Winter Arrhythmia School

Blue Mountain

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Myths and Facts: A Discussion of MRI Imaging for Pacemaker and ICD Patients

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Topics of discussion:

- **Your experience with MR-conditional devices**
- **Overview of MR-conditional devices in the field**
- **Components of MR-conditional systems**
- **CHRS recommendations for device/patient management for MR scan**

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Clicker Question: Does your centre currently implant MR-conditional CIED?

A) No, 0%

B) Yes, <5%

C) Yes, <20%

D) Yes, > 20%

Clicker Question: Does your centre currently provide on-site MR scans for patients implanted with MR-conditional CIED?

A) No scanning, no protocol to scan

B) No scanning, protocol in place to scan if required

C) Yes scanning preformed and protocol in place

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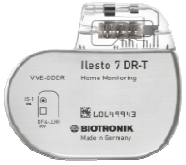
BIOTRONIK ProMRI® - Developing the industry's most complete MR-conditional CRM portfolio

BIOTRONIK starts development of MR-Conditional systems

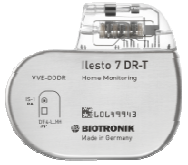
Approval of 1st MR Cond. ICD System

Launch MR Cond. ICD System

BioMonitor



Expansion MR Cond. ICD System



MR Cond. FBS & 3.0 T ICD System

MR Cond. CRT-D Systems

BIOTRONIK's 1st MR Cond. IPG System

Expansion of the MR Cond. IPG Portfolio

MR Cond. CRT-P Systems

MR Cond. Full Body Scan IPG System

Next generation MR Cond. IPG System

2003 **2008** **2009** **2010** **2011** **2012** **2013** **2014**

Approval of 1st MR Cond. IPG System

Launch of 1st MR Cond. IPG System

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Topics of discussion:

- **Your experience with MR-conditional devices**
- **Overview of MR-conditional devices in the field**
- **Components of MR-conditional systems**
  - What's the difference? Combination of leads/devices? Exclusion zone or full body scan?
- **CHRS recommendations for device/patient management for MR scan**
- **Future of MR-conditional devices**

Clicker Question: It is estimated that a patient has an X % chance of requiring an MR examination over his/her lifetime after CIED implantation. X = ?

A) 0-25%

B) 26-50%

C) 51-75%

D) 75-100%

Clicker Question: It is estimated that a patient has an X % chance of requiring an MR examination over his/her lifetime after CIED implantation. X = ?

A) 0-25%

B) 26-50%

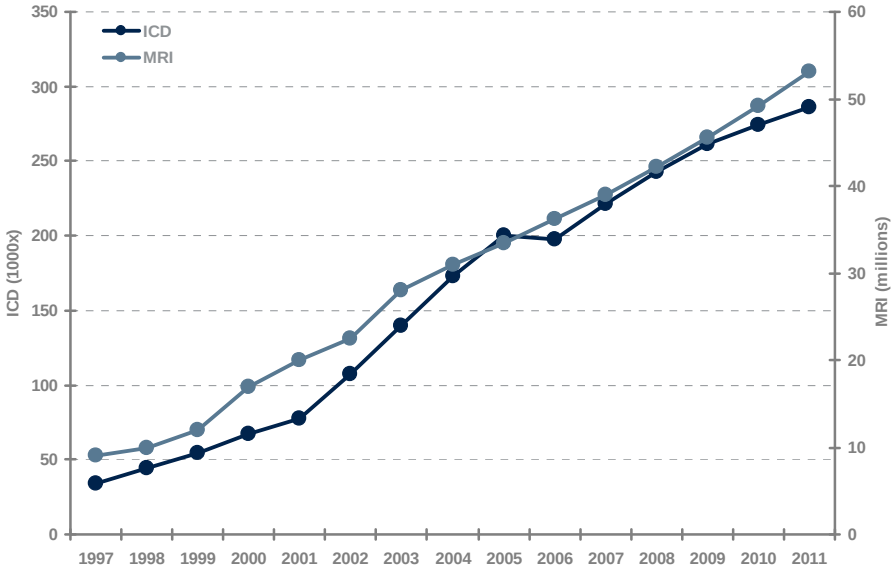
C) 51-75%

D) 75-100%

Kalin R, Stanton MS. Current clinical issues for MR scanning of pacemaker and defibrillator patients. Pacing Clin Electrophysiol 2005;28:326-8.

50-75% of patients with a CIED are indicated for an MR scan

- Over 30 million MRI scans conducted in the US[1].
- 2.5 million US patients have a pacemaker, and this number is growing by 80.000 per year[2].
- Estimated 50%-75% of patients with a device are indicated for an MRI scan[3].

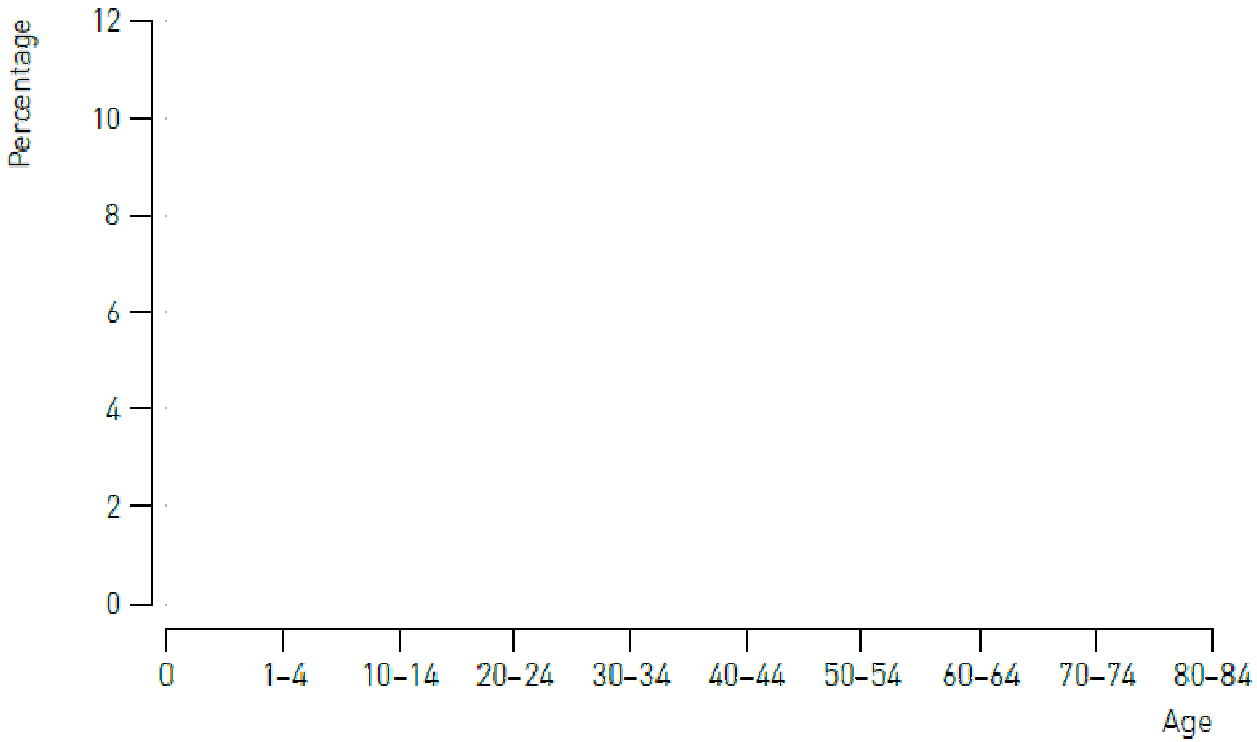


1 Benchmark Report: MRI 2007, IMV medical Information Devision 2008.
2 Sommer t et al, Circulation 2006, 114; 1285-1292
3 Kalin R, Stanton MS. Pacing Clin Electrophysiol 2005;28:326–8

Utilization of MRI Scan

MRI utilization increases by age

– Patients aged 70-74 years are most likely to receive an MRI scan*



* BARMER Health insurance: Arztreport 2011

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Do the terms MRI Safe and MRI conditional have the same meaning?

MR- safe: An item that poses no known hazards in all MRI environments

MR- conditional: An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use (field strength, spatial gradient etc.)

MR-unsafe: An item that is known to pose hazards in all MR environments

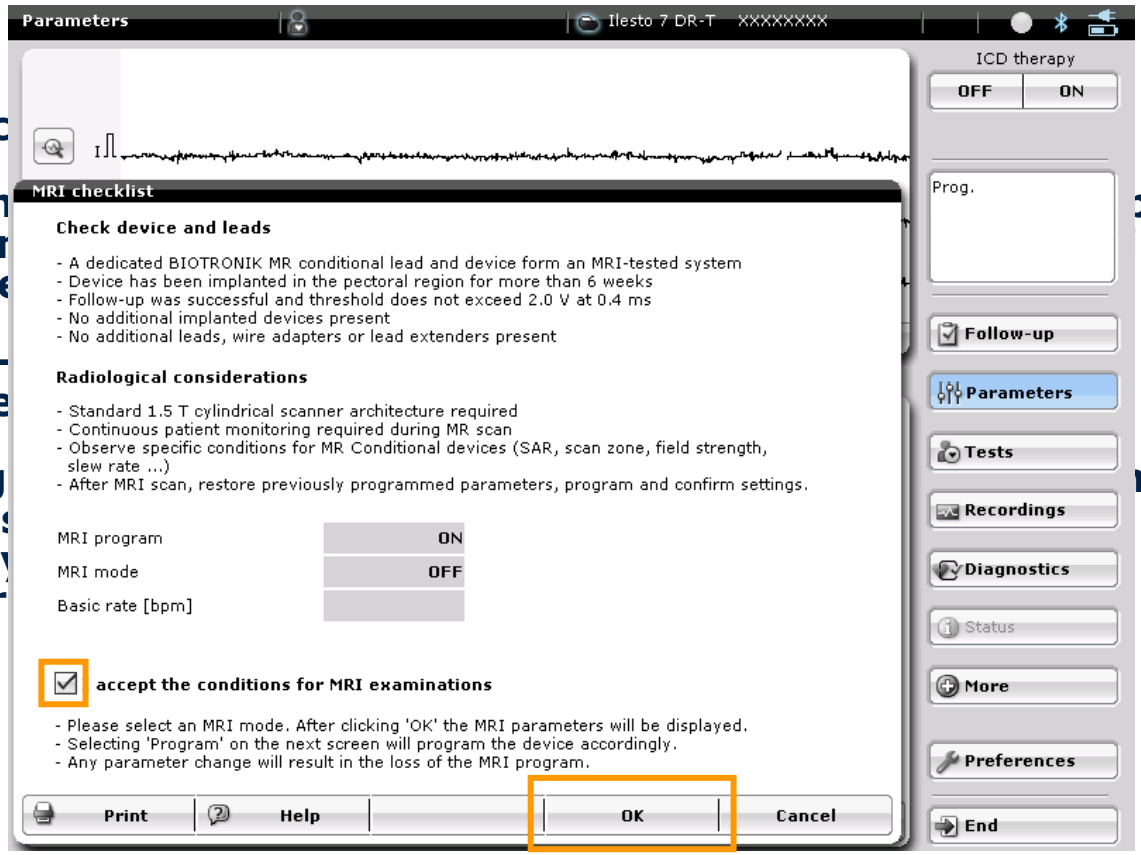
MRI compatibility- what's the big deal?

Manufacturing MRI compatible devices- What's the difference?

- **Three Birdcages for 1.5 & 3.0 Tesla testing**
- **Shielded chambers**
- **RF antenna of clinical MRT is used**

Manufacturing MRI compatible devices- What's the difference? Software

- Spec
- Asyn … pport … ng
- Non- …
- Diag … ng …



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Manufacturing MRI compatible devices- What's the difference? Hardware

- Improved Electromagnetic Interference (EMI) susceptibility
- New chip developed to improve EMI rejection and minimize the number of external component
- Optimized component selection and layout for improved EMI rejection over 16Hz - 3000Mhz
- Significantly reduced the length of the electrical connections between the feedthrough and the electronic circuit
- Minimized EMI radiation inside pacemaker housing

Clicker Question: Approved ProMRI systems are MR-safe.

A) True

B) False

Clicker Question: Approved ProMRI systems are MR-safe.

A) True

B) False

No CIED system is “MR-safe”, but selected CIED systems are “MR-conditional”

Clicker Question: Conditions for MR imaging of an MR-conditional CIED are consistent from vendor to vendor and device to device.

A) True

B) False

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A) True

B) False

Manufacturer-specified scanning parameters are always checked and followed; the MR scanning protocol will vary in accordance with the patient's CIED system. Some systems are initially approved with exclusion zone and then retroactively approved for full body scanning. Recommended to check with vendor before scan to ensure parameters are know.

Clicker Question: MRI for a device with an exclusion zone.

The manufacturer guidelines state that the MRI isocentre can pass no lower than eye level and no higher than hip level. Are images of the C and L spine possible?

A) Yes

B) No

Clicker Question: MRI for a device with an exclusion zone

Are images of the C and L spine possible?

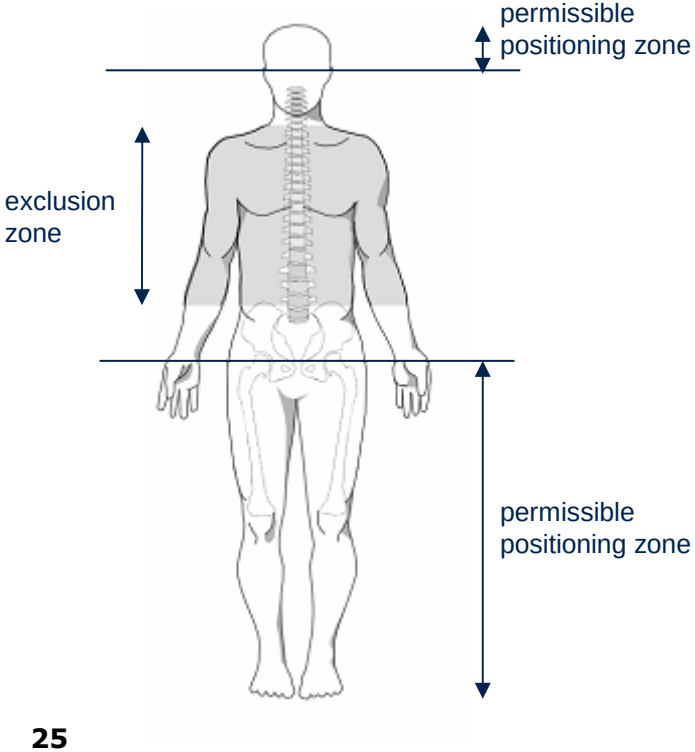
A) Yes

B) No

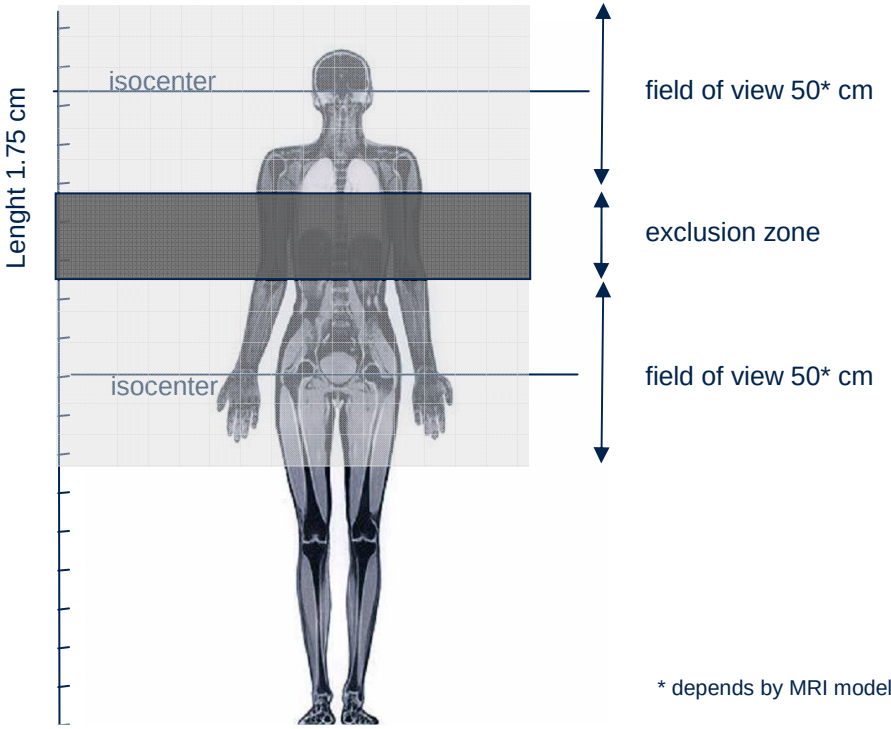
MR Exclusion Zone

Exclusion zone in daily practice

Schematic
Exclusion zone



Actual
Exclusion zone



* depends by MRI model

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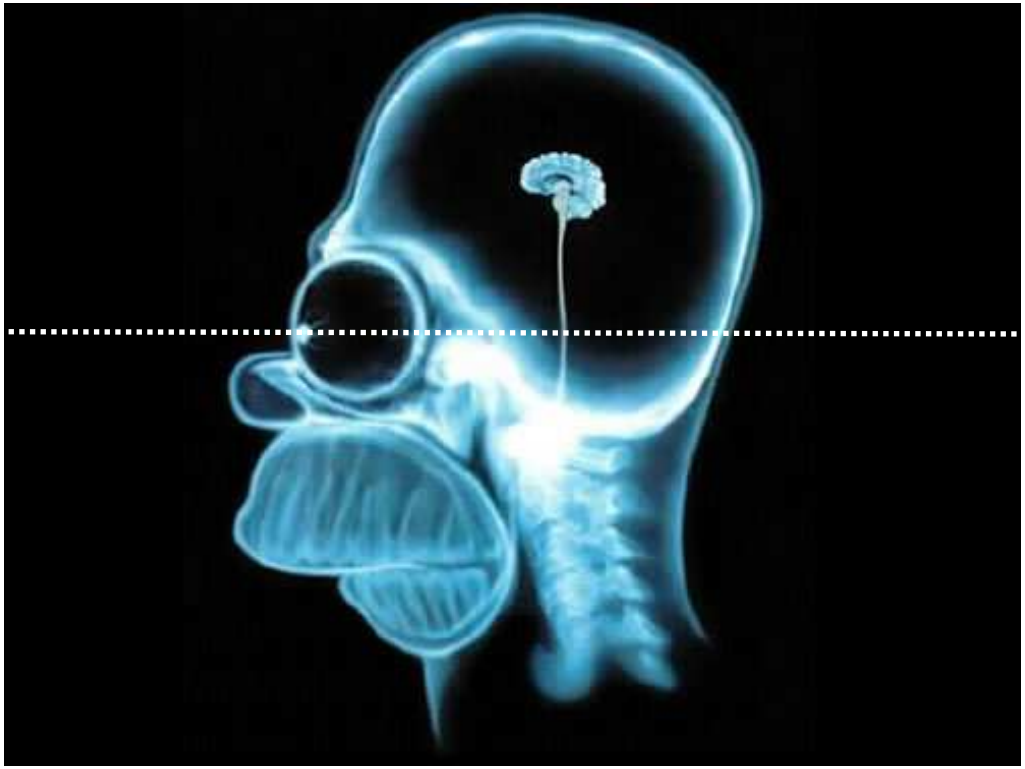
MR Exclusion Zone

Exclusion zone in daily practice

Scan with isocenter on eye level

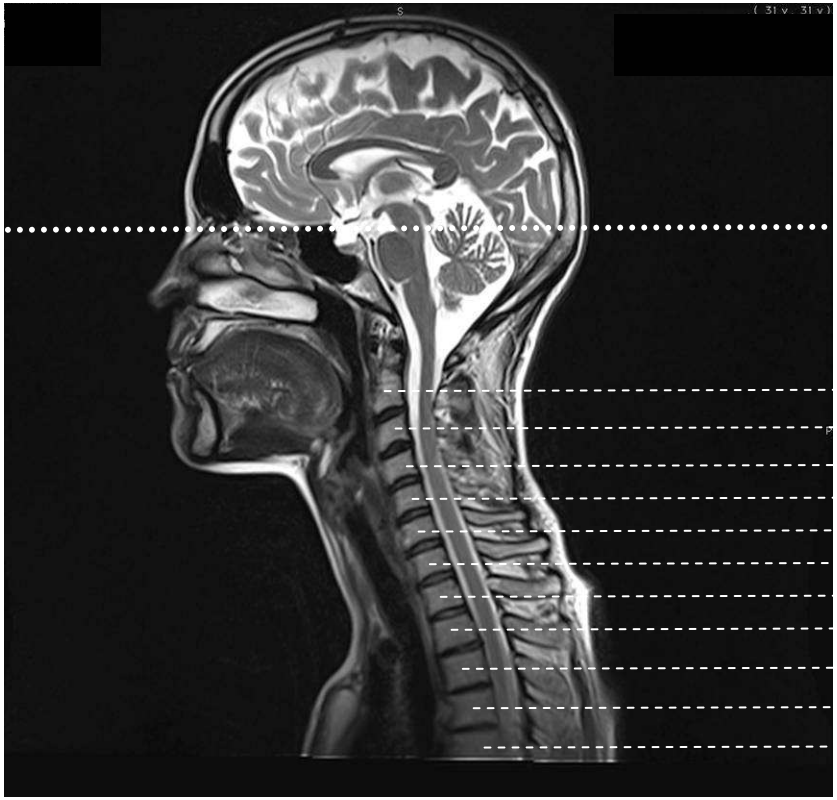


isocenter eye level

MR Exclusion Zone

Exclusion zone in daily practice

Scan with isocenter on eye level



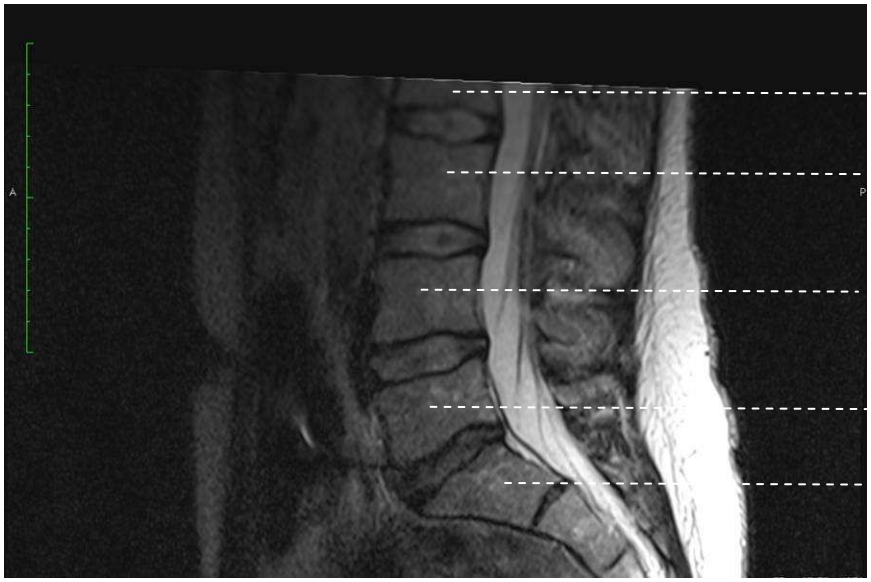
Head, cervical spine and upper thoracic spine (T4) can be examined

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

MR Exclusion Zone

Exclusion zone in daily practice

Scan with iso-center on hip level



Lower lumbar spine can be examined

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

* depends by MRI model

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Clicker Question: A device with an MRI exclusion zone limits what percentage of total indicated MRI Scans?

A) <5%

B) 10-15%

C) 15-25%

D) 25-50%

E) >50%

Clicker Question: A device with an MRI exclusion zone (thoracic area) limits what percentage of total indicated MRI Scans?

A) <5%

B) 10-15%

C) 15-25%

D) 25-50%

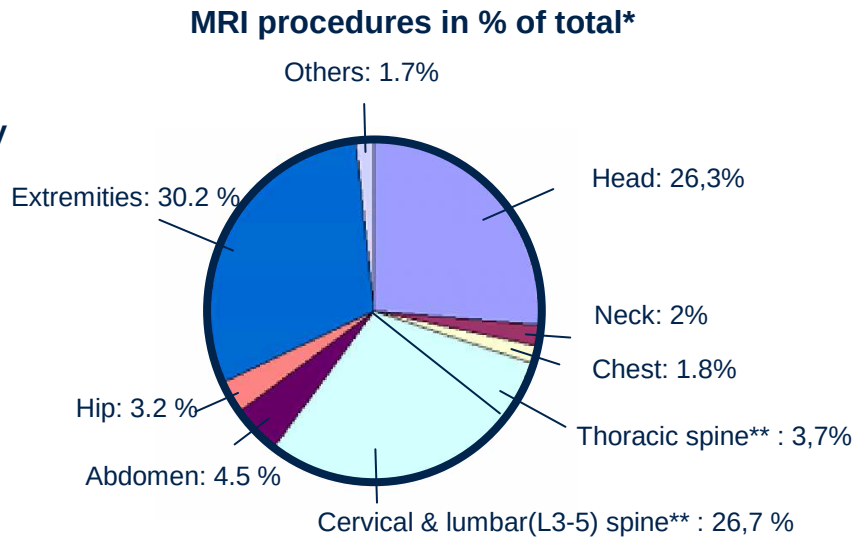
E) >50%

BARMAR: Arztreport 2011. Barmar GEK- large Health Care provider data in Europe

88% of MRI scans can be performed

– BARMER health insurance data show the MRI usage per scan location
– Data are verified by BIOTRONIK radiology consultants

Head	26,3%
Neck	2.0%
Cervical & Lumbar spine	26.7%
Hip	3.2%
Extremities	30.2%
	88.4 %



*BARMAR: Arztreport 2011
** C, T and L spine percentages based on expert evaluation

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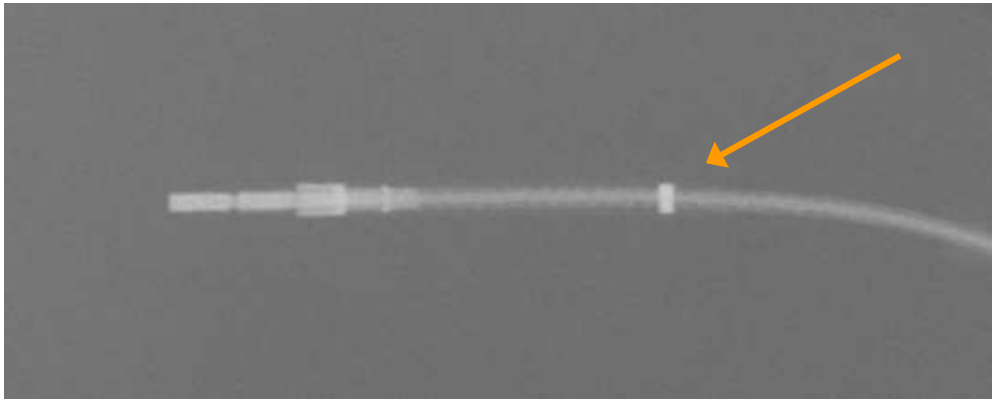
Clicker Question: Are radiopaque markers on devices and leads a reliable way to determine MR-compatibility?



A) Yes

B) No

Clicker Question: Are radiopaque markers on devices and leads a reliable way to determine MR-compatibility?

A) Yes

B) No

How would we tell only with a marker if it was full body, exclusion zone, 1.5T or 3T etc. Also, as "legacy" leads are approved for MR-compatibility, these markers would not appear on these leads. It is unreliable due to this case and would also require checking with the manufacturer for the acceptable scanning parameters when these markers are present

Clicker Question: Biotronik has "back dated" over 30 non-ProMRI lead types as MR Conditional (CE Mark)

With CE Mark, if a ProMRI pacemaker is implanted with these leads, is the system MRI compatible in Canada?

A) Yes

B) No

Clicker Question: Biotronik has "back dated" over 30 non-ProMRI lead types as MR Conditional (CE Mark)

With CE Mark, if a ProMRI pacemaker is implanted with these leads, is the system MRI compatible in Canada?

A) Yes

B) No

Along with the current leads, BIOTRONIK has tested 34 current, non-ProMRI leads and approved them as MRI conditional (with CE Mark). At this time, Health Canada has not granted the back date and therefore, only the currently approved system is considered ProMRI

Clicker Question: A patient is implanted with MR-compatible leads from Company X and an MR-compatible pacemaker from Company Y.

Is this system MR-compatible?

A) Yes

B) No

Clicker Question: A patient is implanted with MR-compatible leads from Company X and an MR-compatible pacemaker from Company Y.

Is this system MR-compatible?

A) Yes

B) No

Labeling for Health Canada has approved "device systems". Although individual components are MR-compatible, this has not been validated and stated as an MR-conditional system.

Topics of discussion:

- Your experience with MR- conditional devices
- Overview of MR- conditional devices in the field
- Components of MR- conditional systems
- **CHRS recommendations for device/patient management for MR scan**

Clicker Question: Which of the following are absolute contraindications for MR scanning?

A) MR scanning protocol outside of manufacturer specifications

B) Presence of abandoned pacing or ICD leads

C) Broken or fractured lead(s)- known or suspected

D) Permanent epicardial pacing or ICD leads

E) A,B and C

F) All of the above

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Clicker Question: Which of the following methods is acceptable to monitor the patients vitals while undergoing MR scan?

A) pulse oximetry

B) Electrocardiographic (ECG)

C) Capability for verbal communication between the MR scan operator and patient

D) All of the above

Clicker Question: Which of the following methods is acceptable to monitor the patients vitals while undergoing MR scan?

A) pulse oximetry

B) Electrocardiographic (ECG)

C) Capability for verbal communication between the MR scan operator and patient

D) All of the above

It is recommended to use either pulse oximetry or ECG in conjunction with verbal interaction according to CHRS consensus

Clicker Question: Monitoring of the MR-conditional CIED patient during MR scanning may be preformed by:

A) MR Technologist

B) MR Radiologist

C) CIED Clinic nurse

D) Cardiologist with knowledge of CIED

E) All of the above

Clicker Question: Monitoring of the MR-conditional CIED patient during MR scanning may be preformed by:

A) MR Technologist

B) MR Radiologist

C) CIED Clinic nurse

D) Cardiologist with knowledge of CIED

E) All of the above

According to CHRS consensus, all of the above are acceptable however, should be evaluated based on the patient's medical status, functional status of the CIED and experience of the staff

Clicker Question: Current approved devices require a CIED clinic staff to test and reprogram devices pre- and post-MR scan.

A) True

B) False

Clicker Question: Current approved devices require a CIED clinic staff to test and reprogram devices pre- and post-MR scan.

A) True

B) False

CIED clinic staff ensures device testing is within appropriate ranges for MR-scan (lead impedance, sensing and capture) and ensures MRI programming for the device during scan. Post scan testing to ensure device functionality and restores permanent programming.

Clicker Question: Next generation MR devices do not required a CIED clinic staff to test and reprogram devices pre- and post-MR scan?

Note: Next generation of MR compatible devices may include devices that auto- detect MRI environment and reprogram themselves or have an MRI activator the radiologist may use to temporarily reprogram the device pre- and post- MR scan.

A) True

B) False

Clicker Question: Next generation MR devices do not required a CIED clinic staff to test and reprogram devices pre- and post-MR scan?

A) True

B) False

Regardless of MRI programming of the device, an full interrogation and evaluation of the CIED system is required pre- and post-MRI as per CHRS guidelines.

Thank you for your participation!