

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

October 31, 2023

Melissa K. Shearer <u>Melissa.shearer@conehealth.com</u>

Exempt from Review – Replacement Equipment		
Record #:	4292	
Date of Request:	September 27, 2023	
Facility Name:	Wesley Long Community Hospital	
FID #:	933540	
Business Name:	The Moses H. Cone Memorial Hospital Operating Corporation	
Business #:	1815	
Project Description:	Replace a fixed CT scanner	
County:	Guilford County	

Dear Ms. Shearer:

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 X.cite fixed CT scanner to replace the Siemens Somatom Definition AS64 serial # 66123 fixed CT scanner. 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,

Gregory F. Yakaboski Project Analyst

Micheala Mitchell

Micheala Mitchell Chief

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

From:	Allen, Amanda
To:	Yakaboski, Greg
Cc:	Shearer, Melissa
Subject:	[External] RE: RE: CT Exemption Request for Wesley Long Community Hospital
Date:	Monday, October 16, 2023 3:23:07 PM

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Greg,

Cone Health submitted the exemption request with the incorrect statue. The correct statue for this request is N.C. G.S.§131E-184(a)(7) for replacement major medical equipment. Cone Health's understanding is that due to the CON threshold change for medical equipment from \$2M to \$3M, this project should be exempt.

Cone Health confirms that the existing CT equipment will be disposed by the vendor and will not be used again in the State without first obtaining a Certificate of Need, if one is required.

Please let us know if you need further information on this request.

Thank you,

Amanda

Amanda Allen, MBA

Cone Health | Strategy and Planning Planning Manager Direct Dial: 336.663.5330| Fax: 336.663.5336 Website: <u>conehealth.com</u> Pronouns: She/Her | <u>Why Include Pronouns?</u>

From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

Sent: Monday, October 16, 2023 3:09 PM

To: Allen, Amanda <amanda.allen@conehealth.com>

Subject: FW: RE: CT Exemption Request for Wesley Long Community Hospital

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Sincerely, *Gregory F. Yakaboski* Project Analyst Division of Health Service Regulation, Certificate of Need NC Department of Health and Human Services Help protect your family and neighbors from COVID-19. *Know the 3 Ws. Wear. Wait. Wash.* #StayStrongNC and get the latest at <u>nc.gov/covid19</u> Office: 919-855-3873 <u>Greg.Yakaboski@dhhs.nc.gov</u> 809 Ruggles Drive, Edgerton Building 2704 Mail Service Center Raleigh, NC 27699-2704

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From: Yakaboski, Greg

Sent: Wednesday, October 4, 2023 1:52 PM

To: Shearer, Melissa <<u>Melissa.Shearer@conehealth.com</u>>

Subject: RE: CT Exemption Request for Wesley Long Community Hospital

Hey Melissa,

2 Requests that I would appreciate your help with:

First Request:

For the above referenced exemption request under Section 184(g) the CT equipment being replaced needs to be on the "Main Campus" of Wesley Long Community Hospital. The definition in Section131E-176(14n) of the CON Law (found on page 380 of the 2023 SMFP) states:

Main Campus- The site of the main building from which a licensed health service facility provides clinical patient services AND exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building. (or basically within 250 yards of that main building)

Could your team email over a drawing showing where the CT equipment will be in relation to the office/location at Wesley Long that "Exercises Financial and Administrative Control over the hospital. The drawing can be very basic or just a picture of the facility with say lines with arrows identifying where the CT will be and where the main office is.

Second Request:

Could you, in the same email, have your team affirmatively state the CT Equipment being replace... such as "the existing CT equipment/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."

I know you referenced that Equipment Quote and said that this sort of statement was in their but I did not see it.

Thanks, Greg

Sincerely,

Gregory F. Yakaboski

Gregory F. Yakaboski

Project Analyst

<u>Division of Health Service Regulation</u>, Certificate of Need <u>NC Department of Health and Human Services</u>

Help protect your family and neighbors from COVID-19.

Know the 3 Ws. Wear. Wait. Wash.

#StayStrongNC and get the latest at nc.gov/covid19

Office: 919-855-3873

Greg.Yakaboski@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building 2704 Mail Service Center Raleigh, NC 27699-2704

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Strategy and Planning 1200 North Elm Street Greensboro, NC 27401-1020 336.663.5600 www.conehealth.com

September 27, 2023

Ms. Micheala Mitchell, Chief Ms. Gloria Hale, Team Leader Healthcare Planning and Certificate of Need Section Division of Health Service Regulation, NC DHHS 2704 Mail Service Center Raleigh, NC 27699-2704

Re: Computed Tomography (CT) Equipment Replacement at Wesley Long Hospital (Lic# H0159/FID#933540)

Dear Ms. Mitchell and Ms. Hale:

I am writing to you today to provide prior written notice that The Moses H. Cone Operating Corporation d/b/a Cone Health intends to replace one (1) computer tomography (CT) scanner at Wesley Long Hospital pursuant to NCGS § 131E-184(g). This equipment replacement project will not increase the total inventory of CT scanners owned and operated by Cone Health.

The existing equipment is a Siemens Somatom 64 slice CT scanner purchased by Cone Health in 2012 that has now reached the end of its useful life. Current downtimes have increased due to the age of the equipment. The existing CT scanner downtimes are extended due to the challenge of finding equipment to repair it. The new Siemens Somatom X.cite replacement CT scanner is not only more efficient, but it will also allow for more patient exams each day due to faster scan times and higher quality images. Please see *Attachment 1* for a comparison of the features of the existing and proposed replacement equipment.

The capital cost for the new Siemens Somatom X.cite machine is \$1,114,836. *Attachment 2* includes a quote from Siemens for the replacement equipment. Page 8 indicates that Siemens will remove and dispose of the existing CT machine. The total capital cost for the project is estimated to be \$1,603,027, including \$488,191 of construction costs, which were estimated by CPL Architecture, the architect for this project, based on their experience with similar projects. A full capital cost breakdown is included in *Attachment 3*. Ms. Micheala Mitchell Ms. Gloria Hale Page 2

The proposed project meets the requirements set forth in NCGS § 131E-184(g). First, the total cost of construction does not exceed the \$3,000,000 threshold. Second, the sole purpose of this capital expenditure is to replace and renovate existing major medical equipment. Third, this project will not lead to a new institutional health service. Finally, this letter serves as prior written notice to the Department.

I look forward to receiving confirmation of the exempt nature of this project. Please feel free to reach out to me with any questions you have.

Sincerely,

Melin K. Slem

Melissa K. Shearer Executive Director Strategy and Planning

Attachment

cc: Ike Ichite, Executive Director, Radiology Services, Cone Health Sherry Nance, Director of Imaging Services, The Moses H. Cone Memorial Hospital and Wesley Long Hospital

Attachment 1

EQUIPMENT COMPARISON

	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 Scanner	CT Scanner
Manufacturer	Siemens	Siemens
Model number	Somatom Definition AS64	Somatom X.cite
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	66123	N/A
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2012	Proj. 2023
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>	N/A	\$1,603,027.00
Total cost of the equipment	N/A	\$1,114,836.00
Location of the equipment <attach a="" equipment="" for="" if="" mobile="" necessary="" separate="" sheet=""></attach>	WL ED	WL ED
Document that the existing equipment is currently in use	Yes/HTM services	N/A
Will the replacement equipment result in any increase in the average charge per procedure?	N/A	No
If so, provide the increase as a percent of the current average charge per procedure	N/A	N/A
Will the replacement equipment result in any increase in the average operating expense per procedure?	N/A	No
If so, provide the increase as a percent of the current average operating expense per procedure	N/A	N/A
Type of procedures performed on the existing equipment <attach a="" if="" necessary="" separate="" sheet=""></attach>	Below	N/A
Type of procedures the replacement equipment will perform <attach a="" if="" necessary="" separate="" sheet=""></attach>	N/A	Same

Date of last revision: 5/17/19

Exams performed on the existing equipment, and the same will apply to the replacement:

Emergency and non-emergent CT Head CT Maxillofacials (sinus, facials IAC, temporal bones) CT Spines (cervical, thoracis and lumbar) CT Neck CT Neck CT Chest CT Chest CT Abd/Pelvis CT Abd/Pelvis CT Angio studies (Head, Chest, Abd/Pelvis, Extremities) CT Perfusion

CT Cardiac Scoring

Attachment 2



PRELIMINARY PROPOSAL

Customer Number: 0000030848

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

Date: 29-06-2023

CONE HEALTH 1200 N ELM ST GREENSBORO, NC 27401

Siemens Medical Solutions USA, Inc. is pleased to submit the following quotation for the products and services described herein at the stated prices and terms, subject to your acceptance of the terms and conditions on the face and back hereof, and on any attachment hereto.

Table of Contents

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SOMATOM X.cite (Quote Nr. CPQ-891604 Rev. 0)	2
OPTIONS for SOMATOM X.cite (Quote Nr. CPQ-891604 Rev. 0)	10

Contract Total: 1,074,900 USD

(total does not include any Optional or Alternate components which may be selected)

Proposal valid until 13-08-2023



PRELIMINARY PROPOSAL

Quote Nr:	CPQ-891604 Rev. 0
Terms of Payment:	00% Down, 80% Delivery, 20% Installation Free On Board: Destination
Purchasing Agreement:	PREMIER PURCHASING PARTNERS LP
	PREMIER PURCHASING PARTNERS LP terms and conditions apply to Quote Nr CPQ-891604
	Customer certifies, and Siemens relies upon such certification, that : (a) PREMIER PP-IM-273 CT is the sole GPO for the purchases described in this Quotation, and (b) the person signing this Quotation is fully authorized under the Customer's policies to choose and indicate for Customer such appropriate GPO.

SOMATOM X.cite

All items listed below are included for this system:

Qty 1	Part No. 14467988	Item Description SOMATOM X.cite Intelligent imaging. Excellence empowered. As the number and complexity of radiological procedures increases, demands on staff are reaching unsustainable levels. Although our advanced CT systems have the potential to expand precision medicine, too often this potential remains untapped.
		SOMATOM® X.cite changes that. Together with myExam Companion, it launches the era of intelligent imaging. Now users of any skill level can unlock system's groundbreaking potential. myExam Companion uses the new possibilities of digitalization to turn data into built-in expertise. This transforms real-time patient characterization - and the way staff operate a CT scanner. myExam Companion guides them through any procedure, automatically adjusting key parameters to individual patients. For technologists, it makes interacting with patients and the CT scanner easier and more natural. For radiologists, it reduces unwarranted variations and generates consistent, comprehensive results.
		SOMATOM X.cite has a patient-friendly, 82-cm bore and a Vectron [™] X-ray tube - for unprecedented power and resolution. This makes it uniquely equipped to improve personalization, no matter how challenging your patient or throughput. From routine exams to advanced quantitative and functional procedures, SOMATOM X.cite empowers excellence in radiology.
		Welcome to the era of intelligent imaging.
1	14468523	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 Customer.
		The Customer agrees to allow connection to Siemens' remote service diagnostic equipment to the secured telecommunications link at his own expenses. The



Siemens Medical Solutions USA, Inc.

40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE

Stephen Argo - +1 (336) 210-6178 craig.argo@siemens-healthineers.com

Qty	Part No.	Item Description
		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	14467997	Standard configuration The Standard configuration bundle contains the following parts:
		105 kW Generator The 105 kW power allows the X-ray generator the use of maximum power of 105 kW in fine adjustable steps. The 105 kW Generator in combination with the Vectron tube enables scanning with 70 kV up to 150 kV in 10 kV steps.
		High-speed 0.3 s This option provides a rotation speed of down to 0.3 sec per rotation, for outstanding image quality and very high scan speeds. Fast gantry rotation times are the prerequisite for highest temporal resolution and are therefore essential for brilliant, motion free imaging especially in cardiovascular imaging.
		IRS X. Standard Contains IRS X. Standard (Imaging Reconstruction System) for the preprocessing and reconstruction of the CT raw data. The reconstruction computer contains of a cluster of high-performance GPU boards performing the preprocessing and reconstruction of the CT data.
		ICS X. Standard Contains ICS X. Standard (Imaging Control System) including High-performance computer CPU.
1	14468005	Patient Table 2000mm / 307kg Patient Table (Vario2) with 2000 mm / 78.7" scanable range with patient table extension. The table has a maximum table load of 307 kg / 676 lbs.
1	14468262	Mattress for PHS 2000mm Mattress for the comfortable positioning of the patient on the CT table.
1	14468306	Accessory tray Tray at the foot of the mattress to place small accessories like e.g. ECG cable.
1	14468638	Infusion Holder Infusion holder smartly attached to the end of the patient table.
1	14468006	Foot Switch for Pat.Table control Foot switch for patient table control
1	14468007	Table Extension Comfortable table accessory to extend the maximum scan range.
1	14468008	Positioning & Fixation Set Positioning & Fixation Set including pediatric cradle, arm support, patient fixation straps and 40 cm positioning straps.
1	14468017	2nd Control-room Monitor The second control room monitor enables additional visual space to support your SOMARIS 10 View&GO workflow.
1	14468043	Cooling System Water Water heat exchanger for the dissipation of heat generated in the gantry to an environmentally friendly cooling water circulation system.
1	14468302	UPS incl. Rack Uninterruptible power supply with battery backup.
		The UPS ensures the supply of power to the computer system and color monitor in the event of line voltage fluctuations and brief power failures.
1	14468321	UPS Cable SET_M



Qty	Part No.	Item Description Short cable set for UPS.
1	14468010	iMAR The iMAR metal artifact reduction algorithm combines three successful approaches (beam hardening correction, normalized sinogram inpainting and frequency split). This makes it possible to reduce metal artifacts caused by metal implants such as coils, metal screws and plates, dental fillings or implants. Along with the algorithm comes the simple user interface of iMAR enabling easy reconstruction of clinical images with reduced metal artifacts. iMAR can be combined with iterative reconstruction methods.
1	14468002	Cardiac Imaging The Cardiac Imaging Package enables comprehensive cardiac assessment and clinical consistency in cardiac CT with ease. Optimized, fully tablet-operated scan preparation, fast scanning, and standardized results in every cardiac case are enabled by the integration with myExam Companion guided cardiac workflow, along with GO technologies that allow you to devote more time to your patients.
		Especially useful for users less experienced in cardiac CT procedures, the exclusive myExam Companion suggests which settings are more appropriate for every patient based on the procedure and patient characteristics and finds the optimal combination of acquisition and reconstruction parameters. By measuring heart rate and rhythm, the system automatically chooses the most appropriate phase of the heart cycle to scan and later reconstruct.
		The Cardiac imaging package includes Physiological Measurement Module, ECG cable, Advanced radiotranslucent ECG cable extension, Cardio Spiral, Cardio Spiral Bi-Segment, Adaptive Cardio Sequence, Cardio BestPhase, Recon&GO - Inline Vessel Ranges (LAD, RCA, CX), View&GO - Inline Heart Isolation, View&GO - Inline Coronary Tree.
1	14468013	Neuro Imaging The Neuro Imaging Package includes Flex 4D Spiral - Neuro, which facilitates volume perfusion studies in head applications for a perfusion range of up to 10 cm. These dynamic procedures are handled on the AWP with the same visual logic as any other procedure, so users of any level of experience can perform them right away. The package also includes a tiltable head holder and Neuro DSA (Digital Subtraction Angiography) at the CT View&GO, which is an all-in-one, cross-specialty viewing solution, CT View&GO provides a single-click, bone-free visualization, Neuro DSA (digital subtraction angiography), for quick and easy neurovascular assessment without increasing dose, because it uses the standard, non-enhanced head scan for the subtraction.
1	14468260	SW Base Package Includes ADMIRE, Advanced Modeled Iterative Reconstruction, images benefit from higher resolution at organ borders and improved delineation of edges, e.g., to better localize lesions.
		SureView algorithm produces pitch-independent images at higher scan speeds.
		High Pitch Spiral - Up to 1.7 pitch for fast scanning with reduced motion artifacts.
		HD FoV for visualization of the human body parts and skin line located outside of the scanner's 82 cm bore.
		Scanner operates on a modern Windows 10 platform with integrated syngo System Security for cyber security protection.
		Scan&GO tablet app for a truly mobile workflow, allowing you to control scan setup remotely.*
		Check&GO with Metal Detection alerts the user when wearable metallic objects are



Qty	Part No.	Item Description
		in the scan field.
		Recon&GO Zero-click postprocessing, making it part of the standard recon tasks: Vascular ranges with Zero-click vessel centerline and labeling of main vessels. Spine Ranges for Zero-click recon of anatomically aligned and numbered spine recons. Zero-click recon of radial and parallel rib visualizations that adapts the rib cage anatomy - displaying all ribs spread out and labeled in one plane.
		CT View&GO - All-in-one, cross-specialty viewing solution, provides a large variety of clinical apps/ tools for smooth reading in just one workflow.
		FAST Planning - Fast, organ-based setting of scan and reconstruction ranges powered by AI.
		FAST ROI - automatically identifies the ROI in the aorta for automatic triggering of bolus-tracking exams.
		Flex Dose Profile - allows optimal dose modulation for long scan ranges such as in regular thorax-abd or chest pain examinations.
		CARE kV – sets tube voltage for each patient and clinical indication with 10 kV steps for dose personalization.
		X-CARE - reduce the organ dose for dose-sensitive body parts while maintaining image quality. *only available for Wireless and Tablet edition
1	14468422	myExam Companion Intelligence that works with you. myExam Companion launches the era of intelligent imaging. Using the new possibilities of digitalization, it turns data into built-in expertise. This helps technologists reduce unwarranted variations - by unlocking your modality's full potential automatically. myExam Companion guides users through any procedure, so they can interact easily and naturally with both the patient and the technology. It helps generate consistent image reconstruction jobs and standardized results.
		Shares expertise. myExam Companion turns data into built-in expertise and shares this with users so they can unlock the full potential of their modality. By enhancing the quality of automated support, it helps make exams easier and reduces complexity- no matter the procedure, patient, system or user.
		Speaks your language. myExam Companion uses clinical language and visuals that are easy to follow, which simplifies operation, even of unfamiliar modalities. It helps technologists interact easily and naturally with the patient and system, so they can focus better - both on the patient and acquiring consistent results.
		Helps you on your way. The proactive guidance of myExam Companion helps technologists of any skill level navigate even the most complex CT procedures with ease. To reduce unwarranted variation, it automatically optimizes acquisition and reconstruction parameters to the individual patient.
1	14468018	Wireless edition Wireless Tablet and Remote Scan Control for mobile workflow.
1	14468021	Extra tablet front Additional wireless Tablet to enable scanner operation from both table sides without



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		PRELIMINARY PROPOSAL
Qty	Part No.	Item Description
		detaching the tablet from the charging docks on the gantry.
1	14468424	Dual Energy Acquisition With TwinSpiral Dual Energy and TwinBeam Dual Energy, the Dual Energy Acquisition package includes two DE scan techniques to acquire excellent spectral imaging. Also included is a new workflow optimized data format with Recon&GO incl. SPP (Spectral Post-processing).
		By allowing you to characterize, highlight, and quantify different materials this produces rich diagnostic information that a conventional single source scan cannot deliver. It does this without dose penalty in comparison to a standard 120 kV scan, and even allows you to further minimize radiation with any of our existing dose- reduction technologies.
1	14468044	Cooling System Water/Air #split Water-to-air heat exchanger for the dissipation (to the air outside) of heat, generated in the gantry.
1	14468045	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 cannot provide either 400V at 50Hz or 460V at 60Hz this transformer is needed.
1	14468047	Service Switch Service switch to shut off the outdoor cooling unit for maintenance or in case of emergency.
1	14468026	Patient Experience Pro Patient Observation Camera By helping you keep an eye on the patient at all times, the gantry-integrated camera makes it easy to provide better care. Directly integrated at the gantry funnel, it allows a closer look at the patient during the whole examination, even when the patient is inside the gantry - when it matters the most. The close-up perspective makes it easy to spot even micro-movements and keep the patient in the right position.
		Visual Patient Instructions (VPI) Intuitive color-coded breathhold count-down displayed on the front and rear part of the tunnel as visual guidance for patients, especially helpful for the hearing-impaired or the ones who cannot follow the local language.
		Ring Moodlight Choose among different color lighting at the gantry ring to create a comfortable environment for patients.
1	PSPD250480Y3 K	Surge Protective Device (SPD)
1	CTSDEF01	CT Slicker Thermoseal seams and flaps deflect fluids, reducing contaminant penetration into the cushion and table. Contaminants are retained on the tabletop or shunted to the floor. Cleanup is faster, more thorough, and contaminant build-up is reduced. Built using heavy, clear, micro matte vinyl, and top grade hook and loop fastening strips (Velcro) to better fit the specified table. Custom vinyl resists tears and minimizes radiologic interference. Latex free. Set includes CT Skirts. Shipped with main cover, a catheter bag holder, and 3 restraining belts unless otherwise noted. Includes warranty from RADSCAN Medical.
1	4SPAS014	Low Contrast CT Phantom & Holder
1	ACCESS_PROT ECT	Access Protection Scan Protocols are password protected allowing only authorized staff members to access and permanently change protocols



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Qty	Part No.	Item Description
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	CARE_BOLUS	CARE Bolus Operating mode for CM-enhancement-triggered data acquisition.
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 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	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.
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	UFC_DETECTO R	UFC Detector Ultra Fast Ceramics (UFC) technology is a unique type of scintillation technology material that quickly and efficiently transforms radiation from the X-ray tube into light signals. Its superb overall quantum efficiency and unique short afterglow enable time-critical X-ray detection at low doses and extremely fast data collection.
1	CT_STELLAR_I NF	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.
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	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	WORKSTREAM 4D	Workstream4D WorkStream 4D further enhances the already superb workflow of SOMATOM CT
reated	20 06 2022 12-16-2	C. Siemenn Medical Colutions UCA Inc. Confidential



Siemens Medical Solutions USA, Inc.

40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE

Stephen Argo - +1 (336) 210-6178 craig.argo@siemens-healthineers.com

Otv	Part No.	Item Description
Qty	Fait NO.	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	CT_LUNGIMAGI NG_X	CT_Lungimaging_X
1	CT_UPS_X	CT_UPS_X
1	CT_XCITE_REC ON_384	X.cite z-Sharp Technology The unique Vectron X-ray tube 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 for each detector element. The two overlapping projections result in an oversampling in z-direction and allow to acquire twice the number of slices per detector row. The resulting measurements interleave half a detector slice width, doubling the scan information without a corresponding increase in dose. This provides a spatial resolution in z-direction of up to 0.30 mm and a corresponding reduction of spiral artifacts in the daily clinical routine.
1	CT_TINFILTER_ X	CT_Tinfilter_X
1	CT_INST_RIED EL_01	Riedel Chiller Start-up by SBT
1	СТ_РМ	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 LL	CT Standard Rigging and Installation
1	CT_ADDL_RIG GING	Additional Rigging CT
1	CT_TRADE_IN_ ALLOW	CT Trade-in-Allowance
1	CT_EP1_28	Essential Training PH 1 (Onsite-28) CT Up to (28) 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 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.
1	CT_EP2_16	Essential Training PH 2 (Onsite-16) CT Up to (16) 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 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.
1	CT_EP2_24	Essential Training PH 2 (Onsite-24) CT Up to (24) 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 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.



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

SIEMENS REPRESENTATIVE

Stephen Argo - +1 (336) 210-6178 craig.argo@siemens-healthineers.com

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	CT_PROTOPT_ 8	CT Protocol Optimization Program - 8hrs This offering provides the customer with up to (8) hours of virtual, simulator-based training with a Siemens Clinical Education Specialist (CES) for development and optimization of up to (50) standardized protocols before and after initial turnover training. This includes: • Consultation with the customer on scan protocol expectations.
		 Use of a simulator workstation to optimize and customize CT scan protocol settings to customer-specific needs. Import of optimized scan protocols for customer's immediate use, either at system

turnover prior to first clinical use or any time thereafter. This educational offering must be completed by the later of (12) months from purchase or install end date. If training is not completed within the applicable time period, Siemens' obligation to provide the training will expire without refund.

System Total 1,074,9

1,074,900 USD



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PRELIMINARY PROPOSAL

OPTIONS on Quote Nr: CPQ-891604 Rev. 0

OPTIONS for SOMATOM X.cite

All items listed below are OPTIONS and will be included on this system ONLY if initialed: (See Detailed Technical Specifications at end of Proposal.)

Qty	Part No.	Item Description	Extended Price
		Optional parts	
1	14468020	 FAST 3D Camera The world's first 3D camera integrated in a CT positioning workflow allows automatic patient positioning in the exam room. The FAST 3D Camera enables more flexible patient preparation and accurate positioning thanks to the combination of the Al-powered FAST 3D Camera with the mobile workflow. A live image of the patient is displayed on the Scan&GO tablet interface for interactive planning. 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 masking 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. 	+ 39,936 USD
		 FAST Direction helps safeguard the right scan direction of the topogram. 	



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PRELIMINARY PROPOSAL

FINANCING: The equipment listed above may be financed through one of our financing partners. 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 Healthineers 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 Healthineers Sales Representative.

Siemens Healthineers Stephen Argo +1 (336) 210-6178 craig.argo@siemens-healthineers.com

Attachment 3

Building Purchase Price	N/A
Purchase Price of Land	N/A
Closing Costs	N/A
Site Preparation	N/A
Construction/Renovation Contract(s)	\$393,468
Landscaping	N/A
Architect / Engineering Fees	\$84,723
Medical Equipment	\$1,114,836
Non-Medical Equipment	\$10,000
Furniture	N/A
Consultant Fees (specify)	N/A
Financing Costs	N/A
Interest during Construction	N/A
Other (specify)	N/A
Total Capital Cost	\$1,603,027

Projected Capital Cost Form

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

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

Signature of Licensed Architect or Engineer

Date Signed: 8.16.23

CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that it is our intent to carry out the proposed project as described.

Date Signed: 9/27/2023

Signature of Officer/Agent

tor, Strategy and Manning Title of Officer/Agent

From:	Mitchell, Micheala L
То:	<u>Stancil, Tiffany C</u>
Cc:	Hale, Gloria
Subject:	FW: [External] No Review Equipment and Replacement Equipment Requests
Date:	Wednesday, September 27, 2023 12:55:02 PM
Attachments:	image001.png
	Cone Health No Review HP CT Scanner 09.27.23.pdf
	Cone Health WI, CT Replacement 09 27 23 pdf

Hi Tiffany,

We are still figuring out who will take exemptions/no reviews for HSA II (Terris' old health service area). For now, can you log these two requests as exemptions and assign to Greg?

Gloria will determine whether they need to go to someone else and let us know.

Micheala Mitchell, JD <u>NC Department of Health and Human Services</u> <u>Division of Health Service Regulation</u> Section Chief, Healthcare Planning and CON Section 809 Ruggles Drive, Edgerton Building 2704 Mail Service Center Raleigh, NC 27699-2704 Office: 919 855 3879 <u>Micheala.Mitchell@dhhs.nc.gov</u>

Don't wait to vaccinate. Find a COVID-19 vaccine location near you at MySpot.nc.gov. Twitter | Facebook | Instagram | YouTube | LinkedIn

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From: Shearer, Melissa < Melissa. Shearer@conehealth.com>

Sent: Wednesday, September 27, 2023 12:40 PM

To: Mitchell, Micheala L < Micheala. Mitchell@dhhs.nc.gov>; Hale, Gloria < gloria.hale@dhhs.nc.gov>

Cc: Allen, Amanda <amanda.allen@conehealth.com>; Kubida, Kristy

<Kristy.Kubida@conehealth.com>

Subject: [External] No Review Equipment and Replacement Equipment Requests

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

This message was sent securely by Cone Health.

Hello Ms. Mitchell and Ms. Hale,

Attached please find two letters requesting No Review or Exemption Determinations for two separate CT Scanner projects for Cone Health. One project is located at MedCenter High Point and the other project is located at Wesley Long Hospital. Please let me know if you have any questions on either project.

Thank you,

Melissa K. Shearer

Cone Health | Strategic Development Executive Director, Strategy and Planning Cell: 336.682.9742 Email: <u>Melissa.shearer@conehealth.com</u> Website: <u>conehealth.com</u>



We promise ... we are right here with you. Because we exist ... to connect health care and well-being. So that ... a tradition of health and well-being is woven into the fabric of our communities.

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