

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

#### VIA EMAIL ONLY

August 9, 2021

Frank Kirschbaum fkirschbaum@wyrick.com

Exempt from Review – Replacement Equipment

**Record #:** 3629

Date of Request: August 3, 2021 Business Name: WR Imaging, LLC

Business #: 3169

Project Description: Temporarily replace a fixed MRI scanner with a mobile MRI scanner followed

by permanent replacement with a new fixed MRI scanner at the diagnostic center

at 3811 Merton Drive in Raleigh

County: Wake

Dear Mr. Kirschbaum:

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 mobile MRI scanner from out of state to temporarily replace the Siemens Magnetom Avanto 1.5T fixed MRI scanner (Serial # 25185). Also, you may proceed to acquire without a certificate of need the Siemens Magnetom Vida 3T fixed MRI scanner to permanently replace the temporary mobile MRI scanner that is to be used in the interim. 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,

Michael J. McKillip Project Analyst

Micheala Mitchell

Micheala Mitraell

Chief, Certificate of Need

cc: Construction Section, DHSR

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

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603

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FRANK KIRSCHBAUM fkirschbaum@wyrick.com

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August 3, 2021

## VIA EMAIL AND USPS: micheala.mitchell@dhhs.nc.gov

Micheala Mitchell Chief, Certificate of Need Department of Health and Human Services Division of Health Service Regulation Healthcare Planning and Certificate of Need Section 809 Ruggles Drive Raleigh, NC 27603

Re: WR Imaging, LLC's Written Notice Requesting Confirmation of Exemption from

CON Review: Replacement of Legacy MRI Scanner; Interim Use of Temporary

Mobile MRI

Dear Ms. Mitchell:

We are writing on behalf of our client WR Imaging, LLC ("WRI"), which owns and operates a diagnostic center located at 3811 Merton Dr, Raleigh, NC 27609 (the "Diagnostic Center"). Pursuant to N.C. Gen. Stat. § 131E-184(a)(7) and 10A NCAC 14C.0202, WRI intends to replace an existing magnetic resonance imaging scanner ("Existing MRI"), a Siemens Magnetom Avanto 1.5T. The Existing MRI has been in use at the Diagnostic Center since 2004, and replaced a unit that was grandfathered under the CON Law. The reason that the Existing MRI is being replaced is because the unit has reached the end of its useful life, meaning that it is at an age where parts will be difficult to acquire, making complete failure of the equipment a possibility, and any repairs that could be made will be more expensive. The Existing MRI will be removed from service in the State of North Carolina.

WRI intends to replace the Existing MRI with a Siemens Magnetom Vida 3T MRI scanner ("Replacement MRI"). The total cost of the Replacement MRI, including associated renovation costs, is One Million Eight Hundred Twenty-Three Thousand Four Hundred Ten Dollars (\$1,823,410.00). See, Exhibit A, Vendor Quote and Construction Estimate; Exhibit B, Equipment Comparison for Replacement MRI. On a temporary basis during the upgrade process, an out-of-state mobile MRI machine ("Temporary Mobile MRI") will be used in place of a fixed MRI. The operation of the Temporary Mobile MRI will not overlap with the Existing MRI or the Replacement MRI, and both the Temporary Mobile MRI and the Existing MRI will be removed

Micheala Mitchell Chief, Certificate of Need August 3, 2021 Page 2 of 4

from service in the state upon installation of the replacement MRI. The purpose of this letter is to provide the Agency with prior written notice of WRI's intent to replace the Existing MRI, including its interim use of the Temporary Mobile MRI, as is required under N.C. Gen. Stat. § 131E-184(a)(7), and to set forth the reasons that the Replacement MRI meets the requirements for the replacement equipment exemption under the statute.

## **Exemption Notice for Replacement Equipment.**

The CON law defines new institutional health service to include, among other things, capital expenditures exceeding Two Million Dollars (\$2,000,000.00) to develop or expand a health service facility and the acquisition of certain major medical equipment costing more than Seven Hundred Fifty Thousand Dollars (\$750,000.00) and the acquisition of a magnetic resonance imaging scanner. See N.C. Gen. Stat. §131E-176(14o),(16)(b),(16)(f1)(7). However, the CON law specifically exempts from review any new institutional health service that is required to provide replacement equipment, provided that the entity proposing the new institutional health service must first provide written notice to the CON Section explaining why the new institutional health service is required "to provide replacement equipment." See N.C. Gen. Stat. § 131E-184(a)(7).

Replacement equipment is defined as "equipment that costs less than two million dollars (\$2,000,000.00) 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." See N.C. Gen. Stat. § 131E-176(22a). Replacement equipment is not "comparable" to the equipment being replaced if:

- 1) the replacement equipment to be acquired is capable of providing a health service that the equipment to be replaced cannot provide; or
- 2) the equipment to be replaced was acquired less than 12 months prior to the date the written notice required by N.C. Gen. Stat. §131E-184(a) is submitted to the CON Section and it was refurbished or reconditioned when it was acquired by the person requesting the exemption. See 10A N.C. Admin. Code 14C.0303(c).

The Replacement MRI falls within the parameters of the exemption for replacement equipment for the reasons listed below.

- 1) The Replacement MRI costs less than two million dollars.
- 2) The Existing MRI was new when purchased by Wake Radiology Services, LLC, predecessor in interest to WRI, in 2004 and is more than 12 months old.
- 3) The Existing MRI is currently in use and has not been taken out of service.
- 4) The Existing MRI will be sold or otherwise disposed of upon acquisition and installation of the Replacement MRI. Specifically, the Existing MRI will be taken out of service and traded into the vendor of the new equipment, and will not remain in service in the State of North Carolina.
- 5) The Replacement MRI, like the Existing MRI, is a high field strength magnet and will be used to provide the same health services as the Existing MRI, and is not capable of

Micheala Mitchell Chief, Certificate of Need August 3, 2021 Page 3 of 4

providing a health service that the Existing MRI cannot provide. While the Replacement MRI utilizes a more powerful magnet than the Existing MRI, both 1.5 Tesla magnets and 3 Tesla magnets are used to provide whole-body MRI scans, meaning scans of all body parts. While a 1.5 Tesla magnet can provide a different health service than a 0.22 Tesla MRI scanner, which is suitable only for extremity scans, the 3 Tesla magnet used by the Replacement Equipment it is not capable of providing a health service that the 1.5 Tesla magnet in the Existing MRI cannot also provide. See Exhibit B, Equipment Comparison for Replacement MRI.

6) The acquisition and installation of the Replacement MRI will not increase patient charges or per-procedure operating expenses more than 10% within 12 months of the replacement equipment being acquired. See Exhibit B, Equipment Comparison for Replacement MRI.

## Conclusion

Based on the foregoing, WRI requests confirmation that its acquisition of the Replacement MRI constitutes the acquisition of Replacement Equipment under the CON law and is exempt from review by the CON Section.

Thank you for your attention to this matter, and please do not hesitate to contact me with any questions.

Sincerely,

WYRICK ROBBINS YATES & PONTON LLP

Frank Kirschbaum

Enclosures

## EXHIBIT A

Vendor Quote for the Replacement MRI &
Construction Estimate for 3T MRI Upfit

# **EXHIBIT B** EQUIPMENT COMPARISON FOR REPLACEMENT MRI

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment	MRI Scanner	MRI Scanner
Manufacturer of Equipment	Siemens	Siemens
Model Number	Siemens Magnetom Avanto 1.5T	Siemens Magnetom Vida 3T
Serial Number	S/N: 25185	Available upon installation
Provider's Method of Identifying Equipment	Serial Number, Affixed Label	Serial Number, Affixed Label
Mobile or Fixed	Fixed	Fixed
Date of Acquisition	November 2004	Proposed, August 2021
Provider Hold Title to Equipment or Have a Capital Lease?	Title	Capital Lease
Specify if Equipment was/is New or Used When Acquired	New	New
Total Cost of Equipment	\$1,726,095	\$ 1,543,410.00*
Fair Market Value of Equipment	\$81,500	\$ 1,624,910.00**
Net Purchase Price of Equipment	Unk.	\$ 1,543,410.00
<b>Locations Where Operated</b>	3811 Merton Dr., Raleigh, NC 27609	3811 Merton Dr., Raleigh, NC 27609
Number of Days Per Year the Equipment is or will be in Use in North Carolina	Approximately 300	Approximately 300
Percent of Change in Patient Charges by Procedure	N/A	Zero Percent
Percent of Change in Per-Procedure Operating Expenses	N/A	Zero Percent
Procedures Currently Performed in Existing Equipment	MRI Procedures	N/A
Procedures New Equipment is Capable of Performing	N/A	MRI Procedures

Total cost \$1,823,410.00, including renovation costs.

Includes \$81,500 trade-in credit for Existing MRI, which will be removed from service in North Carolina. \*\*



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

#### **PROPOSAL**

Customer Number: 0000011225 Date: 08/02/2021

**WR IMAGING LLC** 3949 BROWNING PLACE RALEIGH, NC 27609

Estimated Delivery Date: 11/2021

Estimated delivery date is subject to change based upon factory lead times, acceptance date of this quote, customer site readiness, and other factors. A Siemens representative will contact you regarding the final delivery date.

This quote represents a conversion of Siemens quote #CPQ-325089 Rev. 2 dated 2/26/2021, WR IMAGING LLC Purchase Order #SQ CPQ 325089 dated 3/30/21, and Siemens Sales Order # 30249425, from a MAGNETOM VIDA system to a MAGNETOM LUMINA system as quoted herein.

This proposal includes the trade-in of equipment referenced in Trade Sheet Project # 2021-0652

Quote Nr. CPQ-415887 Rev. 2

## **MAGNETOM Lumina (DE)**

All items listed below are included for this system:

## Qty Part No. Item Description

1 14461710 MAGNETOM Lumina - System

MAGNETOM Lumina leverages the intelligent combination of Tim 4G and the Siemens unique BioMatrix technology to be ready to embrace the unique set of challenges that each and every patient brings to the MRI exam.

#### System Design

- Short and open appearance (186 cm total system length cover-to-cover and 70 cm Open Bore Design) to reduce patient anxiety and claustrophobia
- Whole-body superconductive Zero Helium Boil-Off 3T magnet
- Weight-optimized magnet technology based on high performance 7T magnet design
- Actively Shielded water-cooled Siemens gradient system for maximum performance
- Tim 4G (Total imaging matrix in the 4th generation) for excellent image quality and speed with Siemens unique DirectRX technology enabling all digital-in/digital-out design and Dual-Density Signal Transfer Technology

Push-button exams with GO technologies Select&GO DotGO Recon&GO



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#### **PROPOSAL**

#### MR View&GO

Tim Application Suite allowing excellent head-to-toe imaging for

- Neuro
- Angio
- Cardiac
- Body
- Onco
- Breast
- Ortho
- Pediatric
- Scientific

#### Further included

- High performance host computer and measurement and reconstruction system
- Patient communication including headphones
- syngo MR software including:
- Turbo Suite Essential
- 1D/2D PACE
- BLADE
- Phoenix
- Inline Diffusion
- MDDW (Multiple Direction Diffusion Weighting)
- DESS
- TGSE
- Offline Composing

#### 14460161 MR General Engine #Vi

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.

#### 14456321 **Brain Dot Engine #Se**

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.

#### 14461775 DotGO Routine Package #BM

The DotGO Routine Package includes both:

- Spine Dot Engine and
- Large Joint Dot Engine.

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 autopositioning 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

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## **PROPOSAL**

		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.
1	14441748	Quiet Suite #T+D
		Quiet Suite enables complete, quiet examinations for neurology and orthopedics with at least 70% reduction in sound pressure levels.
1	14460162	Tim Whole Body Suite #Vi
		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-high density 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.
1	14460227	Tim Planning Suite #Vi
		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.
1	14456329	syngo TimCT FastView #Vi
		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.
		<ul> <li>Inline reconstruction of the localizer images during the scan.</li> <li>Localizing images in three planes over the maximum Field of View available for</li> </ul>
		<ul> <li>subsequent planning in all orientations.</li> <li>TimCT FastView runs without laser light positioning to further streamline the workflow for several indications.</li> </ul>
1	14460160	Advanced Diffusion #Vi
		QuietX DWI and RESOLVE together make up the Advanced Diffusion package.
		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.
1	14456327	WARP & Advanced WARP #Vi WARP and Advanced WARP (SEMAC) integrates different techniques tailored to reduce susceptibility artifacts caused by orthopedic MR-conditional metal implants.
1	14456323	Inline Composing syngo #Se  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.
1	14461711	Tim [180x32] XK-Gradient #Lu Tim [180x32] XK-gradients performance level

imaging and increased throughput.

Tim 4G's RF system and innovative coil architecture enables high resolution



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#### **PROPOSAL**

The system provides a maximum number of 180 channels (coil elements) that can be connected simultaneously. Flexible parallel imaging is achieved by 32 independent receiver channels that can be used simultaneously in one single scan and in one single FOV, each generating an independent partial image.

#### XK - gradients

The XK 36/200 gradients are designed for high performance and linearity to support clinical whole body imaging at 3T. The XK gradients combine 36 mT/m peak amplitude with a slew rate of 200 T/m/s.

The force compensated gradient system minimizes vibration levels and acoustic noise.

High-performance measurement and reconstruction system

#### 1 14468981 Coil Package Tim [180x32] #3T

This package includes (if not exchanged with different variants via respective quote items):

- Head/Neck 16 DirectConnect
- BioMatrix Spine 24
- BioMatrix Body 12
- Flex Large 4
- Flex Small 4
- Flex Coil Interface

## 1 14468946 BioMatrix Technology #Al,Lu

The new and unique BioMatrix technology addresses different aspects of patient bio-variability.

## 1 14470794 BioMatrix SliceAdjust #BM

BioMatrix SliceAdjust helps to avoid station boundaries and apparent broken spine artifacts as well as to preserve the SNR for whole-body diffusion.

## 14461712 BioMatrix Table #Lu

The new BioMatrix Table is designed for smooth patient preparation, high patient comfort and easy cleanability. The unique design of the BioMatrix table can support up to 250 kg (550 lbs) without restricting the vertical or horizontal movement.

## 14470796 BioMatrix Select & GO #AI,Lu

Select&GO

The Select&GO interface enables fast and easy single-touch patient positioning. Correct positioning saves unnecessary wasted time for repositioning and additional adjustments, therefore shortening the total room time.

The ergonomically designed Select&GO touch panel is integrated into the front cover on the left-hand side of the patient tunnel for controlling table movement, guidance for patient setup and comfort features. The Select&GO panel is well illuminated for easy visual recognition.

The BioMatrix Select&GO interface enables fast and easy single-touch patient positioning.

The interface is integrated left-hand side of the patient into the front covers. Correct positioning saves unnecessary wasted time for repositioning and additional adjustments, therefore shortening the total room time.

## 14461716 Pure White Design #Lu

MAGNETOM Lumina is available in an appealing design which perfectly integrate into different environments. The Pure White Design comprises a brilliant white front design ring with integrated unique Select&GO panels.

The table cover is presented also in the same color and material selection.



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## **PROPOSAL**

1	14456270	PC Keyboard US English #Vi Standard PC keyboard with 105 keys.
1	14456238	Peripheral Pulse Unit #Vi Peripheral Pulse Unit for Pulse Triggering
1	14461619	<b>Turbo Suite Essential #BM</b> Turbo Suite Essential comprises established acceleration techniques to maximize productivity for all contrasts, orientations and all routine imaging applications from head-to-toe.
1	14456241	Separator 60kW/75kW #Vi 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!
		In these cases, the primary water specifications must fulfill the requirements: XJ: 45kW; water temperature: 6 - 14°C XQ: 60kW; water temperature: 6 - 14°C XT: 75kW; water temperature: 6 - 12°C
		For all gradient systems: Flow: 100+-10l/min; pH value 6-8; max working pressure 6 bar.
		Dimensions: 1950mm x 650mm x 650mm (height x width x depth) Weight: approx. 350kg
1	14475338	syngo Expert-I XA31  This software application enables remote access to the system (connected via local area network) for planning and processing.
1	14470793	<b>BioMatrix Coil Shim #AI,Lu</b> BioMatrix CoilShim helps to reduce patient induced strongly localized B0 inhomogeneities by dedicated local shim channels.
1	14461715	2nd Select&GO #Lu The 2nd Select&GO interface enables fast and easy single-touch patient positioning from both sides of the patient table. The interfaces are integrated left and right into the front covers. Correct positioning saves unnecessary wasted time for repositioning and additional adjustments, therefore shortening the total room time.
1	14475291	SW syngo MR XA31A syngo MR XA31A software with new features and applications.
		Please be aware that certain or all positions of this quote have the software version syngo MR XA31A as prerequisite.
1	14469017	Turbo Suite Excelerate #BM  Turbo Suite Excelerate comprises access to cutting edge acceleration techniques such as Simultaneous Multi-Slice and Compressed Sensing for static 2D and static 3D imaging applications in Neuro, MSK and Body MRI.
1	14469020	Turbo Suite Excelerate Support Turbo Suite Excelerate Support provides Future Security for Turbo Suite Excelerate:
		With the release of syngo MR Numaris software XA20A and XA12M (Amira) the following licenses will be delivered provided that Turbo Suite Excelerate and Turbo

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#### **PROPOSAL**

Suite Excelerate Support were purchased: CS SPACE, CS SEMAC, CS TOF, SMS for TSE\_DIXON, SMS for RESOLVE and QDWI. This fulfills the delivery of the four options defined in the Turbo Suite Excelerate Support Package.

## 1 14402527 **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.

#### 1 14456275 **FREEZEit+ #Vi**

The FREEZEit+ Body Package contains three robust sequences for advanced imaging: TWIST, TWIST-VIBE and StarVIBE.

- TWIST is a Siemens unique sequence for time-resolved (4D) MR angiographic and dynamic imaging in general with high spatial and temporal resolution.
- TWIST-VIBE is a fast, high-resolution 4D imaging sequence, e.g. for multi-arterial liver imaging.
- StarVIBE is a motion-insensitive VIBE sequence using a stack-of-stars trajectory.

### 14409198 Native syngo #Tim

Integrated software package with sequences and protocols for non-contrastenhanced 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.

## 1 14461549 BioMatrix Body 12 long #Vi

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:

- 12 channels
- Dual Density Signal Transfer
- Ultra light-weight
- SlideConnect Technology
- Exchangeable cable design (165 cm / 90 cm cable length optionally available)

The 12-channel coil with its 12 integrated pre-amplifiers ensures excellent signal-tonoise ratio and extensive coverage in all directions. The single SlideConnect plug allows for fast and easy patient preparation, aided by the light-weight design to ensure highest patient comfort.

The coil's extended cable allows for more flexibility in connector selection which is especially helpful if multiple flexible coils need to be combined and challenging imaging set-ups need to be supported like in therapy imaging (e.g. for combined head-neck exams). The light-weight coil ensures highest patient comfort.

The BioMatrix Body 12 long coil features:

- 12-element design with 12 integrated preamplifiers (3 clusters of 4 elements each)
- Operates in an integrated fashion with the BioMatrix Spine 24
- Can be combined with further BioMatrix Body 12 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

The highly flexible design enables a wide variety of applications including:



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#### **PROPOSAL**

- Thorax (incl. heart)
- Abdomen
- Pelvis
- Hip

## 1 14456221 **Shoulder Shape 16 #Vi**

The Shoulder Shape 16 combines the known benefits of Tim 4G coil technology with new highly flexible materials, resulting in unmatched image quality, high patient comfort and easy handling. The Shoulder Shape 16 for examinations of the left or right shoulder consists of an iPAT-compatible 16-channel shoulder coil in a flexible shoulder cup that can be shaped around small and large shoulders. An L-shaped cushion for easy positioning of the patient is included. The 16-element coil with 16 integrated pre-amplifiers ensures maximum signal-to-noise ratio. Shoulder Shape 16 will be connected via a SlideConnect plug for fast and easy coil set-up and patient preparation.

## 1 14418513 **Hand/Wrist 16 #Sk**

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.

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.

## 14456217 Tx/Rx Knee 18 #Vi

New 18-channel transmit/receive coil optimized for knee imaging. The spacious design with a flared opening towards the thigh allows scanning even of large and swollen knees with exceptional image quality and signal to noise ratio. Main features:

- 18-element design (3x6 coil elements) with 18 integrated preamplifiers
- iPAT-compatible
- SlideConnect Technology

#### 1 14418514 Foot/Ankle 16 #Sk

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.

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.

#### 14416954 2/4/8-ch Sentinelle BreastCoil #Sk

The 2-/4-/8-channel Sentinelle Breast Coil consists of a positioning frame with exchangeable coils with different numbers of channels as described in detail in the E text.

The 2-/4-/8-channel Sentinelle Breast Coil can be used as an 8-channel imaging coil, a 4-channel biopsy coil for lateral biopsy access, as well as a 2-channel biopsy coil for medial biopsy access. This coil provides a large biopsy access.

The preamplifiers are integrated into the coil.

The coil is iPAT-compatible.
A positioning guidance is provided.

#### 1 14418519 Tim Coil Interface 3T



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#### **PROPOSAL**

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 3T MAGNETOM system with Tim 4G technology.

#### 1 14468948

#### Head/Neck 16 -> BM Head/Neck 20 #3T

This option swaps the standard Head/Neck 16 for a BioMatrix Head/Neck 20 tiltable with CoilShim.

The BioMatrix Head/Neck 20 tiltable with CoilShim combines the known benefits of Tim 4G coil technology with those of the new Siemens unique BioMatrix technology, resulting in unmatched image quality, high patient comfort and easy handling. Integrated BioMatrix Tuners: The integrated CoilShim elements minimize patient induced local anatomy-specific B0 field inhomogeneity, thus ensuring excellent image quality.

The unique DirectConnect technology allows users to connect the 20 coil elements of the BioMatrix Head/Neck 20 without cables. The possibility to tilt the coil in 3 different positions together with the patient friendly open design allows for maximum patient comfort.

#### The BioMatrix Head/Neck 20 features:

- 20-element design with 20 integrated preamplifiers two rings of 8 elements each and one ring with 4 elements in the neck region
- First cable-less tiltable head coil with DirectConnect technology
- Integrated BioMatrix Tuners: CoilShim technology offering integrated shim elements
- Combined head/neck coil for an optimized workflow of the head/neck region
- Upper coil part removable
- Lower coil part usable without upper part
- Smoothly integrated into the patient table with BioMatrix Spine 24
- Open patient-friendly design
- Cushioned head stabilizers (removable)
- No coil tuning
- iPAT-compatible in all directions
- Dual-Density Signal Transfer enables ultrahigh density coil designs by integrating key RF components into the local coil
- Detachable look-out mirror

#### Applications:

- Head examination
- Neck examination
- MR Head Angiography
- MR Neck Angiography
- Combined head / neck examination
- TMJ (temporo mandibular joints)

#### 1 14416952

## Coil Storage Cart #T+D

Specially designed non-ferromagnetic cart for easy storage of the most commonly used coils and accessories.

## 1 14460249

#### UPS system #Vi

UPS system Liebert GXT4 3000RT230E for MAGNETOM Vida for safeguarding computers. Including Power Cable of 9 m for connecting the UPS.

Power output: 3.0 kVA / 2.7 kW

Bridge time: 3 min full load / 12 min half load

Input voltage: 230 VAC

#### 1 14456316

## **UPS Battery module (Libert GXT4 BATT)**



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

#### **PROPOSAL**

UPS battery module Liebert GXT4 72VBATTE for MAGNETOM Aera, Skyra,

Prisma, ESSENZA, Amira, Spectra, C! for safeguarding computers. Extension for: Liebert GXT4 3000RT230E (14456315)

Extension for Liebert GX14 3000K1230E (14430

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 602 x 85 mm

Weight: approx. 46 kg

## 1 14456228 System Start Timer #Vi

Timer clock that can be installed together with the MAGNETOM MR system to start the system automatically at user-definable times, eliminating waiting times during system boot up.

## 1 14461718 BioMatrix Respiratory Sensors#Al,Lu

Respiratory sensors are integrated in the BioMatrix Spine coil and measure the patient's respiratory signal in head-first and feet-first position. The sensor loops measure the change in impedance resulting from the shift of the tissue and organs during the inhaled and exhaled phase of the patient's respiration as soon as the patient is lying on the table.

The BioMatrix Respiratory Sensors can be used to trigger MR sequences based on the respiratory cycles of the patient without the need and workflow impediments of a respiratory belt.

## 1 14468984 Advanced Cardiac incl. PSIR #AI,Lu 1

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.

## MR Workplace Table, height adjust.

The table is suitable for the syngo Acquisition Workplace and the syngo MR Workplace based on syngo hardware.

This 110V version has motorized table height adjustment.

### 14407261 MR Workplace Container, 50cm

50 cm wide extra case for the syngo host computer with sliding front door to allow change of storage media (CD/DVD/USB).

#### 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.

1 MR\_BTL\_INSTA

## MR Standard Rigging & Install

Created: 08/02/2021 17:43:46 P-CPQ-415887-2-1 Siemens Medical Solutions USA, Inc. Unrestricted



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#### **PROPOSAL**

**IXED** 

MR\_PREINST\_F T+D Preinstall kit for fixed table

MR\_CRYO

Standard Cryogens

MR PM

#### **MR Project Management**

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.

MR\_GOBRAIN

#### **GOBrain**

GOBrain delivers reliable quality at exceptional speed. It enables clinically validated, push-button brain exams, with multiple orientations and all relevant contrasts. This fast exam is more tolerable for patients, and helps reduce motion-related artifacts and the need for rescans and sedation. As a result, GOBrain potentially doubles throughput and reduces costs per scan. Supported by our Tim 4G technology and DotGO, it delivers consistently high quality and maximizes the productivity of your MRI scanner - while improving patient care.

4MR5142869

Armrest #MR

SY\_PR\_TEAMP LAY

#### teamplay Welcome & Registration Package

teamplay is a cloud-based network that brings together your imaging modality users, the systems' dose and 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

HASKRISFG230 41

#### Haskris OPC24 Chiller- 63kW

The Haskris outdoor, air-cooled, water/glycol chiller has been specially designed for medical applications to provide stable, fully dedicated cooling to a single MR system.

The Haskris chiller must be used in combination with a Siemens SEP cabinet.

The Haskris chiller is suitable for use in all siting conditions: normal, coastal, lowambient, and/or OSHPD-compliant locations.

Specifications

Cooling Capacity: 63kW

Fluid Supply Temp: 43°F (6°C) to 59°F (15°C)

Pump Capacity: 32 GPM (120 LPM)

Condenser: Air-cooled (heat dissipated into ambient air) Outdoor ambient air temperature: -40°F (-40°C) to 122°F (50°C)

Electrical: 460V-3Ø-60Hz

Dimensions: 77"W x 40"D x 74"H (196cm x 102cm x 188cm)

Siemens' Pricing Also Includes:

Delivery

Chiller Start-Up (Post Installation)

1x Preventative Maintenance Service Visit



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#### **PROPOSAL**

Remote Monitoring Panel with 1-Year Cellular Connectivity and Cloud Service

Installation:

Customer is responsible for the rigging and installation of the chiller. Customer is responsible for providing a 35% solution of propylene glycol with water; 25 gal (95 L) for the chiller plus 1 gal (3.8 L) per 10 ft (3m) external pipe run assuming 1  $\frac{1}{2}$ " pipe diameter.

Warranty:

12 months from date of Start-Up

1 HASKRIS\_STAR TUP Haskris Chiller Start-Up

Chiller start-up by Haskris vendor after installation of chiller and completion of

1 MR\_BUDG\_AD DL\_RIG **Budgetary Add'I/Out of Scope Rigging** 

1 MR\_TRADE\_IN\_ ALLOW MR Trade-in-Allowance Avanto project 2021-0652 (\$81,500)

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

1 MR\_BD\_LV1

#### **Essential Education Level 1 (MR)**

This Essential Education Bundle provides system training in a blended learning environment using training modules (typically 1 hour):

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).

Essential Training Part 1- Up to (28) hours of on-site clinical education training, scheduled consecutively (Monday – Friday) during standard business hours for a maximum of (4) imaging professionals.

Tuition for (1) imaging professional to attend a virtual classroom course for up to 24 hours.

Essential Training Part 2- 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.

Essential Training Part 2- Up to (28) hours of on-site clinical education training, scheduled consecutively (Monday – Friday) during standard business hours for a maximum of (4) imaging professionals.

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

\$1,543,410.00



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#### PRELIMINARY PROPOSAL

**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.

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## **Construction Estimate**

Project Name: Wake Radiology – 3T MRI Upfit Location: 3811 Merton Drive – Raleigh, NC

Date: 7/22/2021

Proposal To: Margaret King – Wake Radiology

3949 Browning Place – Raleigh, NC 27609

## **Schedule of Values**

Trade	Value	
Design & Permits	\$ 26,000.00	
Concrete	\$ 10,000.00	
EIFS	\$ 9,000.00	
Roofing	\$ 3,000.00	
Mechanical	\$ 69,000.00	
Electrical	\$ 50,000.00	
Rough Carpentry	\$ 14,000.00	
Metal Framing & Drywall	\$ 15,000.00	
Shielding	\$ 25,000.00	
General Conditions	\$ 34,000.00	
Subtotal	\$ 255,000.00	
Overhead & Profit	\$ 25,000.00	
Total	\$ 280,000.00	

We propose hereby to furnish material and labor – for the LUMP SUM COST of:

\*\*\* \$280,000.00

<sup>\*\*</sup> Estimate valid through 12/31/21 \*\*

<sup>\*\*\*</sup> Two Hundred Eighty Six Thousand Dollars and 00/100

From: Mitchell, Micheala L

To: Waller, Martha K

Subject: FW: [External] Exemption Request for Replacement Equipment: WR Imaging, LLC (Wake County)

**Date:** Tuesday, August 3, 2021 3:39:03 PM

Attachments: WR Imaging Exemption Request for Replacement Equipment and Temporary Use of Mobile MRI.pdf

Lumina 3T (2) 8-2-21.pdf

CONSTRUCTION ESTIMATE - WAKE RAD - 3T MRI MERTON DRIVE - RLP 7.22.21.pdf

Here you go, Martha.

Thank you!

Micheala Mitchell, JD

NC Department of Health and Human Services

<u>Division of Health Service Regulation</u>

Section Chief, Healthcare Planning and CON Section

809 Ruggles Drive, Edgerton Building

2704 Mail Service Center Raleigh, NC 27699-2704 Office: 919 855 3879

Micheala.Mitchell@dhhs.nc.gov



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**From:** Trevor P. Presler <TPresler@wyrick.com>

Sent: Tuesday, August 3, 2021 3:28 PM

To: Mitchell, Micheala L < Micheala. Mitchell@dhhs.nc.gov>

**Cc:** Frank Kirschbaum < FKirschbaum@wyrick.com>

Subject: [External] Exemption Request for Replacement Equipment: WR Imaging, LLC (Wake County)

**CAUTION:** External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to <a href="Report Spam">Report Spam</a>.

Dear Ms. Mitchell,

On behalf of Frank Kirschbaum, please find attached an exemption request from WR Imaging, LLC for

the acquisition of replacement equipment and temporary use of a mobile MRI scanner in Wake County. If you need any additional information please don't hesitate to contact us.

Sincerely,

Trevor Presler

Trevor P. Presler ATTORNEY

Direct: 919.228.2901 Cell: 919.428.3525 tpresler@wyrick.com Wyrick Robbins Yates & Ponton LLP

4101 Lake Boone Trail, Suite 300 Raleigh, NC 27607 P: 919.781.4000 F: 919.781.4865

www.wyrick.com



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