



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

March 7, 2024

Emily Cromer
emily.cromer@unchealth.unc.edu

Exempt from Review – Replacement Equipment

Record #: 4394
Date of Request: March 4, 2024
Facility Name: University of North Carolina Medical Center
FID #: 923517
Business Name: UNC Health Care System
Business #: 2991
Project Description: Replace a CT scanner
County: Orange

Dear Ms. Cromer:

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 CT scanner to replace the Siemens Somatom Sensation 64 CT scanner [Serial # 54250]. 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 the 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,

[Handwritten signature of Cynthia Bradford]

Cynthia Bradford
Project Analyst

[Handwritten signature of 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



March 4, 2024

VIA ELECTRONIC MAIL

Cynthia Bradford, Project Analyst  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
NC Department of Health and Human Services

Re: UNC Hospitals Notice of Exemption for Replacement Equipment / Orange County

Dear Ms. Bradford,

University of North Carolina Hospitals (“UNCH”) provides this notice regarding a replacement computed tomography scanner (the “CT Scanner”), and requests confirmation that the acquisition of such replacement equipment, as described in detail below, is exempt from certificate of need (“CON”) review.

**A. Proposed Replacement Equipment Meets Either Exemption Test Under Section 184 of the CON Statute**

UNCH is requesting a determination that its purchase of the replacement equipment is exempt from CON review under the replacement equipment exemption provisions contained in N.C. Gen. Stat. §131E-184(f)(1)-(3) or N.C. Gen. Stat. §131E-184(a)(7).

Under the provisions found at N.C. Gen. Stat. §131E-184(f)(1)-(3), the CON law provides:

- (f) The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the monetary threshold set forth in G.S. 131E-176(22) if all the following conditions are met:
  - (1) The equipment being replaced is located on the main campus.
  - (2) The Department has previously issued a certificate of need for the equipment being replaced. The subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
  - (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

For the purposes of the foregoing Provisions in Section §131E-184(f)(1)-(3), the monetary threshold set forth in N.C. Gen. Stat. § G.S. 131E-176(22) is as follows:

- (22a) Replacement equipment. – Equipment that costs less than three million dollars (\$3,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. In determining whether the replacement equipment costs less than three million dollars (\$3,000,000) the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included.

As per Section (f)(2) of the Main Campus Replacement Equipment Exemption, a CON was not required when the equipment being replaced was originally acquired in 2005.

The term “main campus” is defined by N.C. Gen. Stat. §131E-176(14n) as follows:

- (14n) “Main campus” means all of the following for the purposes of G.S. 131E-184(f) and (g) only:
- a. 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.
  - b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

Although the replacement equipment unit satisfies the replacement equipment test in N.C. Gen. Stat. §131E-184(f)(1)-(3) because it will reside on the Main Campus, the unit also satisfies the replacement equipment exemption test in N.C. Gen. Stat. §131E-184(a)(7) since the unit costs under \$3 million to acquire and install.

## **B. Cost of the Replacement Equipment**

The purchase price of the equipment is \$1,310,285 as shown in the quote from Siemens provided in Exhibit #1. The cost to acquire the replacement equipment – including replacement equipment installation and existing equipment removal – represents a total capital cost of \$2,912,077 and is outlined in Exhibit #2. There will be no other construction costs or other capital costs associated with this replacement equipment.

## **C. Equipment Being Replaced is Located on the Main Campus**

The existing equipment is currently in use and located in the N.C. Children's Hospital, which is on the main campus of UNCH. The replacement equipment will be located within UNC Medical Center, also located on the main campus of UNCH.

## **D. Comparable Equipment**

In addition to the foregoing, to qualify for replacement equipment exemption under either test, the replacement equipment must be comparable to the equipment it replaces and must be sold or otherwise disposed of when replaced. UNCH's proposal meets this test as well. The CON rule codified as 10A N.C.A.C 14C.0303 (the "Regulation") defines "comparable medical equipment" in subsection (c) as follows:

"Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

UNCH intends to use the replacement equipment for substantially the same services for which the entity currently uses the existing equipment. The replacement equipment unit will perform all procedures currently performed on the existing equipment unit. Although it possesses some expanded capabilities due to technological improvements, the replacement equipment will perform the same general range of procedures as the existing equipment unit, see Exhibit #3 Equipment Comparison Chart. The replacement equipment is therefore comparable medical equipment as defined in Subsection (c).

## **E. Disposition of Equipment**

As part of the proposal to acquire the replacement equipment, Siemens will de-install and take possession of the existing equipment. None of the replacement equipment units will be re-sold or re-installed in North Carolina without appropriate CON approval.

In consideration of the above, UNCH understands that this project is exempt from CON review and requests written confirmation that the proposed replacement of the equipment, and related installation and renovation costs as described herein, are exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(f)(1)-(3) and N.C. Gen. Stat. §131E-184(a)(7).

Please do not hesitate to contact me at [Emily.Cromer@unchealth.unc.edu](mailto:Emily.Cromer@unchealth.unc.edu) if you require any additional information.

Sincerely,



**Emily Cromer**  
Director of Regulatory Affairs & Facility Strategy  
UNC Health

**Exhibit 1**



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

**SIEMENS REPRESENTATIVE**  
Edwin Winicki - +1 (336) 688-0978  
edwin.winicki@siemens-healthineers.com

**PRELIMINARY PROPOSAL**

Customer Number: 0000010805

Date: 1-18-2024

**UNIV NORTH CAROLINA HEALTH CARE SYS**  
101 MANNING DR  
CHAPEL HILL, NC 27514

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.

<b><u>Table of Contents</u></b>	<b><u>Page</u></b>
SOMATOM X.cite (Quote Nr. CPQ-1046826 Rev. 0).....	2

**Contract Total: \$ 1,310,285**  
*(total does not include any Optional or Alternate components which may be selected)*

Proposal valid until 9-30-2024

**PRELIMINARY PROPOSAL**

**Quote Nr:** CPQ-1046826 Rev. 0

**Terms of Payment:** 00% Down, 80% Delivery, 20% Installation  
 Free On Board: Destination

**Purchasing Agreement:** VIZIENT SUPPLY LLC

VIZIENT SUPPLY LLC terms and conditions apply to Quote Nr CPQ-1046826

Customer certifies, and Siemens relies upon such certification, that : (a) VIZIENT CT - XR0676 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	Part No.	Item Description
1	14467988	<p><b>SOMATOM X.cite</b>            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.</p> <p>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.</p> <p>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.</p>
1	14468523	<p>Welcome to the era of intelligent imaging.</p> <p><b>Identifier SRS</b>            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.</p> <p>The Customer agrees to allow connection to Siemens' remote service diagnostic equipment to the secured telecommunications link at his own expenses. The</p>

**PRELIMINARY PROPOSAL**

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	14468005	<b>Patient Table 2000mm / 307kg</b> 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	<b>Mattress for PHS 2000mm</b> Mattress for the comfortable positioning of the patient on the CT table.
1	14468306	<b>Accessory tray</b> Tray at the foot of the mattress to place small accessories like e.g. ECG cable.
1	14468638	<b>Infusion Holder</b> Infusion holder smartly attached to the end of the patient table.
1	14468006	<b>Foot Switch for Pat.Table control</b> Foot switch for patient table control
1	14468007	<b>Table Extension</b> Comfortable table accessory to extend the maximum scan range.
1	14482564	<b>Positioning &amp; Fixation Set</b> Positioning & Fixation Set including arm support, patient fixation straps and 40 cm positioning straps.
1	14468017	<b>2nd Control-room Monitor</b> The second control room monitor enables additional visual space to support your SOMARIS 10 View&GO workflow.
1	14468042	<b>Cooling System Air</b> Air cooling for the dissipation of heat generated in the gantry.
1	14468302	<b>UPS incl. Rack</b> 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	<b>UPS Cable SET_M</b> Short cable set for UPS.
1	14468010	<b>iMAR</b> 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	14472496	<b>SW Base Package VA40</b> Item Includes: SureView, High Pitch Spiral 1.7, and HD FoV  CARE: CARE Dose4D, Flex Dose Profile, CARE kV, CARE Child, X-CARE, ADMIRE  FAST: FAST Planning, FAST Adjust, FAST ROI  Check & GO: Metal Detection, Contrast Coverage  Recon& GO: Inline Anatomical Ranges, Inline Table Removal, Inline Bone Removal, Inline Vessel Ranges, Inline Spine Ranges, Inline Rib Ranges, and Multi Recon  CT View & GO: Vessel Extension, Endoscopic View, Diameter/WHO Area, Lung Lesion Segmentation, ROI HU Threshold, and Spine Ranges

**PRELIMINARY PROPOSAL**

Qty	Part No.	Item Description
1	14468422	<p><b>myExam Companion</b> 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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
1	14468018	<p><b>Wireless edition</b> Wireless Tablet and Remote Scan Control for mobile workflow.</p>
1	14468021	<p><b>Extra tablet front</b> Additional wireless Tablet to enable scanner operation from both table sides without detaching the tablet from the charging docks on the gantry.</p>
1	14468025	<p><b>Patient Experience</b> 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.</p> <p>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.</p>
1	14472517	<p><b>myNeedle Guide 3D</b> myNeedle Guide 3D is part of a cross-modality solution with a common user interface and a unified workflow on SHS imaging systems designed to assist you in planning and guiding the needle during percutaneous CT-guided interventions. myNeedle Guide 3D supports all kind of percutaneous procedures, from simple in-plane interventions, to complex, double-angulated 3D procedures. myNeedle Guide 3D supports planning of multiple needle paths by measuring distances and angles from the target to the needle entry point on one or several axial CT slices and as well on Multi Planar Reconstruction. It provides a synchronized workflow between the devices in the examination room and the CT console in the control room. This allows both; independent control of the myNeedle Guide workflow from the examination room and interventions assisted by the technologist from the control room. myNeedle Guide 3D software is an application which is hosted on the second</p>



**PRELIMINARY PROPOSAL**

Qty	Part No.	Item Description
		control room monitor. In parallel a component of the software runs on the standard system tablet. This enables image manipulation and control of the intervention software while in the examination room to stay close-by a patient during an interventional procedure. myNeedle Guide 3D includes dedicated interventional spiral and sequential scanning modes: - i-Spiral scan mode offers flexible volume coverage to adjust it to the clinical scenario and for a dose conscious approach, standard dose reduction algorithm such as CARE Dose4D and CARE kV can be applied as well. - i-Sequence scan mode is referred as FAST i-Sequence as it allows for quick scan repetitions, e.g. for dynamic monitoring of the needle. In addition, a dedicated i-Sequence mode covering full or half of the detector width is provided which allows 3D planning and guidance. - Table Side Rails long for both sides of the patient table to flexibly mount interventional accessories along the patient table.
1	14472520	<b>i-Fluoro</b> i-Fluoro allows for nearly real-time CT fluoroscopic image guidance to support needle positioning in minimal invasive percutaneous procedures. The scan mode i-Fluoro CT scan mode is completely integrated in the interventional workflow of myNeedle Guide. For i-Fluoro scans HandCARE™ can be applied enabling real-time dose modulation to avoid direct X-ray exposure to the physician's hands by switching the radiation off in the upper segment of the 360° tube-rotation. HandCARE™ switches off the x-ray exposure for a 100° angle between three user selectable positions (10:00, 12:00 and 2:00 o'clock). i-Fluoro lets you scan continuously, and view images in near real time at up to 10 frames/s on an additional in-room monitor and as well as on the second control room monitor. The acquired images have an image matrix of 512 x 512.
1	14472521	<b>i-Joystick</b> The i-Joystick supports the table movement in z-direction (in and out of the gantry) during CT-guided minimal invasive procedures directly from the table side. It is connected via cable and can be mounted on both sides of the CT-table. The i-Joystick offers the following movement functionality: - Free movement via joystick lever for precise manual table positioning. - Large move button to trigger easy and fast table movement to dedicated positions, e.g. last scan position.
1	14472522	<b>Tablet dock for patient table</b> A tablet dock for patient table to mount the tablet at the table side. It can be flexibly positioned along both sides of the patient table. The tablet dock is fully adjustable for an ergonomic independent in-room operation during minimal invasive procedures. Optionally the table dock can be plugged in for an uninterrupted power supply for long interventions.
1	14468029	<b>X-Ray Foot Switch</b> Foot switch for triggering scans from the examination room.
1	14472523	<b>Large Ceiling Monitor</b> The space-saving ceiling installation along with the large movement range of the ceiling support allow operating convenience when positioning the monitor. Includes 1x32" flat screen monitor Ceiling support for the accommodation and safe installation of one screen monitor in the examination room. The option supports the display of images in the examination room. Please refer to the Siemens Healthineers official Product Planning Guide regarding mounting
1	14467998	<b>Power configuration</b> The Power 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

**PRELIMINARY PROPOSAL**

Qty	Part No.	Item Description
		<p>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.</p> <p>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.</p> <p>IRS X. Power Contains IRS X. Power (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.</p> <p>ICS X. Power Contains ICS X. Power (Imaging Control System) including High-performance computer CPU.</p>
1	14468009	<p><b>CARE Contrast III</b> CARE Contrast III speeds up clinical workflow and allows efficient and confident monitoring of patients during contrast media injection and scan start, now with the interchange of protocols including contrast media parameters (e.g., flow, concentration) calculated for the average patient.</p> <p>Package includes fully defined protocols including quantified parameterization of flow and concentration for the media, calculated for the average patient.</p>
1	14468002	<p><b>Cardiac Imaging</b> 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.</p> <p>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.</p> <p>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&amp;GO - Inline Vessel Ranges (LAD, RCA, CX), View&amp;GO - Inline Heart Isolation, View&amp;GO - Inline Coronary Tree.</p>
1	14468013	<p><b>Neuro Imaging</b> 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 tilttable head holder and Neuro DSA (Digital Subtraction Angiography) at the CT View&amp;GO, which is an all-in-one, cross-specialty viewing solution, CT View&amp;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.</p>
1	14472519	<p><b>myNeedle Laser</b> myNeedle Laser is embedded in the CT gantry and the functionality is fully integrated in the myNeedle Guide workflow. For a previously planned needle path,</p>

**PRELIMINARY PROPOSAL**

Qty	Part No.	Item Description
		the myNeedle Laser system projects the needle entry point and insertion angle on to the patient with a maximum deviation of 5 mm. The integration of myNeedle Laser in the software and as well in the hardware reduces workflow steps compared to an external laser guidance system.
1	PSPD250480Y3 K	<b>Surge Protective Device (SPD)</b>
1	CTSDEF01	<b>CT Slicker</b> 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	<b>Low Contrast CT Phantom &amp; Holder</b>
1	RSDPSSIP10A	<b>Sterile Drape for CT Interv Panel QTY 10</b> Includes: QTY 10, each drape packaged in one time use Tyveck Pouch Sterilization by irradiation @ 25 - 40 kGys Biological profile and dose setting per AAMI TIR27 Quarterly dose audits performed by NAMSA
1	AS11502247	<b>myNeedle Guide iPad-Cover; Qty 50</b> Sterile covers for protection of the tablet during intervention with myNeedle Guide on the SOMATOM X. platform and the SOMATOM go. platform. Constructed of polyethylene and fitted to allow touch operation through sterile cover. This device is a single use, disposable cover to avoid cross-contamination and maintaining a sterile field.  Dimensions: 36.5x22.5x2.5 cm One package contains 50 pcs.
1	ACCESS_PROT ECT	<b>Access Protection</b> Scan Protocols are password protected allowing only authorized staff members to access and permanently change protocols
1	CARE_DOSE4D	<b>CARE Dose4D</b> 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	<b>CARE Dose Configurator</b> 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	<b>CARE Bolus</b> Operating mode for CM-enhancement-triggered data acquisition.
1	DICOM_SR	<b>DICOM SR Dose Reports</b> DICOM structured file allows for the extraction of dose values (CTDIvol, DLP)
1	DOSELOGS	<b>DoseLogs</b> 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	<b>Dose Alert</b> Dose Alert: Dose Alert automatically adds CTDIvol and DLP values depending on

**PRELIMINARY PROPOSAL**

Qty	Part No.	Item Description
		z-position (scan axis). The Dose Alert window appears, if either of these cumulative values exceeds a user-defined threshold.
1	DOSE_NOTIFICATION	<b>Dose Notification</b> 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	<b>NEMA_XR-29 Standard</b> 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	<b>SureView</b> 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_DETECTOR	<b>UFC Detector</b> 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_INF	<b>Stellar Infinity</b> 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	<b>syngo VRT</b> Advanced 3D functionality as an extension to the basic 3D viewer, containing volume rendering technique (VRT) and advanced editing functions.
1	SYNGO_BONE_REMOVAL	<b>syngo Bone Removal</b> 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	<b>Workstream4D</b> 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	CT_LUNGIMAGING_X	<b>CT_Lungimaging_X</b>
1	CT_UPS_X	<b>CT_UPS_X</b>
1	CT_XCITE_RECON_384	<b>X.cite z-Sharp Technology</b> 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	<b>CT_Tinfilter_X</b>
1	BFLEXOCS_M	<b>Stellant Flex injector-ceiling(med)</b>

**PRELIMINARY PROPOSAL**

Qty	Part No.	Item Description
		Stellant Flex ceiling mounted injector with workstation, NO Informatics, but is Informatics ready.
		Includes Stellant Flex ceiling mounted injector w/medium post (850 mm) and ceiling plate; workstation; installation and warranty through Bayer.
		This post length is recommended for rooms with a floor to structural ceiling height of approximately 10 feet.
1	BIS12_POS	<p><b>Bayer ISI2 interface, POS</b></p> <p>Bayer ISI2 Interface enables CAN III networking between Siemens CT system and Bayer Stellant injector.          Requires appropriate Siemens' CT system functionality (i.e. CareContrast).</p> <p>Installation included if ISI2 Interface is purchased with an injector. Otherwise, installation is to be quoted separately.</p>
1	CT_PM	<p><b>CT Project Management</b></p> <p>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.</p>
1	CT_BTL_INSTALL	<b>CT Standard Rigging and Installation</b>
1	CT_ADDL_RIGGING	<b>Additional Rigging CT</b>
1	CT_EP1_28	<p><b>Essential Training PH 1 (Onsite-28) CT</b></p> <p>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.</p>
1	CT_EP2_16	<p><b>Essential Training PH 2 (Onsite-16) CT</b></p> <p>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.</p>
1	CT_PROTOPT_8	<p><b>CT Protocol Optimization Program - 8hrs</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>• Consultation with the customer on scan protocol expectations.</li> <li>• Use of a simulator workstation to optimize and customize CT scan protocol settings to customer-specific needs.</li> <li>• Import of optimized scan protocols for customer's immediate use, either at system turnover prior to first clinical use or any time thereafter.</li> </ul> <p>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.</p>

**System Total \$ 1,310,285**

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

**SIEMENS REPRESENTATIVE**  
Edwin Winicki - +1 (336) 688-0978  
edwin.winicki@siemens-healthineers.com

### 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  
Edwin Winicki  
+1 (336) 688-0978  
edwin.winicki@siemens-healthineers.com

**Exhibit 2**

**Projected Capital Cost Form**

Building Purchase Price	\$
Purchase Price of Land	\$
Closing Costs	\$
Site Preparation	\$
Construction/Renovation Contract(s)	\$1,432,792
Landscaping	\$
Architect / Engineering Fees	\$169,000
Medical Equipment	\$1,310,285
Non-Medical Equipment	\$
Furniture	\$
Consultant Fees (specify)	\$
Financing Costs	\$
Interest during Construction	\$
Other (Philips XPer Flex Cardio Control Room)	\$
Other (IT Costs for Control Room)	\$
<b>Total Capital Cost</b>	<b>\$2,912,077</b>

**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: 2.23.24



**CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT**

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

\_\_\_\_\_  
Signature of Officer/Agent

Date Signed: \_\_\_\_\_

\_\_\_\_\_  
Title of Officer/Agent

**Exhibit 3****EQUIPMENT COMPARISON**

	<b>EXISTING EQUIPMENT</b>	<b>REPLACEMENT EQUIPMENT</b>
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	CT Scanner	CT Scanner
Manufacturer	Siemens	Siemens
Model number	Somatom Sensation 64	Somatom X.cite
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	Serial #54250	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	7/1/2005	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>	NA	\$2,912,077
Total cost of the equipment	\$1,390,265	\$1,310,285
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	UNCH Main Campus	UNCH Main Campus
Document that the existing equipment is currently in use	See Letter	NA
Will the replacement equipment result in any increase in the <b>average charge per procedure</b> ?	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 <b>average operating expense per procedure</b> ?	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 separate sheet if necessary>	See Attached	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	See Attached



**UNC Hospitals**

Revenue &amp; Usage Report by Service Code

**Dept: 1000-100-330408 - CT SCAN**

For December 2023

<b>Department</b>	<b>EPIC CDM Code Description</b>
<b>CDM Codes included in Dept Statistics</b>	
1000-100-330408 - CT SCAN	HC INJ AA PUDENDAL NRV
1000-100-330408 - CT SCAN	HC INJECTION ANESTHETC AGENT L T PARAVERTEBRAL
1000-100-330408 - CT SCAN	HC FNA WITH IMAGING - INACTIVE
1000-100-330408 - CT SCAN	HC BONE MARROW ASPIRATION
1000-100-330408 - CT SCAN	HC BIOPSY PROSTATE SINGLE MULT
1000-100-330408 - CT SCAN	HC IMAGE GUIDED FLUID COLLECTION DRAINAGE BY CATH PERI RETRO
1000-100-330408 - CT SCAN	HC FNA BX INCL CT GUIDANCE 1ST LESION
1000-100-330408 - CT SCAN	HC CT LUNG CANCER SCREENING - INACTIVE
1000-100-330408 - CT SCAN	HC CT THORAX LOW DOSE LUNG CANCER SCREENING WO CONTRAST
1000-100-330408 - CT SCAN	HC CT COLONOGRAPHY DX WO CONT
1000-100-330408 - CT SCAN	HC CT COLONOGRAPHY DIAG W WO CONT
1000-100-330408 - CT SCAN	HC CT COLONOGRAPHY SCREENING
1000-100-330408 - CT SCAN	HC CT HEART WO CONT W COR CAL SCORE
1000-100-330408 - CT SCAN	HC CT HEART W CONT 3D PP
1000-100-330408 - CT SCAN	HC CT CARD STRUCT MORPH W CONG DISEASE
1000-100-330408 - CT SCAN	HC CTA CARD STRUCT MORPH W CALC
1000-100-330408 - CT SCAN	HC CTA ABD AORTA AND BIL ILIEOFM W CONT
1000-100-330408 - CT SCAN	HC CT GUIDE NEEDLE PLACEMENT
1000-100-330408 - CT SCAN	HC CT GUIDANCE PLACEMENT RADIATION FIELDS
1000-100-330408 - CT SCAN	HC CT HEAD OR BRAIN WO CONT
1000-100-330408 - CT SCAN	HC CT HEAD OR BRAIN W CONT
1000-100-330408 - CT SCAN	HC CT HEAD OR BRAIN WO FLD W CONT
1000-100-330408 - CT SCAN	HC CT ORBIT SELLA PF WO CONT
1000-100-330408 - CT SCAN	HC CT ORBIT SELLA PF W CONT
1000-100-330408 - CT SCAN	HC CT ORBIT SELLA PF WO FLD W CONT
1000-100-330408 - CT SCAN	HC CT MAXILLOFACIAL WO CONT
1000-100-330408 - CT SCAN	HC CT MAXILLOFACIAL W CONT
1000-100-330408 - CT SCAN	HC CT MAXILLOFACIAL WO FLD W CONT
1000-100-330408 - CT SCAN	HC CT NECK SOFT TISSUE WO CONT
1000-100-330408 - CT SCAN	HC CT SOFT TISSUE NECK W CONT
1000-100-330408 - CT SCAN	HC CT SOFT TISSUE NECK WO FLD W CONT
1000-100-330408 - CT SCAN	HC CTA HEAD W CONT INCL NON CONT
1000-100-330408 - CT SCAN	HC CTA NECK W CONT INCL NON CONT
1000-100-330408 - CT SCAN	HC CT THORAX DIAGNOSTIC WO CONT
1000-100-330408 - CT SCAN	HC CT THORAX DIAGNOSTIC W CONT
1000-100-330408 - CT SCAN	HC CT THORAX DIAGNOSTIC WO FLD W CONT
1000-100-330408 - CT SCAN	HC CTA CHEST NONCOR WO W CONT
1000-100-330408 - CT SCAN	HC CT CERVICAL WO CONT
1000-100-330408 - CT SCAN	HC CT CERVICAL W CONT
1000-100-330408 - CT SCAN	HC CT CERVICAL WO FLD W CONT
1000-100-330408 - CT SCAN	HC CT THORACIC WO CONT
1000-100-330408 - CT SCAN	HC CT THORACIC W CONT
1000-100-330408 - CT SCAN	HC CT THORACIC WO FLD W CONT
1000-100-330408 - CT SCAN	HC CT LUMBAR WO CONT
1000-100-330408 - CT SCAN	HC CT LUMBAR W CONT
1000-100-330408 - CT SCAN	HC CT LUMBAR WO FLD W CONT
1000-100-330408 - CT SCAN	HC CTA PELVIS W CONT INCL NON CONT
1000-100-330408 - CT SCAN	HC CT PELVIS WO CONT
1000-100-330408 - CT SCAN	HC CT PELVIS W CONT
1000-100-330408 - CT SCAN	HC CT PELVIS WO FLD W CONT
1000-100-330408 - CT SCAN	HC CT UE WO CONT
1000-100-330408 - CT SCAN	HC CT UE W CONT
1000-100-330408 - CT SCAN	HC CT UE WO FLD W CONT
1000-100-330408 - CT SCAN	HC CTA UE W CONT W NON CONT
1000-100-330408 - CT SCAN	HC CT LE WO CONT
1000-100-330408 - CT SCAN	HC CT LE W CONT
1000-100-330408 - CT SCAN	HC CT LE WO FLD W CONT
1000-100-330408 - CT SCAN	HC CTA LE W CONT AND INCL NON CONT
1000-100-330408 - CT SCAN	HC CT ABDOMEN WO CONT
1000-100-330408 - CT SCAN	HC CT ABDOMEN W CONT
1000-100-330408 - CT SCAN	HC CT ABDOMEN WO W CONT
1000-100-330408 - CT SCAN	HC CTA ABD PELVIS W CONT W NON CONT
1000-100-330408 - CT SCAN	HC CT ABD PELVIS WO CONT
1000-100-330408 - CT SCAN	HC CT ABD PELVIS W CONT

1000-100-330408 - CT SCAN	HC CT ABD PELVIS WO W CONT
1000-100-330408 - CT SCAN	HC CT LIMITED OR LOCALIZED FOLLOW UP
1000-100-330408 - CT SCAN	HC CTA ABDOMEN W CONT W NONCONT
1000-100-330408 - CT SCAN	HC CT CEREBRAL PERFUSION STUDY
1000-100-330408 - CT SCAN	HC ASPIR HEMATOMA ABCES BUL CYST
1000-100-330408 - CT SCAN	HC BIOPSY NEEDLE MUSCLE PERC
1000-100-330408 - CT SCAN	HC BX NDL BONE TROCAR SUPERFICIAL
1000-100-330408 - CT SCAN	HC BX NDL BONE TROCAR DEEP
1000-100-330408 - CT SCAN	HC INJ SINUS TRACT DIAGNOSTIC
1000-100-330408 - CT SCAN	HC ARTHROCENTESIS ASPIR INJ INTERMEDIATE JNT OR BURSA WO US GUIDE
1000-100-330408 - CT SCAN	HC ARTHROCENTESIS A IR INJ MAJOR JNT OR BURSA W O US GUIDE
1000-100-330408 - CT SCAN	HC INJ SACROILIAC JOINT INCLUDING IMAGE GUIDANCE
1000-100-330408 - CT SCAN	HC BIOPSY PLEURA PERC NEEDLE
1000-100-330408 - CT SCAN	HC BX LUNG MEDIASTINUM PERC NDL-INACTIVE
1000-100-330408 - CT SCAN	HC PLACEMENT INTERSTITIAL DEVICE INTRATHORACIC
1000-100-330408 - CT SCAN	HC PLEURAL DRAIN W CATH W IMAGE GUIDANCE
1000-100-330408 - CT SCAN	HC ABLAT LUNG RFA UNI PERC-INACTIVE
1000-100-330408 - CT SCAN	HC BONE MARROW BIOPSY
1000-100-330408 - CT SCAN	HC BIOPSY LYMPH NODE SUPERFICIAL
1000-100-330408 - CT SCAN	HC ABD PARACENTESIS INCL IMAGING
1000-100-330408 - CT SCAN	HC BIOPSY ABD OR RETROPERITONEAL PERCUTANEOUS NEEDLE
1000-100-330408 - CT SCAN	HC PERC ASPIRATION INTERVERTEBRAL DISC OR PARAVERTEBRAL TISSUE
1000-100-330408 - CT SCAN	HC BONE MARROW BIOPSY AND ASPIRATION DIAGNOSTIC
1000-100-330408 - CT SCAN	HC SCREENING CARDIAC CALCIUM SCORE

**From:** [Bradford, Cynthia L](#)  
**To:** [Stancil, Tiffany C](#); [Mitchell, Micheala L](#)  
**Subject:** FW: [External] UNC Hospitals Notice of Exemption for Replacement Equipment / Orange County  
**Date:** Monday, March 4, 2024 2:44:07 PM  
**Attachments:** [2024.03.04 CT Replacement Exemption Letter - Main Campus.pdf](#)

---

FYI

**Cynthia Bradford, MSW**

Project Analyst - Certificate of Need

Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section

[NC Department of Health and Human Services \[protect-us.mimecast.com\]](#)

Office: 919-855-4665

[cynthia.bradford@dhhs.nc.gov](mailto:cynthia.bradford@dhhs.nc.gov)

809 Ruggles Drive

2704 Mail Service Center

Raleigh, NC 27699-2704

*( I work remotely on Thursdays and Fridays, therefore email is the best way to reach me on those days.)*

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

[Twitter](#) | [Facebook](#) | [YouTube](#) | [LinkedIn](#)

---

**From:** McVay, Marjorie <Marjorie.McVay@unchealth.unc.edu>

**Sent:** Monday, March 4, 2024 2:11 PM

**To:** Bradford, Cynthia L <cynthia.bradford@dhhs.nc.gov>

**Cc:** Cromer, Emily <Emily.Cromer@unchealth.unc.edu>

**Subject:** [External] UNC Hospitals Notice of Exemption for Replacement Equipment / Orange County

**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.

Good afternoon,

Please see attached *Notice of Exemption for Replacement Equipment* related to a replacement CT scanner at UNC Hospitals.

Thank you –  
Marjorie

Marjorie McVay  
Strategy Consultant | Regulatory Affairs  
UNC Health  
[Marjorie.McVay@unchealth.unc.edu](mailto:Marjorie.McVay@unchealth.unc.edu)

----- Confidentiality Notice -----

*The information contained in (or attached to) this electronic message may be legally privileged and/or confidential information. If you have received this communication in error, please notify the sender immediately and delete the message.*

---

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.