



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

September 21, 2023

Emily Cromer
Emily.Cromer@unchealth.unc.edu

Exempt from Review – Replacement Equipment

Record #: 4265
Date of Request: August 30, 2023
Facility Name: University of North Carolina Medical Center
FID #: 923517
Business Name: University of North Carolina Hospitals at Chapel Hill
Business #: 1900
Project Description: Replace a PET 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(f). Therefore, you may proceed to acquire without a certificate of need the Siemens PET scanner to replace the Siemens Biograph PET scanner (Serial #4377). 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,

Cynthia Bradford
Project Analyst

Micheala Mitchell
Chief

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

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



August 30, 2023

VIA ELECTRONIC MAIL

Micheala Mitchell, Chief
Cynthia Bradford, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Re: UNC Hospitals / Replacement Equipment Exemption for PET Scanner / Orange

Dear Ms. Mitchell and Ms. Bradford:

UNC Hospitals (“UNCH”) intends to acquire a replacement PET Scanner on its main campus, and requests written confirmation that this project, as described in detail below, is exempt from CON review pursuant to the main campus replacement equipment exemption. UNCH provides this prior written notice of a project exemption from Certificate of Need (“CON”) review.

A. Proposed Replacement Equipment

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).

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.

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.

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, the Department has previously issued a Certificate of Need for the equipment being replaced. See Exhibit 1 for the CON issued for Project ID No. # F-7110-04.

B. Cost of the Replacement Equipment

The purchase price of the equipment as shown in the quote from the vendor provided in Exhibit 2 is \$2,627,244, including replacement equipment installation and existing equipment removal. The total capital cost, including minor renovations, is estimated to be \$3,235,244. Projected capital costs are provided in Exhibit 3. There will be no other capital costs associated with this replacement equipment.

C. Equipment Being Replaced is Located on the Main Campus

The existing equipment is currently located and in use in the Lineberger Comprehensive Cancer Center within the basement level of the main building of the hospital at 101 Manning Drive in Chapel Hill. The replacement equipment will be placed in the same location. Thus, the equipment being replaced is on UNCH’s Main campus.

D. Comparable Equipment

In addition to the foregoing, to qualify for replacement equipment exemption, the replacement equipment must be comparable to the equipment it replaces and must be sold or otherwise disposed of when replaced. 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 4 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. The replacement equipment unit will not 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).

Please do not hesitate to contact me at Emily.Cromer@unchealth.unc.edu if you require any additional information.

Sincerely,

Emily Cromer

Emily Cromer
Director of Regulatory Affairs & Facility Strategy
UNC Health

STATE OF NORTH CAROLINA
 Department of Health and Human Services
 Division of Facility Services

CERTIFICATE OF NEED

for

Project Identification Number F-7110-04

FID# 923517

**ISSUED TO: University of North Carolina Hospitals at Chapel Hill
 101 Manning Drive
 Chapel Hill, NC 27514**

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: University of North Carolina Hospitals at Chapel Hill shall acquire a PET scanner pursuant to Policy AC-3 in the 2004 State Medical Facilities Plan/Orange County

CONDITIONS: See Reverse Side

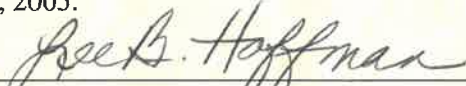
**PHYSICAL LOCATION: 101 Manning Drive
 Chapel Hill, NC 27514**

MAXIMUM CAPITAL EXPENDITURE: \$3,748,926

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: April 1, 2006

This certificate is effective as of the 14th day of November, 2005.


 Chief, Certificate of Need Section
 Division of Facility Services

CONDITIONS:

1. The University of North Carolina Hospitals at Chapel Hill (“UNC”) shall materially comply with all representations made in its certificate of need application, identified as Project I.D. #J-7110-04, and the Supplemental Information provided to the agency on August 1, 2005. In those instances in which any of these representations conflict, UNC shall materially comply with the last-made representations.
2. UNC shall not acquire, as part of this project, any equipment that is not included in the project’s proposed capital expenditure in Section VIII of the application or that would otherwise require a Certificate of Need.

TIMETABLE:

Completion of final drawings and specifications -----	March 31, 2006
Construction Section’s approval of final drawings and specifications-----	May 31, 2006
Contract Award (Notice to Proceed) -----	June 30, 2006
Ordering Equipment-----	September 1, 2006
Arrival of Equipment -----	December 11, 2006
Completion of Construction -----	December 29, 2006
Occupancy/Offering of all services -----	February 1, 2007



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: 08-07-2023

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.

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Biograph Vision 450 (Quote Nr. CPQ-420769 Rev. 2)	Error! Bookmark not defined.
OPTIONS for Biograph Vision 450 (Quote Nr. CPQ-420769 Rev. 2).....	Error! Bookmark not defined.

Contract Total: \$ 2,627,244

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

Proposal valid until 09-29-2023

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

Quote Nr: CPQ-420769 Rev. 2

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-420769

Customer certifies, and Siemens relies upon such certification, that : (a) VIZIENT GROUP BUY FY23 Q4 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.

Biograph Vision 450

Qty	Part No.	Item Description
1	14422691	<p>Biograph Vision 450</p> <p>The Biograph Vision 450 is a whole-body PET•CT tomograph designed for the purposes of oncological, neurological and cardiac imaging and aid in diagnosis. With a single noninvasive procedure, the Biograph produces remarkable CT and PET•CT images that reveal highly-detailed anatomy and biological processes at the molecular level.</p> <p>The Biograph provides:</p> <ul style="list-style-type: none"> - high performance spiral computed tomography (CT) imaging and applications. - high-resolution, high-count rate, positron emission tomography (PET) imaging of metabolic and physiologic processes. - high quality anatomic and metabolic image registration for optimal lesion detection and identification within the body. - high quality attenuation correction and scatter correction for PET imaging.
1	14423382	<p>AIDAN</p> <p>Provides AIDAN, the new intelligent Biograph PET/CT scanner platform, which includes a variety of new algorithms of proprietary ALPHA technology to bring artificial intelligence to PET scanner operations. It also utilizes digital hardware to leverage the use of the digital signal from our detectors along with hardware powerful enough to process AI and a patient focused design to enable continuous bed motion.</p> <p>This is the foundation for many of our new and unique features helping you become more efficient, personalized and standardized and to perform PET/CT exams with ease. AIDAN enables the following optional features:</p> <ul style="list-style-type: none"> FlowMotion AI (optional) OncoFreeze AI (optional) PET FAST Workflow (optional) FlowMotion Multiparametric PET Suite (optional)
1	10249560	<p>Biograph Ge-68 Sources - Medium</p> <p>Calibration sources for the Biograph PET/CT.</p> <p>These sources are to be purchased with a new Biograph Horizon, mCT or Vision 450.</p>
1	10097286	<p>Uniform Source Shield - Medium</p>

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
		Contains shield for the medium Uniform Source for the Biograph PET/CT.
1	14422699	PET Gantry/MARS UPS Uninterruptible Power Supply (UPS) option providing 5 minutes of backup power to the PET gantry and PET acquisition/reconstruction computer, enabling proper shutdown of the PET system in the event of power loss. Specifications: 6.0 KVA, 230 Volts, 50/60 Hz.
1	10249159	Keyboard, English Keyboard in the above-mentioned language.
1	14421307	ultraHD-PET Option (AWP) Utilizing timing information (time-of-flight) between the two PET coincidence events, coupled with resolution recovery of HD•PET, ultraHD•PET option provides improved image signal-to-noise which can be used to either enhance image quality and/or reduce patient acquisition time. The Biograph ultraHD•PET option takes PET imaging to the pinnacle of performance.
1	14422257	FAST 3D Align (AWP) FAST 3D Align automatically corrects misalignment of anatomic structures, organs of the patient. It aligns those to fit it to the selected reconstruction plane for a highly automated reconstruction workflow. Additionally it minimizes the black area in the image through automatic adjustment of the recon field of view.
1	14422262	iMAR (AWP) The iMAR metal artifact reduction algorithm combines three successful approaches (beam hardening correction, normalized sinogram inpainting and frequency split). This allows to reduce metal artifacts caused by metal implants such as coils, metal screws and plates, dental fillings or implants. iMAR is compatible with extended FoV, the extended CT scale as well as the newest dose reduction feature. Along with the new algorithm comes the simple user interface of iMAR enabling easy reconstruction of clinical images with reduced metal artifacts.
1	14422259	DoseMAP (AWP) DoseMAP provides a complete comprehensive CT dose management environment.
1	14423367	syngo Security (AWP) The syngo Security Package provides enhanced security features including user management and audit trail functionality.
1	14422696	Install Kit w/PDU - Vision Items necessary for install. Includes power distribution unit for connecting entire system to a single 3-phase power drop.
1	10412855	Installation US
1	14422687	QualityGuard - Vision Utilizing the intrinsic radioactive properties of LSO detectors, QualityGuard runs during off hours, providing daily and weekly PET quality control without the need to handle the Ge-68 phantom. PET gantry status greets the user in the morning, minimizing the time needed for morning quality control prior to first patient imaging.
1	14421193	PET Cardiac Gating Opt (AWP) Provides PET cardiac gated list mode acquisition, offline histogramming, and reconstruction for improved accuracy in quantitation as well as visualization of cardiac motion. Supports a maximum of 24 gate bins from the list mode PET acquisition. Requires the optional UPMM for ECG signal capture.
1	14423000	ECG module (UPMM) - Vision

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	14421195	<p>Universal Physiological Monitoring Module (UPMM) provides patient cardiac ECG information for either CT or PET cardiac gating. Locates in the patient handling system for convenient patient connection. Includes patient cable.</p> <p>PET Dynamic Option (AWP) Support for list mode acquisition, offline histogramming and reconstruction. Support for retrospective histogramming in any arbitrary frame durations of 3 second or greater, maximum of 100 frames defined by available disk space. Whole body (multi-bed) dynamic support of up to 25 passes. Dynamic Speed feature supports online processing capabilities for list mode imaging allowing reconstruction of dynamic frames from list mode data while acquisition is ongoing.</p>
1	14415608	<p>CT FAST Planning (AWP) Immediate, organ-based setting of scan and recon ranges aiming for a safer, faster and more standardized workflow at the scanner.</p>
1	11297529	<p>Elevate S PET LSO SENIOR System USA Elevate is a Siemens Healthineers customer care program that helps you get the most from your investment. As a valued customer, MI Elevate offers customers a wide range of solutions and benefits for your existing installed Siemens Healthineers MI system.</p> <p>As you consider the options for replacing your older-generation PET/CT system, Siemens is committed to helping you find the solution that best fits your needs and facilitate a smooth transition to your next-generation PET/CT system, enabling you to stay competitive with the latest technology in healthcare.</p> <p>MI Elevate additionally serves as a GREEN initiative. When you Elevate your existing PET/CT, this enables us to reuse and recycle your deinstalled system responsibly, utilizing the whole system or its parts, reducing our environmental impact.</p>
1	11216446	<p>EOS Bonus PET MI Elevate offers customers a wide range of solutions and benefits for your existing installed Siemens Healthineers MI system.</p> <p>While considering the options for replacing your existing PET system the End-Of-Support (EOS) Bonus is designed to help reduce the initial impact of your new system purchase, allowing you to consider future life cycle needs such as serviceability.</p> <p>By signing a service contract at point of sale* you can take advantage of this EOS Bonus offering enabling you to stay competitive with the latest technology in healthcare and continue to protect your investment into the future.</p> <p>* Please see full MI Elevate Terms and Conditions for details such as service contract duration and type.</p>
1	14424017	<p>AIDAN Clin Apps Pkg - mCT/Vision The AIDAN Clinical Applications Package contains the OncoFreeze AI, FlowMotion AI and FAST PET Workflow AI options.</p>
1	14422700	<p>Water Cabinet Kit - Vision Water cabinet with fluid heat exchangers required when connecting Biograph Vision system to facility chilled water.</p>
1	7568103L	<p>Project Mgmt/Site Planning (US only)</p>
1	4SPAS014	<p>Low Contrast CT Phantom & Holder</p>
1	MI_CARE_BOL US	<p>CARE Bolus Operating mode for CM-enhancement-triggered data acquisition.</p>

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	MI_CARE_DAS HBOARD	CARE Dashboard 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
1	MI_CARE_DOS E4D	Care Dose 4D 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	MI_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	MI_CARE_PRO FILE	CARE Profile CARE Profile: Visualization of the dose distribution along the topogram prior to the scan
1	MI_CT_DICOM_ VIEW	DICOM Viewer CT DICOM Viewer - included on each CD; automatically started on the viewer's PC
1	MI_DOSE_SHIE LD	Adaptive Dose Shield Adaptive Dose Shield for spiral acquisition to eliminate pre- and post-spiral over-radiation.
1	MI_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	MI_WORKSTRE AM4D	Workstream 4D WorkStream 4D offers direct generation of sagittal, coronal, oblique or double-oblique reconstructed CT images directly from CT raw data as part of the CT protocol.
1	MIP_CARDIAC_ MAR	PET Cardiac Metal Artifact Reduction Reduces metal artifacts in cardiac PET imaging caused by pacemaker wires, surgical clips, ECG lead wires. It is not intended for use in non-cardiac protocols.
1	MIP_HD_FOV_P RO	HD Field of View Pro HD Field of View Pro (HD FoV Pro) is a CT extended field of view reconstruction algorithm designed to enable visualization of the human body parts and skin line located outside of the standard field of view based on the algorithmic complement of missing detector data outside of the scan FoV to the edge of the PET/CT gantry.
1	MIP_PGC	Prompts Gamma Correction Corrects for high energy gamma ray emission seen with Rb-82, I-124 and Ga-68 imaging
1	MIP_RECON192	mCT/Vision 64 sliceCT z-SharpTech 192 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.
1	MI_MCT_NEMA _XR_29	NEMA_XR-29 Standard

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
1	MIP_LUNGIMG AS64	<p>This system is in compliance with NEMA XR-29 Standard Attributes on CT Equipment Related To Dose Optimization and Management, also know as Smart Dose</p> <p>CT Lung Cancer Screening For well over a decade, CT has been recognized and used as the standard of care for lung nodule detection and sizing. This is due to CT's spatial resolution, geometric accuracy, and ability to create various reconstructions and 3D views. The high contrast environment in the chest between the lungs and the nodules makes for a relatively easy detection task for clinicians using CT images. Recent advances in CT technology have allowed these scans to be effectively performed at lower doses, higher resolutions, and faster scan times.</p> <p>The SOMATOM Definition AS 64 is indicated for use in low dose lung cancer screening for high risk populations*. The Definition AS 64 is delivered with two specific scan protocols to provide low dose lung cancer screening exams at approximately 1.3 mGy CTDI for a standard size adult. These default protocols utilize Siemens proprietary dose reducing features such as CARE Dose4D™, automatic exposure control technology that modulates and adapts dose for every patient, for high image quality at low dose.</p> <p>*As defined by professional medical societies.</p> <p>Lung Imaging This SOMATOM Definition scanner offers two specific scan protocols to provide Lung Imaging at 1.3 mGy CTDI or greater and for use with post-processing applications</p> <p>LungLowDose Uses CARE Dose 4D in conjunction with CARE kV and adaptive dose shield to provide imaging of the lung with a default scanner protocol set at 1.3 mGy CTDI. This protocol provides images from .6 mm and are acquired using .6 mm collimation and a z-sharp mm of 128X0.6 mm off. Default settings of a reference kVp of 120 and quality Reference mAs of 20 with rotation speed of .50 are used to achieve this dose. This protocol is set using a Kernel of B70f, B31F and B70F for axial viewing.</p> <p>LungCARE Uses CARE Dose 4D in conjunction with CARE kV and adaptive dose shield to provide imaging of the lung with a default scanner protocol set at 1.3 mGy CTDI. This protocol provides images from .6 mm and are acquired using .6</p>
1	CTSDEF01	<p>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.</p>
1	BFLEXOCS_S	<p>BAYER MEDRAD Stellant Flex - ceiling Stellant Flex ceiling mounted injector with workstation, NO Informatics, but is Informatics ready.</p> <p>Includes Stellant Flex ceiling mounted injector w/short post (580 mm) and ceiling plate; workstation; installation and warranty through Bayer.</p> <p>This post length is recommended for rooms with a floor to structural ceiling height of approximately 9 or 9.5 feet.</p>
1	MIP_BD_LV2	<p>Essential Education Level 2 (MI)(PET) This education package has been designed specifically to meet the education needs of a current Siemens PET/CT department with a more demanding clinical workload. Components of this education package include: A 12-month subscription to our continuing education platform, PEPconnect,</p>

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description
		including access to up to 50 CEU credits. Onsite hands-on training by a Siemens Clinical Education Specialist for up to 28 hours over four consecutive business days. Ongoing access to pre-scheduled, live-remote, one on one training sessions for 12 months. Browse topics and register your sessions at Siemens PEPconnect. A multi-day Siemens Online Classroom, chosen from a variety of defined offerings. Browse class offerings and register at Siemens PEPconnect Live-remote training by a Siemens professional Clinical Education Specialist for up to 24 hours over three consecutive business days. This Educational offering must be completed (12) months from install end date. If training is not completed within the applicable period, Siemens obligation to provide the training will expire without refund.
1	MIP_EP2_16	Essential Training PH 2 (Onsite-16) PET 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	MIPET_ELV_SN	Elev PETSen (-\$29,000) Deinstall, freight, and/or scrapping is included in this offer.
1	MISYS_BUDG_ADL_RIG	Add'l/Out of Scope Rigging
1	NUSYS_TRADE_IN_ALL	NU-Sys Trade-in-Allowance - Biograph 40 Truepoint 1005 - 2023-2495
1	INVIA612103	4DM Personal Premium Pkg - floating Includes Corridor 4DM Personal SPECT, Corridor 4DM Personal PET, CT Option and CFR Option Corridor4DM Personal is a software only solution for a Windows PC. This software solution provides an image database, DICOM connectivity and the full functionality of the Corridor4DM Software. Features: Systolic Function: LV Volumes (indexed and unindexed), EF, Cardiac Output. Diastolic Function: Peak Filling and Emptying Rates Regional Wall Thickening, Motion, and Time to Peak Contractility Transient Ischemic Dilatation (TID) Myocardial Perfusion Quantification (Extent and Severity) Contractility Histogram Semiquantitative Scoring (SSS, SRS, SDS, VS, SS) Derived Viability Polar Map (delineate between ischemic, viable, and scar tissue) Supported Data: Nuclear Medicine: Static, Dynamic, Gated Planar, Whole Body SPECT Perfusion: Tomo, Recon Tomo, Gated Tomo, Gated Recon Tomo (SA, HLA, VLA, Transverse) SPECT MUGA: Gated Tomo, Gated Recon Tomo (SA, HLA, VLA, Transverse) PET: Recon Tomo and Gated Recon Tomo (SA, HLA, VLA, Transverse) Attenuation Correction Maps 8- and 24-bit DICOM Static and Multi-Frame Screen Captures The CT Option Package includes ECT and CTA Fusion, CT Viewing, and Ca Scoring. Coronary Flow Reserve Option (Rb-82 and Ammonia PET Tracers) Price includes on-site installation for all US and Canadian sites and training by an

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

Qty	Part No.	Item Description
		INVIA product specialist for one day, inclusive of travel. Additionally a one-year Maintenance Agreement, which includes free upgrades, is included at no additional cost.

System Total **\$ 2,627,244**

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

OPTIONS for Biograph Vision 450 on Quote Nr : CPQ-420769 Rev. 2

Qty	Part No.	Item Description	Extended Price
		Optional parts	
1	14415600	SMART Neuro AC (AWP) Calculated attenuation correction for brain imaging reduces the need for CT imaging for attenuation correction while providing images with quantitative units.	+ \$ 11,019
1	14415602	CARE Contrast (US) Integrated solution for a simplified bolus injector coupling. It synchronizes scan and contrast injection and transfers the injector protocol data in the patient protocol, in the e-logbook and to MPPS (if configured).	+ \$ 12,600

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

Projected Capital Cost Form

Building Purchase Price	\$
Purchase Price of Land	\$
Closing Costs	\$
Site Preparation	\$
Construction/Renovation Contract(s)	\$519,000
Landscaping	\$
Architect / Engineering Fees	\$89,000
Medical Equipment	\$2,627,244
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)	\$
Total Capital Cost	\$3,235,244

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.

Steve Trimberger

 Signature of Officer/Agent

Date Signed: _____

 Title of Officer/Agent

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	PET	PET
Manufacturer	Siemens	Siemens
Model number	Biograph	TBD
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	4377	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	June 1, 2007	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	See Exhibit 3
Total cost of the equipment	\$2,463,231	\$2,627,244
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 average charge per procedure ?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the average operating expense per procedure ?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	See Attached	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	See Attached

EPIC CDM Code	EPIC CDM Code Description
73500025	HC CT NECK SOFT TISSUE WO CONT
73500026	HC CT SOFT TISSUE NECK W CONT
73500027	HC CT SOFT TISSUE NECK WO FLD W CONT
73500030	HC CT THORAX DIAGNOSTIC WO CONT
73500031	HC CT THORAX DIAGNOSTIC W CONT
73500056	HC CT ABDOMEN W CONT
73500060	HC CT ABD PELVIS WO CONT
73500061	HC CT ABD PELVIS W CONT
74040001	HC PET CT MYOCARDIAL IMAG MET EVAL
74040002	HC PET CT MYOCARDIAL IMAG SINGLE
74040003	HC PET CT MYOCARDIAL IMAG MULT
74040004	HC PET CT METABOLIC BRAIN
74040005	HC PET LMTD CHEST HEAD NECK
74040006	HC PET SKULL BASE MID THIGH
74040007	HC PET WHOLE BODY
74040008	HC PET CT TUMOR IMAGING LIMITED
74040009	HC PET CT SKULL TO THIGH
74040010	HC PET CT TUMOR IMAGING WHOLE BODY
74040017	HC PET MYOCARDIAL PERFUSION INCLD VENT WALL AND OR EJECT FRACT SINGLE STUDY REST STRESS
74040018	HC PET MYOCARDIAL PERFUSION INCLD VENT WALL AND OR EJECT FRACT MULTIPLE STUDY REST STRESS
74040019	HC PET MYOCARDIAL IMAGING METABOLIC EVAL WITH CT SINGLE STUDY
74040020	HC PET MYOCARDIAL IMAGING PERFUSION EVAL WITH CT SINGLE STUDY AT REST OR STRESS
74040021	HC PET MYOCARDIAL IMAGING PERFUSION EVAL WITH CT MULTIPLE STUDIES AT REST OR STRESS
74040022	HC PET MYOCARDIAL IMAGING COMBINED PERFUSION W METABOLIC DUAL RADIOTRACER WITH CT

From: [Mitchell, Micheala L](#)
To: [Stancil, Tiffany C](#)
Subject: FW: [External] UNC Hospitals PET Scanner Replacement Exemption
Date: Wednesday, August 30, 2023 12:09:06 PM
Attachments: [2023.8.30 UNCH PET Replacement Exemption-Main Campus.pdf](#)

Hey there!

Would you mind logging this as an exemption and assigning to Cindy?

Thanks,

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

Don't wait to vaccinate. Find a COVID-19 vaccine location near you at [MySpot.nc.gov](https://www.myspot.nc.gov).
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From: Cromer, Emily <Emily.Cromer@unchealth.unc.edu>
Sent: Wednesday, August 30, 2023 12:04 PM
To: Bradford, Cynthia L <cynthia.bradford@dhhs.nc.gov>; Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>
Subject: [External] UNC Hospitals PET Scanner Replacement Exemption

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.

Cindy and Micheala,

Attached is a main campus replacement exemption notice for the replacement of an existing PET scanner at UNC Hospitals on its main campus. Please confirm receipt.

Thank you,
Emily

[Emily Cromer](#)

Director of Regulatory Affairs & Facility Strategy
UNC Health
(984) 215-6213
emily.cromer@unchealth.unc.edu

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