

### North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor Aldona Z. Wos, M.D. Ambassador (Ret.) Secretary DHHS

> Drexdal Pratt Division Director

August 7, 2015

Elizabeth Kirkman PO Box 32861 Charlotte, NC 28232-2861

Exempt from Review - Replacement Equipment

Record #:

1670

Facility Name:

Carolinas HealthCare System Cleveland

FID #:

953106

Business Name:

The Charlotte-Mecklenburg Hospital Authority

Business #:

1772

Project Description:

Replace CT scanner

County:

Cleveland

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 30, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Siemens SOMATOM Definition AS CT scanner. This determination is based on your representations that the 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,

«cc:

Julie Halatek Project Analyst

Construction Section, DHSR

Acute and Home Care Licensure and Certification Section, DHSR

Assistant Chief, Healthcare Planning

Healthcare Planning and Certificate of Need Section

Assistant Chief, Certificate of Need

www.ncdhhs.gov
Telephone: 919-855-3873 • Fax: 919-715-4413
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





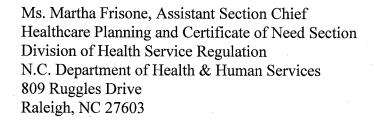
### Carolinas HealthCare System

Edward J. Brown III Chairman

Michael C. Tarwater, FACHE Chief Executive Officer

> Joseph G. Piemont President & COO

June 29, 2015



RE: Replacement of CT Scanner licensed under The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System Cleveland.

Dear Ms. Frisone:

Carolinas HealthCare System Cleveland is planning to replace one of its existing CT scanners with new, technologically comparable equipment. Carolinas HealthCare System Cleveland intends to purchase a Siemens SOMATOM Definition AS CT scanner to replace a 13 year-old GE Lightspeed 4-slice scanner currently located at Carolinas HealthCare System Cleveland. The existing equipment is near the end of its useful life and is at risk for service interruptions due to downtime.

The Siemens SOMATOM Definition AS unit 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 along with supporting documentation. The equipment is currently in use and documentation provided in Attachment B indicates 6,890 procedures were performed from January 2014 through December 2014.

The total cost to acquire, install, and make operational the replacement equipment is \$764,566 which includes construction costs of \$85,000, architecture and engineering fees of \$34,800, equipment costs of \$626,766 (\$528,000 for the CT scanner, \$11,000 for freight of the CT scanner, \$33,576 for sales tax of the CT scanner, \$52,150 for the Injector, \$340 for freight of the



Injector, and \$1,700 for sales tax of the Injector) and Other fees totaling \$18,000. Attachment C provides the quote for the CT scanner from Siemens and the Injector quote from Bayer HealthCare with equipment costs. Please see Attachment D for a letter documenting the equipment will be taken out of service and removed from North Carolina. The total capital cost schedule and certified cost estimate of the renovation required to install the new equipment are provided in Attachment E.

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 \$2.0 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 prior 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 704-446-8475.

Sincerely,

Elizabeth Kirkman, Assistant Vice-President

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**CHS Management Company** 

Attachments

# Attachment A

Comparison of Existing and Replacement Equipment

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| EQUIPMENT COMPARISON   |                             |                                 |
|--|-----------------------------|---------------------------------|
|  | Existing Equipment          | Replacement Equipment           |
| Type of Equipment (List each component)  | GE Lightspeed 4-slice       | Siemens AS 64-slice             |
| Manufacturer of Equipment  | GE                          | Siemens                         |
| Tesla Rating for MRIs  | N/A                         | N/A                             |
| Model Number   | 2281177-2                   | Not Available Until Installed   |
| Serial Number  | 296255CN3                   | Not Available Until Installed   |
| Provider's Method of Identifying Equipment   | CHS Asset # / Serial #      | CHS Asset # / Serial #          |
| 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  | 2002                        | Summer 2015                     |
| Does Provider Hold Title to Equipment or 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=""></use> | \$759,149                   | \$764,566                       |
| Total Cost of Equipment  | \$699,746                   | \$626,766                       |
| Fair Market Value of Equipment   | \$65,000                    | N/A                             |
| Net Purchase Price of Equipment  | \$699,746                   | \$626,766                       |
| Locations Where Operated   | CMC Cleveland-201 E Grover  | CMC Cleveland-201 E Grover      |
|  | St., Shelby, NC 28150       | St., Shelby, NC 28150           |
| 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                                 | All Primary CT Applications | N/A                             |
| Type of Procedures New Equipment is Capable of Performing                                    | N/A                         | All Primary CT Applications     |
|  |                             | (Better cardiac, low dose lung  |
|  |                             | screening and overall radiation |
| :  |                             | dose reduction in all exams     |
|  |                             | pertormed.)                     |

# **Attachment B**

**Equipment Use Documentation** 

### **CHS-Cleveland CT scans**

2014

| January   | 610  |
|-----------|------|
| February  | 478  |
| March     | 574  |
| April     | 564  |
| May       | 630  |
| June      | 582  |
| July      | 540  |
| August    | 611  |
| September | 617  |
| October   | 610  |
| November  | 553  |
| December  | 521  |
| Total     | 6890 |

# Attachment C

**Equipment Vendor Quote** 

Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway, Malvern, PA 19355

Fax: (336) 856-9995

SIEMENS REPRESENTATIVE

Edwin Winicki - (336) 688-0978

Customer Number: 0000035965

Date: 2/20/2015

# CAROLINAS HEALTHCARE SYSTEM 1000 BLYTHE BLVD CHARLOTTE. NC 28203

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.

Quote Nr:

1-A614VN, Rev. 1

Trade:

GE LS-4

**Terms of Payment** 

00% Down, 80% Delivery, 20% Installation

**Purchasing Agreement** 

Free On Board: Destination Premier Purchasing Partners

**Terms and Conditions** 

Premier terms and conditions apply

**Proposal Valid Until** 

9/30/2015

#### **Siemens Definition AS-64**

1 14440593

#### **SOMATOM Definition AS**

The SOMATOM Definition AS (64-slice configuration) is Siemens' state-of-the-art single source CT that provides the possibility to maximize clinical outcome and to minimize radiation dose. The unique STRATON X-ray source utilizes an electron beam that is accurately and rapidly deflected, creating two precise focal spots alternating 4,608 times per second. This doubles the X-ray projections reaching each detector element. The two overlapping projections result in an oversampling in z-direction. The resulting measurements interleave half a detector slice width, doubling the scan information without a corresponding increase in dose. Siemens' proprietary UFC (Ultra Fast Ceramic) detectors and the corresponding 64-slice detector electronics enable a virtually simultaneous readout of two projections for each detector element - resulting in a full 64-slice acquisition. This sampling scheme is identical to that of a 64 x 0.3 mm allowing for reconstruction of 192 slices using 0.1 mm reconstruction interval increment The fast rotation time of 0.33 seconds (0.3 s optional) delivers excellent temporal resolution. The SOMATOM Definition AS is set to raise the standard of patient-centric productivity with FAST CARE Technology. With Siemens' FAST -Fully Assisting Scanner Technologies - the SOMATOM Definition AS can simplify typically time consuming and complex procedures during a CT examination: the scanning process gets more intuitive and the results become more reproducible. The CARE technology includes many unique features like CARE kV that sets the ideal voltage for every examination and adjusts the respective scan parameters or industry's first Adaptive Dose Shield that prevents clinically irrelevant over radiation in spiral scanning. Additionally, its large bore of 78 cm and a table load capacity of up to 307 kg (optional) opens CT to virtually all patients, meaning that virtually no patient is excluded.

14408329

#### CT Replacement AS

SOMATOM Definition AS base configuration.

#### Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway, Malvern, PA 19355

Fax: (336) 856-9995

#### SIEMENS REPRESENTATIVE

Edwin Winicki - (336) 688-0978

#### 1 14420766 **SAFIRE #AWP**

The Sinogram Affirmed Iterative Reconstruction (SAFIRE) enhances spatial resolution, reduces image noise and increases sharpness by introducing multiple iteration steps in the reconstruction process. The resulting superior image quality enables to reduce dose by up to 60%\*. \*In clinical practice, the use of SAFIRE may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task. The following test method was used to determine a 54 to 60% dose reduction when using the SAFIRE reconstruction software. Noise, CT numbers, homogenity, low-contast resolution and high contrast resolution were assessed in a Gammex 438 phantom. Low dose data reconstructed with SAFIRE showed the same image quality compared to full dose data based on this test. Data on file.

#### 1 14420773 FAST CARE Platform

Siemens' unique FAST CARE platform is set to raise the standard of patient-centric productivity. Utilizing FAST - Fully Assisting Scanner Technologies -, typically time-consuming and complex procedures during the scan process are extremely simplified and automated, not only improving workflow efficiency, but optimizing the overall clinical outcome by creating reproducible results, making diagnosis more reliable and reducing patient burden through streamlined examinations. Siemens' desire for as little radiation exposure as possible lies at the heart of the CARE - Combined Applications to Reduce Exposure - research and development philosophy offering a unique portfolio of dose saving features, many of them being introduced as industry's first.

#### 1 14420771 CARE Child

Dedicated pediatric CT imaging, including 70 kV scan modes and specific CARE Dose4D curves and protocols

#### 1 14433993 FAST Planning #AWP

Direct, organ-based setting of scan and recon ranges for a faster and more standardized workflow

#### 1 14419142 Workstream 4D #AWP

WorkStream 4D further enhances the already superb workflow of the SOMATOM Definition AS CT system by offering direct generation of sagittal, coronal, oblique or double-oblique reconstructed images directly from CT raw data as part of the CT protocol.

#### 1 14419144 DICOM SR Viewer #AWP

The DICOM SR (structured report) Viewer allows to read reports created with specific applications (e.g. Circulation, Lung Care, Calcium Scoring and Onco) without the application itself being on the respective computer.

#### 14420824 Standard IRS

Reconstruction computer for the preprocessing and reconstruction of the CT raw data. The reconstruction computer contains a cluster of 2 high-performance GPU boards performing the preprocessing and reconstruction of the CT data. The raw data memory is 900 GByte. The peak recon performance is 40 frames/sec.

#### 1 14428058 Gantry tilt incl. tilted spiral

Allows for sequential scanning with a tilted gantry between +/- 30°, depending on the vertical position of the table. Using the gantry tilt sensitive organs (like eye lenses) can be moved out of the scan range or it eases access during interventional procedures. The tilted spiral allows to utilize the gantry tilt for spiral scan modes.

#### I GINGAS64 Lung Imaging

#### 1 14408147 Adaptive 4-D Spiral

#### 1 14408111 Extended Field of View #AWP

Software program with special reconstruction algorithms that allow for visualization of objects using a FOV up to 78 cm (non-diagnostic image quality). License to use software on a single unit.

#### l 14408152 **UHF**

UHR mode delivers Ultra High resolution in plane of up to 24lp/cm for high defined imaging of small structures such as inner ear, joints or fractures of the bone

#### 14408032 Rear cover incl. gantry panels

Rear Cover including gantry control panels with control functionality from the backside.

#### 14408094 Keyboard English

Keyboard in the above-mentioned language.

#### Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway, Malvern, PA 19355

Fax: (336) 856-9995

#### **SIEMENS REPRESENTATIVE**

Edwin Winicki - (336) 688-0978

| 1 | 14408023 | Cooling System Air |
|---|----------|--------------------|
| 1 | 14408031 | Cable loom 25 m    |

Cable loom used to connect the power distribution system (PDS) with the gantry.

#### 1 14420777 Patient Table 2000 mm

Patient table to support up to 200cm scan range. Motor-driven table height adjustment from min. 48 cm to max. 92 cm, longitudinal movement of the tabletop 200 cm in increments of 0.5 mm, positioning accuracy +/- 0.25 mm from any direction. Horizontal scan range 200 cm. Table height can be controlled alternatively by means of foot switch (2 each on both sides of the patient table). In the case of emergency stop or power failure, the tabletop can also be moved manually in horizontal direction. Max. table load: 227 kg/500 lbs, Table feed speed: 2-200 mm/s, Distance between gantry front and table base 40 cm. Positioning aids: Positioning mattress, mattress protector, head-arm support (inclusive cushion), and non-tiltable head holders with positioning cushion set, patient restraining system for head fixation, restraining-strap set with body fixation strap that can be directly connected to the patient table top, headrest, table extension with positioning mattress, knee-leg support.

#### 1 14408302 Adapt. 3D Intervent. Suite Wireless

The complete solution for 2D and 3D non fluoroscopic and 2D fluoroscopic minimal invasive volume interventions. The Adaptive 3D Intervention Suite contains Adaptive 3D Intervention for 3D volume intervention. Intervention Profor spiral and sequential non-fluoroscopic interventional procedures and complete organ coverage with maximal flexibility and with minimal single click effort i-Fluoro CT for CT allows for 2 dimensional interventional fluoroscopic procedures i-Control CT supports interventional procedures as independent remote unit Foot switch for radiation release (x-ray).

#### 14420921 Table Side Rails

Side rails enable the quick and easy attachment of additional accessories such as an infusion bottle holder and icontrol intervention module to the standard patient table.

#### 1 14408105 **Dual 19" Monitor #AWP**

Second 19-inch monitor for the Acquisition workplace (AWP)

#### 14408324 Ceiling Kit for Second Monitor

The dual monitor solution enables access to images and scan data while interacting with the patient in the scan room. The high resolution, flicker free, 19-inch (48 cm) color flat panel displays are mounted at the ceiling support. Consisting of: Two monitors, video transmitter, video receiver, power supply cable and a 30 m fiber-optic cable set for connecting the flat screen monitor.

#### 1 14408307 Ceiling Support Intervention

Ceiling support for the accommodation and safe installation of one or two flat screen monitors in the examination room for room heights from 2640 mm to 3680 mm.

#### 1 14408319 19" flat screen monitor

The 19" monitor option supports CT interventions and CT fluoroscopy with a display in the examination room.

CT\_RECON\_19

#### AS-64 slice configuration z-Sharp Tech.

The unique STRATON X-ray source utilizes an electron beam that is accurately and rapidly deflected, creating two precise focal spots alternating 4,608 times per second. This doubles the X-ray projections reaching each detector element. The two overlapping projections result in an oversampling in z-direction. The resulting measurements interleave half a detector slice width, doubling the scan information without a corresponding increase in dose. Siemens' proprietary UFC (Ultra Fast Ceramic) detectors and the corresponding 64-slice detector electronics enable a virtually simultaneous readout of two projections for each detector element - resulting in a full 64-slice acquisition. This sampling scheme is identical to that of a 64 x 0.3 mm allowing for reconstruction of 192 slices using 0.1 mm reconstruction interval increment. z-Sharp Technology, utilizing the STRATON X-ray sources and the UFC detectors, provides scan speed independent visualization of 0.33 mm isotropic voxels and a corresponding elimination of spiral artifacts in the daily clinical routine at any position within the scan field.

#### ADAPT\_DOSE SHIELD

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#### **Adaptive Dose Shield**

Adaptive Dose Shield for spiral acquisition to eliminate pre- and post-spiral over-radiation.

#### FAST\_ADJUST FAST Adjust

FAST Adjust: assists the user to handle system settings in a fast and easy way by automatically solving of conflicts within user defined limits by one single click on the FAST Adjust button. The limits for scan time and tube current per scan are defined via the Scan Protocol Assistant. FAST Adjust offers an undo functionality to return to previously set values.

#### Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway, Malvern, PA 19355

Fax: (336) 856-9995

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FAST\_SCAN\_A

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#### **FAST Scan Assistant**

FAST Scan Assistant: An intuitive user interface for solving conflicts by changing the scan time, resp. the pitch and/or the maximum tube current manually.

CARE\_DOSE4

CARE Dose4D

CARE Dose4D delivers the highest possible image quality at the lowest possible dose for patients - maximum detail, minimum dose. Adaptive dose modulation for up to 60% dose reduction

1 CARE\_KV

CARE kV

CARE kV: First automated, organ-sensitive voltage setting to improve image quality and contrast-to-noise-ratio while optimizing dose and potentially reducing it by up to 60%.

CARE\_PROFL

**CARE Profile** 

CARE Profile: Visualization of the dose distribution along the topogram prior to the scan

CARE\_DASHB 1 OARD

**CARE Dashboard** 

Visualization of activated dose reduction features and technologies for each scan range of an examination to analyze and manage the dose to be applied in the scan

1 DICOM\_SR

#### **DICOM SR Dose Reports**

DICOM structured file allows for the extraction of dose values (CDTIvol, DLP)

1 DOSE ALERT

#### Dose Alert

Dose Alert: As requested by the new release of the standard IEC 60601 3rd edition, the SOMATOM Definition automatically adds up CTDIvol and DLP depending on z-position (scan axis). The Dose Alert window appears, if either of these cumulative values exceeds a user-defined threshold.

DOSE\_NOTIFI CATION

#### **Dose Notification**

Dose Notification: As requested by the new release of the standard IEC 60601 3rd edition, the SOMATOM Definition AS provides the ability to set dose reference values (CTDIvol, DLP) for each scan range. If these reference values are exceeded the Dose Notification window informs the user.

ACCESS\_PRO 1 TECT

#### **Access Protection**

Scan Protocols are password protected allowing only authorized staff members to access and permanently change protocols

1 NEMA\_XR-29

### NEMA XR-29 Standard

This system is in compliance with NEMA XR-29 Standard Attributes on CT Equipment Related to Dose Optimization and Management, also known as Smart Dose.

1 CT\_PM

#### **CT Project Management**

A Siemens Project Manager (PM) will be the single point of contact for the implementation of your Siemen's equipment. The assigned PM will work with the customer's facilities management, architect or building contractor to assist you in ensuring that your site is ready for installation. Your PM will provide initial and final drawings and will coordinate the scheduling of the equipment, installation, and rigging, as well as the initiation of on-site clinical education.

CT\_BUDG\_AD

1 DL\_RIG
CT\_STD\_RIG\_I

NST

#### Additional Rigging CT \$ 2,000

#### CT Standard Rigging and Installation

This quotation includes standard rigging and installation of your CT new system. Standard rigging into a room with reasonable access, as determined by Siemens Project Management, during standard working hours (Mon. - Fri./ 8 a.m. to 5 p.m.) It remains the responsibility of the Customer to prepare the room in accordance with the SIEMENS planning documents. Any special rigging requirements (Crane, stairs, etc.) and/or special site requirements (e.g. removal of existing systems, etc.) is an incremental cost and the responsibility of the Customer. All other "out of scope" charges (not covered by the standard rigging and installation) will be identified during the site assessment and remain the responsibility of the Customer.

CT\_STD\_DEIN STALL

#### **CT Standard De-Installation**

1 4SPAS014 PSPD250480Y 1 3K

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Low Contrast CT Phantom & Holder

Surge Protective Device (SPD)

#### Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway, Malvern, PA 19355

Fax: (336) 856-9995

### SIEMENS REPRESENTATIVE

Edwin Winicki - (336) 688-0978

#### 1 CTSDEF01

#### CT Slicker

Thermoseal seams and flaps deflect fluids, reducing contaminant penetration into the cushion and table. Contaminants are retained on the tabletop or shunted to the floor. Cleanup is faster, more thorough, and contaminant build-up is reduced. Built using heavy, clear, micro matte vinyl, and top grade hook and loop fastening strips (Velcro) to better fit the specified table. Custom vinyl resists tears and minimizes radiologic interference. Latex free. Set includes CT Skirts. Shipped with main cover, a catheter bag holder, and 3 restraining belts unless otherwise noted. Includes warranty from RADSCAN Medical.

CT\_TRADE\_IN \_ALLOW CT\_SERV\_CO NTRACT

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CT DEFSYNG

O BCLS

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CT\_PR\_AS64X

#### Project # 2014-2050

#### 1 10,601 # 2014-2000

### Service Evlove Contract

#### **AS64 Excel Comp Conversion Bonus**

#### **Definition Systems Basic syngo Class**

Tuition for (1) imaging professional to attend Siemens Classroom Course at Siemens Training Center. The objectives of this basic syngo class are to introduce the user to the Siemens SOMATOM CT Definition user interface of the syngo platform, scanning parameters and their effect on image quality, and instructions on building protocols, demonstration of software functions, and hands-on sessions. 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 (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 CT\_INITIAL\_32

#### Initial onsite training 32 hrs

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. 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.

#### CT\_FOLLOWU P\_32

#### Follow-up training 32 hrs

Up to (32) 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 CT\_ADD\_16

#### Additional onsite training 16 hours

Up to (16) 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.

#### CT\_DEFSYNG 2 O\_BCLS

#### **Definition Systems Basic syngo Class**

Tuition for (1) imaging professional to attend Siemens Classroom Course at Siemens Training Center. The objectives of this basic syngo class are to introduce the user to the Siemens SOMATOM CT Definition user interface of the syngo platform, scanning parameters and their effect on image quality, and instructions on building protocols, demonstration of software functions, and hands-on sessions. 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 (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.

#### CT\_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.

#### Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway, Malvern, PA 19355

Fax: (336) 856-9995

**SIEMENS REPRESENTATIVE** Edwin Winicki - (336) 688-0978

CT\_TECH\_SY MP

#### Siemens Technologists Symposium

This accredited annual imaging professional symposium will provide multi-modality clinical education sessions for (1) attendee. Registration, economy airfare, and lodging are included for (1) attendee. All arrangements must be arranged through Siemens designated travel agency. 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.

Sell Price (excluding trade):

\$528,000

GE LS-4 Trade Value:

(\$65,000)

Final Price (including trade):

\$463,000

Estimated Tax (final tax is computed at time of installation): \$33,576

Created: 2/20/2015 12:15:00 PM

PRO 1-AWGT5U

Siemens Medical Solutions USA, Inc. Confidential

Page 6 of 6



### Quotation

Quote To: CLEVELAND REGIONAL MEDICAL CENTER 201 E Grover St SHELBY NC 28150-3917 USA Bayer HealthCare LLC

Quotation number: 0020014713 Customer number: 0000167589 Date: 03/23/2015

Page:

Valid from: 03/23/2015 to 07/31/2015

Trey Karn
Professional Sales Consultant
864-415-2397
trey.karn@bayer.com

We deliver according to the following terms and conditions:

Currency: USD

Terms of payment:

30 d. w/o discount of inv. net

Terms of delivery: Carriage paidFOB SHIPPING POINT

| Item | Part No  | Qty                            | Unit Price     | UoM   | Amount     |
|------|--|--------------------------------|----------------|-------|------------|
| 1    | 81058881                                       |                                |                |       |            |
|      | SCT 322<br>STELLANT DUAL \                     | 1 PCE<br>N/ CERTEGRA WKS & OCS | 49,500.00<br>S | 1 PCE | 49,500.00  |
|      | Discount (Value)                               |                                | 20,290.00-     |       | 20,290.00- |
|      | Discount (Value)                               |                                | 8,960.00-      |       | 8,960.00-  |
|      | Net value<br>**GPO MEMBER D<br>**SPECIAL DISCO |                                | 20,250.00      |       | 20,250.00  |
| 2    | 59943360                                       |                                |                |       |            |
|      | INS SCT CS<br>INSTALLATION - S                 | 1 PCE<br>STELLANT WITH OCS     | 2,650.00       | 1 PCE | 2,650.00   |
|      | Discount (Value)                               |                                | 250.00-        |       | 250.00-    |
|      | Net value `                                    |                                | 2,400.00       |       | 2,400.00   |
|      |  |                                | Sub            | Total | 22.650.00  |

If pricing and terms of this order 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.



### Quotation

| Total                      | 22,650.00                         |
|----------------------------|-----------------------------------|
|                            |                                   |
| complete the following inf | ormation:                         |
|                            |                                   |
|                            |                                   |
|                            |                                   |
| ·<br>·-·                   |                                   |
|                            |                                   |
|                            | Total  complete the following inf |

If pricing and terms of this order 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.



#### BAYER PRODUCT TERMS AND CONDITIONS

If Customer is a member of a group purchasing organization ("GPO") who has a contract with Bayer, the terms of that GPO Agreement will supercede the terms herein.

The following terms and conditions will not apply to the license of Bayer's Radimetrics or Certegra products. Such products are subject to a separate license agreement.

- 1. Modifications. The prices and terms on this Quote are not subject to verbal changes or other agreements unless approved in writing by Bayer.
- 2. Acceptance. Bayer's products and services are sold only under the terms and conditions stated on this quotation. Acceptance of any Purchase Order is expressly and exclusively made conditional on your assent to these terms and conditions. Any different or additional terms and conditions that may appear in your Purchase Order or any other document sent by you, shall have no effect. Bayer expressly objects to and rejects all inconsistent or additional terms, conditions and limitations contained on any of your forms or other writings. If you do not communicate your objection to these terms and conditions in writing and within a reasonable time, or if you accept the goods covered by this Quote, you will be deemed to have accepted these terms and conditions and they will control in all instances. If the Products include embedded software or if you are purchasing software, BY HAVING THE SOFTWARE INSTALLED AND USING THE SOFTWARE PURCHASED HEREUNDER, YOU AGREE TO BE BOUND BY THE TERMS OF THIS AGREEMENT. IF YOU DO NOT AGREE TO THE TERMS OF THIS QUOTE, DO NOT INSTALL OR USE THE SOFTWARE AND NOTIFY BAYER IMMEDIATELY.
- 3. Pricing. Prices are based on costs and conditions existing on the date of this Quote and may be changed by Bayer before final acceptance. The pricing for products provided pursuant to this Quote may reflect or be subject to discounts, rebates, or other price reduction programs. Please be advised that you are obligated to: a) fully and accurately disclose the amount of any such discounts, rebates, or other price reductions in your cost reports or claims for reimbursement to Medicare, Medicaid, or health care programs requiring such disclosure and b) provide such documentation to representatives of the Secretary of the Department of Health and Human Services and state agencies upon request. Unless noted otherwise, the value of any product listed as \$0.00 on this Quote may constitute a discount that you should evaluate when filing such reports. You may request additional information from Bayer in order to meet your reporting or disclosure obligations, by writing to the address set forth in this Quote. All payments are due net thirty (30) days on the total invoiced amount. For all new customers Bayer requires a thirty percent (30%) pre-payment for all capital equipment orders, unless otherwise agreed to by Bayer. Bayer must approve any payment terms other than net thirty (30) days.
- 4. Shipping. All shipping dates are tentative. Bayer will make every reasonable effort to meet shipping dates referenced in this Quote. However, Bayer will not be liable for its failure to meet any such date.
- 5. Installation. The cost of installation is not included in the product price and is your responsibility unless otherwise stated. For details on equipment installation, you should consult with your Bayer Sales Representative or refer to your Products Manual, which is included with your equipment.

If this Quote includes installation of an overhead counterpoise system (OCS) it is your responsibility to ensure a suitable mounting location for the system. The counterpoise ceiling plate is required to be installed prior to Bayer installation of the counterpoise system and installed in accordance with the specifications listed in the installation manual. The OCS ceiling plate should always be installed by a qualified Structural Engineer and/or Architect. In addition, if applicable building codes require the use of a conduit, you are responsible for ensuring that a conduit is available prior to Bayer's installation.

If this Quote includes a Certo wireless network it is your responsibility to ensure the approval of the Information Technology Department to allow the operation of the wireless network at your site.

If this Quote includes a Spectris Solaris with an Integrated Continuous Battery Charging System (iCBC), installation will require a standard power outlet in the scan room, or authorization to install a filter through the penetration panel.

6. License. If the Products include embedded software, or if you are purchasing software, Bayer grants to you a non-exclusive license to use such software provided by Bayer, solely in connection with, or to operate, the Products. Use of the software for any other purpose is strictly prohibited. This license is effective on the date you begin using the Products and software and will continue in effect unless you return the Products or software or if the license is terminated because

Please reference the quote number on your PO and fax to 412-406-0952



you breach any provision of these Terms. Upon termination you shall immediately cease use of all software and shall return the Products and software to Bayer. The software copyright is owned by Bayer and is protected by United States copyright laws and international treaty provisions. Bayer does not transfer title to the software to you, but retains the rights to make and license the use of all copies. You shall not copy, translate, disassemble, or decompile nor create or attempt to create, by reverse engineering or otherwise, the source code from the object code of the software. You are not permitted to modify or make derivative works of the software and ownership of any unauthorized modification or derivative work shall vest in Bayer.

7. Warranty. Bayer warrants that all new Bayer products are free from defects in workmanship or material under proper, normal use and service for a period of one year (12 months) from shipment, unless a longer period is provided on the warranty with the products, or as otherwise provided herein.

Bayer warrants that all refurbished Bayer products shall perform in accordance with the documentation provided, under proper, normal use and service for a period of the shorter of a) 90 days from installation or b) six months from shipment, unless a longer period is provided on the warranty with the products, or as otherwise provided herein.

If this Quote includes a Monitor, peripheral accessories on the Monitor such as pulse eximeter sensors, extension cables, power cables, fiber optic cables, ECG leads, capnography accessories (excluding patient connections), blood pressure cuffs, batteries, and extension tubing are warranted for a period of 90 days from the date of installation, but not to exceed six months from the date of shipment.

If this Quote includes disposable products or angiographic catheters, Bayer's warranty shall be limited to repair or replacement of any defective disposable product or angiographic catheter upon receipt of the defective product and a Bayer Return Goods Authorization. You acknowledge that the disposables and the equipment are a system and your actions regarding your equipment may invalidate your warranty on the disposables.

During the warranty period, there shall be no charge for any action deemed necessary by Bayer, including parts, travel, or labor to fulfill the terms of the warranty, during local business hours of 8:30 a.m. to 5:00 p.m., Monday through Friday, except holidays.

Your actions may invalidate this warranty. If Bayer determines that an equipment or disposable problem is due to any of the following, you agree to pay Bayer for all labor, travel, material handling and shipping at Bayer's, or Bayer's agents, standard rates:

- a) Malfunction or damage due to spillage of any type of fluid in or on the unit.
- b) Malfunction due to operator error, including failing to follow specified provisions of the Operations Manual.
- c) Malfunction or damage due to unauthorized modification or repair. Unauthorized actions may jeopardize functionality, reliability, or operator and patient safety. Therefore any unauthorized modification or repair shall render this warranty void and relieve Bayer from any further obligation. Bayer must review and authorize all modifications and repairs. This service may be obtained by contacting the Bayer Service Department.
- d) Malfunction or damage due to the use of non-Bayer or non-approved accessories. The use of accessories in connection with the equipment may jeopardize functionality, reliability or operator and patient safety. Therefore any use of non-Bayer or non-approved accessories (such as non-Bayer disposables or in the case of any PET/CT product, the use of vials or vial shields that are not approved by Bayer) shall render this warranty void and relieve Bayer from any further obligation.
- e) Damage by fire, floods, or other disaster commonly known as "Acts of God".
- f) If the Products include any Counterpoise system, any system malfunction, damage or failures due to improper installation or not meeting Bayer's specific requirements for level and plumb and/or loading as specified in the Bayer manuals.
- g) If the Products include any Counterpoise system, any ceiling or wall support structure used to mount or support an Injector Head Counterpoise System is excluded from Bayer's warranty. Bayer does not in any way warrant such structure.
- 8. Warranty Exclusions. EXCEPT AS PROVIDED IN THE ABOVE WARRANTY SECTION, BAYER EXPRESSLY DISCLAIMS ALL WARRANTIES OR CONDITIONS OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY,

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NONINFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE (WHETHER OR NOT BAYER IS AWARE OF YOUR INTENDED USE OF THE PRODUCT), AND ALL SUCH WARRANTIES ARE EXPRESSLY EXCLUDED. IN NO EVENT SHALL BAYER BE LIABLE FOR ANY LOST PROFITS OR INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE USE OR OPERATION OF BAYER'S PRODUCT OR SERVICE. Some states do not allow the exclusions on limitation of incidental or consequential damages, so the above limitations may not apply. This Limited Warranty gives you specific legal rights and you may also have other rights.

- 9. Software Warranty. If the Products include embedded software or if you are purchasing software, Bayer warrants that the software will substantially conform to the functional specifications contained in the Operations Manual for one year following delivery. This warranty shall not apply if you use the software in a manner that is not authorized or not in accordance with the user instructions or if you modify the Products or the software or if a party other than Bayer provides service to the Products or software. Bayer does not warrant that the software will operate uninterrupted or that it will be free from minor defects or errors that do not materially affect its performance. Your sole and exclusive remedy for any damages or loss in any way connected with the software whether due to Bayer's negligence or breach of any other duty shall be, at Bayer's option: i) to bring the performance of the software into substantial compliance with the functional specifications or ii) return of an appropriate portion of any payment by you with respect to the portion of the software that is not functioning.
- 10. Indemnification. Bayer agrees to indemnify, defend and hold you harmless from any liability, loss, expense, cost, claim or judgment (including attorneys fees), arising out of any claim for property damage, or personal injury or death where the product is alleged to have caused or contributed to the damage, injury or death, provided that this indemnification does not extend to injuries, damages or death to the extent caused by the negligence, reckless disregard or intentional acts of you or any third party.
- 11. Force Majeure. Bayer will not be responsible for delays or non-performance directly or indirectly caused by any acts of God, fire, explosion, flood, war, accident, action by governmental authority, inability to procure supplies and raw materials, delays in transportation, work stoppage, court order, and other causes beyond Bayer's reasonable control.
- 12. Compliance With Laws/Export. In addition to any rights and remedies specifically identified here in this Quote, Bayer shall have all rights and remedies conferred by law. Bayer shall not be required to perform its obligations under this Quote if you have defaulted (e.g. failed to pay) under this Quote or any other contract involving Bayer. This Agreement shall be construed in accordance with the laws of the Commonwealth of Pennsylvania, United States of America. You warrant that you are and will remain in compliance with all export and reexport requirements, laws and regulations of the United States of America and any other applicable export and reexport laws and regulations.
- 13. HIPAA. Bayer represents that it is not a Business Associate as defined in the Health Insurance Portability and Accountability Act ("HIPAA"). The functions Bayer is required to perform hereunder do not require the use or disclosure of Protected Health Information ("PHI"). To the extent any disclosure of PHI does occur, it is incidental and covered under the incidental disclosure rule found in 45 CFR 164.502(a)(1). In addition, to the extent any such incidental disclosure does occur, Bayer agrees to keep all such information confidential.

# Attachment D

**Equipment Disposal Letter** 

February 21, 2015

Carolinas Healthcare System Attn: Mr. Jeff Aho Associate Vice President Carolinas Medical Center 1000 Blythe Boulevard Charlotte, NC 28203

Dear Jeff 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 LS-4 with Serial Number 289985CN4 ("existing equipment") as part of your purchase of the Siemens Definition AS-64 for Carolinas Medical Center - Cleveland. The cost for the deinstallation and removal is included in the price quotation for the replacement equipment, which totals \$463,000 (\$528,000 sale price minus \$65,000 trade).

The system will be removed from Service by a broker designated by Siemens for either resale purposes or parts. The system will not be placed into Service by Siemens in North Carolina without proper state approvals.

Sincerely,

Edwin Winicki

Key Account Executive

Siemens Healthcare, USA

# **Attachment E**

Capital Cost Schedule and Architect Signature

### PROPOSED TOTAL CAPITAL COST OF PROJECT

| Pro               | oject name: CHS CL CT Replacement OSR 2814630 |                           |                                       |          |   |   |   |
|-------------------|---|---------------------------|---------------------------------------|----------|---|---|---|
| Provider/Company: |   | Company:                  | Carolinas HealthCare System Cleveland |          |   |   |   |
|                   |   |                           |                                       |          |   |   |   |
| 4.                | Site C  |                           |                                       |          |   |   |   |
|                   | (1)   | Full purchase price       | of land                               |          |   |   |   |
|                   |   | Acres                     | Price per Acre                        | _\$      |   |   |   |
|                   | (2)   | Closing costs             |                                       |          |   |   |   |
|                   | (3)   | Site Inspection and       | Survey                                |          |   |   | *************************************** |
|                   | (4)   | Legal fees and subso      | nil investigation                     |          |   |   |   |
|                   | (5)   | Site Prenaration Cos      | sts                                   |          |   |   |   |
|                   |   | Soil Borings              |                                       |          |   |   |   |
|                   |   | Clearine-Earthwe          | ork                                   |          |   |   |   |
|                   |   | Fine Grade for S          | lab                                   |          |   | trade to the same | •                                       |
|                   |   | Roads-Paving              |                                       |          |   |   |   |
|                   |   | Concrete Sidewa           | lks                                   |          |   |   |   |
|                   |   | Water and Sewer           | •                                     |          |   |   |   |
|                   |   | Footing Excavati          | ion                                   |          |   | ***************************************   | •                                       |
|                   |   | Footing Backfill          |                                       |          |   |   | _                                       |
|                   |   | Termite Treatmen          | nt                                    |          |   | ***************************************   | -                                       |
|                   |   | Other (Specify)           |                                       |          |   |   | •                                       |
|                   |   | Sub-Total Site Pr         | renaration Costs                      |          |   |   | *************************************** |
|                   | (6)   | Other (Snecify)           |                                       |          |   |   |   |
|                   | (7)   | Sub-Total Site Cost       | ts                                    |          |   |   |   |
| B.                | Const   | truction Contract         |                                       |          |   |   |   |
|                   | (8)   | Cost of Materials         |                                       |          |   |   |   |
|                   |   | General Requirer          | ments                                 |          |   | ***************************************   | •                                       |
|                   |   | Concrete/Masona           | arv                                   |          |   | ***************************************   | •                                       |
|                   |   | Woods/Doors &             | Windows/Finishes                      |          |   | ······································  | •                                       |
|                   |   | Thermal & Mois            | ture Protection                       |          |   | ****  | -                                       |
|                   |   | Equipment/Speci           | ialtv Items                           |          |   |   | -                                       |
|                   |   | Mechanical/Elec           | trical                                |          |   | A   |   |
|                   |   | Other (Snecify)           | ę.                                    |          |   | ,   |   |
|                   |   | Sub-total Cost of Ma      | aterials                              |          |   |   |   |
|                   | (9)   | Cost of Labor             |                                       |          |   |   |   |
|                   | (10)  | Other (Snecify)           |                                       |          | * |   |   |
|                   | (11)  | Sub-Total Construc        | ction Contract                        |          |   |   | 85,000                                  |
| C.                | Misce   | ellaneous Proiect Co      | sts                                   |          |   |   |   |
|                   | (12)  | Building Purchase         |                                       |          |   |   |   |
|                   | (13)  | Fixed Equipment Pu        | ırchase/Lease                         |          |   |   | 626.766                                 |
|                   | (14)  | Movable Equipment         | t Purchase/Lease                      |          |   |   |   |
|                   | (15)  | Furniture                 |                                       |          |   |   |   |
|                   | (16)  | Landscaping               |                                       |          |   |   |   |
|                   | (17)  | Consultant Fees           |                                       |          |   |   |   |
|                   |   | Architect and En          | gineering Fees                        |          |   | 34,800  |   |
|                   |   | Legal Fees                |                                       |          |   |   | -                                       |
|                   | , _   | Market Analysis           |                                       |          |   | ***************************************   |   |
|                   |   | Other (DHSR)              |                                       |          |   | 2.000   |   |
|                   |   | Other (Abatemer           | ntì                                   |          |   | 3.000   | •                                       |
|                   |   | Sub-Total Consultar       | nt Fees                               |          |   |   | 39.800                                  |
|                   | (18)  | Financing Costs (e.g      | z., Bond, Loan, etc.)                 |          |   |   |   |
|                   | (19)  | Interest During Con.      | struction                             |          |   |   |   |
|                   | (20)  | Other (Contingency        | )                                     |          |   |   | 13.000                                  |
|                   | (21)  | Sub-Total Miscella        | neous                                 |          |   |   | 679,566                                 |
|                   | (22)  | <b>Total Capital Cost</b> | of Project (Sum A-                    | C above) |   |   | 764,566                                 |

# PROPOSED TOTAL CAPITAL COST OF PROJECT

| Project Name:  |   |
|--|---|
| Provider/Company:  |   |
|  |   |
| I coutify that to the hart of well-level - level   |   |
| proposed project named above are completed   | , the above construction related costs of the |
| and the second of the second o | ete ana correct.                              |
| Wallow   | NC#3963                                       |
| (Signature of Licensed Architect or Engir  | neer)   |