



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

December 14, 2021

Andrea Gymer
amgymer@novanthealth.org

Lisa Griffin
llgriffin@novanthealth.org

Exempt from Review – Replacement Equipment

Record #: 3754
Date of Request: December 8, 2021
Facility Name: Novant Health Forsyth Medical Center
FID #: 923174
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Replace existing cardiac catheterization equipment (Lab #3)
County: Forsyth

Dear Ms. Gymer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the GE Innova IGS 5 system to replace the existing Siemens Medical Axiom Artis 24241 cath lab, NH ID #50969778. 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,

Celia C. Inman
Celia C. Inman
Project Analyst

Micheala Mitchell
Micheala Mitchell
Chief

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



December 8, 2021

2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

Via Email

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

Re: Novant Health Forsyth Medical Center
Replacement of Cardiac Catheterization Equipment (Lab #3)
FID: 923174; Forsyth County

Dear Ms. Inman:

Novant Health Forsyth Medical Center (“NHFMC”) intends to replace an existing cardiac catheterization equipment currently located at the main campus of NHFMC in Winston-Salem, North Carolina. The existing cardiac catheterization equipment is past its useful life having been acquired in 2005. Therefore, NHFMC will acquire a new GE Innova IGS 5 system. See **Attachment A** for the Equipment Quote which includes the cost of an injector. As part of the equipment cost, the vendor will provide onsite clinical training for the equipment. The total capital cost for the proposed replacement equipment project is estimated to be \$1,272,602. See **Attachment B** for the Projected Capital Cost Form.

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) NHFMC will replace the existing cardiac catheterization 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.
- (4) NHFMC seeks to replace comparable medical equipment currently in use at project cost less than \$2 million.
- (5) The existing equipment was not purchased second-hand nor was the existing equipment leased.
- (6) The existing equipment will be removed from North Carolina.

Ms. Celia Inman
December 8, 2021
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In support of our request, please find attached:

- Attachment A** – Vendor Equipment Quote
- Attachment B** – Project Capital Costs Form
- Attachment C** – NC CON Equipment Comparison Form
- Attachment D** - Excerpt of 2021 License Renewal Application

The Equipment Comparison is included as **Attachment C**. The most recent License Renewal Application is attached as **Attachment D** to document that this cardiac catheterization lab is still in use. It is one of eight CON-approved cardiac catheterization labs located at NHFMC including one recently approved to be relocated to Novant Health Kernersville Medical Center (Project ID # G-12031-21).

NHFMC'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 \$1,272,602. 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 NHFMC's replacement equipment request does not constitute a new institutional health service and is exempt from certificate of need review.

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

Sincerely,



Lisa Griffin
Manager, Strategic Planning

Enclosures

ATTACHMENT A



November 4, 2021
 Quote Number: **2007233227.7**
 Customer ID: **1-23HYCC**
 Agreement Expiration Date: **02-Feb-22**

Novant Health Forsyth Medical Center
 3333 Silas Creek Pkwy
 Winston Salem, NC 27103-3013

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), 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"). "Agreement" 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	\$755,520
Sales and Use Tax Exemption	No Certificate on File

IMPORTANT CUSTOMER ACTIONS:

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
- GE HFS Lease
- Other Financing Loan
- Other Financing Lease
- Provide Finance Company Name

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

Novant Health Forsyth Medical Center

Signature: _____

Print Name: _____

Title: _____

Date: _____

Purchase Order Number, if applicable

GE Precision Healthcare LLC, a GE Healthcare business

Signature: Herb Klann

Title: Sr Sales Manager Imaging

Date: November 4, 2021



November 4, 2021
 Quote Number: **2007233227.7**
 Customer ID: **1-23HYCC**
 Agreement Expiration Date: **02-Feb-22**

To Accept This Quotation

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

Name: Herb Klann
Email herb.klann@ge.com
Phone: 724-504-8778
Fax:

Name: Jeffrey Nottingham
Email: jeffrey.nottingham1@ge.com
Phone:
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 Forsyth Medical Center

Addresses:

Bill To: NOVANT HEALTH FORSYTH MEDICAL CENTER

NOVANT HEALTH FORSYTH, MEMORIAL HOSPITAL 3333 SILAS CREEK PKWY WINSTON-SALEM, NC, 27103-3013

Ship To: NOVANT HEALTH FORSYTH MEDICAL CENTER

MEMORIAL HOSPITAL 3333 SILAS CREEK PKWY WINSTON SALEM, NC, 27103-3013

To Accept This Quotation

- Please sign the quote and any included attachments (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



November 4, 2021
Quote Number: **2007233227.7**
Customer ID: **1-23HYCC**
Agreement Expiration Date: **02-Feb-22**

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

Line	Qty.	Catalog	
1	1	S18921ER	IGS 520 with AutoRight™ configuration with Omega V Table

The Innova IGS 5 with AutoRight™ in its below described IGS 520 configuration with Omega V table unites image quality, an optimal panel size and built-in protocols for imaging versatility, making it suitable for a full range of Interventional X-ray procedures, such as cardiac, electrophysiology and general vascular diagnosis and intervention.

Innova IGS 5 with AutoRight™ Positioner

The Innova IGS 5 with AutoRight™ combines GE's exclusive Innova LC Positioner with an ergonomically designed tableside user interface to provide easy access and control of critical features during an exam. Its patented three-axis isocentric positioner design with floor mounted L-arm and offset C-arm provides maximum positioning flexibility and excellent patient access in all views. The rigid, floor-mounted construction provides minimum vibration and deflection during acquisitions. The three motor-driven axes make even the most complex angulations easy to achieve.

AutoRight™ : Intelligent Image Chain Powered by Edison

AutoRight is the industry's first AI-driven, neural network-based image chain powered by Edison and digital twin, including embedded applied intelligence and advanced modelization featuring a complete re-design of GEHC IGS image chain.

AutoRight, is designed to deliver repeatable & faster choices, making image optimization fully automated, dynamically throughout the entire procedure, from acquisition, to processing and display, regardless of patient size, anatomy or C-arm angulations, which helps remove the burden of manual adjustment.

AutoRight is the right platform to address the growing demand for full combination capabilities in the interventional suite.

AutoRight's live parameter optimization provides consistent image quality with the patient's arms down throughout the whole spin. Not only is the image quality of these difficult acquisitions consistent and repeatable, which can reduce dose exposure, but it also enables the use of advanced applications such as virtual injection planning in 3D and the ability to simulate therapy efficacy.

Overall, it allows the clinical team to better plan for, guide, and assess complex procedures in their daily practice.

AutoRight makes the machine an integral part of the team, capable of relieving clinicians and technologists of the tedious yet complex task of optimizing IQ and dose, helping them focus all their attention and expertise on their patients.

GE Revolution digital flat panel detector

The IGS 520 configuration unites image quality, optimal panel size (20.5 cm x 20.5 cm/8 in x 8 in) for cardiac procedures and built-in protocols for imaging versatility, making it suitable for a wide range of minimally invasive procedures.

The digital detector uses an amorphous silicon photodiode array on a continuous-substrate, single-piece panel with no inherent seams.

The digital detector (20.5 cm x 20.5 cm/8 in x 8 in), is comprised of a 1024 x 1024 array of imaging elements or pixels on a 200-micron pitch. Scintillator thickness and electronic noise are optimized to produce extremely high detective quantum efficiencies, both at high exposures and at fluoroscopic doses.

Image Processing

The detector can translate the widest possible range of X-ray exposure intensities into digital signals without saturation. The system is configured with a removable anti-scatter grid to maximize image quality during routine imaging.

Proprietary DRM image processing transforms this information for display without loss of detail over a wide range of anatomical densities. Moreover, organs in motion generate image blurring but thanks to High contrast fluoro option coming with PCI ASSIST package, that blurring is significantly reduced while the dose is equivalent.

With excellent performance in low-dose fluoroscopy as well as high-dose exposures, the IGS 520 advances GE's leadership in flat-panel imaging. The wide dynamic range of the detector, coupled with 14-bit acquisition and patented image processing, enables excellent visualization of low-contrast objects. Detective Quantum Efficiency (DQE), an important measurement of information capture, is taken to a new level with the Innova detector design.

X-RAY Tube

The Innova IGS 5 with AutoRight™ uses a 100 kW high-frequency Jedi three-phase power unit that provides grid pulsed fluoroscopy capability.

Automatic X-ray technique calculation provides a tube-rating chart that calculates maximum exposure time based on the selected protocol, kV, mA, focal spot and available heat units.

Fluoroscopy and radiography exposure times and mA are automatically controlled by the dynamic exposure optimization system. The range of mA is limited by X-ray tube ratings and regulatory limits. A fluoroscopic timer captures the fluoroscopic procedure

time (reset time is every five minutes).

The Omega V table

The Omega V table is the long version motorized table. It supports a load up to 304 kg and allows imaging coverage with table panning up to 187cm with table dimension: 333cm in length and 46cm in width.

User interface

- SmartBox or SmartHandle (A second SmartBox or SmartHandle can be added at tableside or in the control room) provide simple gantry and table motion access throughout the exam. SmartBox or SmartHandle control system motions, disable/enable patient contouring, system lock/unlock and emergency stop.
- The TSSC provides simple access to key acquisition and review parameters throughout the exam. A second TSSC can be added at tableside or in the control room.
- The Central Touch Screen lets the user control the system functions as well as integrated equipment.
- To provide more AW capabilities at tableside, an optional interface kit enabling to connect an in room wireless mouse to drive the AW from table side is available.
- The IGS system fluoro/acquisition footswitch can optionally come as wireless footswitch.
- Smart Nav is an innovative solution to control some system functionalities from tableside and from the control room. It allows fast function access in displaying menu controls on the reference monitor upon user request. With Smart Nav, the user can keep his/her attention on the screen monitors where clinical images are also displayed. Smart Nav is controlled from the Central Touch Screen, local keypad or remote keypad, providing intuitive and context-based navigation.
- Fluorostore stores, displays, and plays loops of the last 450 (up to 900) fluoro images at the push of a button for streamlined image review, helping to avoid extra images and exposure.
- In Room Browser display the sequences previously acquired on the in-room monitor for interactive table-side selection and review.

The Innova IGS 5 with AutoRight™ system facilitates image management and workflow using standard format and communication protocols.

It also features close integration with the AW and CA1000 workstations to provide advanced image review and processing capabilities.

- Acquisition of data at 14 bits
- Dynamic and chase images stored in 8 bits, maximum 450 images per sequence. Storage capacity: 136,000 dynamic and chase images
- DSA images with 12 bits data stored in 16 bits, maximum 450 images per sequence. Storage capacity: 68,000 DSA images
- DICOM image output on 100Mbit Ethernet with Autosend and background transfer for fast transmission with minimal user interaction.
- Capability to do full resolution 1024 x 1024 DICOM push to retain image quality at acquisition (configurable to 512 x 512 for cardiac acquisitions and 512 x 512 x 256 x 256 x 256 for 3D imaging).
- Patient Worklist capability provides a single point of entry of patient data, increasing staff productivity and eliminating clerical errors: patient information can easily be imported into the digital system from information systems that support DICOM Worklist ServiceClass Provider.
- Multi-destination Push enables images to be sent to multiple remote DICOM destinations sequentially (one after another). Multi-destination helps to support a clinical scenario of handling post processing and archival activities in multiple destinations independently of each other (workstation, PACS). MPPS: Modality Performed Procedure Step allows to share the main exam parameters with the hospital information system.
- For the 3DCT / 3DCT HD option, users can direct-push the 3D acquisition directly to the pre-configured AW, even if the images of the exam are pushed to a PACS or another archiving system.

Line	Qty.	Catalog	
2	1	S18061TP	SMART BOX

SmartBox for Innova IGS with Omega Tables
 New SmartBox for Simplified and Intuitive Joystick Control of Positioner and Table

- Anatomical and mechanical positioning
- Independent or simultaneous movement of all three positioner axes
- Remote SID Control
- Manual or motor assisted 4-way table panning
- Ergonomic design

-Hermetically sealed

Line	Qty.	Catalog	
3	1	S18061EH	Wireless Footswitch Monoplane

Line	Qty.	Catalog	
4	1	S18061MB	2 Inch Comfort Table Mattress

2 Inch Comfort Table Mattress

Line	Qty.	Catalog	
5	1	S18461QM	Clear image - Large Display Monitor with 16 inputs

The GE Large Display Monitor (LDM) is an in-room primary monitor designed to streamline procedure workflow. It includes a video server solution and is fully integrated with the Central Touch Screen at tableside. It also includes a quantity of 2 monitors 48cm (19inch), the AW linkset, the recording system linkset and a quantity of 2 open linkset (Optical Extender DVI/HDMI that allows to connect any Digital 3rd party system and display its images on the LDM).

GE Large Display Monitor specifications:

Diagonal 148 cm (58in)

ActiveDisplay 127 x 72 cm

Display matrix 8 megapixels 3840 x 2160-pixelarray

Calibrated Brightness 400cd/m² Viewing angles 176°, 176° (typical)

Frequency 59.7–60.3 Hz

Contrast ratio At least 3500:1

Video inputs: 16 video inputs. 6 inputs for Live, Reference, AW and optional subtracted Fluoro monochrome signals as well as for a wide variety of other video signals usually used in an interventional environment - including 3 free open inputs compatible with VGA and DVI video formats.

Layouts: up to 200, Organized into user or application groups, Digital zoom (up to 200%)

User interface: Layouts are selectable from the Central Touch Screen

Back-up monitors 48 cm (19 in) live and reference monitors attached at the back of the LDM or on another suspension

Line	Qty.	Catalog	
6	1	S18391PM	Mavig Monitor Suspension for Large Display Monitor with 36m Cable

Mavig Monitor Suspension for Large Display Monitor with 36m Cable

Line	Qty.	Catalog	
7	1	S18461LV	LINKSET IVUS

Link Set for IVUS Volcano

Line	Qty.	Catalog	
8	1	S18461LG	LINKSET DIGITAL and ANALOG US

Link Set for Digital and Analog Ultrasound

Line	Qty.	Catalog	
9	1	S18461AD	ANALOG TO DIGITAL CONVERTOR KIT

Analog to Digital Converter Kit

Line	Qty.	Catalog	
10	1	S18771FV	Large Display Monitor Protective Screen

Line	Qty.	Catalog	
11	2	S18461LZ	LINKSET OPEN1

This kit includes a DVI/HDMI Optical Extender that allows to connect any Digital 3rd party system and display its images on the Large Display Monitor. Suitable for anesthesia monitors, camera, etc.

Line	Qty.	Catalog	
12	1	S18061EB	2nd IP8X Ed3 Footswitch for control room

2nd IP8X Ed3 Footswitch for control room

Line	Qty.	Catalog	
13	1	S18461JB	Additional Ctrl Room 48 cm-19 inch Live LCD HB Monitor - with pedestal

Additional Ctrl Room 48 cm-19 inch Live LCD HB Monitor - with pedestal

Line	Qty.	Catalog	
14	1	S18921LA	Dose and Workflow Optimization Package for IGS 520

Dose & IQ Optimization Package

A package that includes the following features: InnovaSense - InnovaSense is an advanced patient contouring technology that uses an intelligent algorithm during gantry motion to select the optimal position for the image receptor relative to the patient. By reducing the distance from receptor to patient, the system optimizes imaging geometry and helps reduce radiation exposure. The user also can position both the gantry and detector with one integrated operation. Capacitive sensor technology and optimized collision avoidance software enable a speed of pivot and C-arm, of up to 20 per second.

Dose Map - Dose Map is a feature used to calculate, display and record an estimated local cumulated dose during procedures done on the GE X-Ray angiographic system. It is designed to provide to the user a visualization of the distribution of the local cumulated

dose all throughout the exam as well as the current projection of the beam. The local dose is calculated depending on the estimated air kerma, the gantry position, the table position, the table estimated attenuation, the estimated backscatter correction and the system settings. Calculation and cumulated local dose are updated for each acquisition and displayed upon user request or upon configured threshold. The cumulated air kerma display remains the reference for dose management.

Line	Qty.	Catalog	
15	1	S18811PA	Analysis Package

Quantitative Analysis Package

Stenosis Analysis Package on DL Digital System

The Stenosis Analysis Package is an application designed for estimating vessel dimensions and relevant parameters of the arterial Stenosis morphology in X-Ray angiography. The system is capable of automatic detection of vessel edges and display of stenosis severity.

Left Ventricular Analysis Package

The Left Ventricular Analysis Package is an expert reporting tool designed to estimate wall motion dynamics of the left ventricle, and to perform Global Ejection Fraction Analysis in X-Ray angiography. The system is capable of providing Wall Motion and Global Ejection Fraction measurements. Wall Motion is built on the centerline method.

GEF analysis is calculated using both Simpson's rule method and the Dodge-Sandler area-length method

Cardiovascular Analysis Package (on DL system)

The Cardiovascular Analysis Package includes both the Stenosis Analysis Package and the Left Ventricular Analysis Package.

The Stenosis Analysis Package is an application designed to estimate vessel dimensions and relevant parameters of the arterial Stenosis morphology in X-Ray angiography. The system is capable of automatic detection of vessel edges and display of stenosis severity.

The Left Ventricular Analysis Package is an expert reporting tool designed to estimate wall motion dynamics of the left ventricle, and to perform Global Ejection Fraction analysis in X-Ray angiography. The system is capable of providing Wall Motion and Global Ejection Fraction measurements (GEF). Wall Motion is built on the centerline method.

GEF analysis is calculated using both Simpson's rule method and the Dodge-Sandler area-length method.

Line	Qty.	Catalog	
16	1	S18921LE	PCI Assist

PCI ASSIST is a commercial package that includes the following features:

High Contrast Fluoro - Organs in motion generate image blurring, which can make it difficult to assess the size of the lesion as well as stent deployment. To overcome this challenge, we increased the mA peak up to 36%, and decreased the pulse width by 25%. While the dose is equivalent, it is delivered in an efficient way that helps significantly reduce the blurring in the image due to organ motion.

StentViz - StentViz enhances visibility of the stent structure. It is particularly useful in verifying placement and deployment of stents during coronary interventions where moving arteries could make visibility challenging. StentViz processing is fully automated and can be launched at the press of a button on the Central Touch Screen at tableside. The result is automatically displayed on the reference monitor and shows two zoomed and enhanced images of the stent: One with the guidewire in view and a second one with the guidewire subtracted out in the area between the two balloon markers to allow excellent visualization of the stent struts or borders.

StentVesselViz - StentVesselViz Being able to see the position of stent into the vessel is especially critical in cases of complex clinical situations such as bifurcations or calcified lesions. A complete apposition of stent onto vessel wall can contribute to prevent stent thrombosis & restenosis. StentVesselViz improves the user confidence in the assessment of the position, correct deployment and shape of the stent in relation with the vessel in 2D versus cine. Thanks to an intuitive workflow, StentVesselViz is operated smoothly and can help the user position and expand stent The StentVesselViz option delivers from a single acquisition a StentViz image and then the fusion of this one with an image of the injected vessel. Those two images are automatically fading together for optimized and simultaneous visualization of stent into the vessel pre and post deployment.

Line	Qty.	Catalog	
17	1	S18761PS	Power distribution unit - Main transformer 24KVA

Line	Qty.	Catalog	
18	1	S1875PK	FLUORO UPS 20 KVA UL

GE Digital Energy 20KVa UPS for Innova Systems

Line	Qty.	Catalog	
19	1	S18101AT	TEMPLATE

TEMPLATE

Line	Qty.	Catalog	
20	1	S18101AJ	Base Plate LC - Through Floor Kit

Base Plate LC - Through Floor Kit

Line	Qty.	Catalog	
21	1	S18111BD	Long In Board Monitor Bridge with long rails GEMSAM

9'6- INBOARD MONITOR BRIDGE

Line	Qty.	Catalog	
22	1	S18121RD	228 by 578CM I.B RAILS

In Board Rails, 228 inches long, to be used with LCD Monitor Suspensions

Line	Qty.	Catalog	
23	1	E3053JA	Mavig Single Pivot Lower Body Protector

Mavig Single Pivot Lower Body Protector Provides convenience, flexibility and enhanced protection for medical personnel. Helps shield technicians against scatter radiation from sources beneath the tabletop and also helps to protect the lower extremities. Flexible 0.5 mm lead equivalent curtains attached to aluminum alloy pivoting arm. The entire lower body protector can be easily and quickly removed from the table. Warranty Code H- 6 Months: Exchange of non-conforming products, which you return to us during the warranty period. Note: Installation, parts, applications training and on-site service is the buyer's responsibility. • One-piece economical model offers enhanced protection • Comes with single joint adapter • Measures 45 cm W W 73 cm L (18 W 29 in.) Upper portion is 17 cm H (7 in.)

Line	Qty.	Catalog	
24	1	E3053CH	Contour Shield 76 x 61 cm - with center connect

Contour Shield 76 x 61 cm (with center connect)

Line	Qty.	Catalog	
25	1	E3053BC	Mavig Portegra2 360 Trolley with Ceiling Column - 58cm

Portegra2 3600 Ceiling Column w/ Carriage 58 cm

- Lower post allows 3600 rotation
- Upper fixed post is electric with 3300 rotation
- Each has a load capacity of 18 kg (40 lbs.)

Line	Qty.	Catalog	
26	1	E7018JZ	Mavig 2.5m Track without Cable Spooler

Mavig 2.5m Ceiling Track without Cable Spooler

The Ceiling Track is suited for use of ceiling guided accessories, including radiation protective shields, lamps, injectors, monitors, and other equipment.

FEATURES AND BENEFITS

- The unique structure profile ensures smooth running of the carriage
- With little force, the installed system can be moved and positioned
- The carriage glides smoothly, even after many years of routine use
- Adjustable cross-struts simplifies the system installation

Line	Qty.	Catalog	
27	1	E3053CC	2.5m Cable Spooler

Mavig 2.5m Cable Spooler for R-96 & Mach 3 Lamp

This Mavig cable spooler is used when the R-96 or Mach 3 lamp is track-mounted. The spooler yields and retracts the electrical cable as the lamp travels along the track, eliminating all dangling and tangled power supplies. Warranty Period- 6 months- Exchange of non conforming products, which are returned to GE during warranty period Note: Installation,parts,application training

and on-site service are the buyer's responsibility

Line	Qty.	Catalog	
28	1	E3053CM	Cable Holders and Stoppers for Ceiling Track

TS10B04 Cable Holders and Stoppers for 2.5m Ceiling Track (TS1001) to support the Video Monitor/Injector Head cables (Qty 3 Cable Holders)

Line	Qty.	Catalog	
29	1	E4502SS	NR - X-Ray Warning and Room Lighting Control Panel

The X-Ray in use Warning and Room Lighting Control Panel provides an interface between the X-Ray in use warning lights, interior room general lighting, and the X-Ray system. The X-Ray in use portion of the panel provides low voltage control of the X-Ray in Use Warning Lights and the room general lighting is controlled by a pre-wired foot switch

- Designed and tested for GEHC products, for use in CT, PET/CT and X-Ray applications
- Can eliminate procurement inconveniences and delivery delays often associated with acquiring individual components
- Improves servicing safety by the eliminating of the warning light/room general lighting circuit from the imaging control system cabinet. NOTES:
- Customer is responsible for rigging and arranging for installation with a qualified party
- ITEM IS NON-RETURNABLE AND NON-REFUNDABLE

Line	Qty.	Catalog	
30	1	E46001BD	MDP UL OHSPD 480V 60Hz 3 phases for Innova Cerber B systems

The MDP (Main Disconnect Panel) serves as the main power disconnect between the PDU (Power Distribution Unit) of a GE Interventional system and its optional Fluoro UPS, 20 kVA (if present), and the facility power source. The optimally designed MDP saves time, installation labor, and valuable mounting space by consolidating the main circuit breaker, control power source and required warning lights provisions into a compact factory manufactured panel. The panel provides short circuit protection, overload protection and National Electrical Code and Canadian Electrical Code required emergency shutdown for the system. It provides LOTO (lock out/tag out) functions for safe service operation and is part of the EPO (Emergency Power Off) function.

Applications

For general installations of validated Interventional systems, including the Innova IGS 5, Discovery IGS 7 and IGS 6 AutoRight version. It is not compatible with older generations of GE Interventional systems.

Designed for reliability and easy installation

- * The Main Disconnect Panel saves time, installation labor, and valuable mounting space by consolidating the main circuit breaker, the feeder overcurrent devices, magnetic contactors and UPS emergency power-off into one compact panel
- * Reduces installation time and cost by eliminating delays in obtaining individually enclosed components and by eliminating on site assembly
- * Provides short circuit protection, overload protection and National Electrical Code and Canadian Electrical Code required emergency shutdown, and automatically restores power to the GE system
- * Readily accessible remotely operated MDP disconnects all system power as required by NEC
- * 517.72 and Canadian Electrical Code 52-008 and 52-016
- * Seismic ICC-ES-AC156 shake tested approval per OSHPD requirements per BEVCO, OSP-0457-10
- * UL and cUL labeled to conform to local codes minimizing inspection and acceptance issues
- * Customized wiring diagram provides for ease of installation
- * Panel's exterior off-white color helps provide for an attractive, color coordinated appearance
- * May be either surface or semi-flush mounted
- * Narrow 16 in (406.4 mm) wide enclosure conserves valuable wall space
- * UPS emergency power-off functions are included for future, partial system UPS addition
- * Disconnects system power on first loss of incoming power, preventing damage to system components

- * Provides a standardized platform for UPS or other future GE engineered modifications or upgrades
 - * Main power disconnect operating handle can be padlocked in the OFF position for servicing safety and OSHA lock out/tag out
 - * The door has provisions for padlocking closed
 - * Enclosure door is interlocked with ON/OFF disconnect handle to prevent unauthorized access if disconnect is in the ON position
- Built for investment protection
- * Suitable for 380-480V, 50/60 Hz applications*
 - * UL, cUL and OSHPD OSP labeled for 60 Hz installations
 - * 100-ampere main circuit breaker with shunt-trip and individual branch circuit breaker for the FLUORO UPS
 - * Supplied with 24V system emergency off push button and long-life LED pilot lights mounted on front side
 - * Power disconnection is accomplished via the door mounted emergency OFF push button
 - * Suitable for use on systems with 25,000A of short circuit current. It is the installer's responsibility to verify that the available short circuit current is 25,000A or less for compliance to all electrical codes
 - * Holds up to AWG 4/0 cable connections for the three phases of incoming and outgoing breakers
 - * Terminal block for Neutral connection
 - * Panel disconnect provides OSHA LOTO provisions
 - * Factory wired and tested
 - * Custom tailored for GE imaging system requirements

*The control circuit transformer comes factory configured and tested for 480VAC. Primary taps of the transformer can be reconfigured to accept 380, 400 and 415VAC configurations. Secondary taps of the control circuit transformer shall always remain configured for 24VAC.

Components included in E46001BD package

- * Main Disconnect Panel
- * Installation Operations & Service Manual (English Only)
- * (1) Remote Emergency Power Off push button with 2 NC contacts on each EPO, preassembled with stainless steel wall plates, nameplates, and protective shroud
- * Drawings and Electrical Schematics

Physical Characteristics

- * Height: 24.58 in (624 mm)
- * Width: 16.69 in (424 mm)
- * Enclosure depth with handle: 7.87 in (200 mm)
- * Weight: approx. 59 lb (27 kg)

Note: Structural engineer shall define the proper fixing/anchoring hardware.

Line	Qty.	Catalog	
31	1	E6220J	INTERCOM SYSTEM FOR X-RAY

VIS-A-VIS Vitalinq Intercom System for X-ray

The VIS-A-VIS Vitalinq intercom system for X-ray is a two-way communication system that is designed to meet the specific needs that arise during diagnostic and interventional procedures. It enables physicians to have continuous two-way conversation with the control room operator during diagnostic and interventional procedures.

FEATURES/BENEFITS

- Capable of picking up conversation in a normal tone of voice, Vitalinq allows control room operators to respond immediately to physicians' requests
- Larger format and unique pyramidal construction of the microphones contribute to Vitalinq's high intelligibility, even within the acoustically active space of a full-functioning procedure room
- Designed to minimize the loss of articulation by reducing the potential echo path it gathers and transmits speech in a highly efficient manner

SPECIFICATIONS

- Dimensions: 24" x 24" x 20"

- Weight: 47 lbs.

NOTES:

- INSTALLATION IS THE RESPONSIBILITY OF THE CUSTOMER
- Warranty Period 6 months - Exchange of non conforming products, which are returned to GE during warranty period.
- Installation, parts, application training and onsite service is the buyer's responsibility

Line	Qty.	Catalog	
32	4	W0330CV	TIP DAY OF APPLICATIONS TRAINING

A single day of applications training delivered at customer's site for any GE Healthcare Diagnostic Imaging system. Training will be delivered at a mutually agreed upon time between the customer and GE Healthcare (excluding GE Healthcare holidays), and are subject to availability. Training must be completed within 12 months from purchase.

Line	Qty.	Catalog	
33	1	S18061MH	HEAD SUPPORT WIDENER

Head support widener for InnovalQ Table with Tilt and OR Table

Line	Qty.	Catalog	
34	1	E63611EB	Lamp YLED-1F with Portegra2 extension/spring arm 750/950 mm including a total of 5 sterilizable handles

Total Quote Subtotal: **755,520.36**

Qty.	Credits and Adjustments	
1	SiemensAxiomArtis Removal & Trade-in	\$0

Total Quote Net Selling Price: **\$755,520**

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

Optional Items

Please initial the Catalogs you wish to purchase

Catalog Number	Qty.	Description	Net Price	Initial
E7016NH	1	CVI INJECTOR TABLE MOUNT	\$23,560	

ACIST CVi Table Mounted Injector

The ACIST CVi System enhances ease of use, reliability and flexibility in contrast delivery. The adjustable control panel arm, X-ray synchronization capability, and easy-to-use, multi-procedure disposables increase both workflow and productivity. Responsive Angiotouch hand controller puts variable control of contrast volumes and flow rate at your fingertips. Responsive, variable rate delivery of contrast provides quality imaging with less contrast usage, which has been demonstrated to provide cost savings to the lab.

Trade-in Addendum to GE Healthcare Quotation

This Trade-In Addendum ("Addendum"), effective on **November 4, 2021**, between the GE Healthcare business identified on the Quotation and **Novant Health Forsyth Medical Center** ("Customer"), is made a part of Quotation # **2007233227.7** ^ dated **November 4, 2021** ("Quotation") and modifies it as follows:

A. Customer: (i) certifies that it has full legal title to the equipment and/or mobile vehicle ("mobile vehicles" are defined as any systems requiring a vehicle title) listed in Section E ("Trade-In Equipment"), free and clear of all liens and encumbrances; (ii) conveys title and, if applicable, registration and license documents to GE Healthcare effective on the date of removal or receipt of the Trade- In Equipment (mobile vehicles will not be removed from Customer site until GE Healthcare has received a clean title signed over to GE Healthcare); and (iii) affirms that the Trade-In Equipment has never been used on or to provide care to animals. If GE Healthcare removes the Trade-In Equipment, it will do so at its expense at a mutually agreed time. Trade-In Equipment shall be removed no later than thirty days following installation of Customer's new system, unless explicitly otherwise agreed to by the parties in writing.

Mobile vehicles must include the VIN# on this trade-in addendum: VIN# [insert Vin #]. Mobile vehicles must have a valid DOT sticker and be road worthy at the time GE Healthcare is to take possession of them in order for GE Healthcare to accept a mobile vehicle on trade-in. Any and all logos or hospital affiliation stickers must be removed (outside and inside) by Customer and Customer shall clean the mobile vehicle of all debris and medical supplies prior to removal of the mobile vehicle by GE Healthcare.

B. Customer is responsible for: (i) providing timely, unrestricted access to the Trade-In Equipment in a manner that affords GE Healthcare, or third-party purchaser of the Equipment through GE Healthcare, the ability to complete Equipment inspection and testing, and the ability to complete an operating system back-up prior to de-installation within the timeframe required by GE Healthcare or said third-party purchaser, failure of which to provide may result in termination of this Trade-in Addendum and related credits and/or payments; (ii) ensuring that the Trade-In Equipment and the site where it is located are clean and free of bodily fluids; (iii) informing GE Healthcare of site-related safety risks; (iv) properly managing, transporting and disposing of hazardous materials located on site in accordance with applicable legal requirements; (v) rigging, construction, demolition or facility reconditioning expenses, unless expressly stated otherwise in the Quotation; and (vi) risk of loss and damage to the Trade-In Equipment until safety risks are remediated and the Trade-In Equipment is removed or returned.

C. Prior to removal or return to GE Healthcare, Customer must: (i) remove all Protected Health Information as such term is defined in 45 C.F.R. § 160.103 ("PHI") from the Trade-In Equipment; and (ii) indemnify GE Healthcare for any loss resulting from PHI not removed. GE Healthcare has no obligation in connection with PHI not properly removed.

D. GE Healthcare may in its sole discretion reduce the trade-in amount or decline to purchase the Trade-In Equipment and adjust the total purchase price of the Quotation accordingly if: (i) the terms of this Addendum are not met; (ii) Customer fails to provide access to the Trade-In Equipment as required herein; or (ii) the Trade-In Equipment is missing components or is inoperable and/or non-functioning when removed or returned – Customer is required to confirm for GE Healthcare the operability of the Trade-In Equipment prior to the deinstallation of the Equipment. All other terms and conditions of the Quotation remain in full force and effect.

E. Trade-In Equipment:

Trade-In Equipment Mfr.	<u>Model & Description</u>	<u>Quantity</u>	System ID*	Trade-In Amount (\$)
	SiemensAxiomArtis Trade-in	1		\$ 0

This Addendum is executed when: (i) signed by the parties below; (ii) Customer receives this Addendum and signs the Quotation that references the Trade-In Equipment; or (iii) Customer receives this Addendum and issues a purchase order identifying either the terms of the Quotation (which includes a reference to the Trade-In Equipment) or the Governing Agreement identified on the Quotation as governing the order (PO# _____)†.

Novant Health Forsyth Medical Center

GE Healthcare

Signature: _____
Print Name: _____
Title: _____

Signature: _____
Print Name: _____
Title: _____

Date: _____

Date: _____

^ A Quotation number must be provided on this document.

* In the event the Trade-In Equipment does not have a System ID, please record the serial number of each component that comprises the Trade-In Equipment.

† If you are relying upon the purchase order to reflect acceptance of the terms contained herein, please update this document with the applicable PO number upon receipt of the PO. Failure to do so may result in delays surrounding deinstallation of the System(s).

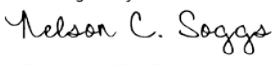
ATTACHMENT B

Projected Capital Cost Form
NH Forsyth Medical Center Cath Lab 3 Replacement

Building Purchase Price		NA
Purchase Price of Land		NA
Closing Costs		NA
Site Preparation		NA
Landscaping		NA
Construction/Renovation Contract(s)	\$	390,800
Architect / Engineering / DHSR Fees	\$	41,658
Medical Equipment (\$755,520 + 23,560)	\$	779,080
Non-Medical Equipment	\$	-
Furniture	\$	-
DPS/IT Systems	\$	7,000
Financing Costs	\$	-
Other: (Identify) CAP Labor	\$	24,064
Other: Contingency	\$	30,000
Total Capital Cost	\$	1,272,602

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.

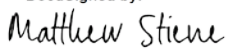
DocuSigned by:

506840220457145

Date Signed: 12/01/2021 | 9:00:22 EST

Signature of Licensed Architect or Engineer
 Nelson Soggs, AIA, LEED AP - 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:

0BCEAC882516150

Date Signed: 12/01/2021 | 8:47:13 EST

Signature of Officer/Agent

Senior Vice President, Construction & Facilities Svcs, Novant Health
 Title of Officer/Agent

ATTACHMENT C

EQUIPMENT COMPARISON

<i>NH Forsyth Medical Center Cardiac Catheterization Lab 3</i>	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	Cath Lab	Cath Lab
Manufacturer	Siemens Medical	GE
Model number	AXIOM ARTIS 24241	Innova IGS 5 system
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	NH ID# 50969778	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	7/22/2005	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>	NA	\$ 1,272,602
Total cost of the equipment	NA	\$779,080
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Cath Lab Dept - Rm #3 .	Cath Lab Dept. - Rm #3
Document that the existing equipment is currently in use	See Enclosed LRA Excerpt	NA
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 separate sheet if necessary>	Cardiac cath procedures	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	Cardiac Cath Procedures

Date of last revision: 5/17/19

ATTACHMENT D

All responses should pertain to October 1, 2019 through September 30, 2020.

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

b. Cardiac Catheterization and Electrophysiology *Winston Salem Hospital Campus only*

Cardiac Catheterization, as defined in NCGS 131E-176(2g)	Diagnostic Cardiac Catheterization**	Interventional Cardiac Catheterization***
1. Number of Units of Fixed Equipment	8	
2. Number of Procedures* Performed in Fixed Units on Patients Age 14 and younger	Ø	Ø
3. Number of Procedures* Performed in Fixed Units on Patients Age 15 and older	2,299	1,256
4. Number of Procedures* Performed in Mobile Units	Ø	Ø
Dedicated Electrophysiology (EP) Equipment		
5. Number of Units of Fixed Equipment	2	
6. Number of Procedures on Dedicated EP Equipment	1,763	

*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 grandfathered 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 non-grandfathered fixed or mobile units of cardiac catheterization equipment owned by hospital:

G-5980-99; G-6740-03; G-6990-04; G-7266-05

* Unable to locate others at this time

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

Number of 8-hour days per week the mobile unit is onsite: N/A 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)

From: [Hunt, Tiffany C](#)
To: [Waller, Martha K](#)
Subject: FW: [External] NY Forsyth Replacement Equipment Exemption Request - Cath Lab #3
Date: Wednesday, December 8, 2021 10:28:54 AM
Attachments: [FMC Cath Lab 3 to Agency 12.08.2021.pdf](#)

Tiffany Hunt
Administrative Specialist 1
Division of Health Service Regulation, Certificate of Need Section North Carolina Department of
Health and Human Services

Main: 919-855-3873
Office: 919-855-3872
Tiffany.C.Hunt@dhhs.nc.gov

Help protect your family and neighbors from COVID-19.
Know the 3 Ws. Wear. Wait. Wash.
#StayStrongNC and get the latest at nc.gov/covid19

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2704 Mail Service Center
Raleigh, NC 27699-2704

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From: Griffin, Lisa L <llgriffin@novanthealth.org>
Sent: Wednesday, December 8, 2021 10:25 AM
To: Inman, Celia C <celia.inman@dhhs.nc.gov>
Cc: Hunt, Tiffany C <Tiffany.C.Hunt@dhhs.nc.gov>
Subject: [External] NY Forsyth Replacement Equipment Exemption Request - Cath Lab #3

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Good morning, Celia,

Attached is an exemption notice regarding the replacement of cardiac cath lab #3 at NH Forsythe Medical Center. Please let me know if you have any questions or need additional information.

Regards,

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 [Novant Health](#) or [Novant Health UVA](#) for up-to-date information.

Estamos aquí para ayudarle con el cuidado que usted necesita. Visite [Novant Health](#) o [Novant Health UVA](#) para información actualizada.

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