

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

VIA EMAIL ONLY

December 3, 2021

Lisa L. Griffin llgriffin@novanthealth.org

Exempt from Review – Replacement Equipment

3751
December 1, 2021
Novant Health Rowan Medical Center
933436
Novant Health, Inc.
1341
Replace existing CT simulator
Rowan

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 go.SIM CT simulator to replace the Toshiba Aquilion LB TSX-201A CT simulator. 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,

Julie M. Jaenza

Julie M. Faenza Project Analyst

Micheala Mitchell

Micheala Mitchell 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



December 1, 2021

<u>Via Email</u>

2085 Frontis Plaza Boulevard Winston-Salem, NC 27103

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

Re: Novant Health Rowan Medical Center Replacement of CT-Simulator FID: 933436; Rowan County

Dear Ms. Faenza:

Novant Health Rowan Medical Center ("NHRMC") intends to replace an existing CT-Simulator currently located in the Radiation-Oncology Department of the Wallace Cancer Institute located at the main campus of NHRMC in Salisbury, North Carolina. The existing CT-Simulator has been in service since 2013 and is need of an upgrade. Therefore, NHRMC will acquire a new Siemens SOMATOM go.SIM unit. See **Attachment A** for the Equipment Quote which includes the removal of the existing equipment on page 8. The total capital cost for the proposed replacement equipment project is estimated to be \$1,329,268. 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) NHRMC will replace the existing cardiac catheterization with the proposed equipment 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 equipment will not be used to provide a new health service.
- (3) The acquisition of the proposed equipment 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) NHRMC 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.
- (6) The existing equipment will be removed from North Carolina.

Ms. Julie Faenza December 1, 2021 Page 2

In support of our request, please find attached:

Attachment A – Vendor Equipment Quote Attachment B – Projected Capital Costs Form Attachment C – NC CON Equipment Comparison Form Attachment D - Excerpt of 2021 License Renewal Application

The Equipment Comparison is included as **Attachment C**. The most recent License Renewal Application is attached as **Attachment D** to document that this simulator is still in use.

NHRMC's acquisition of the replacement equipment 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 \$1,329,268. 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 NHRMC'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

Lisa Griffin Manager, Strategic Planning

Enclosures

ATTACHMENT A



SIEMENS REPRESENTATIVE

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

PRELIMINARY PROPOSAL

Customer Number: 0000009562

Date: 11/05/2021

ROWAN REGIONAL MEDICAL CENTER

612 MOCKSVILLE AVENUE SALISBURY, NC 28144

Estimated Delivery Date: 3/2022

Delivery dates and other contractual obligations of Seller may change due to the effects of the Covid-19 epidemic or other epidemic, including delays and disruptions in the supply chain, manufacturing, or execution as well orders by authorities and prioritization of (new and existing) orders of customers which are essential for the public healthcare. The magnitude of such changes cannot be predicted and might be substantial because it depends on the development of the Covid-19 epidemic or other epidemic.

This proposal includes the trade-in of equipment referenced in Trade Sheet Project # 2021-4028

Quote Nr.

CPQ-457758

SOMATOM go.Sim

All items listed below are included for this system:

Qty	Part No.	Item Description
Qty	Part NO. 14461469	Item Description SOMATOM go.Sim Precise CT simulation requires fail-safe, reproducible, and streamlined workflows. This 64-slice simulator was created for one reason - to reduce errors to potentially reduce time to treatment. The SOMATOM go.Sim helps minimize errors in a complex workflow using embedded hardware and software, such as the integrated lasers (option) with automated laser QA. Driven by intelligence and automation, the system simplifies your tasks and reduces the likelihood of errors allowing you to focus on what matters most: spend more time with patients and improve what is, truly, most important – their therapy outcomes. Package includes 0.5, 1.0 s rotation time Stellar Detector 85 cm bore size
		 SAFIRE 75 kW (equivalent to 187 kW with SAFIRE) Athlon[™] X-ray tube Adaptive Dose Shield Tin Filter Air cooling system Ring mood lighting Patient observation camera Dual 23" / 58 cm flat screen monitor with dual display



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

- External USB 3.0 disks support -syngo System Security
- 1 14461477 Identifier SRS

Smart Remote Service (SRS) is a secured data link that connects your medical system to Siemens service experts. Via SRS, the performance and condition of your equipment can be monitored in real time. SRS makes a broad range of proactive and interactive services available.

A VPN connection is to be provided by user.

The Customer agrees to allow connection to Siemens' remote service diagnostic equipment to the secured telecommunications link at his own expenses. The Customer bears the cost of any technical requirements for any such connection over and beyond the actual product (e.g. establish a broadband connection).

1 14461479 **RT Identifier**

1 14467932

RT Performance Package

Benefit from additional operational and clinical flexibility by configuring your CT Sim with the RT Performance package, a bundle of software and hardware options to boost your performance.

- Ultra-FAST ICS
- Ultra-FAST IRS
- High-speed rotation time 0.35 s
- High Power 70
- 10kV Steps
- HD FoV (up to 85cm)
- SAFIRE
- CT View&GO
- -Sim&GO
- -Beam Placement tools
- -Contouring tools
- -Patient marking tools
- -Vessel Extension
- -Endoscopic View
- -Diameter / WHO Area
- -Lung Lesion Segmentation
- -ROI HU Threshold
- -Spine Ranges
- -Check&GO
- -Metal Detection
- -Recon&GO:
- -Inline Table Removal
- -Inline Bone Removal -Inline Vessel Ranges
- -Inline Spine Ranges
- -Inline Rib Ranges
- -Multi Recon
- SureView
- WorkStream4D
- Adaptive Signal Boost
- FAST CARE
- CARE kV
- CARE Child
- FAST ROI



40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE

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

PRELIMINARY PROPOSAL

		 DynSerio Scan syngo System Security myExam Compass Interleaved Volume Reconstruction (IVR) 2nd control-room monitor
1	14472890	syngo CT VA40
1	14467935	Scan&GO wireless edition Including Scan&GO Tablet and wireless Remote Scan Control
1	14468447	Multi-tablet Scan&GO Max. 3 tablet can be ordered.
1	14467986	UPS An uninterrupted power supply, for the syngo Acquisition Workplace in the event of network fluctuations and brief power failures.
1	14467941	 Long Patient Table RT Fully TG-66 compliant over the full scan range (without table extension) Max. table load 307 kg / 676 lbs Max. table feed speed 1-200 mm/s Vertical table travel range 47.5-90 cm / 18.7"-35.4" (at table top) Vertical table travel speed 28.3 mm/s Scannable range up to 200 cm/78.7" For RT use, the scan range may vary according to RTP overlay and/or 3rd party accessory. The scan range with the Siemens Healthineers Multi-index RTP overlay ist 175cm / 69". For diagnostic use, the scan range can be achieved with Diagnostic table extension. (Diagnostic table extension is not compatible with RT overlays) Positioning mattress Restraining straps RTP excellence package The RTP excellence kit contains a high accuracy installation and adjustment procedure utilizing additional installation tools and a special laser QA phantom to optimize the accuracy of the system.
1	14467944	Foot Switch for Pat.Table control Foot switch for Patient table control
1	14467976	Table Accessory Set More table accessories for further flexibility based on the clinical needs. Includes table side rails, storage box and infusion holder.
1	14467947	Direct Laser Siemens unique integrated moveable laser system allows you to control the patient marking workflow with the RT dedicated tablet and avoid unnecessary switching between different devices to enter laser coordinate. Direct Laser is directly integrated at the scanner gantry, enables less error prone patient marking for an optimized simulation process.



40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE

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

PRELIMINARY PROPOSAL

- Item includes: - Direct Laser - Direct Laser QA
- 1
 14467948
 Direct Laser Steering

 Direct Laser steering allows for integrated control of the moveable laser system,

Direct Laser steering allows for integrated control of the moveable laser system, without the need of an additional workstation. This functionality is compatible with Siemens Direct Laser (integrated moveable laser system on the gantry and associated mobile patient marking workflow) and with select LAP laser systems.

1 14467958 **iMAR**

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 the newest dose reduction feature.

Along with the new algorithm comes the simple user interface of iMAR enabling easy reconstruction of clinical images with reduced metal artifacts.

iMAR only requires to select the desired protocol from a drop down menu which contains the following type of implants:

- Dental fillings
- Neuro coil
- Thoracic coil
- Hip implants
- Extremity implants
- Pacemakers
- Spine implants
- Shoulder implants
- 14467954TwinSpiral Dual Energy

The accuracy of target delineation is limited by the lack of soft-tissue contrast on CT.

A new holistic solution for spectral imaging is introduced. TwinSpiral Dual Energy scan mode offers the possibility to acquire two consecutive spiral data sets at different energies and the two different kV levels with independent mAs modulation deliver a combination of both morphological and functional information within one examination. This new form of dual-energy acquisition uses Tin Filter to achieve optimal spectral separation and can help to improve tumor delineation and reduce target margins in RT Planning.

1 14467949 Respiratory Motion Management

The Respiratory Motion Management package provides all tools for 4D CT image acquisition and post-processing:

- Various 4D CT acquisition modes and protocols accommodate for a wide range of respiratory patterns and workflows. Following functionalities are supported.

- Up to 300 seconds scan time in respiratory motion management acquisition.

- Supports retrospective modes including phase and amplitude reconstructions

Created: 11/05/2021 16:53:02 P-CPQ-457758-2-1

1



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

- Supports the automatic creation of

- Average CT (tAverage)
- temporal MiniIP (tMinIP),
- temporal MaxIP (tMaxIP)
- the easy generation via reconstruction

- Quantitative 4D assessment of 3D tumor trajectory and amplitude and semiautomatic calculation of the midventilation phase

- Contouring propagation to each phase via deformable registration

- 8 series display

1 14467952 ANZAI Interface

Cable to connect to Anzai belt.

1 14467957 Integrated Injector Arm

The gantry-mounted injector arm lets you position the injector where you need it, when you need it. While a traditional injector cart is often in the way, the injector arm makes for a neat and organized working environment and still lets you flexibly arrange the injector.

The integrated injector arm can only be combined with Stellant D w/ Certegra, GO edition, which needs to be ordered from Accessory Solutions (XP AS). The injector head must be ordered and arrive on site prior to the injector arm since the cable of injector head needs to be integrated into gantry during the gantry installation.

Item includes

- Injector arm
- Holder

1 AS11154967 Anzai Respiratory Gating (VI)

With the Respiratory Gating system, the respiratory data is synchronized with the CT acquisition in order to minimize motion artifacts. The system is comprised of load cell with breast belt and a PC based evaluation console that is connected to the CT system, for capture and storage of a signal representing the patient's respiratory cycle. All components can be placed on a trolley for mobile positioning in the examination room. This Respiratory Gating hardware only works together with the respiratory gating software option integrated in the CT system.

1 14467951 Varian RGSC interface

Software license and cable to connect to Varian RGSC gating device.

1 4SPAS056 RGSC w/Wall-Ceiling Mount Camera

(Package includes Siemens parts RSC001002003 and RGA002002000)

Respiratory Gating for Scanners (RGSC) is Varian's solution for respirationsynchronized image acquisition for CT and PET-CT scanners.

Includes RGSC system (workstation unit and real-time unit), wall/ceiling mount, interface, camera, keyboard, mouse, reflector block, phantom, 12 month warranty through Varian and installation by Siemens when sold with Siemens system.

VCD option and training are sold separately.

Created: 11/05/2021 16:53:02 P-CPQ-457758-2-1



40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE

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

PRELIMINARY PROPOSAL

Requires Siemens interface cable - sold separately.

1	PSPD250480Y3 K	Surge Protective Device (SPD)
1	4SPAS014	Low Contrast CT Phantom & Holder
1	CARE_BOLUS	CARE Bolus Operating mode for CM-enhancement-triggered data acquisition.
1	SYNGO_VRT	syngo VRT Advanced 3D functionality as an extension to the basic 3D viewer, containing volume rendering technique (VRT) and advanced editing functions.
1	WORKSTREAM 4D	Workstream4D WorkStream 4D further enhances the already superb workflow of SOMATOM CT scanners 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	SYNGO_BONE_ REMOVAL	syngo Bone Removal 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	ACCESS_PROT ECT	Access Protection Scan Protocols are password protected allowing only authorized staff members to access and permanently change protocols
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	CARE_DOSE_C ONFIG	CARE Dose Configurator CARE Dose Configurator: Enhancement of Siemens' renowned real-time dose modulation CARE Dose4D, introducing new reference curves for each body region and for each body habitus allowing to adjust the configuration even more precisely to the patient's anatomy.
1	DICOM_SR	DICOM SR Dose Reports DICOM structured file allows for the extraction of dose values (CDTIvol, DLP)
1	DOSELOGS	DoseLogs Whenever a dose limit exceeds the established reference dose levels (Dose Notification and Dose Alert) a report is automatically created on the system, enhancing your ability to track radiation dose.



40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE

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

PRELIMINARY PROPOSAL

1 DOSE_NOTIFIC ATION Dose Notification: Dose Notification provides the ability to set dose reference values (CTDNO), DLP) for each scan range. If these reference values are exceeded the Dose Notification window informs the user. 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 OT_LUNGIMAGI NGGO Lung Imaging Go: For well over a decade, CT has been recognized and used as the standard of care for lung nodule visualization and szing. 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 visualization 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 go canners are delivered with specific scan protocols to provide low dose lung cancer screening exams that use Silemens-exclusive Tin Filter Technology to reduce unnecessary radiation. These default protocol also utilize Silemens proprietary dose reducing features such as CARE DosedD**, automatic exposure control technology, that further modulates and adapts dose for every patient, for high image quality at low dose. The SOMATOM go scanners come with default low dose lung analy protocols below 1 mSv. *As defined by professional medical societies. 1 SURE_VIEW SureVieW The Stellar detector's high-end technology includes fully integrated components. As a result, Stellar detector's high-end technology includes fully integrated components. As a result, Stellar detec	1	DOSE_ALERT	Dose Alert Dose Alert: Dose Alert automatically adds CTDIvol and DLP values depending on z-position (scan axis). The Dose Alert window appears, if either of these cumulative values exceeds a user-defined threshold.
1 NEMA_XR-29 NEMA_XR-29 Standard 1 NEMA_XR-29 Standard Attributes on CT Equipment Related to Dose Optimization and Management, also known as Smart Dose. 1 CT_LUNGIMAGI RGO Lung Imaging Go: For well over a decade, CT has been recognized and used as the standard of care for lung nodule visualization 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 visualization task for clinicians using CT images. Recent advances in CT technology have values at the standard of care for lung nodule visualization task for clinicians using CT images. Scott Not Not Not Not Not Not Not Not Not	1	DOSE_NOTIFIC ATION	Dose Notification Dose Notification: Dose Notification provides the ability to set dose reference values (CTDIvol, DLP) for each scan range. If these reference values are exceeded the Dose Notification window informs the user.
 CT_LUNGIMAG NGGO Lung Imaging Go: For well over a decade, CT has been recognized and used as the standard of care for lung nodule visualization 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 visualization 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 go.Platform leverages Tin Filter Technology to further enhance the delivery of low dose lung cancer screening for high risk populations[*]. The SOMATOM go.Platform leverages Tin Filter Technology to further enhance the delivery of low dose lung cancer screening exams that use Slemens-exclusive Tin Filter Technology to reduce unnecessary radiation. These default protocols also utilize Siemens proprietary dose reducing features such as CARE Dose4D^{**}, automatic exposure control technology, that further modulates and adapt dose for every patient, for high image quality at low dose. The SOMATOM go scanners come with default low dose lung imaging protocols below 1 mSv. *As defined by professional medical societies. 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 CT_GO_STELL AR Stellar Low Noise Technology Detector The Stellar detector's high-end technology includes fully integrated components. As a result, Stellar detector technology keeps electronic noise low, increases dose efficiency and improves spatial resolution. The smart configuration of the detector elements simplifies access, eases maintenance, and increases scanner uptime. For SOMATOM go scanners, the Stellar detector features a 3D anti-scatter collimator for even mor	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.
 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 CT_GO_STELL AR Stellar Low Noise Technology Detector The Stellar detector's high-end technology includes fully integrated components. As a result, Stellar detector technology keeps electronic noise low, increases dose efficiency and improves spatial resolution. The smart configuration of the detector elements simplifies access, eases maintenance, and increases scanner uptime. For SOMATOM go scanners, the Stellar detector features a 3D anti-scatter collimator for even more efficient optimization of X-ray energy. BFLEXGO Stellant Flex injector-gantry mount Stellant Flex gantry mounted injector with workstation, NO Informatics, but is Informatics ready. Includes Stellant Flex gantry mounted injector (injector head and J-Bow); workstation; installation and warranty through Bayer. 	1	CT_LUNGIMAGI NGGO	Lung Imaging Go: For well over a decade, CT has been recognized and used as the standard of care for lung nodule visualization 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 visualization 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 go.Platform leverages Tin Filter Technology to further enhance the delivery of low dose lung cancer screening for high risk populations*. The SOMATOM go scanners are delivered with specific scan protocols to provide low dose lung cancer screening features such as CARE Dose4D™, automatic exposure control technology, that further modulates and adapts dose for every patient, for high image quality at low dose. The SOMATOM go scanners come with default low dose lung imaging protocols below 1 mSv. *As defined by professional medical societies.
 CT_GO_STELL AR Stellar Low Noise Technology Detector The Stellar detector's high-end technology includes fully integrated components. As a result, Stellar detector technology keeps electronic noise low, increases dose efficiency and improves spatial resolution. The smart configuration of the detector elements simplifies access, eases maintenance, and increases scanner uptime. For SOMATOM go scanners, the Stellar detector features a 3D anti-scatter collimator for even more efficient optimization of X-ray energy. BFLEXGO Stellant Flex injector-gantry mount Stellant Flex gantry mounted injector with workstation, NO Informatics, but is Informatics ready. Includes Stellant Flex gantry mounted injector (injector head and J-Bow); workstation; installation and warranty through Bayer. 	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 BFLEXGO Stellant Flex injector-gantry mount Stellant Flex gantry mounted injector with workstation, NO Informatics, but is Informatics ready. Includes Stellant Flex gantry mounted injector (injector head and J-Bow); workstation; installation and warranty through Bayer.	1	CT_GO_STELL AR	Stellar Low Noise Technology Detector The Stellar detector's high-end technology includes fully integrated components. As a result, Stellar detector technology keeps electronic noise low, increases dose efficiency and improves spatial resolution. The smart configuration of the detector elements simplifies access, eases maintenance, and increases scanner uptime. For SOMATOM go scanners, the Stellar detector features a 3D anti-scatter collimator for even more efficient optimization of X-ray energy.
Includes Stellant Flex gantry mounted injector (injector head and J-Bow); workstation; installation and warranty through Bayer.	1	BFLEXGO	Stellant Flex injector-gantry mount Stellant Flex gantry mounted injector with workstation, NO Informatics, but is Informatics ready.
			Includes Stellant Flex gantry mounted injector (injector head and J-Bow); workstation; installation and warranty through Bayer.



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

** The gantry mount is required. The gantry mount is supplied by Siemens and is sold as a separate part number. The gantry mount is installed by Siemens.

- 1 QFIXRT4550KV SS3 Qfix kVue CT Overlay kVue™ CT Overlays provide a method of accounting for the dosimetric properties of kVue™ Couch Tops by enabling CT imaging of the treatment specific kVue insert and immobilization accessories to seamlessly support the simulation and treatment planning process.
- 1 QFIXRT4550KV SSPM kVue CT Phantom Holder Phantom holder for use with Qfix's kVue overlay (Siemens part QFIXRT4550KVSS3).
- 1 QFIXRT4551KV 1 Qfix kVue Standard Indexing Insert The kVue™ Standard Insert is a versatile insert used for a wide range of radiotherapy indications.
- 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_BTL_INSTA CT Standard Rigging and Installation
- 1 CT_ADDL_RIG Additional Rigging CT GING
- 1 CT_TRADE_IN_ CT Removal & Trade-in-Allowance, Aquilion LB ALLOW

1 RO_EDU_PKG_ **RO Clinical Edu Training Pkg: Option 2A** 2A The Radiation Oncology education assurance package provides a comprehensive, blended learning approach to meet both the initial and ongoing training needs of the RO-dedicated customer. This package includes: · Initial onsite 4-hour didactic workshop with lectures and simulated hands-on to introduce the Radiation Therapist, Dosimetrist, and/or Physicist to Siemens Computed Tomography as it is used in the Oncology environment. The workshop is delivered in conjunction with an additional 8 hours of onsite applications for protocol building and physicist commissioning support. • 24-hour onsite handover training with a dedicated focus on CT in radiation therapy protocols and workflow. • 16-hour onsite follow-up training to cover syngo.via RTiS • 24-hour onsite follow-up training to cover additional customized applications (e.g. Respiratory Gating/4D CT, DirectDensity, Dual Energy) 1-hour x 2 virtual follow-up to ensure confidence and adoption of system features. applications, and workflow. Education must be completed by the later of (12) months from install end or



SIEMENS REPRESENTATIVE

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

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

PRELIMINARY PROPOSAL

purchase date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.

System Total

<mark>\$887,663</mark>

ATTACHMENT B

Projected Capital Cost Form NH Rowan Medical Center CT-Simulator Replacement

Building Purchase Price	NA
Purchase Price of Land	NA
Closing Costs	NA
Site Preparation	NA
Construction/Renovation Contract(s)	\$ 295,000
Landscaping	\$ -
Architect / Engineering / DHSR Fees	\$ 22,474
Medical Equipment	\$ 887,663
Non-Medical Equipment	\$ -
Furniture	\$ -
DPS/IT Systems	\$ -
Financing Costs	\$ -
Interest during Construction	\$ -
Other: Contingency	\$ 124,131
Total Capital Cost	\$ 1,329,268

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.

NULSON Soggs

Date Signed: 11/24/2021 | 9:22:44 EST

Signature of Licensed Architect or Engineer Nelson Soggs, AIA, LEED AP - Soggs Design

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: Matthew Stiene		11/24/2021 9:21:08 EST
9BCFAC883516459	Date Signed:	
Signature of Officer/Agent		

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

ATTACHMENT C

EQUIPMENT COMPARISON

NH Rowan Medical Center (Wallace Cancer Inst) CT-Simulator Replacement	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	CT-Simulator	CT-Simulator
Manufacturer	Toshiba	Siemens
Model number	Aquilion LB TSX-201A	SOMATOM go.SIM
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	s/n 1LD1312337	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	April 2013	TBD
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <attach a="" capital="" cost="" form="" projected="" signed=""></attach>	NA	\$1,329,268
Total cost of the equipment	NA	\$877,663
Location of the equipment <attach a="" equipment="" for="" if="" mobile="" necessary="" separate="" sheet=""></attach>	Wallace Cancer Institute	Wallace Cancer Institute
Document that the existing equipment is currently in use	See Enclosed LRA Excerpt	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="" if="" necessary="" separate="" sheet=""></attach>	Treatment Planning	NA
Type of procedures the replacement equipment will perform <attach a="" if="" necessary="" separate="" sheet=""></attach>	NA	Treatment Planning

Date of last revision: 5/17/19

ATTACHMENT D

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

11. Linear Accelerator Treatment Data continued

Campus – if multiple sites:		Ovant Health U)allace	Cancer	Institute
	0	lepartment of	Ravan	Medic	al (enter)

a. Number of <u>patients</u> who received a course of radiation oncology treatments on linear accelerators (not the Gamma Knife®). Patients shall be counted once if they receive one course of treatment and more if they receive additional courses of treatment. For example, one patient who receives one course of treatment counts as one, and one patient who receives three courses of treatment counts as three

	~	-		01	
Number	of	Patient	S ~	ハン	

(This number should match the number of patients reported in the Linear Accelerator Patient Origin Table on page 32.)

b.	TOTAL number of Linear Accelerators:	
	Of the TOTAL above,	
	Number of Linear Accelerators configured for stereotactic radiosurgery:	_0
	Number of CyberKnife® Systems:	_0
	Number of other specialized linear accelerators:	0
c.	Number of Gamma Knife® units	_0
d.	Number of <u>treatment</u> simulators ("machine that produces high quality diagnostic radiographs	and precise

("machine that produces high quality diagnostic radiographs and precisely reproduces the geometric relationships of megavoltage radiation therapy equipment to the patient." (GS 131E-176(24b)))

e. Number of grandfathered Linear Accelerators

For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.

f. CON Project ID numbers for all non-grandfathered Linear Accelerators:

From:	Faenza, Julie M
То:	<u>Waller, Martha K</u>
Subject:	FW: [External] NH Rowan CT-Simulator Replacement Equipment Exemption Notice
Date:	Wednesday, December 1, 2021 2:56:25 PM
Attachments:	RMC WCI CT-SIM REER to Agency 12.1.21.pdf

For logging – thanks!!

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 <u>MySpot.nc.gov</u>.

Twitter | Facebook | Instagram | YouTube | LinkedIn

From: Griffin, Lisa L <|lgriffin@novanthealth.org>
Sent: Wednesday, December 1, 2021 2:54 PM
To: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Cc: Hunt, Tiffany C <Tiffany.C.Hunt@dhhs.nc.gov>
Subject: [External] NH Rowan CT-Simulator Replacement Equipment Exemption Notice

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to <u>Report Spam</u>.

Good afternoon,

Attached is an exemption notice regarding the replacement of an existing CT-Simulator at Novant Health Rowan Medical Center. Please let me know if you have any questions or need more information.

Regards,

Lisa Griffin Manager, Strategic Planning Novant Health | Internal Consulting Group (704) 351 – 1132 We are here to help you get the care you need. Visit <u>Novant Health</u> or <u>Novant Health</u> <u>UVA</u> for up-to-date information.

Estamos aquí para ayudarle con el cuidado que usted necesita. Visite <u>Novant Health</u> o <u>Novant Health UVA</u> para información actualizada.

This message and any included attachments are from NOVANT HEALTH INC. and are intended only for the addressee(s). The information contained herein may include trade secrets or privileged or otherwise confidential information. Unauthorized review, forwarding, printing, copying, distributing, or using such information is strictly prohibited and may be unlawful. If you received this message in error, or have reason to believe you are not authorized to receive it, please promptly delete this message and notify the sender by email. If you believe that any information contained in this message is disparaging or harassing or if you find it objectionable please contact Novant Health, Inc. at 1-844-266-8268 or forward the email to reports@novanthealth.org.

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.