



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER  
GOVERNOR

MANDY COHEN, MD, MPH  
SECRETARY

MARK PAYNE  
DIRECTOR

March 29, 2017

Lisa Griffin

**Exempt from Review – Replacement Equipment**

**Record #:** 2213  
**Facility Name:** Novant Health Forsyth Medical Center  
**FID #:** 923174  
**Business Name:** Novant Health, Inc.  
**Business #:** 1341  
**Project Description:** Replace existing fixed cardiac catheterization equipment at NHFMC  
**County:** Forsyth

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of March 27, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Siemens Artis Zee cardiac catheterization equipment to replace the Siemens Axiom Artis, Serial Number 1701. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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,

Handwritten signature of Celia C. Inman in black ink.

Celia C. Inman  
Project Analyst

Handwritten signature of Martha J. Frisone in black ink.

Martha J. Frisone  
Assistant Chief, Certificate of Need

cc: Construction Section, DHR  
Paige Bennett, Assistant Chief, Healthcare Planning, DHR  
Acute and Home Care Licensure and Certification Section, DHR

**HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION**

WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704

AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



Rec'd by Email  
3/27/17



March 27, 2017

Ms. Celia Inman, Project Analyst, Certificate of Need  
Healthcare Planning & Certificate of Need (CON) Section  
North Carolina Department of Health & Human Services  
809 Ruggles Drive  
Raleigh, North Carolina 27603

Novant Health

2085 Frontis Plaza Drive  
Winston-Salem, NC 27103

Re: Replacement Equipment Exemption Request Pursuant to N.C.G.S. 131E-184(a)(7) –  
Cardiac Catheterization Equipment at Novant Health Forsyth Medical Center (NHFMC);  
Forsyth County

Dear Ms. Inman:

This letter outlines Novant Health Forsyth Medical Center's (NHFMC's) project to replace existing fixed cardiac catheterization equipment located in the hospital's Cardiac Catheterization Department (Cath Lab #5) with new Siemens cardiac catheterization equipment. See **Attachment A** for the vendor quote from Siemens Healthineers. The total project costs related to the replacement of the cardiac cath lab are \$907,000, including the new equipment cost of \$563,976. The project cost does not include: sales, property or excise taxes since NHFMC is a non-profit, tax-exempt organization and is not typically subject to these taxes. In addition, the expense for on-site training on the new equipment for the cardiac catheterization staff is covered by the vendor quote on Page 3. The existing equipment is to be traded in and removed by Siemens (see page 3 of the quote in **Attachment A**) and disposed of by Siemens.

Both the existing equipment and the replacement equipment are comparable medical equipment as explained in this letter. This exempt project will replace functionally similar operational equipment in Cardiac Cath Lab #5 at NHFMC and will not increase the inventory of fixed cardiac cath labs in Forsyth County. The proposed new cardiac catheterization equipment is consistent with the replacement equipment definition at N.C.G.S. Section 131E-176(22a) which states that the replacement equipment is comparable to the equipment being replaced if it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements. The existing equipment is used for cardiac catheterization procedures in the hospital Cardiac Catheterization Department and the replacement equipment will be used for cardiac catheterization procedures in the hospital Cardiac Catheterization Department.

Pursuant to 10A NCAC 14C.0303, the proposed cardiac catheterization equipment constitutes replacement equipment because:

1. It is comparable to the equipment currently in use. It has the same technology as the equipment currently in use, although it does possess expanded capabilities due to the technological improvements.
2. It is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service.
3. The acquisition of the new 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.

Ms. Celia Inman

March 27, 2017

Replacement Equipment Exemption – NHFMC Cardiac Catheterization Equipment

Page 2

4. The existing equipment was not purchased second-hand nor was the existing equipment leased.

5. The replacement equipment is not capable of performing procedures that will result in the provision of a new health service or type of procedure that has not been provided with the existing equipment.

Attached for your convenience please find:

- 1) a vendor equipment price quote (**Attachment A**);
- 2) a project/capital cost schedule which identifies the components of the total project costs (**Attachment B**);
- 3) a certified estimate of related construction costs from an independent licensed North Carolina architect (**Attachment C**); and,
- 4) the NC CON equipment comparison form summarizing essential information about the proposed equipment purchase (**Attachment D**).

NHFMC's acquisition of the replacement cardiac catheterization equipment does not require a certificate of need because none of the definitions of "new institutional health service" set forth in N.C.G.S. Section 131E-176(16) is implicated. As discussed above, the total cost for the project is \$907,000. This includes the cost of the equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation and other activities essential to making the equipment operational (such as staff training).

In conclusion, based on the information described above, please confirm that NHFMC's replacement equipment request does not constitute a "new institutional health service" and does fit within the replacement equipment exemption definition. Therefore, the project is not subject to certificate of need review.

Please let me know as soon as possible if you need additional information to assist in your consideration of this request. I can be reached at (704) 384 – 3462 and by email: [llgriffin@novanthealth.org](mailto:llgriffin@novanthealth.org). Thank you for your prompt consideration of this request.

Sincerely,



Lisa Griffin  
Manager, Certificate of Need  
Novant Health, Inc.

Enclosures

cc: Barbara Freedy, Director, CON, Novant Health  
Laura MacFadden, Vice President, Design & Construction, Novant Health

# Attachment A

Siemens Medical Solutions USA, Inc.  
40 Liberty Boulevard, Malvern, PA 19355  
Fax: (866) 309-6967



SIEMENS REPRESENTATIVE  
Stuart Wadley - (919) 605-9227

## PRELIMINARY PROPOSAL

Customer Number: 000006208

Date: 2/21/2017

**FORSYTH MEDICAL CENTER**  
3333 SILAS CREEK PARKWAY  
WINSTON-SALEM, NC 27103

This offer is for CON filing and expires on June 30<sup>th</sup> 2017.

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Quote Nr: **1-CDGR17 Rev. 2**

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### Artis zee floor

All items listed below are included for this system: (See Detailed Technical Specifications at end of Proposal.)

Qty	Part No.	Item Description	Extended Price
1	14445989	<b>Artis zee floor Interv. Card.</b> Artis zee floor for cardiology now features PURE(r). 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.  The floor-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. The patient table is fitted with a freely movable patient positioning tabletop.  The Megalix Cat Plus X-ray tube with flat emitter technology enables small focus sizes and strong, short X-ray pulses.  The as20 flat detector is optimized for cardiology and allows for steep angulations.  Frame rates up to 30 f/s and functions for displaying and storing ECG curves are included.  The complete CARE+CLEAR package offers optimal image quality at the lowest reasonable dose.  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.	
1	14432949	<b>MULTISPACE.F</b> Manual stand rotation for additional work positions.	
1	14432947	<b>Fluoro Loop</b> Storage and review of dynamic fluoroscopic sequences (Fluoro Loop). This saves an additional acquisition and reduces dose. The maximum storable fluoroscopic time depends on the selected pulse rate, e.g. 34 s at 30 p/s, 68 s at 15 p/s.	

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## PRELIMINARY PROPOSAL

Qty	Part No.	Item Description	Extended Price
1	14432944	<b>Scientific QCA</b> Scientific coronary vessel analysis with determination of degree of stenosis, distance measurement and calibration.	
1	14434220	<b>VOLCANO s5i cable set</b> Cable set for operating the Volcano s5i ultrasound system incl. s5iz and s5iu (CORE-System). It contains all cables for connecting the components at the patient table to the s5i imaging system in the control room. This cable set will already be integrated into the Artis table in the factory.  With this item, a display is delivered additionally for the examination room if an Artis Large Display was not ordered. If an Artis Large Display is ordered, the configuration includes a connection kit for the Artis Large Display instead of the 19" display.	
1	14432950	<b>DICOM RIS-Modality Worklist</b> Import of patient/examination data from an external RIS/HIS patient management system with DICOM MWL (Modality Worklist).	
1	14434167	<b>19" color display w/ video cable</b> One additional 19" color display including 36 m cable with DVI-D connection for installation in display ceiling suspension. LCD color display with high luminance and extended field of view.	
1	14434184	<b>4x1 video signal distribution</b> With this item you can show one video signal each from up to 4 units (such as a cardiac catheter recording system, workstation, ultrasound unit, PACS, etc.) on up to two displays (not a Large Display) in the display holder in the examination room.  Note the following conditions if video signals are to be shown on a third-party provider display: <ul style="list-style-type: none"> <li>- The display of external video signals depends on the operational state of the Artis system. If the Artis system has a malfunction or is shut down, the display of external video signals is no longer possible. For this reason, do not feed the video signal into the Artis system if lacking the external video signal could result in a hazardous situation.</li> <li>- A third-party provider's unit may be connected only if it corresponds to the specifications of the video interface on the Siemens system.</li> <li>- The connection may only be established by a Siemens service technician. Note: The connection must be made with fiber-optic cables to ensure that the unit's galvanic isolation is maintained.</li> <li>- A third-party provider's unit must be connected by a technician from the third-party provider or by a hospital technician responsible for the equipment.</li> <li>- It is strongly recommended that a test of image quality be performed by the third-party provider prior to start-up. This test ensures that the required image quality is achieved.</li> <li>- The system configurator is responsible for ensuring that applicable standards are maintained in the current version, e.g. 4 kV insulation</li> </ul> Siemens will not be held liable for the inclusion of third-party provider units with respect to image quality and their suitability for clinical diagnosis.	
2	AXA_PURE_E SSCL	<b>AX Artis PURE Essential Class</b> Tuition for (1) imaging professional to attend Siemens class at Siemens Training Center. The Artis PURE Essentials Course is a 3.5-day classroom course beginning on Tuesday at 8:30 a.m. and ending on Friday at 12:00 p.m. It is designed to provide the participant with an in-depth knowledge of the essential functions of the Artis system as well as the skills needed to perform these functions. Through the use of demonstrations, lectures, and hands-on lab experience using an Artis system, participants will learn Artis system principles and workflows of patient examinations. Additionally, participants have the opportunity to meet other users and share their experiences and solutions to various challenges of the IR, cath lab, and the Hybrid OR environment. This class includes lunch, economy airfare, and lodging for (1) imaging	

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SIEMENS REPRESENTATIVE  
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**PRELIMINARY PROPOSAL**

Qty	Part No.	Item Description	Extended Price
		professional. All arrangements must be arranged through Siemens designated travel agency. This educational offering must be completed by the later of (12) months from purchase or install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.	
1	AXA_ADD_32	<b>Additional onsite training 32 hours</b> Up to (32) 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 end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.	
1	AXA_RIG_ZEE SP_STD	<b>Standard Rigging zee SP</b>	
1	AXA_ADDL_RI GGING	<b>Additional Rigging AXA \$6.840</b>	
1	AXA_TRADE_I N_ALLOW	<b>AXA Trade-in-Allowance \$7,000</b>	
<b>System Total:</b>			<b>\$563,976</b>

# Attachment B



# PROPOSED CAPITAL COSTS

Project Name: **Cath Lab #5 Equipment Replacement**

March 27, 2017

Proponent: **Novant Health Forsyth Medical Center**

**A. Site Costs**

(1)	Full purchase price of land		
	Acres _____ Price per Acre		
(2)	Closing Costs		
(3)	Site Inspection and Survey		
(4)	Legal fees and subsoil investigation		
(5)	Site Preparation Costs		
	Soil Borings		
	Clearing Earthwork		
	Fine Grade For Slab		
	Roads Paving		
	Concrete Sidewalks		
	Water and Sewer		
	Footing Excavation		
	Footing Backfill		
	Termite Treatment		
	Sub-Total Site Preparation Costs		0.00
(6)	Other (specify)		
(7)	<b>Sub-Total Site Costs</b>		<b>0.00</b>

**B. Construction Contract**

	Sub-Total Cost of Materials		112,830.00
(9)	Cost of Labor GC Labor		137,904.00
(10)	Other -		
(11)	<b>Sub-Total Construction Contract</b>		<b>250,734.00</b>

**C. Miscellaneous Project Costs**

(12)	Building Purchase		
(13)	Fixed Equipment Purchase/Lease		563,976.00
	Other: Add Trade-In Value of Old Equipment		7,000.00
(14)	Movable Equipment Purchase/Lease		
(15)	Furniture		
(16)	Landscaping		
(17)	Consult Fees		
	Architect and Engineering Fees	35,000.00	
	Legal Fees		
	Market Analysis		
	Other (Test and Balance )	4,900.00	
	Sub-Total Consultant Fees		39,900.00
(18)	Financing Costs (e.g. Bond Loan, etc)		
(19)	Interest During Construction		
(20)	Other (SPECIFY)		
	Other ( SPECIFY) Contingency		45,390.00
(21)	<b>Sub-Total Miscellaneous</b>		<b>656,266.00</b>
(22)	<b>Total Capital Cost of Project (Sum A-C above)</b>		<b>907,000.00</b>

# Attachment C



2115 Rexford Road, Suite 500  
Charlotte, North Carolina 28211

704.364.3400 Office

ksq.design

March 24, 2017

Mr. Brandon Rich  
Novant Health, Inc.  
3600 Country Club Road, Suite 102  
Winston-Salem, North Carolina 27104

Re: Novant Health | Forsyth Medical Center | Cath Lab 5 Equipment Replacement  
Winston-Salem, North Carolina

Dear Brandon:

We have prepared our estimate for the Cath Lab 5 Equipment Replacement at Forsyth Medical Center. We estimate the construction labor cost will be \$137,904.00 and the construction material cost will be \$112,830.00. Therefore, we estimate the total construction cost to be \$250,734.00.

The architectural and engineering design fees shall be \$35,000.00 and estimated project reimbursables are \$3,200.00. The DHSR review fee is estimated to be \$1,700.00. Therefore, the total estimated cost of construction, including A&E fees and reimbursables, and DHSR review fee is \$290,634.00.

If we can be of further assistance, please do not hesitate to contact me.

Sincerely,

Nelson C. Soggs, AIA, LEED® AP, Associate  
Senior Project Manager  
KSQ Architects, PC dba KSQ Design  
nsoggs@ksq.design



3/24/17

# Attachment D

**Novant Health Forsyth Medical Center -- Cath Lab #5 Replacement**

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Cardiac Catheterization	Cardiac Catheterization
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	n/a	n/a
Model Number	Axiom Artis	Artis Zee
Serial Number	1701	TBD
Provider's Method of Identifying Equipment	Internal Number Scheme	Internal Number Scheme
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	n/a	n/a
Mobile Tractor Serial Number/VIN #	n/a	n/a
Date of Acquisition of Each Component	2003	TBD
Does Provider Hold Title to Equipment of Have a Capital Lease?	Hold Title	Will Hold Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$1,492,488	\$907,000
Total Cost of Equipment	\$950,000	\$563,976
Fair Market Value of Equipment	\$7,000	\$563,976
Net Purchase Price of Equipment	\$950,000	\$563,976
Locations Where Operated	FMC Cardiac Cath Dept.	FMC Cardiac Cath Dept.
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	None	None
Percent of Change in Per Procedure Operating Expenses (by Procedure)	None	None
Type of Procedures Currently Performed on Existing Equipment	Cardiac Catheterization	-----
Type of Procedures New Equipment is Capable of Performing		Cardiac Catheterization