



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

January 18, 2022

Lisa L. Griffin
llgriffin@novanthealth.org

No Review

Record #: 3790
Date of Request: January 14, 2022
Facility Name: Novant Health Mint Hill Medical Center
FID #: 060857
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Acquire a second 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 project described above. Based on the CON law **in effect on the date of this response to your request**, the project as described 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.

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

Micheala Mitchell
Chief

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



January 14, 2022

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 Mint Hill Medical Center
Request for "No Review" Determination to Acquire a CT Scanner
Charlotte, North Carolina (FID # 060857; Mecklenburg County)

Dear Ms. Faenza:

Novant Health Mint Hill Medical Center ("NHMHMC") intends to acquire a second CT scanner at its location in Charlotte, North Carolina. This new CT scanner will be a Siemens SOMATOM Drive and will be located in existing space in the Radiology Department. The proposed equipment and related construction costs which includes the costs of studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making it operational is estimated at total costs of \$1,968,600. Included in Attachment A is the CT scanner vendor quote and in Attachment B is the signed Projected Capital Costs Form.

Under the CON statute, CT scanning equipment is not specifically subject to CON review unless the cost of acquiring the equipment meets the \$2,000,000 threshold for "Major Medical Equipment" set forth in N.C.G.S. 131 E-176(14o). Here the cost of the equipment, including all costs to make the equipment operational, will not exceed \$2,000,000.

Accordingly, NHMHMC requests that the Agency issue a written determination that this project is not subject to CON review. If you need additional information, please do not hesitate to contact me.

Sincerely,

Lisa Griffin

Lisa Griffin
Manager, Strategic Planning

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: 0000269911

Date: 12/30/2021

NH MINT HILL MEDICAL CENTER
8110 HEALTHCARE LOOP
CHARLOTTE, NC 28215

Pricing Valid For 120 days
Estimated Delivery Date: 06/01/2022

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.

Quote Nr. CPQ-455679 Rev. 0

SOMATOM Drive

All items listed below are included for this system:

Qty	Part No.	Item Description	Extended Price
1	14460776	<p>SOMATOM Drive</p> <p>The SOMATOM Drive contains two new Straton MX Sigma tubes and Sigma generators to boost the power and enable an industry standard of low kV imaging with a significant step towards personalization with 10kV steps. Both tubes can be used with Tin Filters, for further dose reduction in non-contrast imaging and lung cancer screening.</p> <p>This is in conjunction with two StellarInfinity Detectors & Integrated IR (Iterative Reconstruction), including key technologies TrueSignal and Edge Technology, the SOMATOM Drive routinely generates ultra-thin 0.5 mm slices e.g. for most accurate stenosis, plaque and stent analysis.</p> <p>Available with 75 ms temporal resolution, faster than any conventional CT on the market, providing whole organ dynamic imaging and routine true Dual Energy scans.</p> <p>All this power and precision is backed by three key technology areas- DistinCT Imaging: focused on providing the most specific parameters for best quality and lowest dose for each individual patient regardless of circumstances that they are in. DistinCT Reading: focused on providing the quickest access to all diagnostic images regardless of the time of day, number of patients or the advanced nature of a study. DistinCT Function: focused on providing access to more quantitative data to enhance patient diagnosis and treatment outcomes.</p> <p>SOMATOM Drive - provides the capabilities to "Drive Precision for all" patients.</p>	
1	14460591	<p>FAST Integrated Workflow</p> <p>We combine our market leading applications to make positioning simple for our</p>	

PRELIMINARY PROPOSAL

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 14460584

DistinCT Imaging

We combine our market leading applications to make this the most Distinct scanner for our customers. Including SureView, Flash Spiral, Dual Adaptive Dose Shields, CARE Dose 4D, CARE kV, CARE Child, CARE Profile, CARE Dashboard, CARE Bolus, Dose MAP, FAST Adjust, XXL Mode 2cm and ADMIRE.

1 14460585

DistinCT Imaging - Advanced

We combine the unique features of the SOMATOM Drive, to push the most distinct CT scanner to its maximum potential, including the full power of the Straton MX Sigma tube - DistinCT - Sigma High Power including, High Power 70 and High Power 80, Dual Power 4cm, 10kV Steps, X-CARE and CARE Contrast III. Additionally Tin Filter scanning allows reaching new levels in low dose non-contrast scans.

1 14460778

DistinCT Reading

We combine our market leading applications to make reporting consistent, fast and simple for our customers. Includes VRT, Workstream 4D and Extended FoV.

1 14447380

DistinCT Reading - Advanced

We combine our advanced applications to make reporting of complex and atypical anatomical structures faster and simpler. Includes iMAR for anatomically driven metal artifact reduction, combines three successful approaches (beam hardening correction, normalized sinogram inpainting

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and frequency split). This allows to reduce metal artifacts caused by metal implants. FAST Spine, providing anatomically aligned preparation of spine recons with just a single click.
HD FoV Pro, designed to enable visualization of the human body parts and skin line located outside of the 50cm standard scan field of view, based on an algorithmic complement of missing detector data outside of the 50cm standard scan FoV. The image quality for the area outside the 50cm standard scan field of view does not meet the image quality of the area inside the 50cm standard scan field of view. Image artefacts may appear, depending on the patient setup and anatomy scanned. zUHR for functionality improved spatial resolution.

- 1 14460588 **DistinCT Function - Cardiac**
Cardiac scanning options to enable the simple to use, routine cardiac CTA and calcium scoring workflows, including beta blocker independent scanning, one heart beat scanning and flex scanning to enable functional imaging at low doses. Includes: Heart View, Cardio Best Phase Plus and syngo Calcium Scoring CT.

- 1 14460589 **DistinCT Function - Dynamic**
Adaptive 4D Spiral - a unique 4D Spiral scan mode that enables the SOMATOM Drive to extend beyond restraints experienced when utilizing a static detector and allows for up to 48 cm (18.89") dynamic CT coverage. This enables use not only in perfusion but also for advanced 4D CT DSA evaluations.

- 1 14441495 **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 14447337 **Multi-purpose table**
The Multi-Purpose table is especially designed for multi-disciplinary use, while still enabling ultra-fast spiral scanning up to 458 mm/s. Its flexible design allows exchange of table tops for routine radiology, Trauma or bariatric use. Table load capacity up to 307 kg / 676 lbs. with bariatric table top (High Capacity Patient & Trauma Table Top). Physiological Measurement Module included.

- 1 14410230 **Mat for MPT Standard Table Top**
Replacement for the positioning mattress for Standard Multi Purpose Table Top.

- 1 14408231 **High Cap. Patient & Trauma Tab.Top**
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 ensure a safe and comfortable positioning for obese patients.

- 1 14408232 **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 14414739 **Mattress for Bariatric Table Top**
This mat has a curved profile and allows comfortable positioning of patients on the flat table top.

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- | | | |
|---|-----------------------|---|
| 1 | 14460582 | <p>FAST IRS
FAST reconstruction computer for the preprocessing and reconstruction of the CT raw data. The reconstruction computer contains a cluster of high-performance GPU boards performing the preprocessing and reconstruction of the CT data.</p> |
| 1 | 14447370 | <p>Ring Light
SOMATOM Drive offers a gantry ring mood light (LED) in different, preset, adjustable colors. Designed not only for aesthetics, they can be used to help create a relaxing atmosphere for your patients.</p> |
| 1 | 14402956 | <p>Computer Desk
New CT desk to accommodate the control components and color monitor.
Width: 1200 mm,
Depth: 800 mm,
Height: 720 mm.</p> |
| 1 | 14402933 | <p>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</p> |
| 1 | 14410345 | <p>Cooling System Water/Air #split
Water-to-air heat exchanger for the dissipation (to the air outside) of heat, generated in the gantry.</p> |
| 1 | 14402886 | <p>Trafo for cooling system water/air
For adequate power consumption the chiller system may need an additional transformer: If the electrical connection to be used can not provide either 400V at 50Hz or 460V at 60Hz this transformer is needed.</p> |
| 1 | 14410242 | <p>Service Switch
Service switch to shut off the outdoor cooling unit for maintenance or in case of emergency</p> |
| 1 | CT_INST_RIED
EL_01 | <p>Riedel Chiller Start-up by SBT</p> |
| 1 | SURE_VIEW | <p>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</p> |
| 1 | CT_STELLAR_I
NF | <p>Stellar Infinity
Siemens' second generation fully integrated detector with TrueSignal and Edge technologies. Due to the full electronic integration of the Stellar Infinity detector, electronic components (microchips, conductors, etc.) are integrated directly at the photo diode. This reduces electronic noise coming from the detector elements and thus significantly improves the signal-to-noise ratio (SNR) for optimized dose efficiency and image quality.</p> |

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- 1 CT_LUNGIMAG
 DRIVE **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 Drive CT is indicated for use in low dose lung cancer screening for high risk populations*. The Drive 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.
- 1 ACCESS_PROT **Access Protection**
 ECT
 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_DRIVE **Standard UPS for SOMATOM Drive**
 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.
- 1 4SPAS014 **Low Contrast CT Phantom & Holder**
- 1 PSPD250480Y3 **Surge Protective Device (SPD)**
 K
- 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 CT_PM **CT Project Management**

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

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

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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_BTL_INSTALL **CT Standard Rigging and Installation**
- 1 CT_ADDL_RIGGING **Additional Rigging CT**

System Total **\$ 1,480,000**

ATTACHMENT B

Projected Capital Cost Form
NH Mint Hill Medical Center Acquire CT Scanner

Building Purchase Price		NA
Purchase Price of Land		NA
Closing Costs		NA
Site Preparation		NA
Landscaping		NA
Construction/Renovation Contract(s)	\$	392,500
Architect / Engineering / DHSR Fees	\$	53,500
Medical Equipment	\$	1,480,000
Non-Medical Equipment	\$	-
Furniture	\$	-
DPS/IT/Telecommunication	\$	22,600
Financing Costs	\$	-
Other: (Identify)	\$	-
Other: Contingency	\$	20,000
Total Capital Cost	\$	1,968,600

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

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

DocuSigned by:

 7B6D3FA2C3374AA...

Date Signed: 01/14/2022 | 1:48:54 EST

Signature of Licensed Architect or Engineer
 Daniel Kinken, AIA, NCARB, LEED - McCulloch England Architects

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...

Date Signed: 01/14/2022 | 2:18:21 EST

Signature of Officer/Agent
 Senior Vice President, Construction & Facilities Svcs, Novant Health
 Title of Officer/Agent

From: [Faenza, Julie M](#)
To: [Waller, Martha K](#)
Subject: FW: [External] NH Mint Hill Medical Center Acquisition of CT Scanner
Date: Friday, January 14, 2022 5:22:19 PM
Attachments: [MHMC Add CT NoReview to Agency 1.14.22.pdf](#)

Julie M. Faenza, Esq.

Project Analyst, Certificate of Need

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

Office: 919-855-3873 (*I am working remotely most of the time; email is the best way to reach me.*)

Julie.Faenza@dhhs.nc.gov

Pronouns: She/her/hers

Don't wait to vaccinate. Find a COVID-19 vaccine location near you at [MySpot.nc.gov](#).

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From: Griffin, Lisa L <llgriffin@novanthealth.org>
Sent: Friday, January 14, 2022 3:25 PM
To: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Cc: Hunt, Tiffany C <Tiffany.C.Hunt@dhhs.nc.gov>
Subject: [External] NH Mint Hill Medical Center Acquisition of 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](#).

Good afternoon,

Attached is a letter concerning the acquisition of a second CT scanner at Novant Health Mint Hill Medical Center. Please let me know if you have questions or need additional information.

Sincerely,

Lisa Griffin

Manager, Strategic Planning
Novant Health | Internal Consulting Group
(704) 351 – 1132

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[UVA](#) for up-to-date information.

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