



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

November 17, 2023

Robbie Roberts
rroberts@wakemed.org

Exempt from Review – Replacement Equipment

Record #: 4316
Date of Request: November 10, 2023
Facility Name: WakeMed Mobile MRI
FID #: 040270
Business Name: WakeMed Mobile MRI
Business #: 2027
Project Description: Replace a mobile MRI scanner
County: Wake

Dear Robbie Roberts:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Siemens Aera mobile MRI scanner to replace the Siemens Symphony mobile MRI scanner [Serial # 23788]. 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,
Crystal Kearney
Project Analyst

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification 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

November 10, 2023

Via Electronic Mail to: Mike.mckillip@dhhs.nc.gov
Mr. Michael J. McKillip, Team Leader
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Request for Exemption from Review/Replace One Unit of Mobile MRI Equipment

Dear Mr. McKillip:

This letter is to inform you of WakeMed's intent to replace one unit of mobile MRI equipment, which was acquired by Certificate of Need identified as Project No. J-7013-04. See Attachment 1 for a copy of the CON. The current mobile MRI went into operation in 2005 and can no longer be properly maintained by the vendor. WakeMed intends to purchase a Siemens MAGNETOM Aera 1.5 Tesla Mobile MRI scanner and temporarily operate a contracted unit until delivery of the permanent replacement, to ensure uninterrupted care to patients.

The purchase price of the equipment as shown in the vendor quote provided in Attachment 2 is \$1,611,989, including replacement equipment and existing equipment removal. The total capital cost of the project, including the temporary unit, is estimated to be \$1,650,789. The equipment to be replaced, a Siemens Symphony 1.5 Tesla unit, is assumed to have zero salvage value, and will be removed from service by the vendor. Please see Attachment 3 for the Equipment Comparison Form. This project will not change the inventory of mobile MRI scanners in the WakeMed system. WakeMed will continue to operate the new mobile MRI scanner at host sites in Wake and Granville Counties and will inform the Agency of any new host sites.

WakeMed believes that this project is exempt from CON review under N.C.G.S. §131E-184 (a)(7), which states:

(a) Except as provided in subsection (b) of this section, 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.

For the purposes of the above Provisions in Section §131E-184(a)(7), as set forth in N.C. Gen. Stat. § G.S. 131E-176(22), "replacement equipment" is defined as the following:

(22a) Replacement equipment. - Equipment that costs less than two million dollars (\$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. In determining whether the replacement equipment costs less than two million dollars (\$2,000,000), 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. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

WakeMed believes this project meets the applicable criteria set forth in N.C.G.S. §131E-184 (a)(7). The proposed project meets the definition of “replacement equipment” as outlined in N.C.G.S. § 131E-176(22a) in that the associated costs do not exceed two million dollars and the project “serves the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced”. WakeMed requests confirmation from the Agency that the proposed project may proceed as described without a CON.

Thank you for your attention this matter. If you have questions or require additional information, please contact me at 919-350-8023 or rroberts@wakemed.org.

Sincerely,



Robbie Roberts
Manager, Market Planning

Attachments

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

CERTIFICATE OF NEED

for

Project Identification Number J-7013-04
FID#040270

ISSUED TO: WakeMed
3000 New Bern Avenue
Raleigh, NC 27620

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: Acquire one mobile magnetic resonance imaging (MRI) scanner. Initially, the sites shall be at a minimum - Sampson Regional Medical Center; Bladen County Hospital; Carteret General Hospital; Lillington Family Medical Center; and Community Family Medicine and Obstetrics (Pittsboro) Wake County.

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Community Family Medicine and Obstetrics
 75 Old Graham Road
 Pittsboro, NC 27312

Sampson Regional Medical Center
 607 Beaman Street
 Clinton, NC 28329

Carteret General Hospital
 3500 Arendell Street
 Morehead City, NC 28577

Bladen County Hospital
 501 South Poplar Street
 Elizabethtown, NC 28337

Lillington Family Medical Center
 7 East Duncan Street
 Lillington, NC 27546

MAXIMUM CAPITAL EXPENDITURE: \$2,552,053

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: July 1, 2005

This certificate is effective as of the 28th day of February, 2005.

Lee B. Hoffman
 Chief, Certificate of Need Section
 Division of Facility Services

CONDITIONS

1. WakeMed shall materially comply with all representations made in its certificate of need application.
2. WakeMed shall acquire one mobile MRI scanner with transporting equipment that will result in establishment of a mobile diagnostic program. The mobile MRI scanner shall be moved each week to provide MRI services to at least two host sites.
3. The mobile MRI shall not, at any time, be converted to a fixed MRI scanner and such equipment shall not, at any time, serve less than two host sites each week. The acquisition of the mobile MRI scanner shall not result in the creation of a diagnostic center located at any of the host sites or any other facility owned, operated or otherwise affiliated with WakeMed.
4. WakeMed shall not change or add host sites unless it first obtains a declaratory ruling authorizing the change in location of the equipment pursuant to North Carolina Statute 150B-4 and the rules of the Department of Health and Human Services, Division of Facility Services.
5. WakeMed 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.
6. WakeMed shall acknowledge acceptance and agree to comply with all conditions states herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance and compliance with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on September 1, 2004

TIMETABLE

Ordering equipment	_____	April 1, 2005
Arrival of equipment	_____	July 1, 2005
Operation of equipment	_____	August 1, 2005



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

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

Customer Number: 0000011224

Date: 06/21/2023

WAKEMED HEALTH AND HOSPITALS
3000 NEW BERN AVE
RALEIGH, NC 27610

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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Contract Total: \$ 1,611,989
(total does not include any Optional or Alternate components which may be selected)

Proposal valid until 01/01/2024

This Quotation shall document a change to Schedule C of the Value Partnership Framework Agreement (“VPFA”) executed by the Parties on September 23, 2020. All changes to Schedule C must be jointly approved and reconciled on the Change Request Form (Exhibit 1 of the VPFA)

Original Line Item: 169
Original Description: MR – RS Aera
Original Quote Number and SO: CPQ-148276 30240370
Original Price: \$1,407,213

New Line Item: 169
New Description: MR – RS Aera
New Quote Number: CPQ-338073
New Price: \$1,611,989
Increase/(Decrease) from Schedule C: \$204,776

Note: New Price computed with higher than contracted discount to offset March 2022 List Price Increase

Note: Price has been reduced by \$87k per the Contract Addendum to the Value Partnership Framework Agreement dated May 15, 2023

The Products described in this Quotation are governed by the terms and conditions of the VPFA effective September 23, 2020 between Siemens Medical Solutions USA, Inc. and WakeMed.

This system quote CPQ-338073 must be purchased with education quote: CPQ-366729.

This proposal includes the trade-in of equipment referenced in Trade Sheet Project #2023-1856.

List Price Total-\$4,058,795



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40 Liberty Boulevard, Malvern, PA 19355

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

Discounted Dollar Amount-\$2,446,806
Discounted Price Total-\$1,611,989

Accepted and Agreed to by:

Siemens Medical Solutions USA Inc.

WAKEMED HEALTH AND HOSPITALS

By (sign): _____

By (sign): _____

Name: Stephen Argo

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

By signing below, signor certifies that no modifications or additions have been made to the Quotation. Any such modifications or additions will be void.

By (Sign): _____

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

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

Quote Nr: CPQ-338073 Rev. 8

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

Purchasing Agreement: PREMIER PURCHASING PARTNERS LP

PREMIER PURCHASING PARTNERS LP terms and conditions apply to Quote Nr CPQ-338073

Customer certifies, and Siemens relies upon such certification, that : (a) PREMIER PP-IM-278 MR 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.

MAGNETOM Aera eco - Mobile and Therapy Options

All items listed below are included for this system:

Qty	Part No.	Item Description	Extended Price
1	14435099	RS Upgrade Magnet Cooling System Replacement of the magnet cooling components (helium compressor and cold head) according to our ecoline standards.	\$ 20,800
1	14457399	RS Standard Coil Package 48+ ch #Ae This package includes: - Head/Neck 20 DirectConnect - Spine 32 DirectConnect - Body 18 - Flex Large 4 - Flex Small 4 - Flex Coil interface	\$ 26,182
1	14442780	RS Quiet Suite #T+D Quiet Suite enables complete, quiet examinations for neurology and orthopedics with at least 70% reduction in sound pressure levels.	\$ 0
1	14431419	RS Tim Whole Body Suite #T+D Tim Whole Body Suite puts it all together. This suite enables table movement for imaging of up to 205 cm (6' 9") FoV without compromise. In combination with Tim's newly designed ultra highdensity array higher spatial and temporal resolution can be achieved along with unmatched flexibility of any coverage up to Whole Body. For faster exams and greater diagnostic confidence.	\$ 9,164
1	14445732	RS Body 30 #1.5T The Tim 4G coil technology with Dual Density Signal Transfer and SlideConnect Technology combines key imaging benefits: excellent image quality, high patient comfort, and unmatched flexibility: - 30 channels or up to 46 (in combination with the Spine 32) - Dual Density Signal Transfer - Ultra light-weight - Highly flexible viscoelastic material - SlideConnect Technology The Body 30 features:	\$ 26,182

Qty	Part No.	Item Description	Extended Price
		<ul style="list-style-type: none"> - 30-element design with 30 integrated preamplifiers (5 clusters of 6 elements each) - Can be combined with further coils for larger coverage - Can be positioned in different orientations (0°, 90°, 180°, 270°) for patient specific adaptations - No coil tuning - iPAT compatible in all directions <p>The highly flexible design allows the usage for:</p> <ul style="list-style-type: none"> - Thorax (incl. heart) - Abdomen - Pelvis (incl. prostate) - Hip - Angiography <p>Dedicated protocols are provided for abdominal imaging.</p> <p>Typically combined with:</p> <ul style="list-style-type: none"> - Spine 32 - Body 18 - Body 18 long (optional) - Peripheral Angio 36 (optional) - Body 30 (optional) 	
1	14431430	<p>RS Shoulder 16 Coil Kit #Ae</p> <p>The new Tim 4G coil technology with Dual Density Signal Transfer and SlideConnect Technology combines key imaging benefits: excellent image quality, high patient comfort, and unmatched flexibility. The Shoulder 16 Coil Kit for examinations of the left or right shoulder consists of a base plate and two different sized iPAT compatible 16 channel coils (Shoulder Large 16 and Shoulder Small 16). These will be attached and can be relocated on the base plate. The 16-element coils with 16 integrated pre-amplifiers ensure maximum signal-to-noise ratio. Shoulder Large 16 and Shoulder Small 16 will be connected via a SlideConnect plug for fast and easy coil set-up and patient preparation.</p>	\$ 15,709
1	14431431	<p>RS Hand/Wrist 16 #Ae</p> <p>The new Tim 4G coil technology with Dual Density Signal Transfer and SlideConnect Technology combines key imaging benefits: excellent image quality, high patient comfort, and unmatched flexibility.</p> <p>Hand/Wrist 16 for examinations of the left or right hand and wrist region consists of a base plate and an iPAT compatible 16-channel coil and allows high resolution imaging of the wrist and the hand within one examination. Hand/Wrist 16 will be connected via a SlideConnect plug for fast and easy patient preparation.</p>	\$ 17,018
1	14457413	<p>RS Tx/Rx Knee 15 Flair 1.5T #Ae</p> <p>New 15-channel transmitter/receiver coil for joint examinations in the area of the lower extremities.</p> <p>Main features :</p> <ul style="list-style-type: none"> - 15-element design (3x5 coil elements) with 15 integrated preamplifiers, - iPAT-compatible - SlideConnect Technology 	\$ 18,851
1	14431432	<p>RS Foot/Ankle 16 #Ae</p> <p>The new Tim 4G coil technology with Dual Density Signal Transfer and DirectConnect Technology combines key imaging benefits: excellent image quality, high patient comfort, and unmatched flexibility.</p> <p>Foot/Ankle 16 for examinations of the left or right foot and ankle region consists of a base plate and an iPAT compatible 16-channel coil and allows high resolution imaging of the foot and ankle within one examination. Foot/Ankle 16 is a cable-less coil and will be connected via DirectConnect for fast and easy patient preparation.</p>	\$ 19,636
1	14457411	<p>RS UPS system</p>	\$ 2,808

Qty	Part No.	Item Description	Extended Price
1	14457412	<p>UPS system Liebert GXT5 3000IRT2UXLE for MAGNETOM Aera, Skyra, Prisma, ESSENZA, Amira, Semptra, Spectra, C! for safeguarding computers. Including Power Cable of 9 m for connecting the UPS. Power output: 3.0 kVA / 3 kW Bridge time: 3 min full load / 12 min half load Input voltage: 230 VAC</p> <p>RS UPS Battery module (Libert GXT4 BATT)</p> <p>UPS battery module Liebert GXT5 72VBATTE for MAGNETOM Aera, Skyra, Prisma, ESSENZA, Amira, Spectra, C! for safeguarding computers. Extension for: Liebert GXT5 3000IRT2UXLE (14456315) Battery type: Closed, maintenance-free Extension of the bridge time to: 21 minutes full load / 48 min half load with one module Dimensions (H x D x W): Battery module: 430 x 540 x 85 mm</p>	\$ 1,040
1	14430263	<p>Weight: approx. 30 kg</p> <p>MR General Engine #BM</p> <p>syngo.MR General Engine extends Numaris/X by adding dedicated workflows and tools for routine and advanced reading of MR examinations. A generic MR Basic workflow is provided, as well as specific MR Neurology, MR Prostate Reading, MR Breast Reading, and MR Cardio-Vascular workflows.</p>	\$ 0
1	14430260	<p>Brain Dot Engine #Am,Se,Vi,So,Lu,AI</p> <p>The Brain Dot Engine provides guided and automated workflows customizable to the site specific standards of care for general brain examinations. The Brain Dot Engine supports the user in achieving reproducible image quality with increased ease of use and time efficient exams. The brain workflow can be personalized to the individual patient condition and clinical need. Several predefined strategies are included, which can be easily selected with one click. They can be changed at any time during the brain workflow.</p>	\$ 0
1	14430265	<p>Tim Planning Suite #BM</p> <p>With the Tim Planning Suite, multiple regions in the entire body can be examined in a minimum of time through measurement planning on a single FoV of any desired size.</p>	\$ 0
1	14430261	<p>syngo TimCT FastView #BM</p> <p>TimCT FastView is the "one go" localizer for the whole body or large body regions such as the whole spine or the whole abdomen. It acquires the complete extended Field of View in one volume with isotropic resolution. Transverse, coronal and sagittal reformats of the volume are calculated Inline and displayed for planning subsequent exams.</p> <ul style="list-style-type: none"> - Inline reconstruction of the localizer images during the scan. - Localizing images in three planes over the maximum Field of View available for subsequent planning in all orientations. - TimCT FastView runs without laser light positioning to further streamline the workflow for several indications. 	\$ 0
1	14430262	<p>Advanced Diffusion #NX</p> <p>QuietX DWI and RESOLVE together make up the Advanced Diffusion package.</p> <p>QuietX DWI enables quieter diffusion-weighted imaging of the brain with up to 70% reduction in sound pressure relative to conventional diffusion-weighted imaging. RESOLVE (Readout Segmentation Of Long Variable Echo-trains) is a multi-shot, readout segmented EPI sequence for high-resolution, low-distortion diffusion-weighted imaging (DWI). This technique is largely insensitive to susceptibility effects, providing anatomically accurate diffusion imaging for the brain, spine, breast and prostate. In combination with syngo.MR Tractography, RESOLVE enables excellent white-matter tract imaging even in regions of high susceptibility, such as the spine.</p>	\$ 0
1	14430264	<p>Inline Composing syngo</p>	\$ 0

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Qty	Part No.	Item Description	Extended Price
1	14478614	Automatic anatomical or angiographic composing of multiple adjacent coronal or sagittal images for presentation and further evaluation. Composed images can be automatically loaded into Graphical Slice Positioning for scan planning purposes. RS syngo Expert-i XA30	\$ 0
1	14478616	This software application enables remote access to the system (connected via local area network) for planning and processing. RS SW syngo MR XA30A	\$ 0
1	14430327	Please be aware that certain or all positions of this quote have the software version syngo MR XA30A as prerequisite. MAGNETOM Aera - System MAGNETOM Aera is designed to provide you the versatility you need to meet the increasing demands in healthcare. Maximize 1.5T with its core technologies Tim® 4G and Dot®, along with its comprehensive application portfolio and experience unique functionalities to increase patient comfort. Every case. Every day. System Design - Short and open appearance (145 cm system length and 70 cm Open Bore Design) to reduce patient anxiety and claustrophobia - Whole-body superconductive Zero Helium Boil-Off 1.5T magnet - Actively Shielded water-cooled Siemens gradient system for maximum performance - TrueForm Magnet and Gradient Design Tim 4G (Total imaging matrix in the 4th generation) for excellent image quality and speed - Siemens unique DirectRF™ technology enabling the all digital-in/ digital-out design - Dual-Density Signal Transfer Technology - Tim Coil Interface Dot (Day optimizing throughput) for higher consistency, flexibility and efficiency - Dot Display - Dot Control Centers - Brain Dot Engine Tim Application Suite allowing excellent head-to-toe imaging - Neuro Suite - Angio Suite - Cardiac Suite - Body Suite - Onco Suite - Breast Suite - Ortho Suite - Pediatric Suite - Scientific Suite Further included - High performance host computer - Patient communication: standard headphones and MagnaCoil™ In-Ear headset - Siemens unique TimCT FastView localizer and CAIPIRINHA - syngo MR software including - 1D/2D PACE - BLADE - iPAT² - Phoenix - Inline Diffusion - WARP	\$ 353,452

Qty	Part No.	Item Description	Extended Price
		<ul style="list-style-type: none"> - MDDW (Multiple Direction Diffusion Weighting) - CISS - DESS - TGSE <p>The system (magnet, electronics and control room) can be installed in 30sqm space. For system cooling either the Eco Chiller options or the Separator is required.</p>	
1	14434766	<p>RS ecoline MR System Delivery</p> <p>With ecoline, Siemens Healthineers offers a portfolio of systems with certified performance at exceptional value.</p> <p>ecoline systems contain components, which have been in use and are refurbished to a quality level as good as new. All ecoline systems are manufactured according to externally certified procedures in compliance with the applicable standards for medical devices¹. This takes place in alignment with the procedures of the global refurbishment standard for medical imaging equipment². Thus, every ecoline system receives our Proven Excellence Label.</p> <p>Siemens Healthineers' ecoline systems provide exceptional value performing and looking like new, configurable to individual customer needs and offered at affordable prices.</p> <p>¹ ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes</p> <p>² IEC 63077:2019 Good refurbishment practices for medical imaging equipment</p>	\$ 0
1	14431420	<p>RS Cover #T+D</p> <p>Cover color and design are subject to availability.</p>	\$ 0
1	14431418	<p>RS Tim Dockable Table #Ae</p> <p>The Tim Dockable Table is designed for maximum patient comfort and smooth patient preparation. Tim Dockable Table can support up to 250 kg (550 lbs) patients without restricting the vertical or horizontal movement.</p> <p>The one step docking mechanism and the innovative multi-directional navigation wheel ensure easy maneuvering and handling. Critically ill or immobile patients can now be prepared outside the examination room for maximum patient care, flexibility and speed.</p>	\$ 19,636
1	14457402	<p>RS Tim [204x48] XQ Gradients #Ae</p> <p>Tim [204x48] XQ-gradients performance level</p> <p>Tim 4G with it's newly designed RF system and innovative coil architecture enables high resolution imaging and increased throughput. The system provides a maximum number of 204 channels (coil elements) that can be connected simultaneously. Flexible parallel imaging is achieved by the 48 independent RF channels that can be used simultaneously in one single scan and in one single FOV, each generating an independent partial image. Maximum SNR is furthermore ensured through the new Tim 4G matrix coil technology. This option includes also Advanced High Order Shim.</p> <p>XQ - gradients</p> <p>The XQ- gradients are designed combining high performance and linearity to support clinical whole body imaging at 1.5T. The force compensated gradient system minimizes vibration levels and accoustic noise. The XQ gradients combine 45 mT/m peak amplitude with a slew rate of 200 T/m/s.</p> <p>High-performance measurement and reconstruction system</p>	\$ 142,952

Qty	Part No.	Item Description	Extended Price
1	14434721	<p>RS Separator 60kW</p> <p>The SEP (Separation cabinet) has to be used if a central hospital chilled water supply is available or if a chiller of any brand/type is already available. The SEP is the interface between the on-site water chiller (of any brand or type) or the interface to the central hospital cooling water supply. For the above-mentioned cases the SEP is mandatory!</p> <p>In these cases, the primary water specifications must fulfill the requirements (i.e. 63 kW heat dissipation; 100+-10l/min flow; 6 to 12°C water temperature; pH value 6 to 8, max. working pressure 6 bar).</p> <p>Dimensions: 1950mm x 650mm x 650mm (height x width x depth) Weight: approx. 340kg</p>	\$ 20,800
1	14442420	<p>RS 2/10/16ch Sentinelle BreastCoil #Ae</p> <p>The 2/10/16-channel Sentinelle Breast Coil can be used as a breast imaging coil, a bilateral biopsy coil, as well as a unilateral biopsy coil providing large biopsy access</p> <p>This coil consists of a positioning frame with exchangeable coils with different numbers of channels as described in detail in the E text.</p> <p>The preamplifiers are integrated into the coil. The coil is iPAT-compatible.</p>	\$ 93,600
1	14431434	<p>RS Tim Coil Interface 1.5T</p> <p>Coil adapter plug for up to 8 receive and 1 transmit channels. This adapter will be required if the following Tim coils will be used on a compatible 1.5T MAGNETOM system with Tim 4G technology.</p>	\$ 1,964
1	14442395	<p>RS Tx/Rx CP Head Coil #Ae</p> <p>Circularly polarized no-tune transmit/receive coil with an open patient-friendly design. The integrated transmit mode allows volume selective excitation. Integrated, extremely low-noise pre-amplifiers permit very high signal-to-noise ratio. Furthermore, the coil is outfit with SlideConnect Technology, allowing for easier patient preparation and less table time for the patient.</p>	\$ 20,945
1	14478546	<p>RS PC Keyboard US English #NX</p> <p>Standard PC keyboard with 105 keys.</p>	\$ 0
1	14478625	<p>RS High-End Computing [204x48] #NX</p> <p>Hardware upgrade option, containing a new high performance measurement and reconstruction system.</p>	\$ 23,563
1	14478613	<p>RS DotGO Routine Package #NX</p> <p>The DotGO Routine Package includes both: - Spine Dot Engine and - Large Joint Dot Engine.</p> <p>As a package they offer a comprehensive set of workflows with guidance and automation, for standardized image quality in Spine and MSK MR imaging. The Spine Dot Engine provides the functionality of Inline Composing and Tim Planning Suite for streamlining workflows in all spine imaging. Tools, such as auto-positioning and vertebral recognition with AutoAlign Spine, AutoCoverage and Spine Labelling support and optimize reproducibility for your cervical, thoracic and lumbar spine imaging for all clinical indications. The Large Joint Dot Engine enhances standardization of the knee, hip and shoulder workflows and optimizes reproducible image quality by incorporating automation tools, such as anatomically based auto-positioning (AutoAlign). Dedicated imaging techniques, such as Advanced WARP, are included and can help to expand the access of diagnostic MRI to a broader range of patient types.</p>	\$ 7,200
1	14478621	<p>RS Turbo Suite Excelerate Edition #NX</p> <p>Turbo Suite Excelerate comprises access to cutting edge acceleration techniques such as Simultaneous Multi-Slice and Compressed Sensing for static 2D and static</p>	\$ 23,563

Qty	Part No.	Item Description	Extended Price
		3D imaging applications in Neuro, MSK and Body MRI.	
1	14478544	RS CS GRASP-VIBE #NX Compressed Sensing GRASP-VIBE (Golden-Angle Radial Sparse Parallel) makes it possible to conduct dynamic contrast-enhanced abdominal exams in free breathing. Acquisition is performed in one continuous run, using a golden-angle stack-of-stars radial scheme that confers robustness towards motion and the flexibility to choose the temporal resolution at reconstruction time. The temporal resolution may even vary over the duration of the scan. Reconstruction is performed using a Compressed Sensing accelerated iterative algorithm with per-voxel through-time regularization. The combination of features enables for free-breathing abdominal exams with both robust diagnostic image quality and the high temporal resolution required to capture the dynamic phases of contrast enhancement. Additional features: - Auto Bolus Detection at reconstruction time - Configuration of exam phases in terms of start time relative to the auto-detected bolus arrival, duration, temporal resolution, and pre-selection for export to PACS - Self-gating for further reduction of residual motion blur - Includes FREEZEit+ #Vi	\$ 17,018
1	14458089	Turbo Suite Essential Turbo Suite Essential comprises established acceleration techniques to maximize productivity for all contrasts, orientations and all routine imaging applications from head-to-toe.	\$ 0
1	14413869	RS SWI #Tim Susceptibility Weighted Imaging is a high-resolution 3D imaging technique for the brain with ultra-high sensitivity for microscopic magnetic field inhomogeneities caused by deoxygenated blood, products of blood decomposition and microscopic iron deposits. Among other things, the method allows for the highly sensitive proof of cerebral hemorrhages and the high-resolution display of venous cerebral blood vessels.	\$ 4,255
1	14413918	RS NATIVE syngo #Tim Integrated software package with sequences and protocols for non-contrast enhanced 3D MRA with high spatial resolution. syngo NATIVE particularly enables imaging of abdominal and peripheral vessels and is an alternative to MR angiography techniques with contrast medium, especially for patients with severe renal insufficiency.	\$ 8,509
1	14445734	RS QISS #T+D Software package with QISS sequence, protocols and Dot AddIn for non-contrast enhanced peripheral MRA. QISS particularly enables higher reproducibility than existing methods and is an alternative to MR angiography techniques with contrast medium, especially for patients with severe renal insufficiency.	\$ 5,236
1	14458314	RS CS Cardiac Cine #NX This option enables the BEAT sequence to perform highly accelerated 2D Cardiac Cine examinations based on a Compressed Sensing technique. It allows higher temporal resolution imaging in real time or in segmented mode, without compromising on spatial resolution. Protocols are provided for full coverage of the heart within a single breath-hold for quantitative functional assessment. In real-time mode, it is robust against arrhythmia and breathing artifacts.	\$ 10,473
1	14478603	RS Advanced Cardiac incl. PSIR #NX This package contains special sequences and protocols for advanced cardiac imaging including 3D and 4D BEAT functionalities. It supports advanced techniques for ventricular function imaging, dynamic imaging, tissue characterization, coronary imaging, and more.	\$ 13,091
1	14478617	RS High bandwidth inversion recovery High bandwidth inversion recovery for reduction of susceptibility-induced artifacts.	\$ 3,927
1	14442779	RS MyoMaps #T+D This package contains special sequences and protocols for inline T1,T2 and T2*	\$ 10,473

Qty	Part No.	Item Description	Extended Price
		calculation at the heart. The generation of T1 and T2 parametric maps is enhanced by the use of motion correction. T1,T2 and T2* parametric maps could be used to support assessment of cardiovascular disease.	
1	14413778	RS Flow Quantification #Tim Special sequences for quantitative assessment of flow including 4D Flow (from SW syngo MR XA30A on).	\$ 3,404
1	14458325	RS syngo.MR Cardiac Flow #MR syngo.MR Cardiac Flow processes velocity-encoded MR images to evaluate blood flow dynamics e.g. in the heart and the great vessels. The application generates quantitative results for physicians in the diagnostic process. The MR cardiac interactive reporting template is included.	\$ 4,713
1	14478589	RS UltraFlex Large 18 #1.5T Light-weight, iPAT compatible, 18-element no-tune receive coil made of highly flexible and soft material. It is used for examinations of larger extremities (e.g. medium to large shoulder, hip, knee ankle and hand) and for abdominal examinations. A dedicated positioning aid for larger extremities, like knee is delivered with the coil.	\$ 15,709
1	14478556	RS Positioning Aids Shoulder&Ankle #NX This package contains additional positioning aids that can be used for the UltraFlex Large 18 and UltraFlex Small 18.	\$ 393
1	MR_CRYO	Standard Cryogens	\$ 8,320
1	MR_PM	MR Project Management A Siemens Project Manager (PM) will be the single point of contact for the implementation of your Siemens' 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.	\$ 0
1	MR_GOKNEE3D	GOKnee3D GOKnee3D is a 10-minute, push-button examination for diagnostic imaging of the knee developed and clinically validated by the US board certified MSK radiologists at John Hopkins University Hospital. GOKnee3D exam consists of AutoAlign localizer in the knee, PD weighted contrast and T2 weighted contrast with fat suppression. The AutoAlign technology provides a push-button functionality and ensures consistency in imaging. The 3D protocols are high resolution and isotropic, enabled by SPACE sequence with CAIPIRINHA technique. Examination time for 3T system is 10 minutes, for a 1.5T system is up to 11 minutes. All given examination times are examination only, adjustments have been excluded. When using GOKnee3D one of two software and coil combinations is required. Measurements made with GOKnee3D using the 15 channel knee coil require software version syngo MR E11C AP04 or higher. Measurements made with GOKnee3D using the 18 channel knee coil require software version syngo MR Numaris VA11A or higher.	\$ 0
1	MR_KTTAMST_AE	SMS Certified AMST mobile Aera Trailer Advanced Mobility by Kentucky Trailer (KTT) mobile MR trailer for use with the Siemens Healthcare MAGNETOM Aera 1.5T (mobile ready) Open Bore MRI System. The standard trailer has been certified by Siemens Healthineers (MR Erlangen) to house the MAGNETOM Mobile ready Aera for diagnostic quality imaging, meeting similar specifications as the fixed in-house scanners. Vehicle sizing and power requirements are prepared to USA Standards.	\$ 625,733
1	BMRXP200	MRXperion injector The MRXperion injector has the following features: Streamlined Injection Workflow Enhanced Point of Care - On-board eGFR and Weight Based Dosing Calculators, an Injection Pressure Graph, and independent Test Inject and KVO functions. Informatics-ready - Connect with the Radimetrics Enterprise Platform for automated	\$ 44,512

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Qty	Part No.	Item Description	Extended Price
		documentation, advanced analytics and viewable patient histories to facilitate standardized injection protocols and enhanced operational consistency. Maximized Uptime Support - Connect to VirtualCare Remote Support for advanced injector system diagnostics, seamless software updates, and fast repairs.	
		Price includes installation, training and one year warranty through Bayer Healthcare.	
1	MR14460428	ACR Phantom Holder (USA) An MR compatible cradle device used to consistently and precisely position the American College of Radiology (ACR) MRI Accreditation phantom, for use with Siemens MAGNETOM standard Head Coil during test measurements for ACR system accreditation or QA testing	\$ 104
1	MRIMAB_100	MRI Armboard w/ Pad	\$ 405
1	MR_STD_RIG_I NST	MR Standard Rigging and Installation MR Standard Rigging and Installation This quotation includes standard rigging and installation of your new MAGNETOM system Standard rigging into a room on ground floor level of the building 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 rigging requiring a crane over 80 tons 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.	\$ 0
1	MR_BTL_INSTA LL	MR Standard Rigging & Install	\$ 28,080
1	MR_PREINST_ DOCK	T+D Preinstall kit for dockable table	\$ 572
1	MR_ADDL_RIG GING	Additional Rigging MR \$10,000	\$ 10,000
1	MR_TRADE_IN_ ALLOW	MR Trade-in-Allowance, Symphony, project #2023-1856, deinstall/expire date 10/2023 (\$68,000)	-\$ 68,000
System Total			\$ 1,611,989

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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.

ACCESSORIES: Don't forget to ask us about our line of OEM imaging accessories to complete your purchase. All accessories can be purchased or financed as part of this order. To purchase accessories directly or to receive our accessories catalog, please call us directly at 1-888-222-9944 or contact your local Sales Representative.

COMPLIANCE: Compliance with legal and internal regulations is an integral part of all business processes at Siemens. Possible infringements can be reported to our communication channel "Let Us Know".

Siemens Medical Solutions USA, Inc. General Terms and Conditions

Intentionally deleted

TRADE-IN EQUIPMENT REQUIREMENTS

TRADE-IN EQUIPMENT REQUIREMENTS

THE FOLLOWING APPLIES ONLY TO THE EXTENT THAT THE QUOTATION INCLUDES AN EQUIPMENT TRADE IN OR IF A TRADE-IN IS LATER ADDED TO THIS QUOTATION VIA A CHANGE ORDER. THESE REQUIREMENTS ARE IN ADDITION TO ANY OTHER REFERENCED TERMS AND CONDITIONS OF THE QUOTATION AND SHALL REMAIN IN EFFECT REGARDLESS OF ANY CONTRARY LANGUAGE IN THE QUOTATION.

This Quotation includes the trade-in equipment described herein and referenced by either the Project Number identified in the Quotation hereof (non-Ultrasound) or the Trade In Part Number (Ultrasound) as further described in the associated Trade Sheet which is incorporated herein by reference. Purchaser certifies that the description of the trade-in equipment as set forth on the Trade Sheet is a true and accurate representation of the equipment, and that the equipment is in good working condition unless otherwise noted on the Trade Sheet.

The trade-in equipment must be made available for removal no later than turnover of the new equipment. Purchaser must vacate the room of all items not listed on the Trade Sheet, or otherwise clearly identify all items listed on the Trade Sheet, prior to the start of the de-installation. If this is not done, Seller will have no liability for items which are subsequently removed or scrapped. If the de-installation or return of the trade-in equipment is delayed by Purchaser for reasons other than a force majeure event, or if upon inspection by Seller it is determined that the equipment does not meet the manufacturer's operating specifications, or if any items listed as included on the Trade Sheet are not made available at the time of de-installation, then trade-in value will be re-evaluated and any loss in value or additional costs incurred by Seller shall be deducted from the established trade-in value and the pricing set forth on this Quotation will be adjusted by change order. In the event that access to the non-ultrasound trade-in equipment is denied past 14 days from turnover, or access to ultrasound trade-in equipment is denied past 30 days from turnover, then Purchaser shall pay to Seller a rental fee in the amount 3.5% of the total trade-in value plus any additional value provided by an Elevate/Promotional program included in this quotation (no less than \$1000) for each month, or part thereof, that access is denied. In addition, if the purchase and installation of the new equipment covered by this Quotation is not completed, then Seller shall invoice Purchaser for all costs and expenses incurred by Seller in connection with the de-installation and removal of the trade-in equipment, including but not limited to labor, materials, rigging out, and transportation, which costs shall be paid by Purchaser within thirty (30) days of the invoice date.

Purchaser further acknowledges and agrees that (i) the trade-in equipment will be free and clear of all liens and encumbrances including, but not limited to, unpaid leases and loans, and that upon request, it will execute a bill of sale or other documents reasonably satisfactory to Siemens to transfer title and ownership of the

equipment to Seller, (ii) it is Purchaser's sole responsibility to delete all protected health information and any other confidential information from the equipment prior to de-installation, without damaging or cannibalizing the equipment or otherwise affecting the operation of the equipment in accordance with its specifications, (iii) the equipment, including all updates, upgrades, modifications, enhancements, revisions, software, S/W disks and manuals, shall be returned to Siemens in good operating condition, reasonable wear and tear excepted, and (iv) to the extent not prohibited by applicable law, Purchaser shall indemnify and hold Seller harmless from and against any and all claims, demands, causes of action, damages, liability, costs and expenses (including reasonable attorney's fees) resulting or arising from Purchaser's failure to comply with item (i) above.

FOR MR SYSTEMS: cryogen levels must be least 65% upon time of de-installation. FOR MOBILE SYSTEMS: system must be road worthy and a state issued title transferring ownership to Seller (or Designee) must be received prior to the removal of the mobile system. FOR MODALITY TRADE SYSTEMS (non-ultrasound): The trade-in equipment must be available for inspection within two weeks of the scheduled de-installation date. In addition, Purchaser must provide a clear path for the removal of the trade-in equipment and on the date of de-installation after final inspection and test by the Seller (or Designee) has occurred, the Purchaser must supply licensed tradespeople to disconnect the power and plumbing (including draining and removing and disposing of any hazardous materials including, but not limited to glycol from the chiller and oil from the transformer, as examples.) Any additional costs due to the need to use a larger rig (other than a standard 80 ton rig), as well as any construction activities, street closings, permits, etc., required to de-install/remove the equipment are out-of-scope costs and will be the responsibility of Purchaser. FOR ULTRASOUND SYSTEMS – Purchaser may provide transducers with the ultrasound unit being traded in, but will not receive additional credit for such transducers.

MR Warranty Information

Product	Period of Warranty ¹	Coverage	Note
New Systems and "ECO" Refurbished Systems Only (Not including consumables)	12 months	Full Warranty (parts & labor) ¹ Principal Coverage Period 8am-5pm Monday through Friday ²	1. MAGNETOM Sempra/Free.MAX/Free.STAR requires Smart Remote Services (SRS) Connection prior to system installation or requires purchase of "No SRS" option.
FIT Upgrades – MAGNETOM_Avanto/Skyra_Fit_BioMatrix, MAGNETOM_Sola/Vida_Fit (Not including consumables)			1.Fit Upgrade warranty excludes Magnet, Magnet Refrigeration System (CryoCare), Liquid Helium Refills and Gradient Coil (if the Gradient Coil is not replaced with the Fit upgrade). These coverages can be purchased separately.

Post-Warranty (after expiration of system warranty) – Replacement of parts prorated only. Does not include labor.			
Magnet	12 months	Parts only	
Spare Parts	6 months	Parts only	
Consumables	Refer to warranty of consumable item		

DNA Warranty Information for On-premise perpetual Applications only

Product	Period of Warranty	Coverage	
syngo plaza, syngo workflow, syngo Dynamics, syngo Carbon	6 months Software	Remote Phone Support, Remote Software Upgrades & Updates, Remote Education	Requires Smart Remote Services (SRS) Connection prior to system installation
Upgrades related to syngo Dynamics, syngo Carbon, Medicalis Workflow Orchestrator, Medicalis Clinical Decision Support, Medicalis Referral Management	No Additional Warranty Included for upgrades	Remote Phone Support, Remote Software Upgrades & Updates, Remote Education	Upgrades via the ESA are a contract component and do not have a separate warranty.

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Hardware	OEM Warranty for Hardware	Parts & Labor (Not Applicable)	
Spare Parts & Consumables	Not Applicable	Not Applicable	
Post-Warranty (after expiration of system warranty) – Replacement of parts prorated only. Does not include labor.			
Spare Parts & Consumables	Not Applicable	Not Applicable	

DNA Warranty Information for On-premise term licenses/Subscriptions & Cloud based Applications

Product	Period of Warranty	Coverage	
syngo Virtual Cockpit, teamplay, AI-Rad Companion	No warranty	Remote Phone Support, Remote Software Upgrades & Updates, Remote Education	
Incremental purchases on Applications, Upgrades related to syngo Virtual Cockpit, teamplay, AI-Rad Companion	No Warranty	Remote Phone Support, Remote Software Upgrades & Updates, Remote Education	Upgrades and incremental purchases on Applications do not have a separate warranty
Hardware	OEM Warranty for Hardware	Parts & Labor (Not Applicable)	
Spare Parts & Consumables	Not Applicable	Not Applicable	

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MRI	MRI
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	1.5T	1.5T
Model Number	Symphony	Aera
Serial Number	23788	TBD
Provider's Method of Identifying Equipment	Capital asset control number	Capital asset control number
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN#	Serial #: 05200525098ASM-61 VIN: 1S9FA482257182829	
Mobile Tractor Serial Number/VIN#	Owned by Taylor Kelly Transport	
Date Acquired	October 2005	NA
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New of Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$2,552,053	\$1,650,789
Total Cost of Equipment	\$1,650,789	\$1,611,989
Fair Market Value of Equipment	NA	\$1,611,989
Net Purchase Price of Equipment	NA	\$1,611,989
Locations Where Operated	WakeMed North Hospital; Central Regional Hospital	WakeMed North Hospital; Central Regional Hospital
Number of Times Existing Equipment was Used to Provide a Health Service during the 12 months prior to the Date of the Written Notice	2,503	NA
Type of Procedures Currently Performed in Existing Equipment	Diagnostic MRI	NA
Type of Procedures New Equipment is Capable of Performing	NA	Diagnostic MRI

From: [Mckillip, Mike](#)
To: [Stancil, Tiffany C](#)
Subject: FW: [External] Request for Exemption - Mobile MRI Replacement
Date: Monday, November 13, 2023 9:35:03 AM
Attachments: [Req for Exemption_Mobile MRI Replacement.pdf](#)

Good morning, Tiffany! This replacement equipment exemption letter request can go to Crystal. Thanks.

Mike

Michael McKillip

Team Leader, Certificate of Need
Division of Health Service Regulation, Healthcare Planning and Certificate of Need
[NC Department of Health and Human Services](#)

Office: 919-855-3877 (I am in the office on Wednesday and Friday, and can best be reached by email on Monday, Tuesday and Thursday.)
mike.mckillip@dhhs.nc.gov

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Raleigh, NC 27699

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From: ROBBIE ROBERTS <RROBERTS@wakemed.org>
Sent: Friday, November 10, 2023 2:09 PM
To: Mckillip, Mike <mike.mckillip@dhhs.nc.gov>
Subject: [External] Request for Exemption - Mobile MRI Replacement

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.

Mike:

Please see the attached Request for Exemption from Review to replace our Mobile MRI scanner. Please let me know if you have questions or need anything else. Thanks.

RR

Robbie Roberts
Manager, Market Planning
WakeMed Health & Hospitals
919-350-8023

rroberts@wakemed.org

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