



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

October 22, 2020

Lisa L. Griffin
llgriffin@novanthealth.org

No Review

Record #: 3383
Facility Name: Novant Health Matthews Medical Center
FID #: 945076
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Acquire a CT scanner
County: Mecklenburg

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in that correspondence is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

You may need to contact the Agency's Radiation Protection, Construction, and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Julie M. Faenza
Project Analyst

Martha J. Frisone
Chief

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



October 13, 2020

2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

Via Email

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

Re: Novant Health Matthews Medical Center
Request for "No Review" Determination to Acquire a 3rd CT Scanner
Charlotte, North Carolina (FID # 945076; Mecklenburg County)

Dear Ms. Faenza:

Novant Health Matthews Medical Center ("NHMMC") intends to acquire a CT scanner at its facility in Charlotte, North Carolina. This new scanner will be Siemens Definition AS with a 128-slice configuration. This CT scanner will be located in existing space in the Radiology Department.

See **Attachment A** for the equipment quote of the Siemens Definition AS. The proposed equipment and related construction costs will not exceed the cost threshold of \$750,000 for Major Medical Equipment acquisitions as defined in N.C.G.S. §131E-176(14o). See **Attachment B** for the Projected Capital Costs Summary.

NHMMC is requesting a determination from the Certificate of Need Section that this proposed project with total costs, including equipment and all related capital costs of \$736,200 is not considered Major Medical Equipment and, as such, is not subject to CON review.

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

Sincerely,

A handwritten signature in blue ink that reads "Lisa Griffin".

Lisa Griffin
Manager, Operational Planning
Novant Health, Inc.

Enclosures

ATTACHMENT A

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



SIEMENS REPRESENTATIVE
Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Customer Number: 0000012492

Date: 9/30/2020

PRESBYTERIAN HOSPITAL MATTHEWS
1500 MATTHEW TOWNSHIP PKWY
MATTHEWS, NC 28105-4656

Multi-unit / multi-modality purchase required.

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

SOMATOM Definition AS eco (AS+ Configuration)

All items listed below are included for this system: *(See Detailed Technical Specifications at end of Proposal.)*

Qty	Part No.	Item Description
1	14430105	<p>RS SOMATOM Definition AS (AS+)</p> <p>The SOMATOM Definition AS (AS+, 128-slice configuration) is Siemens' state-of-the-art single source CT that provides the possibility to maximize clinical outcome and to minimize radiation dose.</p> <p>Using Siemens' z-Sharp technology the system can provide high spatial resolution. The fast rotation time of 0.33 seconds (0.30 s optional) delivers excellent temporal resolution.</p> <p>With this, the SOMATOM Definition AS is set to raise the standard of patient-centric productivity with FAST CARE Technology.</p> <p>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.</p> <p>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.</p> <p>Additionally, its large bore of 78 cm and a table load capacity of up to 307 kg (optional) opens CT to all patients, meaning that virtually no patient is excluded. And even for CT-guided interventional procedures 2D Basic Intervention and HandCARE(tm) is already included. A 3D intervention suite is optional available.</p> <p>Optionally the system can be equipped with iterative reconstruction, the new TwinBeam Dual Energy scan mode and iMAR for iterative metal artifact reduction.</p>
1	14442795	<p>RS ecoline CT System Delivery</p> <p>With ecoline, Siemens Healthineers offers a portfolio of systems with certified performance at exceptional value.</p> <p>ecoline systems contain components, which have been in use and are refurbished to a quality level as good as new. All ecoline systems are manufactured following externally certified processes according to the relevant standards for medical devices¹, including the global refurbishment standard² where applicable. Thus, every ecoline system receives our Proven Excellence Label.</p> <p>Siemens Healthineers' ecoline systems provide exceptional value performing and looking like new, configurable to individual customer needs and offered at affordable prices.</p>

¹ ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

² IEC PAS 63077:2016 Good refurbishment practices for medical imaging equipment

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	14429968	<p>RS High-speed 0.30 s rotation</p> <p>Fast rotation time of 300 milliseconds 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 free cardiovascular imaging.</p>
1	14429973	<p>RS 100 kW Power</p> <p>The 100 kW power allows the X-ray generator the use of maximum power of 100kW in fine adjustable steps.</p>
1	14442484	<p>RS FAST Planning #AWP</p> <p>Immediate, organ-based setting of scan and recon ranges aiming for a faster and more standardized workflow at the scanner</p>
1	14457416	<p>RS FAST Adjust</p> <p>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.</p>
1	14445839	<p>RS FAST 3D Align #AWP</p> <p>FAST 3D Align enables automated alignment of FOV, adjustments and reconstructions of standard views.</p>
1	14457419	<p>RS CARE kV</p> <p>CARE kV automatically proposes the best tube voltage based on the patient's size, the system capabilities, and the type of examination. Once the kV setting has been chosen, CARE kV also automatically adjusts other scan parameters, including the tube current. This reduces dose, maintains a constant image quality, and simplifies processes for technicians.</p>
1	14426921	<p>RS CARE Child</p> <p>Dedicated pediatric CT imaging, including 70 kV scan modes and specific CARE Dose4D curves and protocols.</p>
1	14457418	<p>RS CARE Dashboard</p> <p>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.</p>
1	14457417	<p>RS CARE Profile</p> <p>CARE Profile: Visualization of the dose distribution of the scan range along the topogram prior to the scan.</p>
1	14426919	<p>RS SAFIRE #AWP</p> <p>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 improved image quality enables to reduce dose by up to 60%*.</p> <p>*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, homogeneity, low-contrast 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.</p>
1	14445840	<p>RS iMAR #AWP</p> <p>The iMAR metal artifact reduction algorithm combines three successful approaches (beam hardening correction, normalized sinogram inpainting and frequency split). This allows to reduce metal artifacts caused by metal implants such as coils, metal screws and plates, dental fillings or implants.</p> <p>iMAR is compatible with extended FoV, the extended CT scale as well as dose reduction features.</p> <p>Along with the algorithm comes the simple user interface of iMAR enabling easy reconstruction of clinical images with reduced metal artifacts.</p>

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	14417696	RS 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.
1	14429957	RS Standard IRS Reconstruction computer for the preprocessing and reconstruction of the CT raw data. The reconstruction computer contains of a cluster of 3 high-performance GPU boards performing the preprocessing and reconstruction of the CT data. The raw data memory is 1.5 Tbyte. The peak reconstruction performance is up to 40 frames/sec.
1	14426774	RS 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
1	14429826	RS Workstream 4D #AWP WorkStream 4D further enhances the already superb workflow of the SOMATOM 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	14429827	RS syngo 3D BoneRemoval #AWP Simple, automated bone removal functionality for the syngo 3D application. Preconfigured algorithms for angiography and hip/pelvis fracture scenarios are included to facilitate fast removal of bone structure for three dimensional presentation and analysis of CT data.
1	14417669	RS Rear cover incl. gantry panels Rear Cover including gantry control panels with control functionality from the backside.
1	14426923	RS Multi Purpose Table 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. 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.
1	14426842	RS Mattress for MPT Standard TableTop Replacement for the positioning mattress for Standard Multi-purpose tabletop.
1	14426812	RS High Cap. Patient & Trauma Acc Kit 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.
1	14426725	RS Cooling System Air Air cooling for the dissipation of heat generated in the gantry.
1	14417772	RS Computer Desk New CT desk to accommodate the control components and color monitor. Width: 1200 mm, Depth: 800 mm, Height: 720 mm.
1	14417773	RS 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

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
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_ASSIST	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_LUNGIMA_GASPL	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 Definition AS+ CT is indicated for use in low dose lung cancer screening for high risk populations*. The AS+ is delivered with two specific scan protocols to provide low dose lung cancer screening exams at approximately 1.3 mGy CTDI for a standard size adult. These default protocols utilize Siemens proprietary dose reducing features such as CARE Dose4D(tm), 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.
1	CT_TILTED_SPIRAL	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.
1	ACCESS_PROTECT	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_UPS_DEFINITION_EDGE	Standard UPS for Definition Edge The standard partial system uninterruptible power system (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. The UPS allows for a safe shutdown of the CT scanner in the event of power interruption. The UPS provides 5-7 minutes of power, during which the user is prompted and guided through the process to perform a safe shutdown of the system. This safe shutdown ensures that no data is lost.
1	CT_PM	CT Project Management 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.
1	CT_BUDG_ADDL_RIG	Budgetary Add'l/Out of Scope Rigging @ \$6,700

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



SIEMENS REPRESENTATIVE
Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	CT_BTL_INST ALL	CT Standard Rigging and Installation
1	4SPAS014	Low Contrast CT Phantom & Holder
1	PSPD250480Y 3K	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	SY_PR_TEAM PLAY	teamply Welcome & Registration Package teamply 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://teamply.siemens.com/#/institutionRegistration/1

System Total:

\$462,000

FINANCING: The equipment listed above may be financed through Siemens. Ask us about our full range of financial products that can be tailored to meet your business and cash flow requirements. For further information, please contact your local Sales Representative.

Siemens Healthcare is pleased to submit this Preliminary Pricing Proposal. A Preliminary Pricing Proposal is provided for planning purposes only; it is not contractually binding. To receive a contractually binding proposal for the Products listed above, inclusive of Terms, Conditions, and Warranty coverage, please contact your Siemens Healthcare Sales Representative.

Siemens Healthcare

Stuart Waddey
(919) 605-9227

stuart.waddey@siemens-healthineers.com

ATTACHMENT B

NH Matthews Acquire 3rd CT
Projected Capital Cost Form

Building Purchase Price	NA	
Purchase Price of Land	NA	
Closing Costs	NA	
Site Preparation	NA	
Construction/Renovation Contract(s)	\$225,100	
Landscaping	NA	
Architect / Engineering Fees	\$39,100	
Medical Equipment (CT Scanner)	\$462,000	
Non-Medical Equipment	Included in Construction Capital	
Furniture	NA	
Consultant Fees	NA	
Financing Costs	NA	
Interest during Construction	NA	
Other (Construction Contingency/ Architect Site Visits)	\$10,000	
Total Capital Cost		\$736,200

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

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

Daniel A. Kinken Date Signed: 10-5-2020
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 it is our intent to carry out the proposed project as described.

DocuSigned by:
Matthew Stiene
Signature of Officer/Agent

Date Signed: 10/09/2020 | 3:35:54 EDT

Vice President, Construction & Engineering, Novant Health
Title of Officer/Agent

From: [Flores, Disraeliza](#)
To: [Waller, Martha K](#)
Subject: FW: [External] No Review Letter for NH Matthews Medical Center Acquisition of a 3rd CT Scanner
Date: Tuesday, October 13, 2020 11:38:51 AM
Attachments: [MMC CT3 NoReview to Agency 10.13.20.pdf](#)

Disraeliza Flores
Administrative Assistant
Division of Health Service Regulation
North Carolina Department of Health and Human Services

919-855-3872 office
disraeliza.flores@dhhs.nc.gov

809 Ruggles Drive
Raleigh NC, 27603

2704 Mail Service Center
Raleigh, NC 27699-2704

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From: Griffin, Lisa L <lgriffin@novanthealth.org>
Sent: Tuesday, October 13, 2020 11:34 AM
To: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Cc: Flores, Disraeliza <Disraeliza.Flores@dhhs.nc.gov>
Subject: [External] No Review Letter for NH Matthews Medical Center Acquisition of a 3rd CT Scanner

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov

Good morning,

Attached is a letter requesting a No Review determination for the acquisition of a third CT scanner at Novant Health Matthews Medical Center. Please confirm receipt of this email and also let me know if you have any questions upon review.

Thank you in advance,

Lisa Griffin

Manager, Operational Planning

Novant Health, Inc.

(704) 351 - 1132

We are here to help you get the care you need. Visit [Novant Health](#) or [Novant Health UVA](#) for up-to-date information.

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

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