

Magnetic resonance access for ICD and PM patients: which are the possibilities?

P.G. Golzio

**AOU Città della
Salute e della
Scienza di Torino –
“Molinette”**

Advances in Cardiac
Arrhythmias

Turin, September 27-28,
2013



Cardiac Devices and Magnetic Resonance Imaging

Two parallel stories intended to meet

Electrostimulation history started in **1957**. Different steps led to a fast evolution:

- Integrated circuits development and size reduction
- Dual chamber devices
- physiological pacing
- ICD
- Cardiac Resynchronization Therapy
- Remote patient management control



Magnetic Resonance Imaging was developed in **1946** by physicists Felix Bloch and Edward Purcell. They received Nobel Prize for physics in 1952.

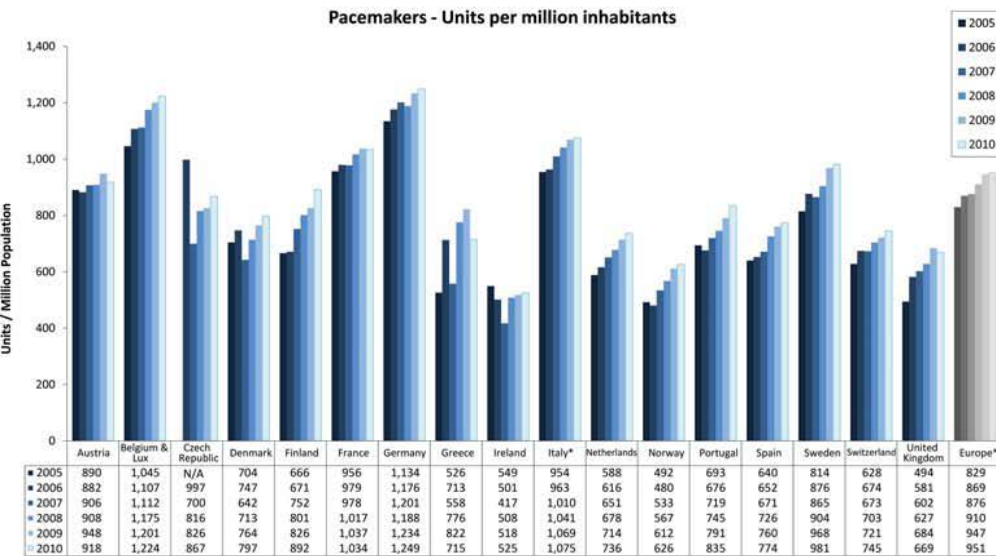
Fast development followed thanks to Paul C. Lauterbur and Sir Peter Mansfield studies that created a system able to:

- show 2D and 3D images
- show images in few minutes

Medicine Nobel Prize in 2003.

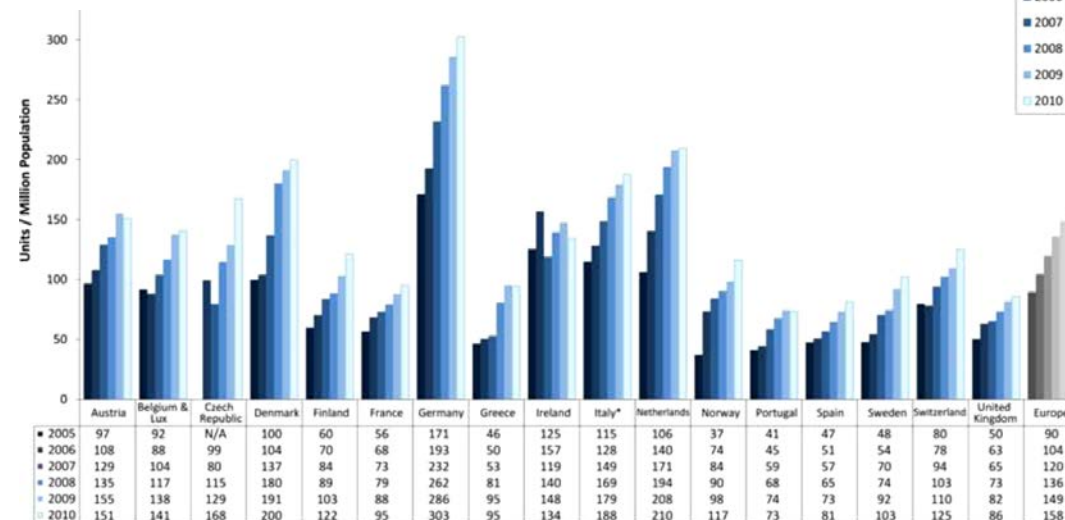


European Cardiac Devices fast growth



Pacemaker units per million population

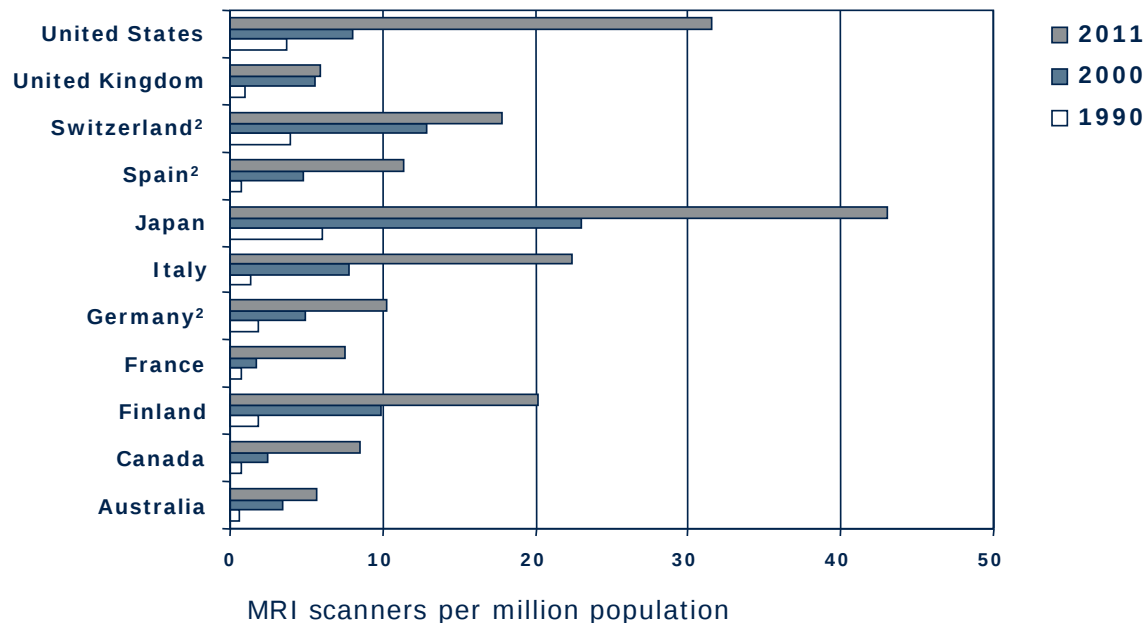
Defibrillators - Units per million inhabitants



ICD units per million population

MRI is one of the fastest growing imaging techniques

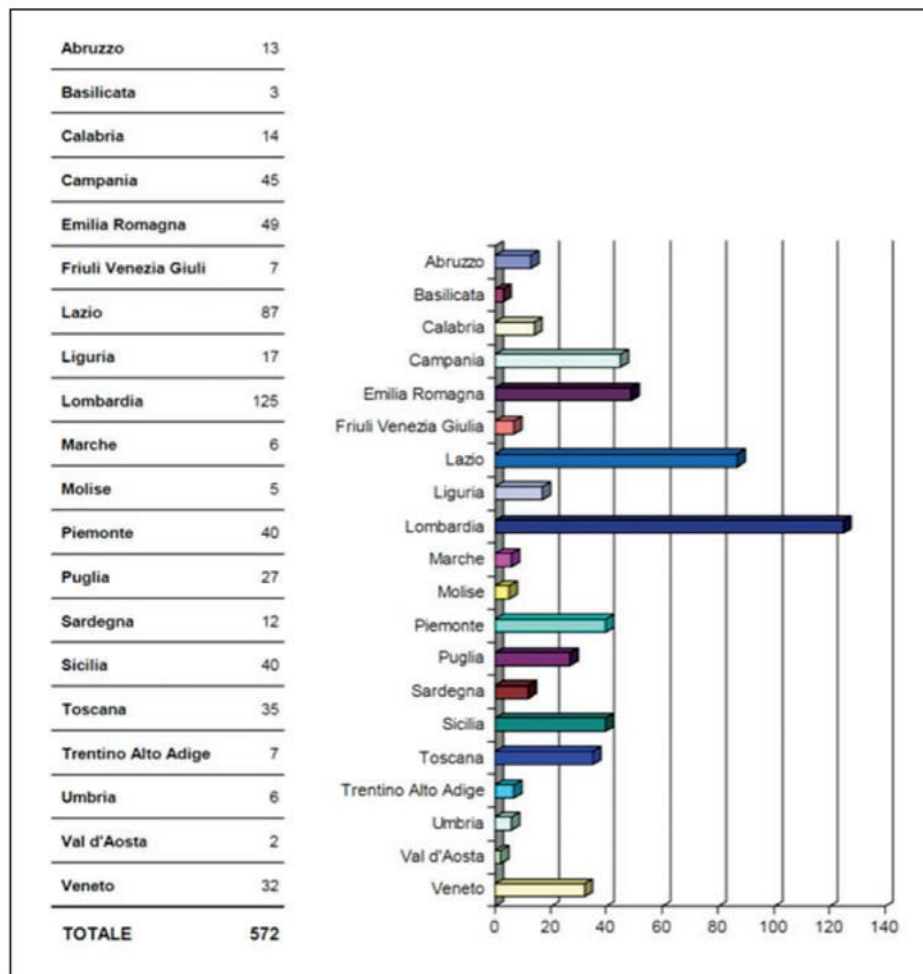
MRI units per million population in 1990, 2000 and 2011¹



¹ OECD Health Data 2012, http://stats.oecd.org/Index.aspx?DataSetCode=HEALTH_REAC

² Data include equipment in hospital only.

Italian MRI distribution in 2012



Type of MRI scanners

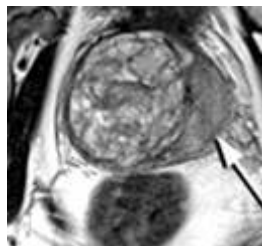
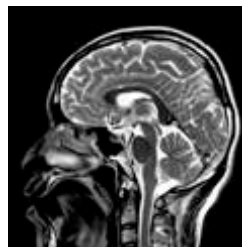
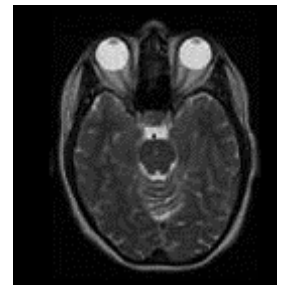


Figura n. 11 - Distribuzione regionale delle apparecchiature RM total body con magnete superconduttore e campo magnetico statico pari a 1,5 tesla

Why are MRIs important?

Magnetic resonance image scanning is the gold standard for soft-tissue imaging for:

- the diagnosis of cancer
- the diagnosis stroke
- the diagnosis of soft-tissue-related diseases
- the evaluation of nervous central system
- the evaluation of musculo skeletal system



MRI: Scelta Diagnostica

“La risonanza magnetica è l'unica e insostituibile metodica per la diagnosi del cancro e dei disturbi neurologici. L'indagine del cervello e del midollo spinale, nella maggior parte dei casi non presenta un'alternativa praticabile.”

– Professor Torsten Sommer

Professore di Radiologia
Responsabile Diagnostica
cardiovascolare per
immagini Università di
Bonn

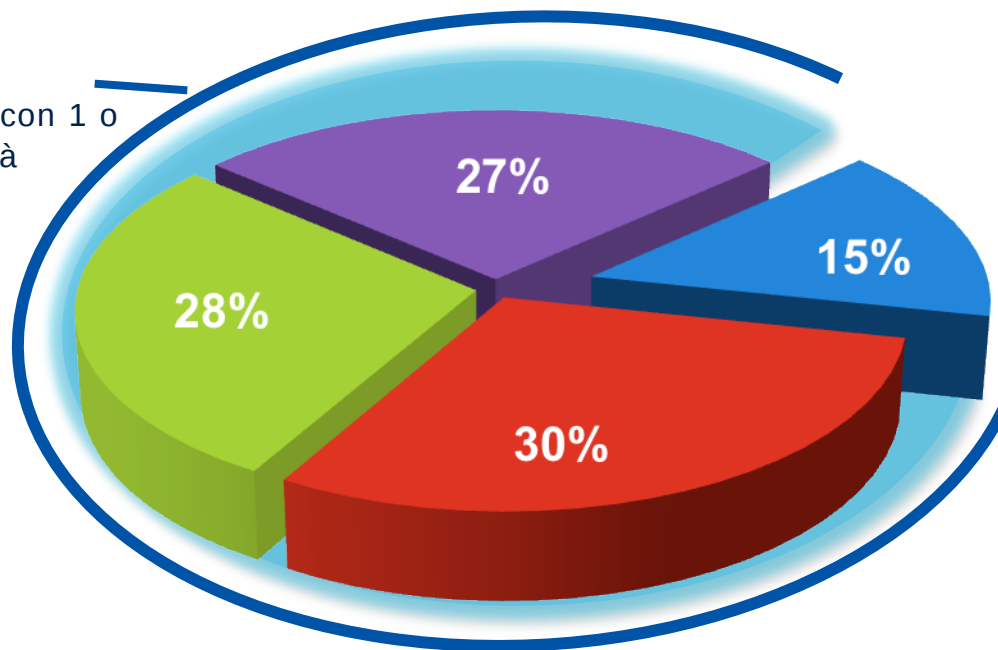
- 
- **ONCOLOGIA**
 - **NEUROLOGIA**
 - **ORTOPEDIA**
 - **CARDIOVASCOLARE (Stroke-related)**
Linee guida American Heart Association/American Stroke Association (Luglio 2010) *
 - **PAZIENTI CON PATOLOGIE DIAGNOSTICATE**
 - Ghiandola pituitaria
 - Sclerosi multipla
 - Alto rischio tromboembolico
 - altro

*Guidelines for the Management of Spontaneous Intracerebral Hemorrhage: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association - Morgenstern et al. 2010;41:2108-2129

Perché per un paziente portatore è importante l'accesso alla Risonanza Magnetica ?

L'**MRI** rappresenta il **gold standard** nello studio e nella diagnosi dei tessuti molli

85 % di pazienti con 1 o più comorbidità



■ Nessuna Comorbidità

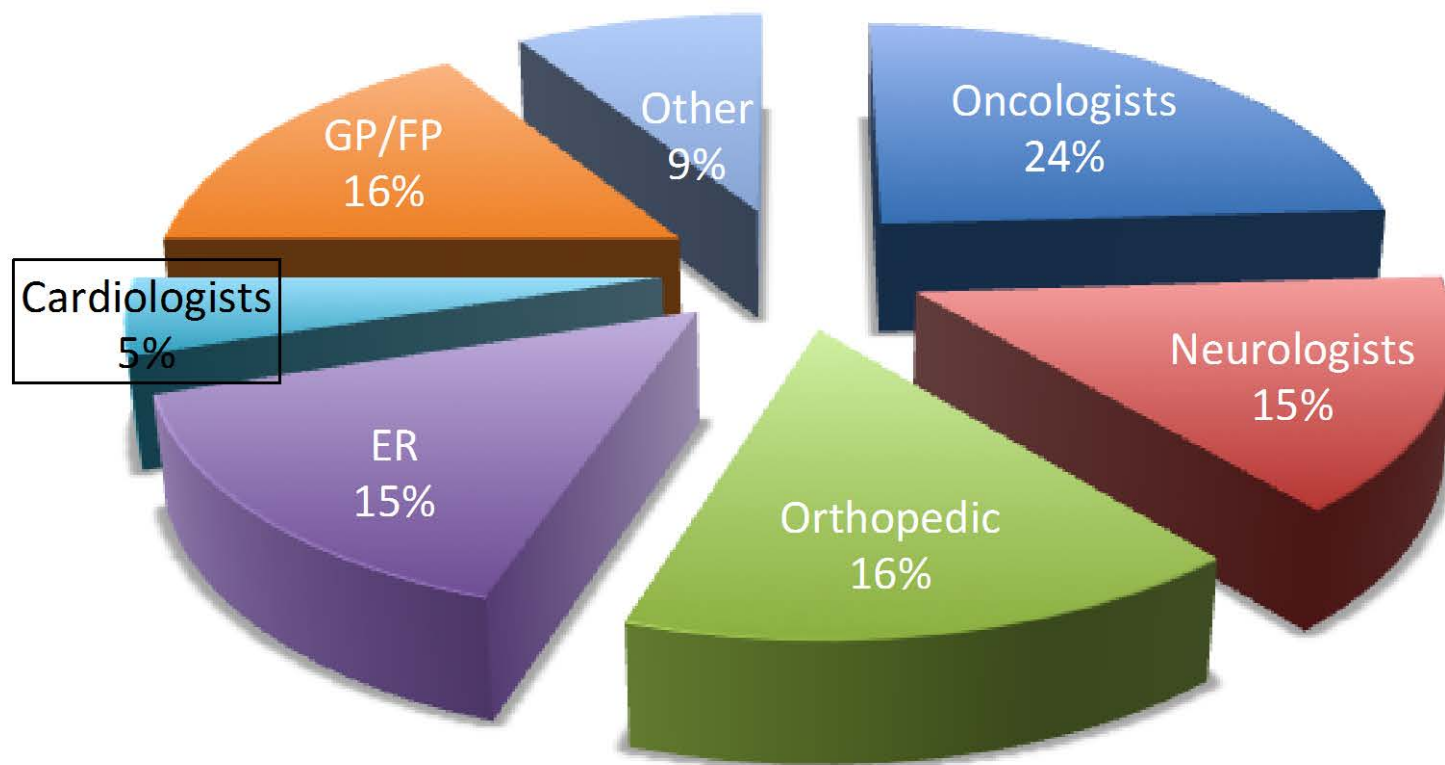
■ 1 Comorbidità

■ 2 Comorbidità

■ 3 o più Comorbidità

L'85% dei pazienti portatori di pacemaker presentano una o più comorbidità. E' estremamente importante riuscire a garantire l'accesso alla migliore metodica diagnostica possibile che la gestione multidisciplinare del paziente

Chi prescrive una indagine MRI?



Why are MRIs important?

Advantages:

- No radiation exposure
- Very few side effects
- Multiplanar
- Multiparameters
- Unparalleled soft-tissue contrast resolution
- Morphologic, structural and functional analysis

Disadvantages:

- High costs
- Limited spread
- Long and complex procedures
- Claustrophobia
- Metallic implants



MR scans in clinical practice

Scan districts

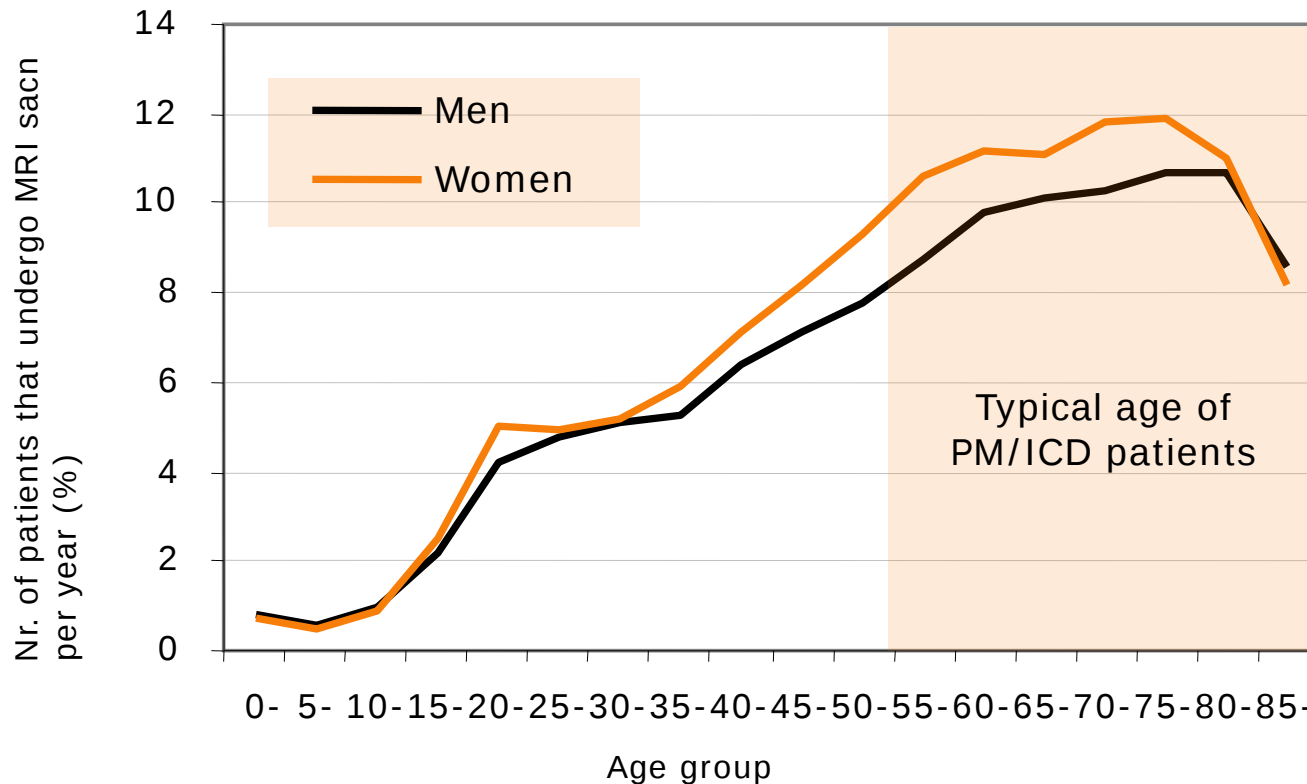
Head and neck	28.3%
Cervical spine	7.6%
Chest	1.8%
Thoracic spine	1.5%
Abdomen	4.5%
Lumbar spine (L1–2)	2.1%
Lumbar spine (L3–5)	19.1%
Hip	3.2%
Extremities	30.2%
Others	1.7%



Source: Based on Barmer GEK Arztreport 2011, published January 2011, www.barmer-gek.de, as well as BIOTRONIK and expert assumptions. Please refer to the MRI manual for further MR scan conditions.

MRI is contraindicated for patients with no MR conditional devices

MRI usage increases by age and is very high in the age group of cardiac device patients*



* Based on Barmer GEK Arztreport 2011, published January 2011, www.barmer-gek.de, as well as BIOTRONIK and expert assumptions.

MRI demands

6 min

Every 6 minutes in europe an MRI scan is denied to a cardiac device patient*

17%

Patient required to undergo an MRI scan within 1 year from the implant**

50%-75%

Estimated probability that an MRI scan will be required to a cardiac device patient within the lifetime of the device**

* Gimbel JR. Europace. July 2010;12(7):915-917 - Gimbel JR. Pacing Clin Electrophysiol. June 2008;31(6):649-651 - Gimbel JR, Bailey SM, Tchou PJ, Ruggieri PM, Wilkoff BL. Pacing Clin Electrophysiol. October 2005;28(10):1041-1046 - Irnich W. Europace. July 2010;12(7): 918-920

** Roguin et al., Europace, 2008, 336-346

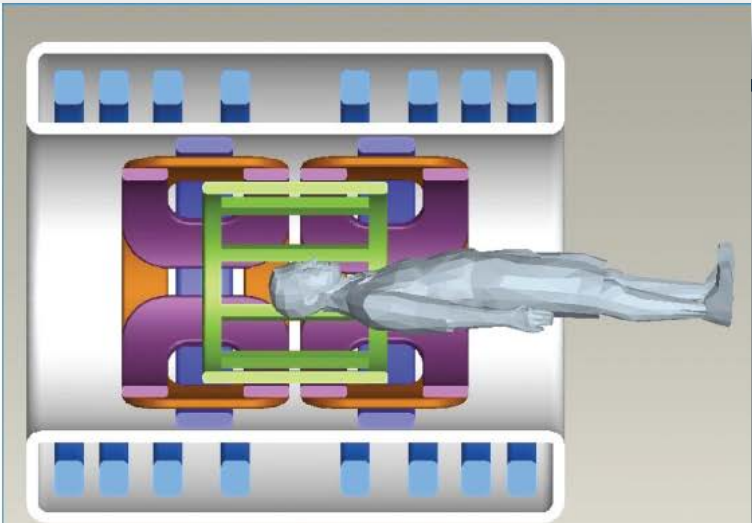
EFFETTI DELLA RISONANZA SUI TESSUTI

Principi fisici

IL CAMPO MAGNETICO

Ambiente MRI: Forze e campi di interazione

	Static	Gradient	RF
Case Heating		●	●
Force and Torque	●		
Vibration	●	●	
Lead Heating			●
Stimulation (UCS)		●	●
Device Interactions	●	●	●



CAMPO MAGNETICO STATICO

Il **campo magnetico statico** di 1,5T è circa 30.000 volte quello terrestre. Questo campo di 1,5T è sufficiente per trasformare un oggetto metallico in un proiettile.

GRADIENTI DI CAMPO

Senza i **gradienti di campo magnetico** gli impulsi/sollecitazioni RF ecciterebbero tutto il tessuto sollecitato dalle radiofrequenze e i segnali di ritorno dal tessuto dopo la sollecitazione potrebbero provenire da qualunque parte del tessuto.

CAMPO RADIO FREQUENZA

Il **campo a RF** è il responsabile per la creazione dell'immagine.

La frequenza del campo RF è proporzionale al campo magnetico statico ed è 64 MHz per un campo magnetico statico a 1.5T. Il campo a Radiofrequenza è veicolato al paziente attraverso impulsi ad alta potenza dell'ordine di migliaia di Watt applicati per pochi millisecondi.

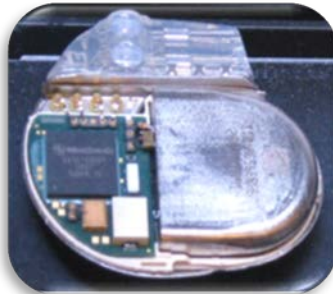
La tecnologia

I MATERIALI

Materiali

- L'evoluzione tecnologica ci ha portato negli anni a modificare i materiali di cui sono fatti i dispositivi.
- Le scelte tecnologiche intraprese ci hanno portato sempre più verso la compatibilità magnetica.

Batteria



Negli anni da materiali ferromagnetici (nichel-cromo etc) si è giunti agli ioni di lito.

Cassa



Il titanio è un materiale non magnetico che opportunamente trattato presenta una ridottissima permeabilità magnetica

Cateteri

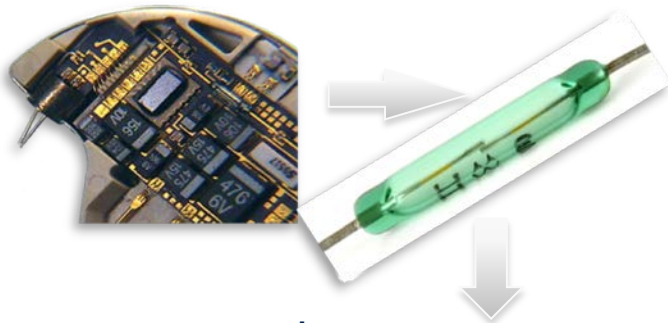


Sono composti di una lega metallica MP35N (lega di nichel, cobalto cromo e molibdeno: =non ferromagnetici)

- In generale i PM possono considerarsi paramagnetici, orientandosi // al campo magnetico (il paziente in genere è sdraiato e già parallelo al campo magnetico).

Componenti elettroniche

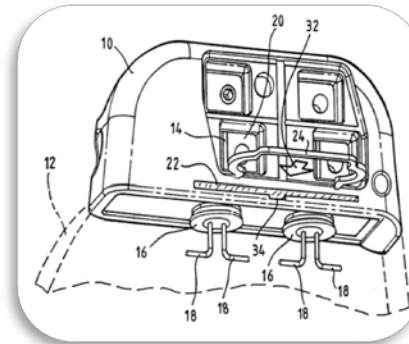
Studiando a fondo l'interattività dei materiali con la risonanza sono via via stati sostituiti i componenti problematici e protette le possibili interferenze



From Reed
switch to Hall
sensor



Completo controllo sul pacemaker



Feedthrough : protezione del
circuitto di alimentazione e della
batteria

Prevenire danni al circuito di
alimentazione da correnti indotte e
fuori controllo

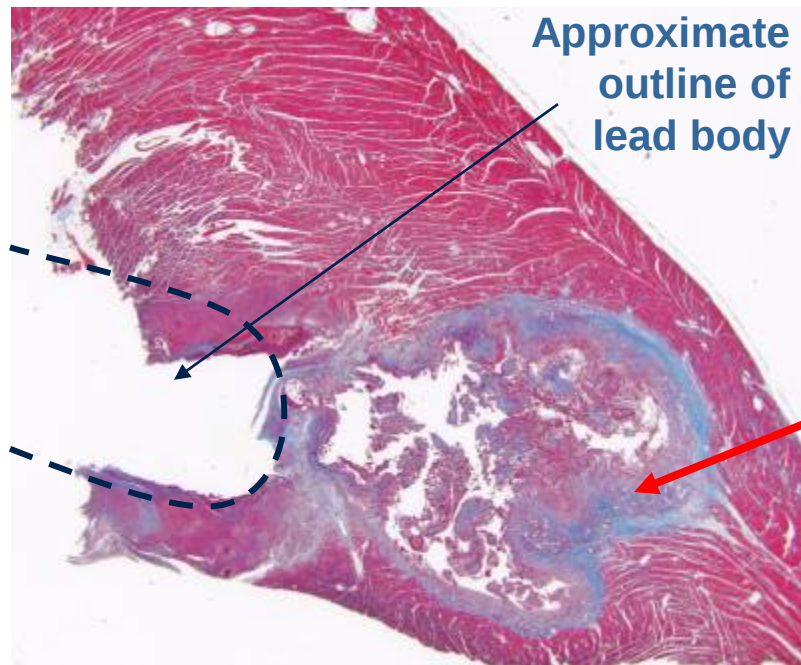
fuori controllo

Tessuti e sistema di stimolazione

EFFETTI DELLA RISONANZA

Example of MRI and device interaction in a non MR conditional pacemaker: tip heating

Potential loss of capture and sensing



Myocardial histology:

- Non MRI conditional lead extracted after MRI scan
- Lesion Area

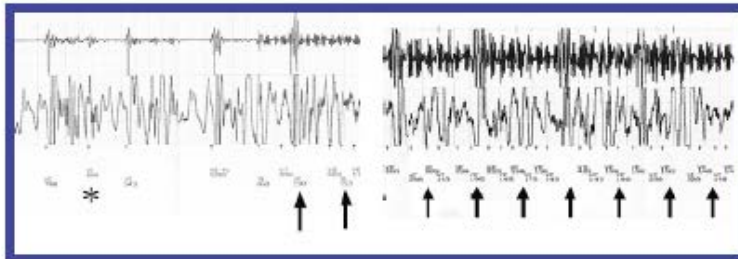
Interrelated factors in the MRI environment carry a risk for patients with ICDs/CRT-Ds

ProMRI ensures safety during MRI scanning

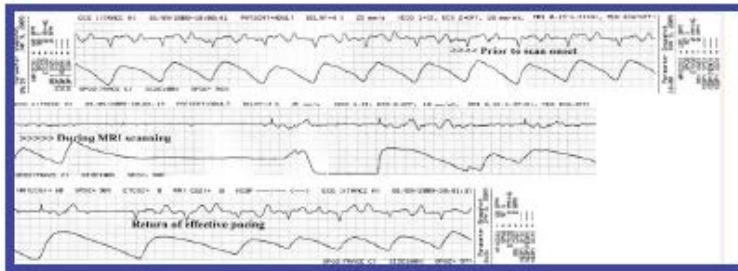
Potential hazard	Mechanism	Solution
Lead heating , increased pacing threshold and potential loss of capture	RF energy dissipates through the lead tip, causing heating of the cardiac tissue	Extensive testing with multiple lead and device combinations and a variety of lead positions
Inappropriate pacing	▪ Over/undersensing ▪ Unintentional stimulation	▪ Specific MRI mode settings ▪ Dedicated testing performed to avoid inappropriate stimulation
Device malfunction	Hardware/software failure caused by strong forces	Specially selected, developed and tested materials, components and hybrid design

Example of MRI and device electrical interaction in a non MR conditional pacemaker

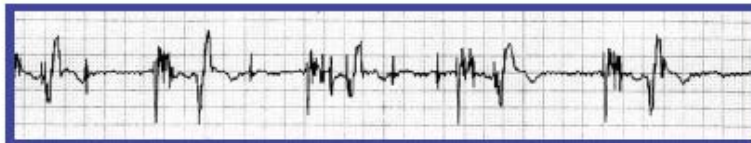
EKG during MRI



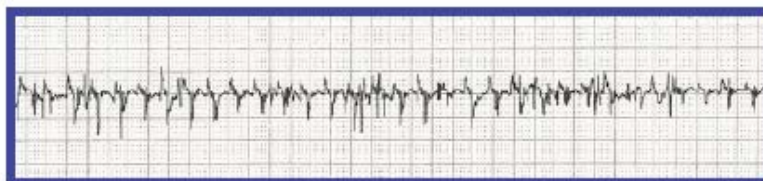
RF oversensing as VF



Asystole (brain)



Ventricular ectopic beat
(lumbar spine)



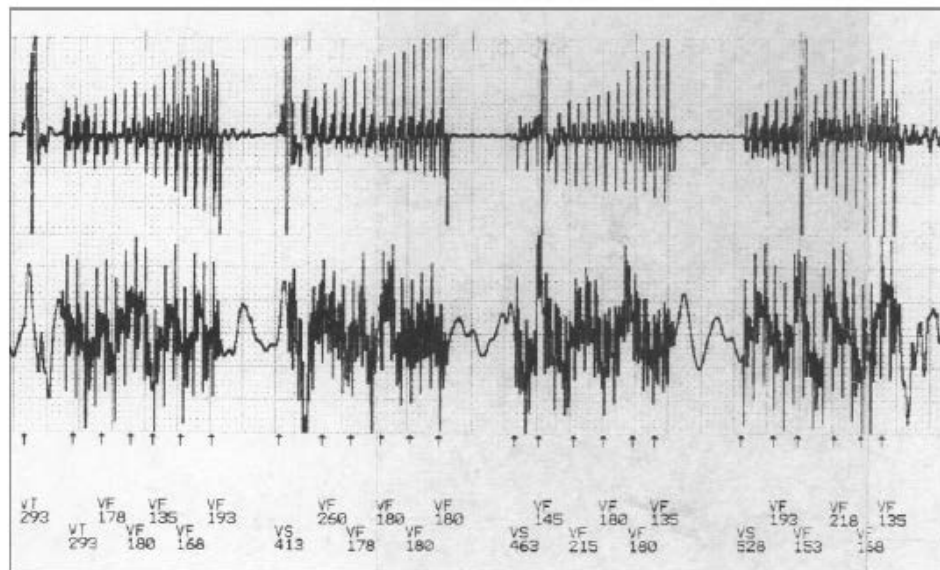
Artifact (brain)

Example of MRI and device electrical interaction in a non MR conditional pacemaker

IMAGES IN CARDIOLOGY

Electromagnetic interference induced by magnetic resonance imaging

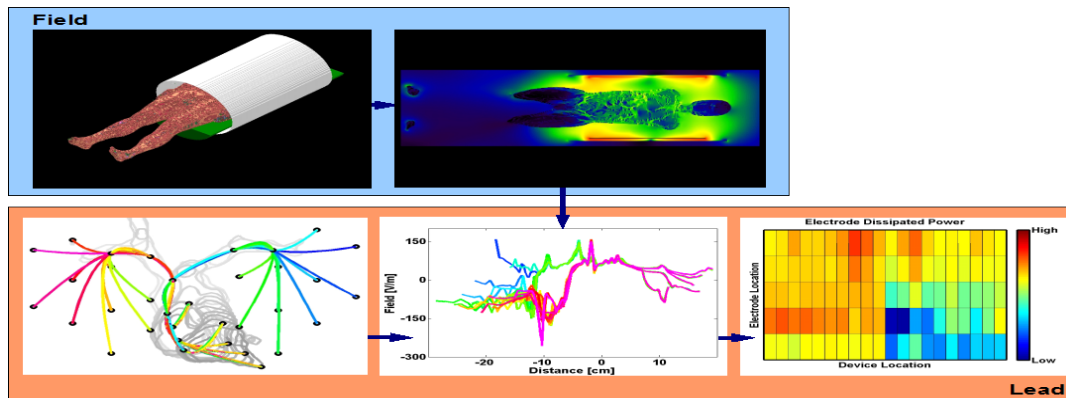
William F McIntyre BSc, Kevin A Michael MBChB, Adrian Baranchuk MD FACC



Valutazione della compatibilità MRI

Compatibilità MRI Oltre ai materiali...

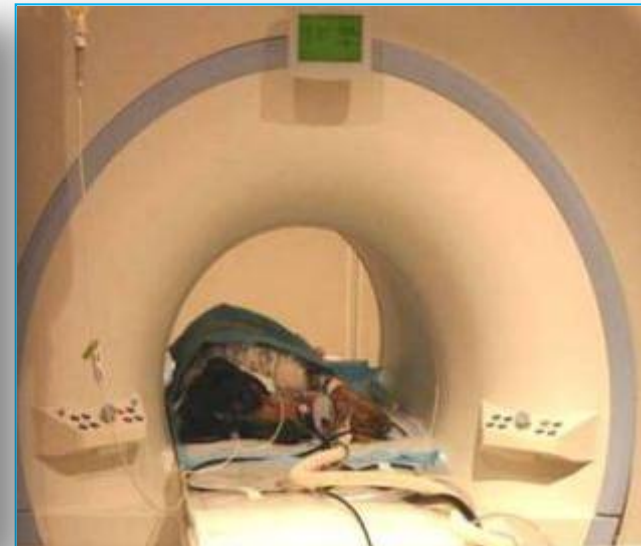
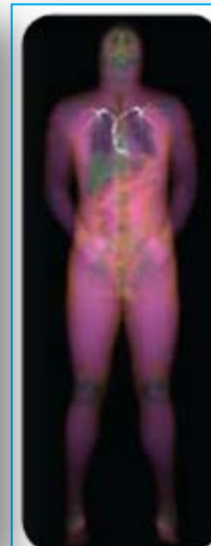
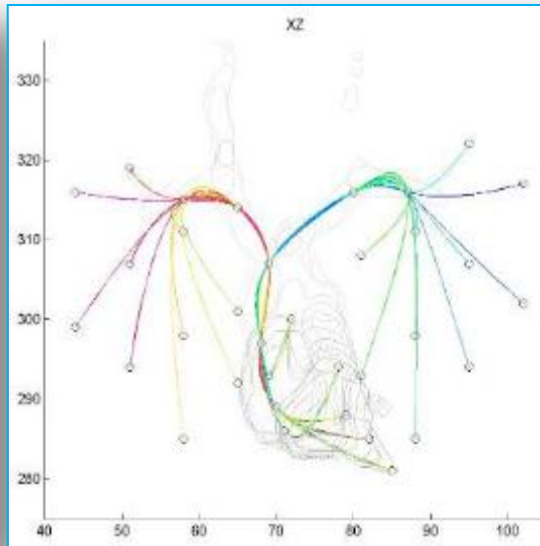
- Oltrepassato il problema materiali arriva il momento di studiare delle interferenze elettromagnetiche.
- È necessario conoscere a fondo e simulare al meglio il comportamento dei dispositivi per creare/ arrivare ad una tecnologia MRI compatibile.



Modello del pattern del campo elettrico all'interno del corpo umano
I differenti colori rappresentano le diverse intensità del campo elettrico

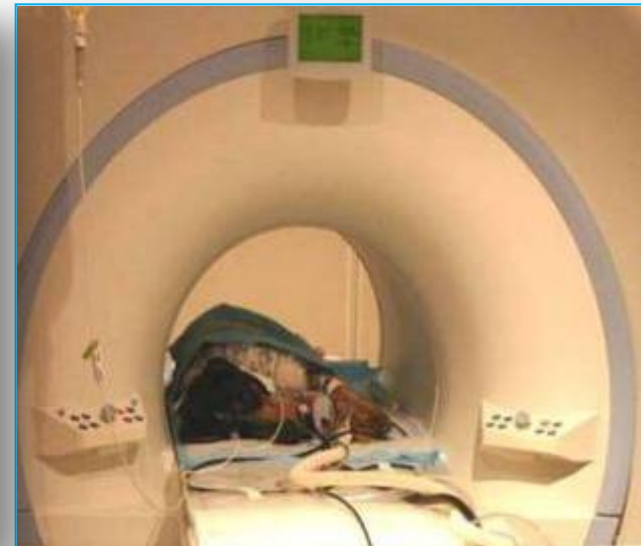
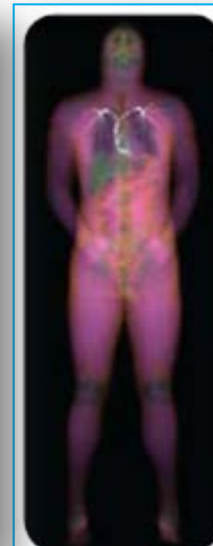
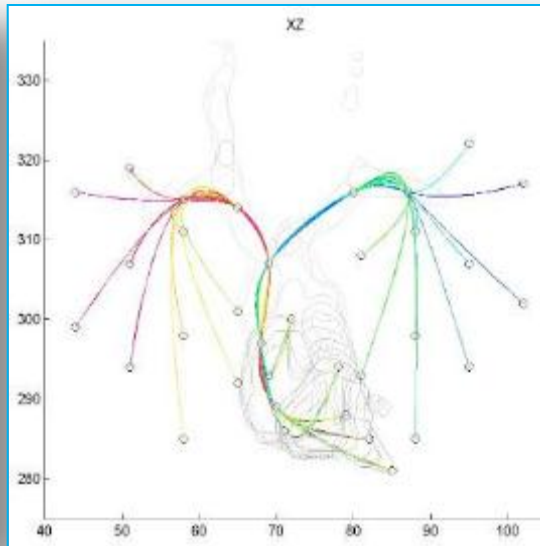
Certification Processes

- Modeling
- Bench testing
- In Vitro Testing
- Phantom testing
- Animal testing
- Clinical trials



Certification Processes

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“Perchè modellizzare?”

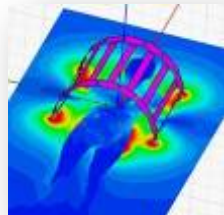
MRI Modelling

L'utilizzo di modellizzazioni permette di esplorare **milioni di combinazioni** di variabili per questa complessa realtà al fine di garantire la sicurezza del paziente all'interno della risonanza magnetica.

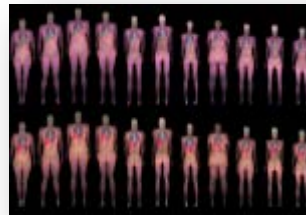
Tutti questi scenari (causa numerosità) non potrebbero essere valutati attraverso un solo studio clinico.



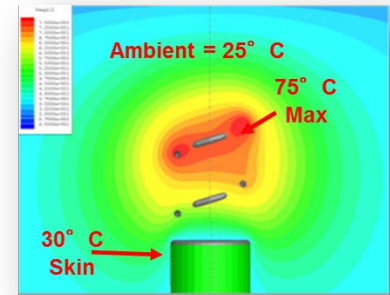
La potenza RF che raggiunge il tessuto cardiaco è calcolata per ciascun dei 100 possibili percorsi di elettrocateretere in ciascuno dei 22 modelli



Scansioni simulate ogni 15 cm

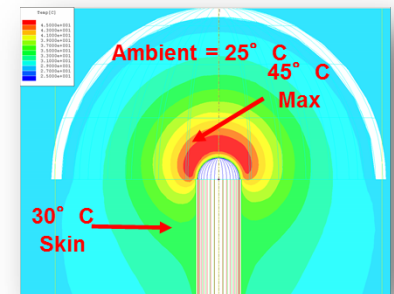


Il riscaldamento in punta dell'elettrocateretere dipende da vari fattori fra cui l'anatomia e le dimensioni del paziente. La *Human library* considera uomini e donne per la valutazione dal 2° al 97° percentile di tutta la popolazione adulta mondiale



Isoterme

(Comportamento punta fissaggio attivo)

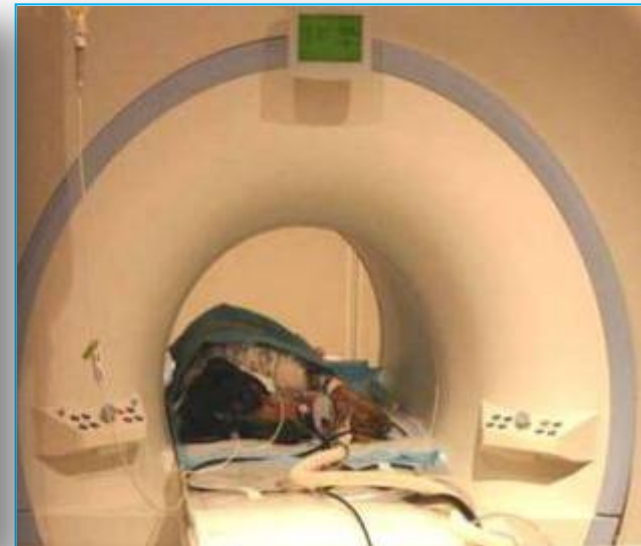
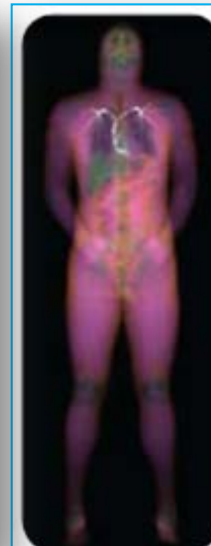
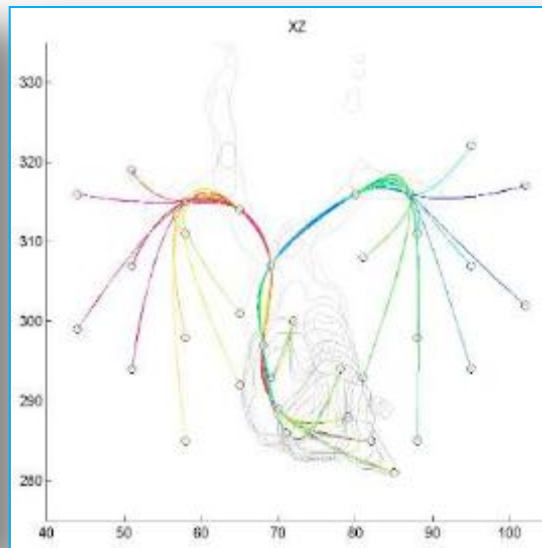


Isoterme

(Comportamento punta fissaggio passivo)

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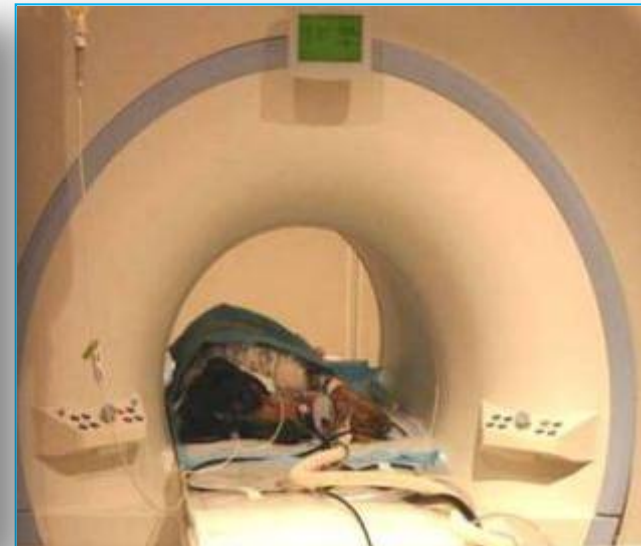
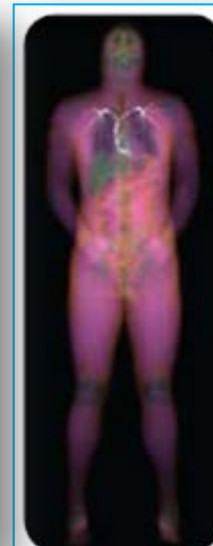
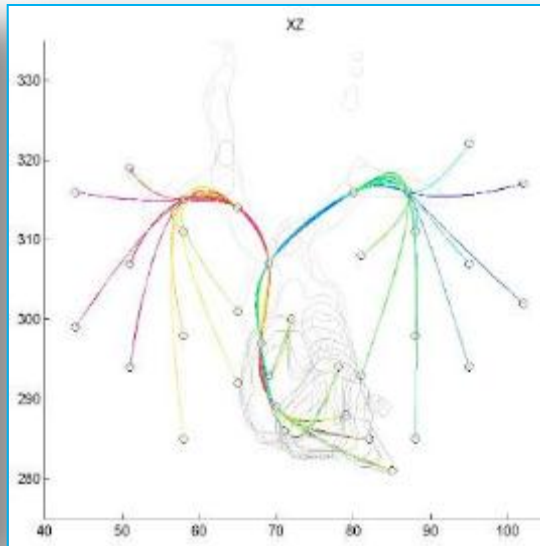
IN VITRO TESTING

- Different MRI scanners were bought for tests
- Different shielded labs built
- 40 researchers dedicated to ProMRI devices development
- Automatic robotic system engineered to test thousands of different leads and device positions



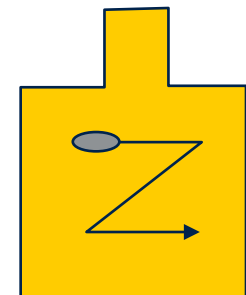
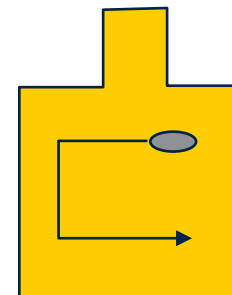
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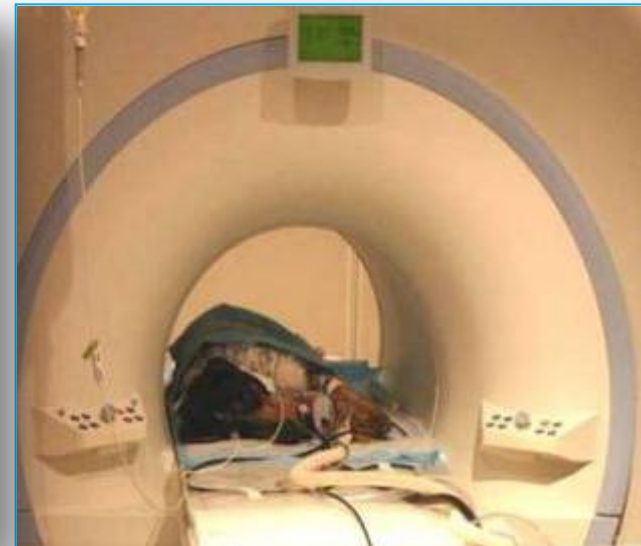
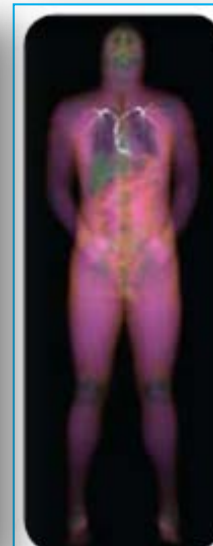
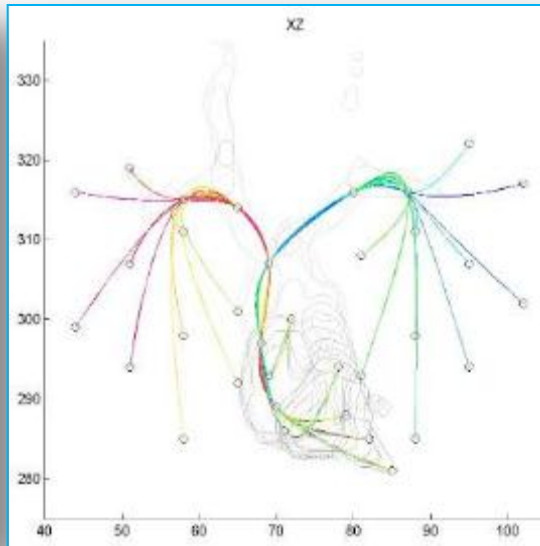
Phantom testing

- Rectangular Simulator used
 - Plexiglass Box
 - Human size
 - Filled with saline solution
- Test made on devices and leads with different spatial combinations:
 - Different leads length
 - Different lead and device positions
 - Different scanning times
 - Different patient positions



Certification Processes

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- **Clinical trials**

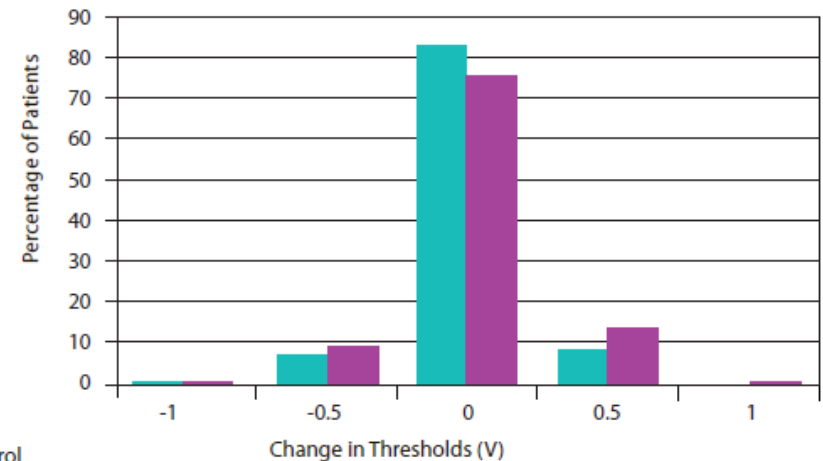
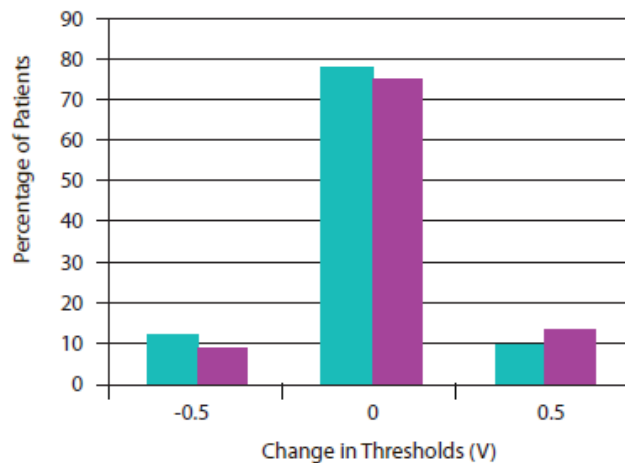


MRI Clinical Study



Prospective, randomized controlled, multi-center study

- 1:1 randomized to receive MRI scans or no MRI scans (control group)
- 464 patients followed-up for 11.2 months
- 53 centers globally



Safety and efficacy of new pacemaker system that can be used in MRI environment.
Willkoff, et al., *Heart Rhythm Journal* 2010

Determining the Risks of Magnetic Resonance Imaging at 1.5 Tesla for Patients With Pacemakers and Implantable Cardioverter Defibrillators

Jennifer D. Cohen, MD, Heather S. Costa, PhD, and Robert J. Russo, MD, PhD*

Primary and secondary end point events in the magnetic resonance imaging group

End Point	Number of Events/Number of Events Possible (%) [95% Confidence Interval]
Primary end point events	
Death	0/125 (0%) [0%–3%]
Device failure	0/125 (0%) [0%–3%]
Lead failure	0/259 (0%) [0%–1%]
Atrial/ventricular arrhythmia	0/125 (0%) [0%–3%]
Loss of capture	0/125 (0%) [0%–3%]
Electrical reset	0/125 (0%) [0%–3%]
Secondary end point events	
Battery voltage decrease ≥ 0.04 V	4/90 (4%) [2%–11%]
Pacing lead threshold increase ≥ 0.5 V	5/195 (3%) [1%–6%]
P-wave amplitude decrease $\geq 50\%$	1/65 (2%) [0.3%–8%]
R-wave amplitude decrease $\geq 25\%$	2/74 (3%) [1%–9%]
Pacing lead impedance change $\geq 50 \Omega$	13/210 (6%) [4%–10%]
High-voltage impedance change $\geq 3 \Omega$	2/17 (12%) [3%–34%]

Ninety-five percent confidence intervals were calculated using the score method without continuity correction.

SISTEMI MRI COMPATIBILI: LO STATO CLINICO

MR conditional devices: definition

Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION

**Safety of Magnetic Resonance Imaging in Patients With Cardiovascular Devices:
An American Heart Association Scientific Statement From the Committee on
Diagnostic and Interventional Cardiac Catheterization, Council on Clinical
Cardiology, and the Council on Cardiovascular Radiology and Intervention:
Endorsed by the American College of Cardiology Foundation, the North
American Society for Cardiac Imaging, and the Society for Cardiovascular
Magnetic Resonance**

Glenn N. Levine, Antoinette S. Gomes, Andrew E. Arai, David A. Bluemke, Scott D.
Flamm, Emanuel Kanal, Warren J. Manning, Edward T. Martin, J. Michael Smith,
Norbert Wilke and Frank S. Shellock

Circulation 2007;116;2878-2891; originally published online Nov 19, 2007;
DOI: 10.1161/CIRCULATIONAHA.107.187256

MR conditional devices: definition

The American Society for Testing and Material International
[www. astm.org](http://www.astm.org)

- MR safe 
 - No known hazards in any MRI environments
- MR conditional 
 - No known hazards in a specified MRI imaging environment with specified conditions of use
- MR unsafe 
 - Hazards in all MRI environments

Device impiantabili e RMN



MRI Unsafe

MR Unsafe - an item that is known to pose hazards in all MRI environments. MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors.



MRI Conditional

MR Conditional - an item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Field conditions that define the MRI environment include static magnetic field strength, spatial gradient, dB/dt (time varying magnetic fields), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item (e.g., the routing of leads used for a neurostimulation system), may be required.



MRI Safe

MR Safe - an item that poses no known hazards in all MRI environments. Using the new terminology, "MR safe" items include non-conducting, non-metallic, non-magnetic items such as a plastic Petri dish. An item may be determined to be MR Safe by providing a scientifically based rationale rather than test data.

MR Conditional systems: device + leads

The certified system of a manufacturer is always made by:

System = Device + Leads



MRI Conditional: which conditions?

- Radiologist have to consider:
 - A closed tube
 - Cylindrical magnets
 - A static magnetic field strength of **1.5 Tesla**
 - No additional local transmitting coils are used
 - The MRI scan can only be performed with the patient in dorsal position
 - The permissible positioning zone and scan **exclusion zone must be observed.**
 - The mean specific absorption rate for the whole body displayed by the MRI scanner must not exceed **2.0 W / kg**.
 - The head absorption rate displayed by the MRI scanner must not exceed **3.2 W / kg**
 - The overall duration of the imaging sequences displayed by the MRI scanner must **not exceed 30 minutes.**
 - The total length of the examination for the device system must be **below 10 hours.**
 - Emergency equipment for reanimation must be kept at hand and properly certified staff must be available.
 - Monitor the patient's hemodynamics during the entire MRI scan by continuously recording at least one of the following parameters:
 - Blood oxygen saturation
 - Blood pressure
 - ECG

MRI Conditional: which conditions?

- Cardiologist have to consider:
 - The implanted system consists only of one or more leads and a pacemaker or ICD or CRT device, which are each labeled MR Conditional separately, and in combination make up an MR Conditional system. L'impianto è all'interno dell'area toracica
 - There are no other implants in the patient's body. For example:
 - Other pacemakers or ICDs or CRT devices
 - Abandoned leads
 - Lead adapters
 - Lead extensions
 - Impianto effettuato da più di 6 settimane
 - The ascertained pacing threshold does not lie above 2.0 V amplitude at 0.4 ms pulse width.
 - The ascertained lead impedance is between 200 and 1500 Ohms.
 - The pacemaker or ICD or CRT device is programmed to a special MRI mode immediately before the MRI scan.

Il pacemaker e gli elettrocatereteri siano etichettati “MR Conditional”

Lista di controllo del Radiologo

- ☐ La MRI sia a cilindro chiuso da 1,5T in modalità di funzionamento normale
- ☐ SAR (Specific Absorption Rate) 2 W/Kg per il corpo
- ☐ SAR (Specific Absorption Rate) 3,2 W/Kg per il capo
- ☐ SlewRate massimo del gradiente ≤ 200 T/m/s

Lista di controllo del Cardiologo

- ☐ L'impianto sia stato eseguito da almeno 6 settimane
- ☐ Il sistema sia impiantato nella regione pettorale
- ☐ Nessun altro catetere, device o adattatore presente o abbandonato nel paziente
- ☐ Gli elettrocatereteri siano elettricamente integri
(impedenza compresa tra 200 e 1500 ohm e soglie di cattura non superiori a 2,0 V a 0,4 ms)

MRI Conditional: non sono tutti uguali

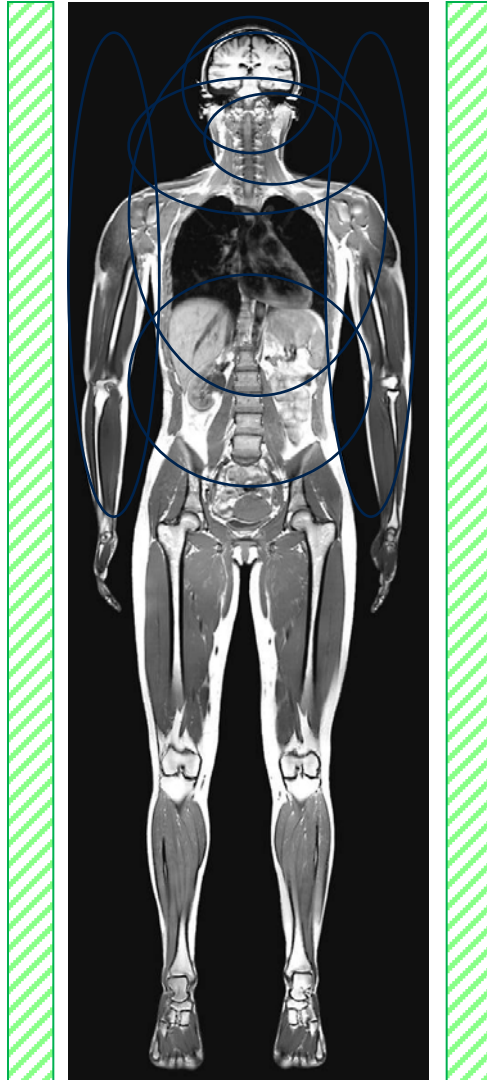
Total Body vs Non Total Body

Sistemi Total Body

Mammo: 2,1%
0,9 scans / 1000 Habitants

MRA-Body: 4,9%
2,1 scans / 1000 Habitants

Limbs: 24%
10,3 scans / 1000 Habitants



Head: 26,7%
11,5 scans / 1000 Habitants

Cardiac: 0,5 %
0,2 scans / 1000 Habitants

Spine: 30,5%
13,1 scans / 1000 Habitants

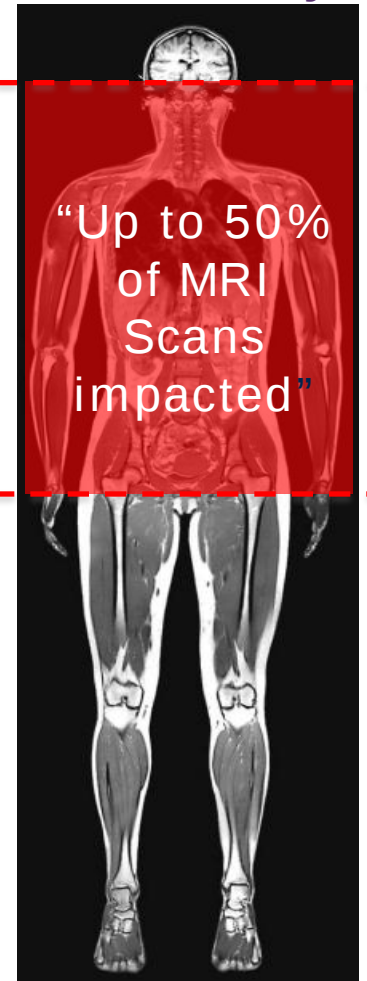
Trunk: 11,4%
4,9 scans / 1000 Habitants

Sistemi non Total Body

Occhi

“Up to 50%
of MRI
Scans
impacted”

Anca



Exclusion zone for BIOTRONIK pacemakers

BIOTRONIK ProMRI®: **FULL TOTAL BODY**

No more exclusion zone with:

- Evia and Estella pacemakers in combination with Safio leads

FULL BODY SCAN IS PERMITTED



Patient size
175 cm

Exclusion zone for ICD scan

BIOTRONIK ProMRI®

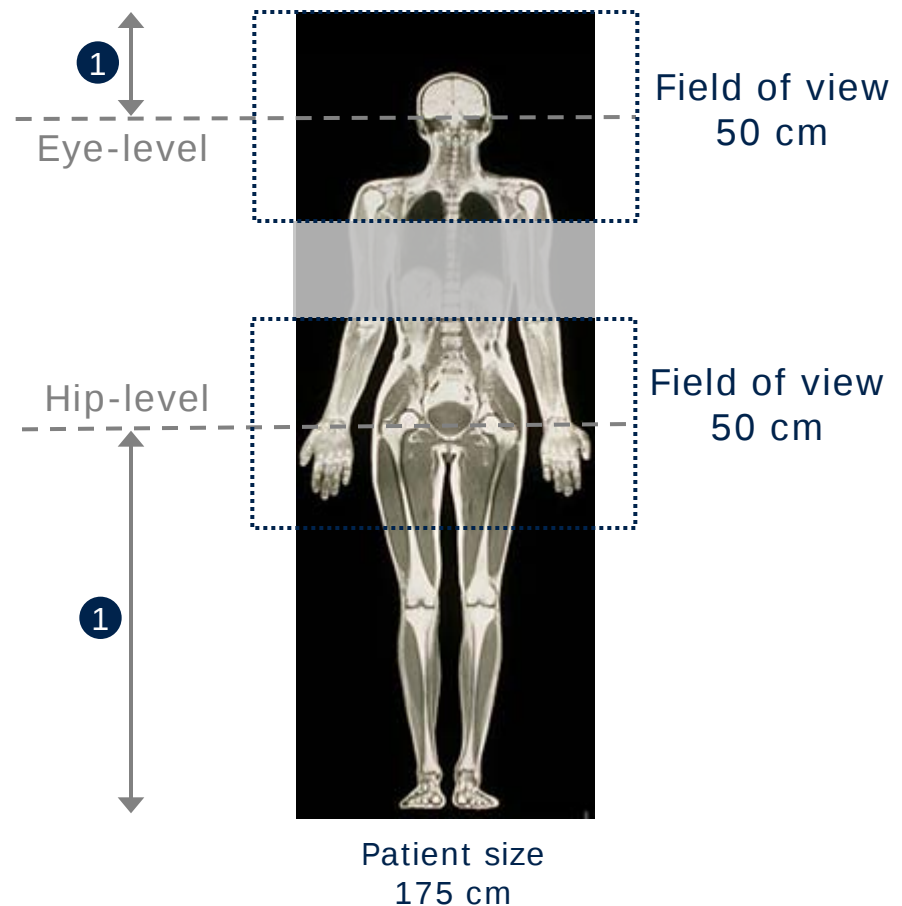
Exclusion zone with ICD:

Starting from the foot end, the maximum allowed positioning mark for the isocenter (laser light) is at the hip bone level.

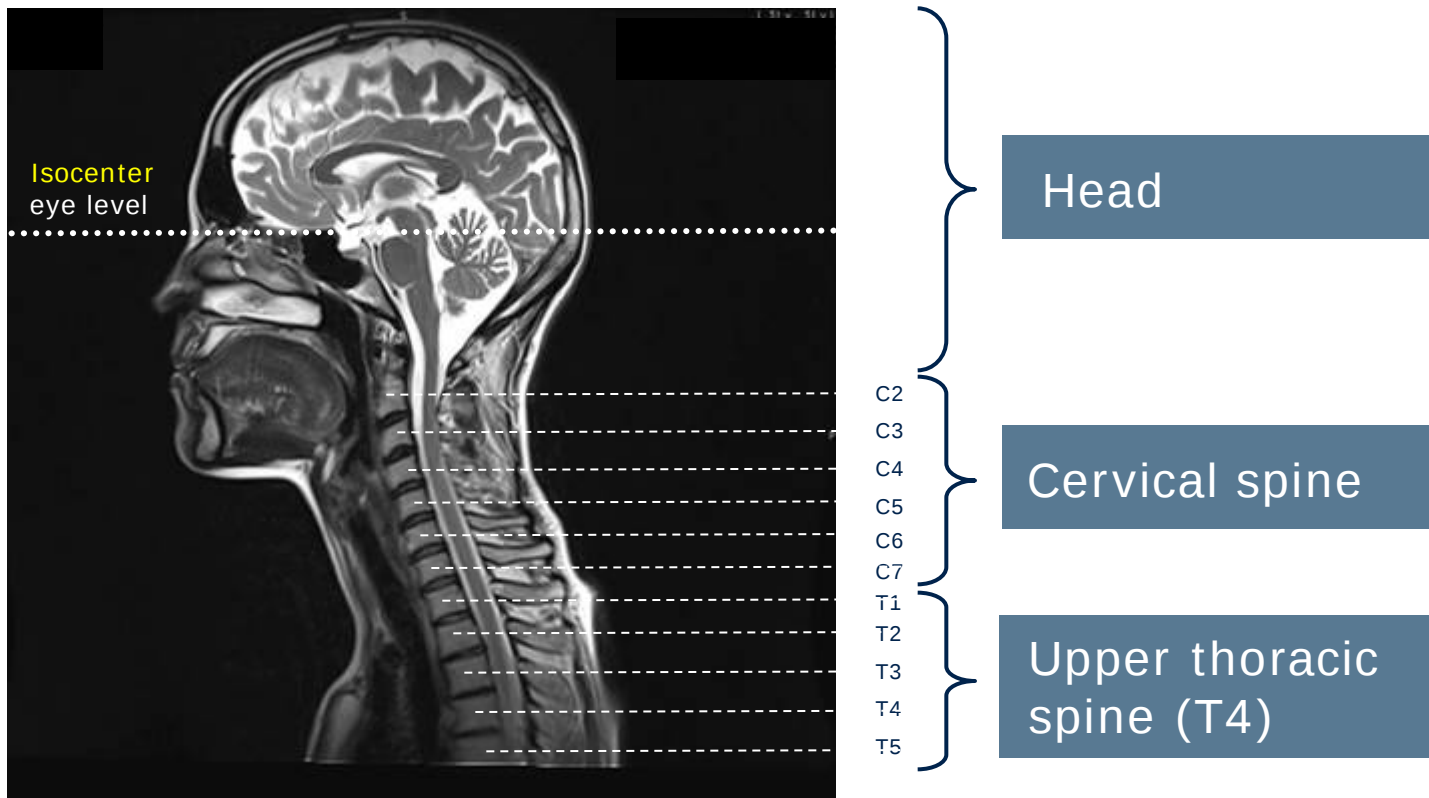
Starting from the top of the skull, the maximum allowed positioning mark for the isocenter is at the level of the eyes.

BIOTRONIK ICD

conditional, non total body, but are the first MR conditional ICD on the market



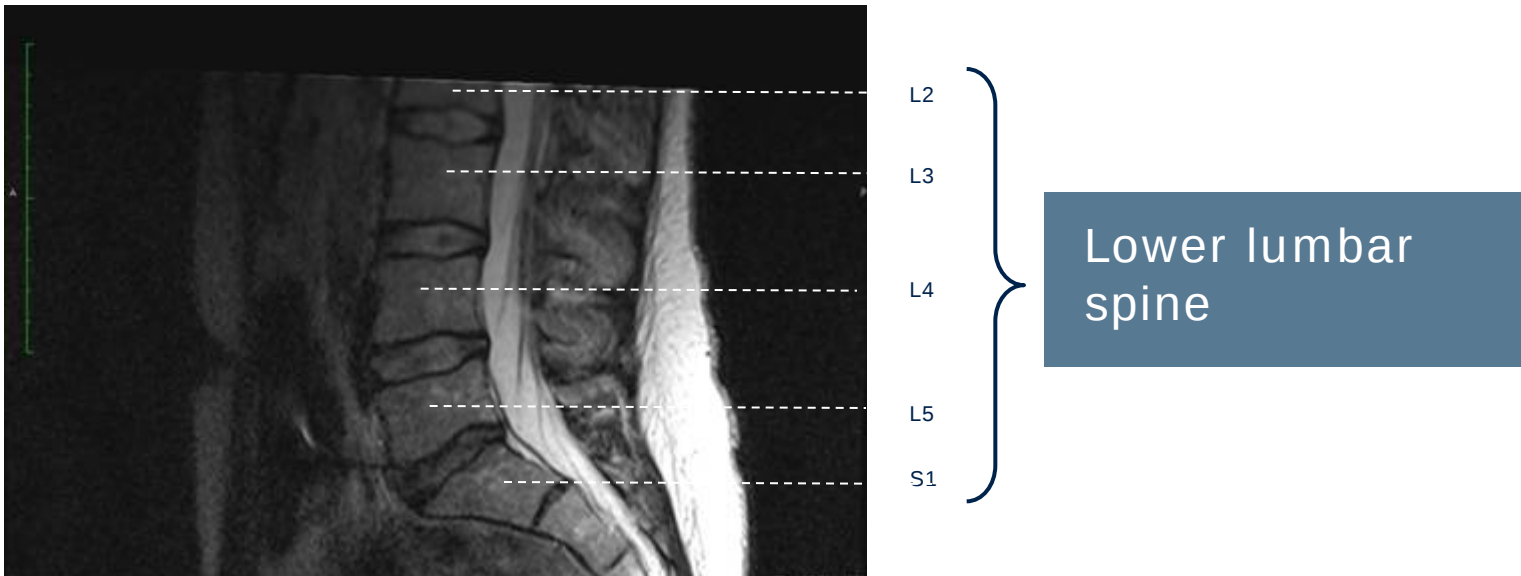
Real patient example with MRI isocenter on eye level



Real patient case with isocenter on eye level and Siemens MRI scanner.
Patient length 1.75 m and scan taken within the ProMRI® conditions.

Data from Biotronik

Real patient example with MRI isocenter on hip level



Real patient case with isocenter on hip level and Siemens MRI scanner.
Patient length 1.75 m and scan taken within the ProMRI® conditions.

Data from Biotronik

CONCLUSIONS

- ProMRI implants are today available for any kind of patient (brady, tachy and CRT).
- ProMRI implants have to be considered...
 - ... for patients with long life expectancy
 - ... for patient at high MRI scan risk
 - ... for patient that already underwent an MRI scan
 - ... or perhaps for EVERYBODY?

