



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

November 10, 2021

Andrea Gymer
amgymer@novanthealth.org

Exempt from Review – Replacement Equipment

Record #: 3728
Date of Request: November 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
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 Siemens Medical Artis Q cath lab to replace the Siemens Medical Axiom Artis DTA 24242 cath lab, Asset #50969593. 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: Radiation Protection Section, DHSR
Construction Section, DHSR
Acute and Home Care Licensure and Certification, 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

November 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
FID: 923174; Forsyth County

Dear Ms. Inman:

Novant Health Forsyth Medical Center (“NFMFC”) 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 2006 as an equipment replacement. Therefore, NHFMC will acquire a new Siemens Artis Q system. See **Attachment A** for the Equipment Quote which includes the removal of the existing equipment on page 7. 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 \$1,305,936. 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
November 8, 2021
Page 2

In support of our request, please find attached:

- Attachment A** – Vendor Equipment Quote
- Attachment B** – Projected Capital Costs
- Attachment C** – NC CON Equipment Comparison chart
- 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 \$1,305,936. 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

Lisa Griffin
Manager, Strategic Planning

Enclosures

ATTACHMENT A

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Michael Holland - +1 (610) 448-1654
michaelholland@siemens-healthineers.com

PRELIMINARY PROPOSAL

Customer Number: 0000006208

Date: 07/21/2021

FORSYTH MEDICAL CENTER
3333 SILAS CREEK PKWY
WINSTON SALEM, NC 27103

Quote Nr. CPQ-224697 Rev. 0

Artis Q ceiling Combo Card./Rad.

All items listed below are included for this system:

Qty	Part No.	Item Description
1	14434092	<p>Artis Q ceiling Combo Card./Rad. Artis Q ceiling for interventional cardiology and radiology The Artis Q product line is setting new standards in interventional imaging.</p> <p>The Artis Q ceiling for interventional cardiology and radiology now features PURE®. PURE adds smooth interaction to Siemens' smart technologies. It is designed to boost productivity and enhance outcomes for certain clinical applications, while increasing image quality and reducing dose.</p> <p>The GIGALIX X-ray tube concentrates high pulse power on small, square-shaped focal spots (flat emitter technology for all focal spots). This provides unprecedented image quality for confidence in challenging situations.</p> <p>The ceiling-mounted C-arm offers highly flexible positioning. The motorized rotation of the C-arm from a head-end position to a lateral position allows for free head access and full patient coverage without rotating the table.</p> <p>The patient table is fitted with a freely movable patient positioning tabletop, a head-end holder and handgrips.</p> <p>The as20 flat detector is optimized for cardiology and allows for steep angulations.</p> <p>Frame rates up to 30 f/s. Hardware and software for displaying and storing ECG curves are included.</p> <p>Digital acquisition technology and digital subtraction angiography with up to 7.5 f/s in 1k matrix are available.</p> <p>With new computer hardware and smart algorithms CLEAR MAX offers maximized image quality. The complete CARE+CLEAR package offers optimal image quality at the lowest reasonable dose.</p> <p>Live and reference images are displayed on two 19" flat screens in the exam room. In the control room live images are displayed on a third screen.</p>
1	14434238	<p>FPD as40HDR Card ins. of as20</p>

PRELIMINARY PROPOSAL

Enlarging your field of view

When ordering this flat detector, the following components of the basic configuration

- as20 flat detector
- GIGALIX 125/40/90 - G (2 foci) X-ray tube assembly with CLEARpulse
- Cardiac collimator

are replaced with

- as40HDR flat detector
- GIGALIX 125/30/40/90 - G (3 foci) X-ray tube assembly with CLEARpulse
- Angio collimator.

1 14432948

Automap

Automatic stand positioning depending on the selected reference image and automatic reference image selection depending on the stand positioning.

1 14432947

Fluoro Loop

Storage and review of dynamic fluoroscopic sequences. This saves an additional acquisition and helps to reduce dose. The maximum storable fluoroscopic time is limited by the maximum DICOM file size of 4 Gbyte.

1 14434169

CLEARstent Live

CLEARstent Live is a real-time stent enhancement tool and provides a stabilized view of the moving stent which is displayed on the Assist/Reference Monitor. CLEARstent Live allows real-time verification of stent positioning while moving the device. This enables the physician to precisely position the stent in relation to the anatomy of the heart and stents that already have been implanted. Contains both CLEARstent Live license and CLEARstent license.

The CLEARstent imaging function allows an improved display of fine stent structures, i.e. the grid of inflated stents. CLEARstent is a post-processed stent enhancement and may be used also on previously acquired images. Using the CLEARstent function special reference images from any scene or fluoroscopy scene acquired natively will be generated. Composite images are created by averaging several frames of a scene and by considering the alignment of balloon markers. If an ECG signal is available, the heart phase will also be taken into account.

1 14432925

PERISTEPPING / PERIVISION

Motorized stepping for real-time bolus chasing.
C-arm stepping with ARTIS pheno and ceiling mounted systems, table stepping with floor mounted and biplane systems.

Peripheral digital angiography with stepping and online subtraction display.

1 14432943

Vascular analysis

Vessel analysis with determination of degree of stenosis, distance measurement and calibration.

2 14432953

Lower body radiation protection

This radiation shield protects the user from scattered radiation when standing at the table side. It can be attached to the accessory rails either on the right or on the left side of the patient positioning table.
It provides the user an additional accessory rail.

PRELIMINARY PROPOSAL

It includes a basic unit
(71.5 cm x 75 cm / 28.2" x 29.5" (l x w); 7.7 kg / 16.98 lb),
one lower body radiation protection pivot swivel element
(77 cm x 48 cm / 30.3" x 18.9" (l x w); 3.8 kg / 8.4 lb)
and three clip-on units
(57 cm / 22.4" x 33 cm / 12.99" (l x h), 2.2 kg / 4.85 lb;
27 cm / 10.6" x 33cm / 12.99", 0.9 kg / 1.98 lb and
27 cm / 10.6" x 25cm / 9.8", 1 kg / 2.2 lb)
with a lead of 0.5 mm / 0.02" Pb.
The maximum weight of the accessory rails is 40 kg (88.2 lb).

Intended only for use with Artis / ARTIS tables.

1 14434157

Moveable upper body rad. protection

This radiation shield protects the user from scattered radiation.

It includes a ceiling rail (4 m / 157.5"), a ceiling mounted and movable stand (80 cm or 57 cm / 31.5" or 22,4"), a support arm (94 cm x 91 cm / 37" x 35.8") and an acrylic glass.

The shield is made of acrylic glass with lead equivalent of 0.5 mm

(w x h: 61 cm x 76 cm / 24" x 29.9"), which can pivot and rotate around a fixed point with a range of 360 degrees.

The operation range is limited when used with Artis floor/biplane MN.

Max. weight: 18 kg / 39.68 lb.

1 14440512

LED Exam Light

Ceiling-mounted, flexible positionable examination light with focusable light system. It is fully integrated into the ceiling-installed radiation protection mounting unit.

- Luminance: Min 60,000 Lux for 100 cm / 39.4" distance
- Working distance: 70 to 140 cm / 27.6" to 55.1"
- Color rendering index Ra at 4500 Kelvin: min. 95
- Color temperature: 4,100+-200 Kelvin
- Focusable light field: 14 to 25 cm / 5.5" to 9.8"
- Total input power: Max. 24 VA

1 14432950

DICOM RIS-Modality Worklist

Import of patient/examination data from an external RIS/HIS patient management system with DICOM MWL (Modality Worklist).

1 14434232

Injector conn. in the control room

Interface for controlling the contrast medium injector in the control room.

Injectors can be offered by Siemens Healthcare Accessory Solutions

1 14432939

2nd 4 pedal wireless footswitch

Additional 4-pedal footswitch for release of fluoroscopy, exposure, and table brake, as well as a configurable additional function. Wireless connection via radio communication.

1 14432904

long TT thin mat. ins. of std. TT

Patient positioning tabletop made of carbon fiber in extended, straight design for interventional radiological or surgical examinations.

Matching the long patient positioning tabletop, special-foam mattress, 4 cm, made of open-pore polyurethane material and a latex-free cover.

Note: The long patient positioning tabletop with the thin mattress replaces the narrow or wide tabletop, including mattress, described in the basic configuration.

PRELIMINARY PROPOSAL

The head-end holder, handles, and shoulder supports are eliminated because they can only be used with the narrow tabletop.

1 14440411

Intercom - Comfort

Intercom system for communication between examination room and control room. It includes

- a microphone with a control box for the control room
- a microphone with an adaptive acoustic filter for background noise suppression for the examination room
- a footswitch for conversation selection for the examination room

1 14443011

Large Display diagn. Protection

The high quality laminated glass protective screen protects the panel of the monitor against mechanical damage and fluid ingress on the front. It is suited for clinical image evaluation.

Features:

The laminated glass enforces high mechanical strength and resistivity against mechanical impact, the special coating reduces reflections for a continuous image quality, excellent spectral transmission of at least 98%, can be added to existing Artis Large Display installations. Weight: approx. 12kg (55") up to 16kg (60")

Note: Observe the maximum permissible load of the display suspension, a combination with other options mounted to the display suspension might be restricted.

2 14455870

Displaykit for 3rd-Party Trolley

The display kit for 3rd-Party Trolley is a precondition when ordering a MAVIG Trolley MD711-SI / MD712-SI. This Kit contains one 19 inch display and needed converter for using the 3rd Party Trolley MAVIG MD711-SI / MD712-SI.

For MD711-SI with one 19 inch display, please order one kit.

For MD711-SI with two 19 inch displays, please order two kits.

1 14434231

Sec. operation in the control room

Interface for connecting the additional system control from the control room.

Rail profile for hanging control modules (e.g. the table module) in the control room.

Safety button for switching off all system functions from the control room.

1 14440510

Secondary Hand Switch Ctrl (C Room)

Additional hand switch for radiation release and additional control functions.

1 14434205

Secondary operation on table

Second control at table side.

1 14434207

Device secondary operation

Additional control module, monoplane, for all functions of the C-arm movements and multileaf collimator. For both acquisition planes for a biplane system.

1 14434208

Table secondary operation

Second control module to remote-control the patient table in the examination room. Table control within the degrees of freedom supported by the motor drive.

Release knob in connection with the standard table for the table with stepping.

Joystick in connection with the operating table or the table with tilting.

1 14455902

ELEVATE bonus EOS (mono)

PRELIMINARY PROPOSAL

- 1 14434176 **Large Display video controller 18**
 Large Display Video Controller 18 is the middle of three different video controller sizes. A maximum of 18 video signals can be connected and displayed simultaneously on the Large Display.
 The Large Display video controller 18 receives various internal and external video signals for presentation to scale on the Large Display.
 Up to 18 external and internal video sources can be connected (max. 14 DVI-D and 4 analog (VGA) channels).
- 1 14443012 **LD High Contrast panel size 55"**
 Large color flat screen display (including cables) for the examination room, with a panel diagonal of 55". This large display version provides an excellent clinical image quality due to its new IPS panel technology.
- 1 14455818 **Artis Freestyle Access cable kit #P**
 Preparation for mounting, connection and display of the wireless "ACUSON Freestyle Elite with Artis Access" ultrasound system on the Large Display of the Artis system.
 Artis Freestyle Access optimizes the workflow when using ultrasound guidance in the interventional suite.
 It provides a zero-cables, zero footprint, fully connected solution for ultrasound guidance in the interventional suite.
- 1 14434172 **Large Display**
 Preparation for the large color flat screen display on a ceiling-mounted, longitudinally mobile, swiveling, rotating, and height-adjustable display holder in the examination room.

 Note: If a Large Display is selected, the Artis basic configuration includes a connection kit for the Large Display instead of the displays for the examination room.
 The type of large display can be chosen with a separate position.
- 1 BART700TABL **Mark 7 Arterion, Table Mount Injector**
 The Arterion Mark 7 Table contrast medium injector allows for the remote installation of the system power supply and installation of the injector head onto a table bracket.

 The injector system includes:
 Power supply and injector head with corresponding cabling
 An adjustable height table bracket for the injector head
 A desk mounted user control console with large touch screen

 Functions
 Pressure limitation:
 for 150 ml syringes 689 to 8273 kPa,
 corresponds to 100 to 1200 psi. .

 Flow rates for 150 ml syringes:
 0.1 to 45 ml/s in increments of 0.1 ml/s
 0.1 to 59.9 ml/min in increments of 0.1 ml/min
 rise/fall: 0 to 9.9 s in increments of 0.1 seconds

 Release delay for injection or radiation:
 0 to 99.9 s in increments of 0.1 s.

PRELIMINARY PROPOSAL

Adjustable volume for 150 ml syringes:
1 ml to the max. syringe capacity in increments of 1 ml.

Fill rate:
Variable syringe filling speed 1-20ml/s.

Injection protocols:
Up to 40 injection protocols possible.

Parameters currently displayed on the touch screen display and on the head display:

- Injection speed
- Injection volume
- Remaining volume
- Injection duration
- Applied pressure

Contrast medium heating:
Nominal 35°C (95°F)±5°C (9°F)

Injection data memory
Up to 50 injection data items stored

Included in the scope of delivery
Injector standard configuration 150 ml
SIEMENS interface cable
Operator Manual
Service manual (English).

Power supply
200 V to 250 V; 50/60 Hz.

1 BINSART700R **Arterion Rack Mnt Install**

1 AT_USD_FREE STYLE **ACUSON Freestyle ultrasound system**
Includes 3 Year Standard Warranty

ACUSON Freestyle Mainframe 11002300

Mainframe for the ACUSON Freestyle™ (FS) Series ultrasound systems, the world's first ultrasound systems that operate with cable-free transducers, a breakthrough in ultrasound imaging. The systems feature superior image quality and new standards in ease of use in an ergonomic and portable design.

Standard features include:

1 AXA_RIG_QSP_STD **Standard Rigging Q Q.Zen SP**

1 AXA_ADDL_RIG GING **Additional Rigging AXA**

1 AXA_ADD_28 **Additional onsite training 28 hrs**

Up to (28) hours of on-site clinical education training, scheduled consecutively (Monday – Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist if applicable. This educational offering must be completed (12) months from install

PRELIMINARY PROPOSAL

end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.

1 AXA_O_SINGLE
_PLANE

Elevate O Single Plane

1 AXA_ELVOFCM
P_DEINS

Elevate O Deinstallation Ceiling-Flr-MP

1 AXA_ELVOFCM
P_DEOFF

Elevate O Deinstal Ceiling-Flr-MP Offset

1 GEL1040136601
278

Black anti-fatigue mat 36x60

Black NewLife EcoPro anti-fatigue mat (36 inches x 60 inches), 3/4 inch polyurethane foam, fluid and dirt resistant with anti-micorbial properties, matte textured surface.

The ultimate employee benefit for workers who stand, are ergonomically designed to provide the perfect balance of premium comfort and optimal support. Proprietary Cellulon®Polyurethane Technology stands up to the tough demands of commercial environments while providing lasting comfort that won't bottom out over time. This eco-friendly line of anti-fatigue mats is certified by the National Floor Safety Institute for its high traction bottom surface.

1 AM0160C

Adept STARSsystem

Radial positioning equipment intended for clinicians working on the right.

Includes STARBoard, leg arm support and STARTable.

A key function of the STARBoard is its ability to present the patients wrist in the hyper-extended position whilst access is achieved, then simply return it to a more relaxed, medially-rotated position, for the duration of the procedure, allowing greater patient comfort. Crafted in carbon fiber for superior strength, radiolucency and durability, the STARBoard is light weight and compact.

STARSupport connects to the STARBoard after radial access is gained facilitating left arm procedures for superior patient comfort.

STARTable not only provides clinicians with an adjustable work surface, the vertical shield reduces X-ray scatter.

Includes one year warranty through Adept.

1 MAVIGMD712

Monitor Cart for 2 Monitors

Versatile mounting for 19" to 24" monitors
Moveable, tiltable and swivelable VESA adapters for 75 and 100 mm
Monitor Width: max 24.4 inches
Maximum payload of up to 26.4 pounds per monitor
Power and video cables can be routed inside the system
4 antistatic and smooth rolling casters, each with a parking brake
Overall dimensions (H x W x D): 61.8 in x 52.2 in x 23.7 in
Weight: 82 pounds

1 AXA_TRADE_IN_ALLOW

Trade-in of a Artis dTA, project 2020-2245

System Total

\$ 1,001,800

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Michael Holland - +1 (610) 448-1654
michaelholland@siemens-healthineers.com

PRELIMINARY PROPOSAL

FINANCING: The equipment listed above may be financed through Siemens. Ask us about our full range of financial products that can be tailored to meet your business and cash flow requirements. For further information, please contact your local Sales Representative.

Siemens Healthcare is pleased to submit this Preliminary Pricing Proposal. A Preliminary Pricing Proposal is provided for planning purposes only; it is not contractually binding. To receive a contractually binding proposal for the Products listed above, inclusive of Terms, Conditions, and Warranty coverage, please contact your Siemens Healthcare Sales Representative.

Siemens Healthcare
Michael Holland
+1 (610) 448-1654
michaelholland@siemens-healthineers.com

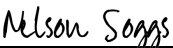
ATTACHMENT B

Projected Capital Cost Form
NH Forsyth Medical Center Cath Lab 6 Replacement

Building Purchase Price		NA
Purchase Price of Land		NA
Closing Costs		NA
Site Preparation		NA
Construction/Renovation Contract(s)	\$	241,747
Landscaping	\$	-
Architect / Engineering / DHSR Fees	\$	37,898
Medical Equipment	\$	1,001,800
Non-Medical Equipment	\$	-
Furniture	\$	-
DPS/IT Systems	\$	1,500
Financing Costs	\$	-
Interest during Construction	\$	-
Other: Contingency	\$	25,000
Total Capital Cost	\$	1,307,945


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:

 _____ Date Signed: 11/04/2021 | 3:42:35 EDT
 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:

 _____ Date Signed: 11/05/2021 | 1:25:36 EDT
 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 6</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	SIEMENS MEDICAL
Model number	AXIOM ARTIS DTA 24242	ARTIS Q
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	NH ASSET # - 50969593	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2/21/2006	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	\$ 1,305,936
Total cost of the equipment	NA	\$ 1,001,800
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Cath Lab Dept. Rm #6	Cath Lab Dept. Rm #6
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] NH Forsyth Medical Center Cardiac Cath Lab 6 Replacement Equipment Exemption
Date: Monday, November 8, 2021 3:58:23 PM
Attachments: [FMC Cath Lab 6 REER to Agency 11.02.2021.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

809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704

[Twitter](#) | [Facebook](#) | [YouTube](#) | [LinkedIn](#)

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.

From: Griffin, Lisa L <llgriffin@novanthealth.org>
Sent: Monday, November 8, 2021 3:55 PM
To: Inman, Celia C <celia.inman@dhhs.nc.gov>
Cc: Hunt, Tiffany C <Tiffany.C.Hunt@dhhs.nc.gov>; Cremeens, Cameron L <clcremeens@novanthealth.org>; Kohli, Sonia <SKohli@novanthealth.org>
Subject: [External] NH Forsyth Medical Center Cardiac Cath Lab 6 Replacement Equipment Exemption

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

Good afternoon, Celia,

Attached is a replacement equipment exemption notice for a cardiac cath lab located at NH Forsyth Medical Center. Let me know if you have any questions or need more information.

Thank you,

Lisa Griffin

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

We are here to help you get the care you need. Visit [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.

This message and any included attachments are from NOVANT HEALTH INC. and are intended only for the addressee(s). The information contained herein may include trade secrets or privileged or otherwise confidential information. Unauthorized review, forwarding, printing, copying, distributing, or using such information is strictly prohibited and may be unlawful. If you received this message in error, or have reason to believe you are not authorized to receive it, please promptly delete this message and notify the sender by email. If you believe that any information contained in this message is disparaging or harassing or if you find it objectionable please contact Novant Health, Inc. at 1-844-266-8268 or forward the email to reports@novanthealth.org.