

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

### VIA EMAIL ONLY

September 30, 2021

Kenneth Burgess

kburgess@poynerspruill.com

**Exempt from Review - Replacement Equipment** 

**Record #: 3691** 

Date of Request: September 17, 2021 Facility Name: Mission Hospital

FID #: 943349

Business Name: MH Mission Hospital, LLLP

Business #: 3045

Project Description: Replace existing MRI scanner

County: Buncombe

Dear Mr. Burgess:

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(f). Therefore, you may proceed to acquire without a certificate of need the GE Healthcare Signa Voyager 1.5T MRI scanner to replace the Siemens Avanto 1.5T MRI scanner. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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,

Ena Lightbourne Project Analyst

Micheala Mitchell Chief

Micheala Mitchell

cc: Construction Section, DHSR

Acute and Home Care Licensure and Certification Section, DHSR

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

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

MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704

https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

# Poyner Spruill "P

September 17, 2021

VIA EMAIL

Micheala Mitchell, Chief Lisa Pittman, Assistant Chief Ena Lightbourne, Project Analyst Healthcare Planning and Certificate of Need Section N.C. Department of Health and Human Services Division of Health Service Regulation 809 Ruggles Drive Raleigh, North Carolina 27603 Via email to: micheala.mitchell@dhhs.nc.gov Lisa.pittman@dhhs.nc.gov

Ena.lightbourne@dhhs.nc.gov

Kenneth L. Burgess Partner D: 919.783.2917 F: 252.972.7045 kburgess@poynerspruill.com

RE: MH Mission Hospital, LLLP Notice of Exemption For Replacement Of MRI, Facility I.D. No. 943349

Dear Micheala, Lisa and Ena:

I am writing on behalf of our client, MH Mission Hospital, LLLP ("Mission"), to provide a Notice of Exemption with respect to Mission's planned replacement of an existing MRI at the Mission Hospital main campus (MRI # 2). Mission owns and operates an existing MRI Scanner located in Room A205.04 at the Mission Hospital main building, located at 509 Biltmore Avenue, Asheville, N.C. ("the Existing MRI" or "MRI #2). Mission plans to replace the Existing MRI at the same site and in the same room at Mission Hospital, the details of which are explained below ("the Project"). The purpose of this letter is to request that the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section ("the CON Section") confirm that the replacement of Mission's Existing MRI is exempt from certificate of need ("CON") review within the meaning of N.C. Gen. Stat. §131E-184(f) and that Mission can proceed to acquire and install the new MRI Scanner without a CON.

### Background

The Existing MRI which Mission proposes to replace is a Siemans Avanto MRI 1.5T scanner. That scanner was purchased a number of years ago and is nearing the end of its useful life. As such, Mission plans to replace the scanner at the same site and in the same physical location at Mission as the existing scanner. The replacement equipment will be a GE Healthcare Signa Voyager 1.5T MRI. In addition, Room A205.04, which is the site of the existing MRI Scanner and will be the site of the replacement MRI Scanner, requires certain upgrades to accommodate the replacement equipment. For the reasons set forth below, Mission's replacement of the Existing MRI and related renovations to Room A205.01 are exempt from CON review pursuant to N.C. Gen. Stat. §131E-184(f).

### Applicable Legal Authorities

The CON Law precludes any person from offering or developing a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178(a). The definition of "new institutional health service" includes, *inter alia*, the following:

- Incurring an obligation for a capital expenditure that exceeds \$2,000,000.00 to develop or expand a health service or health service facility, or which "relates" to the provision of a health service; and
- The acquisition by purchase, donation, lease, transfer or comparable arrangement of "major medical equipment," which is defined as a single unit or single system of components used to provide medical and health services which costs more than \$750,000.00, including the costs of the equipment and all studies, drawings, installation and any other activities essential to acquiring and making the equipment operational.

N.C. Gen. Stat. §§ 131E-176(16)(b), (16)(p) and (14o). These provisions, taken together, would require that an entity proposing to acquire medical equipment which costs more than \$2,000,000 apply for and obtain a CON before acquiring the equipment.

However, the CON Law provides at N.C. Gen. Stat. § 131E-176(14o) that "replacement equipment" as defined at N.C. Gen. Stat. § 131E-176(22a) does not constitute "major medical equipment." In addition, the CON Law contains a specific exemption applicable to "replacement equipment" that costs more than \$2,000,000.00. N.C. Gen. Stat. § 131E-184(f). This exemption, where applicable, eliminates the need to obtain a CON before acquiring and installing replacement equipment. This exemption is described below.

Statutory Exemption For Replacement Equipment Which Costs More Than \$2,000,000

To qualify as "replacement equipment" under the CON Statute, medical equipment must:

• Be purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. In calculating the total cost of the replacement equipment, the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value or the cost of the equipment, whichever is greater.

N.C. Gen. Stat. §131E-176(22a).

Replacement equipment is "comparable" to the equipment being replaced if:

1. It has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements;

<sup>&</sup>lt;sup>1</sup> Major medical equipment, by definition, consists of a single unit or system of units with related functions which is used to provide medical and other health services and which costs more than \$750,000. N.C. Gen. Stat. § 131E-176(14o). The acquisition of major medical equipment requires a CON. However, where medical equipment qualifies as "replacement equipment" under the CON Statute, it does not count as "major medical equipment" and can be acquired without a CON, assuming the acquisition also satisfies certain other exemption-related elements as described in this correspondence. N.C. Gen. Stat. §§ 131E-184(a)(7) and (f).

Micheala Mitchell, Chief September 17, 2021 Page 3



- 2. It is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- 3. The acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

10A N.C. Admin. Code 14C .0303(d)(1)-(3).2

Where the replacement equipment costs more than \$2,000,000, two additional statutory criteria apply, as follows:

- 1. The equipment being replaced is located on the main campus; and
- 2. The Department of Health and Human Services has previously issued a CON for the equipment being replaced, unless a CON was not required at the time the equipment was purchased by the licensed health service facility.

An entity seeking to qualify under the replacement equipment exemption at N.C. Gen. Stat. § 131E-184(f) must provide to the CON Section advance written notice of the acquisition, including an explanation of how the equipment acquisition meets the requirements set forth above. This letter is being submitted to the CON Section on behalf of Mission to satisfy this advance notice requirement.

# The Replacement of the Existing MRI By Mission Qualifies Under the Exemption Set Forth at N.C. Gen. Stat. § 131E-184(f)

The replacement of the Existing MRI at Mission fits within the parameters of the exemption at N.C. Gen. Stat. § 131E-184(f) because:

- 1. The equipment being upgraded is currently in use at Mission. See **Attachment 1** (Statement of Mission's Chief Operating Officer).
- 2. The total estimated cost of the project is \$2,500,000.00,3 placing the project within the parameters of the statutory exception set forth at N.C. Gen. Stat. §131E-184(f). The total project costs consist of medical equipment costs of \$1,220,076.61, related construction and materials costs, certain ancillary non-medical equipment, architect and engineering fees and a generous

<sup>2</sup> Pursuant to 10A NCAC 14C .0303, equipment does not qualify as "replacement equipment" where equipment which was second-hand or reconditioned is being replaced with new equipment within three (3) years of the acquisition of the equipment being replaced, or leased equipment is being replaced with purchased equipment. The existing MRI scanner which is being upgraded was purchased well over three (3) years ago. As such, 10A NCAC 14C .0103 does not apply to this Project.

<sup>&</sup>lt;sup>3</sup> In calculating construction costs, our clients relied upon prior Agency determinations that the construction costs "essential to acquiring and making operational the replacement equipment" should include only those costs directly related to removing the old equipment, installing the new equipment and making sure that equipment operates properly. In the case of a CT scanner, for example, such cost should include upfit of the CT room related solely to the operation of the CT scanner (e.g., shielding, extra electrical connections), but need not include other construction costs associated with that room. Similarly, the Agency has previously determined that costs associated with the installation of equipment in the control room for the CT scanner should be included only to the extent that those costs would be different from construction related to general office space. Mission Hospitals, Inc. v. NC DHHS, N.C.App. \_\_\_\_\_, 696 S.E.2d 163 (2010).

contingency. See **Attachment 2** (certified Total Capital Cost Worksheet). See also **Attachment 1** (Statement of Mission's Chief Operating Officer attesting to the total project costs.

- 3. The Existing MRI scanner will be sold or otherwise disposed of when the replacement equipment is acquired and installed, and will not be reinstalled or used in North Carolina without appropriate CON Section authorization. See **Attachment 3**, page 22 (excerpt from GE Healthcare regarding removal of existing MRI # 2). See also **Attachment 1** (Statement of Mission's Chief Operating Officer attesting that GE Healthcare will remove the existing MRI).
- 4. The new MRI scanner will have the same capabilities as the scanner being replaced, although it may have additional capabilities due to the advancement of MRI Scanner technology, is functionally similar to the existing MRI Scanner and will be used for the same diagnostic or treatment purposes as the equipment being upgraded. See **Attachment** 1 (Statement of Mission's Chief Operating Officer).
- 5. The Project will not increase patient charges or per procedure operating expenses more than 10% within 12 months of the replacement equipment being installed and becoming operational. See **Attachment 1** (Statement of Mission's Chief Operating Officer).
- 6. The equipment is being replaced on the hospital's main campus. The term "campus" is defined at N.C. Gen. Stat. § 131E-176(2c) as "the adjacent grounds and buildings, or grounds and buildings not separated by more than a public right-of-way, of a health service facility and related health care entities." The term "main campus" is defined as the site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building or other areas and structures which are not strictly contiguous to the main building but are within 250 yards of the main building." N.C. Gen. Stat. §131E-176(14n). The Existing MRI is currently located in the main hospital building at Mission. The replacement equipment for the Existing MRI will be located at the same site, in the same room, at Mission's main hospital building. That building is also the cite from which Mission provides clinical patient services and exercises financial and administrative control over the Mission hospital facility. See Attachment 1 (Statement of Mission's Chief Operating Officer).
- 7. Finally, the CON Section has previously issued a CON for the equipment being replaced or a CON was not required at the time the equipment being replaced was acquired. See **Attachment 4** (copy of CON for existing MRI # 2, Project I.D. No. B-006869-03).

### Conclusion

For the reasons set forth herein, we believe that the replacement of Mission's Existing MRI is exempt from CON review and that no CON is required for the Project. We respectfully request that the CON Section provide written confirmation that Mission may proceed with the Project as described without CON Section Review and without obtaining a CON.

Micheala Mitchell, Chief September 17, 2021 Page 5

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Please feel free to let me know if you have questions or need additional information regarding this project.

Very truly yours,

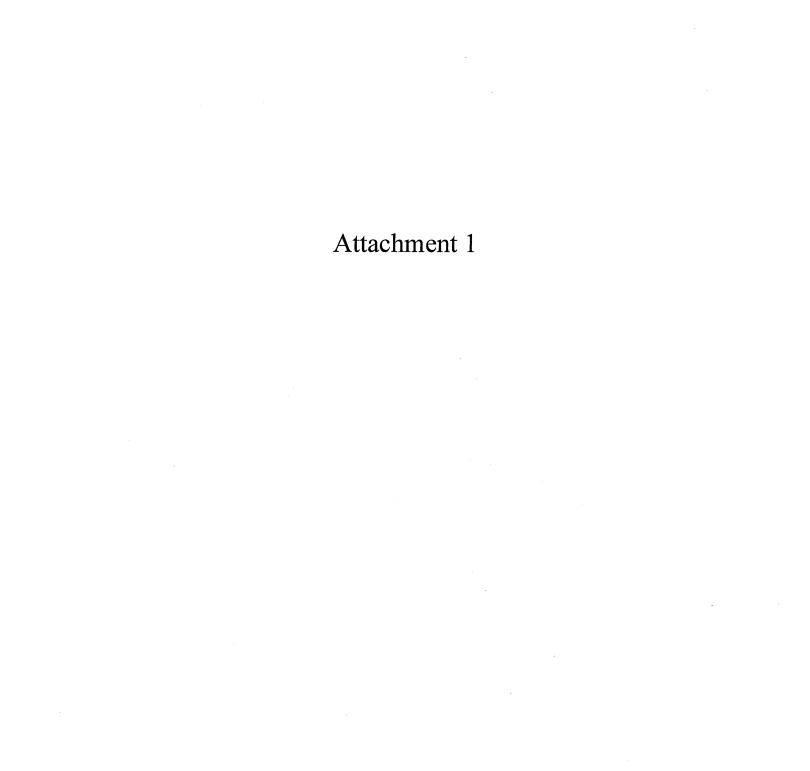
Kenneth L. Burgess

Kenneth L. Burgess

Partner

cc: Joe Rudisill Sondra Smith Jason Desai

Attachments





September 16, 2021

Micheala Mitchell
Chief, Healthcare Planning and Certificate of Need Section
N.C. Division of Health Service Regulation
809 Ruggles Drive
Raleigh, N.C. 27603
Via email to: micheala.mitchell@dhhs.nc.gov

Re: MH Mission Hospital, LLLP's Notice of Exemption of Existing MRI

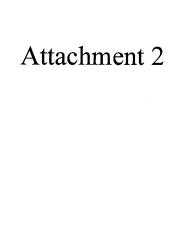
Dear Ms. Mitchell:

MH Mission Hospital ("Mission") will be replacing our existing Siemans Avanto MRI 1.5T scanner ("MRI # 2") with a new GE Healthcare Signa Voyager 1.5T MRI (the "Replacement MRI"). The existing MRI # 2 is located in Room A205.04 in the hospital's main building on the hospital's main campus at 509 Biltmore Avenue in Asheville, N.C. and the Replacement MRI will be located in that same room. The Replacement MRI to be replaced is currently in use. The replacement of this system will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement. MRI #2 which is being replaced was purchased new when acquired. The Replacement MRI will be a new unit, will have the same clinical functionality as existing MRI #2, will be used for the same diagnostic and/or treatment purposes as the existing MRI #2 and will not be used to provide a new health service as that term is defined in the CON Laws. The Replacement MRI does possess expanded capabilities due solely to advancements in MRI scanner technology. The existing MRI # 2 will be traded in as part of the purchase of the Replacement MRI. GE Healthcare, the vendor for the Replacement MRI, is providing Mission with a trade-in on the existing MRI #2 and will be removing existing MRI #2 from Mission as reflected at page 23 of Mission's quote from GE Healthcare.

Best Regards,

Joseph R. Digitally signed by Joseph R. Rudisill Date: 2021.09.16 22:23:14-04'00'

Joseph R. Rudisill Chief Operating Officer MH Mission Hospital, LLLP 509 Biltmore Avenue Asheville, NC 28801 828-213-0185



### Projected Capital Cost Form Mission Hospital MRI Replacement

	att itt sinttinit
Building Purchase Price	NA
Purchase Price of Land	NA
Closing Costs	NA
Site Preparation	NA
Construction/Renovation Contract(s)	\$597,000.00
Landscaping	NA
Architect / Engineering Fees	\$85,000.00
Medical Equipment	\$1,220,079.61
Non-Medical Equipment (ancillary equipment)	\$192,484.18
Furniture	\$0.00
Consultant Fees (specify)	\$0.00
Financing Costs	NA
Interest during Construction	NA
Other (project development costs, contingency, freight, sales tax)	\$405,436.21
Total Capital Cost	\$2,500,000.00

### CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

I certify that, to the best of my knowledge, the projected ca	apital cost for the proj	posed project is
complete and correct.		
Sana O. Allinson	Date Signed: _	09/17/2021
Signature of Licensed Architect or Engineer		

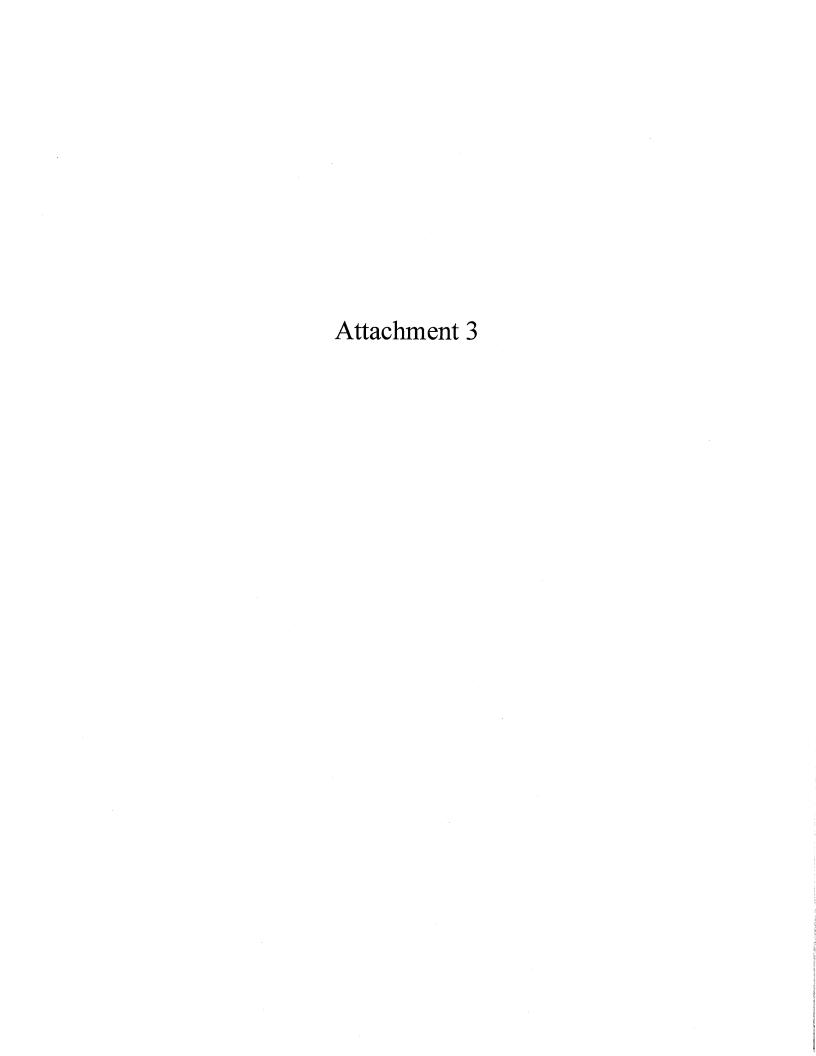
### CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that it is our intent to carry out the proposed project as described.

Date Signed: 09/17/2021

Name Title of Officer/Agent

Date of Last Revision: 5.17.19





Quote Number: 2007099405.20

Customer ID: 1-23R6UV

Agreement Expiration Date: 10/17/2021

Mission Hospital 509 Biltmore Ave Asheville, NC 28801-4601

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), 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 ("Quotation"). "Agreement" 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 ("Quotation Acceptance"). 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:

HCA National

Terms of Delivery

FOB Destination

Billing Terms

80% delivery or Shipment / 20% Acceptance or Installation

Payment Terms

NET 30

Total Quote Net Selling Price

\$1,220,079.61

Sales and Use Tax Exemption

No Certificate on File

	IMPORTANT CUSTOMER ACTION	4S:		
	Please select your planned source of fund shipped, source of funds changes cannot		cash unless you choose another option.	Once equipment has been
	Cash			
	GE HFS Loan	GE HFS Lease		
	Other Financing Loan	Other Financing Lease	Provide Finance Company Name	
j				

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

Signatur	Laurie Haynes Digitally signed by Laurie Haynes Date: 2021 07:23 09:22:10-04:09
Print Nar	Laurie Haynes ne:
Title:C	hief Financial Officer
Date:	uly 23, 2021
Purchase (	Order Number, if applicable

GE Precision Healthcare LLC, a GE Healthcare business

Signature: Anthony Morris

Title: Sr Sales Manager Imaging

Date: July 19, 2021



Quote Number: 2007099405.20

Customer ID: 1-23R6UV

Agreement Expiration Date: 10/17/2021

### To Accept This Quotation

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

Name: Anthony Morris
Email kevin.morris@ge.com
Phone: 803-608-2460

Fax:

### **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

### Mission Hospital

Bill To: MISSION HOSPITAL

Addresses:

MISSION HOSPITAL, ACCOUNTS PAYABLE 509 BILTMORE AVE

ASHEVILLE, NC, 28801-4601

Ship To: MISSION HOSPITAL

509 BILTMORE AVE ASHEVILLE, NC, 28801-4601

### To Accept This Quotation

- 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



Quote Number: 2007099405.20

Customer ID: 1-23R6UV

Agreement Expiration Date: 10/17/2021

### Catalog Item Details

Line	Qty.	Catalog			
1.	1.00	Y0000LC		Pricing Non-Disclosure Language	
List Price	i		Discount	Extended List Price	Net Price

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	(0) 7×	Catalog			
2.	1.00	S7529VB		SIGNATM VOYAGER 1.5T 33 CHANNEL 29.1 MR SYSTEM	
List Pri	<u>ce</u>		Discount	Extended List Price	Net Price

The SIGNA<sup>TM</sup> Voyager 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 SIGNA<sup>TM</sup> 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.

The SIGNA™ Voyager system catalog comprises the RF-architecture electronics, core RF coil suite, gradient electronics, computing platform and MR29.1 operating/imaging software:

- · TDI RF-Receive Technology and RF Coil Suite
- UHE with IGC Gradient and Quiet Acoustic Reduction Technology
- · Computing Platform and DICOM Conformance
- SIGNA™Works AIR™ IQ Edition Workflow
- SIGNA™Works AIR™ IQ Edition Acceleration, Motion Correct and Tissue Suppression Technology
- SIGNA™ Works AIR™ IQ Edition Clinical Applications Toolkits
- SIGNA™ Works AIR™ IQ Edition READYView Advanced Visualization

### TECHNOLOGY FOUNDATION

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

Total Digital Imaging (TDI) and RF Coil Suite

SIGNA<sup>TM</sup> Voyager features the Total Digital Imaging RF-architecture with a 33-channel configuration. The TDI RF-architecture 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 (sold separately) 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



Quote Number: 2007099405.20

Customer ID: 1-23R6UV

Agreement Expiration Date: 10/17/2021

Line 10.

Otv. 1.00

Catalog M70022MC

Main Disconnect Panel - 380V/400V/415V/480V 50/60Hz

**List Price** 

Discount

**Extended List Price** 

**Net Price** 

The Main Disconnect Panel safeguards the MR system's critical electrical components, by providing complete power distribution and emergency-off control.

Line

Otv. 1.00

Catalog M70012RP

English Language Kit

11. List Price

Discount

Discount

**Extended List Price** 

Net Price

English Language Kit

Line Qty. 12.

Catalog

1.00 List Price

R33012AC

Standard Service License

**Extended List Price** 

**Net Price** 

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 Qtv.

Catalog 1.00

S7529HD

AIR™ DIFFUSION PACKAGE WITH AIR™ RECON DL AND AIR X™

for SIGNATM VOYAGER 1.5T

List Price

13.

Discount

**Extended List Price** 

Net Price

The AIR™ Diffusion package for SIGNA™ Voyager 1.5T comprises AIR x™ Auto Graphic Prescription, AIR™ Recon DL with deep learning and advanced diffusion techniques: PROGRES, MUSE, FOCUS and MAGiC DWI. These capabilities come together to deliver clinical versatility, intelligent productivity and enhanced image quality.

- AIR x<sup>TM</sup> Auto Graphic Prescription
- AIR™ Recon DL and DL Reconstruction Engine
- · Diffusion Package with PROGRES, MUSE, FOCUS and MAGIC DWI

AIR x<sup>TM</sup> Auto Graphic Prescription

Change the way you prescribe brain and knee exams. AIR xTM Auto Graphic Prescription uses deep learning algorithms, instead of an atlas-based method, to automatically identify anatomical structures and prescribe slices locations for brain and knee exams. As a result of the deep learning algorithms, AIR xTM automatically adapts slice prescriptions to 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.

AIRTM Recon DL and DL Reconstruction Engine

Level-up your image quality. AIRTM Recon DL is a deep learning-based reconstruction algorithm that utilizes trained neuro networks to remove noise and ringing artifacts from the raw scan data. As a result, AIR™ Recon DL delivers images with enhanced SNR and sharpness while also enabling the reduction in scan time and resulting exam time. AIR™ Recon DL is directly embedded in the reconstruction pipeline to address image quality at the foundation level to produce TrueFidelity images (and therefore is not a traditional filter or a post-processing technique). AIRTM Recon DL is compatible with most 2D applications and select diffusion-weighted EPI sequences and allows the user to tailor the level of application.

- Intelligent pipeline reconstruction produces TrueFidelity images
- Reduces image noise at the foundation level
- Reduced Gibbs and truncation artifacts at the foundation level with intelligent ringing suppression
- · Reduces scan time and resulting exam times
- · Tailor level based on preference

To support the computational intensity of AIR™ Recon DL, this offering package includes the Gen7 DL ICN reconstruction engine with



Quote Number: 2007099405.20

Customer ID: 1-23R6UV

Agreement Expiration Date: 10/17/2021

Total Quote List Price: Total Quote Discount: Total Quote Subtotal:

Qty	Credits and Adjustments
1.00	HCA AIR Recon DL Synergy Discount - \$80,000.00
1.00	End of Service Life Promotional Discount
1.00	HCA Rigging Credit per Agreement
1.00	SIEMENS AVANTO Trade-in

Total Quote Net Selling Price:

\$1,220,079.61

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



### Trade-in Addendum to GE Healthcare Ouotation

This Trade-In Addendum ("Addendum"), effective on July 19, 2021, between the GE Healthcare business identified on the Quotation and Mission Hospital ("Customer"), is made a part of Quotation # 2007099405.20 ^ dated July 19, 2021 ("Quotation") and modifies it as follows:

A. Customer: (i) certifies that it has full legal title to the equipment and/or mobile vehicle ("mobile vehicles" are defined as any systems requiring a vehicle title) listed in Section E ("Trade-In Equipment"), free and clear of all liens and encumbrances; (ii) conveys title and, if applicable, registration and license documents to GE Healthcare effective on the date of removal or receipt of the Trade-In Equipment (mobile vehicles will not be removed from Customer site until GE Healthcare has received a clean title signed over to GE Healthcare); and (iii) affirms that the Trade-In Equipment has never been used on or to provide care to animals. If GE Healthcare removes the Trade-In Equipment, it will do so at its expense at a mutually agreed time. Trade-In Equipment shall be removed no later than thirty days following installation of Customer's new system, unless explicitly otherwise agreed to by the parties in writing.

Mobile vehicles must include the VIN# on this trade-in addendum: VIN# [insert Vin #]. Mobile vehicles must have a valid DOT sticker and be road worthy at the time GE Healthcare is to take possession of them in order for GE Healthcare to accept a mobile vehicle on trade-in. Any and all logos or hospital affiliation stickers must be removed (outside and inside) by Customer and Customer shall clean the mobile vehicle of all debris and medical supplies prior to removal of the mobile vehicle by GE Healthcare.

- B. Customer is responsible for: (i) providing timely, unrestricted access to the Trade-In Equipment in a manner that affords GE Healthcare, or third-party purchaser of the Equipment through GE Healthcare, the ability to complete Equipment inspection and testing, and the ability to complete an operating system back-up prior to de-installation within the timeframe required by GE Healthcare or said third-party purchaser, failure of which to provide may result in termination of this Trade-in Addendum and related credits and/or payments; (ii) ensuring that the Trade-In Equipment and the site where it is located are clean and free of bodily fluids; (iii) informing GE Healthcare of site-related safety risks; (iv) properly managing, transporting and disposing of hazardous materials located on site in accordance with applicable legal requirements; (v) rigging, construction, demolition or facility reconditioning expenses, unless expressly stated otherwise in the Quotation; and (vi) risk of loss and damage to the Trade-In Equipment until safety risks are remediated and the Trade-In Equipment is removed or returned.
- C. Prior to removal or return to GE Healthcare, Customer must: (i) remove all Protected Health Information as such term is defined in 45 C.F.R. § 160.103 ("PHI") from the Trade-In Equipment; and (ii) indemnify GE Healthcare for any loss resulting from PHI not removed. GE Healthcare has no obligation in connection with PHI not properly removed.
- D. GE Healthcare may in its sole discretion reduce the trade-in amount or decline to purchase the Trade-In Equipment and adjust the total purchase price of the Quotation accordingly if: (i) the terms of this Addendum are not met; (ii) Customer fails to provide access to the Trade-In Equipment as required herein; or (ii) the Trade-In Equipment is missing components or is inoperable and/or non-functioning when removed or returned Customer is required to confirm for GE Healthcare the operability of the Trade-In Equipment prior to the deinstallation of the Equipment. All other terms and conditions of the Quotation remain in full force and effect.
- E. Trade-In Equipment:

Trade-In Equipment Mfr.	Model & Description	Quantity	System ID*	Trade-In Amount
				(\$)
	SIEMENS AVANTO Trade-in	1.00	MHCTS828SIEMR01	\$ 0.00

This Addendum is executed when: (i) signed by the parties below; (ii) Customer receives this Addendum and signs the Quotation that references the Trade-In Equipment; or (iii) Customer receives this Addendum and issues a purchase order identifying either the terms of the Quotation (which includes a reference to the Trade-In Equipment) as governing the order (PO#

Mission Hospital	GE Healthcare	
Signature:	Signature:	
Print Name:	Print Name;	
Title:	Title:	
Date:	Date:	

# Attachment 4

# GIATE OF NORTH CAROLING Department of Health and Human Services Division of Facility Services

## CERTIFICATE OF NEED

for

Project Identification Number B-6869-03 FID# 943349

ISSUED TO: Memorial Mission Hospital

509 Biltmore Avenue

Asheville, NC 28801

Pursuant to N.C. Gen. Stat § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person of persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE:

Memorial Mission Hospital shall acquire one fixed MRI scanner for a total of three fixed MRI scanners/Buncombe County

CONDITIONS:

See Reverse Side

PHYSICAL LOCATION:

Memorial Mission Hospital

509 Biltmore Avenue, Asheville, NC 28801

MAXIMUM CAPITAL EXPENDITURE:

\$2,069,003

TIMETABLE:

See Reverse Side

FIRST PROGRESS REPORT DUE: August 30, 2004

This certificate is effective as of the 19th day of December, 2003.

Chief, Certificate of Need Section Division of Facility Services

Web. Hoffman

### **CONDITIONS:**

- 1. Memorial Mission Hospital shall materially comply with all representations made in its certificate of need application.
- 2. Memorial Mission Hospital shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.
- 3. Prior to the issuance of the certificate of need, Memorial Mission Hospital shall provide to the Certificate of Need Section documentation that the proposed health services will accommodate the clinical needs of health professional training programs in the area.
- 4. Prior to the issuance of the certificate of need, Memorial Mission Hospital shall provide to the Certificate of Need Section the projected number of procedures to be performed on the two MRI scanners at Asheville MRI in the third year of operation of the proposed MRI scanner and the assumptions on which the projections are based.
- 5. Prior to the issuance of the certificate of need, Memorial Mission Hospital shall provide to the Certificate of Need Section documentation that one of these MRI technologists shall be present during the hours of operation of the MRI scanner.
- 6. Memorial Mission Hospital shall acknowledge acceptance and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance and compliance with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on December 19, 2003.

### TIMETABLE:

Completion of final drawings and spe	cifications	 	December 15, 2003
Contract Award		 	February 2, 2004
25% completion of construction		 	March 16, 2004
50% completion of construction			April 30; 2004
75% completion of construction			June 15, 2004
Completion of construction		 Program.	July 15, 2004
Order Equipment		 	_ December 1, 2003
Operation of Equipment		 	September 15, 2004
Licensure of facility			September 30, 2004

From: Mitchell, Micheala L Waller, Martha K To:

Subject: Fw: [External] Mission Hospital MRI Replacement Exemption Notice

Date: Friday, September 17, 2021 3:41:18 PM

Attachments: image002.png image003.pnq

image004.png

Mission MRI Exemption Notice and Attachments.pdf

From: Burgess, Kenneth L. <KBurgess@poynerspruill.com>

Sent: Friday, September 17, 2021 3:05 PM

**To:** Mitchell, Micheala L < Micheala. Mitchell@dhhs.nc.gov>; Pittman, Lisa <ena.lightbourne@dhhs.nc.gov>;

Subject: [External] Mission Hospital MRI Replacement Exemption Notice

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

Hi Micheala, Lisa and Ena, attached please find a Notice of Exemption I am filing on behalf of our client MH Mission Hospital, LLLP ("Mission") in connection with the replacement of an MRI on the Mission main campus. Further details regarding the project and the basis for the exemption are set forth in the attachment. Please let me know if you have questions regarding the project or the attached exemption. Happy Friday and have a good weekend. Thanks, Ken Burgess

Kenneth L. Burgess | Partner



1151 Falls Road, Suite 1000

Rocky Mount, N.C. 27804

**D:** 919 783 2917 | **M:** 919 449 4754

Kburgess@poynerspruill.com | www.poynerspruill.com







### \*\*\*\*\*

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