



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

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Drexdal Pratt
Division Director

December 21, 2015

Tim Linker
High Point University Office of Research Administration and Sponsored Programs
One University Parkway
High Point, NC 27268

Exempt from Review – Proposed Research Activity

Record #: 1823
Business Name: High Point University
Business #: 2334
Project Description: Acquire an MRI scanner to be used by High Point University's Department of Physical Therapy for research
County: Guilford

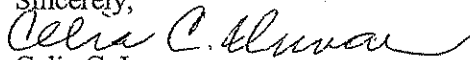
Dear Mr. Linker:


The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that based on your letter of December 17, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-179. Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

However, 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 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.

Please find your application submission check enclosed. There is no fee for your exemption request. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,


Celia C. Inman
Project Analyst


Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Kelli Fisk, Program Assistant, 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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HIGH POINT UNIVERSITY
Office of Research Administration and Sponsored Programs
Email: rasp@highpoint.edu, Phone: (336) 841-9313

December 17, 2015



Ms. Martha Frisone
Assistant Chief
Certificate of Need Section
NC Division of Health Service Regulation
809 Ruggles Dr.
Raleigh, NC 27603

Re: High Point University Certificate of Need Research Exemption Request

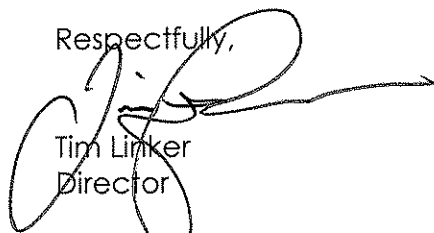
Dear Ms. Frisone:

Please accept this letter and attached documentation as High Point University's (HPU) application for a new institutional health service to be used solely for research without a certificate of need.

This project involves the acquisition of a Easote G-scan Brio MRI scanner to be used by HPU's Department of Physical of Therapy in furtherance of its research efforts as defined under NCGS §131E-179. It is estimated that the scanner with cost between \$850,000 and \$900,000. As such, HPU has enclosed payment as required under NCGS § 131E-182.

Thank you for your time and attention to this request. Should you or your colleagues have questions or concerns, please let me know.

Respectfully,



Tim Linker
Director

Enclosures (3)

cc: President Nido Qubein
Dr. Denny Bolton
Dr. Daniel Erb
Dr. Eric Hegedus
Dr. Dennis Carroll
Dr. Jeffrey Adams
Mr. Steve Potter

Notice of Proposed Research Activity

N.C.G.S. §131E-179 allows a health service facility to offer a new institutional health service to be used solely for research without a certificate of need, if the Department grants an exemption. To request an exemption to offer a new institutional health service to be used solely for research, please respond to the following:

1. Facility Information:

High Point University	56-0529999
(Name)	(FID #)

2. Facility Address:

1030 Mall Loop Rd.	High Point	Guilford
(Street)	(City)	(County)

3. Project Description:

The use of the scans will be for musculoskeletal-related research. Currently, High Point University (HPU) Department of Physical Therapy faculty are interested in evaluating and investigating specific areas including the diagnostic accuracy of the physical examination for shoulder and hip pathology, early detection and prevention of stress fractures, tracking knee osteoarthritis after ACL repair, and the effect of intrinsic muscle wasting on the properties of bone in diabetic feet. The Department will hire eight more faculty members and, based on the specialty physical therapy fields considered, MRI research access is required. The use of this MRI will be for research only. The MRI will not: (a) affect the charges by the facility for the provision of any medical or patient services; (b) substantially change bed capacity of the facility; and (c) substantially change any medical/patient care services provided by the facility. The data gathered are for research use only. At this location, HPU seeks to install an Esaote G-can Brio (documentation attached). This MRI is specifically designed for musculoskeletal applications. This proposed location is in a portion of a university-owned building that is more easily accessible to target research populations and not affiliated with any other enterprise.

4. Document that the proposed project will not:

- a. *Affect the charges of the health service facility for the provision of medical or other patient care services other than services which are included in the research;*

The nearest healthcare facility (roughly 2 miles) with an MRI is High Point Regional/UNC Hospital. The proposed MRI at High Point University will have no effect on the provision of medical/patient care or the charges for that medical/patient care since the proposed MRI is not for such care and is exclusively for research purposes.

- b. Substantially change the bed capacity of the facility; or*
This question is not applicable as High Point University has no bed capacity.
- c. Substantially change the medical or other patient care services of the facility.*
While High Point University has a student health center that provides patient care to enrolled students, the proposed MRI will not change the services offered at the student health center because it will be used for research purposes only.



HUMAN PARTICIPANTS INSTITUTIONAL REVIEW BOARD
HIGH POINT UNIVERSITY

833 Montlieu Avenue • High Point, North Carolina 27262-3598 • (336) 841-9000

August 12, 2015

Protocol #: 201508-384

Protocol Title: The Diagnostic Accuracy of Physical Examination

Primary Investigator: Eric Hegedus, Department of Physical Therapy

Co-investigator: James Smoliga, Department of Physical Therapy

Co-investigator: Alexis Wright, Department of Physical Therapy

Co-investigator: Jeffrey Taylor, Department of Physical Therapy

Co-investigator: Kevin Ford, Department of Physical Therapy

Co-investigator: Steve Dischiavi, Department of Physical Therapy

The High Point University Institutional Review Board (IRB) has reviewed and approved this research protocol under an expedited review in accordance with Title 45 CFR 46.110.

If you require any modifications that alter methodology in a substantial way, change the Principal Investigator (PI) or Co-Investigator(s), or any changes in the selection of your participants, you must notify the IRB before implementing the modifications as required by Title 45 CFR 46.103 (b) 4iii. To report changes, you must submit a new protocol application for review.

The project is approved for one year. A study completion report must be submitted by August 12, 2016. Not filing the final report by the anniversary date will result in the termination of your protocol approval and reporting of this termination to any funding agency as required by Title 45 CFR 46.103 (b) 5.

The IRB approved consent form must be used for all informed consent procedures on all human subjects in this study. The signed consent forms must be kept under lock and key on university property for the duration of the study plus three years. These consent forms are subject to inspection during this time period by the IRB. A copy of the consent must be provided to each subject participating in the study.

All investigators listed in this protocol must maintain current human subjects training certificates for the duration of the study.

If you have any questions related to this research or to the IRB, you may contact me at (336) 841-9246.

Sincerely,

A handwritten signature in cursive script that reads "Kimberly Wear".

Dr. Kimberly Wear
Associate Professor of Psychology
IRB Chair

Dedicated MRI

Take Pride in Performance

O·scan
Dedicated MRI



esaote

Introducing the O-scan

Introducing the O-scan, the newest and most powerful in-office MRI system designed to go where you use it.

The O-scan was specifically engineered with the practice, physician and patient in mind. With the O-scan, it is possible to turn a typical exam room into an MRI suite overnight. Is your office in a high-rise or does it have limited access via elevator? These issues are no problem for the O-scan.

The O-scan exams feature outstanding image quality and high throughput. We have designated the "25 minute exam" for the O-scan, which can be used for any body part to speed results, lower overhead and deliver the optimum study in the shortest period of time.

O-scan, Technology that works for you

- > Open permanent magnet
- > 0.31 Tesla field
- > No RF Shielding Cage required
- > Max RF power: 1500 W
- > Shimming: passive
- > Gradient: ± 20 mT/m
- > Slew rate: 50 mT/m/ms
- > FOV: 14 cm
- > Very compact, installation space of 9' x 10' required
- > Low Power Consumption:
only 1 kW in normal 110V power outlet
- > Complete set of dedicated DPA coils



O-scan & the five Ps

> PARTNERSHIP

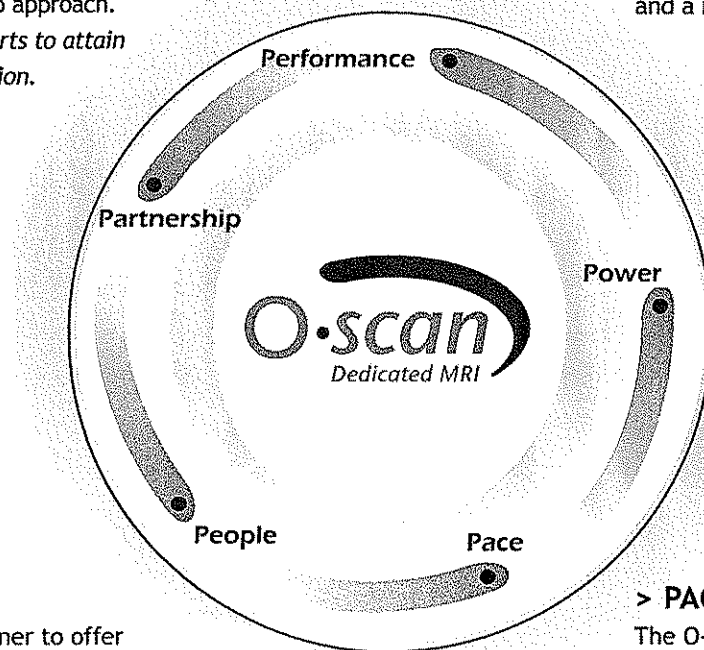
With the O-scan, you'll join thousands of satisfied Esaote MRI customers. We provide the scanner, site testing, installation training and service as part of our turnkey partnership approach. We also fully support efforts to attain ACR or ICAMRL accreditation.

> PERFORMANCE

High-performance components like 50 mT/m gradients and 1.5 kW RF power deliver outstanding reliable performance for all patient types and clinical exams.

> POWER

With the O-scan, you have the most powerful in-office permanent magnet system available. This means faster exams, higher quality imaging and a more satisfied clinical staff.



> PEOPLE

We've designed the scanner to offer your patient a more comfortable experience. Esaote trains your staff to operate the unit.

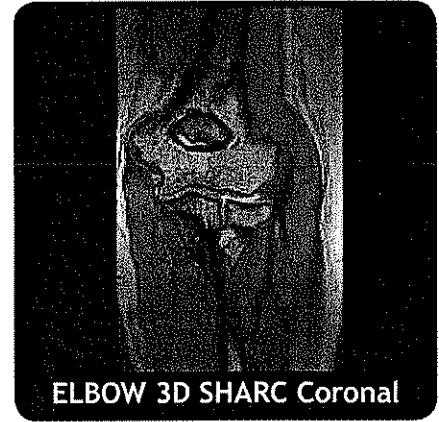
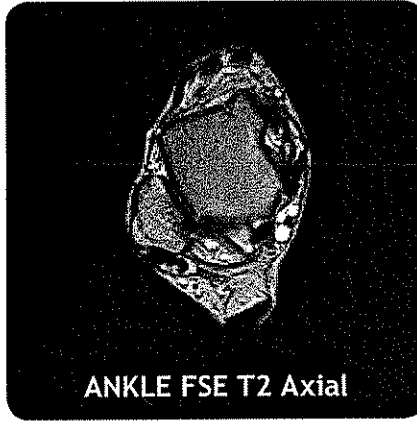
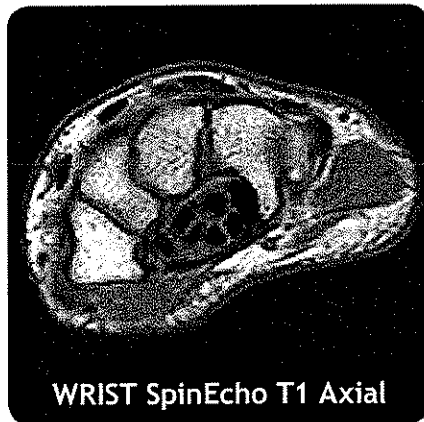
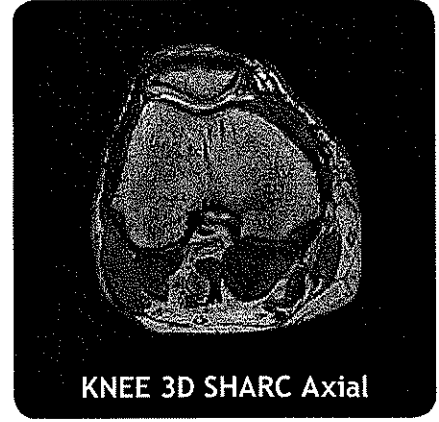
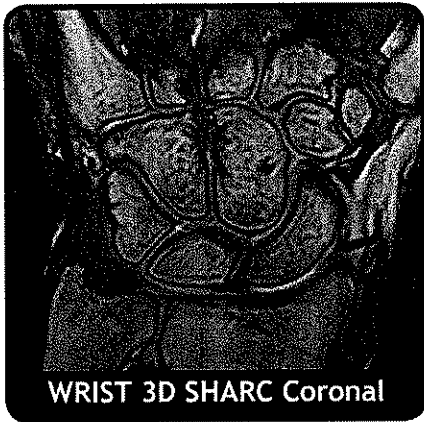
> PACE

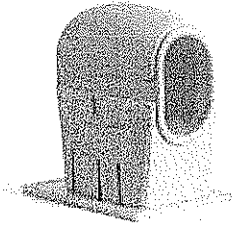
The O-scan, with its fast patient scanning and full PACS integration, can match the pace of patient workflow in your office.

> SUCCESS

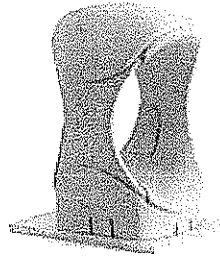
Esaote's Five Ps combine to equal success. For over 15 years, Esaote has researched and developed innovative and effective dedicated MRI systems for office use. The O-scan represents our latest efforts to redefine power and performance in our most compact MRI to date.

O-scan, Superior Image Quality

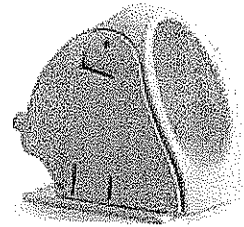




DPA Hand/Wrist Coil



DPA Knee Coil



DPA Foot/Ankle/Elbow Coil



O-scan Hassle-Free MRI

Easy Siting

The O-scan does more in less space. The innovative design features a complete MRI system minimizing the total space needed for installation. Due to its light weight and extremely small five gauss footprint, the O-scan can be easily installed in virtually any office or practice.

The operator console, featuring a Windows interface, can be located either inside or outside the room, accommodating both small sites and large practices.

User Friendly

Windows functionality makes the O-scan easy-to-use. The interface and protocols are custom designed for extremity MRI exams which speed up and simplify the examination procedure.

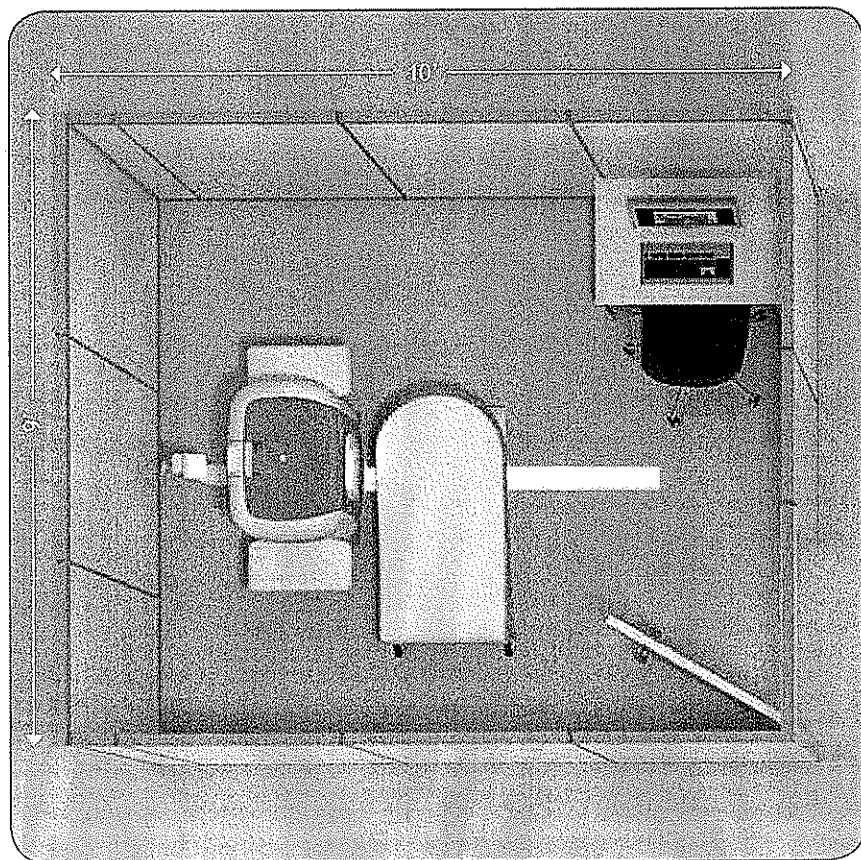
Service

The O-scan system parameters and system components can be checked via ARAS, the remote service program from Esaote. ARAS allows remote monitoring and repair of the system which ensures high uptime and scanner availability.

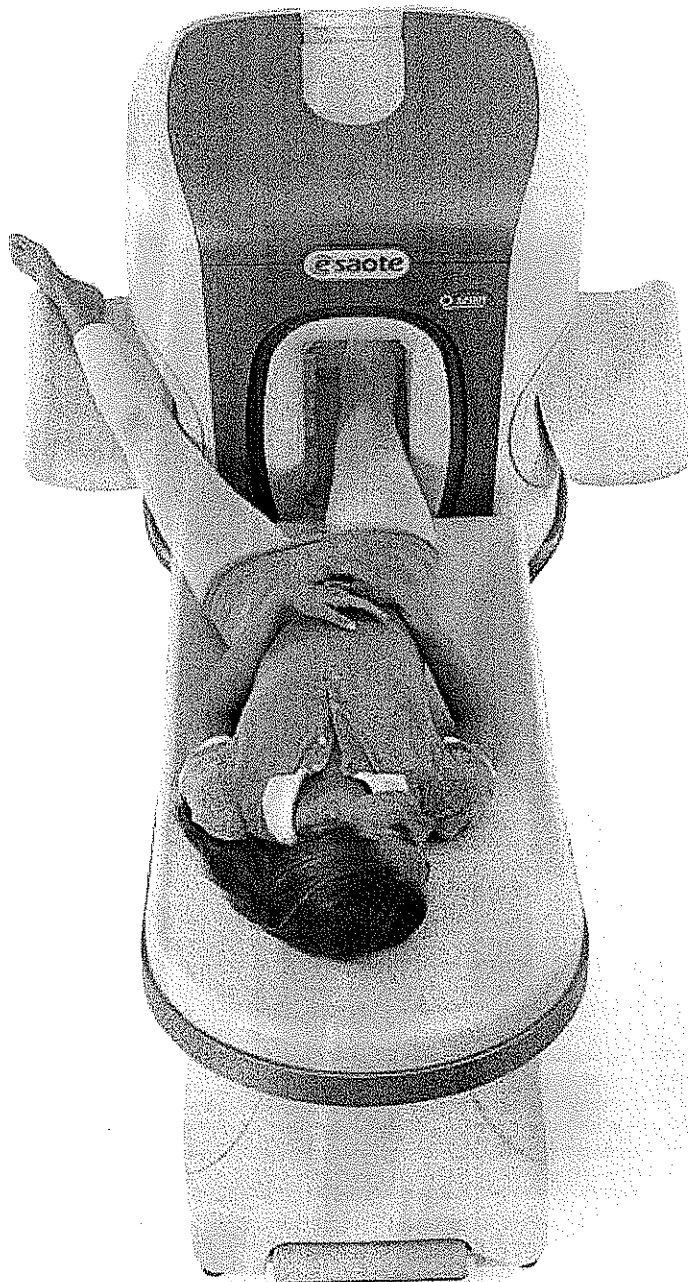
Connectivity

The O-scan comes with network, archiving and documentation features to work either stand alone or as a part of an integrated environment. It has an integrated DVD archive and retrieve software package, printer facility and a patient CD package. The O-scan is also DICOM compliant and offers smart solutions for connectivity and teleradiology:

- > DICOM image transfer to PACS system or Workstation
- > DICOM worklist capabilities allow the system to be connected to a centralized registration system
- > E-MRI Viewer: an Esaote software-only PC program which transforms a normal PC into a DICOM viewer.



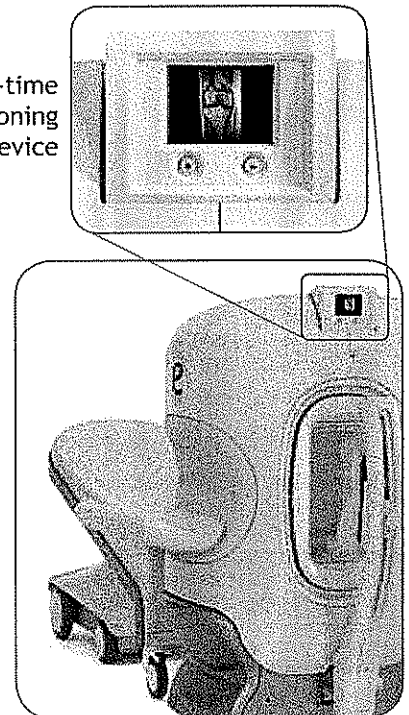
O-scan The Power of Comfort

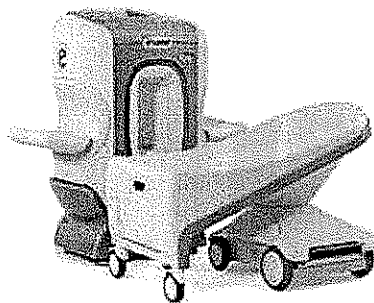


All Esaote MRI systems feature the most patient-comfortable positioning of any MRI system. The system's optimal ergonomics eliminate claustrophobia and give maximum comfort and stability to larger patients.

Thanks to the real-time positioning device, patient positioning is simple, easy and fast with the O-scan.

Real-time
positioning
device





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Esaote S.p.A.

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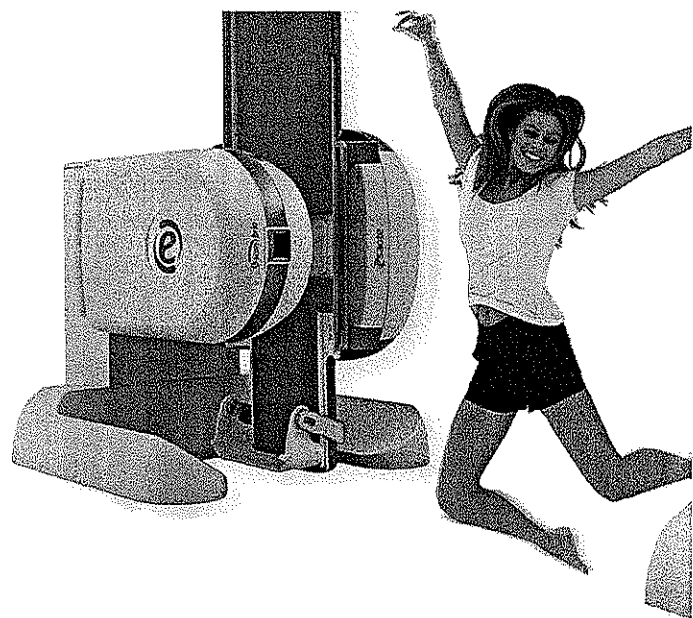


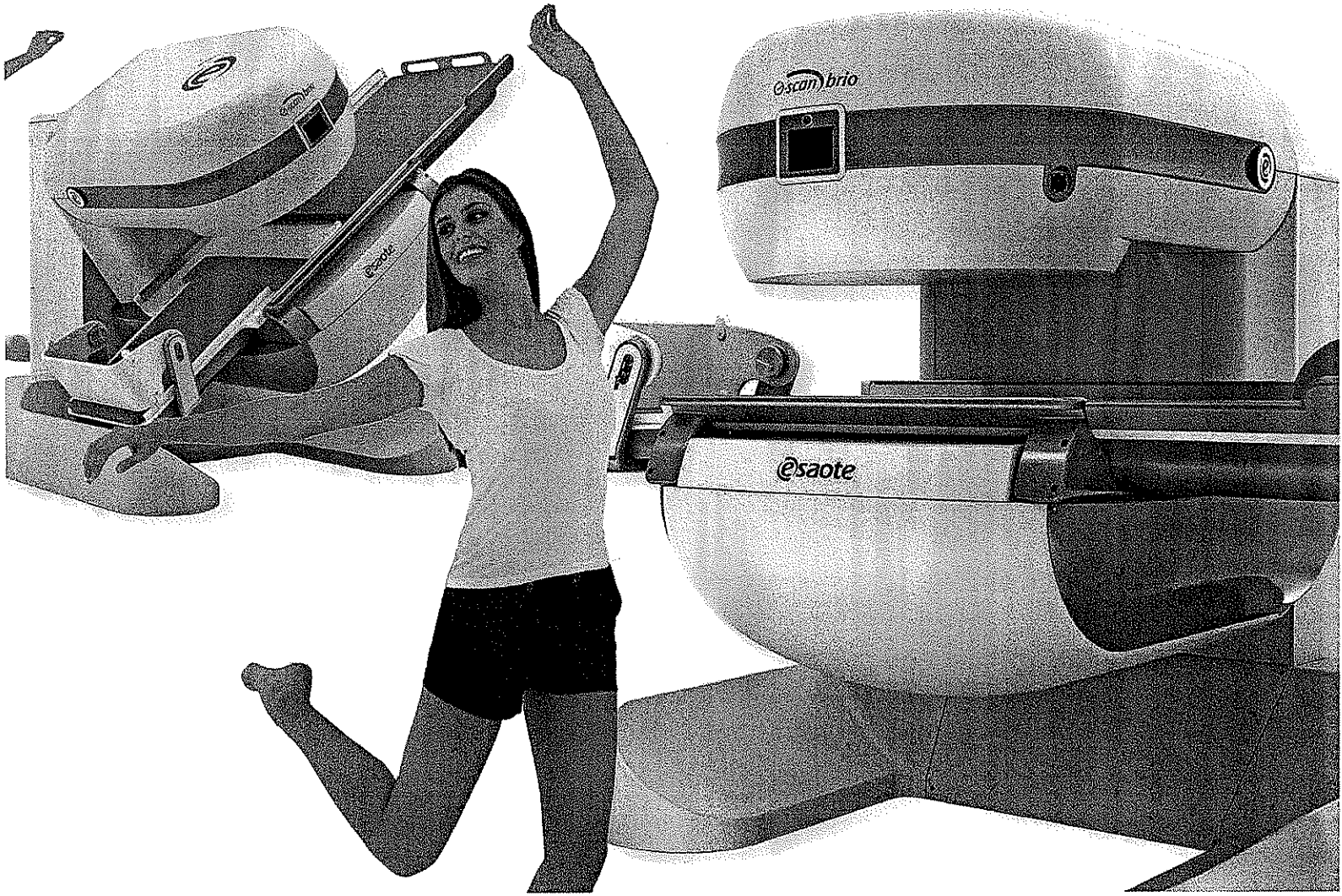
e-scan brio Tilting MRI

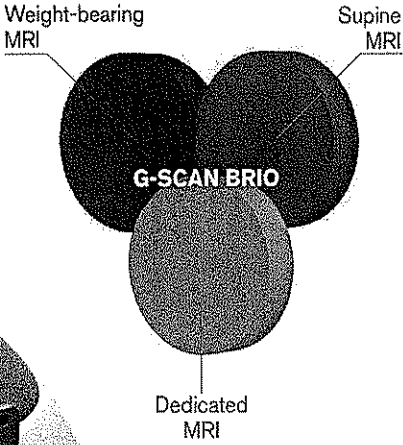
The Key to Confidence

More detail, better accuracy, greater confidence

The **G-scan Brio** is a revolutionary MRI approach for all musculoskeletal applications, which allows you to increase your diagnostic accuracy and confidence. The open and tilting design is the new and innovative way of doing MRI in which the position of the patient becomes an integral part of the outcome of the examination.





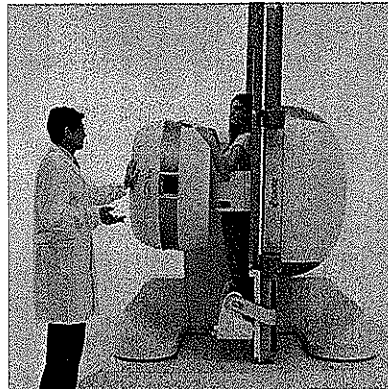


G-scan Brio: adds weight to your diagnosis

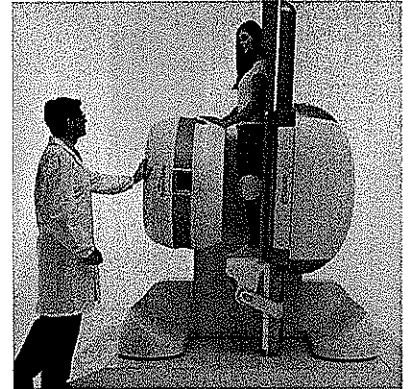
Many symptoms and pathologies occur or are emphasized when the patient is in the weight-bearing position. Conventional MRI may not demonstrate the pathology related to particular symptoms whereas the **G-scan Brio** gives you a new point of view so you can accurately diagnose MSK pathologies which are affected by the weight-bearing position.

G-scan Brio, the law of gravity

With the **G-scan Brio** you can gain a more complete understanding of the joint under examination. The forces of gravity generate bio-mechanical changes in the human anatomy, so MR imaging in the natural standing position allows you to obtain extra details which would not normally be seen.



Weight-bearing exam of the spine



Weight-bearing exam of the knee

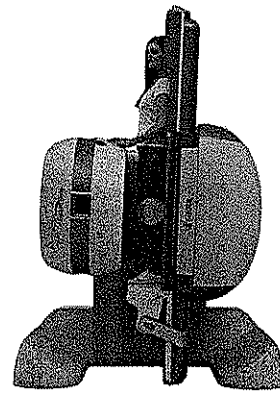
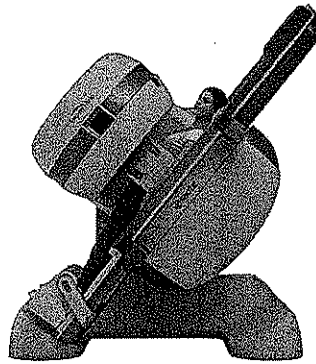
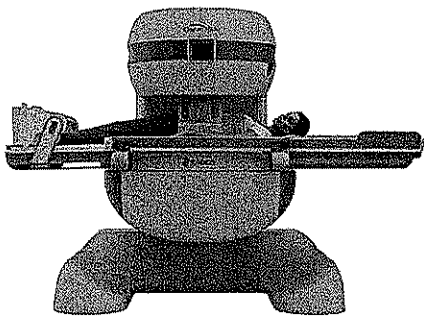


G-scan Brio: smooth and simple positioning

Fast Positioning

The excellent ergonomics and unique features of **G-scan Brio** bring benefits for the operator as well as the patient:

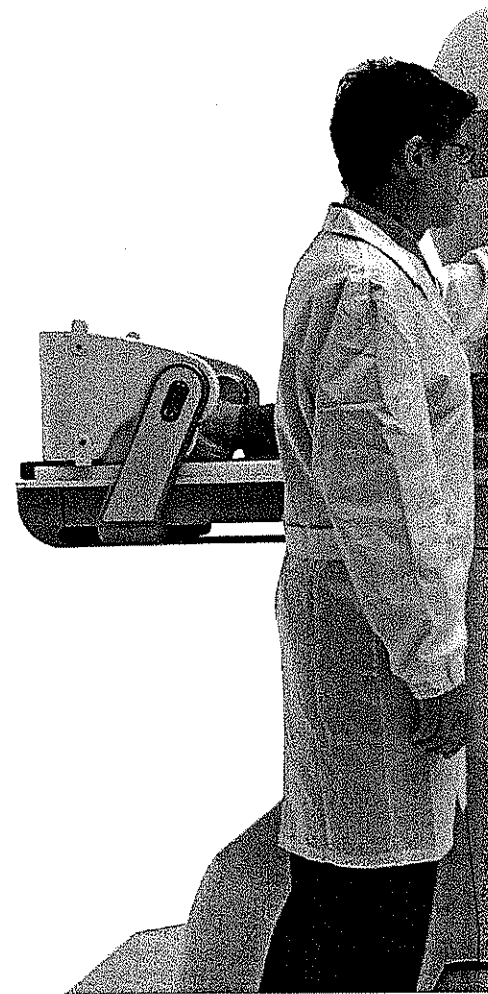
- Easy patient positioning with optimized patient bed
- Easy bed extraction by operator
- Real time MR images
- Only one fixed position for placing coils
- High level of comfort during examination

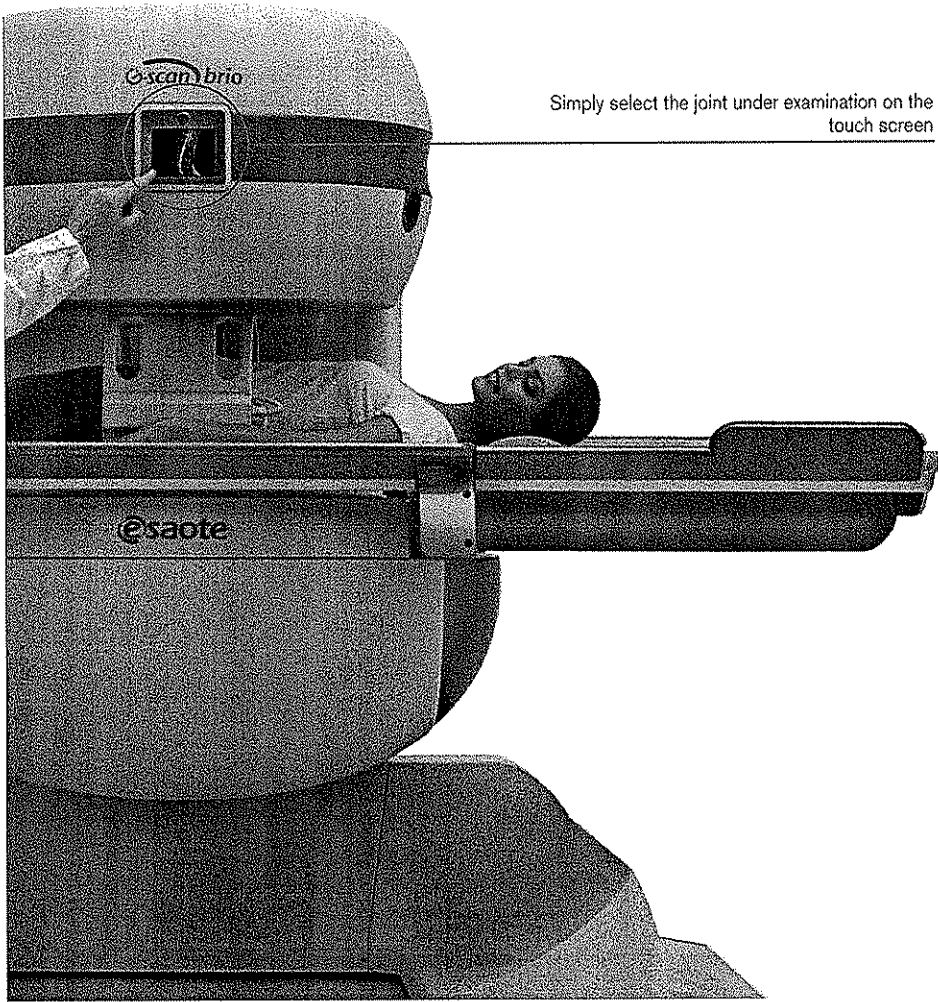


G-scan Brio: Real Time MRI

G-scan Brio is an MRI system specifically developed to perform musculoskeletal examinations. Unlike a multipurpose MRI, all aspects of the **G-scan Brio** system, from coils to user interface, have been developed and optimized to perform musculoskeletal MRI examinations in the most efficient and comfortable way. System handling and patient positioning therefore can be done by a single radiologist or technician.

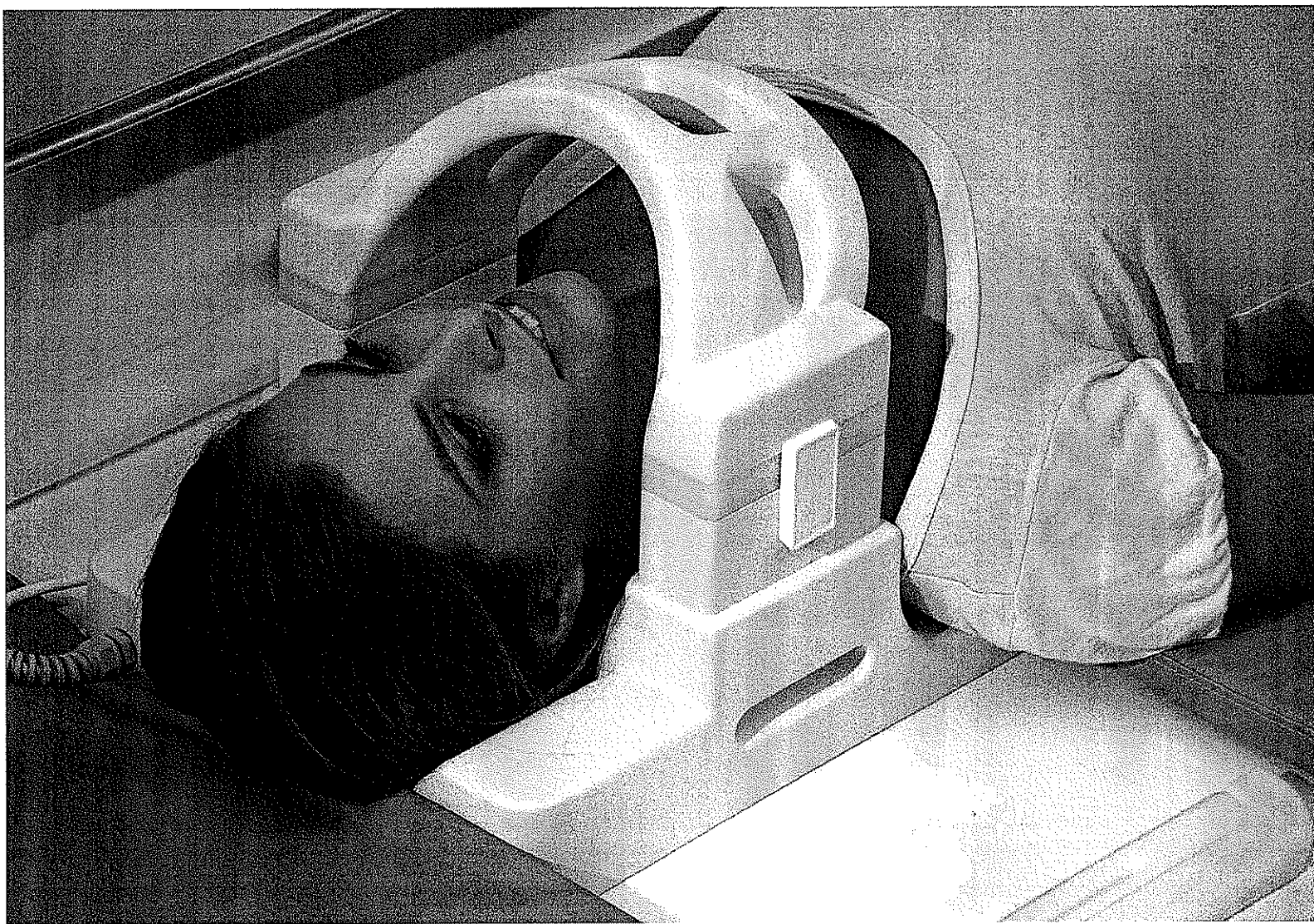
G-scan Brio comes with the real-time MR feature. Using a fast acquisition sequence, the touch screen display on the gantry will show in real-time the MR image of the joint assuring fast and accurate positioning.





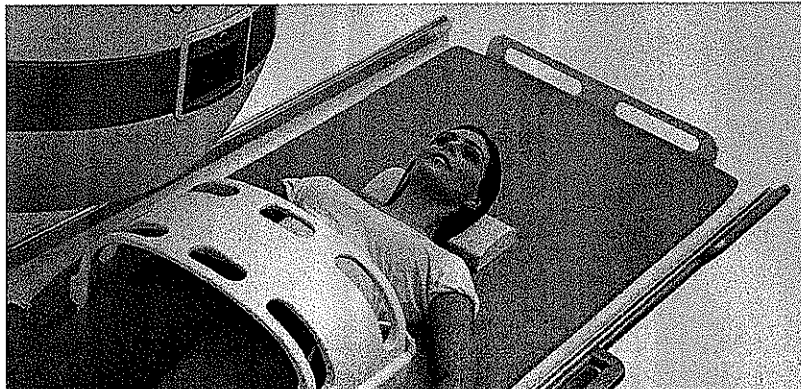
Simply select the joint under examination on the touch screen





G-scan Brio: the right Coil for the best exam performance

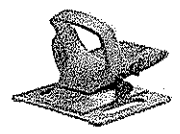
G-scan Brio includes a complete set of receiving coils specially designed for the joints, which guarantees very high sensitivity and patient friendliness. The standard set includes: two 4 channel lumbar spine coils (large and small), a knee coil, a wrist/hand coil, an ankle/foot coil and a shoulder coil which are all Dual Phased Array, a multipurpose flexible coil as well as a linear shoulder and cervical spine coil. An optional DPA cervical spine coil is also available.



4 Channel Lumbar Spine Coil



Optional Cervical Spine Coil DPA



Cervical Spine Coil



Knee Coil DPA



Ankle/Foot Coil DPA



Shoulder Coil DPA



Wrist/Hand Coil DPA



Shoulder Coil



Flexible Coil

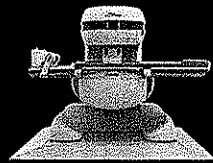
G-scan Brio reveals what supine MRI misses

Images courtesy:

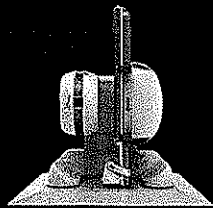
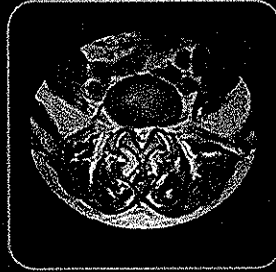
Department of Radiology, University of L'Aquila, Italy

Villa Donatello clinic, Florence, Italy

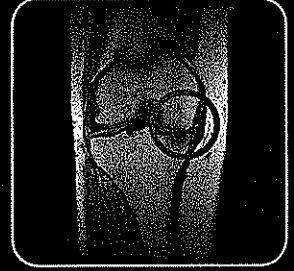
Parker Institutet, Frederiksberg Hospital, Denmark



G-scan Brio
supine



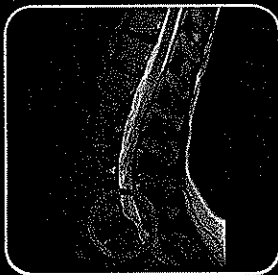
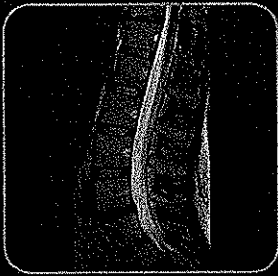
G-scan Brio
weight-bearing



Spine (FSE T2, 4mm)
C-spine in weight-bearing flexion,
evident ligament instability at level
of C4-C5

**Lumbar Spine (Transverse
FSE T2)** Articular facet instability
highlighted in weight-bearing,
while supine exam only shows
arthrosis

Knee (Coronal SE T1)
In weight-bearing the actual
damage to the cartilage of the
medial compartment is clear and
the origin of the bone edema is
well identified. The lesion to the
medial collateral ligament is visible
only in weight-bearing

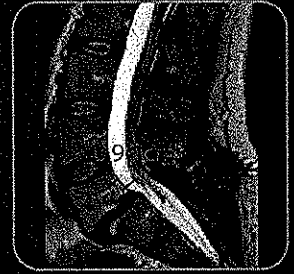


Lumbar Spine (Sagittal FSE T2)
Spondylolisthesis at L4-L5 level, highlighted in the weight-bearing position.



Lumbar Spine (Axial 3D Hyco)
Increased foraminal stenosis evident from weight-bearing exam

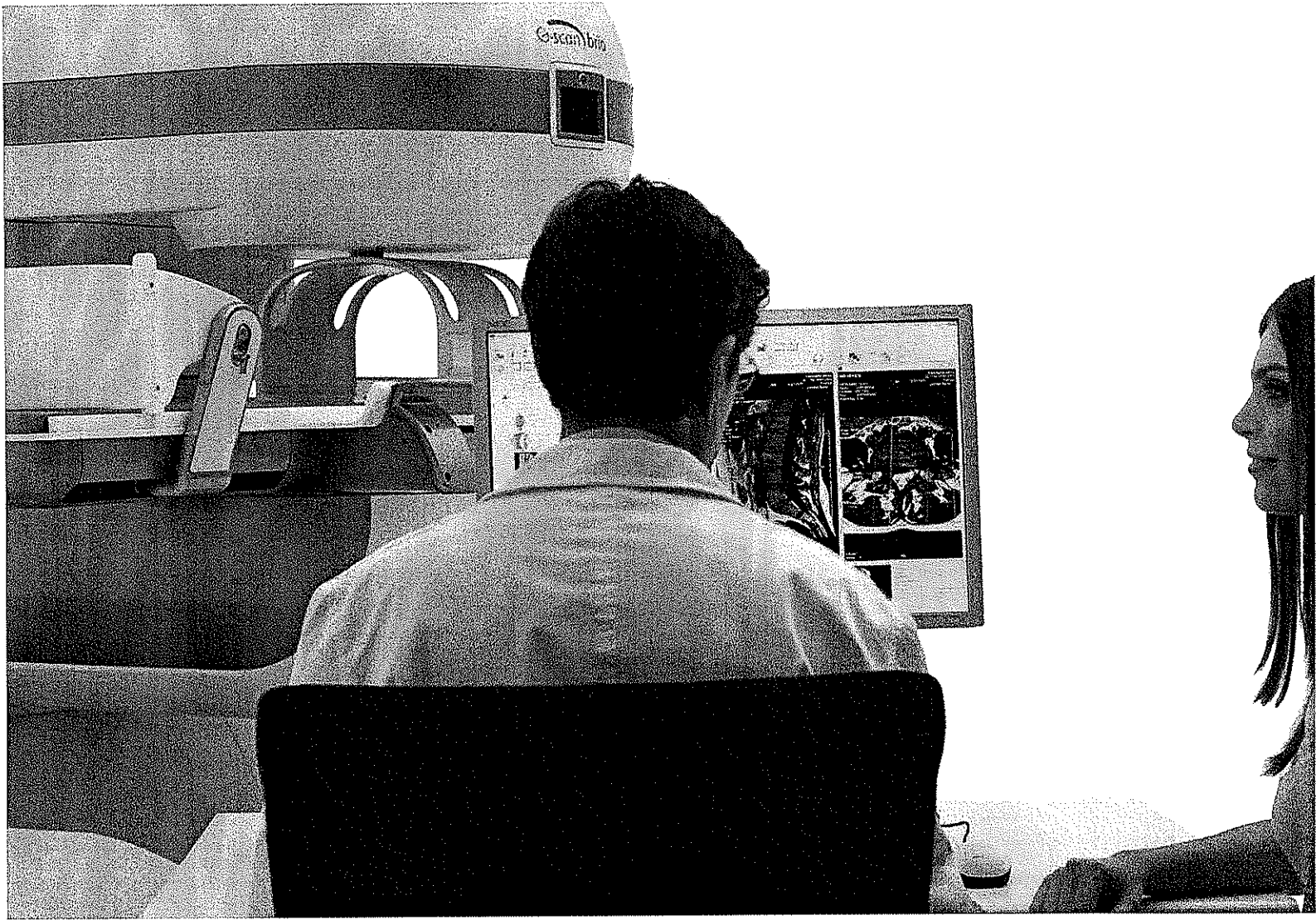
3 Tesla
supine



G-scan Brio
weight-bearing



Lumbar Spine (Sagittal FSE T2)
Spondylolisthesis, anterior shift of the vertebra more evident in the weight-bearing exam

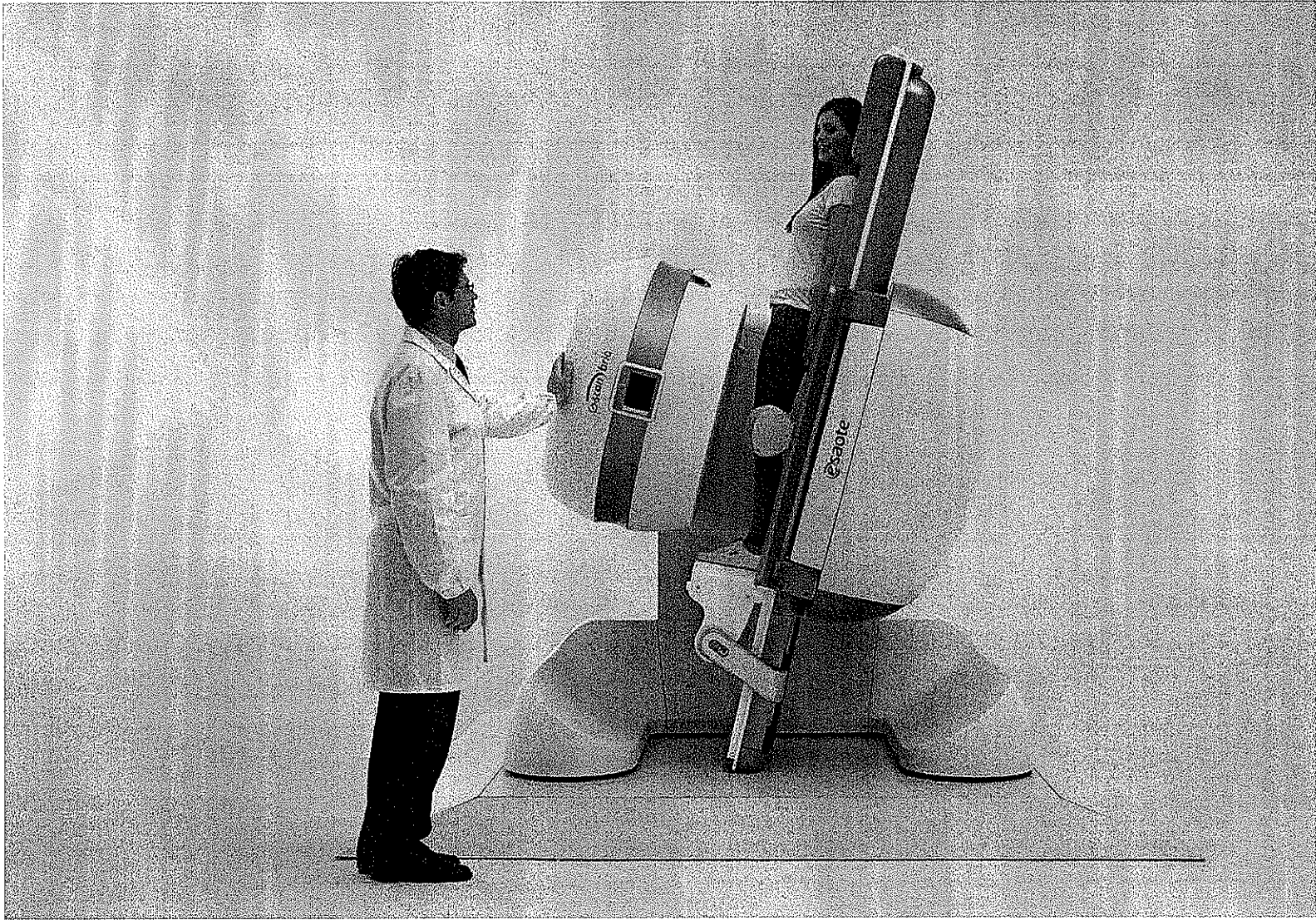


G-scan Brio: intuitive user interface

The user interface is very simple and user friendly, routine exams can be performed by just a few mouse clicks. Even the most expert user will be fully satisfied as all scanning parameters can be personalized and the custom sequences can be stored and integrated in the normal menu structure for subsequent use. Thanks to its unique tilting design, the magnet unit can be rotated to move the patient into a true weight-bearing position.

Normally the patient will be imaged first in the upright weight-bearing position and then in the traditional supine position, also to make differential diagnosis possible. There are several ways of performing weight-bearing MRI but there is only one simple and cost effective way: **G-scan Brio**, the in-office weight-bearing MR.







G-scan Brio: connected to MSK needs

Windows® Interface

The **G-scan Brio** is easy to learn as it uses Windows® functionalities. The interface and protocols are custom designed for extremity and Spine MRI purposes which speeds up and simplifies the examination procedure considerably.

Connectivity

G-scan Brio comes with all network, archiving and documentation features to work either stand alone or as part of an integrated environment. It has an integrated DVD archive and retrieve software package, printer facility and a patient CD package.

G-scan Brio is also DICOM compliant and offers smart solutions for connectivity and teleradiology:

- DICOM image transfer to any PACS or Workstation
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- E-MRI Viewer: an Esaote software only PC program which transforms a normal PC into a DICOM viewer.

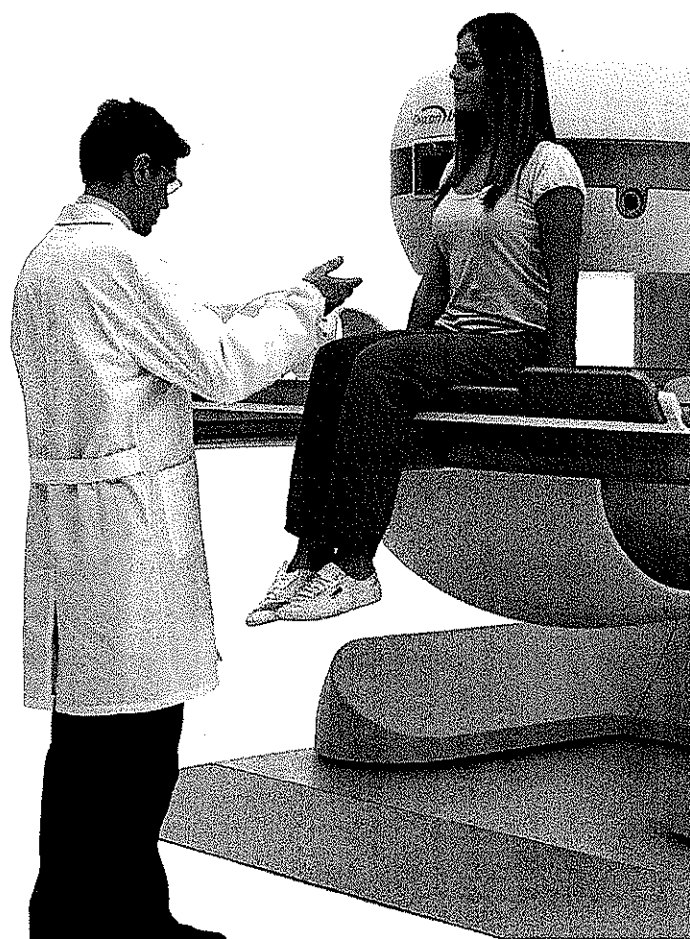
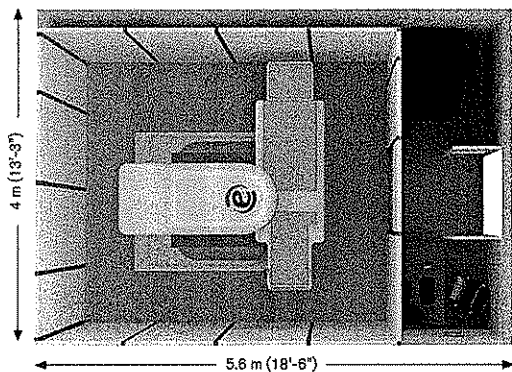
Remote

All Esaote systems come with remote service capability. Many system parameters and system components can be checked via the remote service program specially developed for Esaote MRI systems. Using the remote connection, it is possible for Esaote application specialists to verify image quality and help the local operator set exam parameters. Moreover, it shortens reactions times and improves the time to repair as service visits can be made more efficient with the service technician.

G-scan Brio: Hassle-Free MRI

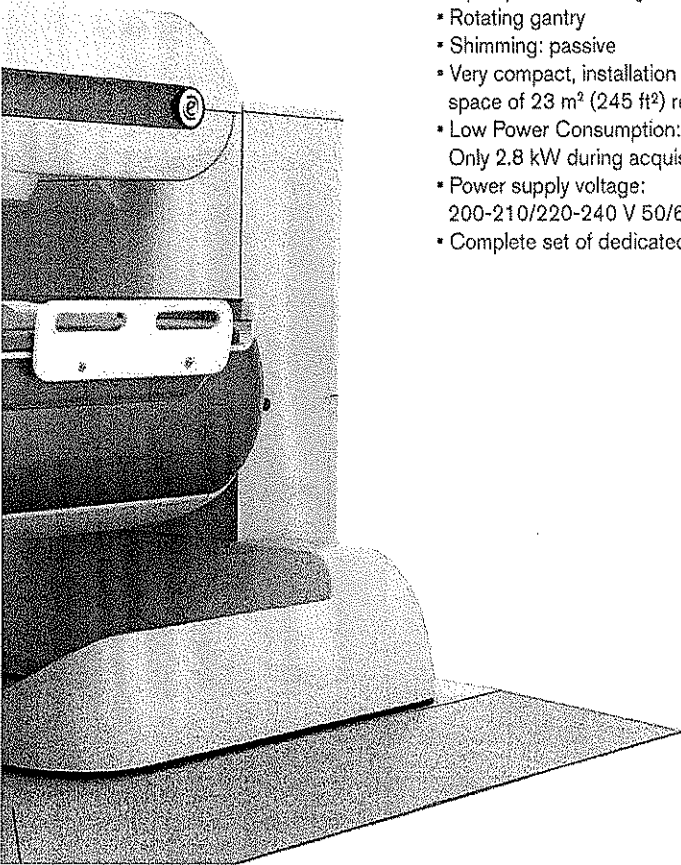
Like all Esaote MRI systems, also **G-scan Brio** is a "one room" MRI system which means that the complete system, magnet, electronics and console can be installed in a single room of only 23 m² (245 ft²).

- **G-scan Brio** is based on an optimized permanent magnet so no cryogenics and no complicated cooling systems are required.
- Dedicated shielding available. The Esaote dedicated shielding is a pavilion style independent shielding that can be installed without any construction works.
- Fast and high quality service. Thanks to the built-in remote service capability, technical assistance is fast and efficient.



G-scan Brio, a turning point in MR imaging

- Open permanent magnet
- Rotating gantry
- Shimming: passive
- Very compact, installation space of 23 m² (245 ft²) required
- Low Power Consumption:
Only 2.8 kW during acquisition
- Power supply voltage:
200-210/220-240 V 50/60 Hz
- Complete set of dedicated coils

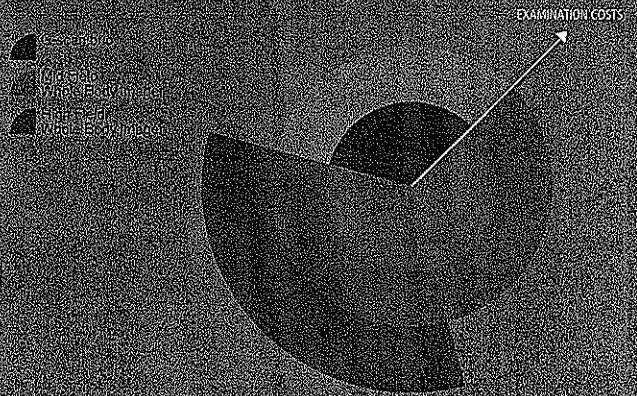


G-scan Brio economics

G-scan Brio is not only a unique system from a clinical and diagnostic viewpoint but it is also easy to site and very economical to run. The low break even point of **G-scan Brio** is fully in line with the economical constraints of today's healthcare environment making it an optimal investment also for the private clinic.

Examination costs

Easy installation, ease of use, low maintenance technology, low energy consumption, no cryogen, remote service possibility all = smart investment.



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