880.100	1	WIRELESS FOOTSWITCH FOR CAT-880B SINGLE AND DUAL PLANE	
		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 peode to be replaced after 500 hours or 1 year 	
		 Dattery needs to be replaced after 500 nours or 1 year 5M may 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	
TS1006-US	1	MAVIG TRACK 4.0 M LENGTH / 335 MM WIDTH WITH SPOOLER	
		The Mavig 4.0 M Ceiling Track with spooler enables up to two devices	
		(maximum of one lamp) to be mounted on a single trolley.	
57CM-COLUMN- TROLLEY.100	1	MAVIG CEILING 360 COLUMN WITH TROLLEY (57 CM) WITH BRAKE STRAP	
		The Mavig 57 cm 360 column with trolley has one electrified pin with 240	
		degrees of rotation capability and a lower pin with 360 degrees of rotation.	
		Each pin has a load capacity of 18 kgs. Each trolley comes standard with a	
		brake manule strap which makes the system more user menuly.	
OT90001-US	1	MAVIG PORTEGRA2 (95/90 CM) EXTENSION SPRING ARM WITH	
		CENTER MOUNTED CONTOUR CUT-OUT SHIELD (61X/6 CM)	
		am and includes a Portogra? Extension Spring Arm with two arms	
		measuring 95 cm and 90 cm. The transparent acrylic shield contains 0.50 mm.	
		Pb and is easily manipulated into position by use of a height adjustable	
		handle.	
LE9017100	1	MAVIG PORTEGRA2 (95/90 CM) EXTENSION SPRING ARM WITH YLED-1F LED LAMP	
93PM-100/2	1	EATON 93PM-100 UPS	
PQUBE-CANON- WM-01	1	POWER QUALITY MONITORING PACKAGE (WALL MOUNT)	



1

MARK7-TABLE/2.100

[KIT] MEDRAD / BAYER MARK 7 ARTERION INJECTOR, INSTALL INCLUDED (TABLE MOUNT)

1 MEDRAD / BAYER MARK 7 ARTERION INJECTOR, INSTALL INCLUDED (TABLE MOUNT)

The Mark 7 Arterion Table Mount injector takes advantage of latest technologies, making it light, maneuverable and easy to use.

Includes:

- Table rail mount
- Ergonomic injector head handle for easier maneuverability
- Unique front-load syringe
- Desk type display control unit
- Imaging system interface
- Injector installation by Medrad 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.

CANON MEDICAL SYSTEMS USA, INC.

TERMS AND CONDITIONS OF SALE

1. <u>TITLE AND RISK OF LOSS</u>. 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. <u>TERMS OF PAYMENT</u>. 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. <u>DELAYS</u>. 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.

EQUIPMENT INSTALLATION. Canon Medical Systems will 4. 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. <u>EQUIPMENT OPERATION</u>. 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.

Canon Medical Systems does not warrant that the operation B. 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 remanufactured. 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. <u>LIMITATION OF LIABILITY</u>. 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. <u>SECURITY INTEREST</u>. 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. <u>**REMOVAL OF EQUIPMENT.**</u> 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.

Made For life

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 Agreement located at: https://us.medical.canon/download/CMI-Capital-License-Agreement which is incorporated herein by reference.

15. <u>CANCELLATION</u>. Customer may not cancel the order subject to this Agreement except with Canon Medical Systems' prior written consent. 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. <u>ASSIGNMENT</u>. 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. <u>ATTORNEY'S FEES AND COSTS</u>. 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. <u>ACCEPTANCE BY CANON MEDICAL SYSTEMS</u>. 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. <u>END USER CERTIFICATION</u>. 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. <u>ENTIRE AGREEMENT</u>. 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.



Novant Health Rowan Regional Medical Center 612 Mocksville Ave Salisbury, NC 28144-2732

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("<u>GE Healthcare</u>"), each as identified below for the sale and purchase of the Products and/or Services identified in this Quotation, together with any applicable schedules referred to herein ("Quotation"). "<u>Agreement</u>" is this Quotation and either: (i) the Governing Agreement identified below; or (ii) if no Governing Agreement is identified, the GE Healthcare Terms and Conditions and Warranties that apply to the Products and/or Services identified in this Quotation. In the event of conflict, the Quotation supersedes.

GE Healthcare can withdraw this Quotation at any time before Customer: (i) signs and returns this Quotation or (ii) provides evidence of Quotation acceptance satisfactory to GE Healthcare ("Quotation Acceptance"). On Quotation Acceptance, this Agreement is the complete and final agreement of the parties relating to the Products and/or Services identified in this Quotation. There is no reliance on any terms other than those expressly stated or incorporated by reference in this Agreement and, except as permitted in this Agreement, no attempt to modify will be binding unless agreed to in writing by the parties. Modifications may result in additional fees and cannot be made without GE Healthcare's prior written consent.

Handwritten or electronic modifications on this Agreement (except an indication of the form of payment, Customer purchase order number and signatures on the signature blocks below) are void.

Governing Agreement:	Novation Vizient Supply LLC
Terms of Delivery	FOB Destination
Billing Terms	80% delivery / 20% Installation
Payment Terms	NET 30
Total Quote Net Selling Price	\$200,037.72
Sales and Use Tax Exemption	No Certificate on File

GE HFS Lease

Please select your planned source of funds. Source of funds is assumed to be cash unless you choose another option. Once equipment has been shipped, source of funds changes cannot be allowed.

____ Cash

__ GE HFS Loan

___Other Financing Loan

Provide Finance Company Name

The parties have caused this Agreement to be executed by their authorized representative as of the last signature date below.

Other Financing Lease

Novant Health Rowan Regional Medic	cal Center
Signature:	
Print Name:	
Title:	
Date:	
Purchase Order Number, if applicable	

GE Precision Healthcare LLC, a GE Healthcare business

Signature: TARA CHAPMAN

Title: Lead Sales Specialist Imaging

Date: December 15, 2022



To Accept This Quotation

Please sign and return this quotation together with your Purchase Order to:

Name: TARA CHAPMAN

Email tara.chapman@ge.com

Phone: 704-640-2778

Fax:

Payment Instructions

Please **remit** payment for invoices associated with this quotation to:

GE Precision Healthcare LLC P.O. Box 96483 Chicago, IL 60693

FEIN: 83-0849145

Novant Health Rowar	Regional Medical Center	Addresses:
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Bill To:	NOVANT HEALTH ROWAN REGIONAL MEDICAL CENTER INC	NOVANT HEALTH ROWAN REGIONAL, MEDICAL CENTER 612 MOCKSVILLE AVE SALISBURY NC, 28144-2732
Ship To	NOVANT HEALTH ROWAN REGIONAL MEDICAL CENTER INC	MEDICAL CENTER 612 MOCKSVILLE AVE NC,28144-2732
То Асс	ept This Quotation	
•	Please sign the quote and any included att	achments (where requested).
•	If requested, please indicate your form of	payment.

- If you include a purchase order, please make sure it references the following information:
 - The correct Quote number and Version number above
 - The correct Remit To information as indicated in "Payment Instructions" above
 - Your correct SHIP TO and BILL TO site name and address
 - The correct Total Price as indicated above

Upon submission of a purchase order in response to this quotation, GE Healthcare requests the following to evidence agreement to contract terms: Signature page on quote filled out with signature and P.O. number **** OR**** Verbiage on the purchase order must state one of the following:

(i)Per the terms of Quotation #_____; (ii) Per the terms of GPO #_____; (iii) Per the terms of MPA# _____: or (iv) Per the terms of SAA #

Include applicable quote/agreement number with the reference on the purchase order. In addition, Source of Funds (choice of Cash/Third Party Load or GE HFS Lease Loan or Third Party Lease through ______), must be indicated, which may be done on the Quote Signature Page (for signed quotes), or the Purchase Order (where quotes are not signed) or via a separate written source of funds statement (if provided by GE Healthcare)."



Catalog Item Details

LineQty.Catalog12.00P1803UDMac-Lab 6.9.6 to BT22 Upgrade

Mac-Lab AltiX BT22 (upgrade from version 6.9.6) Hemodynamic Recording system hardware and software – Advanced system applications for display, recording, analysis and documentation of clinical data and events during adult and pediatric patient hemodynamic studies.

Introducing the ClearView user experience: a contemporary user interface that provides a modern, fresh take on a familiar user experience. ClearView updates include the new ClearView keyboard, wireless barcode scanner, and HD Video package. HD Video provides an enhanced visual experience through updated display monitors, HD video distribution, and the new HD Hub that brings it all together further modernizing the look and reducing the system footprint.

Clinical functionality:

Integrated DFR and FFR algorithms: Integrated Diastolic hyperemia-free ratio and Fractional Flow Reserve Editable phases, Color initiated macros, Valve area analysis, Pull-back pressure analysis, Cardiac Output (FICK and TDCO) calculation

ST Segment software: Real-time review of ST segment changes from user defined baseline during hemodynamic procedures Cath Measurement Display Window: Real-time display of collective measurements acquired during the procedure ETCO2 window - displays ETCO2 waveform, Respiration Rate, Inspiratory and Expiratory values (ETCO2 module/sensor required, sold separately)

DirectConnect introduces further enhancements to system interoperability by providing an open data exchange between Mac-Lab and EMR. DirectConnect updates include a robust HL7 data export now supporting MLLP, an industry standard that sends HL7 to the receiving system in a more adaptable format, system managed .PDF creation and export, ADT import via DICOM MWL, and X-Ray interface.

Built on a foundation focusing on system Security. An in-depth strategy that incorporates Windows® 10 hardening, Microsoft® Security Baselines, increased options for support of Antivirus solutions, encrypted study data in motion and rest, Esignature, and user tracking to ensure maximum protection, keep your network safe and your data private.

Also includes the following catalogs:P1803ACMac-Lab UPG SW OPTIONSP1803CAAltiX BT22 Mac-Lab ComputerP1961CASTANDARD COMPUTER ACCESSORIESP1800SKAltiX BT22 SUPPORT KITP1711CUWireless Barcode ScannerP1701BBHD MONITORS (qty 2)P1711DVHD HubP1711DCHD Hub - CablesP1701TX1000VA ISOLATION TRANSFORMER

Line	Qty.	Catalog	
2	2.00	P1715DF	ClearView English Keyboard

ClearView English keyboard

Line	Qty.	Catalog	
3	2.00	2041390- 001	Masimo SpO2

Line	Qty.	Catalog	
4	2.00	2041390-	MASIMO ENGLISH LANGUAGE
		003	



English, Masimo

Line	Otv.	Catalog	
5	2.00	2041575- 002	60Hz
SW OPT	60HZ POWE	ER LINE FREQU	JENCY PDM
Line	Qty.	Catalog	
6	2.00	2041575-	Software Option Enable Invasive BP
		003	
Line	Qty.	Catalog	
7	2.00	2041390-	Battery
		041	
AIUUII	SATTERY		
Line	Otv.	Catalog	
8	2.00	2041390-	No Bedside Dock
		044	
Bedside I	Dock		
		~	
Line 9	Qty. 2.00	Catalog P1961MB	MLCL PDM Base Station Plus Bed Bail Mount
		ion alua hodaoil.	mount contains the required hardware to mount the DDM have station also to the V ray
table. PD	M mount is s	separate from thi	s offering.
		1	
Line	Qty.	Catalog	
10	2.00	P1961SM	Masimo PDM Accessories with Slim Connect - AHA
MASIMO	PDM ACCI	ESSORIES WIT	H BASE STATION (BASE STATION ETC02 SUPPORT, AHA ECG CABLES-
LEADWI	RES, MASI	MO SP02 FINGI	ER PROBE, CARDIAC OUTPUT CABLE, AND BASE STATION MOUNT)
.	0		
Line 11	Qty. 2.00	Catalog P1961CS	CO2 Sidestream Sensor
Containa	Decnironica	idestreen CO2 -	nodula
Contains	Respironics s	Sucsucalli CUZ II	noune
Line	Otv	Catalog	
12	2.00	P1961UA	120-V UPS
120-V UF	PS		
T •	A :	C (]	
Line	Otv.	Catalog	

ISOLATION TRANSFORMER- PROVIDES POWER ISOLATION FOR SYSTEMS INSTALLED IN PATIENT AREAS.



Line	Qty.	Catalog	
14	2.00	P1803CP	BT22 Pre-Install Kit
The BT22 pr -RJ45 WHIT	re-install kit TE 100FT q	t contains the fol ty 1	llowing:
Line	Qty.	Catalog	
15	2.00	P1961BC	SPEAKER KIT
Line	Qty.	Catalog	
16	2.00	P1701HD	HDMI Audio Kit
HDMI Audio indicator fun	o Kit Incluc actionality	les the HDMI A	udio-Dembedder cabling to connect local and remote speakers for use with audible
Line	Otv.	Catalog	
17	2.00	P1701BB	Widescreen Display
24 inch ultra	slim displa	y monitor with	16:10 aspect ratio and a resolution of 1920 x 1200 pixels.

Line	Qty.	Catalog	
18	2.00	P1711CH	Remote Display Cable Pre-Install Kit - HD

This part is required when ordering a remote display to connect to the Mac-Lab/CardioLab system. One of these will be automatically added for each P1711RD MONITOR AND BOOM ACCESSORIES HD included in the order. This kit contains a 30m HDMI cable, 100 foot power cable and an HDMI to DVI adapter. This kit may be ordered separately for connecting to an LDM if the video connection point is outside of the control room.

Line	Qty.	Catalog	
19	2.00	2016376- 092	INSTL-AFTER HOURS MAC-LAB/CARDIOLAB/COMBOLAB - WEEKEND

Line	Qty.	Catalog	
20	2.00	W0037CD	INVASIVE PRJ MGMT SVCS
		m a t t a a	

INVASIVE PRJ MGMT SVCS

Line	Qty.	Catalog	
21	1.00	P1806UG	INW Server 6.9.6 to BT22 Upgrade

AltiX Invasive Networking (INW) Server upgrade provides the software required to establish the network infrastructure in the Cardiac Cath and EP Labs. The INW server links the Mac-Lab, CardioLab and ComboLab acquisition and client workstations together providing seamless data exchange and replication of lists and macros from one system to another. As well, serves as a central repository of patient studies and waveform data (Cath studies 240,000 |EP Studies 24,000 of typical study sizes). For hardware specifications, please see the GE pre-install manual. Hardware and virtual environment is the responsibility of the customer.



Line	Qty.	Catalog	
22	1.00	W0301CD	TIP Invasive GEHC HQ Training Program
			This training program is designed for customer representatives who have recently
			purchased GEHC Invasive equipment.

This training program is designed for customer representatives who have recently purchased GEHC Invasive equipment. One seat will be provided for a training course held near Milwaukee, Wisconsin at the GE Healthcare Institute. Courses must be scheduled through appropriate GEHC systems. The course includes tuition only. Separate packages may be purchased for travel options. Onsite training days may be available for purchase separately.

All GEHC "Training" terms and conditions apply. Given the unique nature of this program, if this program is purchased as part of a purchase under a Governing Agreement, including any Master Purchase Agreement, Group Purchasing Organization Agreement, or Strategic Alliance Agreement, this program shall take precedence over any conflicting training deliverables set forth therein.

Line	Qty.	Catalog	
23	1.00	W0304CD	TIP Invasive Customer Site Training Program – Upgrade 6
			This training program is designed for customers purchasing upgrades for up to 6
			GEHC Invasive Labs.

This training program is designed for customers purchasing upgrades for up to 6 GEHC Invasive Labs. GEHC will work with the designated Customer contact to agree upon a reasonable training schedule for a pre-defined group of core invasive staff that will leverage blended content delivery and may include a combination of onsite days and virtual offerings. This blended curriculum promotes learner retention and allows for efficient and effective skill development, to include GEHC Answerline and any available on-demand courses ("Virtual Inclusions"). This blended curriculum with multiple delivery platforms promotes learner retention and allows for an efficient and effective skill development.

This program may contain:

- Onsite training (generally 6 days with one trainer)
- Virtual Inclusions may include:
- Remote instructor-led training: Instructor leads a remote training session one-on-one or in a group, typically for 1 hour
- Answerline Support-Access to GEHC experts for clinical, non-emergency applications assistance via phone
- On Demand courses-On healthcare learning system. Self-paced courses and webinars (CE and non-CE).

Training will be delivered at a mutually agreed upon time between the customer and GE Healthcare (excluding GE Healthcare holidays and weekends), are subject to availability and generally will not exceed 6 days. This training program has a term of twelve (12) months commencing on Acceptance, where all onsite training must be scheduled and completed within twelve (12) months of Acceptance and all Virtual Inclusions also expire at the end of such twelve (12) month period. Additional onsite days may be available for purchase separately.

All GEHC "Training" terms and conditions apply. Given the unique nature of this program, if this program is purchased as part of a purchase under a Governing Agreement, including any Master Purchase Agreement, Group Purchasing Organization Agreement, or Strategic Alliance Agreement, this program shall take precedence over any conflicting training deliverables set forth therein.

Line	Qty.	Catalog	
24	1.00	W0320ALL	TRAVEL PACKAGE AIRFARE

The travel airfare package is intended to allow customer the convenience of prepaying its roundtrip airfare expenses when attending a Clinical Education course at the GE Healthcare Institute. If customer stays at a GE Healthcare-designated hotel, transportation to and from the airport will be provided by the hotel. If customer stays at a non-GE Healthcare designated hotel, customer is responsible for its transportation. Customer must make its travel arrangements through a designated GE Healthcare representative. Directions will be provided to customer upon confirmation of training course. The package will expire 12 months from purchase.



December 15, 2022 Quote Number: **2006699364.8** Customer ID: **1-23I3FR** Agreement Expiration Date: **02/13/2023**

This meals and lodging package is intended to allow customer the convenience of prepaying some of its meals and lodging expenses when attending a Clinical Education course at the GE Healthcare Institute. Price is based on a per day basis. Lodging will be at a GE Healthcare-designated hotel. Breakfast is provided by the hotel and lunch is provided at the GE Healthcare Institute. Dinner and weekend meals are customer's responsibility. Transportation to and from the airport and to and from the GE Healthcare Institute is provided by the GE Healthcare-designated hotel. Customer must make its travel arrangements through a designated GE Healthcare representative. Directions will be provided to customer upon confirmation of training course. GE Healthcare will not provide reimbursement for meals not included or for students that fail to comply with directions. The package will expire 12 months from purchase.

Total Quote Net Selling Price: \$200,037.72

If applicable, for more information on this devices' operating system, please visit GE Healthcare's product security portal at: <u>https://securityupdate.gehealthcare.com/en/products</u>



December 15, 2022 Quote Number: 2006699364.8 Customer ID: 1-23I3FR Agreement Expiration Date: 02/13/2023

GPO Agreement Reference Information

Customer:	Novant Health Rowan Regional Medical Center
Contract Number:	Novation Vizient Supply LLC
Billing Terms:	80% delivery / 20% Installation
Payment Terms:	NET 30
Shipping Terms	FOB DESTINATION

Offer subject to the Terms and Conditions of the applicable Group Purchasing Agreements currently in effect between GE Healthcare and Novation Vizient Supply LLC

If applicable, for more information on this devices' operating system, please visit GE Healthcare's product security portal at: <u>https://securityupdate.gehealthcare.com/en/products</u>

This product offering is made per the terms and conditions of Vizient /GE Healthcare GPO Agreements as follows:

Imaging:

XR0882-MR, XR0702-Card./Vasc., XR0673-CT, XR0342-Mammo, XR0895-PET-CT, XR0362-Nuc Med, XR0715-R&F/RAD & XR0592-ICAR-EP/HEMO, XR0692-BMD

Ultrasound: XR0918-Ultrasound

LCS:

CE2512 (Anesthesia), CE7633 (Monitoring), CE3333 (Infant Care), CE7621 (DCAR) and CE0351 (EP).

Vizient: Please login to the Vizient Marketplace Website. If you require assistance or are experiencing issues, please contact Vizient for support: Email: <u>Connect@VizientInc.com</u> and Phone: 866-600-0618.



Proposal

Connor Check connor.check@stryker.com December 19, 2022

Stryker Communications 571 Silveron Blvd. Flower Mound, TX 75028 Tel: 1 877 789 8106 Fax: 1 408 754 2969

Submitted To: NOVANT HEALTH ROWAN MED CTR

Room: EP Lab 2



S-Series Standard Equipment Management System

Introducing a new standard in equipment management. With a completely redesigned user interface and a compact, fully customizable system, it has never been easier to manage your services and maneuver your equipment.

PART #	DESCRIPTION	N Contraction of the second seco		QTY
SMS-2	S-SERIES, ST/	ANDARD MANUAL, 2 ROW, 2 ARM		1
Mounting Details	Shelves	High Voltage Services	Additional Cables	Gas Services
Mounting Plate: Single Common Plate	Shelves: 0	20A/125V Duplex (6 Outlets): 2		Gas Manufacturer: Beacon Medaes
Ceiling Cover: Standalone				Gas Fitting Type: D.I.S.S.
Brake System: Friction		Low Voltage Services		Air Gas: 2
		Blank Plate: 3		Vac Gas: 2
MFR Configuration		Data Pass Thru Plate: 1		N20 Gas: 1
Front MFR Length: 406mm				O2 Gas: 2
Rear MFR Length: 531mm				WAGD Gas: 1
MFR Controls: Front Only				
PART #	DESCRIPTION	1		QTY
P33102	FAIRFIELD A	CCESSORY RAIL KIT, DUAL MFR,		2
Configu	uration Total:			

stryker iSuite Installation

PART #	DESCRIPTION	QTY
RS 0006010	TELETOM INSTALLATION	1
888888401	INSTALLATION-IMPLEMENTATION STAGING CHARGE	1
888888900	PROJECT SERVICES	1
	PRE-INSTALL HARDWARE	
Installation Total		

Project Payment Terms		Discounted Communications Total:	\$20,281.00
Deposit - Required Immediately (100%):	\$20,281.00	Price does not include applicable taxes and shipping	g
Upon Delivery (0%):	\$0.00		
Upon Completion (0%):	\$0.00	Communications Estimated Shipping:	Not included
		Freight Terms:	Prepay & Add

This quote proposal is in accordance with Vizient Contracts CE7202 (Booms, Lights) and/or CE7213 (OR Tables). Referencing the GPO contract number on your Purchase Order is required for contracted Terms and Conditions to apply.

From:	<u>Griffin, Lisa L</u>
То:	<u>Griffin, Lisa L</u>
Subject:	Re: Removal of Existing RMC Cath Lab Equipment
Date:	Tuesday, January 17, 2023 1:29:00 PM

From: Thomas Scheatzle <<u>tscheatzle@us.medical.canon</u>>

Sent: Monday, January 16, 2023 8:37 PM

To: Haynes, Marty <<u>mhaynes@novanthealth.org</u>>

Subject: Re: can you please send me an email stating as part of the acquisition at Rowan, Canon is removing the old unit

External Email: Use Caution opening links or attachments

Marty,

The Novant Health Rowan Medical Center existing Canon Infinix lab will be removed by Canon Medical Systems, USA as part of our Encore + upgrade Customer Loyalty upgrade program.

Please let me know if I can help with anything else.

Respectfully,

Thomas P. Scheatzle Sr. Account Executive Canon Medical Systems USA, Inc. | Sales 2441 Michelle Drive, Tustin, CA 92780 M 803-767-8755 | eFax 706-243-4947 E tscheatzle@us.medical.canon | W us.medical.canon

ATTACHMENT B

Projected Capital Cost Form NH Rowan Medical Center Cath Lab 2 Replacement

Building Purchase Price	NA
Purchase Price of Land	NA
Closing Costs	NA
Site Preparation	NA
Landscaping	NA
Construction/Renovation Contract(s)	\$ 965,927
Architect / Engineering / DHSR Fees	\$ 79,728
Medical Equipment	\$ 1,155,117
Non-Medical Equipment	\$ -
Furniture	\$ 67,557
DPS/IT Systems	\$ 20,540
Financing Costs	\$ -
Other: (Identify)	\$ -
Other: Contingency	\$ 88,589
Total Capital Cost	\$ 2,377,458

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

I certify that, to the best of my knowledge, the projected construction costs for the proposed project is complete and correct.

-DocuSigned by:

Mlson Soggs E068402B9A574A

Date Signed: 01/11/2023 | 12:19:04 EST

Signature of Licensed Architect or Engineer Soggs Design

CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

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

DocuSigned by:		
Matthew Stiene 9BCFAC883516459	Date Signed:	01/11/2023 1:58:09 EST
Signature of Officer/Agent		

Senior Vice President, Construction & Facilities Svcs, Novant Health

Title of Officer/Agent

ATTACHMENT C



Salisbury, NC 28144

704-210-5000 • NovantHealth.org









ATTACHMENT D



North Carolina Department of Health and Human Services Division of Health Service Regulation Certificate of Need Section

2704 Mail Service Center Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor Lanier M. Cansler, Secretary www.ncdhhs.gov/dhsr

Craig R. Smith, Section Chief Phone: 919-855-3873 Fax: 919-733-8139

April 28, 2011

Lisa L. Griffin Manager, Certificate of Need Novant Health, Inc. 2085 Frontis Plaza Blvd. Winston-Salem, NC 27103

RE: Exempt from Review/ Replacement Equipment/ Rowan Regional Medical Center/ Replace existing cardiac catheterization lab equipment / Rowan County

Dear Ms. Griffin:

In response to your letter of March 22, 2011, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, Rowan Regional Medical Center may proceed to acquire, without a certificate of need, the Toshiba Infinix VF-I/SP system to replace the existing Siemens Axiom Artis MP unit, serial number 5436. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further, please be advised that as soon as the replacement equipment is acquired you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update inventory, if not already provided.

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Paula Quirin, Project Analyst Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR Construction Section, DHSR

Craig R Smith, Chief Certificate of Need Section



ATTACHMENT E

All responses should pertain to October 1, 2020 through September 30, 2021.

8. Specialized Cardiac Services *continued* (for questions, call Healthcare Planning at 919-855-3865)

b. Cardiac Catheterization and Electrophysiology

Cardiac Catheterization, as defined in NCGS 131E- 176(2g)	Diagnostic Cardiac Catheterization**	Interventional Cardiac Catheterization***		
1. Number of Units of Fixed Equipment	1			
2. Number of Procedures* Performed in Fixed Units on	0	0		
Patients Age 14 and younger				
3. Number of Procedures* Performed in Fixed Units on	11011	AFII		
Patients Age 15 and older	404	706		
4. Number of Procedures* Performed in Mobile Units	0	0		
Dedicated Electrophysiology (EP) Equipment				
5. Number of Units of Fixed Equipment	Ö			
6. Number of Procedures on Dedicated EP Equipment	120	P		

A EP Procedures are performed predominately in the Vascular bab, There is not a dedicated EP room. *A procedure is defined as one visit or trip by a patient to a catheterization laboratory for a single or multiple catheterizations. Count each visit only once, regardless of the number of diagnostic, interventional, and/or EP catheterizations performed during that visit. For example, if a patient has both a diagnostic and an interventional procedure in one visit, count it as one interventional procedure.

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

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

Number of fixed or mobile units of <u>grandfathered</u> cardiac catheterization equipment owned by hospital (i.e., equipment obtained before a CON was required):

For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.

CON Project ID numbers for all <u>non-grandfathered</u> fixed or mobile units of cardiac catheterization equipment owned by hospital:

Name of Mobile Vendor, if not owned by hospital: N(A)

Number of 8-hour days per week the mobile unit is onsite: ______8-hour days per week. (Examples: Monday through Friday for 8 hours per day is 5 8-hour days per week. Monday, Wednesday, & Friday for 4 hours per day is 1.5 8-hour days per week)

ATTACHMENT F

EQUIPMENT COMPARISON

NH Rowan Medical Center Cath Lab Replacement	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	Cardiac Cath Lab System	Cardiac Cath Lab System
Manufacturer	Toshiba	Canon
Model number	Infinix	Alphenix Core Plus
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	03462	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2012	TBD
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 < Attach a signed Projected Capital Cost form for New Equipment>	\$1,099,982	\$ 2,377,458
Total cost of the equipment	\$739,900	\$ 1,155,117*
Location of the equipment < Attach a separate sheet for mobile equipment if necessary>	NH Smith Heart & Vascular Institute	NH Smith Heart & Vascular Institute
Document that the existing equipment is currently in use	See LRA	See LRA
Will the replacement equipment result in any increase in the average charge per procedure?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the average operating expense per procedure?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment <attach a="" if="" necessary="" separate="" sheet=""></attach>	Cardiac Catheterization	NA
Type of procedures the replacement equipment will perform <attach a="" if="" necessary="" separate="" sheet=""></attach>	NA	Cardiac Catheterization

* Total Equipment = \$ 934,798 Canon Cath System + \$ 200,038 GE MacLab + 20,281 Stryker Equipment = \$ 1,155,117

From:	Griffin, Lisa L
To:	Donihi, Donna D
Cc:	Stancil, Tiffany C; Cremeens, Cameron L
Subject:	[External] NH Rowan Cath Lab Replacement Equipment Exemption Notice
Date:	Tuesday, January 17, 2023 2:38:47 PM
Attachments:	RMC Cath Lab REER to Agency Jan 2023.pdf

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to <u>Report Spam.</u>

Good afternoon,

Attached is a replacement equipment notice for a cardiac catheterization lab at NH Rowan Medical Center.

Please let me know if you have any questions or need additional information.

Thank you,

Lisa Griffin

Manager, Strategic Planning Novant Health | Internal Consulting Group (704) 351 – 1132

We are here to help you get the care you need. Visit <u>Novant Health</u> for up-to-date information.

Estamos aquí para ayudarle con el cuidado que usted necesita. Visite <u>Novant Health</u> para información actualizada.

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