



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

March 14, 2023

Denise M. Gunter
denise.gunter@nelsonmullins.com

Exempt from Review – Acquisition of Facility

Record #: 4154
Date of Request: March 6, 2023
Facility Name: Kings Medical Group
Type of Facility: Diagnostic Center (grandfathered mobile MRI unit, serial #31472)
Acquisition by: Novant Health-Norfolk, LLC
Business #: 3863
County: Mecklenburg

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that the project described above is exempt from certificate of need (CON) review in accordance with G.S. 131E-184(a)(8). Therefore, the above referenced business may proceed to acquire the health service facility identified above without first obtaining a CON. The Agency's determination is limited to the question of whether the above referenced business would have to obtain a CON if the current owners of the health service facility do in fact sell it to the business listed above. Note that pursuant to G.S. 131E-181(b): "*A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need.*"

It should be noted that this 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 Agency and a separate determination regarding whether a certificate of need would be required. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Julie M. Faenza
Project Analyst

Micheala Mitchell
Chief

cc: Acting Assistant Chief, Healthcare Planning

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

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

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March 6, 2023

VIA EMAIL ONLY

Micheala Mitchell, Chief
North Carolina 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: Acquisition of Existing Grandfathered Diagnostic Centers

Dear Ms. Mitchell:

On behalf of Novant Health-Norfolk, LLC¹ (“Novant”), I am writing to request the Agency’s written confirmation that the acquisition of the existing grandfathered diagnostic centers described in this letter is exempt from Certificate of Need review pursuant to N.C. Gen. Stat. § 131-184(a)(8).

I. Details Related to the Diagnostic Centers

Novant intends to acquire two grandfathered diagnostic centers owned by Kings Medical Company (“Kings”). These diagnostic centers are known as Kings I and Kings II. Each of the diagnostic centers is a “mobile diagnostic program” that consists of a grandfathered mobile MRI scanner and related equipment, such as trailer, to pull the scanner. Kings acquired the original mobile MRI scanners and placed them in operation in North Carolina prior to March 18, 1993, when North Carolina’s CON Law began specifically regulating MRI scanners and diagnostic centers. See N.C. Gen. Stat. § 131E-176(7a), (16)f1.7. Subsequently, Kings replaced those scanners by acquiring new MRI scanners that qualified as “replacement equipment” exempt from CON review and as grandfathered MRI scanners. For this reason, Kings mobile MRI scanners are currently identified as “legacy” (or grandfathered) scanners in Column C, Table 17E-1 of the 2023 State Medical Facilities Plan (see, e.g., page 346). The Agency’s letters approving the acquisition of the existing MRI scanners as replacement equipment for grandfathered MRI

¹ Novant Health, Inc. owns a controlling interest in Novant Health-Norfolk, LLC.

scanners are attached as **Exhibit A** and **Exhibit B**. Kings I and Kings II have been in continuous use in North Carolina as grandfathered diagnostic centers with grandfathered MRI scanners since the original acquisitions and have been made available to various host sites in North Carolina via services agreements.

As you may recall from prior correspondence, the MRI scanner used for Kings I was damaged beyond repair in a fire in late 2021, and the Agency authorized Kings to place into operation temporary replacement MRI scanners, pending approval and acquisition of a permanent replacement MRI scanner. The correspondence concerning the temporary scanners is attached as **Exhibit C**. In addition, as shown on page 1 of **Exhibit C**, on February 13, 2023, the Agency authorized Kings to acquire a permanent replacement MRI scanner for the scanner damaged by fire. Kings expects the permanent replacement scanner will be delivered and placed into operation soon.²

II. Overview of CON Law Applicable to the Acquisition

The CON Law expressly exempts from CON review the acquisition of an existing “health service facility, including equipment owned by the health service facility at the time of acquisition”, upon prior written notice to the Agency. N.C. Gen. Stat. § 131E-184(a)(8). The term “health service facility” is defined to include a “diagnostic center.” *Id.* § 131E-176(9b). In turn, a “diagnostic center” is defined to include a “mobile diagnostic program.” *Id.* § 131E-176(7a). Hence, the acquisition of an existing mobile diagnostic program, including the equipment it owns upon the acquisition, is exempt from CON review as the acquisition of an existing health service facility.

Each of the Kings mobile MRI scanners, together with the services each scanner provides to its multiple sites, constitutes a “mobile diagnostic program.” Consequently, each mobile diagnostic program is a “diagnostic center” and, hence, an existing “health service facility.” For these reasons, Novant’s proposed acquisition of the two mobile diagnostic programs, including the mobile MRI scanners and trailers, is exempt from CON review.

Prior decisions by the Agency confirm this conclusion. On November 15, 2017, the Agency determined that an almost identical acquisition by Rex Hospital, Inc. was exempt from CON review. See **Exhibit D**. The decision concerned a mobile cardiac catheterization unit that was grandfathered because the unit was originally acquired and placed into service before March 18, 1993 (the “Mobile Cath Unit”). The Agency agreed with Rex Hospital and determined that the grandfathered Mobile Cath Unit constituted a grandfathered mobile diagnostic program, which in turn constituted a grandfathered diagnostic center. Consequently, the Agency determined that Rex Hospital could acquire

² Kings Medical Company, the owner of Kings I and Kings II, is a wholly owned subsidiary of Kings Medical Group, Inc. (“KMG”). Certain past correspondence to the Agency concerning Kings I and/or Kings II was submitted by KMG as the parent entity.

Micheala Mitchell, Chief
March 6, 2023
Page 3

this grandfathered health care facility, including the Mobile Cath Unit, without first obtaining a CON.

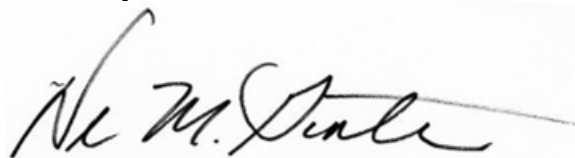
This notice of exempt acquisition is intended to apply to the entirety of Kings I and Kings II, including their equipment, and all rights related thereto. Consequently, the notice applies (without limitation) to King's right, title, and interest in (a) the existing MRI scanners, trailers, and related equipment, (b) the temporary MRI scanner previously approved for use until the permanent replacement MRI scanner is approved and acquired, (c) the permanent replacement MRI scanner for the MRI scanner that was damaged by fire, and (d) the grandfathered status of Kings I and Kings II and the two MRI scanners. It is Novant's understanding that upon the Agency's approval of this notice and the closing the acquisition by Novant, all such rights, title, and interest, including the grandfathered statuses, shall continue in effect and belong to Novant under the CON Law.

This transaction does not involve any other health services that are regulated by the CON Law.

As the parties would like to close this transaction shortly, we would appreciate your prompt response to this letter.

Thank you for your time and consideration. Please do not hesitate to let me know if you have any questions or need additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Denise M. Gunter", with a long horizontal flourish extending to the right.

Denise M. Gunter

DMG:pfb
Enclosures

cc: Forrest Campbell, Esq. (with enclosures)(via email)



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

June 18, 2014

Kimberly Jacobs
Kings Medical Group
1920A Georgetown Road
Hudson, OH 44236

Exempt from Review - Replacement Equipment

Business: Kings Medical Group
Project Description: Replace existing grandfathered GE Signa mobile MRI scanner with a new Siemens Magnetom Espree mobile MRI scanner
Counties: Guilford; Mecklenburg

Dear Ms. Jacobs:

In response to your letter of June 11, 2014, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Siemens Magnetom Espree mobile MRI scanner to replace the existing GE Signa mobile MRI scanner, Serial # R3070. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Celia C. Inman
Celia C. Inman
Project Analyst

Martha J. Frisone
Martha J. Frisone, Interim Chief
Certificate of Need Section

cc: Medical Facilities Planning Branch, DHSR



Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

November 15, 2017

Gary S. Qualls
K & L Gates
430 Davis Drive, Suite 400
Morrisville NC 27560

Exempt from Review – Acquisition of Facility

Record #: 2439
Facility Name: FirstHealth of the Carolinas, Inc.
Type of Facility: Diagnostic center (Grandfathered mobile cardiac catheterization unit)
Acquisition by: UNC Rex Hospital
FID#: 953429
Business #: 1554
County: Wake

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that based on your letter of November 9, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(8). Therefore, UNC Rex Hospital may proceed to acquire the above referenced health service facility without first obtaining a certificate of need. However, you need to contact the Agency's Acute and Home Care Licensure and Certification Section to obtain instructions for changing ownership of the existing facility. Note that pursuant to N.C. Gen. Stat. §131E-181(b): *"A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need."*

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704

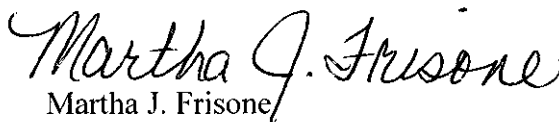
AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



Sincerely,



Michael J. McKillip
Project Analyst



Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHR
Sharetta Blackwell, Program Assistant Healthcare Planning, DHR

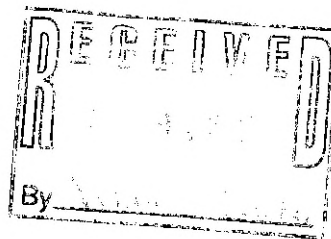


Exhibit D

November 9, 2017

Gary S. Qualls
D 919.466.1182
F 919.516.2182
gary.qualls@klgates.com

Via Hand Delivery

Martha Frisone
Chief, Certificate of Need
Department of Health and Human Services
Division of Health Service Regulation
Health Planning and Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Rex Hospital, Inc. – Exemption Notice for Acquisition of Replacement Cardiac Catheterization Equipment at Rex Hospital’s Main Campus, Wake County

Dear Ms. Frisone:

Our client, Rex Hospital, Inc. d/b/a UNC REX (“Rex”), seeks to acquire a Mobile Cardiac Catheterization Unit from FirstHealth of the Carolinas, Inc. (“FirstHealth”). This Mobile Cardiac Catheterization Unit is grandfathered under the Certificate of Need (“CON”) law because it was in use in the State prior to March 18, 1993 and has been in use continuously. See Exhibits 1 and 2, Exempt from Review Letters dated October 29, 1998 and November 9, 1998. Thus, this “Grandfathered Cath Unit” is also considered a grandfathered mobile Diagnostic Center under N.C. Gen. Stat. § 131E-176(7a) because it is a grandfathered mobile diagnostic program. Currently this Grandfathered Cath Unit is serving Rex two days a week through a contract between FirstHealth and Rex.

Rex intends to:

- (1) acquire the Grandfathered Cath Unit from FirstHealth as an exempt acquisition of an existing grandfathered mobile Diagnostic Center pursuant to N.C. Gen. Stat. §§ 131E-184(a)(8) and 131E-176(7a);
- (2) then replace the Grandfathered Cath Unit (also referred to herein as the “Existing Equipment”) with a different cardiac cath unit (the “Replacement Equipment”) and will house the Replacement Equipment in Rex Hospital rather than in the mobile coach that currently houses the Grandfathered Cath Unit.

Martha Frisone
November 9, 2017
Page 2

I. Step #1: Acquire the Grandfathered Cath Unit as an Exempt Diagnostic Center

As a first step, Rex will acquire the Grandfathered Cath Unit from FirstHealth as an exempt acquisition of an existing grandfathered mobile Diagnostic Center pursuant to N.C. Gen. Stat. §§ 131E-184(a)(8) and 131E-176(7a). Exhibits 1 and 2 are attached as proof of grandfathered status. As referenced above, FirstHealth's Grandfathered Cath Unit is a grandfathered mobile Diagnostic Center under N.C. Gen. Stat. § 131E-176(7a). The Section 176(7a) definition of Diagnostic Center specifically includes mobile diagnostic programs.

II. Step #2: Replacement Equipment Exemption

After the acquisition in Step #1 above, Rex intends to then replace the Grandfathered Cath Unit (also called the "Existing Equipment") with a different cardiac cath unit (the "Replacement Equipment") and will house the Replacement Equipment in Rex Hospital's Heart Tower on its Main Campus¹ rather than in the mobile coach which currently houses the Grandfathered Cath Unit.

Instead of acquiring a new piece of cardiac cath equipment, Rex will instead denominate a unit of existing vascular equipment at Rex as the "Replacement Equipment" and will convert that Replacement Equipment to cardiac cath use by adding software to enable that use. The Replacement Equipment is identified by serial number in Exhibit 3, which is the CON Replacement Equipment Comparison Form ("Comparison Form"). The Replacement Equipment will be located in the same location where it is currently used as a vascular unit.

This letter is to provide the Agency with notice and to request confirmation that:

- 1) Rex may acquire the Grandfathered Cath Unit from FirstHealth as an exempt acquisition of an existing grandfathered mobile Diagnostic Center pursuant to N.C. Gen. Stat. §§ 131E-184(a)(8) and 131E-176(7a);
- 2) Rex's Replacement Equipment described herein is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7); and
- 3) Rex will have the right to reconvert the grandfathered Replacement Equipment to mobile use again without a CON so long as no relevant cost thresholds or other CON new institutional health service definitions are triggered in the process.

¹ Even though this equipment replacement will be on Rex's Main Campus, Rex does not need to invoke the main campus replacement equipment provisions contained in N.C. Gen. Stat. § 131E-184(f) because the costs for the Replacement Equipment here do not exceed \$2 Million.

Martha Frisone
November 9, 2017
Page 3

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of “replacement equipment,” defined as follows in the CON law:

“Replacement equipment” means equipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

See N.C. Gen. Stat. § 131E-176(22a).

In addition to the foregoing, to qualify for this exemption, the replacement equipment must be “comparable” to the equipment it replaces and must be “sold or otherwise disposed of when replaced.” Rex’s proposal qualifies for this exemption.

A. Cost of the Replacement Equipment

The total cost to acquire, install, and make operational the Replacement Equipment is \$13,000. See Exhibit 4 (this shows the costs to upgrade the Existing Equipment -- vascular equipment -- to cardiac cath use). No additional capital costs will be expended regarding the Replacement Equipment because Rex already owns it, having purchased the Replacement Equipment in 2015, where it has since been used as non-cardiac cath vascular equipment.

B. Comparable Equipment

The CON rule codified as 10A N.C.A.C. 14C.0303 (the “Regulation”) defines “comparable medical equipment” in subsection (c) as follows:

“Comparable medical equipment” means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

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

Rex intends to use the Replacement Equipment for substantially the same types of services for which the Existing Equipment it currently used. The Existing Equipment (i.e., the Grandfathered Cath Unit) performs a wide range of cardiac cath procedures, as will the Replacement Equipment.

The Replacement Equipment will perform all procedures currently performed on the Existing Equipment. Although it possesses some expanded capabilities due to technological improvements, the Replacement Equipment will perform the same general range of

Martha Frisone
November 9, 2017
Page 4

procedures as the Existing Equipment. See Exhibit 3, Comparison Form. The Replacement Equipment is therefore “comparable medical equipment” as defined in Subsection (c).

Furthermore, Rex does not intend to increase patient charges or per procedure operating expenses more than 10% within the first 12 months after its acquisition. For further equipment comparison, please refer to Exhibit 3, the Comparison Form.

Subsection (d) of the Regulation further provides that the Replacement Equipment must meet the following tests:

- (1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
- (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- (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.A.C. 14C.0303(d).

The Replacement Equipment will meet all three of the tests set out in Subsection (d). The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Form See Exhibit 3. Moreover, Rex represents that use of the Replacement Equipment will not result in the types of expense or charge increase described in Subsection (d)(3).

D. Disposition of Existing Equipment

As part of the proposal, Rex will decommission the Existing Equipment acquired from FirstHealth and put it in storage. Rex will not operate the Existing Equipment without further authorization from the Agency.

Martha Frisone
November 9, 2017
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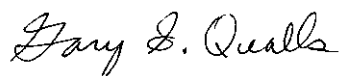
CONCLUSION

Based on the foregoing information, Rex provides exemption notices under N.C. Gen. Stat. §§ 131E-184(a)(7) and (a)(8), and hereby requests that the Agency provide a written response confirm the following:

- 1) Rex may acquire the Grandfathered Cath Unit from FirstHealth as an exempt acquisition of an existing grandfathered mobile Diagnostic Center pursuant to N.C. Gen. Stat. §§ 131E-184(a)(8) and 131E-176(7a);
- 2) Rex's Replacement Equipment described herein is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7); and
- 3) Rex will have the right to reconvert the grandfathered Replacement Equipment to mobile use again without a CON so long as no relevant cost thresholds or other CON new institutional health service definitions are triggered in the process.

If the Agency needs additional information to assist in its consideration of this request, please apprise us as soon as possible. We thank you for your consideration of this notice.

Sincerely,

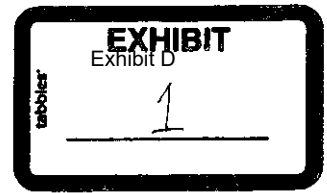


Gary S. Qualls

Martha Frisone
November 9, 2017
Page 6

Exhibits

1. Notice of Exempt Acquisition by FirstHealth of the Carolinas, Inc. dated October 29, 1998
2. Exempt from Review Letter dated November 9, 1998
3. CON Equipment Comparison Form
4. Documentation of Purchase Price of Replacement Equipment (software upgrades to existing equipment)



KILPATRICK STOCKTON LLP

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October 29, 1998

NOAH H. HUFFSTETLER, III
E-mail: nhuffstetler@kilstock.com
Direct Dial: 919.420.1812

HAND DELIVERED

Ms. Lee B. Hoffman, Chief
North Carolina Department of Health and Human Services
Division of Facilities Management
Certificate of Need Section
701 Barbour Drive - Council Bldg.
Raleigh, NC 27602-0629

Re: Notice of Exempt Acquisition by FirstHealth of the Carolinas, Inc.

Dear Ms. Hoffman:

As we have discussed by telephone, Riverside Health System of Newport News, Virginia, currently owns and operates a mobile cardiac catheterization laboratory which was located and in use in North Carolina prior to March 18, 1993, and has been continuously located and utilized in North Carolina to the present date. At the present time this laboratory is used by Riverside to provide services at Roanoke-Chowan Hospital, in Ahoskie, North Carolina. Riverside plans to create a new wholly-owned corporate subsidiary to be known as Riverside North Carolina Catheterization Services, Inc. ("the Provider"). The above-referenced cardiac catheterization laboratory, which is the only equipment of this kind that Riverside currently operates in North Carolina, will be owned by the Provider and any contracts for its use by North Carolina hospitals will be assigned to the Provider. Our client, FirstHealth of the Carolinas, Inc., ("FirstHealth") will purchase the Provider from Riverside and will locate its mobile cardiac catheterization laboratory on the campus of FirstHealth Moore Regional Hospital in Pinehurst, North Carolina. The Provider will thereafter be a wholly owned corporate subsidiary of FirstHealth. At some time in the future, FirstHealth may elect to merge the Provider into FirstHealth or one of its other corporate subsidiaries.

The purposes of this letter are as follows:

- (1) to notify the Department of Human Resources ("Department") of the transaction described above, as provided in N.C.G.S. § 131E-184(a);

KILPATRICK STOCKTON LLP

Ms. Lee B. Hoffman, Chief

October 29, 1998

Page 2

- (2) to explain briefly the reasons for the transaction; and
- (3) to request that the Department confirm that the transaction is exempt from certificate of need review under N.C.G.S. § 131E-184(a)(8).

FirstHealth desires to acquire the Provider from Riverside in order to increase patient access to cardiac catheterization services in its service area. Utilization of cardiac catheterization equipment as a diagnostic and interventional tool continues to increase. As the only tertiary facility in a six county service area, the demand for cardiac catheterization services at FirstHealth Moore Regional Hospital has continued to see significant increases -- approximately 17% per year over the past four years.

FirstHealth believes that this transaction should not require it to first obtain a certificate of need, as provided in N.C.G.S. § 131E-178. As you know, N.C.G.S. § 131E-184(a)(8) provides an exemption from certificate of need review for a proposal to "acquire an existing health service facility, including equipment owned by the health service facility at the time of acquisition." Under N.C.G.S. § 131E-176(9b), the term "health service facility" is defined to include a "diagnostic center." In turn, the term "diagnostic center" is defined by N.C.G.S. § 131E-176(7a) to mean "a freestanding facility, program, or provider, including, but not limited to . . . mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000)." Because this transaction involves the acquisition of a mobile diagnostic program in which the total cost of the medical diagnostic equipment utilized by the facility which costs ten thousand dollars (\$10,000) or more is \$1,124,554, this transaction qualifies for the above-referenced exemption.

This notice is timely, because FirstHealth has not yet incurred "an obligation for a capital expenditure which is a new institutional health service," as that term is defined in N.C.G.S. § 131E-178(c), with respect to the proposed acquisition. However, FirstHealth and Riverside hope to conclude the transaction described in this notice on or before December 1, 1998. Therefore, pursuant to this prior written notice, FirstHealth requests the Department to confirm as soon as possible that the proposed acquisition is exempt from certificate of need review under N.C.G.S. § 131E-184(a). Also, please let us know as soon as possible if you need additional information to assist in your consideration of this request.

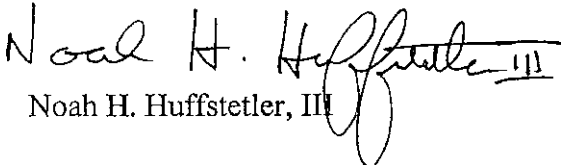
KILPATRICK STOCKTON LLP

Ms. Lee B. Hoffman, Chief
October 29, 1998
Page 3

Thank you for your prompt consideration of this matter. To confirm the timely submission of this notice, we would appreciate your returning to us the enclosed copy of this letter, stamped with the date of its filing. With best regards, we are

Very truly yours,

KILPATRICK STOCKTON LLP


Noah H. Huffstetler, III

cc: Ms. Lynn DeJaco
Ms. Caroline Martin
Mr. Peter S. Brunstetter

RALLIB01:484444.02



North Carolina Department of Health and Human Services
Division of Facility Services

701 Barbour Drive - Post Office Box 29530 Raleigh, N.C. 27626-0530

Courier Number 56-20-05

James B. Hunt, Jr., Governor
H. David Bruton, M.D., Secretary

Lynda D. McDaniel, Director

Certificate of Need Section
Phone: (919) 733-6360
Fax: (919) 733-8139

November 9, 1998

Noah H. Huffsteler, III
Kilpatrick Stockton LLP
Attorneys at Law
4101 Lake Boone Trail, Suite 400
Raleigh, NC 27607-6519

RE: Exempt from Review/ Acquisition by Riverside North Carolina Catheterization Services, Inc. ("Riverside NC"), of Riverside Health System's mobile diagnostic cardiac catheterization program/ Hertford County

RE: Exempt from Review/ Acquisition by FirstHealth of the Carolinas, Inc. ("FirstHealth"), of Riverside North Carolina Catheterization Services, Inc. ("Riverside NC"), including all equipment owned by Riverside NC/ Moore County

Dear Mr. Huffstetler:

In response to your letter of October 29, 1998, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(8). Therefore, FirstHealth may proceed to acquire Riverside Health System's entire cardiac catheterization program in North Carolina, including all cardiac catheterization equipment owned by Riverside Health System that is operated in North Carolina, without first obtaining a certificate of need. This determination is based on the following findings and conclusions:

1. Riverside Health System is located in Virginia and has a mobile diagnostic cardiac catheterization program in North Carolina. The mobile cardiac catheterization equipment currently operated by Riverside Health System is not a "mobile diagnostic program" or a "diagnostic center". Rather, Riverside Health System's entire mobile cardiac catheterization program in North Carolina is the "diagnostic center" as defined in N.C.G.S. 131E-176(7a), which would also be the case if Riverside Health System had more than one piece of mobile cardiac catheterization equipment in North Carolina.
2. Riverside Health System proposes to create a wholly-owned subsidiary to be known as Riverside North Carolina Catheterization Services, Inc. This company will own all cardiac catheterization equipment operated by Riverside Health System in North Carolina. Further, all contracts for

Noah Huffstetler
Page 2
November 9, 1998

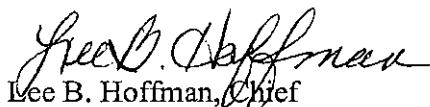
provision of cardiac catheterization services between Riverside Health System and North Carolina Hospitals will be assigned to Riverside NC. Therefore, Riverside Health System will no longer be a diagnostic center in North Carolina. Rather, Riverside North Carolina Catheterization Services, Inc. will acquire Riverside Health System's entire mobile cardiac catheterization program in North Carolina and consequently, will become the diagnostic center.

3. There will be no net increase in the number of diagnostic centers in North Carolina because Riverside Health System's diagnostic center in North Carolina, is being acquired by Riverside North Carolina Catheterization Services, Inc., which will become the new diagnostic center.
4. After Riverside NC becomes a diagnostic center, FirstHealth will acquire Riverside NC, including all equipment owned by Riverside NC. Riverside NC will become a wholly owned corporate subsidiary of FirstHealth.

Note that pursuant to N.C.G.S. §131E-181(b): "*A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need.*"

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,



Lee B. Hoffman, Chief
Certificate of Need Section

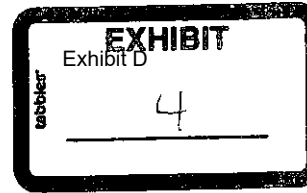
cc: Section Chief, Licensure and Certification Section, DFS

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Floor Mounted Single Plane X-ray	Ceiling Mounted Single Plane X-ray
Manufacturer of Equipment	Siemens	Philips
Tesla Rating for MRIs	n/a	n/a
Model Number	Axiom Artis 7412807	Allura Xper FD20
Serial Number	35610	71267710
Provider's Method of Identifying Equipment	Room Number Location	Room Number Location
Specify if Mobile or Fixed	Mobile	Fixed
Mobile Trailer Serial Number/VIN #	1TKH05126XB027601	n/a
Mobile Tractor Serial Number/VIN #	unknown	n/a
Date of Acquisition of Each Component	Not Yet Acquired	Not Yet Acquired
Does Provider Hold Title to Equipment or Have a Capital Lease?	Yes	Yes
Specify if Equipment Was/Is New or Used When Acquired	Used	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	n/a	n/a
Total Cost of Equipment	<\$50,000	\$13,000.00
Fair Market Value of Equipment	n/a	
Net Purchase Price of Equipment	n/a	
Locations Where Operated	UNC REX Healthcare	UNC REX Healthcare
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	n/a	n/a
Percent of Change in Per Procedure Operating Expenses (by Procedure)	n/a	n/a
Type of Procedures Currently Performed on Existing Equipment	Cardiac Catheterization and Vascular Imaging	n/a
Type of Procedures New Equipment is Capable of Performing	n/a	Cardiac Catheterization and Vascular Imaging



PO DATE: 10/17/2017



Acknowledge by email to purchase@unchealth.unc.edu (preferred) or fax 919-957-5786 with availability, Ship date, and Reference Nbr upon receipt of this PO.

If shipping charges contractually apply, ship Bill 3rd Party via FedEx account # 321417647, FOB Destination. If weight exceeds 150lbs, call 888-457-5851 for instructions.

TO PHILIPS MEDICAL SYSTEMS
CONTRACTS ADMINISTRATION
22100 BOTHELL-EVERETTE HWY
BOTHELL WA 98041-3003
ACCOUNT:

PURCHASE ORDER NUMBER

95100004687-0-9

SHOW PO NUMBER ON ALL SHIPPING LABELS, INVOICES, PACKING LIST, BILLS OF LADING. COPIES OF PACKING LIST MUST ACCOMPANY ALL SHIPMENTS. FAILURE TO COMPLY WILL RESULT IN REJECTION OF SHIPMENTS AND NONPAYMENT OF INVOICES.

MAIL REX Healthcare
INVOICE Accounts Payable Department
TO: 4400 Emperor Boulevard
Suite 100
Durham, NC 27703

Contact Susan Phillippi (Agent)
Phone 984-974-6590

SHIP TO: REX HEALTHCARE
4420 LAKE BOONE TRAIL
REX HEART & VASCULAR TOWER
ATTN JASON DUBRAY 919.357.7154
PO 95100004687-0-9
RALEIGH NC 27607

SHIP TERMS: Free On Board Destination		SHIP VIA: INSTALLED		PRICE	TOTAL
TERMS: NET 30		FREIGHT TERMS: Vendor Expense			

LINE	QTY	UOM	DESCRIPTION	PRICE	TOTAL
1	1.0000	LO	Purchase Order Currency: US Dollars Invoice by mail QUOTE 1-1085JCP DATED 9.23.2017 ATTN: BETHANN GRIFFITH-SUBIK 18-241500.01 101000-200700-510018241500.01-15002 NCVA VENTRICULAR QUANT SW PKG Deliver on November 3, 2017 SOFTWARE LICENSE UPGRADE	13,000.0000	13,000.00

PRODUCT TOTAL: \$13,000.00

TOTAL

\$13,000.00

<http://www.uncmedicalcenter.org/app/files/public/3464/pdf-medctr-about-us-purchasing-terms-conditions.pdf>

(If vendor prefers a hard copy of UNC Health Care Terms and Conditions of Purchase, please contact the Purchasing Agent shown on the face of this Purchase Order.)



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne
Assistant Secretary for Audit and
Health Service Regulation

April 22, 2016

Kimberly Jacobs
Kings Medical Group
1920A Georgetown Road
Hudson, OH 44236

Exempt from Review – Replacement Equipment

Record #: 1929
Business Name: Kings Medical Group
Business #: 1068
Project Description: Replace a grandfathered mobile MRI scanner
County: Durham

Dear Ms. Jacobs:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of April 11, 2016, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Siemens 1.5T Magnetom Espree mobile MRI scanner. This determination is based on your representations that the unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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,

Bernetta Thorne-Williams
Bernetta Thorne-Williams
Project Analyst

Martha J. Frisone
Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Kelli Fisk, Program Assistant, Healthcare Planning, DHSR



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

Exhibit C

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

February 13, 2023

Kimberly Jacobs
Kimberly.Jacobs@kingsmedical.com

Exempt from Review – Replacement Equipment

Record #: 4127
Date of Request: January 31, 2023
Business Name: Kings Medical Group
Business #: 842
Project Description: Permanently replace grandfathered mobile MRI scanner damaged due to fire
Counties: Buncombe & Mecklenburg

Dear Ms. Jacobs:

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 Siemens 1.5T Espree (serial #30075) mobile MRI scanner, which was a temporary replacement for the Siemens 1.5T Espree (serial #31421) mobile MRI scanner irreparably damaged by fire. This determination is based on your representations that the existing unit serving as the temporary replacement (Siemens 1.5T Espree serial #30075) 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. Faenza
Project Analyst

Micheala Mitchell
Chief

cc: Forrest W. Campbell, Jr. (fcampbell@brookspierce.com)

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

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Suite 150
Richfield, OH 44286
330.528.1765
kingsmedical.com

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January 26, 2023

VIA EMAIL ONLY

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

Re: Replacement Equipment Exemption for Fire-Damaged Mobile MRI Scanner and Trailer
Kings Medical Group
Business #: 842
Counties: Buncombe & Mecklenburg

Dear Ms. Mitchell:

On behalf of Kings Medical Group (“KMG”), I am writing to request a replacement equipment exemption pursuant to N.C. Gen. Stat. § 131E-184(a)(7). As the Agency may recall, in November 2021, one of the KMG legacy mobile MRI scanners, a Siemens Espree 1.T scanner, was irreparably damaged in a fire. This unit is known internally as Kings 1, and identified by serial number 31421 (the “Original Equipment”). In order to maintain service to our customer, Foundation Health Mobile Imaging, LLC, KMG asked for, and received, two temporary replacement equipment exemptions. The most recent temporary replacement MRI scanner is currently in use and has been used at least 10 times in the last 12 months to provide a health service. Please see **Exhibit A** attached to this letter

Due to global supply chain issues, it has taken some time to obtain a permanent replacement for the Original Equipment. The permanent replacement is a new GE Signa Voyager 1.5T mobile MRI scanner and US Lamboo Medical Mobile Unit powered by SVSR (the “Replacement Equipment”). The Replacement Equipment is expected to arrive in the spring of 2023. As detailed on **Exhibits B and C** attached to this letter, the total cost of the Replacement Equipment is \$1,750,000. Adding 8% sales tax bring the total to \$1,890,000. This includes all costs essential to acquiring and making the equipment operational (MRI, coils, trailer, injector, shield, and

chiller). Since the Replacement Equipment is mobile, there are no construction costs. The underlying quote is attached as **Exhibit D**.

As **Exhibit B** shows, the Replacement Equipment is comparable to the Original Equipment because the Replacement Equipment is not capable of providing a health service that the Original Equipment cannot provide. Further, the Original Equipment was not acquired less than 12 months prior to the date of this exemption request. While the irreparably damaged Original Equipment is not currently in use, **Exhibit A** shows that we obtained permission for temporary replacements, and the most recent temporary replacement has been in continuous use since February 2022. Accordingly, we have satisfied the “currently in use” requirement in N.C. Gen. Stat. § 131E-176(22a) and 10A NCAC 14C .0303(b).

If approved, the Replacement Equipment will be used at the same locations the temporary replacement scanner has been serving. These are:

1. Open MRI & Imaging of Asheville (Buncombe County);
2. Novant Health Imaging Steele Creek (Mecklenburg County);
3. Novant Health Imaging University (Mecklenburg County); and
4. Novant Health Mint Hill Medical Center (Mecklenburg County).

When the Replacement Equipment is ready to be used, the temporary replacement scanner will be removed from North Carolina and will not be returned to service in North Carolina absent Agency approval. Thus, this request will not cause an increase in the inventory of MRI scanners in North Carolina.

We respectfully request that the Agency issue its written determination that the acquisition of the Replacement Equipment as described in this letter is exempt from CON review.

Please let me know if you need any additional information.

Thank you for your time and consideration.

Sincerely,



Kimberly Jacobs
Chief Executive Officer

Exhibit A



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Exhibit C

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

February 15, 2022

Kimberly Jacobs
Kimberly.Jacobs@kingsmedical.com

Exempt from Review – Replacement Equipment

Record #: 3816
Date of Request: February 10, 2022
Business Name: Kings Medical Group
Business #: 842
Project Description: Temporarily replace grandfathered mobile MRI scanner due to fire damage
County: Buncombe & Mecklenburg

Dear Ms. Jacobs:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Siemens 1.5T Espree (serial #30075) to temporarily replace the Siemens 1.5T Espree (serial #31421) damaged by fire. This determination is based on your representations that the existing mobile MRI scanner is a total loss and cannot be used again; the replacement mobile MRI scanner from the out-of-state vendor will be removed and will not be used again in the State without first obtaining a certificate of need if one is required once the permanent replacement mobile MRI scanner is obtained; and Kings Medical Group will submit an exemption request for the permanent replacement mobile MRI scanner once it is obtained.

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,

Handwritten signature of Julie M. Faenza

Julie M. Faenza
Project Analyst

Handwritten signature of Micheala Mitchell

Micheala Mitchell
Chief

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

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Suite 150
Richfield, OH 44286
330.528.1765
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February 7, 2022

VIA EMAIL ONLY TO: DHSR.CON.Public.Info.Request@dhhs.nc.gov

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

Dear Ms. Mitchell:

As you may recall, on November 18, 2021, Kings Medical Group ("KMG") notified you about a fire that damaged the trailer and grandfathered MRI scanner, a Siemens 1.5 Espree known as Kings 1, serial number 31421 ("31421 Scanner"). By letter dated November 18, 2021, the Agency permitted KMG to temporarily replace the 31421 Scanner with a Siemens 1.5T Espree owned by Shared Imaging of Streamwood, IL, serial number 30781 (the "30781 Scanner"). A copy of the prior correspondence on this topic is attached for reference. KMG's agreement with Shared Imaging is ending February 18, 2022, so the 30781 Scanner will leave North Carolina and will not be used by KMG again in North Carolina absent further CON approval. In the meantime, so that we may continue to provide services to our customer, MedQuest/Novant, we have now been able to secure an out of state KMG-owned mobile scanner with the serial number 30075 ("30075 Scanner") to temporarily replace the 31421 Scanner. The 30075 Scanner is also a Siemens 1.5T unit. The associated trailer Vin# is 1M9A3A8272H022361.

The 30075 Scanner will be made available to Novant/MedQuest under a services agreement. The host sites that would be covered by this new temporary arrangement are:

1. Open MRI & Imaging of Asheville (Buncombe County)
2. Novant Health Imaging Steele Creek (Mecklenburg County)
3. Novant Health Imaging University (Mecklenburg County)
4. Novant Health Mint Hill Medical Center (Mecklenburg County)

We would like to implement the 30075 Scanner by February 19, 2022. We are not certain right now how long we will need this new temporary replacement but expect it will last for several months while a permanent replacement for the 31421 Scanner is sourced. When we have the details of the permanent

replacement for the 31421 Scanner, we will follow up with a replacement equipment exemption request.

Under the circumstances, and since time is of the essence so as not to create disruption to patients, we would appreciate your prompt written confirmation that we may proceed with the temporary replacement of the 31421 Scanner.

Thank you for your time, and please feel free to contact with me any questions.

Sincerely,

Kimberly Jacobs

Kings Medical Group

From: [Mitchell, Micheala L](#)
To: [Waller, Martha K](#)
Subject: FW: [External] Replacement Request for Mobile MRI Unit
Date: Thursday, February 10, 2022 3:47:09 PM
Attachments: [Outlook-41ccyg5n.png](#)
[3743 Multi Kings Medical Group Exemption.pdf](#)
[Medquest Trailer Fire replacement interim mobile 2.10.2022.pdf](#)

Exemptions for logging.

Thanks,

Micheala Mitchell, JD
[NC Department of Health and Human Services](#)
[Division of Health Service Regulation](#)
Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704
Office: 919 855 3879
Micheala.Mitchell@dhhs.nc.gov

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From: Kimberly Jacobs <Kimberly.Jacobs@kingsmedical.com>
Sent: Thursday, February 10, 2022 3:44 PM
To: DHSR.CON.Request <DHSR.CON.Request@dhhs.nc.gov>; Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>
Cc: Eric Evans <Eric.Evans@kingsmedical.com>; Jessica Spachner <Jessica.Spachner@kingsmedical.com>
Subject: [External] Replacement Request for Mobile MRI Unit

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Micheala Mitchell, Chief
Certificate of Need and Health Planning Section
North Carolina Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive

Raleigh, North Carolina 27603

Dear Ms. Mitchell:

As you may recall, on November 18, 2021, Kings Medical Group (“KMG”) notified you about a fire that damaged the trailer and grandfathered MRI scanner, a Siemens 1.5 Espree known as Kings 1, serial number 31421 (“31421 Scanner”). By letter dated November 18, 2021, the Agency permitted KMG to temporarily replace the 31421 Scanner with a Siemens 1.5T Espree owned by Shared Imaging of Streamwood, IL, serial number 30781 (the “30781 Scanner”). A copy of the prior correspondence on this topic is attached for reference. KMG’s agreement with Shared Imaging is ending February 18, 2022, so the 30781 Scanner will leave North Carolina and will not be used by KMG again in North Carolina absent further CON approval. In the meantime, so that we may continue to provide services to our customer, MedQuest/Novant, we have now been able to secure an out of state KMG-owned mobile scanner with the serial number 30075 (“30075 Scanner”) to temporarily replace the 31421 Scanner. The 30075 Scanner is also a Siemens 1.5T unit. The associated trailer Vin# is 1M9A3A8272H022361.

The 30075 Scanner will be made available to Novant/MedQuest under a services agreement. The host sites that would be covered by this new temporary arrangement are:

1. Open MRI & Imaging of Asheville (Buncombe County)
2. Novant Health Imaging Steele Creek (Mecklenburg County)
3. Novant Health Imaging University (Mecklenburg County)
4. Novant Health Mint Hill Medical Center (Mecklenburg County)

We would like to implement the 30075 Scanner by February 19, 2022. We are not certain right now how long we will need this new temporary replacement but expect it will last for several months while a permanent replacement for the 31421 Scanner is sourced. When we have the details of the permanent replacement for the 31421 Scanner, we will follow up with a replacement equipment exemption request.

Under the circumstances, and since time is of the essence so as not to create disruption to patients, we would appreciate your prompt written confirmation that we may proceed with the temporary replacement of the 31421 Scanner.

Thank you for your time, and please feel free to contact with me any questions.

Sincerely,
Kimberly

Kimberly Jacobs | Chief Executive Officer

KMG | *An Employee Owned Company*

Direct: 330.671.7113





NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Exhibit C

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

November 18, 2021

Kimberly Jacobs
Kimberly.Jacobs@kingsmedical.com

Exempt from Review – Replacement Equipment

Record #: 3743
Date of Request: November 18, 2021
Business Name: Kings Medical Group
Business #: 842
Project Description: Temporarily replace grandfathered mobile MRI scanner due to fire damage
Counties: Buncombe & Mecklenburg

Dear Ms. Jacobs:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Siemens 1.5T Espree (serial #30781) to temporarily replace the Siemens 1.5T Espree (serial #31421) damaged by fire. This determination is based on your representations that the existing mobile MRI scanner is a total loss and cannot be used again; the replacement mobile MRI scanner from the out-of-state vendor will be removed and will not be used again in the State without first obtaining a certificate of need if one is required once the permanent replacement mobile MRI scanner is obtained; and Kings Medical Group will submit an exemption request for the permanent replacement mobile MRI scanner once it is obtained.

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,

Handwritten signature of Julie M. Faenza

Julie M. Faenza
Project Analyst

Handwritten signature of Micheala Mitchell

Micheala Mitchell
Chief

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

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
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https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

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From: [Faenza, Julie M](#)
To: [Waller, Martha K](#)
Subject: FW: [External] Temporary CON Replacement - Mobile Siemens MRI
Date: Thursday, November 18, 2021 9:59:09 AM
Attachments: [Outlook-5tdofhzh.png](#)

Can we please log this as an exemption request? Thanks!

Julie M. Faenza, Esq.

Project Analyst, Certificate of Need

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

Office: 919-855-3873 (*I am working remotely most of the time; email is the best way to reach me.*)

Julie.Faenza@dhhs.nc.gov

Pronouns: She/her/hers

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From: Kimberly Jacobs <Kimberly.Jacobs@kingsmedical.com>

Sent: Thursday, November 18, 2021 9:54 AM

To: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>; Pittman, Lisa <lisa.pittman@dhhs.nc.gov>; Lightbourne, Ena <ena.lightbourne@dhhs.nc.gov>; Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>

Cc: deshepard@medquestmail.com; Eric Evans <Eric.Evans@kingsmedical.com>; Jessica Spachner <Jessica.Spachner@kingsmedical.com>; David L. Sweitzer <david.sweitzer@kingsmedical.com>

Subject: [External] Temporary CON Replacement - Mobile Siemens MRI

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Good morning CON Team,

Kings Medical Group (KMG) operates grandfathered mobile MRI scanners in North Carolina. The trailer for one of our mobiles, a Siemens 1.5T Espree having a serial number of 31421, known as Kings 1, caught on fire on Monday, November 8, 2021 while travelling on NC Highway 16 North near Denver, NC. The unit is believed to be a total loss and we are currently working to source a permanent replacement.

In the meantime, KMG needs to maintain services to its customer, Foundation Health Mobile Imaging, LLC (FHMI), a subsidiary of Novant Health, Inc., at various host sites so that patients can be treated without further service interruption. Due to the fire damage, many patients have already had to be rescheduled. Acquiring a permanent replacement MRI scanner for Kings 1 is going to take several months, due to global supply chain issues. KMG has no other mobile MRI inventory it can deploy to these host sites in the interim.

As a temporary solution, KMG proposes to enter into a contract with an out of state vendor, Shared Imaging of Streamwood, IL., to temporarily replace the damaged MRI. The temporary replacement mobile MRI will be a Siemens 1.5T Espree having a serial number of 30781, just like the one involved in the fire. The temporary replacement mobile scanner will be made available to FHMI under a services agreement. The host sites that would be covered by this temporary arrangement are:

1. Open MRI & Imaging of Asheville (Buncombe County)
2. Novant Health Imaging Steele Creek (Mecklenburg County)
3. Novant Health Imaging University (Mecklenburg County)
4. Novant Health Mint Hill Medical Center (Mecklenburg County)

We would like to implement the temporary replacement by November 19, 2021. We are not certain right now how long we will need the temporary replacement, but expect it will last for several months. When the permanent replacement for Kings 1 is ready, the temporary arrangement with Shared Imaging will end, and the Shared Imaging scanner will be taken out of North Carolina. When we have the details of the permanent replacement for Kings 1, we will follow up with a replacement equipment exemption request.

Under the circumstances, and since time is of the essence so as not to create further disruption to patients, may we proceed with the temporary replacement of Kings 1?

Thank you for your time, and please feel free to contact with me any questions.

Kimberly

Kimberly Jacobs | Chief Executive Officer

KMG | *An Employee Owned Company*

Direct: 330.671.7113



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Exhibit B

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	Mobile MRI Scanner & trailer	Mobile MRI Scanner & trailer
Manufacturer	Siemens	GE
Model number	Espreo	Voyager
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	SN 31421	TBD
Is the equipment mobile or fixed?	Mobile	Mobile
Date of acquisition	2012	Est. Spring 2023
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>	\$1,500,000	\$1,890,000
Total cost of the equipment	\$1,500,000	\$1,890,000
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	See attached	See attached
Document that the existing equipment is currently in use	See attached	N/A
Will the replacement equipment result in any increase in the average charge per procedure ?		No
If so, provide the increase as a percent of the current average charge per procedure		
Will the replacement equipment result in any increase in the average operating expense per procedure ?		No
If so, provide the increase as a percent of the current average operating expense per procedure		
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	MRI scans	
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>		MRI scans

Exhibit C

**Projected Capital Cost Form
Permanent Replacement for Kings 1 Legacy Mobile MRI Scanner**

Building Purchase Price	\$ N/A
Purchase Price of Land	\$ N/A
Closing Costs	\$N/A
Site Preparation	\$N/A
Construction/Renovation Contract(s)	\$N/A
Landscaping	\$N/A
Architect / Engineering Fees	\$N/A
Medical Equipment	\$1,890,000
Non-Medical Equipment	\$N/A
Furniture	\$N/A
Consultant Fees (specify)	\$N/A
Financing Costs	\$N/A
Interest during Construction	\$N/A
Other (specify)	\$N/A
Total Capital Cost	\$1,890,000

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER


I certify that, to the best of my knowledge, the projected capital cost for the proposed project is complete and correct.

Signature of Licensed Architect or Engineer

Date Signed:

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.



Signature of Officer/Agent

Date Signed: 1/26/2023

Chief Executive Officer

Title of Officer/Agent

Exhibit D



Kings Medical Group Inc
 4125 Highlander Pkwy Ste 150
 Richfield, OH 44286-9087

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:	Novation 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	\$1,750,000.00
Sales and Use Tax Exemption	Certificate on File

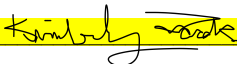
IMPORTANT CUSTOMER ACTIONS:

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 GE HFS Lease
- Other Financing Loan Other Financing Lease Provide Finance Company Name _____

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

Kings Medical Group Inc

Signature: 

Print Name: Kimberly Jacobs

Title: Chief Executive Officer

Date: 3/16/2022

Purchase Order Number, if applicable

GE Precision Healthcare LLC, a GE Healthcare business

Signature: Scott Hillenbrand

Title: Account Manager - VASO Mfr Rep

Date: February 7, 2022

To Accept This Quotation

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

Name: Scott Hillenbrand
Email: scott.hillenbrand@ge.com
Phone: +1 4407599899
Fax:

Name: Herb Klann
Email: herb.klann@ge.com
Phone: 724-504-8778
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

Kings Medical Group Inc**Addresses:**

Bill To: KINGS MEDICAL GROUP INC

KINGS MEDICAL GROUP INC, ACCOUNTS PAYABLE 4125
HIGHLANDER PKWY STE 150 RICHFIELD OH, 44286-9087

Ship To: SVSR INC

866 W MEMORIAL HWY NC,28634

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

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 # _____.

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	Y0000GD	US Lamboo Medical Mobile Unit powered by SVSR

US Lamboo Medical Mobile Unit powered by SVSR

Line	Qty.	Catalog	
2	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	
3	1.00	S7529VD	SIGNA™ VOYAGER 1.5T 33 CHANNEL 29.1 MOBILE MR SYSTEM with Fixed Table

The SIGNA™ 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™ 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 is designed for installation in the mobile environment. The system catalog comprises the magnet, RF-architecture electronics, core RF coil suite, gradient electronics, computing platform, patient table and MR29.1 operating/imaging software. 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
- Computing Platform and DICOM Conformance
- SIGNA™Works AIR™ IQ Edition Workflow SIGNA™Works with Comfort Plus Patient Table
- 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 magnet, RF-architecture, gradient and computing technology infrastructure on SIGNA™ 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 SIGNA™ 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 SIGNA™ 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 SIGNA™ 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 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 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 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

Computing Platform and DICOM Conformance – Host PC Platform – Intel Xeon W-2123 CPU

SIGNA™ Voyager utilizes a parallel, multi-processor design to enable simultaneous scanning, reconstruction, filming, post-processing, archiving and networking. Both the host computer and reconstruction systems use the Scientific Linux operating system. The host computer PC utilizes a single tower configuration and includes an LDC monitor and keyboard assembly with an integrated intercom speaker, microphone, volume controls, and emergency stop switch. Start scan, pause scan, stop scan and table advanced to center “hot” keys are also included.

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

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.

SIGNA™WORKS AIR™ IQ EDITION WORKFLOW WITH COMFORT PLUS TABLE

The SIGNA™Works AIR™ IQ Edition workflow tools comprise the Comfort Plus patient table, modality worklist, protocol libraries, workflow manager, auto-functions, inline viewing and inline processing. Together these tools are designed to change the way you work by simplifying and accelerating the scanning process from set-up to acquisition to post-processing. With SIGNA™Works, 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, SIGNA™Works AIR™ workflow maintains the flexibility needed to rapidly adapt and optimize exams for specific patient situations including the ability to pause and resume a scan without the need to start over.

The SIGNA™ Voyager offers a fully integrated Comfort Plus patient table that includes the embedded TDI Posterior Array (previously described) to address exam efficiency as well as patient comfort. The Comfort Plus patient table can be lowered to a very low height to facilitate transfer of wheelchair patients. The cradle width has also been increased by ~30% from previous generations to enhance the ability to accommodate a broad range of patients.

- Maximum patient weight for scanning: 550 LBS
- Maximum patient weight for lift: 550 LBS
- Automated vertical and longitudinal power drive
- Fast longitudinal speed: 25 cm/sec
- Slow longitudinal speed: 1.9 cm/sec
- IntelliTouch & laser land-marking
- Laser alignment land-marking

The SIGNA™Works AIR™ IQ Edition workflow tools comprise the modality worklist, protocol libraries, workflow manager, auto-functions, inline viewing and inline processing. Together these tools are designed to change the way you work by simplifying and accelerating the scanning process from set-up to acquisition to post-processing. With SIGNA™Works, 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, SIGNA™Works AIR™ workflow maintains the flexibility needed to rapidly adapt and optimize exams for specific patient situations.

With AIR™ 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 into 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, and commonly used protocols can be flagged as favorites for quick selection from the Modality Worklist. When AIR™ Recon DL (sold separately) and HyperWorks (sold separately) are purchased, associated protocols are unlocked for use.

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.

In the scan room, the AIR Touch™ user interface simplifies coil activation 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, 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.

Auto Functions when selected can 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) helping to address rescans. For breath-hold scanning, Auto Protocol Optimization provides alternative choices for spatial resolution and breath-hold time based on the original protocol.

For multi-station exams, such as brain and spine, chest and body or lower leg run-offs, AIR™ Workflow streamlines localization and scanning. Whole Body Localizer automates the acquisition and pasting of multi-station scans for planning, and Whole-Body automated multi-station scanning can be performed with FSE-IR, 3D SPGR and DWI diffusion. Once scanning and processing are complete, Split Exam provides the capability to extract a subset of series from the exam and 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

SIGNA™WORKS AIR™ IQ EDITION CLINICAL APPLICATIONS TOOLKITS

SIGNA™Works AIR IQ Edition is designed to change the way you work by simplifying and accelerating the scanning process from set-up to acquisition to post-processing while delivering access to a broad range of clinical imaging capability. The AIR™ IQ Edition of SIGNA™Works comprises the operating software, pulse sequence families, clinical applications and visualization toolkits as well as acceleration, motion correction and tissue suppression technology.

The technology tools in the SIGNA™Works AIR™ IQ Edition 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

Reduce scan set-up and acquisition time with a suite of techniques highlighted by AIR™ Workflow, parallel imaging and partial k-space techniques. Many techniques can be used in combination for additive effects.

- AIR Touch™ intelligent activation reduces set-up time by reducing coil selection and optimization to one finger touch and one mouse click. AIR™ Touch then activates coil elements based on the anatomy, FOV and ARC parallel imaging factor.
- AIR™ Recon is a smart reconstruction algorithm that reduces background noise and artifacts enabling enhanced image quality without the need for longer scan times. AIR™ Recon is compatible with a broad range of imaging sequences: the FSE fast spin echo, 3D Cube fast spin echo, SPGR/FSPGR, GRE/FGRE, PROPELLER MB, eDWI, FOCUS DWI, FIESTA, Black Blood, Time Course, MDE, SSMDE and StarMap.
- ARC parallel imaging reduces scan time using an auto-calibrating (data-driven) technique. ARC selectively acquires data using an adaptive algorithm. As a result, ARC enables smaller FOV prescription with less sensitivity to motion and prevents 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.
- Flexible No Phase Wrap reduces scan time by reducing the number of increments acquired 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 FatSat, ASPIR, STIR T1 and Auto Body Navigators to enable usage for a broad range of exams.

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.
- STIR uses an inversion pulse to null either the signal from fat or water based on the timing of the pulse.
- SPECIAL essentially combines FatSat and STIR by using a frequency selective inversion pulse that targets and suppresses the signal from fat.
- ASPIR enhances fat suppression by using a spectrally selective (instead of a single frequency) inversion pulse to null the signal from fat.
- IDEAL is a 3-point Dixon technique that separates the signal from fat and water based on phase shift and enables the generation of water-only, fat-only, in-phase and out-of-phase images.
- Flex is 2-point Dixon techniques that separates the signal from fat and water based on phase shift and enables the generation of water-only, fat-only, in-phase and out-of-phase images.

Clinical Toolkits

The SIGNA™Works AIR™ IQ Edition clinical imaging tools are organized and optimized to address six clinical work areas: NeuroWorks, OrthoWorks, BodyWorks, OncoWorks, CVWorks and PaedWorks.

NeuroWorks comprises pre-programmed protocols, clinical applications and visualization tools designed for the challenges of brain and brachial plexus imaging. Resulting capability starts with simplified prescription and protocol set-up. Imaging capability extends to sensor-free motion correction, advanced volumetric imaging, enhanced diffusion, susceptibility assessment and selective tissue suppression techniques. Post-processing capability augments the portfolio with 3D multi-planar reformat, volume segmentation/rendering, diffusion and fibertrak assessment and dynamic contrast-enhanced assessment.

- 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
- Flex 2-point Dixon fat-water separation for 2D FSE and 3D Cube
- 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
- eDWI enhanced diffusion with Multi-B value and SmartNEX
- DTI diffusion tensor imaging
- FiberTrak post-processing for diffusion tensor
- Enhance 3D velocity phase-sensitive non-contrast MRA
- Enhance 2D in-flow non-contrast MRA
- 3D SWAN 2.0 GRE-based multi-echo susceptibility imaging
- PROBE PRESS single voxel spectroscopy
- BrainStat GVF and AIF parametric maps
- READYView and BrainView post-processing

OrthoWorks delivers pre-programmed protocols, clinical applications and visualization tools designed for the challenges of joint, long bone and spine imaging. Resulting capability starts with fast-spin echo techniques as the foundation for articular cartilage, ligaments, menisci and sub-chondral bone imaging. Imaging capability also extends to sensor-free motion correction, advanced volumetric imaging, selective tissue suppression, cartilage assessment and spectral imaging for MR-Conditional implants. Post-

processing capability augments the portfolio with 3D multi-planar reformat, volume segmentation/rendering and T2 cartilage mapping.

- FSE and frFSE fast spin echo imaging suites with dynamic phase correction
- FatSat, STIR, SPECIAL, ASPIR, Spectral Spatial fat-suppression tools
- MARS High Bandwidth distortion reduction for FSE
- MAVRIC SL FSE-based volumetric spectral imaging for MR-Conditional implants with T1, PD, T2 and STIR
- 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
- Flex 2-point Dixon fat-water separation for 2D FSE and 3D Cube
- 3D COSMIC modified steady state imaging
- 2D/3D MERGE T2* multi-echo fast gradient echo imaging
- CartiGram T2 cartilage mapping
- READYView post-processing

BodyWorks delivers pre-programmed protocols, clinical applications and visualization tools designed for the challenges of imaging the upper abdomen, liver, male pelvis and female pelvis. Resulting capability starts with sensor-free motion correction and navigators that enable the ability to conduct free-breathing exams with a broad range of contrast weighting capability. Imaging capability further extends to snap-shot imaging, volumetric MRCP imaging, dynamic volumetric imaging, enhanced diffusion, iron deposition and selective tissue suppression techniques. Post-processing capability augments the portfolio with 3D multi-planar reformat and high-definition maximum/minimum intensity pixel projection.

- 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
- eDWI enhanced diffusion with Multi-B value and SmartNEX
- 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
- 3D LAVA Flex GRE 2-point Dixon fat-water separation for dynamic or single-phase imaging
- IDEAL FSE 3-point Dixon fat-water separation
- Flex GRE 2-point Dixon fat-water separation
- 3D MRCP frFSE imaging
- 2D Fat Sat FIESTA fast steady state imaging
- Enhanced SSFSE Snapshot multi-slice imaging with SmartR
- Whole-Body multi-station localizer and pasting
- Whole-Body multi-station FSE-IR, 3D SPGR and DWI imaging
- Enhance 2D in-flow with IR non-contrast MRA
- StarMap iron assessment for liver and heart (acquisition)
- Multiphase DynaPlan
- SmartPrep automated bolus detection
- Fluoro Trigger real-time bolus monitoring
- READYView and BodyView post-processing

OncoWorks delivers pre-programmed protocols, multi-station, contrast-timing, clinical applications and visualization tools designed for the challenges of imaging throughout the brain, spine and body. Resulting capability starts with tools that simplify and streamline the steps associated with multi-station acquisition and the timing of contrast delivery. Imaging capability includes sensor-free motion correction and navigators that enable the ability to conduct free-breathing exams with a broad range of contrast weighting capability. Capability further extends to snap-shot imaging, dynamic volumetric imaging, enhanced diffusion and selective tissue suppression techniques. Post-processing capability augments the portfolio with 3D multi-planar reformat, volume segmentation/rendering, diffusion assessment and auto-contour.

- 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
- Flex 2-point Dixon fat-water separation for 2D FSE and Cube
- 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 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 with SmartR
- Whole-Body multi-station localizer and pasting
- Whole-Body multi-station FSE-IR, 3D SPGR and DWI imaging
- eDWI enhanced diffusion with Multi-B value and SmartNEX
- 3D LAVA and TurboLAVA with Turbo ARC and SPECIAL
- Multiphase DynaPlan
- SmartPrep automated bolus detection
- Fluoro Trigger real-time bolus monitoring
- READYView, BrainView and BodyView post-processing

CVWorks delivers pre-programmed protocols, multi-station, contrast-timing, clinical applications and visualization tools designed for the challenges of imaging vascular structures and the heart. Resulting capability starts with tools that simplify and streamline the steps associated with multi-station acquisition and the timing of contrast delivery. Imaging capability includes sensor-free navigators that enable the ability to conduct free-breathing exams. For MRA, imaging capability includes 2D and 3D time-of-flight and phase contrast MRA, non-contrast MRA and dynamic MRA techniques. For the heart, imaging capability includes techniques for morphology, function, tissue characterization and iron deposition. Post-processing capability augments the portfolio with interactive vascular imaging for MRA and high-definition maximum/minimum pixel projection.

- 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 IR Prep gated fast gradient echo imaging
- Black Blood SSFSE single-shot FSE-based imaging
- Cine IR fast-gradient echo cardiac cine imaging with IR-prep pulse
- 2D/PS MDE phase sensitive tissue characterization
- StarMap iron assessment for liver and heart (acquisition)
- 2D/3D Time-Of-Flight & 2D Gated Time-of-Flight
- 2D/3D Phase Contrast & Phase Contrast Cine
- TRICKS dynamic contrast enhanced 3D MRA
- Inhance 3D DeltaFlow non-contrast MRA
- Inhance 2D in-flow non-contrast MRA
- SmartPrep automated bolus detection
- Fluoro Trigger real-time bolus monitoring
- 3D QuickStep automated multi-station imaging
- READYView post-processing

PaedWorks delivers pre-programmed protocols, clinical applications and visualization tools designed for the challenges of imaging pediatric patients. Resulting capability starts with sensor-free motion correction and navigators that enable the ability to conduct free-breathing exams with a broad range of contrast weighting. Imaging capability further extends to advanced volumetric imaging, dynamic volumetric imaging, enhanced diffusion, susceptibility assessment, selective tissue suppression techniques and spectral imaging for MR-Conditional implants. Post-processing capability augments the portfolio with 3D multi-planar reformat, volume segmentation/rendering and diffusion assessment.

- 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 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
- eDWI enhanced diffusion with Multi-B value and SmartNEX
- DTI diffusion tensor imaging
- FiberTrak post-processing for diffusion tensor

- SWAN 2.0 3D GRE-based multi-echo susceptibility imaging
- PROBE PRESS single voxel spectroscopy
- MAVRIC SL FSE-based spectral imaging for MR-Conditional implants
- Auto Navigators diaphragm tracker free-breathing scanning
- 3D LAVA and Turbo LAVA with Turbo ARC and SPECIAL for dynamic or single-phase imaging
- 3D LAVA Flex GRE 2-point Dixon fat-water separation for dynamic or single-phase imaging
- Enhanced SSFSE Snapshot multi-slice imaging with SmartR
- Black Blood SSFSE single-shot FSE-based imaging
- Cine IR fast-gradient echo cardiac cine imaging with IR-prep pulse
- 2D PS/MDE phase sensitive tissue characterization
- StarMap iron assessment for liver and heart (acquisition)
- BrainStat GVF and AIF parametric maps
- READYView and BrainView post-processing

Advanced Visualization and Post-Processing

READYView is a SIGNA™ Works AIR™ IQ Edition 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	
4	1.00	M70072AR	SIGNA Voyager 33 to 49 Channel Upgrade

SIGNA Voyager 33 to 49 Channel Upgrade

Line	Qty.	Catalog	
5	1.00	M70012TS	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	Qty.	Catalog	
6	1.00	M70012RP	English Language Kit

English Language Kit

Line	Qty.	Catalog	
7	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	Qty.	Catalog	
8	1.00	S7529HQ	AIR™ XT WITH DIFFUSION PACKAGE for SIGNA™ VOYAGER 1.5T

The AIR™ XT and Diffusion package for SIGNA™ Voyager 1.5T comprises the 16ch AIR™ AA, 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.

- 16-channel AIR™ Anterior Array
- AIR x™ Auto Graphic Prescription
- AIR™ Recon DL and DL Reconstruction Engine
- Diffusion Package with PROGRES, MUSE, FOCUS and MAGiC DWI

16-channel AIR™ Anterior Array

Transform patient and coil set-up. The 16-channel AIR™ Anterior Array uses next generation technology and design to deliver superb SNR and acceleration performance, while also improving the overall patient and user experience. Inca conductors and E-mode modules enable the AIR™ AA coil to adapt to various patient shapes and sizes, with an ultra-lightweight distribution of less than 0.5 grams/cm². The AIR™ AA can be used for torso, cardiac, abdomen, prostate, pelvis, hip, peripheral vascular and long bone examinations in conjunction with other coils.

AIR x™ Auto Graphic Prescription

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

AIR™ Recon DL and DL Reconstruction Engine

Level-up your image quality. AIR™ 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). AIR™ 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 enhanced performance.
 Diffusion Package

Extend diffusion capability. The Diffusion Package delivers techniques that reduce distortion, correct for motion and increase spatial resolution 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 for large to small fields-of-view. MUSE is compatible with Auto Body Navigators, respiratory and cardiac gating, ARC and ASSET acceleration, FatSat and STIR. For small fields-of-view, FOCUS enables high spatial resolution for small organ-specific imaging. 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.

To further extend diffusion capability, 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.

The AIR™ XT with Diffusion package for SIGNA™ Voyager 1.5T requires the MR29.1 software platform (sold separately).

Line	Qty.	Catalog	
9	1.00	M7001NE	1.5T 3-Channel Shoulder Array

The 1.5T 3-channel Shoulder Array offers the increased signal-to-noise characteristic of phased-array technology, along with a unique sleeve design that delivers exceptional joint-imaging capabilities. The coil provides clear definition of the shoulder joint, specifically the head of the humerus, clavicle, acromion, supraspinatus muscle and ligaments. Patient comfort pads and restraining straps are included.

Line	Qty.	Catalog	
10	1.00	M7006YJ	1.5T AIR™ Multi-Purpose Coil Large & Medium with Positioners

A package includes 1.5T AIR™ Multi-Purpose (MP) Coils, Large and Medium, with a coil positioner kit.

The 21-channel 1.5T AIR Multi-purpose (MP) Large and The 20-channel 1.5T AIR MP Medium are the next generation multipurpose coils that allow flexibility in any direction to conform to the patient's anatomy. Based on the innovative AIR™ Coil technologies, those 1.5T AIR™ MP Coils provide good image quality and acceleration performance, while improving the overall patient and user experience. Those coil have been designed to adapt various patient shapes and sizes, expanding positioning versatility. AIR™ MP Coil Large is recommended to be used for Shoulder, Forearm, Prostate, Hip/bony pelvis, Knee (large patients), Long bone, Foot/ankle. AIR™ MP Coil Medium is recommended to be used for Cardiac, Elbow, Hand/wrist, Knee (small patients), Forefoot.

The AIR™ MP Coil positioner kit includes a knee positioner, a foot-ankle positioner, a wedge pad, a u-shaped pad and a strap kit. Those are compatible with both AIR™ MP Coils Large and Medium for positioning.

Line	Qty.	Catalog	
11	1.00	E8823NA	MRI Audio 1505 Complete system (for SIGNA Premier, Discovery™ MR750/750w,

Optima™ MR450/450w, SIGNA™ PET/MR, SIGNA Architect/Artist/Voyager/Pioneer, SIGNA HDxt, and SIGNA Creator/Explorer hardware v25.3 and Pioneer hardware v26.1)

MRI Audio 1505 Complete music system for MRI systems is designed for comfort and allows the patient to listen to music while being scanned in an MRI. The technologist is in full control of the system headphones, microphone, sound source and volume controls. Standard 3.5 mm plug for music source allows any compatible music player, tablet or phone. In-ear headphones work with any head coil.

Package includes:

- Digital amplifier
- iPad Mini
- iPad Mini mount with lock
- 3G transducer
- In-ear headphones, 29dB noise reduction
- Over-ear headphones, 29dB noise reduction
- Disposable ear tips (300 pairs)
- Technologist's speakers
- 6 ft RCA 3.5 mm cable
- Auto-voice/MIC adapter

Line	Qty.	Catalog	
12	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, Cockcroft-Gault, Modified Cockcroft-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
- 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

Line	Qty.	Catalog	
13	1.00	E88221XC	Penetration Panel for MEDRAD MRXperion injector

The penetration panel filter kit 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.

Penetration panel filter kit option includes:

- Filter assembly
- Mounting/centering ring
- Mounting screws
- Conductive O-ring (pre-installed on the filter)
- Power supply cable - 10 ft. (3 m)
- Installation instructions

Line	Qty.	Catalog	
14	1.00	E80141HG	Mobile Mount Support for Stellant D and Flex and MRXperion

Line	Qty.	Catalog	
15	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	
16	1.00	NI_MR_PU RC_SUPPL Y	Lamboo Mobile Trailer for Signa Voyager

Hardware and software items sourced directly from 3rd parties Comments

Total Quote Subtotal: \$1,750,000.00

Total Quote Net Selling Price: \$1,750,000.00

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

GPO Agreement Reference Information

Customer:	Kings Medical Group Inc
Contract Number:	Novation 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 Novation Vizient Supply LLC

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

This product offering is made per the terms and conditions of Vizient /GE Healthcare GPO Agreements as follows:

Imaging:

XR0882-MR, XR0702-Card./Vasc., XR0673-CT, XR0342-Mammo, XR0351-PET-CT, XR0362-Nuc Med, XR0715-R&F/RAD & XR0592-ICAR-EP/HEMO, XR0692-BMD

Ultrasound:

XR0431-Ultrasound

LCS:

CE2512 (Anesthesia), CE3033 (Monitoring), CE3333 (Infant Care), CE2881 (DCAR) and CE0351 (EP).

Vizient: Please login to the Vizient Marketplace Website. If you require assistance or are experiencing issues, please contact Vizient for support: Email: Connect@VizientInc.com and Phone: 866-600-0618.

From: [Mitchell, Micheala L](#)
To: [Stancil, Tiffany C](#)
Subject: FW: [External] Exemption Request--Kings Medical Group Replacement MRI
Date: Tuesday, January 31, 2023 2:40:15 PM
Attachments: [Kings Medical Group Ltr for Permanent Replacement 1-26-23 4871-0054-9966 v.1.pdf](#)

Tiffany,

Would you mind logging this one and assigning it to Julie?

Thanks,

Micheala Mitchell, JD
(*she/her/hers*)
Section Chief, Healthcare Planning and CON Section
[NC Department of Health and Human Services](#)
[Division of Health Service Regulation](#)
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704
Office: 919 855 3879
Micheala.Mitchell@dhhs.nc.gov

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From: Forrest W. Campbell, Jr. <FCAMPBELL@brookspierce.com>
Sent: Tuesday, January 31, 2023 2:33 PM
To: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>
Cc: Kimberly Jacobs <Kimberly.Jacobs@kingsmedical.com>
Subject: [External] Exemption Request--Kings Medical Group Replacement MRI

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

Dear Micheala,

I hope you're doing well. We represent Kings Medical Group. Attached is a letter from Kings CEO, Kimberly Jacobs, requesting confirmation that Kings proposed acquisition of a replacement mobile MRI scanner is exempt from review. The letter includes Exhibits A-D.

Please let me know if you have any questions.

Thanks—Forrest

[Forrest W. Campbell, Jr.](#)



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f: 336.232.9179

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230 North Elm Street
Greensboro, NC 27401
P.O. Box 26000 (27420)

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This email has been scanned for viruses and malware by Mimecast Ltd.

From: [Denise Gunter](#)
To: [Stancil, Tiffany C](#); [Faenza, Julie M](#)
Cc: [Forrest Campbell \(fcampbell@brookspierce.com\)](mailto:fcampbell@brookspierce.com)
Subject: [External] Notice of Exempt Acquisition for Mobile Diagnostic Program
Date: Monday, March 6, 2023 3:16:53 PM
Attachments: [March 6 2023 Letter.pdf](#)
[Exemption Letter 2016 Replacement 4875-8215-0464 v.1.pdf](#)
[Exemption Letter 2014 Replacement 4892-0003-7440 v.1.pdf](#)
[Replacement Approval 2-13-2023 for Permanent MRI 4874-2418-6448 v.1.pdf](#)
[NC DHSR HPCON 2017 Exemption for UNC Rex Hospital 4880-1346-7707 v.1.pdf](#)

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Good afternoon,

Attached for filing is a notice of exempt acquisition with attached Exhibits A-D. Could you please confirm that you have received it?

Thanks.



DENISE M. GUNTER PARTNER
denise.gunter@nelsonmullins.com

She/Her/Hers

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