

DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER GOVERNOR MANDY COHEN, MD, MPH SECRETARY

> MARK PAYNE DIRECTOR

December 21, 2017

Heidi Ambrose 1144 N. Road Street Elizabeth City, North Carolina 27909

Exempt from Review - Replacement Equipment

Record #:

2460

Facility Name:

Sentara Albemarle Regional Medical Center

FID#:

952933

Business Name:

Sentara Albemarle Regional Medical Center, LLC

Business #:

54

Project Description:

Replace the existing CT scanner at Sentara Kitty Hawk Advanced Imaging Center and

move the replacement CT scanner to Sentara Albemarle Regional Medical Center

County:

Pasquotank

Dear Ms. Ambrose:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of December 13, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Siemens SOMATOM Definition AS 64-slice CT scanner to replace Siemens SOMATOM Definition AS 64-slice CT scanner. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you need to contact the Agency's Construction, Radiation Protection and Acute and Home Care Licensure and Certification Section 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 separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely

Yane Rhoe-Jones

Project Analyst

Martha J. Frisone

Chief, Healthcare Planning and Certificate of Need Section

cc: Construction Section, DHSR

Radiation Protection Section, DHSR

Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR Acute and Home Care Licensure and Certification Section, DHSR

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV TELEPHONE 919-855-3873

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





Sentara Albemarle Medical Center 1144 N. Road Street Elizabeth City, NC 27909

Tel: 252.335.0531 www.sentara.com

December 13, 2017

Ms. Martha Frisone, Chief Healthcare Planning & Certificate of Need Section Division of Health Service Regulation 2704 Mail Service Center Raleigh, NC 27699-2704

RE: Equipment Replacement and Relocation Exemption for Sentara Albemarle Medical Center

Dear Ms. Frisone:

Pursuant to N.C.G.S. 131E-184 (a)(7) -Exemptions from Review-of the Certificate of Need Statute, I am writing to inform you of Sentara Albemarle Regional Medical Center, LLC's (SAMC's) plans to replace one existing CT scanner currently located at its diagnostic center, known as Sentara Kitty Hawk, FID # 020173, and relocate it to SAMC's main hospital campus, located at 1144 North Road Street, Elizabeth City, FID # 952933.

Pursuant to N.C.G.S. 131E-184 (a)(7), "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, which notice includes an explanation of why the new institutional health service is required, for any of the following: . . . (7) To provide replacement equipment."

N.C.G.S. 131E-176 (22a) states "[r]eplacement equipment' means equipment that costs less than two million dollars (\$2,000,000) and is purchased with the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced."

The total capital cost of the project is estimated be \$1,566,876, which therefore meets the definition of "replacement equipment" set forth in N.C.G.S. 131E-176(22). Please see Attachment 1 for a proposed capital cost table demonstrating the construction and non-equipment costs, noting that the equipment costs are not included in that attachment. Please see Attachment 2 for equipment quote for the proposed equipment. The table below shows the sum of these costs.

Item	Source	Estimated Cost
Construction Costs and Consulting Fees	Attachment 1	\$817,000
CT Scanner	Attachment 2	\$749,876
Total		\$1,566,876

The replacement equipment will be purchased for the sole purpose of replacing comparable equipment currently in use. "Comparable medical equipment" is defined under 10A NCAC 14C .0303(c) as "equipment which is functionally similar and which is used for the same diagnostic and treatment purposes." Further, replacement equipment is considered comparable to the existing equipment under the following circumstances as outlined under 10A NCAC 14C .0303(d):

- 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
- 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.

As discussed below, SAMC's proposed new replacement equipment is considered comparable pursuant to 10 NCAC 14C .0303 for the following reasons:

- The proposed replacement equipment will be used specifically for the provision of performing CT scans, as is the existing equipment. The replacement equipment will perform all procedures currently performed on the existing equipment. Although the replacement equipment possesses some expanded capabilities due to technological improvements, the replacement equipment will perform the same general range of services. Essentially the replacement equipment will have the same functionality as the equipment currently in use.
- 2. The function of, and services provided by the replacement equipment, will essentially be identical to the existing equipment. SAMC intends to use the replacement equipment for the same procedures which are currently available on the existing equipment. No new health service will be provided as a result of the replacement. Please refer to Attachment 3 for an equipment comparison table demonstrating that the proposed replacement equipment is comparable to the equipment currently in use.
- 3. The acquisition and operation of the replacement equipment will not result in an increase of more than 10 percent in patient charges or the operational cost per patient of providing the service within the first twelve months after the replacement equipment is acquired.

As noted on Attachment 3, the equipment comparison table, regarding the costs for the original equipment, SAMC has provided the historical costs associated with relocating the existing CT scanner to its current location at Sentara Kitty Hawk, including the value of the equipment at that time. As background information, the equipment was originally located at SAMC (then known as Albemarle Hospital) in 2009, when the hospital was under different management. In 2015, the scanner was relocated to its current location at SKH. Since SAMC was not part of Sentara Healthcare in 2009, the documents identifying the specific costs related to the original acquisition of the CT scanner are not available; however, the costs shown in Attachment 3 are the costs incurred to relocate the scanner in 2015, when the facilities were part of Sentara. In any case, it is known that the equipment was originally purchased as new in 2009, as discussed below, which is the relevant issue to meeting the definition of "replacement equipment." As part of this replacement project, the equipment would be replaced and relocated back to SAMC, where it was originally located.

It is important to note that 10 NCAC 14C .0303 also defines equipment that is "not comparable" under subsection (e). Replacement equipment is not considered comparable if:

- the replacement equipment is new or reconditioned, the existing equipment was purchased second-hand, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or
- the replacement equipment is new, the existing equipment was reconditioned when purchased, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or

- 3. 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; or
- the replacement equipment is purchased and the existing equipment is leased, unless the lease is a capital lease; or
- 5. the replacement equipment is a dedicated PET scanner and the existing equipment is:
 - A. a gamma camera with coincidence capability; or
 - B. nuclear medicine equipment that was designed, built, or modified to detect only the single photon emitted from nuclear events other than positron annihilation.

The replacement equipment will be purchased in new condition as was the existing equipment being replaced. As noted above, although the replacement equipment possesses some expanded capabilities due to technological improvements, the replacement equipment will perform the same general range of services as the existing unit. SAMC owns the existing equipment and will own the replacement equipment. Therefore, the replacement equipment does not meet the definition of "not comparable." Further, the existing equipment is currently in operation, and, upon replacement, SAMC will dispose of the equipment by having it removed and returned to the vendor, as documented in the letter included in Attachment 4.

The need for the replacement and relocation is based on two factors. First, SAMC intends to close Sentara Kitty Hawk later this month, at which time it will cease offering ambulatory surgical services as well as diagnostic imaging services, including CT scans. Thus, the equipment needs to be relocated to continue offering services. Second, the existing equipment is outdated and needs to be replaced as part of the relocation. As the Agency is aware, SAMC has filed multiple requests for temporary replacement equipment using Sentara's mobile CT scanner. The use of the mobile CT scanner has been driven by downtime on SAMC's sole existing CT scanner, which as shown on SAMC's 2017 Hospital License Renewal Application, performed over 25,000 HECT scans in FY 2016. The replacement of the existing CT scanner at Sentara Kitty Hawk and its relocation to SAMC will improve the availability of CT services at SAMC while minimizing the need for the use of Sentara's temporary mobile CT service. The replacement and relocation will enable SAMC to enhance its CT services, which are particularly valuable for emergency and inpatients, as well as outpatients, without acquiring additional equipment that it does not already own and operate.

Please let me know if I can provide any additional information to expedite this exemption notification.

Sincerely.

Heidi Ambrose Director, Radiology

Sentara Albemarle Medical Center

Leich Derl

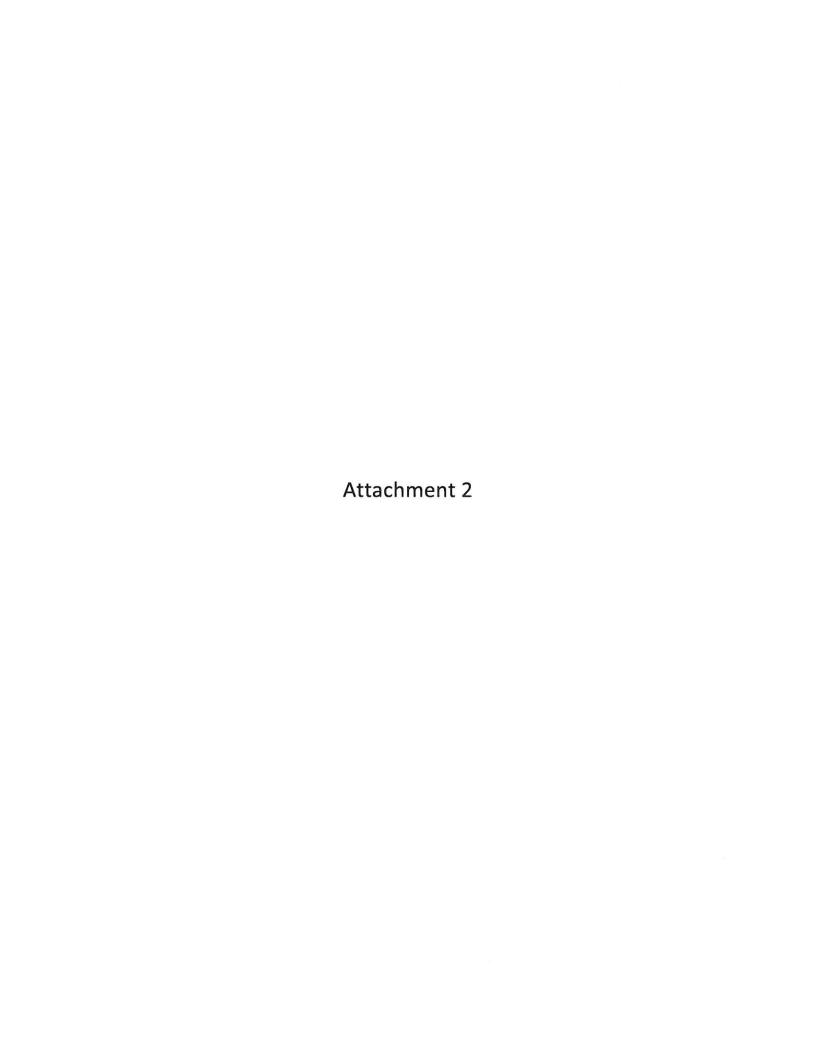
Attachments



PROPOSED CAPITAL COSTS

Project Name:	Sentara Albemarle Medical Center Re	placement CT Scanner	
Proponent:	Sentara Albemarle Regional Medical C	Center, LLC	
Α.	Site Costs		
(1)	Full purchase price of land	\$	_
	Acres Price per Acre	\$	
(2)	Closing costs	\$	
(3)	Site Inspection and Survey	\$	_
(4)	Legal fees and subsoil investigation.	\$	_
(5)	Site Preparation Costs		_
	Soil Borings	\$	
	Clearing-Earthwork \$		
	Fine Grade For Slab \$		
	Roads-Paving Concrete Sidewalks \$	\$	
	Concrete Sidewalks \$ Water and Sewer	<u> </u>	
	Footing Excavation \$	Υ	
	Footing Backfill	\$	
	Termite Treatment \$		
	Other (Specify)	\$	
7-1	Sub-Total Site Preparation Costs	\$	
(6)	Other (Specify)	\$	
(7)	Sub-Total Site Costs		\$
В.	Construction Contract		
(8)	Cost of Materials		
(-)	General Requirements	\$	
	Concrete/Masonry	\$	
	Woods/Doors & Windows/Finishes	\$	
	Thermal & Moisture Protection	\$	
	Equipment/Specialty Items Mechanical/Electrical	\$	
	Other (Specify)	\$	
	Sub-Total Cost of Materials	\$\$	
(9)	Cost of Labor	\$	-
	Other (Specify)	\$	=
	Sub-Total Construction Contract	Y	\$ 748,000
C.	Miscellaneous Project Costs		
	Building Purchase	č	
	Fixed Equipment Purchase/Lease	۶ د	-
	Movable Equipment Purchase/Lease	۶	-
		\$	
	Furniture	\$	
	Landscaping Consultant Fees	\$	
0.00			
	Architect and Engineering Fees \$ 69,000	J	

	Market Analysis \$		
	Other (Specify) \$		2.000
(10)	Sub-Total Consultant Fees		9,000
(18)	Financing Costs (e.g. Bond, Loan, etc.)	\$	_
(19) (20)	Interest During Construction Other (Specify)	د	
(21)	Sub-Total Miscellaneous	>	
(21)	Total Capital Cost of Project (Sum A-C	ahove)	\$ 817,000
(22)	Total capital cost of Project (Sum A-C	above)	J 617,000
PX	· ·		Date Certified: <u>12-12-17</u>
(Signature of L	icensed Architect or Engineer)		
and that it is n	ny intent to carry out the proposed proje	The second secon	oposed project are complete and correct ad. Date Signed:





Fax: (866) 309-6967

SIEMENS REPRESENTATIVE Anthony Quaranta - (410) 960-2592

Date: 11/16/2016 Customer Number: 0000004323

SENTARA ALBEMARLE MEDICAL CENTER

1144 N. ROAD STREET ELIZABETH CITY, NC 27909-3386

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.

SOMATOM Definition AS - New Scalable Configuration (Quot General Terms and Conditions	10
Contract Total: \$749,876 (total does not include any Optional or Alternate components	which may be selected)
Proposal valid until 12/30/2016	
Estimated Delivery Date: 07/2017	
Estimated delivery date is subject to change based upon factor customer site readiness, and other factors. A Siemens representate.	
The Sentara Healthcare/Siemens Master Procurement Agree	ment #20104449 applies.
This offer is only valid if a firm, non-contingent order is placed accompany the equipment order.	with Siemens and a signed POS contract must
This Quotation is specific to SENTARA Albemarle, and contain Siemens, including but not limited to discounts and pricing. The quotation or any portion hereof to, or discuss any of the information other customer or consultant, buying group, or other third particles.	ne Customer may not distribute or disclose this nation (including pricing) contained herein with, any
Accepted and Agreed to by:	
Siemens Medical Solutions USA, Inc.	SENTARA ALBEMARLE MEDICAL CENTER
By (sign): Name: Anthony Quaranta Title: Account Executive	By (sign): Name: Title: Date:

By signing below, signor certifies that no modifications or additions have been made to the Quotation.



Fax: (866) 309-6967

SIEMENS REPRESENTATIVE Anthony Quaranta - (410) 960-2592

Any such modifications or add	ditions will be void
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By (sign):

Created: 11/16/2016 11:04:00 AM

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Quote Nr:

1-IK5SMS Rev. 0

Terms of Payment:

00% Down, 80% Delivery, 20% Installation

Free On Board: Destination VIZIENT SUPPLY LLC

Purchasing Agreement:

VIZIENT SUPPLY LLC terms and conditions apply to Quote

Nr 1-IK5SMS

SOMATOM Definition AS - New Scalable Configuration

All items listed below are included for this system:

Part No. Qty

Item Description

14444263 1

SOMATOM Definition AS (64slice)

The SOMATOM Definition AS (64-slice configuration) is Siemens' state-of-the-art single source CT that provides the possibility to maximize clinical outcome and to minimize radiation dose. 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 The fast rotation time of 0.33 seconds (0.3 s optional) delivers excellent temporal resolution. The SOMATOM Definition AS is set to raise the standard of patient-centric productivity with FAST CARE Technology. With Siemens' FAST Fully Assisting Scanner Technologies - the SOMATOM Definition AS can simplify typically time consuming and complex procedures during a CT examination: the scanning process gets more intuitive and the results become more reproducible. The CARE technology includes many unique features like CARE kV that sets the ideal voltage for every examination and adjusts the respective scan parameters or industry's first Adaptive Dose Shield that prevents clinically irrelevant over radiation in spiral scanning.

14420766

SAFIRE #AWP

The Sinogram Affirmed Iterative Reconstruction (SAFIRE) enhances spatial resolution, reduces image noise and increases sharpness by introducing multiple iteration steps in the reconstruction process. The resulting superior image quality enables to reduce dose by up to 60%*.

*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. The following test method was used to determine a 54 to 60% dose reduction when using the SAFIRE reconstruction software. Noise, CT numbers, homogenity, low-contast resolution and high contrast resolution were assessed in a Gammex 438 phantom. Low dose data reconstructed with SAFIRE showed the same image quality compared to full dose data based on this test. Data on file.

14444243

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.

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Qty	Part No.	Item Description
1	14408037	HeartView CT Scanning technique and program for ECG controlled data acquisition and image reconstruction with SOMATOM. The package comprises: HeartView CT option on the syngo Acquisition Workplace console for the ECG-controlled acquisition and reconstruction of artifactfree images of the heart. The ECG signal is supplied by an ECG device integrated in the gantry. The use of the software of this option is restricted to a single system unit.
1	14408038	Cardio BestPhase Plus #AWP Cardio BestPhase, a software dedicated to automatically detect the optimal phase for motion-less coronary visualization. The phase is defined in either end-systole, end-diastole or both timepoints and automatically reconstructed.
1	14408215	Physiological Monitoring Module The Physiological Measurement Module allows to connect a 3 Channel ECG cable for ECG controlled cardiac acquisition.
1	14408040	ECG cable IEC2 #D ECG cable, IEC2 (AHA/US color coding).
1	14420773	FAST CARE Platform Siemens' unique FAST CARE platform is set to raise the standard of patient-centric productivity. Utilizing FAST - Fully Assisting Scanner Technologies -, typically time-consuming and complex procedures during the scan process are extremely simplified and automated, not only improving workflow efficiency, but optimizing the overall clinical outcome by creating reproducible results, making diagnosis more reliable and reducing patient burden through streamlined examinations. Siemens' desire for as little radiation exposure as possible lies at the heart of the CARE - Combined Applications to Reduce Exposure - research and development philosophy offering a unique portfolio of dose saving features, many of them being introduced as industry's first.
1	14420771	CARE Child Dedicated pediatric CT imaging, including 70 kV scan modes and specific CARE Dose4D curves and protocols
1	14433993	FAST Planning #AWP Direct, organ-based setting of scan and recon ranges for a faster and more standardized workflow
1	14419142	Workstream 4D #AWP WorkStream 4D further enhances the already superb workflow of the SOMATOM CT system 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	14419144	DICOM SR Viewer #AWP The DICOM SR (structured report) Viewer allows to read reports created with specific applications (e.g. Circulation, Lung Care, Calcium Scoring and Onco) without the application itself being on the respective computer.
1	14408111	Extended Field of View #AWP Software program with special reconstruction algorithms that allow for visualization of objects using a FOV up to 78 cm (non-diagnostic image quality). License to use software on a single unit.
1	14408152	UHR UHR mode delivers Ultra High resolution in plane of up to 24lp/cm for high defined imaging of small structures such as inner ear, joints or fractures of the bone
1	14420824	Standard IRS Reconstruction computer for the preprocessing and reconstruction of the CT raw data. The reconstruction computer contains a cluster of 2 high-performance GPU boards performing the preprocessing and reconstruction of the CT data. The raw data memory is 900 GByte. The peak recon performance is 40 frames/sec.
1	14408032	Rear cover incl. gantry panels Rear Cover including gantry control panels with control functionality from the backside.

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Qty	Part No.	Item Description
1	14420777	Patient Table 2000 mm Patient table to support up to 200cm scan range. Motor-driven table height adjustment from min. 49 cm to max. 92 cm, longitudinal movement of the tabletop 200 cm in increments of 0.5 mm, positioning accuracy +/- 0.25 mm from any direction. Horizontal scan range 200 cm. Table height can be controlled alternatively by means of foot switch (2 each on both sides of the patient table). In the case of emergency stop or power failure, the tabletop can also be moved manually in horizontal direction. Max. table load: 227 kg/500 lbs, Table feed speed: 2-200 mm/s, Distance between gantry front and table base 40 cm. Positioning aids: Mattress protector, head-arm support (inclusive cushion), and non-tiltable head holders with positioning cushion set, patient restraining system for head fixation, restraining-strap set with body fixation strap that can be directly connected to the patient table top, headrest, table extension, knee-leg support.
1	14420929	Mattress for Patient Table For the comfortable positioning of the patient on the CT table.
1	14408101	Computer Desk #AWP New CT desk to accommodate the control components and color monitor. Width: 1200 mm, Depth: 800 mm, Height: 720 mm.
1	14408102	Computer Cabinet #AWP New cabinet to accommodate the computer system and UPS. Matched to the design of the control console table. Width: 800 mm, Depth: 800 mm, Height: 720 mm
1	14408023	Cooling System Water Water heat exchanger for the dissipation of heat loss generated in the gantry to an environmentally friendly cooling water circulation system. This optimizes system availability independently of the cooling water flow rate and temperature. System operation temperature 4 - 16 degrees C and 500 - 2500 I/h flow rate.
1	14408027	Cooling System Water/Air #split Water-to-air heat exchanger for the dissipation (to the air outside) of heat, generated in the gantry.
1	14410140	Trafo for Cooling system Water/Air The Trafo powers the Cooling System Water/Air
1	14410248	Service Switch Service switch to shut off the outdoor cooling unit for maintenance or in case of emergency
1	CT_INST_RIED EL_01	Riedel Chiller Start-up by SBT
1	CT_RECON_19 2	AS-64 slice configuration z-Sharp Tech. The unique STRATON X-ray source utilizes an electron beam that is accurately and rapidly deflected, creating two precise focal spots alternating 4,608 times per second. This doubles the X-ray projections reaching each detector element. The two overlapping projections result in an oversampling in z-direction. The resulting measurements interleave half a detector slice width, doubling the scan information without a corresponding increase in dose. Siemens' proprietary UFC (Ultra Fast Ceramic) detectors and the corresponding 64-slice detector electronics enable a virtually simultaneous readout of two projections for each detector element - resulting in a full 64-slice acquisition. This sampling scheme is identical to that of a 64 x 0.3 mm allowing for reconstruction of 192 slices using 0.1 mm reconstruction interval increment. z-Sharp Technology, utilizing the STRATON X-ray sources and the UFC detectors, provides scan speed independent visualization of 0.33 mm isotropic voxels and a corresponding
1	ADAPT_DOSE _SHIELD	elimination of spiral artifacts in the daily clinical routine at any position within the scan field. Adaptive Dose Shield
		Adaptive Dose Shield for spiral acquisition to eliminate pre- and post-spiral over-radiation.
1	SURE_VIEW	SureView Provides exceptional image quality at any pitch setting, enabling you to scan faster because you can scan at any pitch without degrading image quality



Siemens Medical Solutions USA, Inc.

40 Liberty Boulevard, Malvern, PA 19355

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Qty	Part No.	Item Description
1	FAST_ADJUST	FAST Adjust FAST Adjust: assists the user to handle system settings in a fast and easy way by automatically solving of conflicts
		within user defined limits by one single click on the FAST Adjust button. The limits for scan time and tube current per scan are defined via the Scan Protocol Assistant. FAST Adjust offers an undo functionality to return to previously set values.
1	FAST_SCAN_A SSIST	FAST Scan Assistant
	0405 00054	FAST Scan Assistant: An intuitive user interface for solving conflicts by changing the scan time, resp. the pitch and/or the maximum tube current manually.
1	CARE_DOSE4 D	CARE Dose4D
		CARE Dose4D delivers the highest possible image quality at the lowest possible dose for patients - maximum detail, minimum dose. Adaptive dose modulation for up to 60% dose reduction
1	CARE_KV	CARE kV
	CT_LUNGIMA	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	GINGAS64	Lung Imaging
		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.
		The SOMATOM Definition AS64 CT is indicated for use in low dose lung cancer screening for high risk populations*. The AS64 is delivered with two specific scan protocols to provide low dose lung cancer screening exams at approximately 1.5 mGy CTDI for a standard size adult. These default protocols utilize Siemens proprietary dose reducing features such as CARE Dose4D(tm), automatic exposure control technology that modulates and adapts dose for every patient, for high image quality at low dose.
	CARE_PROFL	*As defined by professional medical societies.
1	E	CARE Profile
	CARE_DASHB	CARE Profile: Visualization of the dose distribution along the topogram prior to the scan
1	OARD	CARE Dashboard
	UFC_DETECT	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	OR _	UFC Detector
		Ultra Fast Ceramics (UFC) technology is a unique type of scintillation technology material that quickly and efficiently transforms radiation from the X-ray tube into light signals. Its superb overall quantum efficiency and unique short afterglow enable time-critical X-ray detection at low doses and extremely fast data collection.
1	ACCESS_PRO TECT	Access Protection
		Scan Protocols are password protected allowing only authorized staff members to access and permanently change protocols
1	DOSE_ALERT	Dose Alert
		Dose Alert: As requested by the new release of the standard IEC 60601 3rd edition, the SOMATOM Definition automatically adds up CTDIvol and DLP depending on z-position (scan axis). The Dose Alert window appears, if either of these cumulative values exceeds a user-defined threshold.
1	DOSE_NOTIFI CATION	Dose Notification
		Dose Notification: As requested by the new release of the standard IEC 60601 3rd edition, the SOMATOM Definition AS 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	DICOM_SR	DICOM SR Dose Reports DICOM structured file allows for the extraction of dose values (CDTIvol, DLP)



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Qty	Part No.	Item Description
1	DOSELOGS	DoseLogs
		Whenever a limit exceeds of the set up reference dose levels (Dose Notification and Dose Alert) automatically a report is created on the system
1	NEMA_XR-29	NEMA_XR-29 Standard
	OT LIDS DEE	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	CT_UPS_DEF_ AS	Standard UPS for Definition AS
		The standard partial system uninterruptible power system (UPS) is built directly into the power distribution cabinet (PDC) and supports the critical circuits for table and gantry electronics, console computer, image reconstruction system, and the internal Ethernet switch (to ensure connectivity). This enables safe removal of patient if outage occurs during scanning.
		The UPS allows for a safe shutdown of the CT scanner in the event of power interruption. The UPS provides 5-7 minutes of power, during which the user is prompted and guided through the process to perform a safe shutdown of the system. This safe shutdown ensures that no data is lost.
1	CT_PM	CT Project Management
	OT DUDG AD	A Siemens Project Manager (PM) will be the single point of contact for the implementation of your Siemen's equipment. The assigned PM will work with the customer's facilities management, architect or building contractor to assist you in ensuring that your site is ready for installation. Your PM will provide initial and final drawings and will coordinate the scheduling of the equipment, installation, and rigging, as well as the initiation of on-site clinical education.
1	CT_BUDG_AD DL_RIG CT_STD_RIG_I	Budgetary Add'I/Out of Scope Rigging @ \$5,000
1	NST	CT Standard Rigging and Installation
		This quotation includes standard rigging and installation of your CT new system.
		Standard rigging into a room with reasonable access, as determined by Siemens Project Management, during standard working hours (Mon Fri./ 8 a.m. to 5 p.m.)
		It remains the responsibility of the Customer to prepare the room in accordance with the SIEMENS planning documents.
		Any special rigging requirements (Crane, stairs, etc.) and/or special site requirements (e.g. removal of existing systems, etc.) is an incremental cost and the responsibility of the Customer.
		All other "out of scope" charges (not covered by the standard rigging and installation) will be identified during the site assessment and remain the responsibility of the Customer.
1	4SPAS014	Low Contrast CT Phantom & Holder
1	PSPD250480Y 3K	Surge Protective Device (SPD)
1	CTSDEF01	CT Slicker
		Thermoseal seams and flaps deflect fluids, reducing contaminant penetration into the cushion and table. Contaminants are retained on the tabletop or shunted to the floor. Cleanup is faster, more thorough, and contaminant build-up is reduced.
		Built using heavy, clear, micro matte vinyl, and top grade hook and loop fastening strips (Velcro) to better fit the specified table. Custom vinyl resists tears and minimizes radiologic interference. Latex free. Set includes CT Skirts. Shipped with main cover, a catheter bag holder, and 3 restraining belts unless otherwise noted. Includes warranty from RADSCAN Medical.
	CT ADD 24	Additional onsite training 24 hours
1	CT_ADD_24	Up to (24) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist if applicable. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	SY_PR_TEAM PLAY	teamplay Welcome & Registration Package
		teamplay is a cloud-based network that brings together your imaging modality users, the systems' dose and



Fax: (866) 309-6967

SIEMENS REPRESENTATIVE Anthony Quaranta - (410) 960-2592

Qty Part No. Item Description

utilization data, and the users' expertise to help you improve the delivery of care to your patients. Basic features are provided free of charge. Premium features (benchmarking, non-Siemens devices) are provided on a trial basis for three months at no charge, and may be used thereafter on a subscription fee basis.

To register: http://teamplay.siemens.com/#/institutionRegistration/1

1 CT_ADD 32 Additional onsite training 32 hours

Up to (32) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist 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.

System Total: \$749,876

Created: 11/16/2016 11:04:00 AM

PRO 1-ILSMND



EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	CT Scanner	CT Scanner
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	NA	NA
Model Number	Somatom Definition AS 64-slice	Somatom Definition AS 64
Serial Number	81009155370	TBD
Provider's Method of Identifying Equipment	System review for patient safety and clinical platform	System review for patient safety and clinical platform
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	NA
Date of Acquisition of Each Component	5/7/2009	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Will Hold Title
Specify if Equipment Was/Is New or Used When Acquired	New – Transferred as Used	New
Total Capital Cost of Project (Including Construction, etc.)	\$381,055*	\$1,566,876
Total Cost of Equipment	\$145,000*	\$749,876
Fair Market Value of Equipment	\$145,000*	\$749,876
Net Purchase Price of Equipment	\$145,000*	\$749,876
Locations Where Operated	Sentara Albemarle Medical Center, then Sentara Kitty Hawk	Sentara Albemarle Medical Center
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	<10%	<10%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	<10%	<10%
Type of Procedures Currently Performed on Existing Equipment	CT scans	NA
Type of Procedures New Equipment is Capable of Performing	NA	CT scans

^{*}Indicates cost to transfer from Sentara Albemarle Medical Center to Sentara Kitty Hawk in 2015; see exemption letter for additional clarification.





Sentara Albemarle Medical Center 1144 N. Road Street Elizabeth City, NC 27909

Tel: 252.335.0531 www.sentara.com

December 13, 2017

Ms. Martha Frisone, Chief Healthcare Planning & Certificate of Need Section Division of Health Service Regulation 2704 Mail Service Center Raleigh, NC 27699-2704

Dear Ms. Frisone:

Sentara Albemarle Regional Medical Center, LLC (SAMC) currently owns and operates a Siemens Somatom Definition AS 64-slice CT Scanner (SN 81009155370) that, apart from maintenance or other downtime, has been in operation continuously at Sentara Kitty Hawk since it was originally installed. The equipment is still in operation today.

SAMC proposes to replace the existing equipment and relocate it to SAMC's main hospital campus in Elizabeth City. SAMC will dispose of the existing equipment by having it removed from Sentara Kitty Hawk and returned to the vendor. SAMC has no intention to use the existing equipment after its replacement.

Please contact me with any questions regarding this matter.

Sincerely,

Coleen Santa Ana, MHA

President

Sentara Albemarle Medical Center