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

May 14, 2015

Carla Hollis
500 Jefferson Street
Whiteville, NC 28472

Exempt from Review - Replacement Equipment

Facility:	Columbus Regional Healthcare System
Project Description:	Replace existing fixed MRI
County:	Columbus
FID #:	923111

Dear Ms. Hollis:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of May 1, 2015, 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 GE Optima MR450W 1.5 Tesla MRI to replace the existing GE Sigma Openspeed 0.7 Tesla MRI. 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.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

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,

Tanya S. Rupp
Project Analyst

Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Assistant Chief, Healthcare Planning

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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Columbus Regional
HEALTHCARE SYSTEM

Received by the CON Section MAY 5 2015

May 1, 2015

Mr. Craig R. Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, North Carolina 27696-2704

RE: Notice of Exemption: Replacement of MRI Equipment
Columbus Regional Healthcare System
Whiteville, NC

Dear Mr. Smith:

Through this letter, Columbus Regional Healthcare System ("CRHS") is providing prior written notice of its plans to replace an existing fixed MRI located in the Imaging Department of the CRHS campus with new fixed MRI. No new service will be offered in connection with this project. Please confirm that the replacement of this equipment does not constitute a new institutional health service subject to certificate of need ("CON") review within the meaning of N.C. Gen. Stat. § 131E-176(16) and is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(7).

The existing fixed MRI is a ten-year-old General Electric ("GE") Signa OpenSpeed MRI which is currently located in the Imaging Department on the CRHS campus. The existing equipment is near the end of its useful life and is at risk for service interruptions due to downtime and limited availability of service parts. The replacement equipment is a GE General Electric ("GE") Optima MRI 450W, 1.5T.

The total capital cost related to the replacement of the equipment including removal of the existing unit, installation of the replacement unit and purchase of the equipment is $1,986,765; see attached. The cost for the new MRI is $1,328,490; see attached purchase order. The existing MRI will be taken out of service and will not be reinstalled in the State of North Carolina. See attached letter from vendor removing the equipment.

500 Jefferson Street ■ Whiteville, North Carolina 28472
Telephone: 910-642-8011
www.crhealthcare.org

The North Carolina Certificate of Need Act defines "replacement equipment" as "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." N.C. Gen. Stat. § 131E-176(22a). As discussed above, CRHS's proposed replacement of its existing CT scanner meets these conditions. The capital expenditures for the proposed project will not exceed $2,000,000, and the existing equipment will be sold when replaced.

Attached please find additional information demonstrating the equipment to be acquired is consistent with the definition of replacement equipment in N.C. Gen. Stat. § 131E-176(22a) and 10A N.C.A.C. 14C.0303.

1. A description of the basic technology and functions of the existing and replacement equipment, including the diagnostic and treatment purposes for which the equipment is used or capable of being used.

Existing Equipment

GE Signa Openspeed 0.7 T with Excite Platform
The current MRI in use at Columbus Regional Healthcare is a GE Signa Openspeed 0.7 T magnet. The unit features 8 channels and in comparison of today's standards is somewhat limited. The unit features a standard coil package, which includes the following: Spine, Head, Knee, Shoulder, Abdomen, Hand/Wrist, and Foot/Ankle. The existing unit has been in place for 10 years and is no longer supported by the manufacturer. Part availability for this unit is also scarce placing Columbus Regional Healthcare at an increased risk of a significant interruption to patient care if this unit is not replaced.

Replacement Equipment

GE Optima MRI 450W, 1.5T

- Magnet – Highly homogeneous magnet with a 50 x 50 x 50 cm field of view to cover more anatomy in fewer scans.
- Digital RF (OpTix) – High channel count, analog to digital-optical signal conversion inside the scan room to minimize noise and signal degradation.
- Acoustic Reduction Technology (ART) –Both passive and active noise reduction technologies, Art reduces acoustic noise to improve the patient environment.
- Non-contrast imaging – Allows the ability to perform high-resolution non-contrast lower extremity imaging with Inhance DeltaFlow, arterial and venous neuro imaging, quantitative perfusion imaging, and consistent and reliable free-breathing imaging of the arterial and venous vasculature with Inhance Inflow IR. All without contrast agent.
- Exceptional breast imaging –IDEAL and VIBRANT Flex applications allow improved imaging quality for breast MR.
- Two-station whole-spine imaging – Allows the acquisition of an entire spine in a fraction of the time – and with multiple contrasts.

- 3D Arterial Spin Labeling (3D ASL) – Allows the generation of full-coverage and high-SNR 3D image of the brain, a great addition for aiding with the diagnosis of cerebrovascular conditions.

2. Brochures or letters from the vendors describing the capabilities of the replacement equipment. See Attached.

3. The original purchase price for the existing MRI was $1,395,891.

4. A copy of the title, if any, for the existing equipment or the capital lease for the existing equipment. Not Applicable.

5. A letter from CRHS's Director of Radiology, dated 4/9/15, documenting that the existing equipment is currently in use and has not been taken out of service. See Attached.

We look forward to receiving your letter confirming CRHS's replacement of a MRI in its Imaging Department on the CRHS campus is exempt from CON review. If you have any questions or require further information regarding this project please contact me at (910) 642-1776.

Sincerely,

Carla Hollis
Chief Executive Officer
Columbus Regional Healthcare System

Attachments

MRI - RENOVATION COLUMBUS REGIONAL HEALTHCARE SYSTEM WHITEVILLE, NC WIP# 100000-180135	
	Preliminary Project Budget
TOTAL CONSTRUCTION	$322,500
TOTAL EQUIPMENT & FURNITURE	$1,446,665
TOTAL INFORMATION SYSTEMS	$5,800
TOTAL PROFESSIONAL FEES	$96,200
TOTAL PROJECT CONTINGENCIES	$115,600
PROJECT TOTALS	$1,986,765

Printed on 4/30/2015

Cust Account #: **111134**

PURCHASE ORDER

PO Number: **5535**

Corporation: CR HEALTHCARE SYSTEM

Tax Exempt ID:

Vendor: GE HEALTHCARE **Vnd No:** 191 **Phone:** 800-292-8514 **Fax No:** **Address:** PO BOX 100867 ATLANTA, GA 30384 **Est Arr Date:**	**Ship To:** 500 JEFFERSON STREET WHITEVILLE, NC 28472 **Phone:** 910-642-1745 **Fax:** 910-642-9306 **Contact:** THERON MCKVIAN **E-mail:** tmckvian@crhealthcare.org **Ship Via:**	**Bill To:** 500 JEFFERSON STREET WHITEVILLE, NC 28472 **Phone:** 910-642-8011 **Fax:** 910-642-9306 **Contact:** **E-mail:** **Terms:** INV NET 30	**Created On:** 06/27/2013 **Printed On:** 04/24/2015 08:53:28 **Special Instructions:** Non-binding PO for MRI

Line	Qty / UOM Pck Ref	Item ID / Vendor Catalog #	Description Notes	GL Acct / Corporation Deliver to Location	Order Price	Line Total	--Receiving-- 1st 2nd 3rd 4th
1	1 EA		QUOTATION # PR11-C2377 V 10 CAT# S7024SF----SILENT OPTIMA MR450w 1.5T GEM SEE QUOTE FOR DETAILS	100000-174101 501 RAD - RADIOLOGY	1,328,490.28000	1,328,490.28000	

IF SHIPPING CHARGES APPLY, SHIP BILL 3RD PARTY VIA FEDEX GND ACCT # 367414073.

Authorized Signature Theron D. McKvian

PO Total: **$1,328,490.28**

April 9, 2015

To whom it may concern:

The Imaging Department at Columbus Regional Healthcare currently has a GE Signa OpenSpeed MRI. As Director of Imaging, I certify that this unit is still in use and has not been taken out of service.

Sincerely,

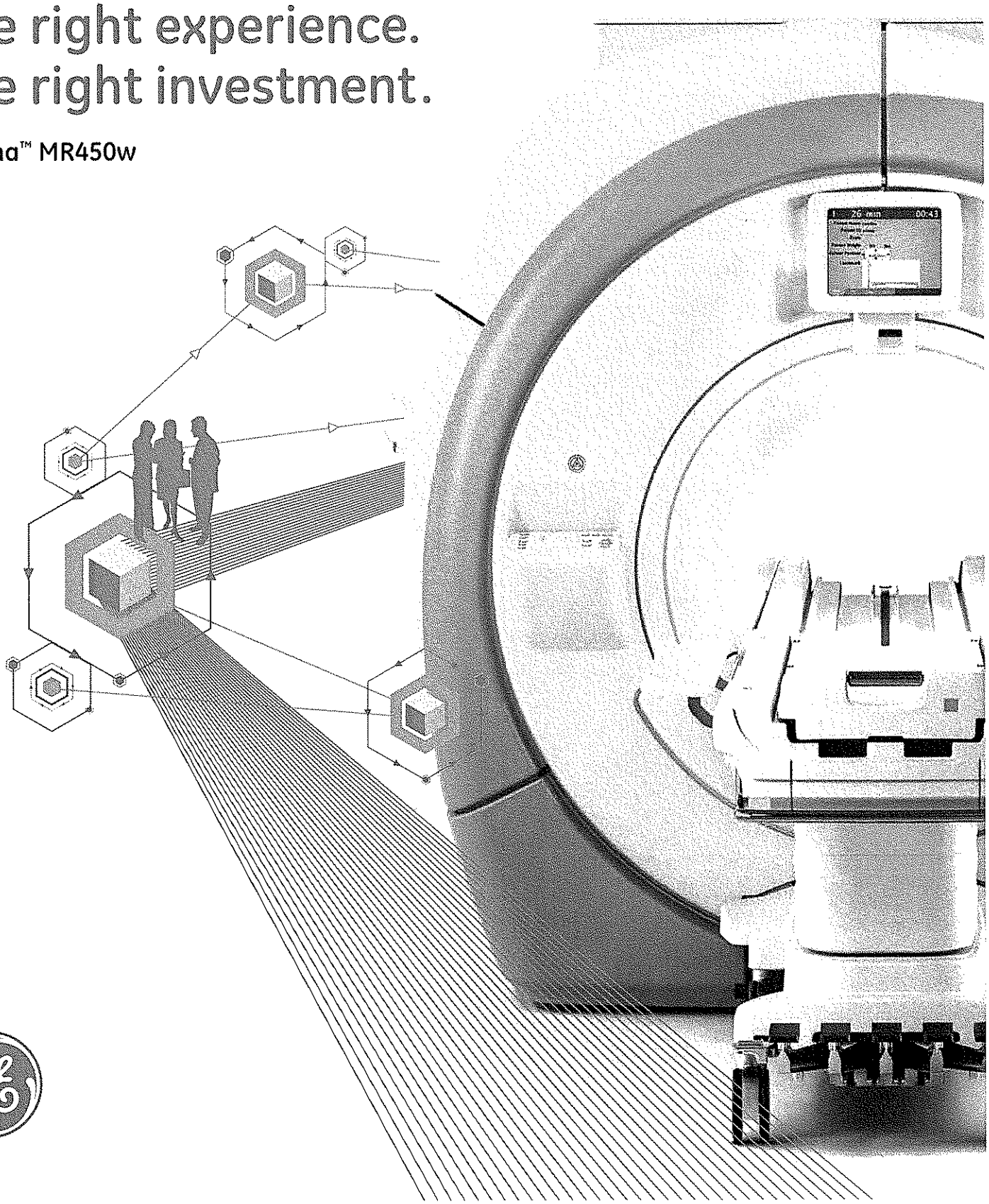
Jason Beck
Director of Imaging
Columbus Regional Healthcare System

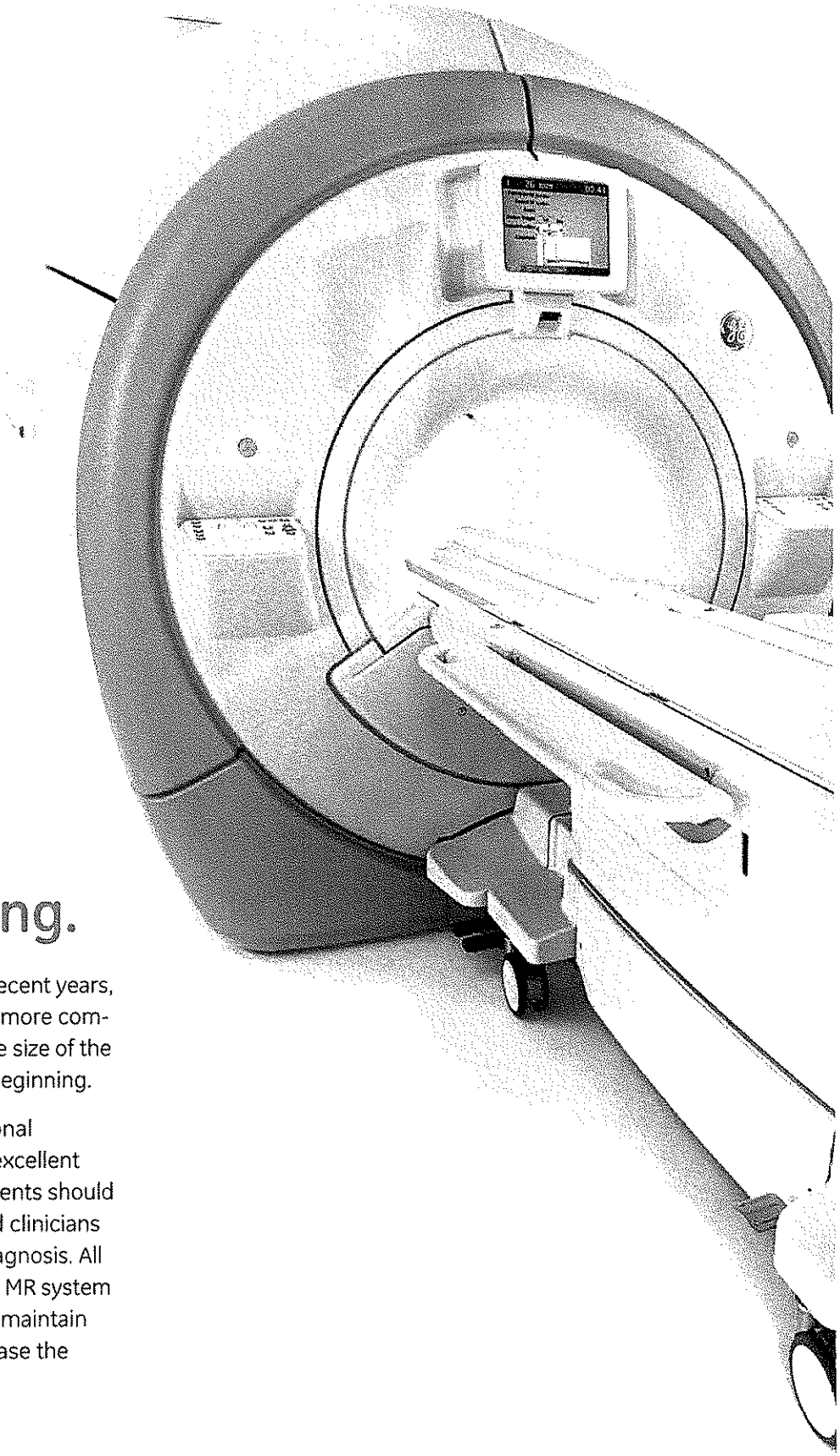
(910) 642-9324

GE Healthcare

The right capabilities.
The right experience.
The right investment.

Optima™ MR450w





The world of MR is always changing.

Patient expectations of MR have shifted in recent years, as people have begun demanding a better, more comfortable scanning experience. Increasing the size of the bore is a good first step—but it's only the beginning.

The right system should overcome traditional limitations of wide-bore MR, offering both excellent images and a user-friendly experience. Patients should be more comfortable during their scan, and clinicians more comfortable in making a definitive diagnosis. All the while, organizations should expect their MR system to help them deliver solid financial returns, maintain a high standard of patient safety, and increase the quality of their care.

Today, the right way has arrived.

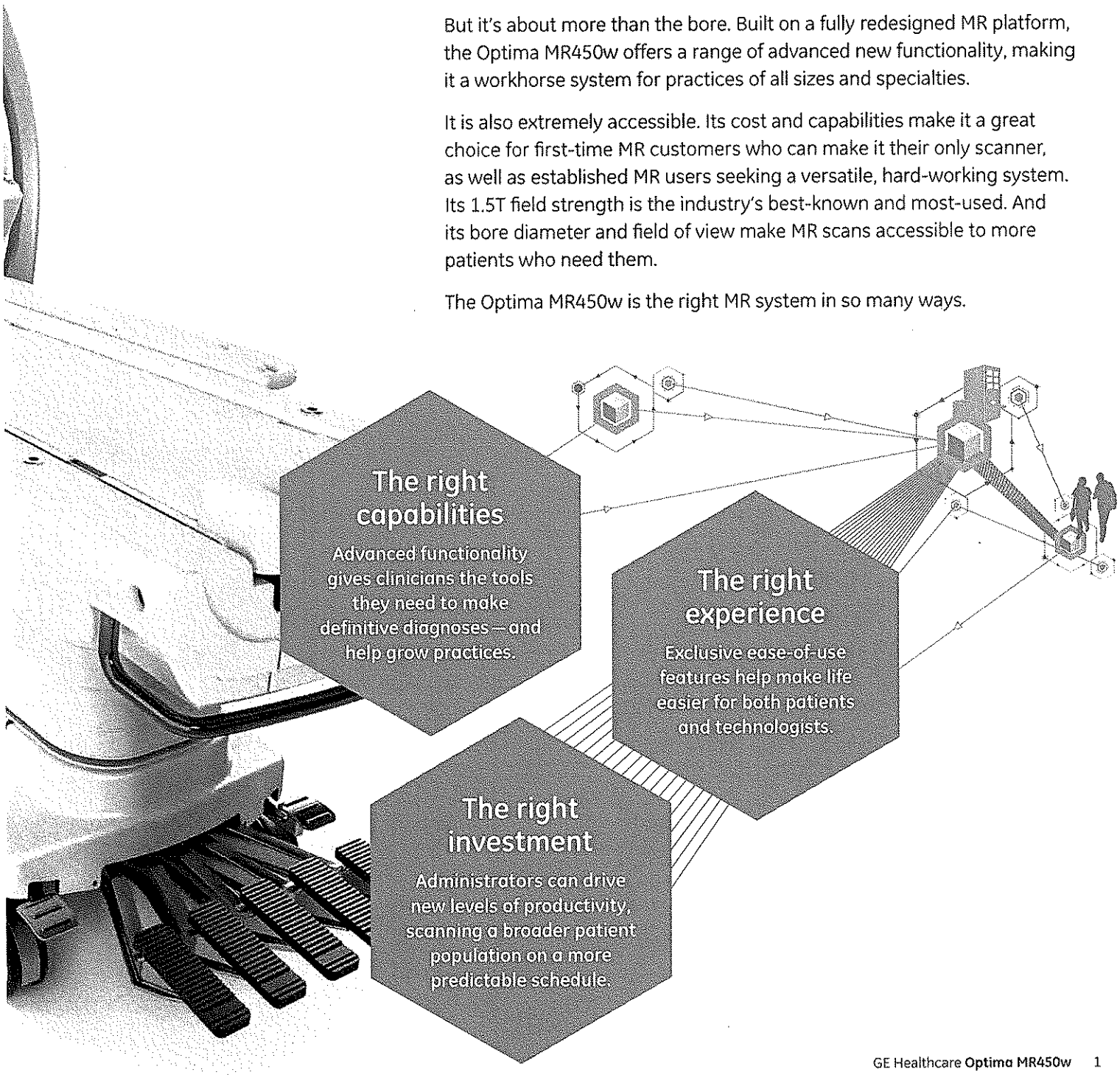
The Optima MR450w is wide-bore MR done right.

Thanks to cutting-edge technologies, we've advanced the capabilities of wide-bore MR by delivering both uncompromised image quality and high productivity — all with an expansive 50cm field of view.

But it's about more than the bore. Built on a fully redesigned MR platform, the Optima MR450w offers a range of advanced new functionality, making it a workhorse system for practices of all sizes and specialties.

It is also extremely accessible. Its cost and capabilities make it a great choice for first-time MR customers who can make it their only scanner, as well as established MR users seeking a versatile, hard-working system. Its 1.5T field strength is the industry's best-known and most-used. And its bore diameter and field of view make MR scans accessible to more patients who need them.

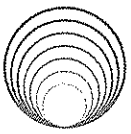
The Optima MR450w is the right MR system in so many ways.



The right capabilities — to diagnose *and* grow.

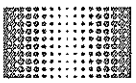
The Optima MR450w delivers exquisite image quality to aid in your diagnosis. To meet your high quality expectations, the advanced capabilities of our Discovery™ MR platform have been applied in the Optima MR450w, making it both versatile and powerful.

FROM ADVANCED TECHNOLOGIES...



Redesigned magnet

A completely new 145cm long magnet is designed to ensure uniform tissue contrast in a patient-friendly space.



eXtreme gradients

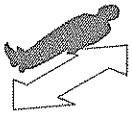
Strong whole-body gradients deliver 34 mT/m amplitude and 150 T/m/s slew rate on each axis, yielding scans that are fast, accurate, and highly reproducible.

OpTix RF digital receiver

An exclusive optical RF system increases signal clarity and maximizes signal intensity for clean, crisp images.

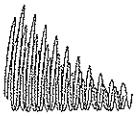
Anatomy-optimized RF coils

High-density coils focus elements around the anatomy of interest and provide extended coverage where needed, for optimal image quality in virtually every procedure.



Express patient table

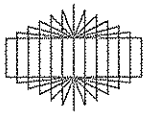
A fully removable table minimizes time between scans to help boost productivity.



Acoustic Reduction Technology

Reduce an acquisition's acoustic noise with virtually no compromise to image quality.

...COME POWERFUL ABILITIES.

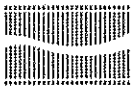


Large field of view

With a 50cm field of view, you can cover more anatomy in fewer scans.

Unmatched breast imaging

Thanks to applications like IDEAL and VIBRANT-FLEX, no comparable solution can capture so much so well.



Two-station whole-spine imaging

Acquire an entire spine in a fraction of the time—and with multiple contrasts.

Holistic Liver Assessment

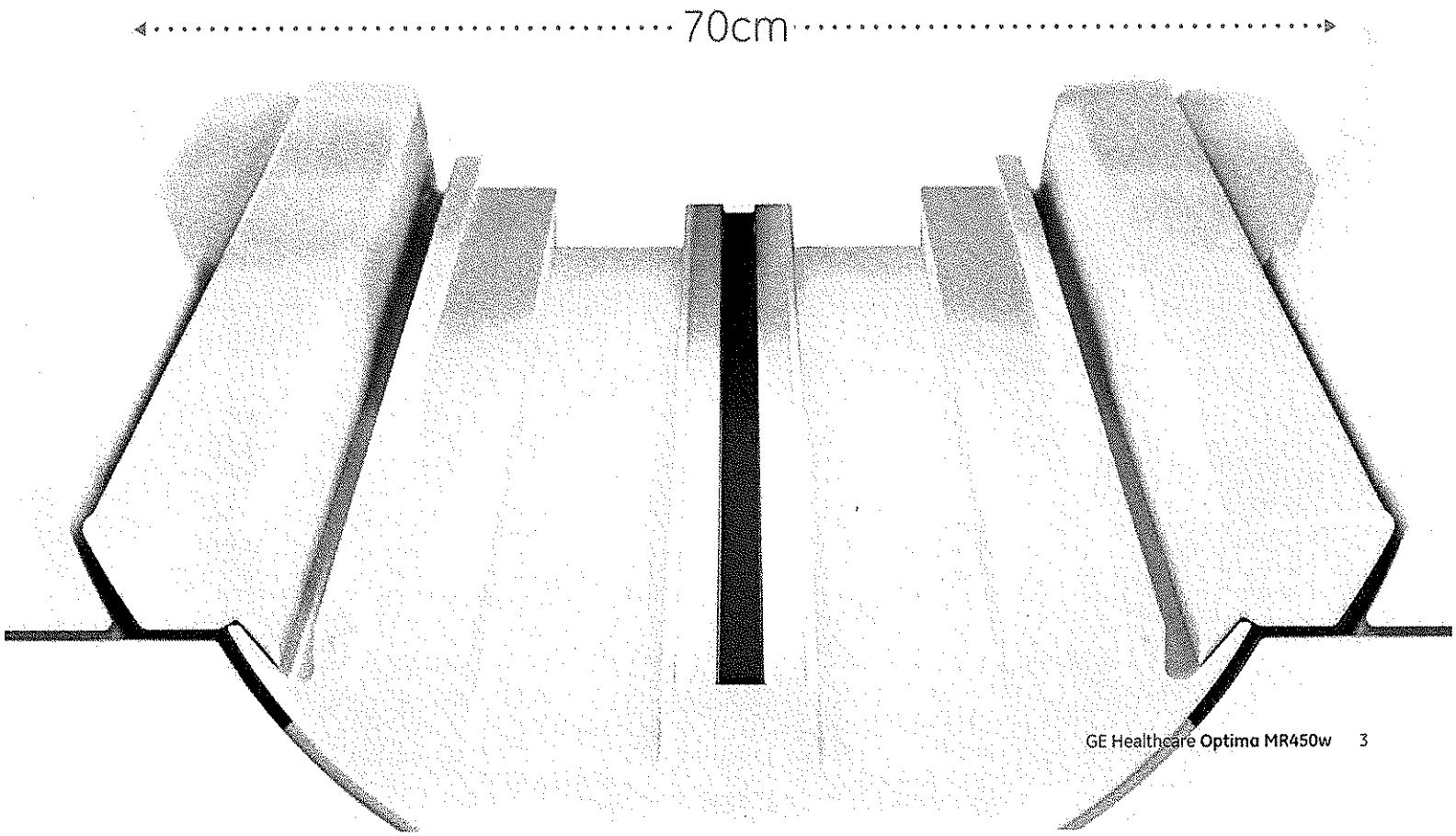
An industry first, MR-Touch opens up new opportunities for care by identifying variations in liver tissue stiffness.

3-D Arterial Spin Labeling (3D ASL)

Generate a full-coverage, high-SNR 3D image of the brain, great for evaluating cerebrovascular conditions such as stroke.

Growing your offerings — and your practice

Along with these capabilities, the system's wider bore opens up additional pathways for diagnosis and treatment. Greater patient positioning freedom and access enables interventional procedures. Such procedures give practices new ways to care for patients, opening new opportunities for increased patient referrals.



The right experience — for patients

The Optima MR450w comes with a 70cm bore, offering a more comfortable experience for your patients — especially larger individuals, children, and those prone to claustrophobia. And the improved patient experience goes beyond the bore — next-generation clinical applications help reduce exam time and improved patient comfort features result in a cooler, quieter experience.

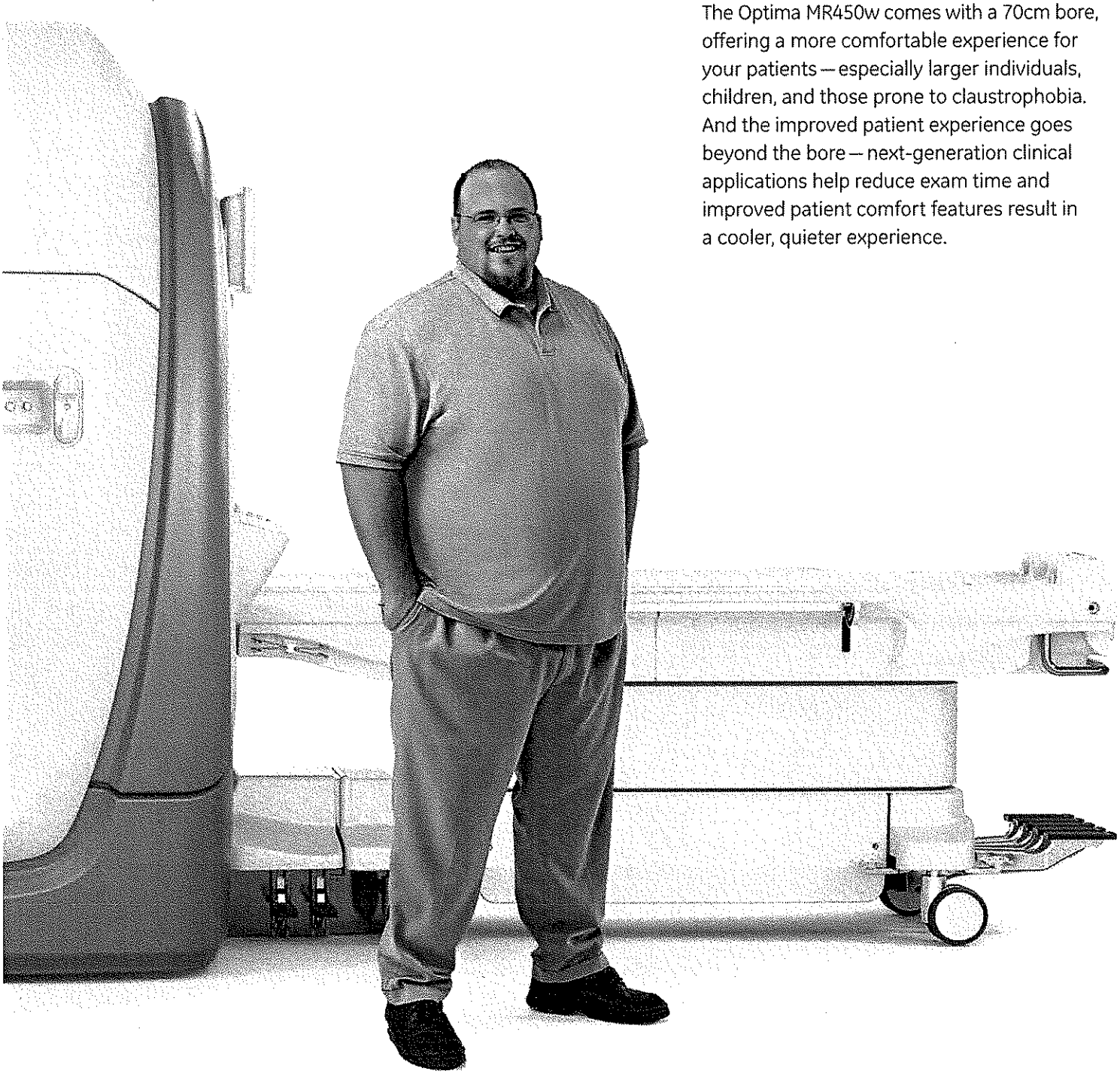


Image A

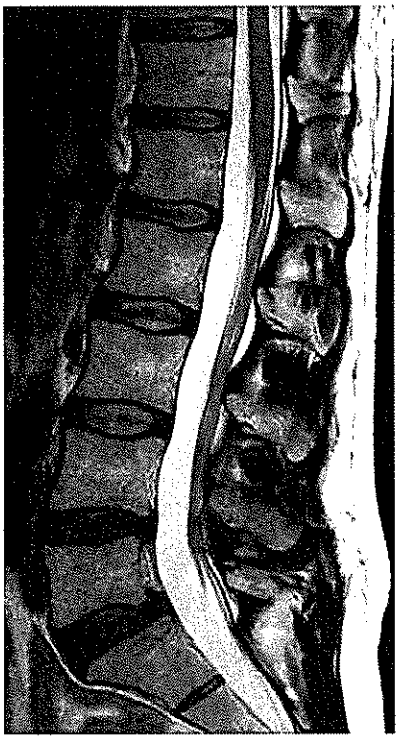


Image B

A work of ART

Acoustic Reduction Technology delivers a quieter patient experience.

The right MR experience goes beyond bore size and positioning — patients today are also demanding a quieter MR acquisition. New Acoustic Reduction Technology (ART) delivers just that, reducing acoustic noise.

ART is a highly useful application that's usable in brain, spine and MSK scans. And because ART reduces noise by optimizing the gradient performance, there's virtually no compromise to image quality.

Image B, captured at the same resolution and scan time as image A, was acquired using ART. The acquisition was 10 dBA quieter — with virtually no compromise to image quality.

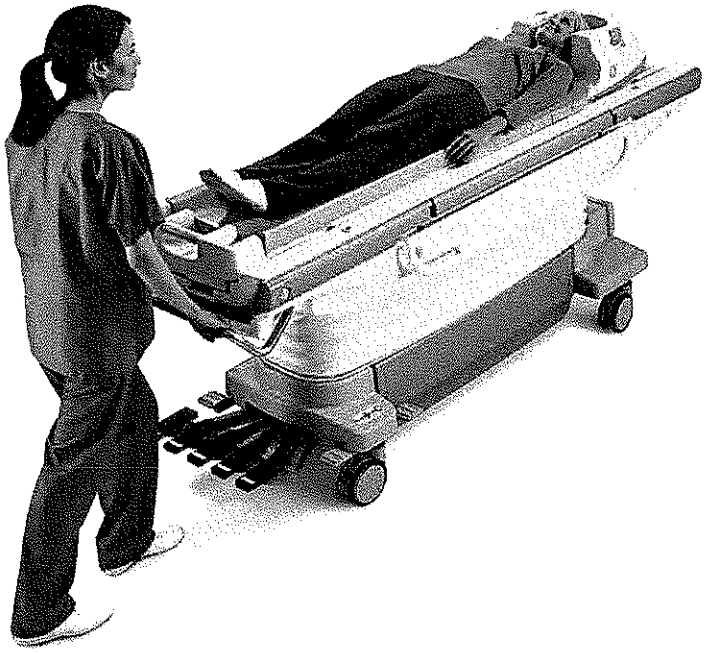
Express Patient Table

Transfer patients once to improve throughput.

Easily docked and undocked by a single technologist, the Express detachable patient table helps improve workflow and efficiency by minimizing time between scans. It allows for faster patient positioning accuracy compared to fixed table designs, and can support up to 500 lbs.

Patients are able to prep in private, and single transfers of patients directly onto the MR table create a more comfortable patient experience. In the event of an emergency, just one technologist can typically undock the table and safely transport the patient out of the room in under 30 seconds.

Beyond productivity, the table enables new kinds of growth for your practice, including interventional radiology and advanced breast imaging.



The right experience — for technologists

Staying on schedule has an added benefit — it may help increase the job satisfaction of technologists, aiding in their retention. This can help enable administrators to hold onto talent longer, saving on turnover and training costs.

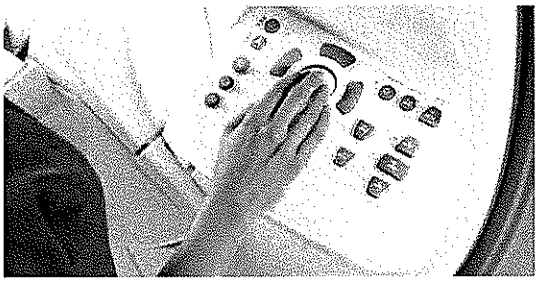
In-Room Operator Console

Fast exam setup — at your fingertips.

Mounted conveniently on the front of the magnet, the high-resolution color console of the Optima MR450w consolidates patient set-up information and operator controls in one place that's easy to see. View patient, system and scan information, control and select parameters, change scanner configurations, and initiate scans in real time right in the room. Save footsteps by eliminating multiple trips to and from the control room.

When AutoStart™ is selected on the iROC, the system will start scanning automatically when the scan room door is closed.

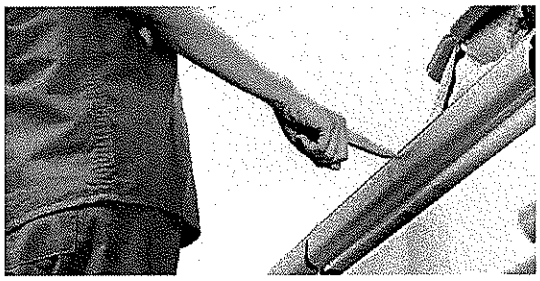
Optional



Dual-sided scanner control panels

Within reach.

Control the scanner from either side of the patient table and easily access cardiac or peripheral gating leads and IV lines. Backlit buttons indicate the next logical step in the exam process, simplifying patient setup.



IntelliTouch patient positioning

Start scanning in just two simple steps.

Set up your patients in as little as 30 seconds, and in just two simple steps. Along with the use of the detachable table, IntelliTouch patient positioning shortens in-room set-up time by up to 70% over fixed-table designs.

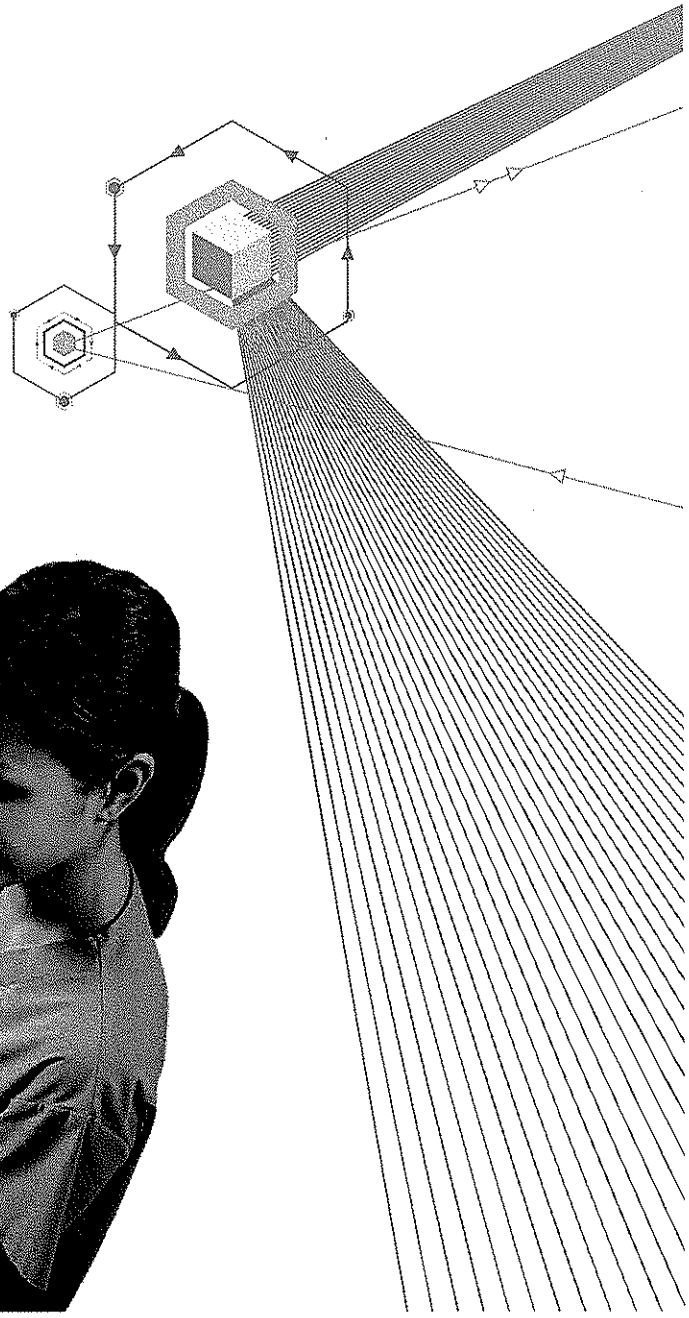
To operate, simply press the IntelliTouch strip on either side of the patient table at the landmark location, then press the Advance to Scan button to begin scanning.

Optional

The right investment — for administrators.

In today's economic environment, productivity and throughput are top-of-mind for administrators everywhere. The Optima MR450w allows you to keep up with evolving expectations around comfort, capabilities, and definitive diagnosis. With an advanced suite of clinical applications — including IDEAL, LAVA-Flex, VIBRANT-Flex, and Cube — you can handle more patients with fewer scans, helping boost the efficiency of your practice and making scheduling more predictable.

Buying GE is a good long-term investment. With the GE Continuum, we can help you maintain your clinical capabilities and your competitive edge. And our world-class service organization will keep uptime high, year after year.



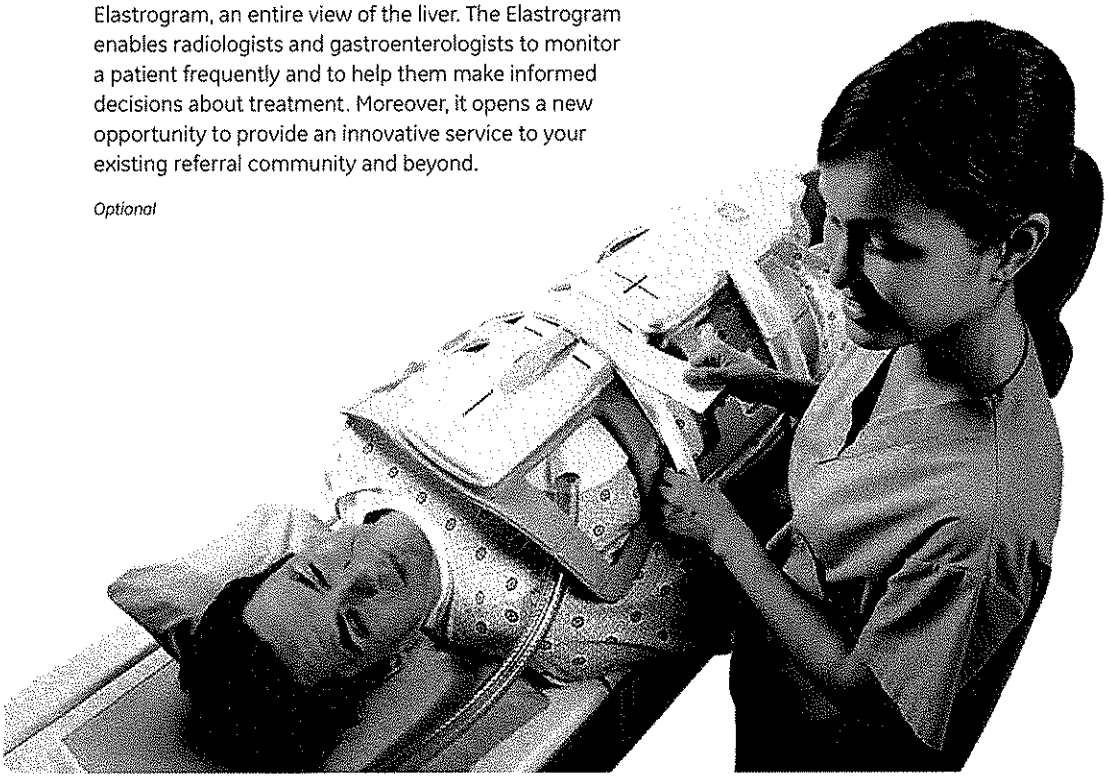
▹ Introducing MR-Touch

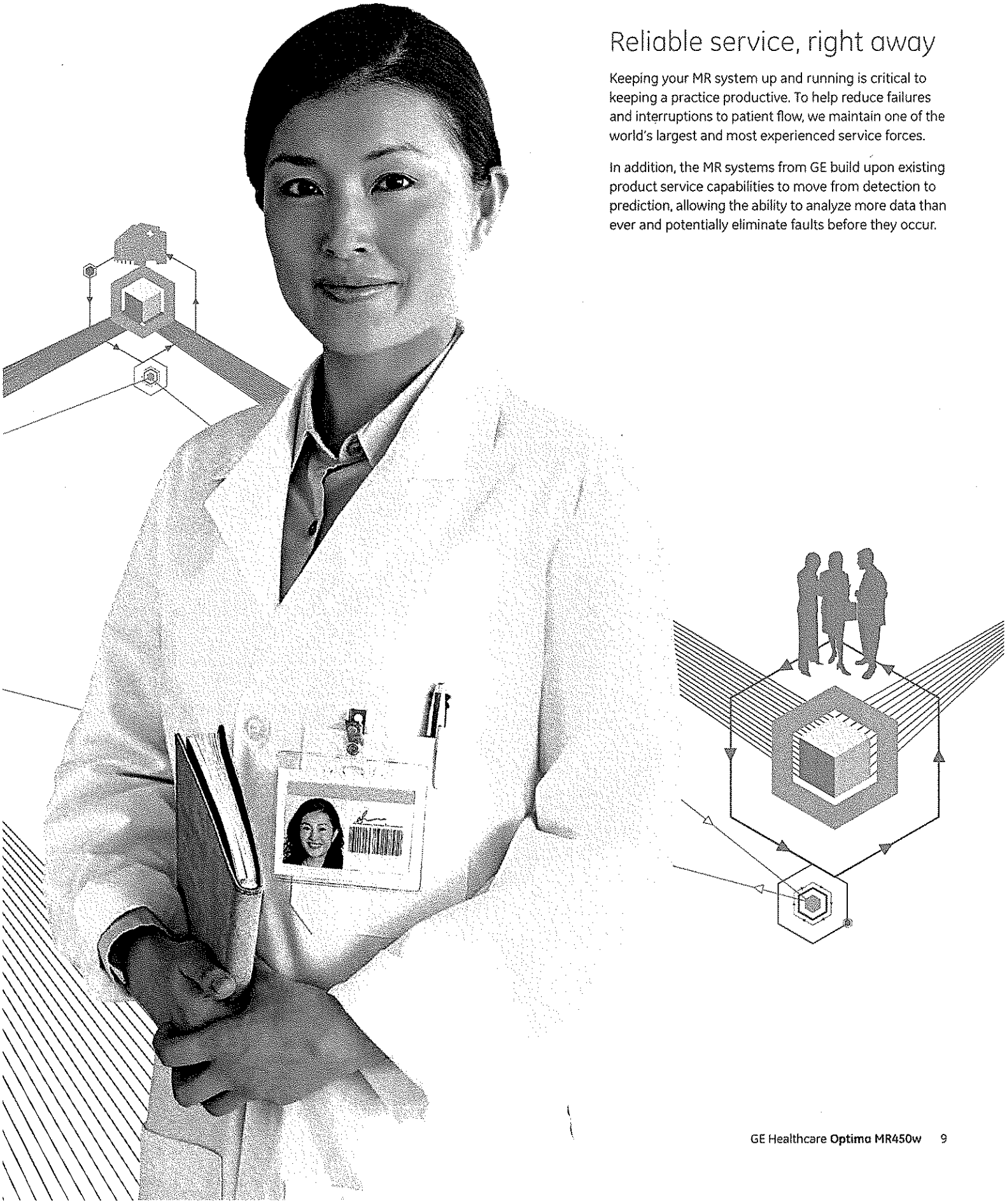
MR Elastography for non-invasive, holistic liver assessment.

Patients who suffer from chronic liver diseases such as fibrosis and cirrhosis often require ongoing observation by a gastroenterologist. This can entail invasive procedures that don't always provide a full picture of the liver.

The new MR-Touch, developed by GE with the Mayo Clinic, approaches liver exams by using acoustic waves to identify variations in tissue stiffness. This provides an Elastrogram, an entire view of the liver. The Elastrogram enables radiologists and gastroenterologists to monitor a patient frequently and to help them make informed decisions about treatment. Moreover, it opens a new opportunity to provide an innovative service to your existing referral community and beyond.

Optional





Reliable service, right away

Keeping your MR system up and running is critical to keeping a practice productive. To help reduce failures and interruptions to patient flow, we maintain one of the world's largest and most experienced service forces.

In addition, the MR systems from GE build upon existing product service capabilities to move from detection to prediction, allowing the ability to analyze more data than ever and potentially eliminate faults before they occur.

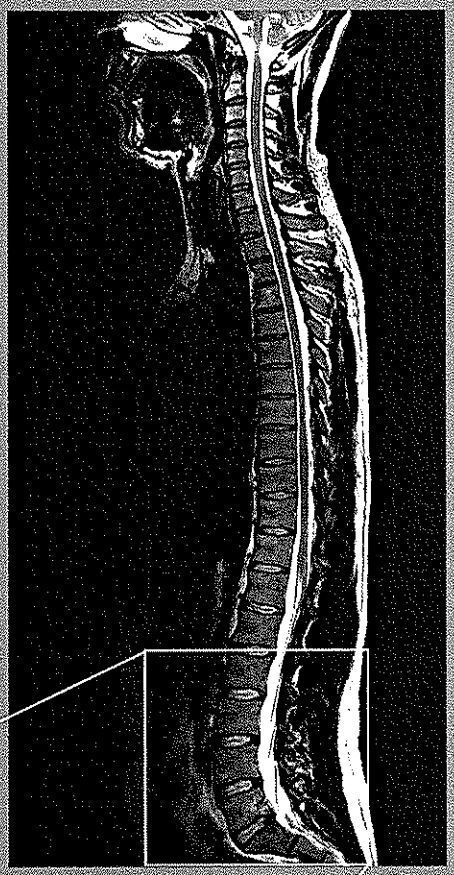
Image Gallery

The following pages illustrate how the Optima MR450w generates stellar images across areas of care.

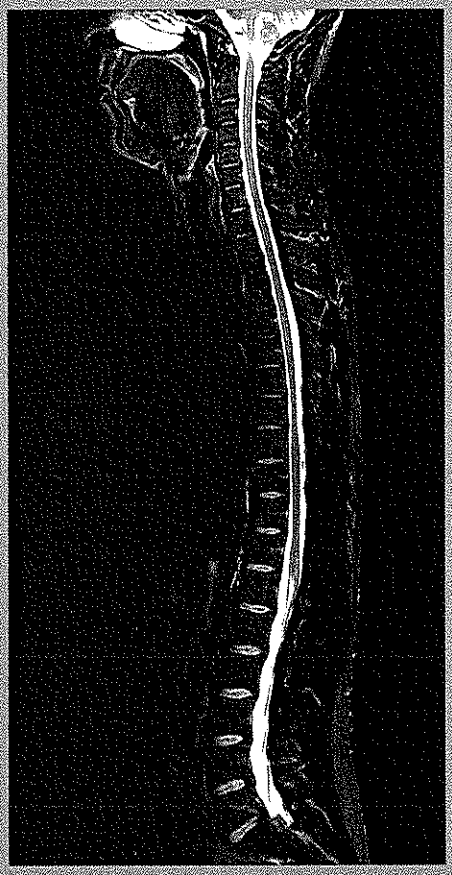
Spine

T1 FLAIR

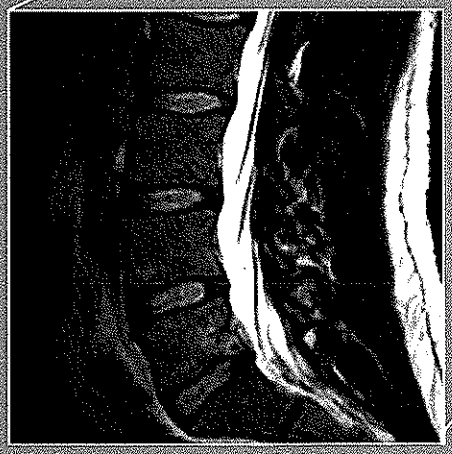
Two-station Whole Spine



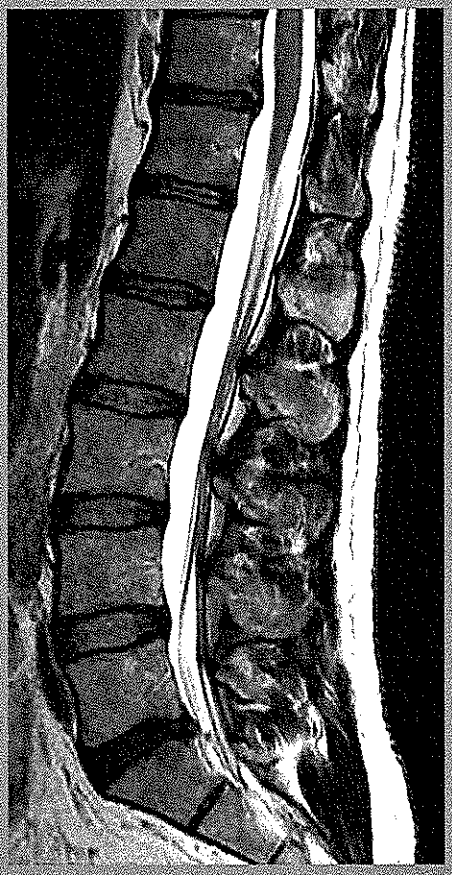
IDEAL In-phase



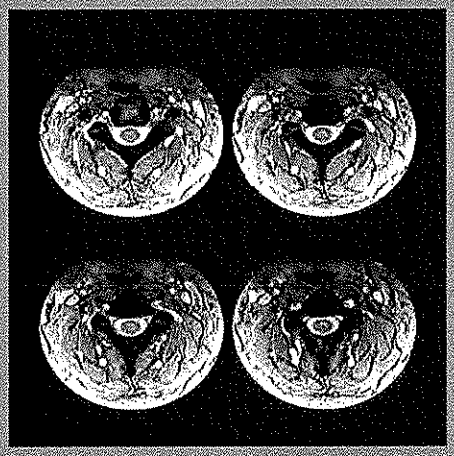
IDEAL Water Only



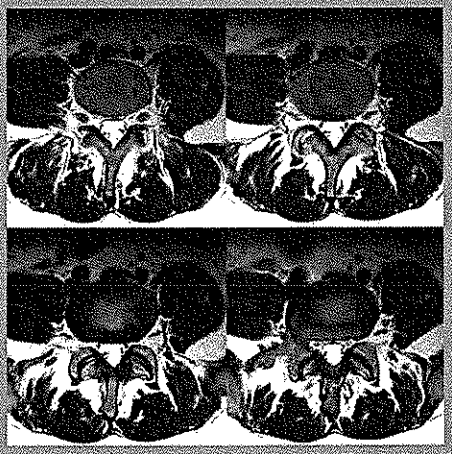
frFSE T2



frFSE T2 with ARC (acquired in 56 sec.)

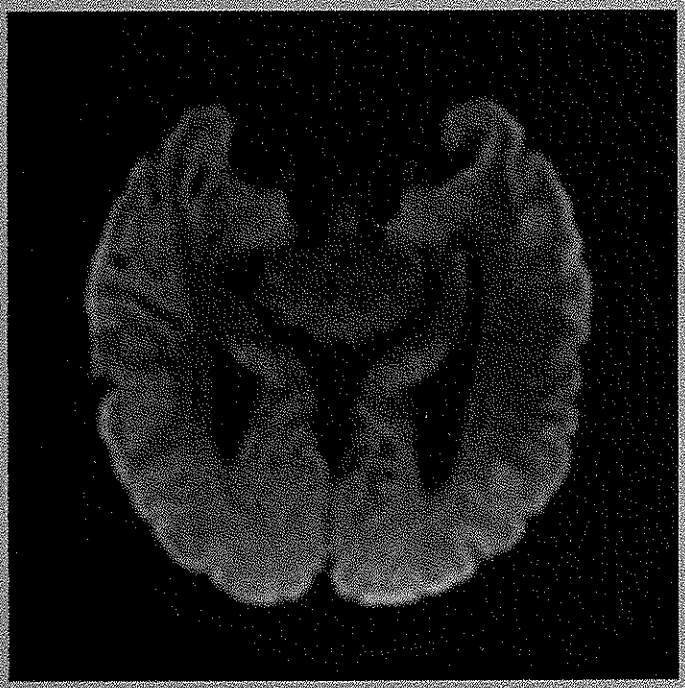


3D MERGE

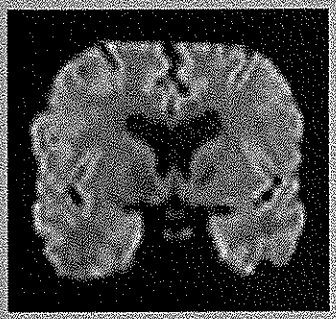


frFSE T2

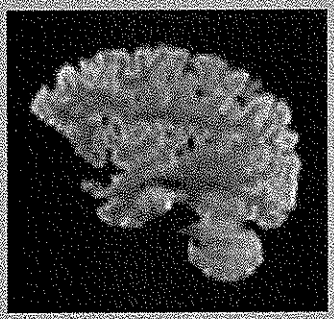
Neuro



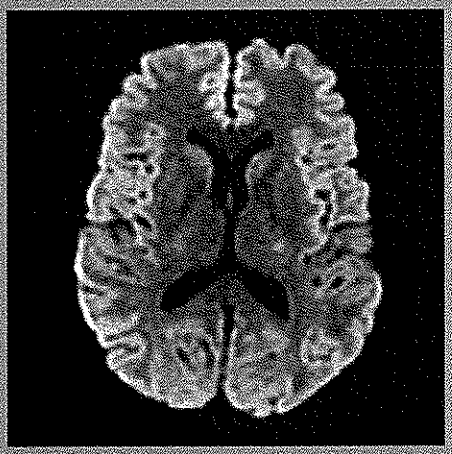
High Resolution Tetrahedral eDWI
Diffusion imaging is a demanding application for gradients in any environment. Combining eXtreme gradient technology and tetrahedral gradient encoding provides shorter TEs, less susceptibility and more SNR.



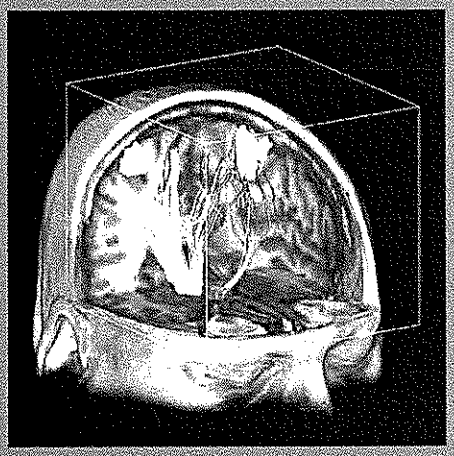
Reformat



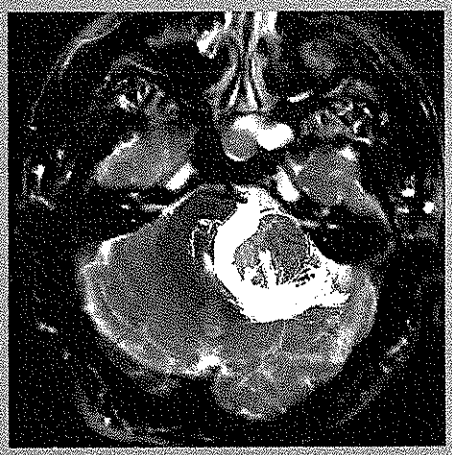
Reformat



3mm DTI with 20 Directions
The Optima MR450w delivers uncompromised high-resolution, 20-direction diffusion tensor images. Using a robust and efficient seeding process, FiberTrak effectively generates three-dimensional renderings of the diffusion along white matter tracts.



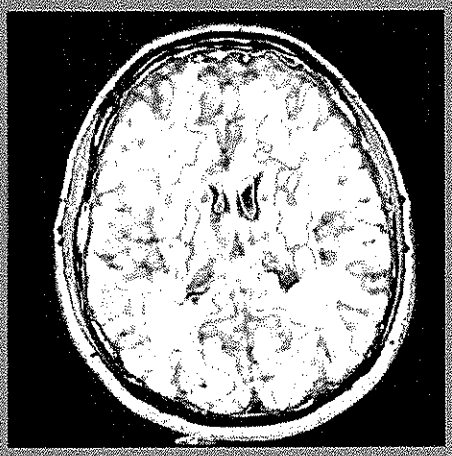
BrainWave Fusion
BrainWave Fusion provides the ability to fuse high-resolution anatomical images with fMRI activation maps and diffusion tensor fiber maps.

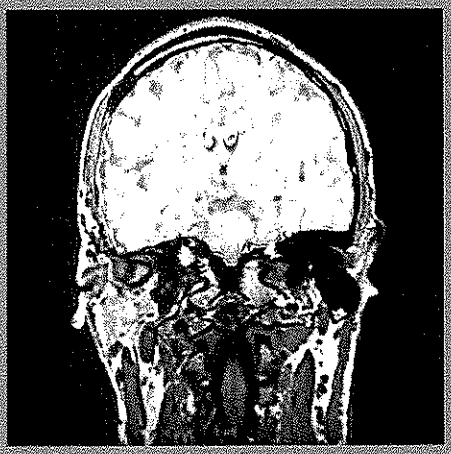


FiberTrack of 22 direction DTI overlaid on 512 x 512 PROPELLER T2

3D Arterial Spin Labeling (3D ASL)

This technique offers full brain coverage delivering robust, high SNR 3D images. It works by generating a 3D FSE acquisition with spiral readout, with pulsed continuous labeling close to the image slab. Background suppression is then added for motion insensitivity. The application is great for evaluating cerebro-vascular conditions such as stroke.

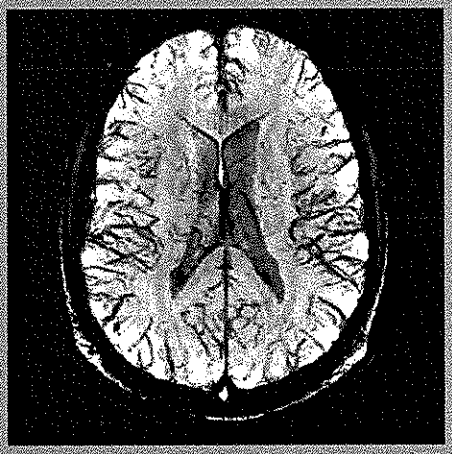




High-resolution 3D TOF MRA demonstrating the benefits of the additional SNR provided by OpTix RF.

PROPELLER DWI

PROPELLER DWI corrects for susceptibility artifacts at air/tissue interfaces, which are commonly seen in the temporal lobes when using standard EPI sequences. It also reduces artifacts from dental and/or surgical implants.



SWAN

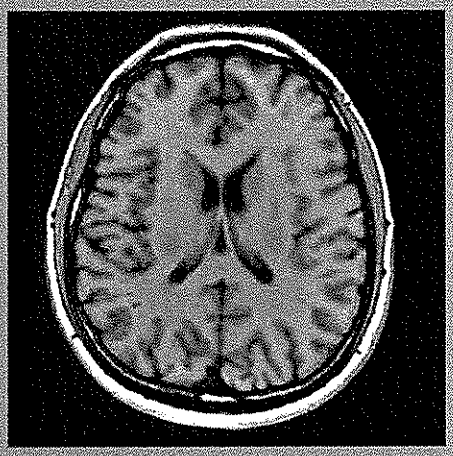
SWAN is a unique 3D T2*-weighted technique that provides the ability to clearly delineate small vessels. As a 3D application, SWAN benefits from the added SNR of the OpTix optical RF technology.

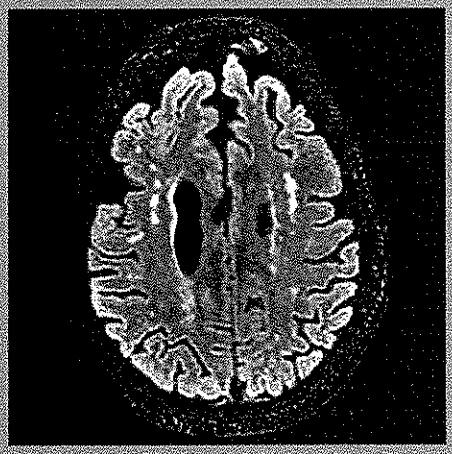
Neuro

Continued

Cube T1

Cube is a volumetric imaging technique with isotropic resolution – scan once and reformat into any plane with excellent resolution. Cube utilizes a unique, advanced acceleration technique, ARC, which reduces scan times for 3D imaging and allows you to reduce voxel size in order to enhance the quality of the reformatted planes.





Cube T2 FLAIR

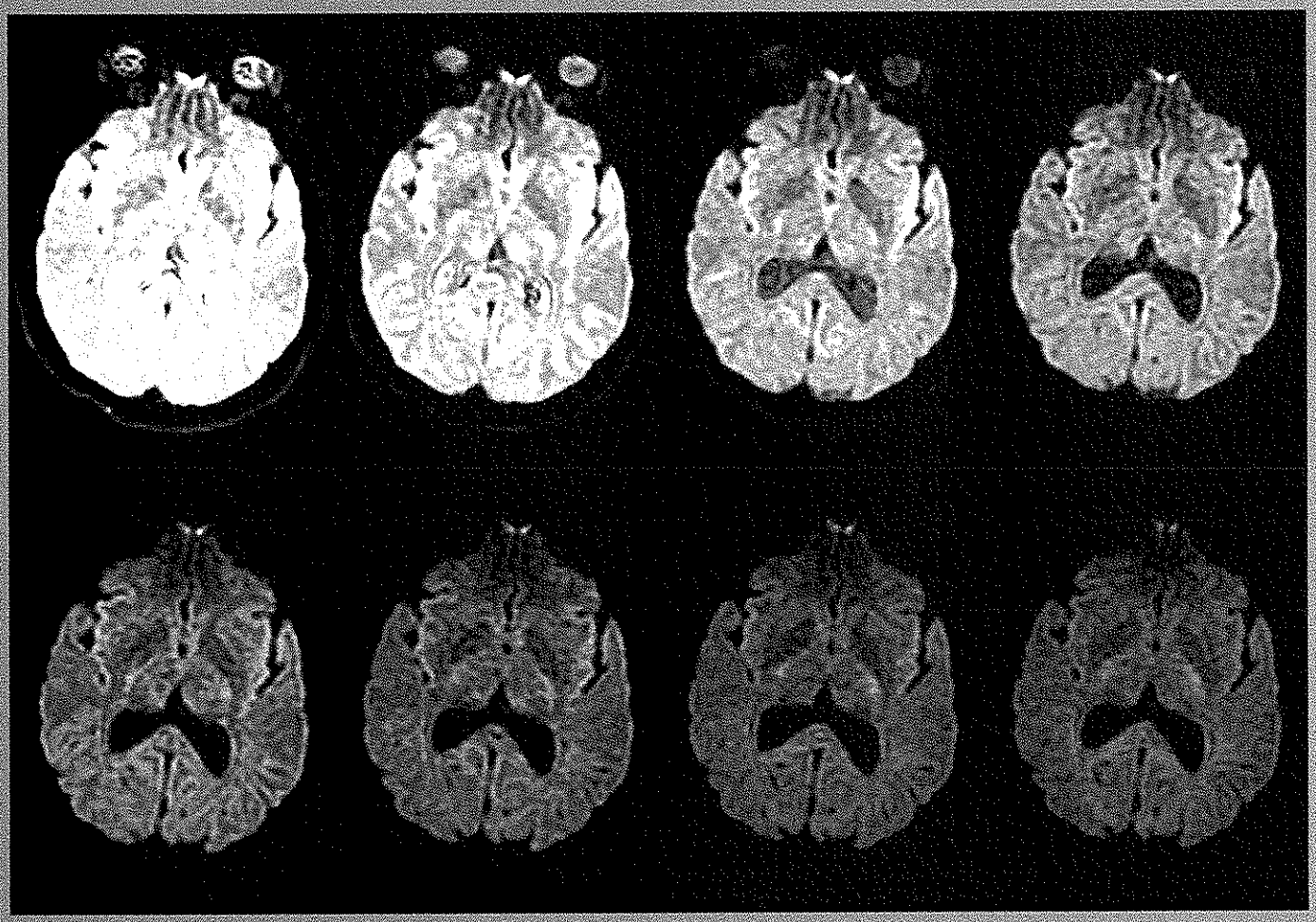
Cube is compatible with multiple contrasts making it a versatile technique for rapid but uncompromised neuro imaging.

Neuro

Continued

Multi B-value eDWI

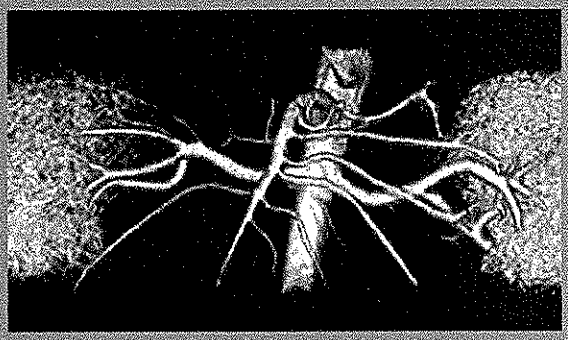
This new technique represents the next level in diffusion imaging, delivering more SNR, less scan time, and more accurate ADC. It applies an EPI single shot sequence with adjustable multiple b values, using either IR-prep or SSRF pulses for fat suppression. It can operate with a respiratory or cardiac triggered sequence.



Multi B-value eDWI of the brain showing b values ranging from 250 to 2000.

Non-contrast Angiography

Inhance Inflow IR eliminates the need for contrast on renal MRA studies, and does it without adding time-consuming set-up. Combined with the Express user interface with automated fat and background suppression, prescription is dramatically simplified.

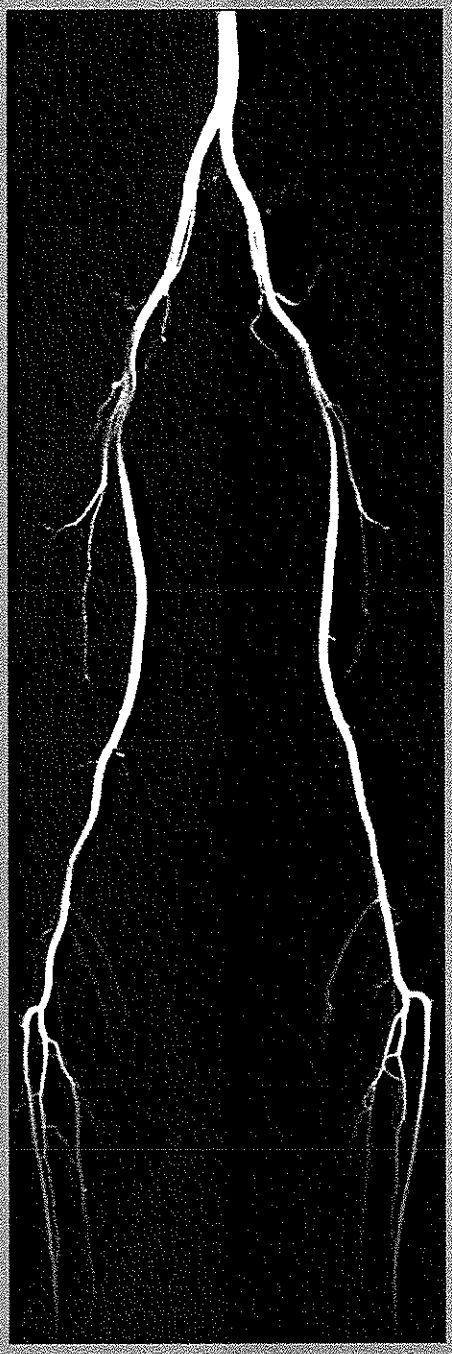


Inhance Inflow IR

Inhance Inflow IR

Inhance 3D DeltaFlow

This application delivers excellent contrast and surrounding tissue subtraction—all without use of a contrast agent. It subtracts the systolic from the diastolic phase, helping eliminate venous and background signal.

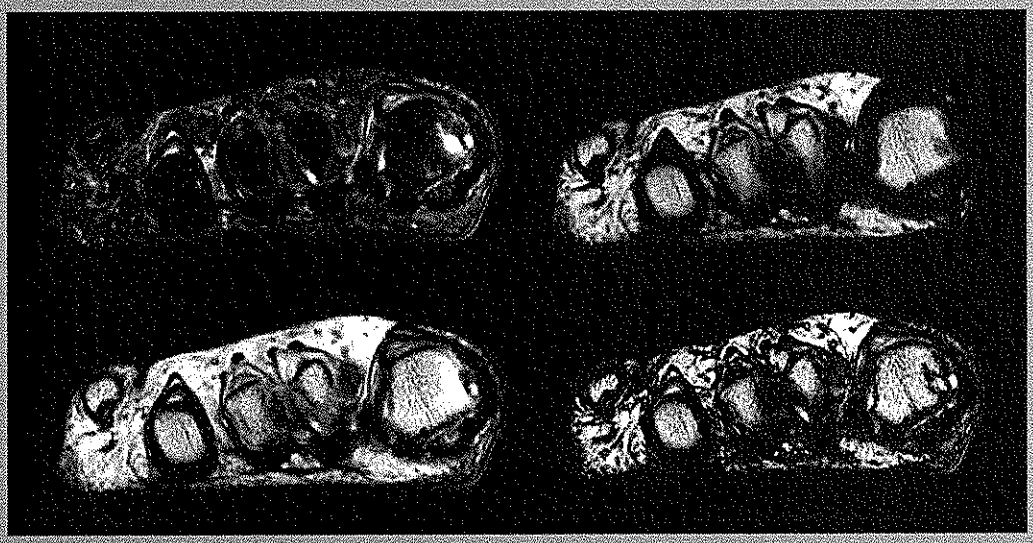


Inhance 3D Velocity

Inhance 3D Velocity is a non-contrast enhanced technique designed to acquire angiographic images of the brain and renal arteries with excellent background suppression in short scan times. The technique is capable of obtaining the whole neurovascular anatomy in 5–6 minutes.

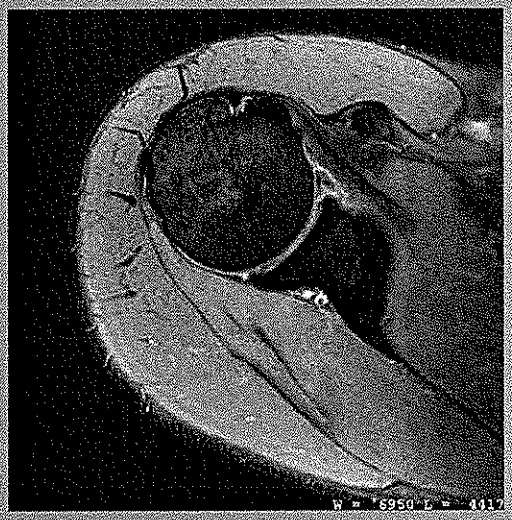
MSK

With the Optima MR450w, patients can be imaged in a more comfortable position.



IDEAL

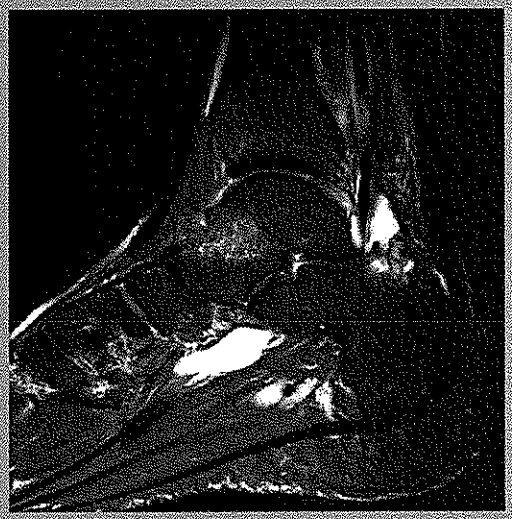
3D MERGE is designed to deliver enhanced contrast and SNR for musculoskeletal and spine imaging. It also benefits from the additional SNR of the OpTix RF technology.



3D MERGE

T2 Fat Sat

The performance of the new Optima MR450w magnet delivers uncompromised off-center imaging with uniform fat saturation performance in a wide bore environment.

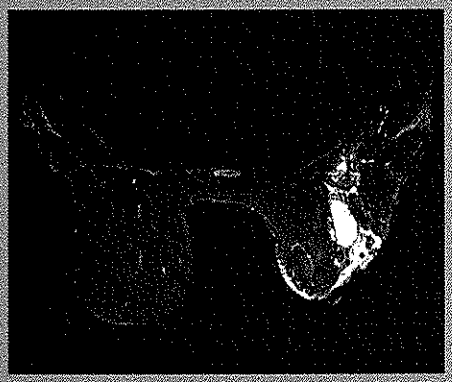


T2 Fat Sat

PD (640 x 320 resolution in 3:37)

Breast

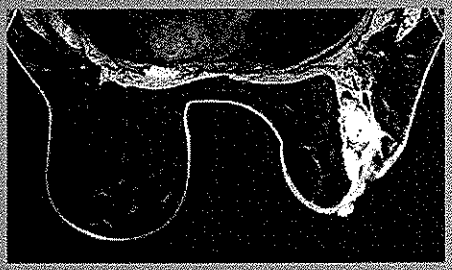
IDEAL provides a robust, high-resolution alternative to FSE Fat Sat or STIR for T2 fat-suppressed breast imaging.



IDEAL Water Only

DWI

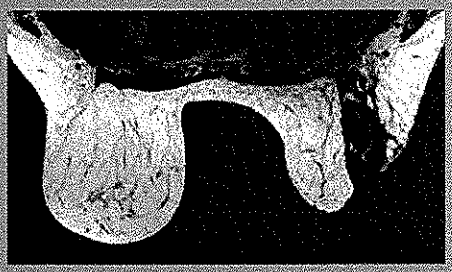
The Optima MR450w performs excellent breast diffusion imaging. Breast diffusion can be performed with the HD Breast Array or with the integrated body coil, which allows for a larger imaging field.



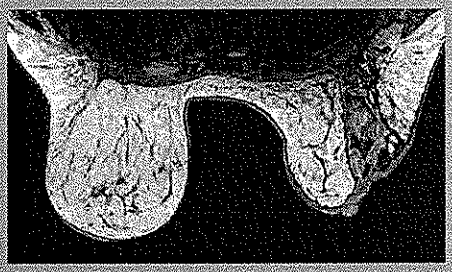
VIBRANT-Flex Water Only

VIBRANT-Flex In-phase

VIBRANT-Flex generates up to 4 contrasts with high-resolution in just one short scan and virtually eliminates fat suppression failures in breast imaging — even over a large FOV with irregular anatomy. As a result, you gain 4X more data and enhanced ability to "do it once and do it right" on an exam that you don't want to repeat.



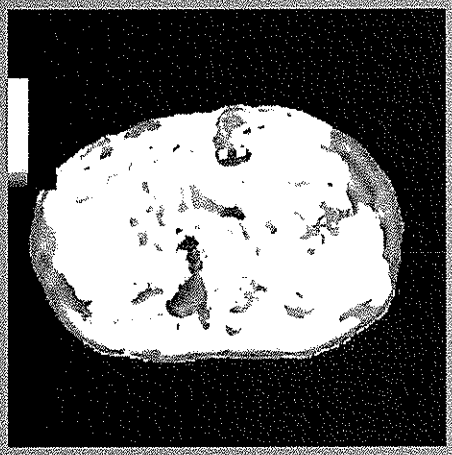
VIBRANT-Flex Fat Only



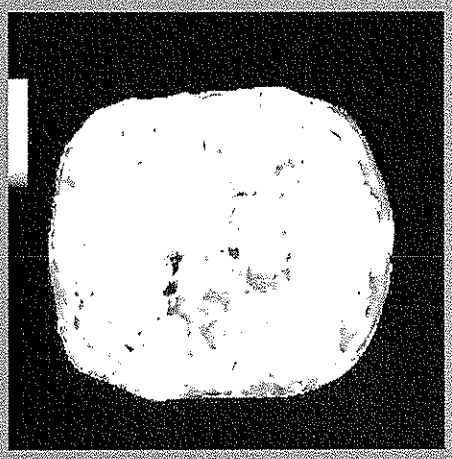
VIBRANT-Flex Out-of-phase

Liver

In these elastograms — acquired with MR-Touch — relative stiffness is shown on a color scale ranging from softest (purple) to hardest (red). The stiffness of normal liver tissue is very low, as seen in the left example. The red in the right image shows high-tissue stiffness.

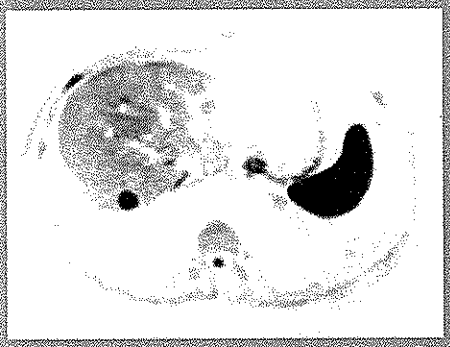


MR-Touch Elastogram (volunteer)

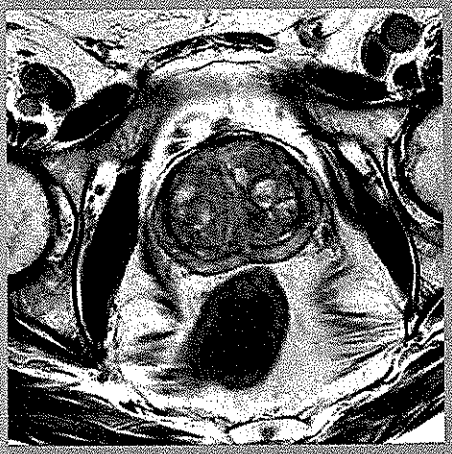


MR-Touch Elastogram (patient with cirrhosis)

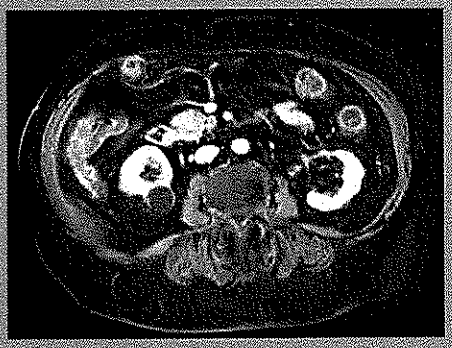
Abdominal



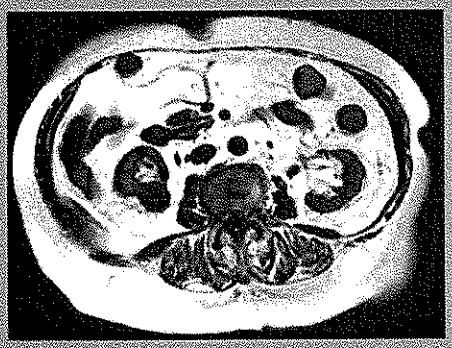
eDWI



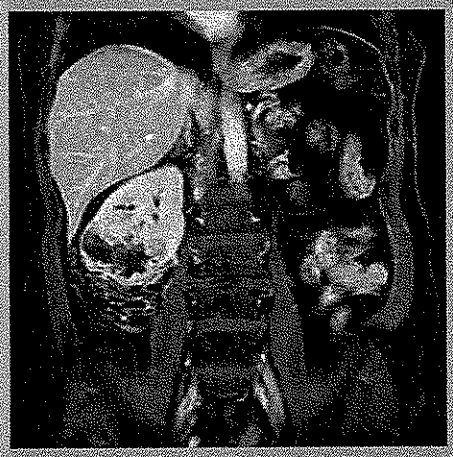
T2 FSE



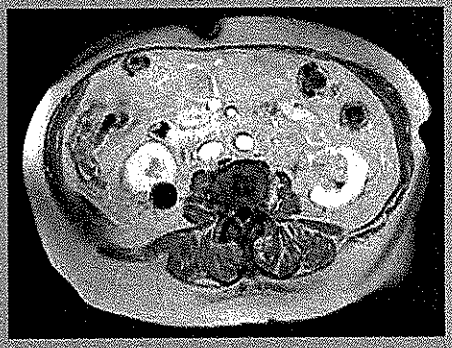
LAVA-Flex Water Only



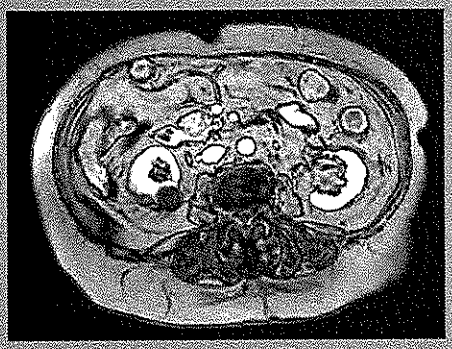
LAVA-Flex Fat Only



LAVA-Flex



LAVA-Flex In-phase



LAVA-Flex Out-of-phase

LAVA-Flex generates up to 4 contrasts with high resolution in just one short scan, and virtually eliminates fat suppression failures even over a large FOV whole abdomen.

The eXtreme gradients and OpTix RF technology enable the Optima MR450w to deliver excellent large FOV diffusion imaging. With ARC, this 21-slice SSFSE series was acquired in 15 seconds.

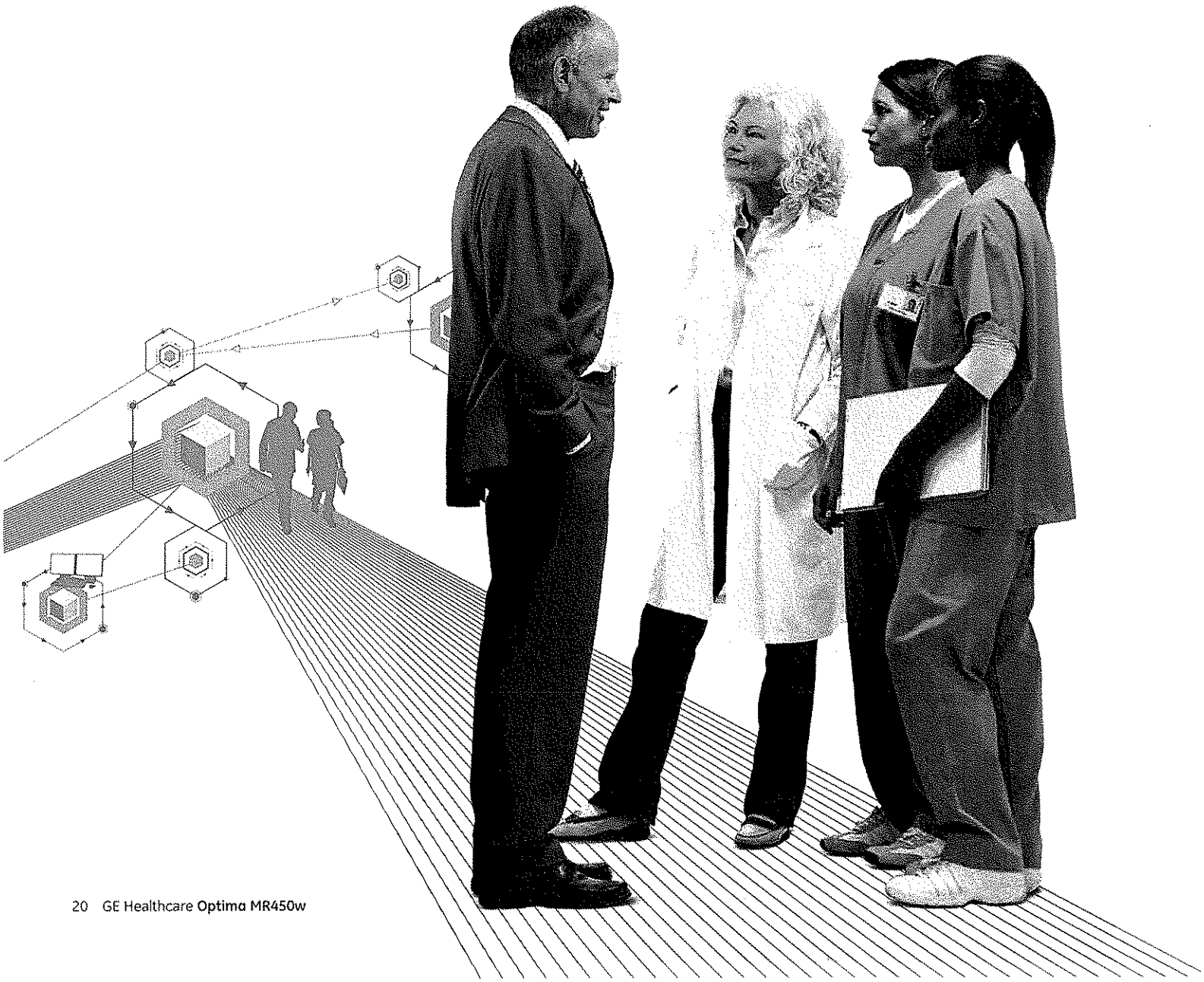
The right choice.

For those seeking to realize the true potential of wide-bore MR, the Optima MR450w is the clear choice. That choice brings more than excellent patient care—it also provides a range of benefits for every key stakeholder in your practice.

Radiologists get the high-quality images they demand for definitive diagnoses.

Administrators get satisfied patients, precise scheduling, and opportunities for growth.

And technologists get to handle more patients with less hassle, capturing images with more consistency.



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About GE Healthcare

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help our customers to deliver better care to more people around the world at a lower cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

Our "healthymagination" vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access and improving quality around the world. Headquartered in the United Kingdom, GE Healthcare is a unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employees are committed to serving healthcare professionals and their patients in more than 100 countries. For more information about GE Healthcare, visit our website at www.gehealthcare.com.

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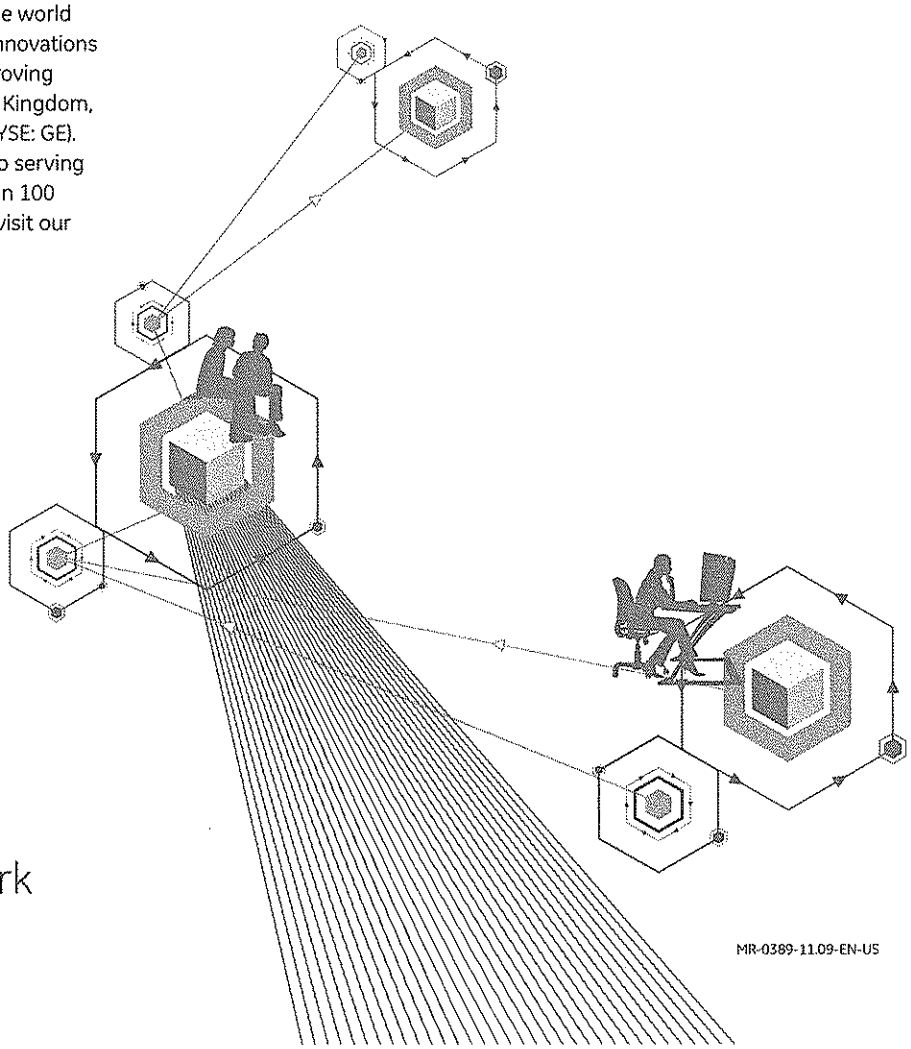
3000 North Grandview
Waukesha, WI 53188
USA



imagination at work

MR-0389-11.09-EN-US

Compass Medical Equipment, Inc.

103 Sullivan Place
Pooler, Georgia 31322
912-450-1919(o)
914-325-1186(c)

April 29, 2015

Re: GE Open Speed SR 70 MRI System

Location: Columbus Regional Healthcare System
500 Jefferson Street
Whiteville, N.C. 28472

To Whom It May Concern:

Compass Medical Equipment, Inc. with principal offices in Lake Grove, New York and a local office in Pooler, Georgia has been working with Columbus Regional Healthcare System on the removal of a 2004 GE Open Speed MRI System, Serial T157. Subject to final discussion and de-installation co-ordination, this system is scheduled for removal by September 1st, 2015. Due to its' age and type of system, it will be used for parts only and will not be re-installed as a complete system in North Carolina or elsewhere.

Please advise if there is any additional information required.

Sincerely,

Ronald J. Bachner
Managing Director

Compass Medical Equipment, Inc.

www.compassmedicalequipment.com
(912) 450-1919 (Office)
(914) 325-1186 (Mobile)
(631) 677-3400 (FAX)
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