



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

February 12, 2020

Dan Goodwin  
7420 Market Street  
Wilmington, NC 28401

**Exempt from Review – Replacement Equipment**

**Record #:** 3214  
**Facility Name:** New Hanover Medical Group, P.A.  
**FID #:** 060492  
**Business Name:** New Hanover Medical Group, P.A.  
**Business #:** 1306  
**Project Description:** Replace existing CT scanner  
**County:** New Hanover

Dear Mr. Goodwin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of February 3, 2020, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the SIEMENS Go UP CT scanner to replace the SIEMENS Emotion CT scanner, serial number 2250. 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.

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

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a


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

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

Sincerely,

  
Tanya M. Saporito  
Project Analyst

  
Martha J. Frisone  
Chief

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

New Hanover Medical Group, PA  
1306  
NR 3214

February 3, 2020

Ms. Martha Frisone, Chief  
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: Letter of Exemption – Replace CT Scanner / New Hanover County  
FID# 060492

0-7546-06

Dear Ms. Frisone:

Pursuant to 10A NCAC 14C.0202, New Hanover Medical Group (“NHMG”) intends to replace its computed tomography (CT) scanner and requests a determination that such replacement is exempt from review because it falls within the definition of NCGS § 131E-184 (a)(7) and the regulations set out in 10A NCAC 14C.0303. The CT scanner is located at the NHMG diagnostic center in Ogden.

#### CT Replacement

Site	Equipment to be Replaced	Trade-in of Existing	Total Project Cost
New Hanover Medical Group, Ogden	Siemens Emotion	Y	\$256,930

#### Exemption from Review

Pursuant to NCGS § 131E-184(a): “The department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, when notice includes an explanation of why the new institutional health service is required, for any of the following: ... (7) To provide replacement equipment.”

NCGS § 131E-176(22a) defines “replacement equipment” as equipment that costs less than \$2,000,000 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.

#### Applicable Regulations

10A NCAC 14C.0303 defines “comparable medical equipment” as equipment that “is functionally similar and which is used for the same diagnostic or treatment purposes.” Replacement equipment is comparable if:

- (1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
- (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- (3) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

Replacement equipment is not comparable to the equipment being replaced if the replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment.

### **Compliance**

NHMG hereby certifies that:

1. The estimated project cost for the replacement of the existing CT scanner is less than \$2,000,000.
2. The replacement equipment will be purchased for the sole purpose of replacing comparable equipment currently in use, which will be traded in for disposal and removed from North Carolina. A comparison of the existing and replacement equipment is provided in Exhibit A.
3. The replacement equipment is functionally similar to existing equipment and will be used for the same diagnostic and/or treatment procedures as the equipment currently in use.
4. No increase in charges will occur within the first twelve months after the replacement equipment is acquired.
5. The average cost per CT scan will not increase as a result of the equipment replacement.

### **Determination Requested**

NHMG requests that the Division of Health Service Regulation make a determination that the replacement of its CT scanner, as proposed herein does not constitute a new institutional health service and is thus exempt from certificate of need review.

If you require additional information concerning this request, please contact me at 910-343-9991.

Sincerely,



Dan Goodwin  
Vice President, NHRMC Physician Group

Exhibit A - Existing/Replacement Equipment Comparison  
Exhibit B - CT Quote

**EQUIPMENT COMPARISON**

**Exhibit A**

	<b>EXISTING EQUIPMENT</b>	<b>REPLACEMENT EQUIPMENT</b>
Equipment Location	New Hanover Medical Group, Ogden	New Hanover Medical Group, Ogden
Type of Equipment	CT	CT
Manufacturer	SIEMENS	SIEMENS
Model	Emotion	Go UP
Serial Number	2250	TBD at purchase
Date of Acquisition	June 2008	December 2019
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.)	N/A	\$256,930
Total Cost of Equipment	N/A	\$256,930
Percent of Change in Patient Charges (by Procedure)	N/A	0%
Type of Procedures Currently Performed on Existing Equipment	CT scan	CT scan

Exhibit B



Siemens Medical Solutions USA, Inc.  
40 Liberty Boulevard, Malvern, PA 19355  
Fax: (866) 309-6967

SIEMENS REPRESENTATIVE  
Stephen Argo - (336) 210-6178

## PROPOSAL

Customer Number: 0000109885

Date: 1/20/2020

**NEW HANOVER MEDICAL GROUP**  
7420 MARKET STREET  
WILMINGTON, NC 28411

Pricing valid until 04/20/20.

Trade-in of existing Emotion 6 required.

POS service agreement required.

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Quote Nr: **1-RH011I Rev. 0**

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### SOMATOM go.Up

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

Qty	Part No.	Item Description	Extended Price
1	14447579	<b>SOMATOM go.Up</b> The result of a major global co-creation project, the SOMATOM go platform is specifically designed to overcome the obstacles associated with acquiring, operating, and maintaining a CT scanner.  Built around a new mobile workflow, the SOMATOM go features a line-up of innovative solutions - tablet, remote control, camera, and a new workplace design - that bring an unparalleled level of flexibility and mobility to daily CT routines. The solutions also help to enhance patient comfort for potentially higher levels of patient satisfaction.  The SOMATOM go platform addresses workflow at the scanner and beyond. By reducing repetitive workflow steps, GO Technologies help standardize and simplify all departmental processes - from patient setup to image distribution, archiving, and reading.  The included Stellar detector lowers image noise in every scan, while advanced iterative reconstruction from SAFIRE delivers excellent image quality at very low doses*. The Stellar detector's high-end technology includes fully integrated components and an advanced 3D anti-scatter collimator. It keeps electronic noise low, increases dose efficiency, and improves spatial resolution.  Also inherited from high-end scanners, the Tin Filter (Sn) cuts out lower energies to reduce dose and optimize image quality at the interface between soft tissue and air. This has direct benefits in lung and colon imaging, for example.  SOMATOM go.Up delivers up to 64 reconstructed slices at sub-millimeter collimation across the entire 2.2 cm detector width for faster scanning, fewer motion artifacts, and shorter breath-hold.	\$197,800

**PROPOSAL**

Qty	Part No.	Item Description	Extended Price
		*In clinical practice, the use of SAFIRE may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.	
1	14449436	<b>ELEVATE O &gt; go.Up</b> Elevate from an old Siemens CT scanner to the SOMATOM go.Up	\$0
1	14449477	<b>227 kg Patient Table</b> 227 Kg Patient table (Vario 1)	\$0
1	14447592	<b>High-speed 0.8 s</b> Faster gantry rotation speed of 0.8 seconds for fast acquisition of large anatomical regions or reduced motion artifacts.	\$5,060
1	14447591	<b>Standard AWP</b> Standard Computers	\$0
1	14468351	<b>High Power 80</b> Includes High Power 80	\$4,600
1	14449457	<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.	\$18,400
1	14468354	<b>syngo.CT CaScoring</b> Item includes syngo.CT CaScoring	\$4,600
1	14447580	<b>SW Base Package</b> Included with your SOMATOM go. Scanner: Scan&GO mobile workflow, including tablet, remote control, camera, and a new workplace design Check&GO flags problems with scan coverage or contrast distribution as they occur Recon&GO reduces post-processing to just one click, with: Inline Anatomical Ranges, Inline Table and Bone Removal, Inline Vessel Ranges and Multi Recon-performing multiple reconstructions in one step CT View&GO provides a variety of clinical applications and tools for smooth reading in just one workflow  SAFIRE Equipped with Sinogram Affirmed Iterative Reconstruction (SAFIRE) SOMATOM go. scanners achieve higher efficiency in dose reduction while maintaining excellent image quality by introducing multiple iteration steps in the reconstruction process  Interleaved Volume Reconstruction Extracts the maximum amount of diagnostic information from measured data and enhances spatial sampling in z-direction, independent of pitch  CARE Dose4D Automated adjustment of the dose level depending on patient size	\$0

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Qty	Part No.	Item Description	Extended Price
		<p>CARE Filter and Pediatric Protocols with 80 kV and a large range of adjustable mAs values for optimum adaptation of the radiation exposure to the age and weight of the child to be examined</p> <p>HD FoV**            Allow image creation using a FOV up to 65 cm, which is optimal for visualization of obese patients and those that are positioned outside the CT isocenter</p> <p>*In clinical practice, the use of SAFIRE may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.</p> <p>** The image quality for the area outside the standard 50 cm scan field does not meet the image quality specifications shown in the technical data sheet and image artifacts may appear, depending on the anatomy scanned.</p>	
1	14468467	<p><b>SW Base Extension VA30</b>            Item includes            Check&amp;GO Metal Detection, Flex Dose Profile and Onco Volumetry            Tilted spiral only for SOMATOM go.Up</p>	\$0
1	14468468	<p><b>myExam Compass</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. No matter the patient, operator or throughput, it helps generate consistently excellent results - and improve diagnostic accuracy. Being a part of myExam Companion, myExam Compass is based on the condensed knowledge of thousands of scans and protocols from our installed base. Through AI, the most optimal patterns have been recognized and aggregated into clinical decision trees provided ex-factory.</p>	\$0
1	14468466	<p><b>TwinSpiral Dual Energy</b>            A new holistic solution for spectral imaging is introduced. The TwinSpiral scan mode offers the possibility to acquire two consecutive spiral data sets at different energies used for non-contrast scans and the two different kV levels with independent mAs modulation deliver a combination of both morphological and functional information within one examination.</p>	\$0
1	14447581	<p><b>Scan&amp;GO wireless edition</b>            A central element of optimizing performance and generating daily revenue is an entirely new approach to operating the scanner. Built around a new mobile workflow, the SOMATOM go. platform features a line-up of innovative solutions - tablet, remote control, camera, and a new workplace design - that bring an unparalleled level of flexibility and mobility to daily CT routines. The solutions also enhance patient comfort for potentially higher levels of patient satisfaction.</p>	\$0
1	14447586	<p><b>Foot Switch for Pat.Table control</b>            Foot switch for Patient table control</p>	\$1,472
1	14461350	<p><b>Multipurpose Positioning Mattress</b>            Multipurpose Positioning Mattress is compatible with the dedicated scanner patient table. The mattress includes a foam insert and makes it easier to slide patients on and off the table. This way, patient positioning can be further optimized.            This mattress can also be used with an optional syngo Osteo CT software and phantom to enable bone mineral density measurements.</p>	\$460



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Qty	Part No.	Item Description	Extended Price
1	14449454	<b>Table Extension</b> Table extension	\$598
1	14449730	<b>Positioning &amp; Fixation Set</b> Including Pediatric Cradle, Arm support, Patient fixation with slider	\$1,610
1	14447609	<b>UPS</b> UPS. An uninterrupted power supply, for the syngo Acquisition Workplace in the event of network fluctuations and brief power failures.	\$1,012
1	CT_GO_STELLAR	<b>Stellar Low Noise Technology Detector</b> The Stellar detector's high-end technology includes fully integrated components. As a result, Stellar detector technology keeps electronic noise low, increases dose efficiency and improves spatial resolution. The smart configuration of the detector elements simplifies access, eases maintenance, and increases scanner uptime. For SOMATOM go scanners, the Stellar detector features a 3D anti-scatter collimator for even more efficient optimization of X-ray energy.	\$0
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	\$0
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	\$0
1	CT_LUNGIMA GINGGO	<b>Lung Imaging</b> Lung Imaging Go: For well over a decade, CT has been recognized and used as the standard of care for lung nodule visualization and sizing. This is due to CT's spatial resolution, geometric accuracy, and ability to create various reconstructions and 3D views. The high contrast environment in the chest between the lungs and the nodules makes for a relatively easy visualization task for clinicians using CT images. Recent advances in CT technology have allowed these scans to be effectively performed at lower doses, higher resolutions, and faster scan times. The SOMATOM go.Platform leverages Tin Filter Technology to further enhance the delivery of low dose lung cancer screening for high risk populations*. The SOMATOM go scanners are delivered with specific scan protocols to provide low dose lung cancer screening exams that use Siemens-exclusive Tin Filter Technology to reduce unnecessary radiation. These default protocols also utilize Siemens proprietary dose reducing features such as CARE Dose4D(tm), automatic exposure control technology, that further modulates and adapts dose for every patient, for high image quality at low dose. The SOMATOM go scanners come with default low dose lung imaging protocols below 1 mSv. *As defined by professional medical societies.	\$0
1	WORKSTREAM4D	<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.	\$0
1	ACCESS_PROTECT	<b>Access Protection</b> Scan Protocols are password protected allowing only authorized staff members to access and permanently change protocols	\$0
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.	\$0

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PROPOSAL

OPTIONS on Quote Nr: 1-RH011I Rev. 0

OPTIONS for SOMATOM go.Up

All items listed below are OPTIONS:

Qty	Part No.	Item Description	Extended Price
1	14468352	<b>Inline Spine Ranges</b> Item includes Inline Spine Ranges	+ \$4,600
1	14460866	<b>307 kg Patient Table</b> Patient table with 676 lb / 300 kg weight limit designed to accommodate virtually all patients with a long scan range of 2000 mm.	+ \$18,400
1	CT_GOBASIC_ CLS_TL	<b>CT Go Basic Class with Travel</b> Tuition for (1) imaging professional to attend a 2-day classroom course at Siemens Training Center in Cary, NC. The objectives of this course are to introduce the user to the Siemens SOMATOM go. platform, new patient-centric mobile workflow and technologies including Scan&Go, Check&Go, Recon&Go, CT View&Go, Guide&Go. Users will be able to understand the effect of choosing various parameters on image quality and dose. The instructor will combine didactic interactive discussions with hands-on training of key CT system operating hardware and workflow software functions. This class includes lunch, economy airfare, and lodging for (1) imaging professional. All arrangements must be arranged through Siemens designated travel agency. 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.	+ \$4,500
1	CT_ELEARN	<b>e.learning CEU subscription (12 mths)</b> This (12) month multi-modality e.learning subscription will provide access for (10) imaging professionals at the customer site to utilize up to (50 CEUs). 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.	+ \$650

**FINANCING:** The equipment listed above may be financed through Siemens. Ask us about our full range of financial products that can be tailored to meet your business and cash flow requirements. For further information, please contact your local Sales Representative.

Siemens Healthcare is pleased to submit this Preliminary Pricing Proposal. A Preliminary Pricing Proposal is provided for planning purposes only; it is not contractually binding. To receive a contractually binding proposal for the Products listed above, inclusive of Terms, Conditions, and Warranty coverage, please contact your Siemens Healthcare Sales Representative.

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

## Waller, Martha K

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**From:** dlegarth@nc.rr.com  
**Sent:** Thursday, February 6, 2020 2:29 PM  
**To:** Tanya, Saporito; Waller, Martha K  
**Subject:** [External] NHRMC Letters of Exemption #2  
**Attachments:** 2020 NHRMC MRI Replacement.pdf; 2020 NHMG CT Replacement.pdf

**CAUTION:** External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [report.spam@nc.gov](mailto:report.spam@nc.gov)

Hi Tanya,

Attached please find two additional Letters of Exemption for NHRMC and NH Medical Group.

**David Legarth**



**Mail Address:**  
P.O. Box 1936  
Apex, NC 27502

**FedEx/UPS Address:**  
108 Curley Maple Court  
Apex, NC 27502

**Phone:**  
(919)244-7609