



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

October 25, 2019

Andrea Gymer
agymer@novanthealth.org

Exempt from Review – Replacement Equipment

Record #: 3088
Facility Name: Novant Health Forsyth Medical Center
FID #: 923174
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Replace existing cardiac catheterization equipment
County: Forsyth


Dear Ms. Gymer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of October 21, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(f). Therefore, you may proceed to acquire without a certificate of need the GE Healthcare IGS 730 Innovo cardiac catheterization (cath) equipment to replace the Phillips 98900037251, Serial #3724490 cardiac cath equipment. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

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
Project Analyst


Martha J. Frison
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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



Reviewed by Healthcare
OCT 21 2019
Planning & CON Section

October 21, 2019

Via Email

2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

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 Lab
Winston-Salem, North Carolina (FID # 923174; Forsyth County)

Dear Ms. Inman:

Novant Health Forsyth Medical Center (NHFC) intends to replace an existing cardiac catheterization (cath) lab located at the hospital in Winston-Salem, North Carolina pursuant to N.C. Gen. Stat. 131E-184(f). The existing cath lab is over twenty years old and is past its useful life. It is located on the first floor of the hospital where the original cath lab department was located and has been regularly operating as a back-up cath lab (known internally as Cath Lab D). As part of this project, NHFC is relocating this cath lab to the 2nd floor of the North Tower to be located near the other cath and electrophysiology labs to a newly built out room to be known as Cath Lab #7. NHFC will acquire a new GE IGS 730Innovo system to outfit this lab. See **Attachment A** for the equipment quote. Also included is a quote to relocate the MAC Lab recording software system from the current lab location to the new lab location. As part of the equipment cost, the vendor will provide onsite clinical training for the equipment. The existing equipment will be traded in and will be removed by the vendor and not used within North Carolina without appropriate CON notice. See page 9 of the equipment quote. The total capital cost for the proposed replacement equipment project is estimated to be \$2,245,336¹. See **Attachment B** for the Projected Capital Cost form.

NHFC'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 Cardiac Catheterization Department at NHFC, which is located at 3333 Silas Creek Pkwy, Winston-Salem, North Carolina, 27103. At this location, NHFC's President and COO, Chad Setliff's office is located in Administration on the Main Floor and 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 annual License Renewal Application which is excerpted in **Attachment D**.

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

Re: NHPMC Replacement of Cardiac Catheterization Equipment

October 21, 2019

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Previous Certificate of Need:

Given the age of the existing cath lab, we are unable to locate documentation regarding its acquisition nor any replacements specific to this lab. The existing cath lab equipment dates from 1998 and is believed to be one of the original cath labs in use at NHFMC. NHFMC has been approved for eight (8) cath labs since 2005 and this lab is one of those approved cath labs.

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) NHFMC will 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.

In support of our request, please find attached:

- Attachment A – Vendor Equipment Quote**
- Attachment B – Project Capital Costs**
- Attachment C – Main Campus Map**
- Attachment D - In Use Documentation**
- Attachment E – Equipment Comparison Form**

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 \$2,245,336. 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 exemption request does not constitute a new institutional health service and is exempt from certificate of need review.

Re: NHPMC Replacement of Cardiac Catheterization Equipment
October 21, 2019
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**If you need additional information, please do not hesitate to contact me at (704) 384 – 3462 or
llgriffin@novanthealth.org.**

Sincerely,



Lisa Griffin
Manager, Operational Planning
Novant Health, Inc.

Enclosures

ATTACHMENT A



GE Healthcare

September 3, 2019
Quote Number: 2006102013.1
Customer ID: 1-23HYCC
Agreement Expiration Date: 12/31/2019

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	\$1,100,972.60
Sales and Use Tax Exemption	No Certificate on File

INDICATE FORM OF PAYMENT:

(If there is potential to finance with a lease transaction, by GE HEF otherwise, select lease)

- Cash*
- Lease
- GE HEF Loan
- If financing, please provide name of finance company: _____

*Selecting "Cash" or not identifying GE HEF as the finance company declines the option for GE HEF financing.

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: Imaging Account Manager

Date: September 3, 2019



September 3, 2019
 Quote Number: 2006102013.1
 Customer ID: 1-23HYCC
 Agreement Expiration Date: 12/31/2019

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:

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

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 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)."

Line	Qty.	Catalog	
1	1.00	S18631BM	IGS 730 with InnovalQ table Configuration

With its innovative laser-guided motion technology, the Discovery™ IGS 7 system in its IGS 730 configuration with InnovalQ table offers predictable and precise positioning capabilities for a wide variety of interventional and hybrid procedures.

Discovery IGS 7 Positioner

The Discovery IGS 7 system delivers cutting-edge gantry motion that combines benefits of floor and ceiling-mounted systems. It keeps the ceiling space above the patient free of suspended elements, supporting compliance with aseptic requirements and facilitating installation of ceiling-suspended equipment, such as anesthesia booms, monitor suspensions, surgical lamps or laminar flow. Still, the gantry is not fixed on the floor: It can move around the imaging table or park away to free access around the patient.

The C-arm is mounted on the Advanced Guided Vehicle (AGV), a motorized and mobile L-arm. Based on laser guidance, the AGV can move freely from imaging position to parking or back-out positions, using predefined trajectories to provide excellent patient access. The motion is predictable, precise, and easy to use, allowing fine control and positioning at any moment in the procedure. Parking locations and back-out distances are customizable for different room configurations. The AGV can also pan longitudinally along the table to extend across the anatomical coverage, while minimizing table panning. It enables the user to image patients from head to foot. The Discovery IGS 7 system features a Wide Bore C-arm with an extra-large source to isocenter distance (also called Source to Object Distance or SOD). The Wide Bore C-arm significantly enhances flexibility in system angulations and iso-centering, while limiting collisions between the tube or detector and the table. It also helps decrease patient skin dose. The patented three-axis isocentric positioner design of the offset C-arm provides maximum positioning flexibility and excellent patient access in all views. Sterile drapes can be attached to the tube, detector and C-arm of the system to maintain integrity of the sterile field.

GE Revolution digital flat panel detector

The IGS 730 configuration with InnovalQ table unites image quality, optimal panel size (31 x 31cm square) and built-in protocols for imaging versatility, making it suitable for a wide range of minimally invasive procedures.

The key element in the image chain is GE patented Revolution digital detector, which captures dynamic and fluoroscopic images in digital form with very efficient X-ray dose. It uses an amorphous silicon photodiode array on a continuous-substrate, single-piece panel with no inherent seams and is comprised of a 1536 x 1536 array of imaging elements (pixels) on a 200-micron pitch. Scintillator thickness and electronic noise are optimized to produce extremely high detective quantum efficiencies (DQE), both at record and fluoroscopic doses.

X-RAY Tube

The GE Revolution digital flat panel detector can translate a wide range of X-ray exposure intensities into digital signals without saturation. When applied, proprietary DRM image processing transforms this information for display without loss of detail over a wide range of anatomical densities. The wide dynamic range of the detector, coupled with 14-bit acquisition and patented image processing, enables excellent visualization of low contrast objects. The system is configured with a removable anti-scatter grid to maximize image quality during routine imaging. Removal of the grid can improve the X-ray dose efficiency for infants (e.g. less than one year old) for field of view (FOV) smaller than 20 cm (7.9 in). The Discovery IGS 7 system uses a 100 kW high-frequency Jedl 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 InnovalQ table

The InnovalQ Table is a fully motorized tilting table featuring motorized longitudinal and lateral motions even when tilted for effortless, automated and flexible positioning. Variable-force positioning allows for smooth and precise motion over the complete range of speeds, particularly at low positioning speeds when more positioning accuracy is needed. Horizontal eight-way float movement also permits manual panning. It supports a load up to 320 kg and allows imaging coverage with table panning up to 195cm with table dimension: 333cm in length and 46cm in width.

User interface

The SmartBox provides a simple control of the positioner and the table. A second SmartBox can be added at tableside or in the control room.

TheTSSC 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.

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 Discovery IGS 7 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.

Data acquisition is at 14 bits

Dynamic and chase images are stored in 8 bits, maximum 450 images per sequence. Storage capacity: 136,000 dynamic and chase images?

DSA and breeze images with 12 bits data are stored in 16 bits, maximum 450 images per sequence. Storage capacity: 68,000 DSA and breeze images?

DICOM images are output on 100Mbit Ethernet with Autosend and background transfer for fast transmission with minimal user interaction.

The user can do full resolution 1024 x 1024 DICOMpush to retain image quality at acquisition (configurable to 512 x 512 for cardiac acquisitions)?

Patient Worklist capability provides a single point of entry of patient data, helping enhance staff productivity and minimize clerical errors: Patient information can easily be imported to the digital imaging system from information systems that support DICOM Worklist Service Class Provider

Multi-destination Push enables images to be sent to multiple remote DICOM destinations sequentially. Multi-destination Push helps 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/ 3DCTH option, the users can direct-push the 3D acquisition directly to the GE AW workstation, even if the images of the exam are pushed to a PACS or another archiving system.

Line	Qty.	Catalog	
2	1.00	S18461JE	Sub-No-Sub fluoro display

Sub-No-Sub fluoro display

Line	Qty.	Catalog	
3	1.00	S18391PN	In Room Monitor and Mavig Monitor Suspension for 6 LCD Monitor with 36m Cable

In Room Monitor and Mavig Monitor Suspension for 6 LCD Monitor with 36m Cable

Line	Qty.	Catalog	
4	1.00	S18461JE	Sub-No-Sub fluoro display

Sub-No-Sub fluoro display

Line	Qty.	Catalog	
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September 3, 2019
Quote Number: 2006102013.1
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Agreement Expiration Date: 12/31/2019

5 1.00 S18061EH Wireless Footswitch Monoplane

Line	Qty.	Catalog	
6	1.00	S18621TA	Arm imaging Trajectories

Arm Imaging Trajectories

The Discovery IGS gantry moves along pre-programmed trajectories. The arm imaging trajectories are a set of additional trajectories designed to image the patient's arms from either the left or the right side of the table, while optimizing access to the patient for the physician during imaging.

Line	Qty.	Catalog	
7	1.00	S18771DA	FE Letter - QC mode Option activation

FE Letter - QC mode Option activation

Line	Qty.	Catalog	
8	1.00	S18761PP	NPA PDU Main Transformer-24KVA

The Power Distribution Unit provides power for the components of the system and centralizes the ON/OFF function

Line	Qty.	Catalog	
9	1.00	S1875PK	FLUORO UPS 20 KVA UL

GE Digital Energy 20KVa UPS for Innova Systems

Line	Qty.	Catalog	
10	1.00	S18741TC	ELEGANCE ADD-ON KIT AGIL

Elegance Table Plate

Line	Qty.	Catalog	
11	1.00	S18101SY	AGV Room Template

AGV Room Template

Line	Qty.	Catalog	
12	1.00	S18111BC	Short In Board Monitor Bridge with short rails GEMSAM

7 ft. 9 In. Inboard Monitor Bridge

Line	Qty.	Catalog	
13	1.00	S18121RD	228 by 578CM I.B RAILS

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

Line	Qty.	Catalog	
14	1.00	Services-CE-Americas-Launch-CV-Apps	Launch CV Applications Training

Line	Qty.	Catalog	
15	1.00	W0302CV	TIP Vascular System Group 2 Training Program

This training program is designed for customers purchasing a GEHC Vascular system to include IGS6 and IGS7. GEHC will work with the designated Customer contact to agree upon a reasonable training schedule for a pre-defined group of core technologists that will leverage blended content delivery and may include a combination of onsite days and virtual offerings, to include TIP Virtual Assist, the GEHC Answerline, and 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 16 days)
 - Virtual Inclusions may include:
 - o Remote instructor-led training: Instructor leads a remote training session one-on-one or in a group, typically for 1 hour
 - o Answerline Support-Access to GEHC experts for clinical, non-emergency applications assistance via phone or by using the iLink button on the imaging console
 - o Tip Virtual Assist-Direct interactive access to a GEHC expert for enhanced support.
 - o On Demand courses-On healthcare learning system. Self-paced courses and webinars (CE and non-CE).
- Onsite training days will be mutually agreed upon, but generally will not exceed 20 days. Onsite training will be provided from 8am-5pm local time Monday-Friday. Virtual Offerings are unlimited. This training program has a term of six (6) months commencing on Acceptance, where all onsite training must be scheduled and completed within six (6) months of Acceptance, and all Virtual Inclusions also expire at the end of such six (6) 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	
16	1.00	E8007PT	Medrad Stellant P3T Cardiac Protocol Option

P3T Cardiac computes custom injection protocols as well as scan timing for each patient, enabling personalized care and patient safety while maintaining efficient workflow.

- Utilizes the power of DualFlow technology (simultaneous injection of contrast and saline) to obtain functional cardiac data
- Enables more consistent images across varied patients, studies and technologists
- Eliminates the need to estimate injection protocols for complicated studies

Line	Qty.	Catalog	
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17 1.00 E8007PJ OCS III Mounting Plate

Line	Qty.	Catalog	
18	1.00	E80141DB	MEDRAD Stellant D DualFlow ISI-ready on ceiling mount (85cm post length) with Certegra Workstation

GE Healthcare now offers the Medrad Stellant D injector with Certegra workstation. The dual syringe CT injection system is reliable and easy to use. It features saline flush and DualFlow capabilities allowing users to test vein accesses with saline, and prime patient tubing with saline to save contrast.

Medrad Stellant D CT Injection System users are armed with:

- Automation features to help maximize throughput: integrated auto load, auto retract, auto prime and auto syringe sensing
- Save up to 250 protocols
- Quick, easy install and detachment
- Check for air confirmation button and arming on the injector head
- Pressure monitor graph and flow profile preview
- Up to 6 phases including pause and hold capabilities
- Programmable pressure limit
- Colour touch screen
- Either ceiling counterpoise or pedestal-mount configurations

Certegra Workstation

From study set-up and preparation to study administration and results management, the Certegra Workstation serves as a workflow-centralized technologist interface to help users enhance efficiencies and patient care, enabling options such as P3T 2.0 (Personalized Patient Protocol) software environment.

The benefits of DualFlow (simultaneous injection of contrast and saline)

- Provide more uniform attenuation of the right and left ventricles
- Minimize artefacts by achieving proper attenuation levels
- Visualize the right coronary arteries and right ventricles in a single study by achieving more uniform attenuation

Ceiling-mount configuration includes:

- Dual injector head on Overhead Ceiling Counterpoise
- Syringe heat maintainer
- Certegra Workstation with USB drive
- DualFlow software
- ISI-ready software to accept ISI900G integrated injector option†
- Base control unit
- 22.8 m (75 ft) head extension cable
- 7.6m (25 ft) base to display cable
- Power cord, North America
- Power cord, international
- Product information package
- Operations manual
- Installation, customer's operational training at time of installation, and one year full on-site warranty in Bayer service countries

System Specifications

- Flow Rate (range & increments): 0.1 to 10 ml/sec in 0.1 ml increments
- Volume (range & increments): 1 ml to syringe capacity in 1 ml increments
- Programmable Pressure Limit 200 ml syringe: 325 psi, 2241 kPa
- Scan delay: 0-300 seconds (5 minutes) in 1 second increments
- Pause: 1-900 seconds (15 minutes) in 1 second increments
- Hold: maximum HOLD time is 20 minutes



- Syringes (volume capacity): 200 ml sterile disposable syringe
- Number of phases: 6
- Number of protocols: 250
- Electrical Requirements (VAC/Hz): 100-240 VAC, 50/60 Hz
- Syringe Heat Maintainer Range: 35 °C +/-5, 95 °F +/-9
- Dual Injector Head: 15.5 cm (6.1") H x 30.7 cm (12.1") W x 36.8 cm (14.5") D, 8.1 kg (17.0 lb) without syringe
- Certegra Workstation (CWS): 34.2 cm (13.5") H x 40.0 cm (15.8") W x 30.0 cm (10.2") D, 8.0 kg (17.6 lb)
- Base Unit: 29.2 cm (11.5") H x 27.9 cm (11.0") W x 22.2 cm (8.8") D

Qty.	Credits and Adjustments	
1.00	Trade-in	0.00

Total Quote Net Selling Price:

\$1,100,972.60

Trade-in Addendum to GE Healthcare Quotation

This Trade-In Addendum ("Addendum"), effective on **September 3, 2019**, between the GE Healthcare business identified on the Quotation and ("Customer"), is made a part of Quotation # **2006102013.1** ^ ("Quotation") and modifies it as follows:

- A. Customer: (i) certifies that it has full legal title to the equipment and/or mobile vehicle listed in Section E ("Trade-In Equipment"), free and clear of all liens and encumbrances; and (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. If GE Healthcare removes the Trade-In Equipment, it will do so at its expense at a mutually agreed time.
- B. Customer is responsible for: (i) providing timely, unrestricted access to the Trade-In Equipment in a manner that affords GE Healthcare the ability to complete Equipment inspection and testing prior to de-installation within the timeframe required by GE Healthcare, 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 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 reduce the trade-in amount or decline to purchase the Trade-In Equipment if: (i) the terms of this Addendum are not met; or (ii) it is missing components or is Inoperable when removed or returned. All other terms and conditions of the Quotation remain in full force and effect.
- E. Trade-In Equipment:

<u>Equipment/Vehicle Mfr</u>	<u>Model & Description</u> Trade-in	<u>Quantity</u> 1.00	<u>* ID / Serial #</u>	<u>Trade-In Amount</u> \$ 0.00
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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: _____

Signature: _____

Print Name: _____

Print Name: _____

Title: _____

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).



September 3, 2019
Quote Number: 2006102013.1
Customer ID: 1-23HYCC
Agreement Expiration Date: 12/31/2019

GPO Agreement Reference Information

Customer:	Novant Health Forsyth 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

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

Imaging:

XR0391-MR, XR0311-Card./Vasc., XR0321-CT, XR0342-Mammo, XR0351-PET-CT, XR0362-Nuc Med, XR0380-R&F/RAD & CE0351 and ICAR-EP/HEMO

Ultrasound:

XR0431-Ultrasound

Vizient: Please login to the Vizient Marketplace Website. If you require assistance or are experiencing issues, please contact Vizient for support:

Email: Connect@VizientInc.com and Phone: 866-600-0618.

GE HEALTHCARE

SERVICE QUOTATION

Rev # 1
 Quote # HBSS2416 Customer Name NOVANT HEALTH FORSYTH MEDICAL CENTER
 Total Net Amount \$ 3,500.00 Inside Sales Rep

Product (Custom Service)	Description	Service Start Date	Service End Date	Term (Months)	Quantity	Term Price(\$)
CATHLAB 2 MLCL RELOCATION	UPFRONT SERVICE	07/01/2019	07/31/2019	1	1	3,500.00
Total(\$)						3,500.00

Relocate from Cath #2 to Cath #7

Total(\$) 3,500.00



ATTACHMENT B

Projected Capital Cost Form
FMC Cardiac Catheterization Lab #7 Replacement

Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction/Renovation Contract(s)	\$ 1,089,463
Landscaping	
Architect / Engineering Fees	\$ 51,400
Medical Equipment	\$ 1,104,473
Non-Medical Equipment	\$ -
Furniture	
Consultant Fees (Engineering Fees)	\$ -
Financing Costs	
Interest during Construction	
Other (construction contingency)	\$ -
Total Capital Cost	\$ 2,245,336

Included in Medical Equipment:
 CT Scanner 1,100,973
 Injector 3,500
 Total 1,104,473

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER


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


 Signature of Licensed Architect or Engineer

Date Signed: 9/23/19

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.


 Signature of Officer/Agent

Date Signed: 9/25/19

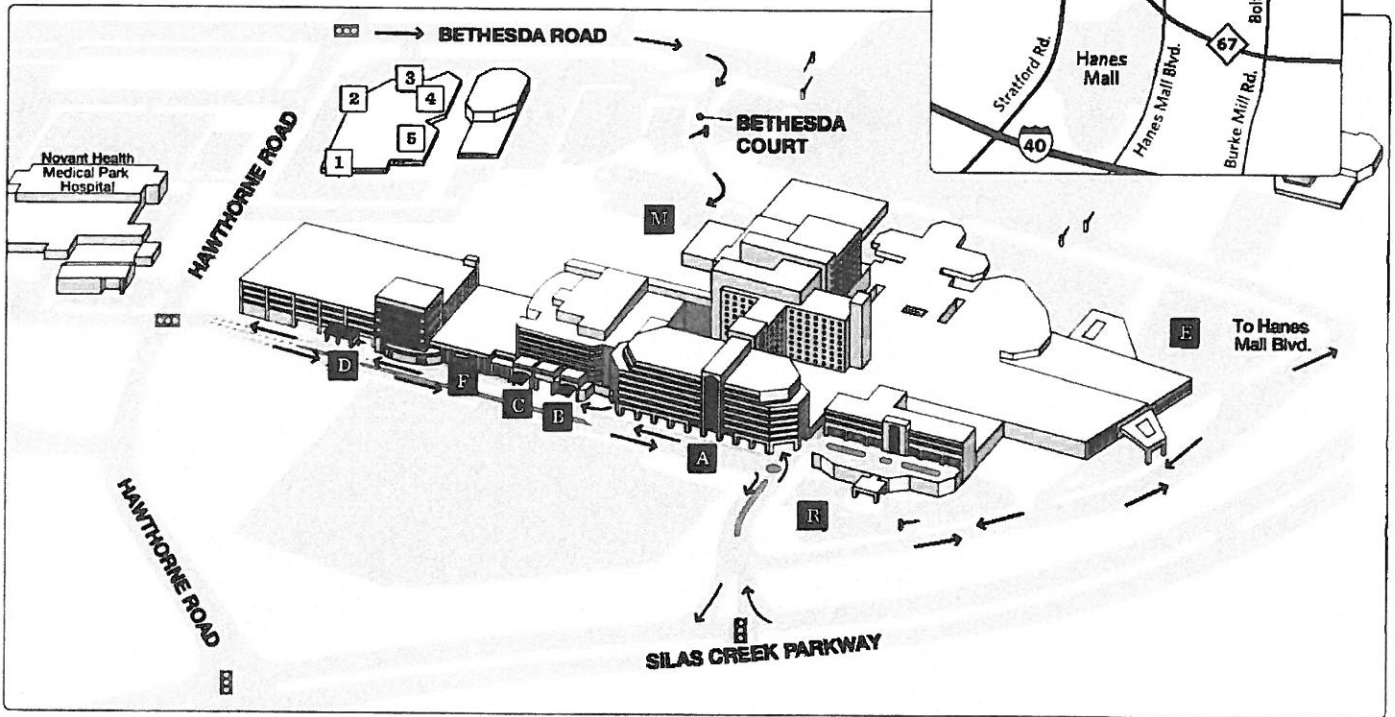
President + COO NHFMC
 Title of Officer/Agent

ATTACHMENT C



Campus map

Novant Health Forsyth Medical Center



Entrance **A**

- Administration
- Cashier/business office
- EKG
- Endoscopy lab
- EOPS
- Lab services
- Outpatient day center
- Patient registration
- Radiology
- SPPU (Day of surgery)
- Valet parking

Entrance **B**

- All registration from 7 p.m.-5:30 a.m. and weekends (after 5:30 a.m.)*
- Birthing center
 - Community rooms
 - Gyn anesthesia unit
 - Gyn surgery
 - Prenatal care
 - Novant Health Maya Angelou Women's Health & Wellness Center
 - Valet parking

Entrance **C**

- Cardiac procedures
- Preanesthesia visits
- Valet parking

Entrance **D**

- Handicapped
- Public parking deck

Entrance **E**

- Emergency Services

Entrance **F**

- Conference center

Entrance **M**

- 1010 Bethesda Court
Winston-Salem, NC 27103
- Novant Health Cancer Center
 - Patient parking (Radiology and Cancer Center only)
 - PET/CT, nuclear medicine & MRI
 - Novant Health Imaging
 - Novant Health Oncology Specialists
 - Valet parking

Entrance **R**

- CHF clinic
- Infant audiology
- Heart & Wellness
- Rehabilitation services
- Wellness programs

- 1** Novant Health Hawthorne Outpatient Surgery
- 2** Novant Health Rehabilitation Center
- 3** Novant Health Wound Care
- 4** Forsyth Nutrition Center
- 5** Salem Room

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ATTACHMENT D

All responses should pertain to October 1, 2017 through September 30, 2018.

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	8	
2. Number of Procedures* Performed in Fixed Units on Patients Age 14 and younger	- 0 -	- 0 -
3. Number of Procedures* Performed in Fixed Units on Patients Age 15 and older	3,024	752
4. Number of Procedures* Performed in Mobile Units	- 0 -	- 0 -
Dedicated Electrophysiology (EP) Equipment		
5. Number of Units of Fixed Equipment	2	
6. Number of Procedures on Dedicated EP Equipment	1,541	

*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:

6-5980-99 ; 6-6740-09 ; 6-6990-04 ; 6-7266-05

*Records unable to locate 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)

ATTACHMENT E

EQUIPMENT COMPARISON

<i>NH Forsyth Cath Lab 7 Replacement</i>	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type	Cardiac Cath Lab	Cardiac Cath Lab
(e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)		
Manufacturer	Phillips	GE Healthcare
Model number	989600037251	IGS 730 Innovo
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	SN 3724490	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	September 1998	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*	\$2,245,336
Total cost of the equipment	NA*	\$1,104,473
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	1 st Floor; Old Cath Lab D	2 nd Floor North Tower Cath Lab #7
Document that the existing equipment is currently in use	See Letter	----
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	-----
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	-----	Cardiac Cath Procedures
Date of last revision: 5/17/19		

Note * - No information was available on this certificate of need or equipment since it is over 20 years old.