



North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section

2704 Mail Service Center • Raleigh, North Carolina 27699-2704
<http://www.ncdhhs.gov/dhsr/>

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
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Craig R. Smith, Section Chief
Phone: (919) 855-3873
Fax: (919) 733-8139

October 19, 2012

Greg Bass, Director
CHS Management Company
P.O. Box 32861
Charlotte, NC 28232

Exempt from Review - Replacement Equipment

Facility: Carolinas Medical Center (CMC)
Project Description: Replace an existing MRI scanner in MRI room #2
County: Mecklenburg
FID #: 944734

Dear Mr. Bass:

In response to your letter of October 12, 2012 the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Siemens Magnetom Avanto 1.5T MRI scanner to replace the existing GE Signa Excite HD 1.5T MRI scanner, Serial # R5328. 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. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided. In addition, you should contact the Construction Section to determine if they have any requirements for development of the proposed project.

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Fatimah Wilson, Project Analyst

Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Branch, DHSR
Construction Section, DHSR





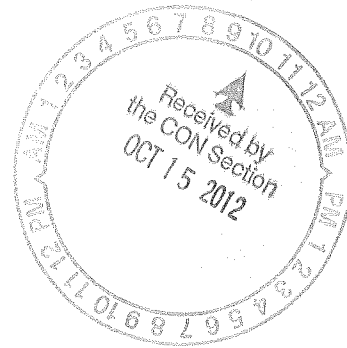
Factual

Carolinah HealthCare System

James E.S. Hynes
Chairman

Michael C. Tarwater, FACHE
Chief Executive Officer

Joseph G. Piemont
President & COO



October 12, 2012

Mr. Craig R. Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603-0530

RE: Replacement of Magnetic Resonance Imaging Scanner Equipment on the campus of
Carolinah Medical Center

Dear Mr. Smith:

Carolinah Medical Center (CMC) is planning to replace an existing magnetic resonance imaging (MRI) scanner with new, technologically comparable equipment. CMC intends to purchase a Siemens 1.5 Tesla Magnetom Avanto scanner to replace a five-year-old GE Signa Excite HD scanner currently located in MRI scanner room number two on the fourth floor of the medical center. The existing equipment is near the end of its useful life and is at risk for service interruptions due to downtime.

The Siemens Magnetom Avanto will be used for the same types of procedures as the existing equipment and it will not be used to provide a new health service. A chart comparing the existing equipment and the replacement equipment is included in Attachment A. The existing equipment provided 3,822 scans in the period from January to August 2012.

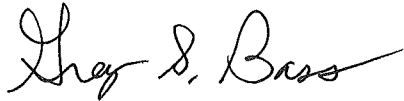
The purchase price of the new MRI scanner is \$606,821 as shown in the quote from Siemens provided in Attachment B. Siemens will also take possession of the old equipment and a letter included as Attachment C documents the equipment will be taken out of service and removed from North Carolina. The projected total capital expenditure for the removal of the existing equipment, renovation of the room and installation of the replacement equipment is \$1,036,818. The project cost does not include any sales taxes as Carolinah Medical Center is a division of The Charlotte-Mecklenburg Hospital Authority which is a governmental authority not subject to sales tax. The certified total capital cost schedule required to install the new equipment is provided in Attachment D.

Craig R. Smith
October 12, 2012
Page 2

The North Carolina Certificate of Need statutes provide a definition of replacement equipment in N.C.G.S. 131E-176(22a). The definition requires the replacement equipment be comparable to the existing medical equipment and cost less than \$2 million when installed. The statutes further provide in 131E-184(a)(7) an exemption from certificate of need review for replacement equipment projects if prior notice is provided to the CON Section.

This letter serves as notification of our intent to proceed with this project. We would appreciate your written concurrence that this project is exempt from CON review. If you have any questions or require further information regarding this project, please contact me at 704-355-0314.

Sincerely,

A handwritten signature in black ink that reads "Greg S. Bass". The signature is written in a cursive style with a long horizontal stroke at the end.

Greg S. Bass, Director
CHS Management Company

Attachments

Attachment A

Comparison of Existing and Replacement Equipment

Carolinas Medical Center – MRI Scanner #2 Replacement
Attachment A - EQUIPMENT COMPARISON

	Existing Equipment	Replacement Equipment
Type of Equipment (List each component)	Fixed MRI Scanner	Fixed MRI Scanner
Manufacturer of Equipment	General Electric	Siemens
Model Number	Signa Excite HD 1.5T	Magnetom Avanto 1.5T
Serial Number	R5328	N/A
Provider's Method of Identifying Equipment	Site # 704355MAIN	Site
Specify if Mobile or Fixed	Fixed	Fixed
Date of Acquisition of Each Component	6/18/2007	Fall 2012
Does Provider Hold Title to Equipment or Have a Capital Lease?	Purchased	Purchase
Specify if Equipment Was/Is New or Used When Acquired	New	Used
Total Capital Cost of Project (Including Construction, etc.)	\$1,900,000	\$1,036,818
Total Cost of Equipment	\$1,599,888	\$606,821
Fair Market Value of Equipment	\$1,599,888	\$606,821
Net Purchase Price of Equipment	\$1,599,888	\$606,821
Locations Where Operated	Carolinas Medical Center MRI Room #2	Carolinas Medical Center MRI Room #2
Number Days in Use/To Be Used in N.C. per Year	M-Sat 6 days/week	M-Sat 6 days/week
Percent of Change in Patient Charges (by procedure)	0	0
Percent of Change in Per Procedure Operating Expenses (by procedure)	0	0
Type of Procedures Currently Performed on Existing Equipment	MRI Scans of all body parts	
Type of Procedures New Equipment is Capable of Performing		MRI Scans of all body parts

Attachment B
Equipment Vendor Quote

SIEMENS

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway, Malvern, PA 19355
Fax: (866) 309-6967

SIEMENS REPRESENTATIVE
Shawn Elliott - (615) 517-5699

PRELIMINARY PROPOSAL

Customer Number: 0000035965

Date: 12/12/2011

CAROLINAS HEALTHCARE SYSTEM
1000 BLYTHE BLVD
CHARLOTTE, NC 28203

Quote Nr: 1-3K7ZNU Rev. 0

MAGNETOM Avanto, RS Proven Excellence System

All items listed below are included for this system:

Qty	Part No.	Item Description
1	14413774	RS MAGNETOM Avanto - System Refurbished Siemens systems for the Magnetic Resonance Imaging are systems which were previously owned and which have been refurbished by the Siemens Refurbished Systems business unit so that they meet Siemens' stringent quality standards. It is the goal of the Siemens RS business unit to assure excellent functionality and reliability, similar to that of new systems. This allows Siemens to provide a 12 month warranty for refurbished MR systems. Important note: This offer is subject to confirmation, due to the limited availability of refurbished systems. The availability will be clarified prior to the signing of any contract.
1	14413897	RS I-class #Tim I-class is the new generation of Tim-based MRI scanners, which enables innovative applications and workflow efficiency. The I-class package comprises: - 3D Distortion Correction - MPPS - ImageFilter SW - PhoenixZIP - DICOM Study Split
1	14413789	RS PC Keyboard US english # Tim Standard PC keyboard with 101 keys.
1	14413763	RS Cover #Avanto Cover color and design are subject to availability.
1	14413770	RS Inline Diffusion #Tim Automatic real-time calculation of trace-weighted images and ADC maps with Inline technology. Compatible to single-shot diffusion-weighted EPI.
1	14413793	RS Shoulder Array Coil #Av;S This iPAT compatible coil for examinations of the left or right shoulder consists of a base plate and two receive array coil attachments available in different sizes, these will be attached and can be relocated on the basis plate.
1	14413794	RS CP Extremity Coil #Tim Circularly Polarized no-tune transmit/receive coil for joint examinations in the region of the lower extremities.
1	14410641	RS MR Workplace Table 1.2m Table suited for syngo Acquisition Workplace and syngo MR Workplace based on syngo Hardware.
1	14410644	RS MR Workplace Container; 50cm 50 cm wide extra case for the syngo host computer with sliding front door to allow change of storage media (CD/DVD/USB).

SIEMENS

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51 Valley Stream Parkway, Malvern, PA 19355
Fax: (866) 309-6967

SIEMENS REPRESENTATIVE
Shawn Elliott - (615) 517-5699

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	14413806	RS Cable Set syngo 11/9 #Av Cable length inside the cabin 11 m, cable length outside the cabin 9 m. Inclusive Ethernet Twisted Pair Adapter and 10 m cable.
1	14413853	RS Venting Kit Sea Freight #Av,Es Overpressure valve as a transport safety device for cold delivery of the magnet by sea (designed for atmospheric pressure conditions at sea level during ocean and land-borne transport).
1	14406340	RS Helium Fill 30/70 #S;Av;Es;TATS Helium Fill for cold delivery ex works.
1	MR_STD_RIG_ INST	MR Standard Rigging and Installation
1	MR_BTL_INST ALL	MR Standard Rigging & Install
1	MR_CRYO	Standard Cryogenics
1	MR_PM	MR Project Management
1	4MR5142869	Armrest #MR
1	MR_INITIAL_32	Initial onsite training 32 hrs
1	MR_FOLLOWUP_P_24	Follow-up training 24 hrs
1	MR_INT_SYN_BCLS	Basic syngo MR Class
1	CHILINST_AVT	Chiller Start-up and Warranty for TIM
1	14413757	RS Tim [76x18] Q-engine #Av Tim [76x18] Q-engine performance level Tim [76x18] is Total imaging matrix with 76 seamlessly integrated coil elements, combinable to 18 RF channels. It is for demanding high-end applications and optimized throughput. Tim [76x18] has flexibility in Parallel Imaging. PAT factors up to 4 (one direction) or 12 (in two directions, optional) help speed acquisitions. Maximum SNR is ensured through the new matrix coil technology. Q-engine Gradient System with AudioComfort Siemens Q-engine are actively shielded, water cooled worldclass gradients with AudioComfort. The Q-engine is designed combining high performance and quietness.
1	14413761	RS Label Tim [76x18] #Av Label on the front cover displaying the Tim level of the system.
1	14413766	RS Remov. Matrix Table w.Trolley #Av The patient table is mounted directly to the magnet assembly. The table can support up to 200 kg (440 lbs) patients with unrestricted vertical and horizontal movement. The removable table allows docking of the table top with a trolley for preparing patients outside the scan room for maximum flexibility and speed.
1	14413775	RS Advanced High Order Shim #Av;S The 'Advanced High Order Shim' System includes 5 non-linear 2nd order electric channels for precise additional fine-tuning of homogeneity once the patient is inside the system.
1	14413807	RS Separator #Av;Es The SEP (Separation cabinet) has to be used if a central hospital chilled water supply is available or if a chiller of any brand/type is already available. In these cases, the primary water specifications must fulfill the requirements (e.g. 60kW heat dissipation; 90l/min flow; 6 to 12°C water temperature; ph value 6 to 8). Dimension: 1800mm x 650mm x 650mm (height x width x depth) Weight: 400kg
1	14413825	RS UPS Cable #Tim Power cable for the UPS-system UPS Powerware PW 9125-3000i (8857810) at the ACC of the MAGNETOM Tim systems for backing up the computer. Standard cable length 9 m.

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Fax: (866) 309-6967

SIEMENS REPRESENTATIVE
Shawn Elliott - (615) 517-5699

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	14417559	RS UPS system UPS system Eaton PW9130-3000G-3000T-XLEU for MAGNETOM Tim and MAGNETOM Symphony systems for safeguarding computers. Power output: 3.0 kVA / 2.7 kW Bridge time: 5 min full load / 14 min half load Input voltage: 230 VAC
1	14417560	RS UPS Battery module UPS battery module Eaton PW 9130N-3000T-EBM for all MAGNETOM Tim and MAGNETOM Symphony systems for safeguarding computers. Extension for: PW9130i-3000T Battery type: Closed, maintenance-free Extension of the bridge time to: 24 minutes with a module Dimensions (H x W x D): Battery module: 346 x 214 x 412 mm incl. bracket set Weight: approx. 50 kg
1	MR_BUDG_AD DL_RIG	Budgetary Add'l/Out of Scope Rigging
1	MR_TRADE_IN _ALLOW	MR Trade-in-Allowance
1	14413854	RS Diffusion Tensor Imaging #Tim Single Shot EPI sequence for measuring diffusion-weighted data sets with up to 256 directions of diffusion weighting. Based on these data sets, the diffusion tensor itself and parametric maps derived from it (e.g. fractional anisotropy) are calculated automatically and in real-time. The package supports both the clinical applications (e.g. diseases of the white matter) and advanced research applications.
1	14413773	RS Single Voxel Spectroscopy #Tim Integrated software package including sequences and protocols for proton spectroscopy to examine metabolic changes in the brain (e.g. in tumors and degenerative diseases).
1	14406267	RS Spectroscopy Evaluation syngo Comprehensive software package for evaluation of spectroscopy data on the syngo Acquisition Workplace.
1	14418038	RS 2D Chemical Shift Imaging #Tim Integrated software package with sequences and protocols for proton 2D Chemical Shift Imaging (2D CSI) to examine metabolic changes in the brain (e.g. in tumors and degenerative diseases).
1	14418039	RS 3D Chemical Shift Imaging #Tim Integrated software package with sequences and protocols for proton 3D Chemical Shift Imaging (3D CSI) to examine metabolic changes in the brain (e.g. in tumors and degenerative diseases) as well as in the prostate.
1	14413881	RS 8-channel Foot/ Ankle Coil #Av;S The 8-channel foot-ankle coil is an iPAT-compatible "no-tune" receiver coil for the examination of the foot and the ankle joint.

System Total: \$606,821

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. To place an order for the above listed items, please notify your Siemens Healthcare Sales Representative who will submit to you a formal Siemens Healthcare Proposal, inclusive of Terms, Conditions, and Warranty coverage. Only a formal Siemens Healthcare Proposal may be used to create a binding order for this equipment.

Siemens Healthcare

Shawn Elliott
(615) 517-5699
shawn.d.elliott@siemens.com

Attachment C

Used Equipment Vendor Disposal Letter

11 October, 2012

Jeff G. Aho
Administrative Director, CMC/LCH Radiology
Carolinas Healthcare Systems
1000 Blyth Blvd
Charlotte, NC

RE: GE MR Removal, serial number R5328,

Mr. Aho

The purpose of this letter is to confirm that Siemens Medical Solutions, USA, Inc (Siemens) will be responsible for removing your existing General Electric 1.5t MR with serial number R5328 (existing equipment) as part of your purchase of the Siemens RS Magnetom Avanto 1.5t MR system. The cost for the deinstallation and removal is included in your contract price for replacement equipment.

The system will be removed from Service by a broker designated by Siemens for either re-sale purposes or parts. The system will not be placed into Service by Siemens in North Carolina without proper State Approvals.

David Crooks PMP
Project Manager
Siemens Medical Solutions



Attachment D
Capital Cost Schedule

Project name: CMC MRI #2 Capital Cost Schedule

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	\$	-
Other (Specify)	\$	-
Sub-Total Site Preparation Costs	\$	-
(6) Other (Specify)	\$	-
(7) Sub-Total Site Costs		\$ -

B. Construction Contract

(8) Cost of Materials		
General Requirements	\$	-
Concrete/Masonry	\$	-
Doors & Windows/Finishes	\$	-
Thermal & Moisture Protection	\$	-
Equipment/Specialty Items	\$	-
Mechanical/Electrical	\$	-
Other (Specify)	\$	-
Sub-total Cost of Materials	\$	-
(9) Cost of Labor	\$	-
(10) Other (Specify)	\$	-
(11) Sub-Total Construction Contract		\$ 363,005

C. Miscellaneous Project Costs

(12) Building Purchase	\$	-
(13) Fixed Equipment Purchase/Lease	\$	606,821
(14) Movable Equipment Purchase/Lease	\$	-
(15) Furniture	\$	-
(16) Landscaping	\$	-
(17) Consultant Fees		
Architect and Engineering Fees	\$	56,992
Legal Fees	\$	-
Market Analysis	\$	-
Other (Specify)	\$	-
Sub-Total Consultant Fees	\$	56,992
(18) Financing Costs (e.g., Bond, Loan, etc.)	\$	-
(19) Interest During Construction		
(20) Other (Contingency)	\$	10,000
(21) Sub-Total Miscellaneous		\$ 673,813

D. Total Capital Cost of Project (Sum A-C above) \$ 1,036,818

I certify that, to the best of my knowledge, the construction costs of the proposed project named above are complete and correct.



(Signature of Licensed Architect or Engineer)

10-11-2012

Date Certified