

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

May 8, 2023

Gary S. Qualls Gary.Qualls@klgates.com

Exempt from Review – Replacement Equipment			
Record #:	4191		
Date of Request:	April 13, 2023		
Business Name:	Carolinas Imaging Services		
Business #:	389		
Project Description:	Replace existing mobile MRI scanner		
County:	Stanly		

Dear Mr. Qualls:

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 GE Signa Voyager 1.5T mobile MRI scanner to replace the GE Signa Excite 1.5T mobile MRI scanner (serial #R6099). 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,

Julie M. Jaenza

Julie M. Faenza Project Analyst

Micheala Mitchell

Micheala Mitchell Chief

cc: Radiation Protection Section, DHSR

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

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

Faenza, Julie M

From:	Qualls, Gary <gary.qualls@klgates.com></gary.qualls@klgates.com>
Sent:	Tuesday, April 25, 2023 2:37 PM
То:	Faenza, Julie M; Mitchell, Micheala L
Subject:	RE: [External] Carolinas Imaging Services – Exemption Notice for Acquisition of
	Replacement Mobile MRI Scanner

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Julie:

Sorry for the confusion. We cited the wrong Project ID number.

The correct Project ID number for this scanner is F-7040-04. The client has informed me that everything else is the same. For example, the client completed the comparison sheet (Exhibit 3) for the right equipment, we just referenced the wrong Project ID number in the letter. Let me know if you need any additional information in order to take action on this.

Thanks

Gary

And proved your shared like of the state of

Gary S. Qualls Partner K&L Gates LLP 430 Davis Drive, Suite 400 Morrisville, NC 27560 Phone: 919-466-1182 Fax: 919-516-2072 gary.qualls@klgates.com www.klgates.com

From: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Sent: Friday, April 21, 2023 3:21 PM
To: Qualls, Gary <Gary.Qualls@klgates.com>; Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>
Subject: RE: [External] Carolinas Imaging Services – Exemption Notice for Acquisition of Replacement Mobile MRI Scanner

Hi Gary – are you sure this is the correct CON for the mobile MRI that is being replaced? That CON was relinquished pursuant to a settlement agreement. I've attached both for your convenience. Can you confirm whether or not the CON listed in the letter is correct or not? Thanks!

Julie M. Faenza, Esq. Pronouns: She/her Project Analyst, Certificate of Need <u>Division of Health Service Regulation</u>, <u>Healthcare Planning and Certificate of Need Section</u> <u>NC Department of Health and Human Services</u> Office: 919-855-3873 Julie.Faenza@dhhs.nc.gov

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Twitter | Facebook | Instagram | YouTube | LinkedIn

From: Qualls, Gary <<u>Gary.Qualls@klgates.com</u>>
 Sent: Thursday, April 13, 2023 1:09 PM
 To: Mitchell, Micheala L <<u>Micheala.Mitchell@dhhs.nc.gov</u>>; Faenza, Julie M <<u>Julie.Faenza@dhhs.nc.gov</u>>
 Subject: [External] Carolinas Imaging Services – Exemption Notice for Acquisition of Replacement Mobile MRI Scanner

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Micheala and Julie:

Please accept this Carolinas Imaging Services – Exemption Notice for Acquisition of Replacement Mobile MRI Scanner for filing. Please confirm receipt for my records.

Thanks

Gary



Gary S. Qualls Partner K&L Gates LLP 430 Davis Drive, Suite 400 Morrisville, NC 27560 Phone: 919-466-1182 Fax: 919-516-2072 gary.qualls@klgates.com www.klgates.com This electronic message contains information from the law firm of K&L Gates LLP. The contents may be privileged and confidential and are intended for the use of the intended addressee(s) only. If you are not an intended addressee, note that any disclosure, copying, distribution, or use of the contents of this message is prohibited. If you have received this e-mail in error, please contact me at Gary.Qualls@klgates.com.-4

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April 13, 2023

Gary S. Qualls Gary.Qualls@klgates.com

T 919-466-1182

<u>Via E-mail Delivery</u> Micheala Mitchell, Chief Julie Faenza, Project Analyst Department of Health and Human Services Division of Health Service Regulation Healthcare Planning and Certificate of Need Section 809 Ruggles Drive Raleigh, North Carolina 27603

RE: Carolinas Imaging Services – Exemption Notice for Acquisition of Replacement Mobile MRI Scanner

Dear Ms. Mitchell and Ms. Faenza:

Our client, Carolinas Imaging Services ("CIS"), seeks to acquire a GE Signa Voyager Mobile MRI Scanner (the "Mobile Scanner" or "Replacement Equipment") to replace the existing mobile MRI Scanner (the "Existing Scanner" or "Existing Equipment"), which was acquired by a Certificate of Need ("CON") identified as Project ID NO. F-6868-03.

The purpose of this letter is to request a determination that CIS's purchase of the Replacement Equipment is exempt from CON review under the replacement equipment exemption provisions contained in N.C. Gen. Stat. 131E-184(a)(7).

Section 184(a)(7) Exemption

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of "replacement equipment," as provided in N.C. Gen. Stat. § 131E-184(a)(7), set forth below:

(a) Except as provided in subsection (b), 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.

The CON Law then defines "replacement equipment," as follows:

"Replacement equipment" means equipment that costs less than three million dollars (\$3,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced

See N.C. Gen. Stat. § 131E-176(22a).

Therefore, to qualify for this exemption:

- 1. the Replacement Equipment must cost less than \$3 Million;
- 2. the Replacement Equipment must be "comparable" to the equipment it replaces, as defined by rule;
- 3. the Existing Equipment must be "currently in use" as defined by rule; and
- 4. the Existing Equipment must be "sold or otherwise disposed of when replaced."

CIS's proposal qualifies for this exemption, as explained below.

I. <u>Cost of the Replacement Equipment</u>

As indicated in the price quotation (Exhibit 1), CIS will pay \$1,222,810.57 to acquire the Replacement Equipment. The Agency historically has not counted mobile coach costs toward the mobile equipment capital costs for CON threshold purposes. However, for completeness, we have conservatively included the costs for the replacement coach, which are \$552,500.00. See Exhibit 2 (Price Quote for Coach).

Thus, the total CON-relevant capital costs to replace the Mobile Scanner are \$1,222,810.57. However, even if one were to conservatively include the coach's costs, the total capital costs would still be only \$1,775,310.57, well below the \$3,000,000 threshold for replacement equipment in N.C. Gen. Stat. § 131E-176(22a).

II. <u>Comparable Equipment</u>

The CON rule codified as 10A N.C.A.C. 14C.0303 (the "Replacement Equipment Rule"), at Subsection (c), defines comparable equipment by defining what is <u>not</u> comparable, as follows:

- (c) Replacement equipment is not "comparable" 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 G.S. 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.

10A N.C.A.C. 14C.0303(c).

A. <u>No New Health Service</u>

CIS intends to use the Replacement Equipment for substantially the same MRI procedures for which CIS currently uses the Existing Equipment. See Exhibit 3 (Comparison Sheet). Although it possesses some expanded capabilities due to technological improvements, the Replacement Equipment is capable of performing substantially the same general range of MRI services as the Existing Equipment. Thus, the Replacement Equipment will not be used to provide a new health service. See 10A N.C.A.C. 14C.0303(c)(1).

B. <u>Temporal Requirement</u>

Moreover, in accordance with Subsection 14C.0303(c)(2) of the Replacement Equipment Rule, the Existing Equipment is much more than a year old, having been acquired in 2006. See Exhibit 3.

III. <u>Currently In Use</u>

The "currently in use" definition in the Replacement Equipment Rule reads as follows:

"Currently in use" means that the equipment to be replaced has been used by the person requesting the exemption at least 10 times to provide a health service during the 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section.

10A N.C.A.C. 14C.0303(b).

The Existing Equipment is "currently in use" in accordance with N.C. Gen. Stat. § 131E-176(22a) and 10A N.C.A.C. 14C.0303(b) because it has been used on a weekly basis for MRI scans over the past year.

IV. **Disposition of Equipment**

CIS will dispose of the Existing Equipment by trading it in for the Replacement Equipment, and will therefore no longer operate the Existing Equipment in North Carolina.

Conclusion

Based on the foregoing information, CIS hereby requests that the Agency provide a written response confirming that the acquisition of the Replacement Equipment described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please do not hesitate to apprise us. We thank you for your consideration of this request.

Sincerely,

Hary S. Qualla Gary S. Qualls

<u>Exhibits</u>

- 1. Price Quotation for Replacement Mobile MRI Scanner
- 2. Price Quotation for Coach
- 3. CON Equipment Comparison Form

Exhibit 1



US Radiology Specialists 4200 Six Forks Rd Ste 1000 Raleigh, NC 27609-2686

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("<u>GE Healthcare</u>"), each as identified below for the sale and purchase of the Products and/or Services identified in this Quotation, together with any applicable schedules referred to herein ("<u>Quotation</u>"). "<u>Agreement</u>" is this Quotation and either: (i) the Governing Agreement identified below; or (ii) if no Governing Agreement is identified, the GE Healthcare Terms and Conditions and Warranties that apply to the Products and/or Services identified in this Quotation. In the event of conflict, the Quotation supersedes.

GE Healthcare can withdraw this Quotation at any time before Customer: (i) signs and returns this Quotation or (ii) provides evidence of Quotation acceptance satisfactory to GE Healthcare ("<u>Quotation Acceptance</u>"). On Quotation Acceptance, this Agreement is the complete and final agreement of the parties relating to the Products and/or Services identified in this Quotation. There is no reliance on any terms other than those expressly stated or incorporated by reference in this Agreement and, except as permitted in this Agreement, no attempt to modify will be binding unless agreed to in writing by the parties. Modifications may result in additional fees and cannot be made without GE Healthcare's prior written consent.

Handwritten or electronic modifications on this Agreement (except an indication of the form of payment, Customer purchase order number and signatures on the signature blocks below) are void.

Governing Agreement:	Vizient Supply LLC
Terms of Delivery	FOB Destination
Billing Terms	80% on Delivery / 20% on Acceptance
Payment Terms	45 Net
Total Quote Net Selling Price	\$1,222,810.57
Sales and Use Tax Exemption	No Certificate on File

-IMPORTANT CUSTOMER ACTIONS:-

Please select your planned source of funds. Source of funds is assumed to be cash unless you choose another option. Once equipment has been shipped, source of funds changes cannot be allowed.

___ Cash

___ GE HFS Loan

___ Other Financing Loan

Provide Finance Company Name

The parties have caused this Agreement to be executed by their authorized representative as of the last signature date below.

__ Other Financing Lease

_ GE HFS Lease

US Radiology Specialists	GE Precision Healthcare LLC, a GE Healthcare business
Signature:	Signature: TARA CHAPMAN
Print Name:	Title: Lead Sales Specialist Imaging
Title:	Date: March 21, 2023
Date:	
Purchase Order Number, if applicable	
	EXHIBIT
	tabbies



To Accept This Quotation

Please sign and return this quotation together with your Purchase Order to:

Name: TARA CHAPMAN

Email tara.chapman@ge.com

Phone: 704-640-2778

Fax:

Name: Scott Ramsey

Email: scott.ramsey@ge.com

Phone: 919-621-1657

Fax: 919-869-1618

US Radiology Specialists

Addresses:

Bill To: US Radiology Specialists

Ship To: US Radiology Specialists

To Accept This Quotation

4200 Six Forks Rd Ste 1000, Raleigh, NC, US, 27609-2686 4200 Six Forks Rd Ste 1000, Raleigh, NC, US, 27609-2686

- Please sign the quote and any included attachments (where requested).
- If requested, please indicate your form of payment.
 - If you include a purchase order, please make sure it references the following information:
 - The correct Quote number and Version number above
 - The correct Remit To information as indicated in "Payment Instructions" above
 - Your correct SHIP TO and BILL TO site name and address
 - The correct Total Price as indicated above

Upon submission of a purchase order in response to this quotation, GE Healthcare requests the following to evidence agreement to contract terms: Signature page on quote filled out with signature and P.O. number **** OR**** Verbiage on the purchase order must state one of the following:

(i)Per the terms of Quotation # _____, (ii) Per the terms of GPO # _____; (iii) Per the terms of MPA# _____: or (iv) Per the terms of SAA #

Payment Instructions

Please **remit** payment for invoices associated with this quotation to:

GE Precision Healthcare LLC P.O. Box 96483 Chicago, IL 60693

FEIN: 83-0849145

Include applicable quote/agreement number with the reference on the purchase order. In addition, Source of Funds (choice of Cash/Third Party Load or GE HFS Lease Loan or Third Party Lease through _____), must be indicated, which may be done on the Quote Signature Page (for signed quotes), or the Purchase Order (where quotes are not signed) or via a separate written source of funds statement (if provided by GE Healthcare)."



Catalog Item Details

Line	Qty.	Catalog	
1	1.00	Y0000LC	Pricing Non-Disclosure Language

This CONFIDENTIAL offer may not be shared with any third parties, buying evaluation groups or anyone not directly employed by customer. This offer is being extended in relation to a national show-site agreement, research partnership, or other non-standard transaction. If required for publishing, GE will happily provide a list price quote.

Line	Qty.	Catalog	
2	1.00	Y0000GD	US Lamboo Medical Mobile Unit powered by SVSR (For tracking purpose only -
			non purchasable catalog)

US Lamboo Medical Mobile Unit powered by SVSR (For tracking purpose only - non purchasable catalog)

Line	Qty.	Catalog	
3	1.00	S7530VF	SIGNA™ Voyager Dockable Table 30.0 Mobile MR System

For a period of 3 years from Equipment Acceptance, GE Healthcare will provide Customer (as part of the Equipment warranty) with the following software changes to the extent they maintain existing software features of the Equipment and are made generally available to GE Healthcare's installed customer base as part of warranty: (i) updates, which consist of error corrections or modifications; (ii) interface modifications; and (iii) security patches that have been validated by GE Healthcare to be compatible with the Equipment. Software upgrades (including revisions or enhancements to (i) the Equipment's software or (ii) separately licensed Software), which improve or expand existing software features and are made generally available for purchase under a separate GE Healthcare license, are excluded. Additional hardware required to implement the software changes are excluded. GE Healthcare remote connectivity to the Equipment is required per GE Healthcare terms and conditions.

The SIGNATM Voyager MR30 1.5T 70cm wide-bore magnetic resonance system was designed to enable you to deliver both clinical excellence and operational efficiency while addressing the cost of ownership for 1.5T wide-bore technology. With SIGNATM Voyager simplify and accelerate the scanning process from set-up to acquisition to post-processing for your technical staff, with access to an extensive range of clinical imaging and advanced visualization capability for your clinicians.

This configuration of SIGNA[™] Voyager MR30 is designed for installation in the mobile environment. The system catalog comprises the magnet, RF-architecture electronics, core RF coil suite, gradient electronics, reconstruction engine and patient table. In addition, the necessary system cabinets, site collectors, installation collectors and calibration phantoms required for installation are part of this system catalog:

- · 1.5T high-homogeneity magnet for the mobile environment
- TDI RF-Receive Technology and RF Coil Suite
- · UHE with IGC Gradient and Quiet Acoustic Reduction Technology
- Reconstruction Engine
- MR 30 for SIGNA[™] ADVANCED APPLICATIONS

TECHNOLOGY FOUNDATION

The magnet, RF-architecture, gradient and computing technology infrastructure on SIGNATM Voyager is designed to deliver the signal-to-noise, dynamic range, spatial resolution, temporal resolution and computational power needed to enable demanding clinical applications.

High-Homogeneity Magnet

The magnet is the foundation of the system, and the high-homogeneity SIGNATM Voyager magnet is designed to provide large field-of-view imaging with uniform image quality. As a result, large anatomy can be imaged with a FOV of up to 50 cm, and off-center anatomy, such as the upper extremity, can be imaged without the need to position the anatomy at the magnet center. In addition, the SIGNATM Voyager magnet delivers the robust fat suppression capability needed for musculoskeletal and body imaging as well as the performance needed for demanding applications such as diffusion imaging and spectroscopy. To address siting and operating costs, the SIGNATM Voyager magnet utilizes active-shielding technology to enable flexible siting, including siting in the mobile environment, and zero-boil technology to address the need for helium refills.



- Patient bore: 70 cm x 70 cm
- Patient aperture: 74 cm
- 2-way in-bore intercom system
- Adjustable in-bore lighting
- Adjustable in-bore ventilation
- Shielding: active
- Shimming: active and passive

Total Digital Imaging (TDI) and RF Coil Suite

SIGNA[™] Voyager MR30 features the Total Digital Imaging RF-architecture with a 33-channel configuration. The TDI RFarchitecture uses a Direct Digital Interface (DDI) to convert the signal from each coil element to a digitized signal (there is no mixing of signal from multiple elements to the same digitizer) to deliver high signal, low noise with extended dynamic range or gray-scale capability.

The SIGNA[™] Voyager coil suite is designed to enhance patient comfort and image quality while simplifying workflow. The suite includes:

- (1) Integrated T/R Body Coil
- (1) TDI Posterior Array
- (1) TDI Head-Neck Unit

The TDI Posterior Array is designed to simplify workflow and enhance efficiency for the technologist. The PA coil is embedded in the patient table and can be used in conjunction with the HNU (included) and the Anterior Array (sold separately). Whole-body imaging and parallel imaging in 3 directions are supported. In addition, the system will automatically select the appropriate subset of coil elements based on the prescribed FOV and is invisible to additional surface coils when they are placed directly on top of the surface.

- Elements: 32
- Length: 120.5 cm; Width: 46.6 cm
- S/I coverage: 113 cm
- Parallel imaging in all three scan planes

The TDI Head and Neck Unit comprises the baseplate and the anatomically optimized Neuro-vascular array and the Open-face array. The superior end of the HNU can be elevated to enhance patient comfort and access. The HNU is designed to be used in conjunction with the TDI Posterior Array and the Anterior Array (sold separately). Parallel imaging in 3 directions is supported.

- · Elements: up to 21 combined with PA
- Length: 53 cm; Width: 35 cm
- Height with NV Array: 35 cm
- Height with Open Array: 25.7 cm
- S/I coverage: up to 32 cm with the NV
- Parallel imaging in all three scan planes

UHE with IGC Gradient Technology and Quiet Technology

SIGNA[™] Voyager introduces the Ultra High Efficiency (UHE) gradient system with Intelligent Gradient Control technology (IGC). IGC gradient driver employs a digital control system that utilizes predictive models of the electrical and thermal characteristics of the gradient coil to maximize performance. As a result, SIGNA[™] Voyager delivers exceptional minimum TR and TE capability while reducing power consumption. The gradient coil and the RF body coil are integrated into a single module which is water and air-cooled for optimum duty-cycle performance and patient comfort. In addition, the gradients are non-resonant and actively shielded to minimize eddy currents to deliver high fidelity, accuracy and reproducibility over a large FOV.

- Peak amplitude per axis: 36 mT/m
- Up to 150 T/m/s instantaneous peak slew rate per axis
- Maximum FOV: 50 cm x 50 cm x 50 cm
- Duty Cycle: 100%

Designed to deliver an enhanced patient experience, SIGNA[™] Voyager features Quiet Acoustic Reduction Technology (ART) that Page 4 of 20 GE Healthcare Confidential and Proprietary



significantly addresses both vibrational noise and airborne sound. Quiet acoustic reduction uses 5 levels of isolation, dampening and gradient optimization technology to mitigate vibration and mute sound.

- Gradient & RF coil isolation isolates the resonance module from the magnet
- · Vibro-acoustic isolation --isolates the magnet from the building
- Mass-damped acoustic barriers further mutes sound
- Gradient waveform optimization user selectable

Reconstruction Engine - Gen7 Dual Intel Xeon Gold 5118

SIGNA[™] Voyager enhances data reconstruction with access to the Orchestra platform and Smart AIR[™] Recon. The Orchestra computing toolbox enables the integration of advanced reconstruction elements to support demanding, data intense, applications as well as access to the reconstruction algorithms. AIR[™] Recon uses a smart reconstruction algorithm that reduces background noise and artifacts enhancing image quality without the need for longer scan times. Smart AIR[™] Recon is available on several key applications.

- Memory: >= 128 GB
- Hard Disk Storage: 960 GB
- 2D FFT/second (256 x 256 Full FOV): 63,000 2DFFT/second

SIGNA[™] Voyager generates MR Image, Secondary Capture, Structured Report, and Gray Scale Softcopy Presentation State DICOM objects. The DICOM networking supports both send and query retrieve as well as send with storage commit to integrate with PACS archive. Please refer to the DICOM Compliance Statement for details.

The SIGNA[™] Voyager MR30 eXpress Patient Table is a crucial part of AIR[™] Workflow. The eXpress table is a mobile patient transport device that houses the TDI Posterior RF Array (described earlier) and touch sensitive AIR[™] Touch land-marking. The fully detachable table is easily docked and undocked by a single operator and moved in and out of the exam room for patient transport and preparation. The eXpress table and embedded PA coil are designed to enable offline (outside the scan room) patient preparation as well as rapid egress when needed.

- Maximum patient weight for scanning: 550 LBS
- Maximum patient weight mobile: 550 LBS
- Maximum patient weight for lift: 550 LBS
- Automated vertical and longitudinal power drive
- Cradle size: 236 cm long x 56 cm wide
- Integrated arm boards & non-ferrous IV pole
- IntelliTouch & laser land-marking
- Laser alignment land-marking

MR 30 for SIGNA™ ADVANCED APPLICATIONS

The MR 30 for SIGNA[™] clinical imaging tools are organized and optimized to address six clinical work areas: NeuroWorks, OrthoWorks, BodyWorks, OncoWorks, CVWorks and PaedWorks. Each clinical toolkit comprises pre-programmed protocols, clinical applications and visualization tools designed for the challenges of each imaging area. In addition, MR 30 for SIGNA[™] provides advanced applications that extend and enhance the clinical capability and performance of the MR 30 toolkits (quoted and described separately).

Advanced Application for NeuroWorks

- · eDWI enhanced diffusion with Multi-B value and SmartNEX
- DTI diffusion tensor imaging
- · FiberTrak post-processing for diffusion tensor to display white matter tracking
- · 3D SWAN 2.0 GRE-based multi-echo susceptibility imaging including phase image
- PROBE PRESS SV brain spectroscopy
- Inhance 2.0 non-contrast MRA suite (3D velocity, 2D inflow, inflow IR, and Deltaflow)

Advanced Applications OrthoWorks

- MAVRIC SL 3D FSE-based spectral imaging for MR-Conditional implants with T1, PD, T2 and STIR
- CartiGram T2 cartilage mapping



Advanced Applications for BodyWorks

- · 3D LAVA GRE 2-point Dixon fat-water separation for dynamic or single-phase imaging (breath-hold or free-breathing)
- IDEAL FSE 3-point Dixon fat-water separation
- · Flex 2-point Dixon fat-water separation for 2D FSE, 3D Cube and GRE
- · Inhance 2.0 non-contrast MRA suite with 3D velocity, 2D inflow, inflow IR and Deltaflow
- StarMap iron assessment for liver and heart (acquisition)

Advanced Applications for OncoWorks

- · eDWI enhanced diffusion with Multi-B value and SmartNEX
- · 3D LAVA GRE 2-point Dixon fat-water separation for dynamic or single-phase imaging (breath-hold or free-breathing)

Advanced Applications for CVWorks

- · Cine IR fast gradient echo with IR-prep pulse
- · 2D MDE IR-prep and gated, fast gradient echo imaging with wide bandwidth suppression and single-shot
- · 2D PS MDE phase sensitive tissue characterization with wide bandwidth suppression and single-shot

In addition, the MR30 for SIGNA[™] upgrade may require additional upgrades based on the upgrade checklist for your specific system. These elements are described and quoted separately, and may include:

• GOC (PC)

Line	Qty.	Catalog	
4	1.00	M70082AE	MR 30 Software for SIGNA™ Voyager

MR 30 for SIGNA[™] delivers the foundational operating software, pulse sequence families, clinical applications toolkits, and visualization toolkits as well as acceleration and motion correction tools. MR 30 for SIGNA[™] software features several new enhancements that improve Exam, Patient Setup and Scanning workflows.

MR 30 for SIGNA[™] is the latest platform software to bring the highest performance to SIGNA[™] MR. MR 30 introduces several base security, workflow and image quality enhancements, as well as enabling GE Healthcare's the latest innovations in Deep Learning Reconstruction*. Each scanner running MR 30 Platform will enjoy industry-leading cybersecurity features* by upgrade to Secure Scientific Linux (SLES 15), enabling the latest features for securing the scanner against bad actors and other threats for years to come. MR 30 software brings in additional workflow efficiency, including a new Window Width/Window Level feature that applies consistent levels across all images in the database; simplified setup for Automatic Phase Correction; an improved phase correction algorithm for LAVA FLEX* images and a Motion Compensation option when using Cardiac T1-Mapping applications such as FIESTA. The system will also now support a system preference to set the orientation of axial Breast images. Systems already equipped with HyperSense* will see the feature expanded to support SWAN and Contrast Enhanced MRA applications. The MR 30 for SIGNA[™] software release brings AIR[™] Recon DL* 3D, motion-insensitive PROPELLER and a host of additional applications such as DTI, FSE Flex, CartiGram, as well as phase sensitive MDE and MoCo MOLLI T1 mapping for cardiac imaging.

(* indicated applications may be purchasable options for certain regions and systems).

The latest enhancements include several key improvements to Exam, Patient Setup and Scanning workflows:

- Split Exam create/assign separate exam number for a sub-set of series
- · AIR™ Recon smart algorithm for brain, MSK, body, cardiac, PROPELLER MB and FOCUS DWI imaging
- Whole-Body automated multi-station localizer and auto pasting
- · Whole-Body automated multi-station FSE-IR, 3D SPGR and DWI imaging
- SnapShot SSFSE multi-slice per breath-hold imaging
- · Cube flexibility for modifying/reducing scan time
- Dynamic phase correction for FSE imaging
- Uniformity optimization for large FOV body diffusion
- · Flexible ZIP allows for flexible resolution by percentage to enhance the sharpness while decreasing the scan time



EXPRESS EXAM WORKFLOW

MR 30 for SIGNATM workflow tools comprise the modality worklist, protocol libraries, workflow manager, auto-functions, inline viewing and inline processing. Together these tools are designed to help change the way you work by simplifying and accelerating the scanning process from set-up to acquisition to post-processing. With MR 30, workflow can begin before the patient enters the magnet room and exams can be completed with a few mouse clicks delivering quality and consistency for all patients and from all technologists. At the same time, MR 30 workflow maintains the flexibility needed to rapidly adapt and optimize exams for specific patient situations.

MR30 Workflow delivers new capabilities that speed set-ups for all exams and streamline scanning for multi-station and combination exams. With MR30 Workflow, scan set-up starts with Modality Worklist, an automated method to obtain patient, exam and protocol information from a DICOM work-list server. For sites with full DICOM connectivity, once a patient has been selected from the Modality Worklist, the In-Room Operator Console will automatically highlight the relevant exam details. The Modality Worklist enables complete control of the MR protocol prescription, but also reduces work by allowing the MR protocol to be selected and linked to the patient record in advance of the patient's arrival.

Protocol Tools enable exam automation while also giving the user complete control of protocols for prescription, saving, searching, and sharing. Protocols are organized in two libraries: GE Optimized (preloaded protocols) and Site Authored (customized and saved). Protocols can be saved based on patient demographics, anatomy, scan type, or identification number for rapid search and selection. Commonly used protocols can be flagged as favorites for quick selection from the Modality Worklist.

In addition to pre-programmed protocols, ProtoCopy enables a complete exam protocol to be shared with the click of a mouse. GE protocols provided with the system include Protocol Notes designed to guide the user through the procedure. For special applications, Protocol Notes also include video guides with step-by-step video-based demonstration and instruction. Protocol Notes can be edited by the user to reflect protocol modifications to aid communication among users.

With the patient positioned, IntelliTouch and AIR Touch[™] together simplify coil selection to one touch and one click. AIR Touch[™] automatically determines coil element locations based on the IntelliTouch landmark and intelligently generates the coil configuration with elements activated to optimize image quality for coverage, uniformity, and parallel imaging acceleration factor.

At the console, the MR 30 WorkFlow Manager implements the selected protocol. The Workflow Manager controls location prescription, acquisition, processing, visualization, and networking, and can fully automate these steps, if requested by the user. Once the target anatomy has been prescribed, the Linking feature can be used to translate appropriate parameters to all subsequent series that have been linked, eliminating the need for further action by the user.

When selected, AutoStart will automatically initiate the localizer, coil selection, series-to-series scanning, multi-station scanning, prescription of scan plans for brain exams, as well as delivered instructions to the patient.

• Pause and Resume allows the user to pause a scan in progress (even in automated mode), to respond to a patient need, and then resume mid-scan without starting the scan over.

• For breath-hold scanning, Auto Protocol Optimization provides automated alternative choices for spatial resolution and breathhold time based on the original protocol. Technologists are liberated from troublesome scan time and image quality adjustments by selecting from pre-calculated options determined by the system.

• Whole Body Localizer automates the acquisition and pasting of multi-station scans for planning, and Whole-Body Imaging enables automated multi-station scanning with FSE-IR, 3D SPGR and DWI diffusion contrasts.

• Once scanning and processing are complete, Split Exam provides the capability to extract a subset of series from multi-station and combination exams to create/assign a separate exam number for accession numbers in billing and PACS systems.

Inline Processing automatically completes post-processing steps for the user after the images have been reconstructed and saved into the database. For certain tasks, such as vascular segmentation, the user must accept the results, or complete additional steps prior to saving the images to the database. These automated processing steps can be saved to the (scan) protocol to ensure consistent output and workflow:

- · Diffusion weighted series: automatic compute and save
- · Diffusion tensor series: automatic compute and save
- eDWI: automatic compute and save
- Image filtering: automatic compute and save
- Maximum/Minimum Intensity Projection: automatic compute and save
- Pasting: automatic compute and save



- Reformat to orthogonal plane: automatic compute and save
- T2 map for cartilage: automatic compute and save
- 3D Volume Viewer: automatic load
- Image Fusion: automatic load
- Interactive Vascular Imaging: automatic load
- FiberTrak: automatic load
- Spectroscopy: automatic load

MR 30 for SIGNA™ TECHNOLOGIES

The acceleration, motion correction and tissue suppression technologies in MR 30 for SIGNATM are designed to address overall workflow, rescans and scan time as well as the impact of challenging patients, challenging anatomy and challenging physiology.

Acceleration Technology

MR 30 for SIGNATM delivers a suite of acceleration techniques designed to help address acquisition time.

• Smart Algorithm AIRTM Recon uses a smart reconstruction algorithm to address background noise and artifacts enabling enhanced image quality without the need for longer scan times and is compatible with critical imaging sequences including PROPELLER MB, 3D Cube, and FSE.

• ARC parallel imaging reduces scan time by using an adaptive auto-calibrating (data-driven) technique to selectively acquire data. As a result, ARC enables smaller FOV prescription with less sensitivity to motion and coil calibration artifacts.

• ASSET parallel imaging reduces scan time using an array spatial sensitivity (image driven) technique. ASSET takes advantage of the data produced by the multiple coil elements to reduce the total data needed to create an image.

• Flexible No Phase Wrap reduces scan time by reducing the number of increments acquired to address wrap-around based on a flexible user-selectable factor.

Fraction NEX reduces scan time by reducing the number of data averages.

Motion Correction Technology

Enable free-breathing body exams and address the effects of motion with patient-adaptive technologies that proactively detect and correct for motion without hardware dependencies or the need for user intervention.

• Auto Body Navigators deliver real-time, respiratory motion compensated imaging for a broad range of sequences, including T1w dynamic contrast-enhanced imaging. Auto Body Navigators use a software-based tracking pulse that is automatically placed for the user and allows on-the-fly adjustment to adapt to challenging patient circumstances, again without the need for hardware.

• PROPELLER MB combines radial acquisition and motion correction post-processing to mitigate the effects of motion without the need to position the patient over a sensor. PROPELLER MB can be used to generate T1, T2, PD, T1 FLAIR, and T2 FLAIR contrasts and is compatible with Auto Body Navigators to enable usage for a broad range of exams. With MR 30 for SIGNATM, PROPELLER MB motion correction benefits from AIRTM Recon smart algorithm image quality.

Tissue Suppression Technology

Modify the contribution of fat or water signal with multiple tissue suppression techniques.

- · FatSat uses a frequency selective pulse to target and suppress the signal from fat
- WaterSat frequency selective water suppression
- STIR inversion pulse fat or water suppression
- SPECIAL frequency selective fat suppression
- ASPIR spectrally selective fat suppression
- Flex 2-point Dixon techniques to separate fat and water signals

MR 30 for SIGNA™ CLINICAL APPLICATIONS

MR 30 for SIGNATM clinical imaging tools are organized and optimized to address six clinical work areas: NeuroWorks, OrthoWorks, BodyWorks, OncoWorks, CVWorks and PaedWorks. Each clinical toolkit comprises pre-programmed protocols, clinical applications and visualization tools designed for the challenges of each imaging area. The resulting capability starts with simplified prescription and protocol set-up. Imaging capability extends to patient management and clinical workflow enhancements. Post-processing capability augments the portfolio with specialized tools designed to speed the review and processing tasks typically performed.



NeuroWorks Toolkit

- READYBrain auto-align for automated brain exam prescription
- · PROPELLER MB motion robust radial-FSE with T1, PD, T2, T2 FLAIR, T1 FLAIR with STIR and ASPIR
- PROPELLER DW Duo FSE-based diffusion with susceptibility reduction
- 3D Cube 2.0 FSE-based imaging with T1, T2, T1 FLAIR, T2 FLAIR and STIR
- 3D Cube Dual Inversion Recovery for gray or white matter nulling
- 3D COSMIC modified steady state imaging
- 2D/3D MERGE T2* multi-echo fast gradient echo imaging
- 3D BRAVO IR prepared fast SPGR imaging with concentric k-space filling
- · 3D MP-RAGE IR prepared fast SPGR imaging with sequential k-space filling
- 3D FIESTA and 3D FIESTA-C fast steady state imaging
- · BrainStat GVF and AIF parametric maps
- READYView and BrainView post-processing which include time series, DWI/ADC maps, DTI, variable echo, BOLD, and spectroscopy (SV, 2D, 3D)

OrthoWorks Toolkit

- · FSE and frFSE fast spin echo imaging suites with dynamic phase correction
- High Bandwidth distortion reduction for FSE
- · FatSat, STIR, SPECIAL, ASPIR, Spectral Spatial fat-suppression tools
- MARS High Bandwidth distortion reduction for FSE
- PROPELLER MB motion robust radial FSE with T1, PD, T2 and Fat Suppression (STIR and ASPIR)
- 3D Cube 2.0 FSE-based imaging with T1, T2, and STIR
- 3D COSMIC modified steady state imaging
- 2D/3D MERGE T2* multi-echo fast gradient echo imaging
- READYView post-processing

BodyWorks Toolkit

- · Auto Navigators diaphragm tracker for free-breathing scanning
- · PROPELLER MB motion robust radial FSE with T1 and Fat Suppression (STIR and ASPIR)
- · 3D Cube FSE-based imaging with T1, T2, and STIR
- 3D Dual Echo gradient echo in/out phase imaging
- 3D LAVA and Turbo LAVA with Turbo ARC and SPECIAL for dynamic or single-phase imaging (breath-hold or free-
- breathing)
- 3D MRCP frFSE imaging
- 2D Fat Sat FIESTA fast steady state imaging
- Enhanced SSFSE Snapshot multi-slice imaging
- Whole-Body multi-station localizer and pasting
- · Whole-Body multi-station FSE-IR, 3D SPGR and DWI imaging
- Multiphase DynaPlan
- SmartPrep automated bolus detection
- · Fluoro Trigger real-time bolus monitoring

OncoWorks Toolkit

- · Auto Navigators diaphragm tracker for free-breathing scanning
- PROPELLER MB motion robust radial-FSE with T1, PD, T2, T2 FLAIR, T1 FLAIR with STIR and ASPIR
- PROPELLER DW Duo FSE-based diffusion imaging with susceptibility reduction
- 3D Cube 2.0 FSE-based imaging with T1, T2, T1 FLAIR, T2 FLAIR and STIR
- 3D Cube Dual Inversion Recovery for gray or while matter nulling
- · 3D BRAVO IR prepared fast SPGR imaging with concentric k-space filling
- · 3D MP-RAGE IR prepared fast SPGR imaging with sequential k-space filling
- Enhanced SSFSE Snapshot multi-slice imaging
- · Whole-Body multi-station localizer and pasting
- · Whole-Body multi-station FSE-IR, 3D SPGR and DWI imaging

• 3D LAVA and Turbo LAVA with Turbo ARC and SPECIAL for dynamic or single-phase imaging (breath-hold or free-

breathing)

• Multiphase DynaPlan



- · SmartPrep automated bolus detection
- · Fluoro Trigger real-time bolus monitoring
- READYView, BrainView and BodyView post-processing

CVWorks Toolkit

- · Auto Navigators diaphragm tracker for free-breathing scanning
- · iDrive for free breathing cardiac planning
- · 2D FIESTA Cine gated steady-state, multi-phase imaging
- 3D FS FIESTA steady-state imaging with Fat Sat
- · 2D/3D Time-Of-Flight & 2D Gated Time-of-Flight
- · 2D/3D Phase Contrast & Phase Contrast Cine
- SmartPrep automated bolus detection
- Fluoro Trigger real-time bolus monitoring
- 3D QuickStep automated multi-station imaging
- READYView post-processing

PaedWorks Toolkit

- · PROPELLER MB motion robust radial-FSE with T1, PD, T2, T2 FLAIR, T1 FLAIR with STIR and ASPIR
- · 3D Cube 2.0 FSE-based imaging with T1, T2, T1 FLAIR, T2 FLAIR and STIR
- · 3D Cube Dual Inversion Recovery for gray or while matter nulling
- 3D COSMIC modified steady state imaging
- 2D/3D MERGE T2* multi-echo fast gradient echo imaging
- · 3D BRAVO IR prepared fast SPGR imaging with concentric k-space filling
- · 3D MP-RAGE IR prepared fast SPGR imaging with sequential k-space filling
- 3D FIESTA and 3D FIESTA-C fast steady state imaging
- · Auto Navigators diaphragm tracker free-breathing scanning

 3D LAVA and Turbo LAVA with Turbo ARC and SPECIAL for dynamic or single-phase imaging (breath-hold or freebreathing)

- · 3D LAVA GRE 2-point Dixon fat-water separation for dynamic or single-phase imaging (breath-hold or free-breathing)
- · Enhanced SSFSE Snapshot multi-slice imaging
- · BrainStat GVF and AIF parametric maps
- READYView and BrainView post-processing

READYView Advanced Visualization

READYView is an MR 30 advanced visualization tool designed to simplify the quantitative analyses of multiple data sets. READYView automatically selects the most relevant post-processing protocol for the user and provides guided workflow and general assistance for the processing algorithms. In addition, the user can customize workflows with adjustable layouts, personalized parameter settings and custom review steps. Key capabilities of READYView include the ability to analyze, export and save:

- Time series
- Diffusion weighted series
- Diffusion tensor series
- Variable echo series
- · Blood oxygen level dependent (BOLD) series fMRI processing
- · Spectroscopy data (single voxel and 2D or 3D CSI)
- MR Touch (MR elastography) series

Line Qty. Catalog 5 1.00 M70024HR SIGNA_LX1.MR30.0 SW eDelivery

Software eDelivery is used to associate the MRI scanner with GE HealthCare's remote software delivery infrastructure. No items are being delivered physically or electronically. (For tracking purpose only – non purchasable catalog)



Line Qty. Catalog 6 1.00 M70072HA SIGNA™ Voyager MR30 GOC

Computing Platform

The MR30 upgrade takes SIGNA[™] to the latest computing performance level that utilizes a parallel, multi-processor design to enable simultaneous scanning, reconstruction, filming, post-processing, archiving and networking. The host computer uses the SuSe Linux Enterprise Server operating system and a single tower configuration. (The reconstruction engine is sold separately and offers a choice of performance levels.)

Host PC Platform - Intel Xeon W-2123 CPU

- Memory: 64 GB
- Hard Disk Storage: 1024 GB SSD
- · Media Drives: CD/DVD

Line Otv. Catalog 1.00 M70072AR SIGNA Voyager 33 to 49 Channel Upgrade SIGNA Voyager 33 to 49 Channel Upgrade Line Qty. Catalog 1.00 M70012TS 8 Voyager Scan Room Collector - Long The Long Scan Room Collector contains a collection of cables such as gradient cables and other materials necessary for system interconnections. The long configuration is designed for room configurations that require a long length based on distance between system components. Line Otv. Catalog M70012RP **English Language Kit** 9 1.00 English Language Kit Line Qty. Catalog 10 1.00 R33012AC **Standard Service License** The Standard Service License provides access to service tools used to perform basic level service on the Equipment and is included at no charge for the warranty period. Line Catalog Qty. 11 S7530RD 1.00 AIR™ Recon DL 2D and 3D and AIRx™ Package Comprehensive AIR™ Recon DL package for 70cm 1.5T MR Systems

AIRTM Recon DL is a pioneering, deep-learning based reconstruction algorithm that improves SNR and sharpness of 2D, DWI, PROPELLER and 3D images. This propriety technique improves image quality at the foundational level by removing image noise and ringing artifacts while enabling shorter scan times. With AIRTM Recon DL, customers will be able to:

- · Increase productivity by enabling shorter scan times
- · Remove noise in the images through trained deep learning algorithms.
- · Eliminate Gibbs and truncation artifacts with intelligent ringing suppression
- Delivers sharper, clearer, beautiful MR images
- Apply a tailored level of AIR[™] Recon DL based on preference
- Enable the most commonly applied 2D, DWI, PROPELLER and 3D sequences without anatomical limitations
- Visualize AIRTM Recon DL images directly at the MR console without reconstruction delays



AIR xTM Auto Graphic Prescription package

AIR x[™] Auto Graphic Prescription replaces traditional atlas-based methods with deep learning algorithms to automatically identify anatomical structures and prescribe slices locations for brain and knee exams. As a result of the deep learning algorithms, AIR x[™] automatically adapts slice prescriptions for normal patient variants in various patient anatomies and structures to enable consistency and productivity for slice positioning from technologist to technologist, patient to patient and the same patient overtime. The AIR x[™] Auto Graphic Prescription package provides solutions for two high-volume exams, brain, and knee.

- AIR x[™] auto graphic slice prescription for brain exams
- AIR x[™] auto graphic slice prescription for knee exams

NOTE: This Application bundle is only available for SIGNA[™] Artist and Voyager systems when sold with MR30 Application software.

Line	Qty.	Catalog	
12	1.00	S7529SB	DIFFUSION

The Diffusion toolkit delivers capabilities that reduce distortion, correct for motion and increase spatial resolution and sensitivity for diffusion and diffusion tensor imaging.

- · PROGRES distortion and motion correction for diffusion
- MUSE multi-shot high-resolution diffusion
- FOCUS DWI 2D slice-selective high-resolution diffusion
- MAGiC DWI diffusion-based synthetic multiple b-value imaging

PROGRES combines with diffusion and diffusion tensor sequences to enhance performance by using a reverse polarity technique to address distortion and correct for motion. The technique then outputs images with reduced susceptibility artifacts with no significant impact in overall scan time.

For high resolution diffusion the toolkit provides two techniques. MUSE DWI uses a multi-shot technique, and can be combined with PROGRES, to deliver high resolution with reduced distortion. PROGRES is compatible with Auto Body Navigators, ASSET acceleration, FatSat and STIR. FOCUS enables high spatial resolution for small organ-specific fields-of-view. FOCUS DWI uses 2D slice selective excitation pulses to constrain/reduce the phase FOV and address artifacts from motion and unsuppressed tissue outside the FOV.

MAGiC DWI generates multiple synthetic b-values from one scan and allows the modification of b-values in real time without further scanning. As a result, higher diffusion values can be achieved in shorter scan times without stressing protocol parameters or sacrificing contrast or anatomy coverage. MAGiC DWI can be combined with the full range of diffusion sequences.

Line	Qty.	Catalog	
13	1.00	M7005DH	MAGIC 1.5T

MAGiC enables one-and-done imaging capability by delivering six different contrasts in a single scan. MAGiC utilizes a multidelay multi-echo acquisition. The data acquired is processed using a novel technique to generate T1, T2, T1FLAIR, T2FLAIR, PD, and STIR weighted images, all at once in as little as one-third the time taken to acquire all six contrasts using separate sequences. MAGiC generates all the different contrasts from the same scan, and the images have perfect registration due to no change in the anatomy being imaged from patient movement between scans.

MAGiC expands the potential to acquire more advanced sequences such as spectroscopy, susceptibility weighted imaging (each sold separately) etc., in the time it took to perform just the routine exam.

MAGiC gives the user the ability to change the contrast of images after the acquisition. This is performed by adjusting the TR, TE, and/or TI parameters post-acquisition to generate the specific contrast desired. The range of contrasts that can be generated include IR REAL, PSIR in addition to the aforementioned six contrasts.

MAGiC also enables users to generate quantitative T1, T2, R1, R2, and PD maps for further analysis of MRI scan data.



14	1.00	M7006NA	1 5T 16 abannel AID Antonian Annan
14	1.00	IVI / UUDINA	1.5T 16-channel AIR Anterior Array

The 16-channel AIR Anterior Array (AA) is the next generation anterior array coil that allows flexibility in any direction to conform to the patient's anatomy. Based on the innovative AIRTM Coil technologies, the 1.5T 16ch AIR AA provides excellent image quality and acceleration performance, while improving the overall patient and user experience. The coil has been designed to adapt to various patient shapes and sizes, expanding positioning versatility.

Line	Qty.	Catalog	
15	1.00	S7529QT	1.5T AIR™ MP Arrays and 16CH T/R Knee

This promotional coil package comprises:

- Large and Medium Multi-Purpose AIR[™] Coils with coil positioner kit
- 16ch T/R Knee Array

The 21-channel 1.5T AIRTM MP Large and the 20-channel 1.5T AIRTM MP Medium Arrays utilize innovative AIRTM Coil technologies to expand positioning versatility, enhance patient and user experience, and deliver high performance acceleration and image quality.

These next generation multipurpose coils are designed to conform to various patient shapes and sizes and allow positioning in any direction. AIRTM MP Coil Large Array is recommended for use for Shoulder, Knee, Foot, Ankle, Hip, and Prostate imaging, and the AIRTM MP Coil Medium is recommended for Wrist, Elbow, and Cardiac Imaging.

The AIR[™] MP Coil Positioner Kit provides a knee positioner, a foot-ankle positioner, a wedge pad, a U-shaped pad, and a strap kit. The Positioner Kit is compatible with both AIR[™] MP Large and Medium Coils for positioning.

The 16-channel 1.5T Knee coil is a transmit/receive phased array design optimized for high resolution imaging of the knee with parallel imaging acceleration in 3 directions to address acquisition time. The coil is sized to accommodate a broad range of patient sizes and features a two-part design to address workflow. Offset imaging is fully supported with adjustable left-right coil positioning.

Line	Qty.	Catalog	
16	1.00	E8800XA	NeoCoil Sentinel G1 Wireless Music System for MRI Systems

The NeoCoil Wireless Audio/Music system provides audio entertainment and facilitates communications between the patient and technologist. Wireless solution eliminates multiple cords and standard 3.5mm audio jack allows any compatible music source. Integrates audio entertainment, the technologist's voice, and AutoVoice for optimum patient communication

MR Conditional wireless audio system for use with high field MRI up to 3.0T

Dramatically attenuates gradient noise

When the technologist uses the intercom or when the feature AutoVoice is used, the music is interrupted for clear communication Wireless solution operates on 3 batteries

Package includes:

Wireless 29dB headphones (over-ear)...uses 2 battery packs

Wireless airtube/earbud assembly (in-ear)...uses 1 battery pack

Disposable 29dB earbud inserts, 125 pair (250/box)

Battery charging dock (can wall mount or desk; charges up to 4 batteries in under 6 hours)

Audio cable, 3.5mm

(3) Individual Li-Po 3.7V Battery Packs (rated for 12 hours continuous use)

Transmitter and console interface - wall-mounted transmitter including couplers for penetration panel (2.4 GHz ISM band) Audio Source - Amazon® Fire® tablet, tablet stand, tablet lock, and (2) speakers

GE MRI compatibility:

Compatible with all MRI systems including Creator/Explorer v25.3 and Pioneer hardware v26.1



Line	Qty.	Catalog	
17	1.00	E8800XH	Neocoil Individual battery packNeoCoil Individual Li-Po 3.7V Battery Pack for Sentinel G1
•	Removable b	pattery pack for u	se with NeoCoil wireless system
•	Rechargeabl	e Li-Po 3.7 V	
•	1000 mAh		
•	12 hours of c	continuous use	
•	Complete sy	stem (E8800XA	and E8800XK) already includes this item
•	Expected life	e of approximate	ly 1 year

Line	Qty.	Catalog	
18	1.00	E8822JB	Sanitary Covers for Headset - 1000/Box

Sanitary covers for audio headsets. Packaged 1000 units per box.

Line	Qty.	Catalog	
19	1.00	E88221XA	Medrad MRXperion injector on pedestal mount

The Medrad® MRXperion[™] MR Injection System is a smart performer in the MR suite, delivering contrast fluid and data management.

Streamlined Injection Workflow

- · Less time preparing for the injection and more
- · time to focus on the patient and optimize
- procedure management.

Convenience at Point of Care

- On-board eGFR and Weight Based Dosing
- · Calculators, an Injection Pressure Graph,
- · Independent Test Inject and KVO functions.

Real-time Support

- · Connect to VirtualCare® Remote Support* for
- · advanced injector system diagnostics, seamless

Improved Efficiencies

- · Snap-on/Twist-off Syringe Design
- · Auto plunger advance and retract when attaching and detaching syringes
- Automatic filling and priming
- · Injection/post-injection reminders
- · Injection pressure graph

Reproducible Quality

- · Proven track record of design and performance
- · On-site field service and VirtualCare® Remote Support* for advanced injection system diagnostics and real-time support

Personalized Care

- · Patient-Centric workflow design
- Protocol storage/retrieval
- · On-board eGFR and Weight Based Dosing Calculators
- · Injection enabled when head is tilted down

The MRXperion[™] Injector package includes:

- · Dual injector head on pedestal with integral double hook IV pole
- Scan room unit power supply with 40 ft. (12 m) DC cable



- Scan room fiber optic cable 40 ft. (12 m)
- Control room fiber optic cable 150 ft. (45 m)
- Fiber optic quick disconnect panel
- · Fiber optic penetration panel kit
- · Control room unit (display and pod) with hand-switch
- Display and pod power supplies
- CAT5 cable (display to pod) 1 ft. (0.3m)
- CAT5 cable (pod to hospital network) 25 ft. (7.6m)
- Power cords North America and Japan (3 each), 10 ft. (3 m)
- Power cords International (3 each), 10 ft. (3 m)
- Operators manual (English)
- Multi-lingual Operators manual CD
- · Quick guides (English) for injector and hanger
- Installation manual (English)
- · Service manual and schematics manual CDs (English)
- · Warranty packet
- Installation, customer's operational training at time of installation, and one year full on-site warranty in Bayer service countries
- LAN port for VirtualCare Remote Service

An optional penetration panel filter kit E88221XC is intended to be used for an alternate installation of the power supply of the MEDRAD® MRXperion[™] Injection System outside of a MR scan room.

System Specifications

System Capabilities

- Syringe Capacities:
- Syringe A: 65ml
- Syringe B: 115ml
- Programmable volume range (ml):
- Syringe A: 0.5 ml to max syringe volume in 0.1 ml increments from 0.5 ml to 31 ml, 1ml increments above 31 ml
- Syringe B: 1 ml to max syringe volume in 1 ml increments
- Programmable flow rate range (ml/sec)
- 0.01 to 10 ml/s in 0.01 ml/s increments between 0.01 and 3.1 ml/s
- 0.1 ml/s increments between 3.1 and 10 ml/s
- KVO (Keep Vein Open): 6 factory presets of 0.25 ml every 15, 20, 30, 45, 60 or 75 sec
- Test Inject: configurable from 0.5 ml to 20 ml in 0.1 ml increments
- Pressure range (psi): 6 factory presets from 100 to 325 PSI (690 to 2240 kPa)
- Injection / Post Injection Reminders: up to 5 settings of 1 sec to 20 minutes in 1 sec increments
- Injection protocol storage: 60 protocols up to 6 phases each
- · Injection Hold / Pause: up to 20 minutes in 1 sec increments
- eGFR Calculator
- · For adults: MDRD, Cockroft-Gault, Modified Cockroft-Gault and CKD-EPI methods
- · For children: Bedside Schwartz method
- Weight Based Dosing Calculator: user Configurable
- Remote Service Capability: with optional VirtualCare Remote Support

Dimensions and Weight

- **Control Room Unit**
- 15.58" (39.58 cm) W
- 12.71" (32.28 cm) H
- 10.23" (25.98 cm) D
- 17.6 lbs (8.0 kg)

Scan Room Unit

- 23.30" (59.0 cm) W
- 71.40" (181.0 cm) H
- 23.30" (59.0 cm) D
- 95.7 lbs (43.4 kg)

Power Supply • 7.60" (19.0 cm) W

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GE Healthcare

- 3.40" (9.0 cm) H
- 15.40" (39.0 cm) D
- 5 lbs (2.3 kg)

Electrical

- Voltage Requirements
- 100-240 VAC
- 50/60 Hz
- 120VA 210VA

March 21, 2023

Quote Number: 2009889416.3

Agreement Expiration Date: 03/31/2023

Customer ID: U-00593777

Line	Qty.	Catalog	
20	1.00	E88221XC	Penetration Panel for MEDRAD MRXperion injector
The penet	tration panel t	filter kit is intende	ed to be used for an alternate installation of the power supply of the MEDRAD®
MRXperi	on™ Injectio	n System outside	of a MR scan room.
Penetratio	on panel filter	kit option includ	les:
· Filter as	sembly		
 Mountir 	ng/centering r	ing	
 Mountir 	ng screws	-	
Conduct	tive O-ring (p	re-installed on th	e filter)

- Power supply cable 10 ft. (3 m)
- · Installation instructions

Line	Qty.	Catalog	
21	1.00	E80141HG	Medrad Mobile Mount Support for Stellant D and Flex and MRXperion

Overview

The Mobile Mount support is compatible with the MEDRAD Stellant D, MEDRAD Stellant FLEX, and the MEDRAD MRXperion injection systems.

Line	Qty.	Catalog	and a start of the second s
22	1.00	W0301MR	TIP MR 1.5T Training Program

This training program is designed for customers purchasing a GEHC 1.5T MR system. GEHC will work with the designated Customer contact to agree upon a reasonable training schedule for a pre-defined group of core technologists that will leverage blended content delivery and may include a combination of onsite days and virtual offerings, to include TiP Virtual Assist, the GEHC Answerline and available on-demand courses ("Virtual Inclusions"). This blended curriculum with multiple delivery platforms promotes learner retention and allows for an efficient and effective skill development.

This program may contain:

- · Onsite training (generally 12 days)
- · Virtual Inclusions may include:
- · Remote instructor-led training: Instructor leads a remote training session one-on-one or in a group, typically for 1 hour
- Answerline Support-Access to GEHC experts for clinical, non-emergency applications assistance via phone or by using the iLinq button on the imaging console
- Tip Virtual Assist-Direct interactive access to a GEHC expert for enhanced support.
- On Demand courses-On healthcare learning system. Self-paced courses and webinars (CE and non-CE).

Training will be delivered at a mutually agreed upon time between the customer and GE Healthcare (excluding GE Healthcare holidays and weekends), are subject to availability and generally will not exceed 15 days. This training program has a term of



twelve (12) months commencing on Acceptance, where all onsite training must be scheduled and completed within twelve (12) months of Acceptance and all Virtual Inclusions also expire at the end of such twelve (12) month period. Additional onsite days may be available for purchase separately.

All GEHC "Training" terms and conditions apply. Given the unique nature of this program, if this program is purchased as part of a purchase under a Governing Agreement, including any Master Purchase Agreement, Group Purchasing Organization Agreement, or Strategic Alliance Agreement, this program shall take precedence over any conflicting training deliverables set forth therein.

Line	Qty.	Catalog	
23	4.00	W0330MR	TIP DAY OF APPLICATIONS TRAINING

A single day of applications training delivered at customer's site for any GE Healthcare Diagnostic Imaging system. Training will be delivered at a mutually agreed upon time between the customer and GE Healthcare (excluding GE Healthcare holidays), and are subject to availability. Training must be completed within 12 months from purchase.

Line	Qty.	Catalog	
24	2.00	M70072AR	SIGNA Voyager 33 to 49 Channel Upgrade

SIGNA Voyager 33 to 49 Channel Upgrade

Line	Qty.	Catalog	
25	8.00	W0330MR	TIP DAY OF APPLICATIONS TRAINING

A single day of applications training delivered at customer's site for any GE Healthcare Diagnostic Imaging system. Training will be delivered at a mutually agreed upon time between the customer and GE Healthcare (excluding GE Healthcare holidays), and are subject to availability. Training must be completed within 12 months from purchase.

Line	Qty.	Catalog	
26	1.00	SV_MR_E XT_WARR	6 Months Additional Warranty \$64,976
Service Ex	ktended War	ranty Comments	

Total Quote Net Selling Price: \$1,

\$1,222,810.57

If applicable, for more information on this devices' operating system, please visit GE Healthcare's product security portal at: <u>https://securityupdate.gehealthcare.com/en/products</u>



Optional Items Please initial the Catalogs you wish to purchase

Catalog Number	Qty.	Description	Net Price Initial
S7529HS	1.00	HyperSense 2.0 Package	\$54,050.00
		HyperSense 2.0 package is GE's compressed sensing application providing scan time reduction technique while maintaining SNR through an interative reconstruction algorithm. This application can deliver higher spatial resolution images or reduced scan times, enabling faster imaging without the penalties commonly found with conventional parallel imaging.	
		HyperSense has been expanded to include T1 acquisitions including MP-RAGE & BRAVO for neuro imaging and LAVA, LAVA-Flex, DISCO and DISCO-Flex for body applications, and Vibrant for breast applications. In addition, HyperSense is now compatible with other 3D gradient echo sequences, such as MERGE, FIESTA and COSMIC.	
Catalog Number	Qty.	Description	Net Price Initial
S7529DT	1.00	DISCO Trio	\$47,000.00
		DISCO makes critical scans achievable by driving speed and performance without sacrificing spatial resolution on dynamic T1 imaging. DISCO is commonly used in liver, prostate, and breast imaging, and lets you choose your fat suppression (fat sat, LAVA, LAVA Flex, or none), your breathing options (Auto navigated or breath hold), and how you review it (source images or reformatted as an MRA). It provides highly accelerated, LAVA based volumetric imaging for high resolution 3D volumetric results without compromising temporal imaging performance and delivering 1.5mm isotropic results of whole organ coverage in as low as 3 seconds per phase. DISCO Star and LAVA Star (Stack-of-stars) provides a better patient experience when it comes to abdominal MR imaging. Patients with limited breath-hold capability or are unable to follow breathing commands now have the option of a complete, free-breathing dynamic or single phase abdominal imaging that's independent of the patient. DISCO Star and LAVA Star provide image reconstruction in seconds without the need of any extra hardware for processing, so it doesn't disrupt the technologist's workflow. With simple, push button dynamic imaging, technologists can overcome timing challenges for dynamic imaging and avoid repeat scans due to motion artifacts or timing issues. DISCO Star is a motion robust, free-breathing 3D radial (stack of stars) scan acquired in one continuous dynamic arterial phase to drive worry-free, consistent image quality regardless of the patient's condition. DISCO Star employs radial in-plane trajectory to provide active motion compensation without navigators or bellows. Not only can DISCO Star compensate for breathing artifacts, but also swallowing, bowel motion and other sources of motion artifacts for dynamic scans. The offering also includes LAVA Star, which provides the same motion robust, free-breathing scan for single phase (pre-contrast or delayed) imaging. Like DISCO Star, LAVA Star also employs radial in-plane trajectory to provide active motion compe	





GPO Agreement Reference Information

Customer:	US Radiology Specialists
Contract Number:	Vizient Supply LLC
Billing Terms:	80% on Delivery / 20% on Acceptance
Payment Terms:	45 Net
Shipping Terms	FOB DESTINATION

Offer subject to the Terms and Conditions of the applicable Group Purchasing Agreements currently in effect between GE Healthcare and Vizient Supply LLC

If applicable, for more information on this devices' operating system, please visit GE Healthcare's product security portal at: <u>https://securityupdate.gehealthcare.com/en/products</u>

Exhibit 2



Custom Specialty Solutions

An ISO9001:2015 Certified Company



Project Proposal TB-23-1128-R1

EFFECTIVE DATE: March 21, 2023

PURCHASER:Charlotte Radiology2614 E. 7th St. Charlotte, NC 28204ATTN: Steven Downey

- SELLER: AMST a Kentucky Trailer company Tom Biwan – Sr. Director of Sales Email: <u>tbiwan@kytrailer.com</u>
- TYPE OF UNIT:New Mobile Unit configured to the specifications for the GE
SIGNA Voyager 1.5T Wide Bore MRI System.

Vehicle shall conform in every way to the specifications attached hereto as scope of work and incorporated herein with Purchaser provided (description of items provided by the purchaser) equipment.

PRICE: F.O.B. University Park, IL.	\$ 569,000.00
Less CON Competitive Situation Discount	(20,00.00.00)
Total Vehicle Price after Discount:	\$ 549,000.00

• Not including Purchaser authorized change orders, and/or taxes.

STATUATORY AND REGULATORY REQUIREMENTS:

• It is the responsibility of the purchaser to understand all compliance and code regulations that may govern this vehicle at the sites in which it will operate.

Available Options Not Included Above: (Please check off selected options):

• FGI Support Option package as outlined in Appendix C:

	 Fire Detection Option: 	\$	41,900.00
	 Fire Suppression Option: 	\$	68,400.00
	 This is one or the other, not both. 		
0	Intertek 3rd party ETL/FGI Inspection	\$	14,500.00
0	 Code Blue Button 		1,000.00
0	Nurses Call Button		1,000.00
0	Prep for patient injector	\$	1,500.00



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0	16" wide x 30" tall window in Gaven Scan Room Door \$ 5,000.00		
0	Wave guide pass through in scan room wall \$ 1,200.00		
0	42" wide stair with handrails on both sides of the stair \$ 1,500.00		
0	Combination Keyless Locking Mechanism for main entry door \$ 3,808.00		
0	Oversize Patient Lift 72"x94" +12" threshold	\$	5,000.00
0	Sky Factory ceiling lighting system (installed)		
	 (6) 2'x2' panels for 6' x 4' layout 	\$	10,569.00
0	Wall Mural in scan room	\$	3,000.00
0	Fire Detection System	\$	3,724.00
0	Fire Suppression System	\$	26,500.00
0	Extra technologist lift pendent	\$	378.00
0	Extra driver lift pendent \$ 416.00		
0	PE Stamped Drawings for regulatory approval \$ 3,000.00		
0	Thermal curtain package for extreme weather operation \$ 4,905.00		
0	Removable patient bench behind curtain at front of control room \$ 1,500.00		
0	Sink portable or direct connect in control room	\$	3,800.00
0	Patient Gurney (Non Ferrous) Ferno 30NM	\$	11,365.00
	 22" wide x 76" long x 32" tall (400lb load limit) 		
0	Entry Stair Platform with hand rails on both sides	\$	4,800.00
	 Stairs can run perpendicular or parallel forward to mobile u 	unit	
	 Stair is narrower than door so handrail is offset from bottor 	n to	top
0	External Customer Graphics	\$	TBD
	 We have this capability call for details 		
0	 Emergency Heating System \$ 10,645.0 		
0	 Transportation to site \$ TBD 		
0	Extended Warranty and Preventative Maintenance Service Contra	act	
	 Please see Addendum A: Warranty Extension and Mainter for details. 	nanc	e Program



 Pricing for Year 1 during initial 12-month warranty 	\$ 15,750.00
 Pricing for Year 2: 	\$ 36,000.00
 Pricing for Year 3 	\$ 36,000.00
 Pricing for Year 4 	\$ 36,000.00
 Pricing for Year 5: 	\$ 36,000.00
Total Price for Full 5-Year Warranty and PM Service:	\$159,750.00

o Preventative Maintenance Agreement only

o Please see Addendum B: Preventative Maintenance Agreement for details

 Pricing for Year 1 during initial 12-month warranty 	\$ 15,750.00
 Pricing for Year 2 	\$ 15,750.00
 Pricing for Year 3 	\$ 15,750.00
 Pricing for Year 4 	\$ 15,750.00
 Pricing for Year 5 	\$ 15,750.00
Total Price for 5-Year Preventative Maintenance Agreement:	\$ 78,750.00

VALIDITY:

- This quote is valid for 60 days from effective date.
- Please request updated quote after this quote expires. Do not assume that the price will be honored beyond the expiration date.

PAYMENT TERMS:

- 50% down payment deposit
- 50% due at acceptance at AMST Facility prior to shipment
- Note: AMST will not release the MSO (Manufacturer's certificate of origin) until we have received payment in full for the vehicle.

CHANGE ORDERS:

• This Agreement is a fixed price contract and change orders, as well as any other changes to the terms of this Agreement, if any, shall be approved in writing in advance and require signatures by both parties prior to execution of such changes.

WARRANTY AND POST DELIVERY OBLIGATIONS:

• (12) Months on workmanship and paint. See warranty statement for details



a Kentucky Trailer company

AMST 611 Commerce Center Drive University Park, IL 60484 (708) 235-2800 main number (708) 235-2002 fax

OWNERSHIP OF DOCUMENTS:

 All design and production documents shall remain the property of Seller and may not be duplicated, copied or reproduced in any form without the prior written consent of Seller in advance. Documents may be copied and distributed for Purchaser internal company use only.

TAXES, TITLE AND TRANSPORTATION:

• The Purchase Price for the vehicle and the services related thereto does not include any sales or similar taxes or levies and Purchaser accepts responsibility for said expenses, including vehicle registration.

PRODUCTION TIMELINE:

 Will be conveyed by OEM once purchase agreements have been executed with both OEM and AMST.

ASSIGNMENT:

• Neither party hereto may assign this Agreement or any rights nor obligations arising out of this Agreement to a third party without the prior written consent of the other party.

WAIVER:

• No delay or failure by either party hereto to exercise any right under this Agreement, and no partial or single exercise of that right shall constitute a waiver of fact or any other right, unless otherwise expressly provided herein.

INSPECTION PRIOR TO SHIPMENT:

 At the Purchasers discretion a representative of the Purchaser will be responsible to inspect the vehicle at 611 Commerce Center Drive University Park, IL prior to shipment. If Purchaser chooses not to inspect at our facility unit will be deemed to be accepted upon completion and preparation for shipment.

MISCELLANEOUS:

 This Agreement represents the entire agreement between the parties hereto in respect to its subject matter and supersedes all previous arrangements, understandings and discussions. Any part of this Agreement which conflicts with applicable law now in effect or which may be enacted in the future, shall be null and void, but only to the extent of such conflict, and all other parts of this agreement shall remain in full force and effect. Paragraph headings are used for identification purposes only and are not intended to limit the content thereof.



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IF THIS AGREEMENT IS TERMINATED UNLESS DONE IN ACCORDANCE WITH THIS AGREEMENT, AFTER DEPOSIT HAS BEEN MADE, PURCHASER WILL FORFEIT ITS DEPOSIT, WITHOUT FURTHER LIABILITY OR PENALTY TO SELLER.

In witness whereof, Seller and Purchaser have executed this Agreement as of the day and year first set forth above as the "Effective Date".

AMST a Kentucky Trailer company	
Signature	Date
Charlotte Radiology Signature:	Date
	Signature

Exhibit 3

EQUIPMENT COMPARISON

	EXISTING	REPLACEMENT
	EQUIPMENT	EQUIPMENT
Type of Equipment (List Each Component)	1.5 MRI	1.5 MRI
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	1.5 Tesla	1.5 Tesla
Model Number	Signa Excite	Signa Voyager
Serial Number	R6099	
Provider's Method of Identifying Equipment	CIS Mobile MRI	CIS Mobile MRI
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	2M592146571109010	
Mobile Tractor Serial Number/VIN #	N/A We use a service	
Date of Acquisition of Each Component	2006	
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	
Specify if Equipment Was/Is New or Used When Acquired	New	
Total Capital Cost of Project (Including Construction, etc.) < Use Attached Form>	NA	\$
Total Cost of Equipment	2.52M	\$
Fair Market Value of Equipment	NA	\$
Net Purchase Price of Equipment	NA	\$
Locations Where Operated	Anson, Wadesboro, West	Anson, Wadesboro, West
	Stanley	Stanley, Charlotte
Number Days In Use/To be Used in N.C. Per Year	3	5
Percent of Change in Patient Charges (by Procedure)	NA	4%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	1%
Type of Procedures Currently Performed on Existing Equipment	All MRI and MRA	NA
	procedures excluding	
	Cardiac and Breast	
Type of Procedures New Equipment is Capable of Performing	NA	All MRI and MRA
		procedures excluding
		Cardiac and Breast

	EXHIBIT	
tabbles'	3	

From:	Mitchell, Micheala L
То:	<u>Stancil, Tiffany C</u>
Cc:	Faenza, Julie M
Subject:	FW: [External] Carolinas Imaging Services – Exemption Notice for Acquisition of Replacement Mobile MRI Scanner
Date:	Thursday, April 13, 2023 2:24:18 PM
Attachments:	20230413 Via E-mail Delivery Micheala Mitchell, Chief Julie Faen.pdf

Hi Tiffany,

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

Thanks,

Micheala Mitchell, JD <u>NC Department of Health and Human Services</u> <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 <u>Micheala.Mitchell@dhhs.nc.gov</u>

Don't wait to vaccinate. Find a COVID-19 vaccine location near you at MySpot.nc.gov. Twitter | Facebook | Instagram | YouTube | LinkedIn

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From: Qualls, Gary <Gary.Qualls@klgates.com>

Sent: Thursday, April 13, 2023 1:09 PM

To: Mitchell, Micheala L < Micheala.Mitchell@dhhs.nc.gov>; Faenza, Julie M

<Julie.Faenza@dhhs.nc.gov>

Subject: [External] Carolinas Imaging Services – Exemption Notice for Acquisition of Replacement Mobile MRI Scanner

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

Micheala and Julie:

Please accept this Carolinas Imaging Services – Exemption Notice for Acquisition of Replacement Mobile MRI Scanner for filing. Please confirm receipt for my records.

Thanks

Gary



Gary S. Qualls Partner K&L Gates LLP 430 Davis Drive, Suite 400 Morrisville, NC 27560 Phone: 919-466-1182 Fax: 919-516-2072 gary.qualls@klgates.com www.klgates.com

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