



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

September 21, 2021

Lisa Griffin
llgriffin@novanthealth.org

Exempt from Review – Replacement Equipment

Record #: 3679
Date of Request: September 16, 2021
Facility Name: Novant Health Thomasville Medical Center
FID #: 923112
Business Name: Novant Health, Inc. and
Thomasville Medical Center
Business #s: 1341 and
1847
Project Description: Replace existing CT
County: Davidson

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project 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 Edge Plus CT scanner to replace the Siemens 08874427, SN 57051, CT scanner. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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,

Celia C. Inman
Project Analyst

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection Section, DHSR
Construction Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

September 16, 2021

2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

Via Email

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

Re: Novant Health Thomasville Medical Center
Replacement of Existing CT Scanner
Thomasville, NC (FID # 923112; Davidson County)

Dear Ms. Inman:

Novant Health Thomasville Medical Center (“NHTMC”) intends to replace an existing CT scanner currently located at its campus of NHTMC in Thomasville, North Carolina. The existing CT scanner is located in the Radiology Department at NHTMC and has been in operation since 2015 and is in need of an upgrade. As a result, NHTMC will acquire a new Siemens SOMATOM Edge Plus scanner. In addition, a new injector is required for operation of the new CT scanner. See **Attachment A** for the Equipment Quotes related to the scanner and the injector. As part of the equipment cost, the vendor will remove the existing CT scanner and not return it to use in North Carolina without appropriate Certificate of Need approvals. The total capital cost for the proposed replacement equipment project is estimated to be \$1,772,743¹. See **Attachment B** for the Projected Capital Cost Form.

The proposed project meets the definition of “replacement equipment” found in G.S. 131E-176(22a) and 10A N.C.A.C 14C.0303 for the following reasons:

- (1) NHTMC will replace the existing CT unit with the proposed CT unit that is functionally similar and will be used for the same diagnostic purposes, although it possesses expanded capabilities due to technological improvements.
- (2) The proposed CT unit will not be used to provide a new health service.
- (3) The acquisition of the proposed CT unit will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.
- (4) NHTMC seeks to replace comparable medical equipment currently in use at project cost less than \$2 million.
- (5) The existing equipment was not purchased second-hand nor was the existing equipment leased.

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

Celia Inman
September 16, 2021
Page 2

In support of our request, please find attached:

- Attachment A** – Vendor Equipment Quotes
- Attachment B** – Projected Capital Cost Form
- Attachment C** – Equipment Comparison Form
- Attachment D** – Excerpt of LRA Documenting CT is In-Use

NHTMC's acquisition of the replacement CT unit does not require a certificate of need because none of the definitions of "new institutional health services" set forth in N.C.G.S. Section 131E-176(16) apply to the proposed project. As outlined above, the total cost for the project is \$1,772,743. The proposed capital cost includes equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation and other activities essential to making the equipment operational.

Based on the information provided, please confirm that NHTMC's replacement equipment request does not constitute a new institutional health service and is exempt from certificate of need review.

If you need additional information, please do not hesitate to contact me.

Sincerely,



Lisa Griffin
Manager, Strategic Planning & Certificate of Need
Novant Health, Inc.

Enclosures

ATTACHMENT A

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Mathew Hayes - +1 (336) 263-4273
mathew.hayes@siemens-healthineers.com

PRELIMINARY PROPOSAL

Customer Number: 0000005455

Date: 06/25/2021

THOMASVILLE MEDICAL CENTER
207 OLD LEXINGTON RD
THOMASVILLE, NC 27360

Estimated Delivery Date: XX/XX/XXXX

Estimated delivery date is subject to change based upon factory lead times, acceptance date of this quote, customer site readiness, and other factors. A Siemens representative will contact you regarding the final delivery date.

Trade-in of existing Sensation 40 required.

Quote Nr. CPQ-236278 Rev. 0

SOMATOM Edge Plus

All items listed below are included for this system:

Qty	Part No.	Item Description
1	14449715	<p>SOMATOM Edge Plus</p> <p>The SOMATOM Edge Plus is based on a Straton MX Sigma tube and Sigma generator to boost the power and enable an industry standard of low kV imaging. Straton MX Sigma also enables to use 10kV steps from 70-140kV.</p> <p>The system contains unique Split Filter Technology, which enables routine ready TwinBeam Dual Energy imaging by simultaneous acquisition of a tin filtered and gold filtered spectrum as well as low dose non-contrast imaging using the Tin Filter part only.</p> <p>This in conjunction with the StellarInfinity Detector & Integrated IR (Iterative Reconstruction), including key technologies, TrueSignal and Edge Technology, the SOMATOM Edge Plus routinely generates ultra-thin 0.5 mm slices e.g. for most accurate stenosis, plaque and stent analysis.</p> <p>The system is also available with 142 ms temp. resolution, long dynamic range imaging and routine Dual Energy scans.</p> <p>The SOMATOM Edge Plus offers world's first 3D camera integrated workflow (optional). The FAST 3D camera captures the patient's shape, position, and height in three dimensions.</p> <p>These technologies are enabling new applications to automate positioning and safeguard correct and consistent imaging:</p> <p>FAST Isocentering, at the push of a button, provides the correct isocenter position, enabling the right dose modulation and consistent images.</p> <p>FAST Range supports scanning the correct body region in the topogram with no cut-off – by automatically aligning the identified anatomical position with the protocol.</p>

PRELIMINARY PROPOSAL

FAST Direction helps safeguard the right scan direction of the topogram, which is crucial when moving the table with infused patients. With all this SOMATOM Edge Plus - provides the capabilities to “Changing views in CT”.

1 14460726

ELEVATE O Edge Plus

Elevate from an old Siemens CT scanner to a SOMATOM Edge Plus.

1 14449774

FAST Integrated Workflow

We combine our market leading applications to make positioning simple for our customers.

The world’s first 3D camera integrated into a CT positioning workflow is available as an option and allows automatic patient positioning in the examination room.

The FAST 3D camera captures the patient’s shape, position, and height in three dimensions.

Using infrared measurement, it even recognizes body contours: for example, when people are wearing heavy clothes or blankets.

Specialized applications support accurate and reproducible positioning: FAST Isocentering, at the push of a button, provides the correct isocenter position, enabling the right dose modulation and consistent images.

FAST Range supports scanning the correct body region in the topogram with no cut-off – by aligning the automatically identified anatomical position with the protocol.

FAST Direction helps safeguard the right scan direction of the topogram, which is crucial when moving the table with infused patients.

FAST Topo - enables faster scan speeds in topograms, which minimizes breath-hold artifacts. It also has the potential to decrease the topogram dose.

FAST Planning - assists scan and reconstruction planning, based on a topogram, to provide an easier, faster and standardized workflow in CT scanning.

FAST 3D Align - automatically corrects misalignment of anatomic structures, organs of the patient. It aligns those to fit it to the selected reconstruction plane for a highly automated reconstruction workflow. Additionally, it minimizes the black area in the image by automatically adjusting the recon field of view selection.

1 14449877

100 kW Power

Increase the X-ray generator power to a full potential of 100kW.

1 14449878

High-speed 0.28 s rotation

Fast rotation time of 0.28 seconds for unprecedented image quality and highest scan speed. Fast gantry rotation times are the prerequisite for highest temporal resolution and are therefore essential for brilliant, motion artifact free cardiovascular imaging.

1 14449718

Imaging Package

We combine our market leading technologies and applications to make this the most

PRELIMINARY PROPOSAL

personalized scanner for our customers. Including SureView, High Pitch Spiral 1.7, Adaptive Dose Shield, CARE Dose 4D, CARE kV, CARE Child, CARE Profile, CARE Dashboard, CARE Bolus, Dose MAP, FAST Adjust and ADMIRE.

- 1 14449719 **Advanced Imaging Package**
 We combine the unique features of the SOMATOM Edge Plus, to push the most distinct CT scanner to its maximum potential, including the full power of the Straton MX Sigma tube - Sigma High Power including, High Power 70 and High Power 80, High Power 90, High Power 100 and 10kV Steps. Additionally Tin Filter scanning allows reaching new levels in low dose non-contrast scans.
- 1 14449767 **iMAR #AWP**
 The iMAR metal artifact reduction algorithm combines three successful iterative approaches to reduce metal artifacts (beam hardening correction, normalized sinogram inpainting, and frequency split). Siemens algorithm allows for artifact reduction based on the unique composition of metal implants such as coils, metal screws and plates, dental fillings or implants.

 iMAR is compatible with extended FoV and all Siemens dose reduction features.
- 1 14449764 **Reading Package**
 We combine our market leading applications to make reading and reporting consistent, fast and simple for our customers. Includes VRT, Workstream 4D and Extended FoV.
- 1 14449772 **Function - Cardiac Package**
 Cardiac scanning options to enable a simple to use, routine cardiac CTA and calcium scoring workflows. Includes: Heart View, Cardio Best Phase Plus, syngo Calcium Scoring CT and FAST Phase.
- 1 14449855 **Physiological Measurement Module**
 The Physiological Measurement Module allows connection of a 3 Channel ECG cable for ECG controlled cardiac acquisition.

 Item includes ECG cable.
- 1 14460573 **Function - DE Package**
 This package includes the Dual Spiral Dual Energy scan mode as well as FAST DE Results for a straight forward Dual Energy workflow.
 syngo DE Scan for Single Source # AWP offers the possibility to acquire two spiral data sets in sequence at different energies. The results are two data sets with diverse information. All features to reduce patient radiation like dose modulation or iterative reconstruction can be applied.
 With FAST DE Results you can select Dual Energy applications at the AWP and the results will be sent directly to the PACS without any interaction needed. FAST DE Results is as easy as selecting a recon job and will enhance you daily workflow significantly.
- 1 14449760 **UHR**
 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.

PRELIMINARY PROPOSAL

- 1 14449759 **FAST IRS**
 Reconstruction computer for the preprocessing and reconstruction of the CT raw data. The reconstruction computer contains of a cluster of high-performance GPU boards performing the preprocessing and reconstruction of the CT data. The peak reconstruction performance is up to 80 frames/sec.
- 1 14449861 **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 Pro for 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).
- 1 14449798 **Table Side Rails**
 Side rails enable the quick and easy attachment of additional accessories such as an infusion bottle holder and i-control intervention module to the patient table.
- 1 14449831 **Dual Monitor Ceiling Support**
 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. The space-saving ceiling installation along with the large movement range of the support allows maximum operating convenience when positioning the monitor.

 Ceiling Support Base
 Ceiling support for the accommodation and safe installation of one or two flat screen monitors in the examination room.

 19" flat screen monitors (2x)
 The 19" monitors support CT interventions and CT fluoroscopy with a display in the examination room.
- 1 14449830 **Dual Monitor 19" Intervention #AWP**
 Siemens proprietary syngo software visualizes the examination workflow in individual process steps on so-called task cards, such as the patient registration, examination, viewing or 3D task card. The dual monitor feature enables the split of the syngo task cards on two monitors in two different ways. This option includes the syngo dual monitor software and a second high resolution, flicker-free, 19-inch (48 cm) color flat panel display for medical diagnostic applications. This display provides a resolution of 1280 x 1024 and has a wide viewing angle, features high contrast even under high ambient light conditions. Display light output stability is ensured by controlled backlight throughout the whole lifetime.
 The dual monitors provide two possibilities for viewing:
 - One monitor can display the viewing task card, for instance for the interactive review of image data. All other syngo task cards are displayed on the second monitor.

PRELIMINARY PROPOSAL

- Both monitors display the 3D-Basic task card, enabling the viewing and manipulation of two different datasets on two monitors. It enables the comparison of two series from the same patient e.g. pre- and post-contrast or the comparison of two studies from the same patient e.g. pre- and post-surgery.

- | | | |
|---|----------|---|
| 1 | 14449785 | <p>Multi-purpose table</p> <p>Patient table to support up to 200 cm scan range. Motor-driven table height adjustment from min. 55 cm to max. 92 cm, longitudinal movement of the tabletop 200 cm in increments of 0.5 mm, positioning accuracy (horizontal) is +/- 0.5 mm. The accuracy of the repositioning (horizontal) is specified as +/- 0.25 mm. 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 (with bariatric table top up to 307 kg/676 lbs); table feed speed: 1-200 mm/s; distance between gantry front and table base 40 cm.</p> <p>Positioning aids: 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, knee-leg support.</p> |
| 1 | 14449802 | <p>Tiltable Head Holder</p> <p>Tiltable Head Holder for the fixation of the patient's head. Tilt range between +30 till - 15 degree.</p> |
| 1 | 14449789 | <p>Mattress for MPT Standard TableTop</p> <p>Replacement for the positioning mattress for Standard Multi Purpose Table Top.</p> |
| 1 | 14449793 | <p>High Cap. Patient & Trauma Tab.Top</p> <p>The high capacity and trauma table top offers the capability to support up to 307 kg/676 lbs of patient weight. It allows easy positioning and transfer from and to the table, due to its flat surface. Special accessories and an extended table top width of 530 mm enable a safe and comfortable positioning for obese patients.</p> |
| 1 | 14449794 | <p>High Cap. Patient & Trauma Acc Kit</p> <p>The High capacity and Trauma accessory kit contains additional Patient restraint set with a width of 400mm and additional table extensions for feet and head.</p> |
| 1 | 14449795 | <p>Mat for High Cap.& Trauma Table Top</p> <p>This mat has a curved profile and allows comfortable positioning of patients on the flat table top.</p> |
| 1 | 14449720 | <p>Cooling System Air</p> <p>SOMATOM Edge Plus air cooling for the dissipation of heat generated in the gantry.</p> |
| 1 | 14449809 | <p>Computer Desk</p> <p>New CT desk to accommodate the control components and color monitor.</p> <p>Width: 1200 mm,
Depth: 800 mm,
Height: 720 mm.</p> |

PRELIMINARY PROPOSAL

- 1 14449812 **Computer Cabinet**
 New cabinet to accommodate the computer system and UPS. Matched to the design of the control console table.
 Width: 800 mm,
 Depth: 800 mm,
 Height: 720 mm
- 1 4SPAS014 **Low Contrast CT Phantom & Holder**
- 1 PSPD250480Y3
K **Surge Protective Device (SPD)**
- 1 CTSP4002 **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.

 Includes warranty from RADSCAN Medical.
- 1 SURE_VIEW **SureView**
 Provides exceptional image quality at any pitch setting, enabling you to scan faster because you can scan at any pitch without degrading image quality
- 1 FAST_SCAN_A
SSIST **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.
- 1 ADAPT_DOSE_
SHIELD **Adaptive Dose Shield**
 Adaptive Dose Shield for spiral acquisition to eliminate pre- and post-spiral over-radiation.
- 1 CARE_DOSE4D **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 CT_LUNGIMAG
EDGEPL **Lung Imaging**
 For well over a decade, CT has been recognized and used as the standard of care for lung nodule detection and sizing. This is due to CT's spatial resolution, geometric accuracy, and ability to create various reconstructions and 3D views. The high contrast environment in the chest between the lungs and the nodules makes for a relatively easy detection task for clinicians using CT images. Recent advances in CT technology have allowed these scans to be effectively performed at lower doses, higher resolutions, and faster scan times.

 The SOMATOM Edge Plus CT is indicated for use in low dose lung cancer

PRELIMINARY PROPOSAL

screening for high risk populations*. The Edge Plus is delivered with two specific scan protocols to provide low dose lung cancer screening exams at approximately 0.33 mGy CTDI for a standard size adult. These default protocols utilize Siemens proprietary dose reducing features such as CARE Dose4D™, automatic exposure control technology that modulates and adapts dose for every patient, for high image quality at low dose.

*.As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information

- | | | |
|---|------------------|--|
| 1 | CT_TILTED_SPIRAL | <p>Gantry tilt incl. tilted spiral</p> <p>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.</p> |
| 1 | ACCESS_PROTECT | <p>Access Protection</p> <p>Scan Protocols are password protected allowing only authorized staff members to access and permanently change protocols</p> |
| 1 | NEMA_XR-29 | <p>NEMA_XR-29 Standard</p> <p>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.</p> |
| 1 | CT_UPS_EDGE_PLUS | <p>Standard UPS for Edge Plus</p> <p>The standard partial system uninterruptible power supply (UPS) is built directly into the power distribution cabinet (PDC) and supports the critical circuits for table and gantry electronics, console computer, image reconstruction system, and the internal Ethernet switch (to ensure connectivity). This enables safe removal of patient if outage occurs during scanning.</p> |
| 1 | CT_PM | <p>CT Project Management</p> <p>A Siemens Project Manager (PM) will be the single point of contact for the implementation of your Siemens 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.</p> |
| 1 | CT_ADDL_RIGGING | <p>Additional Rigging CT</p> |
| 1 | CT_BTL_INSTALL | <p>CT Standard Rigging and Installation</p> |
| 1 | CT_PR_ELV_EP_LUS | <p>CT Edge Plus Elevate Bonus</p> |

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Mathew Hayes - +1 (336) 263-4273
mathew.hayes@siemens-healthineers.com

PRELIMINARY PROPOSAL

- 1 CT_TRADE_IN_ALLOW **Removal of existing Sensation 40; FL# 400-185471**

- 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.

- 1 SY_PR_TEAMPLAY **teampay Welcome & Registration Package**
teampay is a cloud-based network that brings together your imaging modality users, the systems' dose and utilization data, and the users' expertise to help you improve the delivery of care to your patients. Basic features are provided free of charge. Premium features (benchmarking, non-Siemens devices) are provided on a trial basis for three months at no charge, and may be used thereafter on a subscription fee basis.
To register: <http://teampay.siemens.com/#/institutionRegistration/1>

System Total \$ 960,476.00

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Mathew Hayes - +1 (336) 263-4273
mathew.hayes@siemens-healthineers.com

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
Mathew Hayes
+1 (336) 263-4273
mathew.hayes@siemens-healthineers.com

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-00050309

This quotation has been prepared for: Thomasville Medical Center

Issued on 9/8/2021

Valid until 12/10/2021

Trade-in required Yes

Your Bayer Sales Team:

Christopher Delverne 724-940-7873, , christopher.delverne@bayer.com

Quotation Overview

VIZIENT RADIOLOGY - NEW 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 , or refer to your invoice, for an itemized breakdown of quoted products.

Imaging Products and Services

Product Name	YOUR PRICE
Stellant FLEX - Medrad® Stellant® FLEX Injection System(s)	\$31,626.20
TOTAL (Local taxes, shipping and/or handling to be invoiced when applicable)	\$31,626.20



Products and Services Details

Stellant FLEX - Medrad® Stellant® FLEX Injection System(s) and Related Products/Services

Item(s)							YOUR PRICE
Medrad® Stellant® Flex® OCS CT Injection System	Stellant Flex OCS	1			Stellant 34646		\$24,475.00
Certegra Patient Weight Dosing Software - Abdomen Application	MIS P3TA	1					\$3,750.00
Installation - Medrad® Stellant® FLEX CT Injection System - Overhead Counterpoise System	INS SCT FLEX CS	1					\$3,185.00
2-150 ml FLEX Syringes, 60" Tubing w T-Connector, 2 Small Spikes / 20 per box	FLEXD-150-SPK	1					\$216.20
Subtotal							\$31,626.20

TOTAL **\$31,626.20**

GRAND TOTAL (Local taxes, shipping and/or handling to be invoiced when applicable) **\$31,626.20**

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



Quotation prepared for: Thomasville Medical Center

Issued on 9/8/2021

Valid until 12/10/2021

This quotation has been prepared for: **Thomasville Medical Center**

Issued on 9/8/2021

Valid until 12/10/2021

Trade-in required Yes

Your Bayer Sales Team:

Christopher Delverne 724-940-7873, , christopher.delverne@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-00050309, and email this form to Sales Support at risalessupport@bayer.com AND your Service Inside Sales, Christopher Delverne, at christopher.delverne@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

WINSTON SALEM

Customer contact

Address

2085 Frontis Plaza Blvd
Winston Salem, NC 27103

Billing Information

2085 Frontis Plaza Blvd
Winston Salem, NC 27103

Customer Number

3897527

Phone

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

Please print and sign

Date

MM/DD/YYYY

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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Quotation continued

Quotation prepared for: Thomasville Medical Center

Issued on 9/8/2021

Valid until 12/10/2021

Bayer Product Terms and Conditions

Please click on the relevant product name below to review terms and conditions

DEVICES

[Bayer Product Terms and Conditions](#)

Quotation continued



Quotation prepared for: Thomasville Medical Center

Issued on 9/8/2021

Valid until 12/10/2021

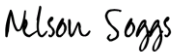
ATTACHMENT B

Projected Capital Cost Form
NH Thomasville Medical Center CT Scanner Replacement

Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction/Renovation Contract(s)	\$ 557,937
Landscaping	
Architect / Engineering Fees	\$ 65,950
Medical Equipment	\$ 992,102
Non-Medical Equipment	\$ -
Furniture	
Consultant Fees	\$ -
DHSR Fee	\$ 1,750
Interest during Construction	
Other (Contingency)	\$ 155,004
Total Capital Cost	\$ 1,772,743

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

I certify that, to the best of my knowledge, the projected construction cost for the proposed project is complete and correct.

DocuSigned by:

 E068402B9A574AE...

09/16/2021 | 8:31:28 EDT

Date Signed: _____

 Signature of Licensed Architect or Engineer

CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that is our intent to carry out the proposed project as described.

DocuSigned by:

 9BCFAC883516459...

09/16/2021 | 10:09:34 EDT

Date Signed: _____

 Signature of Officer/Agent

 Senior Vice-President, Construction & Facilities, Novant Health

 Title of Officer/Agent

ATTACHMENT C

EQUIPMENT COMPARISON

<i>NH Thomasville Medical Center CT Scanner Replacement</i>	<i>EXISTING EQUIPMENT</i>	<i>REPLACEMENT EQUIPMENT</i>
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	CT Scanner	CT Scanner
Manufacturer	Siemens	Siemens
Model number	08874427	SOMATOM Edge Plus
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	SN 57051	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	March 2015	TBD
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	Used	New
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>	NA	\$992,102
Total cost of the equipment	NA	\$1,772,743
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Radiology	Radiology
Document that the existing equipment is currently in use	LRA Excerpt Attached	NA
Will the replacement equipment result in any increase in the average charge per procedure ?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the average operating expense per procedure ?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	CT Scans	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	CT Scans

ATTACHMENT D

All responses should pertain to **October 1, 2019** through **September 30, 2020**.

d. Mobile MRI Services Campus – if multiple sites: _____

During the reporting period,

1. Did the facility own one or more mobile MRI scanners? ___ Yes No

If Yes, how many? _____ Of these, how many are grandfathered? _____
 CON Project ID numbers for non-grandfathered mobile scanners owned by facility:

Did the facility contract for mobile MRI services? ___ Yes No

If Yes, name of mobile vendor: _____

e. Other MRI

Patients served on units listed in the next table should not be included in the MRI Patient Origin Table on page 30 of this application. For hospitals that operate medical equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus.

Campus – if multiple sites: _____

Other Scanners	Units	Inpatient Procedures*			Outpatient Procedures*			TOTAL Procedures
		With Contrast or Sedation	Without Contrast or Sedation	TOTAL Inpatient	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Outpatient	
Other Human Research MRI scanners								
Intraoperative MRI (iMRI)								

* An **MRI procedure** is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom.

f. Computed Tomography (CT). Campus – if multiple sites: _____

How many fixed CT scanners does the hospital have? 2

Does the hospital contract for mobile CT scanner services? ___ Yes No

If yes, identify the mobile CT vendor N/A

Complete the following table for fixed and mobile CT scanners.

	Type of CT Scan	FIXED CT Scanner # of Scans	MOBILE CT Scanner # of Scans
1	Head without contrast	3,880	
2	Head with contrast	899	
3	Head without and with contrast	11	
4	Body without contrast	3,586	
5	Body with contrast	5,219	
6	Body without contrast and with contrast	270	
7	Biopsy in addition to body scan with or without contrast	3	
8	Abscess drainage in addition to body scan with or without contrast	5	
	Total	13,873	

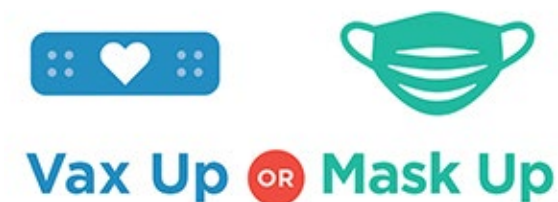
From: [Inman, Celia C](#)
To: [Waller, Martha K](#)
Cc: [Hale, Gloria](#)
Subject: FW: [External] Replacement Equipment Exemption Notice for NH Thomasville Medical Center
Date: Thursday, September 16, 2021 11:59:17 AM
Attachments: [TMC CT REER Letter to Agency 09.16.21.pdf](#)

Received this request this morning.

Celia C. Inman

Project Analyst, Certificate of Need

[Division of Health Service Regulation](#), Healthcare Planning and Certificate of Need Section
[NC Department of Health and Human Services](#)



Find a vaccine location, get questions answered and more at
YourSpotYourShot.nc.gov.

Office: 919-855-3873 *(Due to the pandemic, I am primarily working from home, so e-mail works best to reach me at this time.)*

Celia.Inman@dhhs.nc.gov

809 Ruggles Drive, Edgerton
2704 Mail Service Center
Raleigh, NC 27603

[Twitter](#) | [Facebook](#) | [YouTube](#) | [LinkedIn](#)

From: Griffin, Lisa L <lgriffin@novanthealth.org>
Sent: Thursday, September 16, 2021 11:41 AM
To: Inman, Celia C <celia.inman@dhhs.nc.gov>
Cc: Hale, Gloria <gloria.hale@dhhs.nc.gov>
Subject: [External] Replacement Equipment Exemption Notice for NH Thomasville Medical Center

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Celia,

Attached is an exemption notice to replace an existing CT scanner at Novant Health Thomasville Medical Center.

Let me know if you have any questions or need more information.

Thank you in advance,

Lisa Griffin

Manager, Planning & Certificate of Need
Novant Health | Internal Consulting Group
(704) 351 – 1132

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Estamos aquí para ayudarle con el cuidado que usted necesita. Visite [Novant Health](#) o [Novant Health UVA](#) para información actualizada.

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