



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

VIA EMAIL ONLY

February 22, 2018

Lisa Griffin

Exempt from Review – Replacement Equipment

Record #: 2524
Facility Name: Novant Health Forsyth Medical Center
FID #: 923174
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Replace existing electrophysiology lab 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 February 20, 2018, 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 Electrophysiology Lab equipment to replace the Siemens Artis Zee Electrophysiology Lab #1 equipment, Serial Number 010073020040251. 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

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

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. Frisone
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR

February 20, 2018

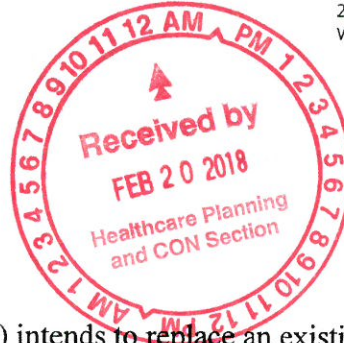
Via Email



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

2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

Re: Novant Health Forsyth Medical Center
Replacement of Electrophysiology Lab #1
Winston-Salem, NC (Forsyth County)



Dear Ms. Inman:

Novant Health Forsyth Medical Center (“NHFMC”) intends to replace an existing electrophysiology lab equipment currently located at the main campus of NHFMC in Winston-Salem, North Carolina. The existing electrophysiology equipment is past its useful life. Therefore, NHFMC will acquire a new Siemens Healthcare Artis Zee system. See **Attachment A** for the Equipment Quote including the removal and trade-in of the existing unit indicated as “Promotions.” 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 \$1,080,215¹. See **Attachment B** – Project Capital Cost.

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 electrophysiology 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.
- (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.

In support of our request, please find attached:

- Attachment A** – Vendor Equipment Quote
- Attachment B** – Project Capital Costs & Certified Architects Letter
- Attachment C** – NC CON Equipment Comparison chart

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

Ms. Celia Inman
Re: NHFMC Replacement of Electrophysiology Lab #1
February 20, 2018
Page 2

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 \$1,080,215. 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 at (704) 384 - 3462.

Sincerely,



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

Enclosures

Cc: Barbara Freedy, Director, CON, Novant Health

**ATTACHMENT A –
Equipment Quote**



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

SIEMENS REPRESENTATIVE
Stuart Wadley - (919) 605-9227

Customer Number: 0000006208

Date: 12/22/2017

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

Siemens Medical Solutions USA, Inc. is pleased to submit the following quotation for the products and services described herein at the stated prices and terms, subject to your acceptance of the terms and conditions on the face and back hereof, and on any attachment hereto.

<u>Table of Contents</u>	<u>Page</u>
Artis zee ceiling (Quote Nr. 1-LVSUVG Rev. 2).....	3
General Terms and Conditions	9
Warranty Information	17

Contract Total: \$625,000

Proposal valid until 3/31/2018

Accepted and Agreed to by:

Siemens Medical Solutions USA, Inc.

FORSYTH MEDICAL CENTER

By (sign): _____
Name: Stuart Wadley
Title: Account Executive
Date: _____

By (sign): _____
Name: _____
Title: _____
Date: _____

By signing below, signor certifies that no modifications or additions have been made to the Quotation. Any such modifications or additions will be void.

By (sign): _____

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

SIEMENS REPRESENTATIVE
Stuart Waddey - (919) 605-9227

Quote Nr: 1-LVSUVG Rev. 2

Terms of Payment: 00% Down, 80% Delivery, 20% Installation
Free On Board: Destination

Purchasing Agreement: VIZIENT SUPPLY LLC

VIZIENT SUPPLY LLC terms and conditions apply to Quote Nr 1-LVSUVG

Artis zee ceiling

All items listed below are included for this system:

Qty	Part No.	Item Description	Extended Price
1	14446000	<p>Artis zee ceiling EP</p> <p>Artis zee ceiling for electrophysiology 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 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. 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. Digital acquisition technology with up to 7.5 f/s in 1k/12 bit matrix is available. 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.</p>	\$452,335
1	14432948	<p>Automap</p> <p>Automatic stand positioning depending on the selected reference image and automatic reference image selection depending on the stand positioning.</p>	\$1,322
1	14432939	<p>2nd 4 pedal wireless footswitch</p> <p>Additional 4-pedal footswitch for release of fluoroscopy, exposure, and table brake, as well as a configurable additional function. Wireless connection via radio communication.</p>	\$4,189
1	14432897	<p>Head-end table tilting</p> <p>Motorized tilt and stepping of the patient table in longitudinal direction for electrophysiological or peripheral examinations, for example, as well as for stabilizing a patient. Includes a power-assisted tabletop control module.</p>	\$8,963

Notes:

Table tilting reduces the maximum patient weight to 200 kg. As before however, it is possible to install up to 40 kg of additional accessories.

Note: It is mandatory to provide UPS back up with this table option in order to comply with IEC 60601-2-43 CL. 201.15.101. Reason: In the event of power failure a neutral table position

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Qty	Part No.	Item Description	Extended Price
		suitable for CPR must be reachable within 15 seconds. Please include a suitable UPS from Siemens as required or make sure any existing / planned UPS provision for your installation site will satisfy the requirement	
1	14434144	long TT thick 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 tabletop, special-foam mattress, 7 cm, made of open-pore polyurethane material and a latex-free cover. Note: The long patient positioning tabletop with the thick mattress replaces the narrow or wide tabletop with the thin mattress described in the basic configuration. The head-end holder, handles, and shoulder supports (if part of the basic configuration) are eliminated because they can only be used with the narrow tabletop.	\$94
1	14432947	Fluoro Loop 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.	\$8,771
1	14432926	Card acq. mode w/high speed Fast acquisition module for DR and DSA as well as digital card acquisition technology with frame rates of 7.5, 10, 15 and 30 f/s, acquisition, display and storage in 1k matrix.	\$13,809
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. 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.	\$9,410
1	14434157	Moveable upper body rad. protection This radiation shield protects the user from scattered radiation. For room heights up to 290 cm / 114.2". 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 (75 cm x 90 cm / 29.5" x 35.4") 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.	\$7,071
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: 60,000 Lux for 100 cm / 39.4" distance	\$5,642

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Stuart Waddey - (919) 605-9227

Qty	Part No.	Item Description	Extended Price
		<ul style="list-style-type: none"> - Working distance: 70 to 140 cm / 27.6" to 55.1" - Color rendering index Ra at 4500 Kelvin: 95 - Color temperature: 4,300 Kelvin - Focusable light field: 14 to 25 cm / 5.5" to 9.8" - Diameter of light head: 33 cm / 13" - Number of LEDs: 19 - Total input power: 20 VA 	
1	14440411	<p>Intercom - Comfort</p> <p>Intercom system for communication between examination room and control room. It includes</p> <ul style="list-style-type: none"> - 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 <p>The microphone of the examination room is installed on the ceiling.</p>	\$923
1	14443011	<p>Large Display diagn. Protection</p> <p>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.</p> <p>Features:</p> <p>The laminated glass enforces high mechanical strenght and resistivity against mechanical impact, the special coating reduces reflections for a continuous image quality, excellent spectral transmissison of at least 98%, can be added to existing Artis Large Display installations. Weight: approx. 12kg (55") up to 16kg (60")</p> <p>Note: Observe the maximum permissible load of the display suspension, a combination with other options mounted to the display suspension might be restricted.</p>	\$4,750
1	14434205	<p>Secondary operation on table</p> <p>Second control at tableside.</p>	\$353
1	14434207	<p>Device secondary operation</p> <p>Additional control module, monoplane, for all functions of the C-arm movements and multileaf collimator. For both acquisition planes for a biplane system.</p>	\$4,073
1	14434208	<p>Table secondary operation</p> <p>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.</p> <p>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.</p>	\$1,145
1	14432950	<p>DICOM RIS-Modality Worklist</p> <p>Import of patient/examination data from an external RIS/HIS patient management system with DICOM MWL (Modality Worklist).</p>	\$786
1	14434201	<p>OEM recording system interface</p> <p>Cable connection to an OEM measurement system.</p> <p>Holder for the ECG interface when using an OEM measurement system in the examination room.</p> <p>Recording, storage, and display of an ECG lead. Displayed together with the image</p>	\$1,243

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Qty	Part No.	Item Description	Extended Price
		information on a single monitor.	
1	14427424	AX ELEVATE #R ROW Buy Back(dTA/dTC) AT Elevate program for ceiling-mounted AXIOM Artis systems with flat detectors that will be replaced by a new Artis zee system.	\$0
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.	\$53,343
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).	\$30,775
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.	\$0
1	14434187	19" b/w display (ref) A 19" high-contrast -display for reference image display.	\$3,956
1	AXA_ADD_12	Additional onsite training 12 hours Up to (12) 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.	\$4,200
1	AXA_ADD_24	Additional onsite training 24 hours Up to (24) 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.	\$6,300
1	AXA_ADD_32	Additional onsite training 32 hours 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.	\$7,800
1	EPW935515UPS	Eaton Powerware 9355 15 kVA UPS Includes UPS, battery, maintenance bypass panel, and one year on-site parts and labor coverage (24x7) by Eaton Powerware. This UPS is recommended when protection and uninterruptible power is required for the Artis' C-arm and table. Emergency fluoroscopy is not available with this UPS. If emergency fluoroscopy is required, the 9390 - 160 kVA UPS is recommended for the full system. One UPS per lab.	\$20,801

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Qty	Part No.	Item Description	Extended Price
		Additional seismic brackets are required to make this system OSHPD approved.	
1	AXA_R_FD_C ILING	Elevate R FD Ceiling Promotion*	- \$50,000
1	AXA_ELVRFC MP_DEINS	Elevate R Deinstallation Ceiling-Flr-MP	\$20,000
1	AXA_ELVRFC MP_DEOFF	Elevate R Deinstal Ceiling-Flr-MP Offset*	- \$20,000
2	NT60010635	Blue anti-fatigue floor mat for hospital	\$276
1	AXA_RIG_ZEE SP_STD	Standard Rigging zee SP	\$13,500
1	AXA_ADDL_RI GGING	Additional Rigging AXA \$9,170	\$9,170
System Total:			\$625,000

*Promotion = Trade-in + Removal = \$70,000

ATTACHMENT B –

- **Project Capital Cost Form**
- **Certified Architect's Letter**

PROPOSED CAPITAL COSTS

Project Name: **Electrophysiology Lab #1 Replacement**

February 20, 2018

Facility **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)	Sub-Total Site Costs		0.00

B. Construction Contract

(8)	Cost of Materials:		
	General Requirements	100,000.00	
	Woods/Doors & Window/Finishes	0.00	
	Equipment/Specialty Items	0.00	
	Mechanical/Electrical/Plumbing	41,750.00	
	Sub-Total Cost of Materials		141,750.00
(9)	Cost of Labor GC Labor		173,250.00
(10)	Other -		
	Other Construction Contingency	0.00	
	Other Demo & Final Clean	0.00	
	Other General Liability	0.00	
	Other Builders Risk	0.00	
	Other Allowance Permit	0.00	
	Other Fees	0.00	
	Sub-Total Other		0.00
(11)	Sub-Total Construction Contract		315,000.00

C. Miscellaneous Project Costs

(12)	Building Purchase		
(13)	Fixed Equipment Purchase - Siemens Healthcare		625,000.00
	Other: Add Trade-In Value of Old Equipment		50,000.00
	Other: Removal of Old Equipment		20,000.00
(14)	Movable Equipment Purchase/Lease		
(15)	Furniture		
(16)	Landscaping		
(17)	Consult Fees		
	Architect and Engineering Fees per Letter	29,500.00	
	Other : Project Reimbursables per Letter	2,000.00	
	Special Instructions Test & Balance	4,900.00	
	Sub-Total Consultant Fees		36,400.00
(18)	Financing Costs (e.g. Bond Loan, etc)		
(19)	Interest During Construction		
(20)	Other: DHSR Inspection Fees per Letter		1,705.00
	Other: Misc Fees & Contingency		32,110.00
	Other: (Specify)		0.00
(21)	Sub-Total Miscellaneous		765,215.00
(22)	Total Capital Cost of Project (Sum A-C above)		1,080,215.00



2115 Rexford Road, Suite 500
Charlotte, North Carolina 28211

704.364.3400 Office

ksq design

November 3, 2017

Ms. Amanda Lautermilch
Novant Health, Inc.
3600 Country Club Road, Suite 201
Winston-Salem, North Carolina 27104

Re: Novant Health | Forsyth Medical Center | EP Lab 1 Equipment Replacement
Winston-Salem, North Carolina

Dear Amanda:

We have prepared our estimate for the EP Lab 1 Equipment Replacement at Forsyth Medical Center. We estimate the construction labor cost will be \$173,250.00 and the construction material cost will be \$141,750.00. Therefore, we estimate the total construction cost to be \$315,000.00.

The architectural and engineering design fees shall be \$29,500.00 and estimated project reimbursables are \$2,000.00. The DHSR review fee is estimated to be \$1,705.00. Therefore, the total estimated cost of construction, including A&E fees and reimbursables, and DHSR review fee is \$348,205.00.

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@ksqdesign.com

11/03/17

**ATTACHMENT C –
NC Equipment Comparison Form**

FMC EP Lab 1 Replacement	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Electrophysiology Lab	Electrophysiology Lab
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	n/a	n/a
Model Number	Artis Zee	Artis Zee
Serial Number	010073020040251	TBD
Provider's Method of Identifying Equipment	Internal Number System	Internal Number System
Specify if Mobile or Fixed	Fixed	Fixes
Mobile Trailer Serial Number/VIN #	n/a	n/a
Mobile Tractor Serial Number/VIN #	n/a	n/a
Date of Acquisition of Each Component	August 2004	TBD
Does Provider Hold Title to Equipment of Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$ 1,058,638	\$ 1,080,215
Total Cost of Equipment	\$ 725,752	\$ 625,000
Fair Market Value of Equipment	\$ 50,000	\$ 625,000
Net Purchase Price of Equipment	----	\$ 625,000
Locations Where Operated	FMC EP Lab	FMC EP Lab
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	Electrophysiology	-----
Type of Procedures New Equipment is Capable of Performing	-----	Electrophysiology