



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

March 7, 2017

Lisa Griffin
Novant Health, Inc.
2085 Frontis Plaza Drive
Winston-Salem, NC 27103

Exempt from Review – Replacement Equipment

Record #: 2183
Facility Name: Novant Health Presbyterian Medical Center (NHPMC)
FID #: 943501
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Replace cardiac catheterization lab located in NHPMC's Cath Lab Room #4
County: Mecklenburg

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 14, 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 One cardiac catheterization lab to replace the Philips Allura FD 20/20 cardiac catheterization lab located in Cath Lab #4. 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.

In addition, in your letter of February 14, 2017, you state that the replacement cardiac catheterization lab would be relocated to Novant Health Huntersville Medical Center. This constitutes a request for material compliance and is addressed by the Agency in separate correspondence.

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.

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



Ms. Lisa Griffin
March 7, 2017
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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,



Gloria C. Hale
Project Analyst



Martha J. Frisone
Assistant Chief, Certificate of Need

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

February 14, 2017

Ms. Martha J. Frisone, Assistant Chief
Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603



Re: Replacement Equipment Exemption and Relocation Request for Novant Health Presbyterian Medical Center's Cardiac Catheterization Lab #4/Mecklenburg County/HSA III

Dear Ms. Frisone:

Pursuant to N.C. Gen. Stat. § 131E-184(a)(7), this letter serves as prior written notice to the CON Section of Novant Health Presbyterian Medical Center's (NHPMC) plan (the Project) to replace an existing, operational cardiac catheterization lab (the Existing Cath Lab) located in NHPMC Cath Lab Room #4 in Charlotte and relocate it to Novant Health Presbyterian Huntersville Medical Center (NHHMC) in Huntersville, North Carolina. The new cardiac catheterization lab will be located at NHHMC on the first floor of the hospital, adjacent to the existing Endovascular Lab. Both NHPMC and NHHMC are owned by Novant Health, Inc. and are located in Mecklenburg County. Separate correspondence has been submitted to the CON Section explaining why the transfer of the equipment from NHPMC to NHHMC is not governed by the CON Law.

The Existing Cath Lab is a Philips Allura FD 20/20 model that was purchased as new equipment in 2006. The replacement unit (the Replacement Cath Lab) is a new Siemens Artis One model. See **Attachment E**, which compares the Existing Cath Lab with the Replacement Cath Lab. The total cost of the Project is **\$1,999,576**. See **Attachment C**, which is a signed capital cost sheet. This amount includes all costs essential to acquiring the Replacement Cath Lab and making it operational. See **Attachment A** for the Replacement Cath Lab vendor quote from Siemens Medical Solutions, reflecting a cost of \$647,235 for the Replacement Cath Lab itself. The expenses for on-site training on the Replacement Cath Lab for the NHHMC cardiac catheterization staff are covered by the vendor as indicated on pages 3 and 5 of the vendor quote in **Attachment A**. Also included as movable equipment related to the purchase of the Replacement Cath Lab and included in **Attachment A** are a balloon pump (\$62,376), a Volcano Guided Therapy System (\$105,000), and, a Bayer injector system (\$28,775). First Call Parts of Salem, Virginia will remove the Existing Cath Lab from NHPMC for a cost of \$22,500 (see **Attachment B**) and will ensure that the Existing Cath Lab will not be returned to North

Carolina without appropriate CON approval. As outlined in the architect's letter (**Attachment D**), the construction costs are \$955,373 and architectural and engineering costs are \$95,120.¹ These costs, as well as Project contingency, permitting and IT fees, are also included in **Attachment C**. The Project costs do not include sales, property or excise taxes since NHPMC and NHHMC are non-profit, tax-exempt organizations that are not subject to these taxes.

This Project meets the definition of "replacement equipment" found at N.C. Gen. Stat. § 131E-176(22a). The sole purpose of this Project is to replace comparable medical equipment currently in use. The Existing Cath Lab will remain in use until the Replacement Cath Lab is installed, and then the Existing Cath Lab will be disposed of pursuant to **Attachment B**. Thus, this Project does not increase the inventory of existing and approved cardiac catheterization labs in Mecklenburg County. The total cost of the Project, \$1,999,576, is within the \$2 million threshold in N.C. Gen. Stat. § 131E-176(22a).

This Project also meets the requirements of 10A NCAC 14C.0303. As set forth above, all activities essential to acquiring and making operational the Replacement Cath Lab have been included in the Project cost of \$1,999,576. See 10A NCAC 14C.0303(b). The Existing and Replacement Cath Labs are "comparable medical equipment" pursuant to 10A NCAC 14C.0303(c) because they are functionally similar and are used for the same diagnostic or treatment purposes. Further, the Project meets the requirements of 10A NCAC 14C.0303(d)(1)-(3) because :

1. The Replacement Cath Lab has the same technology as the equipment currently in use, although it does possess expanded capabilities due to technological improvements;
2. The Replacement Cath Lab is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use (see **Exhibit E**) and is not used to provide a new health service; and
3. The acquisition of the Replacement Cath Lab 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 Cath Lab is acquired.

None of the exclusions set forth in 10A NCAC 14C.0303(e)(1)-(5) applies to this Project. See **Attachment E**.

In conclusion, based on the information described above, please confirm in writing that this Project is exempt from CON review.

¹ Please note that the Replacement Cath Lab will be installed directly at NHHMC; it will not be installed first at NHPMC and then moved, as this would require additional and unnecessary expense.

Ms. Martha Frisone
February 14, 2017
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Due to lead times associated with ordering the Replacement Cath Lab, we would appreciate your earliest consideration of this request.

If you have any questions, please contact me at (704) 384 - 3462. Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink that reads "Lisa L. Griffin". The signature is written in a cursive, flowing style.

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

cc: Barbara Freedy, Director, CON, Novant Health, Inc.
Laura MacFadden, VP, Design & Construction, Novant Health, Inc.
Regina Hartung, VP, Cardiac Services, NH Presbyterian Medical Center

File: HMC Cath Lab REER Cover Lt 02.14.2017.doc

Attachment A



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

SIEMENS REPRESENTATIVE
Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Customer Number: 0000059463

Date: 1/3/2017

PRESBYTERIAN HOSP HUNTERSVILLE
10030 GILEAD RD
HUNTERSVILLE, NC 28078

This proposal is valid till 06/30/2017. This date supersedes any other validity date indicated in the proposal

Quote Nr: **1-IY2RK1 Rev. 0**

Artis one

All items listed below are included for this system:

Qty	Part No.	Item Description
1	14440516	Artis one BC Card The "Artis one cardiology" configuration can be extended with optional features for interventional radiology combination applications. Artis one is a system that leaves the beaten track and marks a new approach to interventional imaging. The system provides proven, state-of-the-art technology, such as the MEGALIX Cat Plus X-ray tube featuring a unique flat emitter. In addition it offers next-generation tools for uncompromised imaging, such as the optionally available CLEARstent Live to verify stent positioning in real time. Artis one features an integrated display of up to four external video sources, connection kits for one external video source is included as standard. Intelligent operation is enhanced by a configurable heads-up display, allowing you to interact with the system in a completely new, intuitive way. So you can keep your attention where you need it. And because the solution is so easy to understand and deploy, it will have a positive impact on your whole organization. Broaden your procedure mix and hit the sweet spot of your business. Meet a system that is designed differently. Artis one. Designed around you.
1	14432948	Automap Automatic stand positioning depending on the selected reference image and automatic reference image selection depending on the stand positioning.
3	14440576	Display connection kit DVI cable to connect 3rd party systems in the control room, and showing their video on the 30" examination room display. This kit is not needed when the Panoramic Display is ordered.
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.
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

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
		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	14440518	<p>HeartSweep</p> <p>HeartSweep is rotational angiography with simultaneous rotation around two axes. This enables covering nearly every trajectory in a short time to display an entire vascular tree in all the standard angulations in a single acquisition.</p>
2	14432953	<p>Lower body radiation protection</p> <p>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).</p> <p>Product may not be used in conjunction with a TRUMPF or MAQUET surgery table.</p>
1	14440574	<p>Mobil upper body rad. Prot. XL</p> <p>This enlarged radiation shield with a curtain provides for the user an increased protection from scattered radiation compared to the smaller one. It includes two scattered radiation protection blankets, a protective curtain and a ceiling rail (4m/ 157.5"). The blankets cover the patient's body in order to increase the reduction rate of scattered radiation. The curtain increases the scattered radiation protection by closing the gap between patient and shield. The shield is made of acrylic glass with lead equivalent of 0.5 mm/0.2" (w x h: 78 cm x 90 cm/ 30.7" x 35.4") which can pivot and rotate around a fixed point with a range of 360 degrees. The shield has a special patient cut-out for interventional examinations. It is mounted on a counter-weighted, height-adjustable support arm that is fixed on a column with a height of 800 mm/ 31.5".</p>
1	14440418	<p>Infusion bottle holder</p> <p>This infusion bottle holder can be mounted at the accessory rail of the patient table. It holds up to 4 infusion bottles. It includes an infusion bottle holder made of stainless steel with 4 retaining rings. Length: 84 - 138 cm (21.6" - 54.3") Weight: 1.3kg (2.87 lb) Product may not be used in conjunction with a TRUMPF or MAQUET surgery table.</p>
1	14440565	<p>Body Module</p> <p>Table insert with attached accessory rails for mounting control modules in the abdominal part of the patient positioning tabletop.</p>
1	14440521	<p>VOLCANO s5i Cable Kit</p> <p>Cable set for operating the Volcano s5i ultrasound system incl. s5iz and s5iu (CORE-System). This cable set will already be integrated into the Artis one table in the factory.</p>

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
		It contains all cables for connecting the components at the patient table to the s5i imaging system in the control room.
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	14440559	21" color display (e.g. Sensis) One extra 21" display in the examination room, in an expanded display suspension system.
1	AXA_INITIAL_2 4	Initial onsite training 24 hrs 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. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. 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_FOLLOW UP_24	Follow-up training 24 hrs Up to (24) hours of follow-up on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. 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_FOLLOW UP_12	Follow-up training 12 hrs Up to (12) hours of follow-up on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. 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_ARTS1M	Artis One Essential Class, w/Travel Tuition for (1) imaging professional to attend Siemens class at Siemens Training Center or designated training facility. The course is designed to provide the participant with an introduction to the Artis One system and new functions with the Artis One. Through the use of demonstrations, lectures, and hands-on labs experience using an Artis One system, participants will learn Artis One 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. This class includes lunch, economy airfare, and lodging for (1) imaging 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.
2	NT60010635	Blue anti-fatigue floor mat for hospital
1	AXA_RIG_ZEE SP_STD	Standard Rigging zee SP
1	AXA_BUDG_A DDL_RIG	Budgetary Add'l/Out of Scope Rigging \$7,000

PRELIMINARY PROPOSAL

Quote Nr: **1-IYBGXN Rev. 0**

ACUSON Freestyle ultrasound system

All items listed below are included for this system:

Qty	Part No.	Item Description
1	11002300	<p>ACUSON Freestyle Mainframe</p> <p>The ACUSON Freestyle(tm) ultrasound system* is the world's first ultrasound system that operates with wireless transducers, a breakthrough in ultrasound imaging. The system features superior image quality and a new standard in ease of use in an ergonomic and portable design.</p> <p>Standard features include:</p> <ul style="list-style-type: none"> - B-mode - Color flow mapping - Spatial compounding - Speckle reduction - Auto image optimization - Supports wireless transducers - One (1) transducer cable adapter - Two (2) batteries for wireless transducers - DICOM Storage, Storage Commitment, Modality Worklist and Echo - DICOM networking: Ethernet (wired) and 802.11b/g (wireless) - Factory default and user customizable exam types - High resolution flat panel display - A/C and battery operation - Two (2) charger bays for wireless transducer batteries <p>*Product pending shipment confirmation</p>
1	11002400	<p>Freestyle 3.5 Software</p> <p>The 3.5 Release for the ACUSON Freestyle(tm) ultrasound system continues the advancement of imaging performance and ease of use to meet the increasing clinical demands.</p> <p>The release features include needle visualization enhancement, advancement in image quality with new speckle filters and presets, enhanced user interface, mobile link application, and additional workflow improvements. These features are standard:</p> <ul style="list-style-type: none"> •Needle Visualization Enhancement improves the visibility of in-plane and out-of-plane needles, especially at steeper angles, using the ACUSON Freestyle system's software algorithm using unique multi-beam spatial compounding and other optimization techniques, while maintaining excellent image quality of the anatomical target and surrounding structures. •Wireless Enterprise Authentication enables wireless connection to enterprise networks to send to PACS. This is based on qualified sites that meet certain network specifications. •ACUSON Freestyle(tm) mobile link app connects the system to a Microsoft(r) Window(r) device* to view, open, and share images from the patient study list, create patient study worklists and send them to the ACUSON Freestyle system to start new studies faster and easier with privacy and security protection. <p>NOTE: Image viewing on the ACUSON Freestyle mobile link app is for informational purposes only, and is not intended for diagnostic use.</p> <p>*Windows 8.1 is required. Device is not included.</p>

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	11002709	Freestyle 3.5 Lang Kit English English operating instructions for the ACUSON Freestyle(tm) ultrasound system.
1	11002331	Freestyle Cordset North America Custom power cordset for use with the ACUSON Freestyle(tm) ultrasound system in the North America. Product pending shipment confirmation.
1	11002302	L13-5 Transducer, Freestyle Linear wireless transducer 13-5 MHz. Includes one transducer battery. Product pending shipment confirmation.
1	11002301	L8-3 Transducer, Freestyle Linear wireless transducer 8-3 MHz. Includes one transducer battery. Product pending shipment confirmation.
1	11003358	Freestyle Probe Sheath Set Supply of transducer Sheath covers for the ACUSON Freestyle
1	11002306	Freestyle GCX Roll Stand ACUSON Freestyle(tm) ultrasound system GCX roll stand allows for easy maneuverability and ergonomic positioning. Quick-release, tilt-adjustable system mount and storage baskets. Product pending shipment confirmation.
1	11002307	Freestyle Keyboard USB keyboard designed for medical environments. Easy-to-clean and disinfect. Product pending shipment confirmation.
1	11002726	Freestyle Manual CD 3.5 Operating instructions for the ACUSON Freestyle(tm) ultrasound system.
1	USD_INITIAL_4	Initial onsite training 4 hrs -FMV \$1750 Up to (4) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. 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	ACU_SVC_FST YLE_2YR	USD Ext Warrnty FStyle 2nd yr (FMV \$4.1k)
1	ACU_XWR_FS TYLE_2YR	Offset for FStyle Ext Warranty 2nd yr
1	ACU_SVC_FST YLE_3YR	USD Ext Warrnty FStyle 3rd yr (FMV \$4.1k)
1	ACU_XWR_FS TYLE_3YR	Offset for FStyle Ext Warranty 3rd yr
1	AXA_PR_FREE STYLE	AT Artis Free Combo Promo Purchase an Artis Zee or Q system (excluding MP) with an Acuson Freestyle to receive promotional pricing on the Freestyle ultrasound system. This offer is only valid until September 30th, 2017 and delivery of these products must be taken by December 31st, 2017.

System Total: \$647,235

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



SIEMENS REPRESENTATIVE
Stuart Wadley - (919) 605-9227

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

Stuart Wadley
(919) 605-9227
stuart.wadley@siemens.com

Maquet Medical Systems, USA
 45 Barbour Pond Drive
 Wayne, NJ 07470
 Telephone (800) 777-4222

Date: 12/28/2016

To: Novant Health Huntersville Medical Center 10030 Gilead Road Huntersville NC 28078 Affiliation: Vizient Tier 3	Telephone: Quote Number: JFIR-AH3QDZ-1 Sales Representative: William Pryse
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Contact: Marty Haynes Title: Department:	Phone: (336)-277-0260 Fax:
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Item	Qty	P/N	Description					
1	1	D998-00-0800-53	CARDIOSAVE Hybrid and one (1) year warranty Product includes CARDIOSAVE Blood Pressure Transducer Adapter Cable CARDIOSAVE ECG Trunk Cable - 5 lead - AAMI CARDIOSAVE ESIS Lead Wires 50" - 5 Lead (Op Rm) - AAMI Helium - 3 refillable tanks, 104L External Signal Cable CARDIOSAVE Hybrid Operators Manual - disc CARDIOSAVE Non-locking Male Luer Plug Helium Cylinder Washer Thermal Recorder Chart Paper Starter Pack Fiber Optic Cleaning Swabs (qty 5) Fiber Optic Connector Cleaner CARDIOSAVE Plastic Weather Cover (for off cart configuration) Handheld Doppler					
2	1	D998-00-0803	Cardiosave Trainer					
3	1	USSV.CDSVPOSE.W	CRDSVE - MCare SILVR Pln - POSEW					
4	1	24/7 REMOTE SUPPORT	Available 24/7 Remote Support via Win-IABP					
5	1	EDUCATION	Initial Clinical Education on IABP					
6	1	CLINICAL SUPPORT	24 Hour Clinical Support					
							TOTAL NET w/OPTIONS	
							\$62,376.13	



**CAPITAL EQUIPMENT PURCHASE AGREEMENT
Volcano CORE® Precision Guided Therapy System**

Customer agrees to purchase one (1) Volcano CORE® Precision Guided Therapy System as outlined below. This offer is valid until June 30, 2017.

Quotation Date: 1/3/2017

Payment terms are net thirty (30). CORE® Unit(s) will be shipped FOB origin, freight pre-paid and added to invoice.

<u>Qty</u>	<u>Catalog Number</u>	<u>Product</u>	<u>Customer Price</u>
1	CORE01	CORE® Precision Guided Therapy System <i>Included: CORE CPU, one (1) bedside controller and one (1) control room controller, Phased Array PIM Body, Power Transformer, Connection Box, 19"NEC Monitor Kit, DICOM Network Connection, ChromaFlo Functionality, Cable Pre-Install Kit, Operator's Manual and seven (7) year Software Support Agreement ("SSA") which provides for unspecified Updates to the CORE software releases and is incorporated herein by reference. A copy of the SSA is available from your Volcano Sales Representative or online at www.volcanocorp.com/products/pdf-files/software-support.pdf.</i>	Included
1		End User License Agreement <i>Customer agrees that use and maintenance of Volcano Software embedded in capital products are subject to the terms of the End User License Agreement, as it may be updated by Volcano from time to time ("EULA"). A copy of the EULA is also available online at www.volcanocorp.com/products/pdf-files/end-user.pdf. The terms of the EULA are incorporated herein by reference.</i>	Included
1	REV04	CORE® Revolution <i>Includes SpinVision PIMr and PIM Cable</i>	Included
1	FFR04	CORE® FFR <i>Includes PIMffr and PIMffr Cable</i>	Included
1	PRN01	CORE® Printer	Included
1	CPAD01	CORE® Control Pad <i>Bedside touchscreen controller offering system control from the sterile field</i>	Included
1	435-0100.30	IFR® Modality <i>iFR Hyperemia-Free Lesion Assessment Modality CORE Interface, Operator's Manual. Customer agrees that use of the iFR Application Software License with interface to CORE is subject to the terms of the End User License Agreement.</i>	Included
1		Installation Cost	Included
1		One (1) Year Warranty	

Total Amount Due: \$105,000.00

The pricing outlined in this Agreement is based on the anticipated needs of Customer. Additional components, accessories or installation costs may be required.

To better facilitate continuing product and clinical education, Customer will grant Volcano trained personnel a minimum of two (2) days of cath lab access per month for a period of two (2) years.

Customer agrees that Volcano will be their sole source provider of single-patient use IVUS catheter and FFR products (collectively, "Disposables") for a period of two years upon acceptance of this Agreement. The disposable prices listed herein include a price protection guarantee on the products and catalog numbers listed. If the source terms are not met, Volcano Disposables pricing will revert to published list pricing until a new Agreement is reached.

Customer may acquire Disposables for use with its System directly through Volcano Customer Service:

- Phone (800) 228 4728
- Fax (916) 638 8812
- Email cs@volcanocorp.com

All disposables will be shipped FOB origin, freight pre-paid and added to invoice. Volcano payment terms are net thirty (30).

Except as specifically outlined in this agreement, Volcano makes no commitment, promise or legal obligation to deliver any future product, service, or enhancements to existing products, features, and/or functionality. Any and all of the aforementioned may only be provided under terms to be agreed upon in writing when and if such products become commercially available.

The pricing, terms and conditions offered herein is confidential and proprietary and Customer shall not disclose such pricing, terms or conditions to any third party, unless required to do so by law. The confidentiality requirement includes the prohibition of disclosure, whether blinded as to its source or otherwise, to any group purchasing organization, consultant, online comparative source, sub-contractor or temporary employee which may, from time to time, be retained by Customer. This confidentiality requirement is not only specific to the proposal herein but also to any resultant Agreement with Volcano. With any breach of this confidentiality requirement, Volcano may rescind or terminate the proposal immediately and may seek any and all remedies available to it as a result of this breach including injunctive relief and damages.

[Signature page follows]



ACCEPTED BY:

Novant Health – Presbyterian Huntersville

10030 Gilead Road
Huntersville, NC 28078

Phone (704) 316-4000
Fax

ACCEPTED BY:

VOLCANO CORPORATION

2870 Kilgore Road
Rancho Cordova, CA 95670

Phone (800) 228-4728
Fax (916) 638-8812

Authorized Agent Name (please print)

Authorized Agent Name (please print)

Signature

Signature

Title

Title

Date

Date

*Please send a purchase order and this signed Agreement to Volcano Customer Service.
Fax (916) 638-8812 or email cs@volcanocorp.com. Pricing and terms are subject to management approval.*

NOVANT HEALTH

721854

Quotation

Sales Support
tel (800) 633-7231
fax (412) 406-0952
radiologysolutions.bayer.com

Bayer HealthCare LLC
1 Bayer Drive
Indianola, PA 15051



Quote No. Q-00005275

This quotation has been prepared for: Novant Health Huntersville Medical Center

Issued on 1/3/2017

Valid until 3/4/2017

Trade-in required No

Your Bayer Sales Team:

Harold Karn, Senior Professional Sales Consultant, trey.karn@bayer.com

Quotation Overview

VIZIENT RADIOLOGY Pricing Applied

Bayer's diagnostic imaging products, software, and equipment service help healthcare teams in radiology address their critical performance, quality, uptime, and scheduling requirements.

Please note: If pricing and terms of this [order/quote] are based upon your current Group Purchasing Organization (GPO) affiliation, any change to your current affiliation may require a new quote or updated terms and pricing.

>See Products and Services Details in this quote for an itemized breakdown of quoted products.

Imaging Products and Services

Product Name	YOUR PRICE
Arterion - Medrad® Mark 7 Arterion® Injection System	\$28,775.00
TOTAL (Local taxes, shipping and/or handling to be invoiced when applicable)	\$28,775.00

TOTAL	\$28,775.00
GRAND TOTAL (Local taxes, shipping and/or handling to be invoiced when applicable)	\$28,775.00

If your organization is tax exempt, please notify Sales Support at 1-800-633-7231.

Quotation

Sales Support
tel (800) 633-7231
fax (412) 406-0952
radiologysolutions.bayer.com

Bayer HealthCare LLC
1 Bayer Drive
Indianola, PA 15051



Quote No. Q-00005275

This quotation has been prepared for: Novant Health Huntersville Medical Center

Issued on 1/3/2017

Valid until 3/4/2017

Trade-in required No

Your Bayer Sales Team:

Harold Karn, Senior Professional Sales Consultant, trey.karn@bayer.com

If you are using this quote as a purchase order, please complete the Acceptance and Billing information below:

Acceptance and Billing

Your signature below indicates your acceptance of this Agreement, including the terms and conditions included as part of this document. Please complete the information below, along with your Purchase Order referencing Quote # Q-00005275, and email this form to Sales Support at risalesupport@bayer.com AND your SC, Harold Karn, at trey.karn@bayer.com.

If pricing and terms of this order are based on your current Group Purchasing Organization (GPO) affiliation, any change to your current affiliation may require a new quote or updated terms and pricing.

Payment terms

30 days due net

Terms of Delivery

HUNTERSVILLE

Customer contact

Marty Haynes

Address

10030 Gilead Rd
Huntersville, NC 28078

Billing Information

10030 Gilead Rd
Huntersville, NC 28078

Customer Number

131906

Phone

(336) 277-0280

Additional Customer Comments

PO#

Write PO number

PO Amount

Write PO amount

Customer Approver

Write customer name

Customer Approver Title

Write customer title

Billing Email Address (if applicable)

Write email address

Customer Approver Signature

X

Date

MM/DD/YYYY

Please print and sign

BAYER, the Bayer Cross, Certegra, P3T, Medrad, Stellant, XDS, Veris, Spectris Solaris, Spectris, DirectCARE, PartnerCARE, VirtualCare, SelectCARE, Mark 7 Arterion, and Mark V ProVis are registered trademarks of the Bayer group of companies. Radimetrics, MRXperion, Avanta, Twist & Go, and VFlow are trademarks of the Bayer group of companies.
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Attachment B



Redefining Replacement Medical Parts

Customer Information:
Novant Health
119 Brookstown Avenue, Suite 400
Winston-Salem, NC 27101

Date: 1/31/2017
Offer: FD20
Page: 1 of 2

Attention: Marty Haynes
Phone: 336-277-0260
Email: mhaynes@novanthealth.org

Re. Agreement to Buy

First Call Parts (FCP, the Buyer) is pleased to present to Novant Health, (the Seller) the following agreement for products and/or services described herein at the stated prices and terms, subject to your acceptance of the terms and conditions and on any attachment hereto.

First Call Parts (Buyer) agrees to buy from Novant Health (the Seller) the following used X-ray Equipment ("the Equipment").

Quantity	Item	Price
1	2006 Philips FD20 Lab, Software Version 7.2.9. Will include all software, manuals, and accessories	\$10,000
1	System above contains 03/2016 Xray Tube and 10/2012 Detector. Items must pass image calibration at time of removal.	\$12,500

Price: \$22,500 meeting above criteria, Includes deinstallation services

TITLE:

Title to the equipment shall pass from Seller to Buyer upon the start of deinstallation.

RISK OF LOSS:

Risk of Loss to the equipment shall pass to Buyer upon Seller's release of the equipment for delivery. Until such time, in the event of loss or damage to equipment, Seller can, as its sole liability and Buyer's exclusive remedy: (1) Terminate this Agreement and return to Buyer all monies it has paid to Seller, or (2) renegotiate with the Buyer the purchase price to be paid by Buyer.

WARRANTY DISCLAIMER: Equipment must be fully functional before deinstallation. After deinstallation starts, no Warranty is expressed or implied by the Seller.

Governing Law. This Agreement, without regard for the place of execution, performance, or payment, shall be governed, construed, and enforced in accordance with the laws of the Commonwealth of Virginia and applicable federal laws of the United States.

Additional Condition To The Agreement. Any controversy arising in connection herewith shall be litigated in Roanoke, Virginia, USA. The parties hereto hereby submit exclusively to the jurisdiction of the Circuit Court for the City of Roanoke, Virginia, or the United States District Court for the Western District of Virginia, Roanoke, Division, and said designated courts shall have jurisdiction over any and all controversies arising out of or connected with this Agreement.



The parties hereto waive any other venue to which they might otherwise be entitled by virtue of domicile, habitual residence, place of occurrence of any event giving rise to the controversy, or otherwise.

In addition, the Seller agrees to pay all expenses of FCP associated with or arising from any collection efforts to recover sums due pursuant to this Agreement, whether suit be brought or not, including, without limitation, all court or collection costs, and all reasonable attorney's fees and expert fees. This bid is subject to inspection and acceptance of the equipment. If the equipment is not accepted, a full refund of any monies paid made will be made. Inspection must be made within 10 business days from signing of this contract.

This price will remain in effect for Thirty (30) Days.

The following signatures evidence acceptance of this agreement by both parties listed below

First Call Parts, Inc.

Novant Health

David Trask

Authorized Signature

Vice President

Title: _____

Date: _____

Date: _____

Attachment C

PROPOSED CAPITAL COSTS

Project Name: **NHHMC Cath Lab**

February 7, 2017

Proponent: **Novant Health Huntersville 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		\$	-	
(6)	Other (specify)		\$	-	
(7)	Sub-Total Site Costs		\$	-	

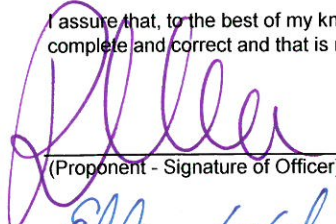
B. Construction Contract

(8)	Cost of Materials				
	General Requirements	\$		28,620.00	
	Concrete/Masonry	\$		16,662.00	
	Woods/Doors & Windows/Finishes	\$		161,412.00	
	Thermal & Moisture Protection	\$		15,000.00	
	Equipment/Specialty Items	\$		33,413.00	
	Mechanical/Electrical	\$		224,460.00	
	Other	\$		404,209.00	
	Sub-Total Cost of Materials		\$	883,776.00	
(9)	Cost of Labor GC Labor		\$	61,260.00	
(10)	Other - (Specify)		\$	10,337.00	
(11)	Sub-Total Construction Contract		\$	955,373.00	


C. Miscellaneous Project Costs

(12)	Building Purchase		\$	-	
(13)	Fixed Equipment Purchase/Lease		\$	647,235.00	
	Other: PMC Cath Lab #4 Equipment Removal		\$	22,500.00	
(14)	Movable Equipment Purchase/Lease		\$	196,151.00	
(15)	Furniture		\$	-	
(16)	Landscaping		\$	-	
(17)	Consult Fees				
	Architect and Engineering Fees	\$		95,120.00	
	Market Analysis	\$		-	
	Other - (Specify)	\$		-	
	Sub-Total Consultant Fees		\$	95,120.00	
(18)	Financing Costs (e.g. Bond Loan, etc)		\$	-	
(19)	Interest During Construction		\$	-	
(20)	Other (Information Technology)		\$	17,500.00	
	Other (Low Voltage)		\$	10,000.00	
	Other (Project Contingency @ 3%)		\$	55,697.00	
(21)	Sub-Total Miscellaneous		\$	1,044,203.00	
(22)	Total Capital Cost of Project (Sum A-C above)		\$	1,999,576.00	

I assure that, to the best of my knowledge, the above capital costs for the proposed project are complete and correct and that is my intent to carry out the proposed project as described.


VP Heart & Vascular Institute Novant Health

 (Proponent - Signature of Officer) (Title of Officer)


VP McCulloch England Architects

 Architect - (Certifying construction Cost Only)

Attachment D

100 Queens Road
Suite 200
Charlotte, NC 28204
704/372-2740
www.McCullochEngland.com



January 20, 2017
H1664/17

Mr. Gary Ballard
Director of Construction Logistics and Medical Equipment Planning
Novant Health
Novant Health Presbyterian Medical Center
200 Hawthorne Lane
Charlotte, NC 28233

Re: Cath Lab Addition and Renovation
Novant Health Huntersville Medical Center
Huntersville, North Carolina

Dear Gary:

This letter shall certify to the best of our knowledge, that the construction costs shown below are the costs which might be expected for this scope of work.

Preliminary Construction Cost Estimate

NHHMC Bed and OR Expansion

Estimated Construction Cost: \$ 955,373.00
(Includes contingencies)

Estimated Architectural / Engineering Fee: \$ 95,120.00

Preliminary Estimated Construction Schedule

- 4.5 Months

The Preliminary Construction Cost Estimate and schedule duration have been established with the assistance of Vannoy Construction of Charlotte, North Carolina.

This estimate is for construction costs and Architectural / Engineering fees only. The above estimate does not include equipment, furniture, financing costs, security costs, IT systems costs, or other costs generally attributable to a project of this nature.

If you should require any additional information, please do not hesitate to contact me.

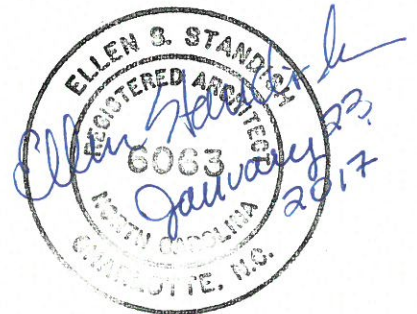
Sincerely,

McCulloch England Associates Architects

Ellen S. Standish, AIA
Ellen S. Standish, AIA LEED AP
Vice President

Richard A. Henly AIA
Larry E. May, Jr. AIA
Grace O. Murray AIA
Michael D. Rowell AIA
Ellen S. Standish AIA
Richard B. Butler AIA
James M. Wiley AIA
Jack L. Gill AIA
Michael K. Satterfield AIA
Steve A. Assante AIA
Daniel A. Kinken AIA
Garrett M. Olin AIA

An Architectural Corporation



Attachment E

Novant Health Huntersville Cardiac Cath Lab Replacement		EXISTING EQUIPMENT (PMC Cath Lab #4)	REPLACEMENT EQUIPMENT (HMC Cath Lab)
Type of Equipment (List Each Component)		Cath Lab	Cath Lab
Manufacturer of Equipment		Philips	Siemens
Tesla Rating for MRIs		n/a	n/a
Model Number		Allura FD 20/20	Artis One
Serial Number		0513314	TBD
Provider's Method of Identifying Equipment		Site ID: 536174	Internal Numbering System
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		1/10/2006	TBD
Does Provider Hold Title to Equipment of Have a Capital Lease?		Holds title	HMC 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 for New>		\$1,491,203.81	\$1,999,576
Total Cost of Equipment		\$1,250,015.94	\$647,235
Fair Market Value of Equipment		\$22,500	\$647,235
Net Purchase Price of Equipment		n/a	\$647,235
Locations Where Operated		PMC Cath Lab #4	HMC
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 Cath Procedures	----
Type of Procedures New Equipment is Capable of Performing		----	Cardiac Cath Procedures