

DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER GOVERNOR

MANDY COHEN, MD, MPH

SECRETARY

MARK PAYNE DIRECTOR

VIA EMAIL ONLY

August 19, 2019

Lisa Griffin llgriffin@novanthealth.org

Exempt from Review - Replacement Equipment

Record #:

3023

Facility Name:

Novant Health Forsyth Medical Center

FID #:

923174

Business Name:

Novant Health, Inc.

Business #:

1341

Project Description: Replace existing CT Simulator

County:

Forsyth

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of August 6, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Siemens Somatom Confidence CT Simulator equipment to replace the Philips CT Simulator, Model # 453567088051, Serial # 97370. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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

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

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603 MAILING ADDRESS: 2704 MAIL SERVICE CENTER •RALEIGH, NC 27699-2704 AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER

Ms. Griffin Page 2 August 19, 2019

separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Celia C. Inman Project Analyst

Martha J. Frisone

Chief, Healthcare Planning and

Certificate of Need

cc:

Construction Section, DHSR

Acute and Home Care Licensure and Certification Section, DHSR

Radiation Protection Section, DHSR

New HEALTH

2085 Frontis Plaza Boulevard Winston-Salem, NC 27103

August 6, 2019

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 Forsyth Medical Center

Replacement of CT-Simulator

Winston-Salem, North Carolina (FID # 923174; Forsyth County)

Dear Ms. Inman:

Novant Health Forsyth Medical Center (NHFMC) intends to replace an existing CT-Simulator located in the Radiation Oncology Department at the hospital in Winston-Salem, North Carolina. The existing CT-Simulator is over ten years old and is past its useful life. This CT-Simulator is still in use, as reported on the Annual License Renewal Application (LRA) in **Attachment A**. NHFMC intends to acquire a new Siemens Somotom Confidence 64-slice CT simulator. See **Attachment B** for the Equipment Quote including the removal and trade-in of the existing unit indicated at the top of Page 2. Also included are quotes for the Vision RT guidance system and LAP lasers needed for the new CT-Simulator to function. As part of the equipment cost, the vendor will provide onsite clinical training for the equipment. The total capital cost for the proposed replacement equipment project is estimated to be \$1,800,830\frac{1}{2}. See **Attachment C** for the Project Capital Cost Summary.

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) NHFMC will replace the existing CT-Simulator equipment 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) NHFMC 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.

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

Sale Acres

\$11% - N/A

Re: NHFMC Replacement of CT-Simulator

August 6, 2019

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In support of our request, please find attached:

Attachment A - Excerpt of 2019 LRA

Attachment B – Vendor Equipment Quotes

Attachment C - Project Capital Costs Summary

Attachment D - Equipment Comparison chart

NHFMC'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 \$1,800,830. 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 NHFMC's replacement equipment exemption 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 at (704) 384 - 3462.

Sincerely,

Lisa Griffin

Manager, Operational Planning

Novant Health, Inc.

Enclosures

ATTACHMENT A

License No: H0209
Facility ID: 923174

1	1. Linear Accelerator Treatment Data continued
C	Campus - if multiple sites: FOLSYTH MEDICAL CENTOL
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
	Number of Patients 1035 (This number should match the number of patients reported in the Linear Accelerator Patient Origin Table on page 32.)
ъ.	TOTAL number of Linear Accelerators:
	Of the TOTAL above,
	Number of Linear Accelerators configured for stereotactic radiosurgery:
	Number of CyberKnife® Systems:
	Number of other specialized linear accelerators:
c.	Number of Gamma Knife® units - O ·
d.	Number of <u>treatment simulators</u> ("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
F	or questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.
f.	CON Project ID numbers for all non-grandfathered Linear Accelerators: 6-6586-02
	Remaining are grandfathered

ATTACHMENT B

*



SIEMENS REPRESENTATIVE Jessica Barr - (610) 314-8055

PRELIMINARY PROPOSAL

Customer Number: 0000006208

Date: 7/9/2019

FORSYTH MEDICAL CENTER 3333 SILAS CREEK PKWY WINSTON SALEM, NC 27103

This quote is based upon standard delivery terms and conditions (e.g., standard work hours, first floor delivery, etc.), basic rigging; mechanical installation and calibration. Siemens Medical Solutions USA, Inc., Project Management shall perform a site-specific assessment to ascertain any variations that are out of scope and not covered by the standard terms (examples such as, but not limited to: larger crane, nonstandard work hours, removal of existing equipment, etc.). Any noted variations identified by Siemens Project Management shall remain the responsibility of the customer and will be subject to additional fees.

The technical training costs above are discounted by 15%, contingent on acceptance of the Shared Expert service agreement proposal. The training candidate prerequisite for these courses is previous completion of Siemens Definition AS CT training. This technical training is provided to Novant employees only.

Proposal valid until 9/30/2019

Quote Nr:

1-Q20SGN Rev. 1

SOMATOM Confidence (64-slice Configuration)

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

Qty Part No.

Item Description

14447476

SOMATOM Confidence (64-slice)

Whether you strive for advanced treatment techniques or for patient care that is both standardized and personalized - there are significant developments in Radiation Therapy that call for utmost precision.

This is why we designed our new dedicated CT scanner for RT: the SCMATOM Confidence(i) RT Pro. Thanks to images that are optimized for both contouring and dose calculation and a workflow that helps reduce sources of error, it brings together standardization and personalization.

There is no more compromise between efficiency, patient satisfaction, and clinical outcomes. Face present and future RT challenges with confidence:

Blaze a new trail in RT.

1 14447438

RT Pro

Item includes

- Extended Field of View #AWP
- HD FoV Pro #AWP

Designed to enable visualization of the human body parts and skin line located outside of the 50cm standard scan field of view outside of the 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.

- SAFIRE

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PRO 1-QIZYD5

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PRELIMINARY PROPOSAL

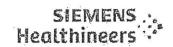
Qty	Part No.	ttem Description
1	14447441	RT Identifier
1	14447451	Rear cover incl. Touch Panels Sleek touch-control screens on both the front and rear sides of the gantry.
1	14420824	Standard IRS Reconstruction computer for the preprocessing and reconstruction of the CT raw data. The reconstruction computer 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	14408022	Cooling System Air Air cooling for the dissipation of heat generated in the gentry.
1	14444243	iMAR #AWP The iMAR metal artifact reduction algorithm combines three successful approaches (beam hardening correction, normalized striogram inpainting and frequency split). This allows to reduce metal artifacts caused by metal implants such as rolls, 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.
1	14447,443	DirectDensity Software feature that enables user to obtain relative electron densities directly from the CT images, allowing patients to be scanned at any kV setting**; and simplifying physics work for treatment planning. It includes - CARE kV, first automated, organ-sensitive voitage setting to improve image quality and contrast-to-noise-ratio - CARE Child, dedicated pediatric CT imaging, including 70 kV scan modes and specific CARE Dose4D curves and protocols **DirectDensity(tm) reconstruction is designed for use in Radiation Therapy Planning (RTP) only. DirectDensity(tm) reconstruction is not intended to be used for diagnostic imaging. **As shown by measurements with a Gammex 467 Tissue Characterization Phantom comparing standard reconstruction (kernel D30) and DirectDensity(tm) reconstruction (kernel E30). HU value to relative electron density conversion for the standard reconstruction was based on a two-linear-equations approach with individual calibration for each tube voltage. For DirectDensity(tm) images, a single tube-voltage-independent linear conversion was used.
1	14444245	syngo DE Scan for Single Source#AWP The syngo Dual Energy Scan for Single Source option offers the possibility to acquire two spiral data sets in sequence at different energies. The results are two data sets with diverse information. All features to reduce patient radiation like dose modulation or iterative reconstruction can be applied.
1	14444246	FAST DE Results #AWP With FAST DE Results you can select Dual Energy applications at the AWP and the results will be sent directly to the PACS for a straight forward Dual Energy workflow.
1	14447444	Respiratory Motion Management -Advanced 4DCT/respiratory gating package that allows for prospective or retrospective acquisitions - Acquire, review/edit wave form, reconstruct, generate MIP, mintP, and AverageCT, and view 4D movie loop (optional) all on the console

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complete integration with control console
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- Compatible with multiple hardware devices including the Arizal Bell and the Varian RGSC, both of which offer

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SIEMENS REPRESENTATIVE Jessica Barr - (610) 314-8055

	:	PRELIMINARY PROPOSAL
Qty	Part No.	Item Description
1	14460701	FAST 4D Enables guided 4D workflows and auto adjustment of scan parameters depending on breathing rate. The new algorithm analyses the breathing curve and selects automatically one out of 3 respiratory protocols. A pre-selection of the breathing rate is no longer required. FAST 4D also provides user feedback if patient's breathing is in range or if re-teaching is recommended.
1	14444255	Varian RGSC online înterface Cable to connect to Varian RGSC device.
1	14447445	Multi-purpose table & RTP Table Top Includes as standard: - 227 kg/500 ib: capacity table - Stemens RTP flat table top, with standard 14 cm indexing - 165 cm scan range for RT scans Offers as optional: - Concave table top for backup diagnostic scanning
1	14447504	FAST CARE Package Suite of automation and dose-saving tools to streamline workflow and simplify dose management. Includes: - FAST Adjust - CARE Profile: - CARE Dashboard - FAST Planning - DoseMAP
1	14444867	syngo.via RT Bundle (Identifier) RT system bundled with syngo.via
1	14456962	syngo.via Workstation Software VB30 The syngo.via Workstation offers 2D, 3D, 4D multi-modality routine reading capabilities and a variety of advanced applications tailored to the Workstation. The combination of syngo.via Software and Workstation Hardware is ideal for 1 - 2 users. The availability of all applications and workflows included in syngo.via Workstation is virtually

unlimited, i.e. the number of opened cases is only constrained by server HW resources.

The syngo via client runs on standard Windows computers in the network and integrates into radiologist's reading workplace (RIS; PACS) for efficient image reading based on a wide range of clinical applications (advanced visualization applications) for different clinical cases. Those applications are available as additional options for syngo,via.

The optional advanced visualization applications/Engines follow the flexible concurrent user model (users working at the same time). The service support for syngo via requires the provision of an administrator with dedicated lasks and a minimum broadband internet connection bandwidth.

14460556

syngo.via RTiS Sim&Contour #2

The package contains 2 users (1 Advanced Sim + 1 MM Contouring user), syngo via RT image Suite is a dedicated RT software that is designed to make virtual simulation, image assessment, and contouring easier and better integrated - while also offering capabilities that go beyond the current standard.

This configuration supports two users - one for simulation and basic contouring tasks and one for advanced contouring and image assessment. For concurrent use, one user can access the application via the workstallon while the other has access via a client installed on another computer, e.g. the scanner console.

Functionality for all users:

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PRELIMINARY PROPOSAL

Qty Part No.

Item Description

- Image review and contouring on CT, MR, PET, PET-CT, CBCT, 4D CT, time-resolved CT / MR images (e.g. perfusion).
- Direct4D for creation of tMIP, tminIP, AverageCT, phase splitting, 4D contouring, tumor motion analysis, semiautomatic generation of ITV / Mid Ventilation phase.
- Automatic rigid image registration with automatic alignment when datasets are loaded.
- Multiple contouring lools, Incl. auto contouring for organs-at-risk (brain, heart, lungs, liver, kidneys, femoral heads) and parallel contouring on multiple images.
- Collaboration tools

Advanced Simulation user (additional functionality):

- Beam Placement, Patient marking with reference point & isocenter management and laser steering.
- Client based accss to syngo, via RT Image

Suite from the scanner console.

- Simultaneous display of up to 4 images series over two panels (2 series + 2 fused series).

Advanced Contouring user (additional functionality)

- Simultaneously display of up to 8 image series (4 series + 4 fused series).
- Deformable Image Registration including contour warping and advanced evaluation of registration (spyglass, deformation vector map, colorwash).
- Treatment dose display, warp and accumulation with RT Dose Display

14456549

syngo.via Project Identifier

System identifier for syngo via project

14456827

Workplace/Workstation Hardware

syngo.via Server-based Workstation HW; tower floorstand configuration.

14457028

Prime HW Support WS 5v

Prime HW Support (Workplace/Workstation HW ? ML110 Gen10) for 5 years

14413099

EIZO MX241W Display

The EIZO MX 242W is a color widescreen LCD monitor for diagnostic use and clinical review with a resolution of 1920 x 1200 pixels.

14456981

WebViewer User #1 Integrated Server

syngo via WebViewer is a web-based client server add-on to syngo via.

If provides high-speed 2D and 3D image data review and basic manipulation functionality within the healthcare institution's network and through secure VPN connection both over LAN and wireless connections. The integrated server can be used for internal image distribution only (internet access only by VPN infrastructure).

The syngo via WebViewer runs on PC, Mac and laplops equipped with appropriate browsers, as well as on Apple Pad.

14429311

PACS-Driven Implementation Pkg.

This PACS-Driven Implementation Package includes installation and integration services for syngo, via in a radiologic workflow mainly supported by the PACS functionality.

This package includes professional services, such as:

- Installation of the syngo via server software on the server hardware
- Installation of the syngo via client software on one clinical workplace for one user
- Connection to up to 5 DICOM nodes
- Image call-up of syngo via from the PACS' user interface
- Assistance in setting up image call-up of syngo via from the PACS' user Interface. This may require the purchase of software and services from the PACS vendor.
- Configuration of basic syngo via workflows and rules
- Integration of one syngo via client workplace with one syngo MultiModality Workplace.
- Installation of WebViewer integrated license (syngo.via SW version VA30 or higher, country restrictions might Siemens Medical Solutions USA, Inc. Confidential

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SIEMENS REPRESENTATIVE Jessica Barr - (610) 314-8055

	PRELIMINARY PROPOSAL				
Qty	Part No.	Item Description apply): - Installation of the syngo.via WebViewer client application on one Mobile Device or Web Client system if requested by the customer. Ensure that the customer's Web Clients / Mobile Devices fulfill the minimum requirements according to the syngo.via WebViewer Data Sheet, Verification of the syngo.via WebViewer basic functionality - If applicable: Integration into the Local Area Network of the customer and to Siemens Remote Service over the internet connection plus basic installation service for the syngo.via HW system at the customer's site.			
1	14445228	syngo.via local impl. (Identifier) Identifier for professional services completely provided by locally organized resources.			
1	14429312L	Via Workstation Server HW Installation Basic installation of the syngo.via Workstation hardware with the operating system at the customer's site by the hardware supplier. Integration into the Local Area Network of the customer and to Slemens Remote Service over internet connection. Please check that the following information is included in the customer quote: correct and complete delivery location, customer's contact person for implementation planning. See also the questions in the Sales Checklist, which supports you in evaluation of the customer's requirements.			
1	SY_VIRINTL_4	Virtual Initial Consultation, syngo.via This virtual Initial consultation session, up to 4 hrs in duration, is designed to define the clinical customization of syngo.via specific to radiology workflow. Through direct communication with a clinical education specialist, this session will identify and configure site-specific workflow and imaging storage and retrieval parameters. This educational offering must be conducted no more than 4 weeks before the scheduled system turnover event. This consultation session will be scheduled during standard business hours. Monday through Enday. If training is not completed within the applicable time period, Stemens obligation to provide the training will expire without refund.			
1	SY_INITIAL_16	initial onsite training 16 hrs syngo.via Up to (16) hours of on-site clinical applications training on syngo.via basic navigation and modality specific clinical workflows, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4)users. Training will focus on the use of syngo.via in clinical routine and customization of systems based on workflow needs. This educational offering must be completed (12) months from turnover date. If training is not completed within the applicable time period, Stemens obligation to provide the training will expire without refund.			
1	CT_PM	CT Project Management A Siemens Project Manager (PM) will be the single point of contact for the implementation of your Slemen'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	ÇT_STD_RIG_I NST	CT Standard Rigging and Installation This quotation includes standard rigging and installation of your CT new system. Standard rigging into a room with reasonable access, as determined by Siemens Project Management, during standard working hours (Mon Fri.) 8 a.m. to 5 p.m.) It remains the responsibility of the Customer to prepare the room in accordance with the SIEMENS planning documents. Any special rigging requirements (Crane, stairs, etc.) and/or special site requirements (e.g. removal of existing systems, etc.) is an incremental cost and the responsibility of the Customer. All other out of scope charges (not covered by the standard rigging and installation) will be identified during the site assessment and remain the responsibility of the Customer.			
	CT EDUOPTIO				

Clinical Education & Training: Option 3

Siemens offers multiple options for clinical education and training on your new system. These options enable a more personalized approach to the introduction to system operation, features, and benefits and will help ensure that your technologists and physicians have the opportunity to engage in the level of training that best meets your current clinical needs and business objectives.

The following items are the education and training modules are highly recommended for the operation of your new

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CT_EDUOPTIO N3

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SIEMENS REPRESENTATIVE Jessica Barr - (610) 314-8055

PRELIMINARY PROPOSAL

	PRELIMINARY PROPOSAL					
Qty	Part No.	Item Description				
		Stemens system and are most effective for sites where technologists and/or physicians have limited experience on Stemens' systems. With a focus on routine procedures, this option also provides additional opportunities to further increase efficiencies.				
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_FOLLOWU P_16	Follow-up training 16 hrs				
		Up to (16) hours of follow-up on-site clinical education training, scheduled consecutively (Monday - Enday) during standard business hours for a maximum of (4) imaging 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	CT_CONVERP	Education Pkg for Conversion Customers				
		This educational package is designed to assist customers in the transition to Siemens CT scanning systems. The package offering consists of two 4 hour customized workshop sessions at the customer's facility-both sessions must be scheduled for and subsequently completed within a 24 hour window, access to Siemens Learning Center for 12 months and up to a total of 100 CE's. 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_ADD_24	Additional onsite training 24 hours				
		Up to (24) hours of on-site clinical education training, scheduled consecutively (Monday - Enday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist if applicable. 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.				
i	SY_PR_TEAM PLAY	teamplay Welcome & Registration Package				
•	I BW	teamplay is a cloud-based network that brings together your imaging modallty 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-Slemens 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				
	PSPD250480Y					
1	3K	Surge Protective Device (SPD)				

Low Contrast CT Phantom & Holder

1 4SPAS014 LAPDORNAVG 1 RWALL

DoradoNova/Green/CARINAnav/Wall

Includes: Three movable solid state red crosshalt lasers on a computerized rails. CARINAnay Virtual Simulation Patient Laser Marking System compatible with all DORADO laser systems.

Each laser rail contains two Class II 532nm green diode lasers. Six axes adjustment, Final adjustment without removing the cover.

Positioning and travel accuracy < 0.3 mm. Each rail contains a microcomputer, an absolute encoder for dual feedback position verification. Auto calibration. On-rail function processing. Variable speed laser movement. Brackets for angular installation.

Bi-directional data communication between control software and the laser rails.

Wilke laser alignment installation and quality assurance phantom with calibrated level and leveling plate:



SIEMENS REPRESENTATIVE Jessica Barr - (610) 314-8055

PRELIMINARY PROPOSAL

Qty Part No.

Item Description

The CARINAnav system is LAP's state of the art tablet wireless access control unit with a modern graphical touchscreen user interface. The CARINAnav software intuitively displays three point isocenters, skin markers, MLC points, and reference points in an easy to read tabular format. Data is imported via the LAP proprietary file format interface.

Key Features: In CT Room Touchscreen Tablet P.C. LAP Proprietary File Format Interface Wireless BT Communication

Medical Grade Touchscreen Tablet Computer 10 Touchscreen Interface. Docking Charger Statlon w/ Wall Mount Bracket Operating System: Windows 8.

One year warranty through LAP

Installation by LAP must be included and is sold as a separate line item (LAPLI3).

1 LAPLI3 LAP001380900

Installation, LAP Laser System

; L

LAP CARINAnav Upgrade DLS

Upgrade option for the LAP's CARINAnav product, If will enhance the features of CARINAnav 1.2 with a direct laser steering (DLS) function for Stemens syngo.via:RT Image Suite VB20.

The Siemens syngo, via RT Image Suite VB20 is able to control LAP's DORADO or DORADOnova laser systems directly via a CARINAnav system. The CARINAnav system has to have the CARINAnav Upgrade DLS installed to allow the direct laser steering (DLS) functionality. Only one user interaction LAP Zero is needed for referencing the lasers. All other user interactions are done in syngo via. RT Image Suite VB20

1 4SPAS057

RGSC w/Couch Mount Camera

(Package Includes Siemens parts RSC001002003 and RGA002002001)

Respiratory Galling for Scanners (RGSC) is Varian's solution for respiration-synchronized 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 Slemens when sold with Siemens system.

VCD option and training are sold separately.

CT_RECON_19

Requires Siemens Interface cable - sold separately.

AS-64 slice configuration z-Sharp Tech.

The unique STRATON X-ray source utilizes an electron beam that is accurately and rapidly deflected, creating two precise focal spots alternating 4,608 times per second. This doubles the X-ray projections reaching each detector element. The two overlapping projections result in an oversampling in z-direction. The resulting measurements interleave half a detector slice width, doubling the scan information without a corresponding increase in dose. Siemens' proprietary UFC (Ultra Fast Ceramic) detectors and the corresponding 64-slice detector electronics enable a virtually simultaneous readout of two projections for each detector element - resulting in a full 64-slice acquisition. This sampling scheme is identical to that of a 64 x 0.3 mm allowing for reconstruction of 192 slices using 0.1 mm reconstruction interval increment. z-Sharp Technology, utilizing the STRATON X-ray sources and the UFC detectors, provides scan speed independent visualization of 0,33 mm isotropic voxels and a corresponding elimination of spiral artifacts in the daily clinical routine at any position within the scan field.



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PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
	CT_UPS_DEF_	Standard UPS for Definition AS
1	AS	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.
	ACCESS_PRO	
1	TECT	Access Protection
		Scan Protocols are password protected allowing only authorized staff members to access and permanently change protocols
1	ADAPT_DOSE SHIELD	Adaptive Dose Shield
^		Adaptive Dose Shield for spiral acquisition to eliminate pre- and post-spiral over-radiation.
1	CARE_ANALY	CARE Analytics
	1100	Stand-alone tool, for installation in any PC in the hospital network, allowing evaluation of DICOM dose Structured Reports (DICOM SR)
2	CARE_DASHB	CARE Dashboard
1	UARD	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
-	CARE_DOSE4	CARE DAD
1	D	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
	CARE_DOSE_	
1	CONFIG	CARE Dose Configurator: CARE Dose Configurator: Enhancement of Stemens' 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	CARE KV	CARE KV
		CARE kV: First automated, organ-sensitive voltage setting to improve image quality and contrast-to-noise-ratio while optimizing dose and potentially reducing it by up to 60%.
1	CARE_PROFL E	CARE Profile
	- :	CARE Profile: Visualization of the dose distribution along the topogram prior to the scan
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.
1	DOSE_ALERT	Dose Alert
	DOSE_NOTIFI	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	CATION	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.
-1	FAST_ADJUST	FAST Adjust
	- Pinionis - AP	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
PRO 1-0	: 7/9/2019 8:05:00 QIZYD5	PM Siemens Medical Solutions USA, Inc. Confidential Page 8 of 10



SIEMENS REPRESENTATIVE Jessica Barr - (610) 314-8055

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
	FACT COAN'A	per scen are defined via the Scan Protocol Assistant, FAST Adjust offers an undo functionality to return to previously set values;
1	FAST_SCAN_A	FAST Scan Assistant
	1	FAST Scan Assistant: An intuitive user interface for solving conflicts by changing the scan time, resp. the pilich and/or the maximum tube current manually.
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	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	CT_BUDG_AD DL_RIG	Budgetary Add'I/Out of Scope Rigging
1	14444262	Open Interface Respiratory Gating
		Interface kit to connect to an external respiratory device (e.g. Varian RPM).
1	CT_BIOMD_TR	Biomedical Training: New Syngo Standard Security implementations (Course #XX0SYNSEC)
		This educational offering must be completed by the later of (12) months from purchase of training or if applicable, completion of installation. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
	CT_BIOMO_TR	
1	N	Biomedical Training: Confidence system update training (Course #CT2CONFI)
		This educational offering must be completed by the later of (12) months from purchase of training or if applicable, completion of installation: If training is not completed within the applicable time period. Signers obligation to provide the training will expire without refund.

System Total:

\$865,389

SIEMENS REPRESENTATIVE Jessica Barr - (610) 314-8055

Extended

+ \$35,724

Price

PRELIMINARY PROPOSAL

OPTIONS on Quote Nr:

1-Q20SGN Rev. 1

OPTIONS for SOMATOM Confidence (64-slice Configuration)

All items listed below are OPTIONS:

Qty Part No.

BSCT322

Item Description

Stellant D Dual Ceiling w/Certegra WS

Stellant D Dual Ceiling mounted with Certegra Workstation NO Informatics. Short ceiling post

- 580 mm.

Other ceiling post lengths are available (different part numbers): 850 mm and 1000 mm.

Includes Stellant D, Dual Head, ceiling mounted injector; Certegra workstation; installation and

warranty through Medrad.

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

Jessica Barr (610) 314-8055 jessica.barr@siemens-healthineers.com

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	v	

ATTACHMENT C

Sales Proposal:

SQ19-00342

Date: 05/08/2019

Customer Code:

C80408



Pos.	Qty.	ИM	Description	:	Unit Price	Price		
	1	PCS	DORADO Bridge 3 gr LAP Item No.: 000752		53,495,00 USD	53,495.00 USI		
	į		**	1 .				
			Three movable solid state green crosshair lasers on a computerized rails. Each laser rail contains two Class II DPSS 532nm green YAG lasers with active cooling systems, Six axes adjustment. Final adjustment without removing the cover.					
			Positioning and travel and Each rail contains a milencoder for dual feedb Auto calibration. On-ra Variable speed laser management.	crocomputer, an ack position verifition proces	absolute ication.			
			No distance restricted cabling between all de	fire rated plenum vices.	RS-485			
			Entire system is house extruded aluminum hor and is completely independing. Distortion free g	using. Mounts to pendent of the wa	the floor alls and			
			"Bridge Dimensions: 11	1'6'" Wide x 8'6""	Height"			
			Bi-directional data com software and the laser to all LAP CARINA soft	rails. Input comp				
			Wilke laser alignment assurance phantom with leveling plate.					
			ISO 9001 Certified Manufacturing ISO 13485 Certified Medical Device Manufacturing UL 60601-1 2nd and 3rd Edition Certified Medical Product					
	1	PCS	CARINAnav Baaske		8,445,00 USD	8,445.00 USE		

LAP of America Laser Applications L.L.C. 161 Commerce Rd

Suite 3 Boynton Beach, FL 33426 USA

LAP of America, L.L.C. SQ-002 Rev 1.0

The Sales Proposal is subject to the Terms of Purchase and the use of the software in and/or supplied with our equipment is subject to the License Conditions attached to this Sales Proposal, both of which can be found under www.fap-laser.com/terms-fi. Any acceptance of the Sales Proposal shall be limited to such terms and conditions.

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Sales Proposal:

SQ19-00342

Date: 05/08/2019

Customer Code:

C80408



Pos.	Qty.	ПM	Description		Unit Price	Price
			CARINAnav Virtual Simu System compatible with a DORADOnova systems. LAP's state of the art tab control unit with a modernuser interface. The CARINAnav softwarthree point isocenters, skin markers, MLC points points in an easy to read Data is imported via the file format and DICOM R Key Features: In CT Room Touchscree LAP Proprietary File Ford Wireless BT Communication DICOM RT Interface Medical Grade Touchscree 1.3" Touchscreen Interface 1.3" Touchscreen Interface 1.3" Touchscreen Interface 2.28×150×13 mm Weight: approx 554g Power Supply: 100 ~ 240 Desk Docking Charger S	all DORADO and The CARINAnav let wireless access graphical touch e intuitively display, and reference tabular format. LAP proprietary T interface. In Tablet PC mat Interface tion een Tablet Compose OV AC, 47-63Hz.	system is ss screen ays	
			Wall Mount Operating System: Winde ISO 9001 Certified Manu ISO 13485 Certified Med UL 60601-1 2nd and 3rd Certified Medical Product FCC Class B, CE, ROHS ES5.2, IP 65 Patent no. 5657368	facturing ical Device Manu Edition		
3	1	PCS	DORADOnova/DORADO	D Installation	5,750.00 USD	5,750.00 USD
			Installation on vibration fr		erator	

43

Sales Proposal:

SQ19-00342

Date: 05/08/2019

Customer Code:

C80408



Pos.	Qty.	UM	Description	Unit Price	Price
		,,	training for DORADO/DORADOnova 3		
	:		Simulation Laser System and Control Syste	m.	
	;				
	1		Pre-installation room preparation support		
			including: typical architectural drawings,		
	:		pre-installation manuals, email communicati	ion,	
	i		and telephone support.		
			Actual room preparation not included.		
	;				
			Two days duration during normal working he		
	1		(9am-5pm). After hours work may be availal	ble	
	1		for an additional charge.		
			_		
	1		Includes all travel and expenses.		
			_		
			If room preparation is insufficient for		
			the mounting of the lasers an additional		
	÷		charge of \$750 per day will be incurred.		
			~		
			If the installation cannot be completed		
			in a single visit as result of insufficient		
			room preparation then an additional full		
	-		installation charge will be incurred.		
			-		
			Two to four weeks advance notice typically		
			required for scheduling.		
				Net Value	67,690.00 USD
	•			Sales Tax	0.00 USD

Total

67,690.00 USD



Vision RT Inc 8840 Stanford Boulevard Suite 3200 Columbia, MD 21045 Tel: 866 778-2379 Fax: 651 229-3531

Email: sales@visionrt.com

Prepared For:

Michelle Roddy, Manager, Radiation

Oncology

Customer:

Novant Health

Novant Health Forsyth Medical Center-

CAPITAL

3333 Silas Creek Parkway Forsyth Medical Capital Winston Salem NC 27103

USA

Prepared By:

Trip Thomas

Email:

tthomas@visionrt.com

Mobile:

Offer Expires:

07 November 2019

Date Issued: 07 May 2019

Reference:

TTH1906359V2

Date

08 July 2019

65,840 USD

Revised:

Summary of o	ffer	Site	Qty
GateCT trackin	g solution for facilitating 4D CT reconstruction (Siemens).	Novant - Forsyth	.1
Code #	Description	Qty	Price
GCT-SIE	GateCT®: Real time tracking for 4D CT reconstruction	tion 1	Included
	Including		
	GateCT Workstation (remote)	1	Included
	Gating interface to Siemens CT scanner	1	Included
	Calibration plate	1	Included
	PSU for AlignRT HD Camera	1	Included
	AlignRT HD camera unit	1	Included
	Installation and training for all items quoted (see note	1)	

* The above price excludes shipping costs, import duties and any applicable sales taxes.

Notes:

Offer price

For AlignRT or GateCT systems, any additional mounting or fixing mechanism or construction costs required to use the Product in treatment or CT room(s) shall be the responsibility of the customer.

This Quotation is subject to Vision RT's standard terms and conditions of sale (the "Terms and Conditions") as attached. Defined Terms in this Quotation shall have the same meaning as given to them in the Terms and Conditions.

Warranty period is 12 months as per the attached Terms and Conditions of Sale.

Full product support during the Warranty Period and during any subsequent service plan will only be available if the customer provides internet access to Vision RT to allow Axeda support.

CONDITIONS OF PAYMENT

The terms of payment are as follows:

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

To Milk and a line	7		1			
Building Purchase Price			Į.			
Purchase Price of Land			ļ			
Closing Costs		:	Į			
Site Preparation	4]			
Construction/Renovation Contract(s)	\$	520,000				
Landscaping			l			
Architect / Engineering Fees	\$	47,700	J			
Medical Equipment	\$	1,034,643	>Sum Quotes;	\$	865,389	CT-Simulator
Non-Medical Equipment	\$	9,500]	\$	55,840	Vision RT System
Furniture			Ì	\$	67,690	LAP Laser
Consultant Fees	\$	-	1	\$	35,724	Injector
Financing Costs				\$	1,034,643	
Interest during Construction		,				
Other (Certification & Review Fees)	\$:	5,775				
Other (Disposal of Existing Equipment)	\$	19,500				
Other (Project Contingency)	\$	163,712				
Total Capital Cost	\$	1,800,830				
I certify that, to the best of my knowledg complete and correct.		ted capital cost for			ect is	
** See enclosed Certified Architect's Lette	the state of the s	****	Date Signed:			
Signature of Licensed Architect or Engine	er					
CERTIFICATION BY AN OFFICER OR AGEN	IT FOR THE P	ROPONENT				
I certify that, to the best of my knowledge	e, the project	ed total capital cos	t for the pro	posed	project	
is complete and correct and that is our in						
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				in.	11	
have the			Date Signed:	\mathcal{A}'	111	7
Signature of Officer/Agent			- .			
A						
I finderly row wHEme	5) 					
Title of Officer/Agent						



200 West Trement Seemile | Suction 200 Charlotte | North Carolina 25203

704 364 3400 Office

ksq design

July 16, 2019

Mr. Pete Downey Novant Health, Inc. Corporate Design Services 3600 Country Club Road, Suite 102 Winston-Salem, NC 27104

Re:

Novant Health | Forsyth Medical Center | CT Simulator Equipment Replacement

Dear Pete:

I have prepared our estimate for the Novant Health Forsyth Medical Center CT Simulator Equipment Replacement project. We estimate the construction cost will be \$285,000.00 for materials and \$235,000.00 for labor. Therefore, the total estimated construction cost is \$520,000.00.

The architectural and engineering design fees shall be \$43,800.00 and estimated project reimbursable expenses are \$3,900.00. Therefore, the total estimated architectural and engineering fee and reimbursable expenses is \$47,700.00.

If I can be of further assistance, please do not hesitate to contact me. Sincerely,

Nelson C. Soggs, AIA, LEED® AP

Nelson Choggs

Associate Principal

KSQ Design

nsoggs@ksq.design

ATTACHMENT D

EQUIPMENT COMPARISON

NH Forsyth Medical Center CT-Simulator Replacement	EXISTING EQUIPMENT	REPLACEMENT
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	Philips	Siemens
Model number	453567088051	Somatom Confidence
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	Serial # 7370	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	03/18/2009	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 signed Projected Capital Cost form>	ŅĀ	\$1,8,00,830
Total cost of the equipment	\$837,737	\$1,034,643
Location of the equipment Attach a separate sheet for mobile equipment if necessary>	FMC Rad-Onc Dept.	FMC Rad-Onc Dept.
Document that the existing equipment is currently in use	See 2019 LRA	NA
Will the replacement equipment result in any increase in the average charge per procedure?	AN	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>	CT-Simulation/Treatment Planning	NA
Type of procedures the replacement equipment will perform <attach a="" if="" necessary="" separate="" sheet=""></attach>	NA	CT-Simulation /Treatment Planning

Date of last revision: 5/17/19