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

January 10, 2020

Andrea Gymer <amgymer@novanthealth.org>
Griffin, Lisa L <llgriffin@novanthealth.org>

No Review

Record #:	**3181**
Facility Name:	Novant Health Forsyth Medical Center
FID #:	923174
Business Name:	Novant Health, Inc.
Business #:	1341
Project Description:	Acquire a CT scanner for less than $750,000 to be located at Novant Health Imaging Maplewood
County:	Forsyth

Dear Ms. Gymer:

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 Construction, Radiation, and/or Acute and Home Care 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,

Celia C. Inman
Project Analyst

Martha J. Frisone
Chief

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

Received by Healthcare Planning & CON Section JAN - 6 2020

NOVANT HEALTH

2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

January 6, 2020

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 Imaging Mapleweed Center
Request for "No Review" Determination to Acquire a CT Scanner
Winston-Salem, North Carolina (FID # 923174; Forsyth County)

Dear Ms. Inman:

Novant Health Imaging Maplewood ("Maplewood"), a hospital-based department of Novant Health Forsyth Medical Center, intends to acquire a CT scanner at its facility in Winston-Salem, North Carolina. This new scanner will be Siemens SOMATOM Definition AS with a 64-slice configuration. This CT scanner will be located in the space vacated by the existing CT scanner which is being relocated and replaced at Novant Health Kernersville Medical Center. The replacement equipment exemption notice for that project is being sent under separate cover.

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

Maplewood 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 $697,585 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 at (704) 384 - 3462.

Sincerely,

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 Healthineers

SIEMENS REPRESENTATIVE
Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Customer Number: 0000007799

Date: 12/10/2019

MEDQUEST ASSOCIATES INC
3480 PRESTON RIDGE ROAD, STE 600
ALPHARETTA, GA 30005

Quote Nr: **1-R6QFDG Rev. 0**

SOMATOM Definition AS eco (64-slice Configuration)

All items listed below are included for this system:

Qty	Part No.	Item Description
1	14430096	**RS SOMATOM Definition AS (64slice)** 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. Using Siemens' z-Sharp technology the system can provide high spatial resolution. The fast rotation time of 0.33 seconds (0.3 s optional) delivers excellent temporal resolution. With this, 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 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. Optionally the system can be equipped with iterative reconstruction and iMAR for iterative metal artifact reduction.
1	14442795	**RS ecoline CT System Delivery** With ecoline, Siemens Healthineers offers a portfolio of systems with certified performance at exceptional value. 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 devices[1], including the global refurbishment standard[2] where applicable. Thus, every ecoline system receives our Proven Excellence Label. Siemens Healthineers´ ecoline systems provide exceptional value performing and looking like new, configurable to individual customer needs and offered at affordable prices. [1] ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

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
		[2] IEC PAS 63077:2016 Good refurbishment practices for medical imaging equipment
1	14442484	**RS FAST Planning #AWP** Immediate, organ-based setting of scan and recon ranges aiming for a faster and more standardized workflow at the scanner
1	14457416	**RS 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.
1	14445839	**RS FAST 3D Align #AWP** FAST 3D Align enables automated alignment of FOV, adjustments and reconstructions of standard views.
1	14457419	**RS CARE kV** 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.
1	14426921	**RS CARE Child** Dedicated pediatric CT imaging, including 70 kV scan modes and specific CARE Dose4D curves and protocols.
1	14457418	**RS 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	14457417	**RS CARE Profile** CARE Profile: Visualization of the dose distribution of the scan range along the topogram prior to the scan.
1	14426919	**RS 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 improved 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, 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.
1	14445840	**RS iMAR #AWP** 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. iMAR is compatible with extended FoV, the extended CT scale as well as dose reduction features. Along with the algorithm comes the simple user interface of iMAR enabling easy reconstruction of clinical images with reduced metal artifacts.

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

SIEMENS Healthineers

SIEMENS REPRESENTATIVE
Stuart Waddey - (919) 605-9227

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	14429942	**RS Standard IRS** Reconstruction computer for the preprocessing and reconstruction of the CT raw data. The reconstruction computer contains a cluster of 1 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	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	14426726	**RS Patient Table 2000 mm** Patient table to support up to 200cm scan range. Motor-driven table height adjustment from min. 49 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: 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	14427534	**RS Mattress for Patient Table** For the comfortable positioning of the patient on the CT table.
1	14417672	**RS Cooling System Water** Water heat exchanger for the dissipation of heat loss generated in the gantry to an environmentally friendly cooling water circulation system. This optimizes system availability independently of the cooling water flow rate and temperature. System operation temperature 4 - 16 degrees C and 500 - 2500 l/h flow rate.
1	14417768	**RS Cooling System Water/Air #split** Water-to-air heat exchanger for the dissipation (to the air outside) of heat, generated in the gantry.
1	14426835	**RS Trafo for Cooling System Water/Air** The transformer powers the Cooling System Water/Air.

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

SIEMENS Healthineers

SIEMENS REPRESENTATIVE
Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	14426843	**RS Service Switch** Service switch to shut off the outdoor cooling unit for maintenance or in case of emergency
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
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_LUNGIMGEDGE	**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 Edge CT is indicated for use in low dose lung cancer screening for high risk populations*. The Edge 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.

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

SIEMENS Healthineers

SIEMENS REPRESENTATIVE
Stuart Waddey - (919) 605-9227

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
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_DEF_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 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.
1	CT_BUDG_ADDL_RIG	**Budgetary Add'l/Out of Scope Rigging**
1	CT_BTL_INSTALL	**CT Standard Rigging and Installation**
1	4SPAS014	**Low Contrast CT Phantom & Holder**
1	PSPD250480Y3K	**Surge Protective Device (SPD)**
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.
1	CT_INST_RIEDEL_01	**Riedel Chiller Start-up by SBT**
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	CT_FOLLOWUP_16	**Follow-up training 16 hrs** Up to (16) hours of follow-up on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging

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
		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	SY_PR_TEAM PLAY	**teamplay Welcome & Registration Package** teamplay 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://teamplay.siemens.com/#/institutionRegistration/1

System Total: $427,000

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

Quotation continued

Quotation prepared for: Forsyth Medical Center Imaging Maplewood Clinic **Issued on** 12/10/2019 **Valid until** 12/17/2019

Products and Services Details

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

Item(s)	Catalog No.	Qty			Trade-In	Multi-Unit Discount	Additional Discounts	YOUR PRICE
Medrad® Stellant® Flex® OCS CT Injection System	Stellant Flex OCS	1			Stellant 20041			
Certegra Patient Weight Dosing Software - Abdomen Application	CWKS P3TA	1						
Installation - Medrad® Stellant® FLEX CT Injection System - Overhead Counterpoise System	INS SCT FLEX CS	1						

Subtotal

TOTAL

GRAND TOTAL (Local taxes, shipping and/or handling to be invoiced when applicable) **$30,685.00**

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

All Pricing is in U.S. Currency.

ATTACHMENT B

MAPLEWOOD ACQUIRE CT

Projected Capital Cost Form

Building Purchase Price	NA
Purchase Price of Land	NA
Closing Costs	NA
Site Preparation	NA
Construction/Renovation Contract(s)	$200,000 (Not to Exceed)
Landscaping	NA
Architect / Engineering Fees	$14,900
Medical Equipment	$457,685
Non-Medical Equipment	NA
Furniture	NA
Consultant Fees (specify)	NA
Financing Costs	NA
Interest during Construction	NA
Other (Construction Contingency)	$25,000
Total Capital Cost	$697,585

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.

Signature of Licensed Architect or Engineer

Date Signed: 12/11/19

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.

Signature of Officer/Agent

Date Signed: 1-3-19

Chief Executive Officer

Title of Officer/Agent ERIC HENRY, VP Professional Support Services

NOVANT HEALTH, INC.

Date of Last Revision: 5.17.19