Advanced Concepts in MRI Safety for Physicists: MRI Safety of Devices in the MR Environment

R. Jason Stafford, PhD Department of Imaging Physics



THE UNIVERSITY OF TEXAS MDAnderson Cancer Center



AAPM Spring Clinical Meeting 2019

Learning Objectives

- Learning objectives:
 - Review relevant physics for understanding safety issues of devices in the MR environment
 - Understand some of the testing procedures used for communicating the MR conditions for on-label scanning in the vendor's FDA cleared device labeling.
 - Learn how to assess conditions for safe scanning of MR conditional devices based on scanner specifications and patient examination to be performed.
 - Apply information to real-world examples from clinical scenarios



Introduction

- Implanted medical devices in the MR environment pose unique safety risks to both patient and staff
- Medical physicists often turned to as MR Safety Expert (MRSE) to help assess risks associated with presence of these devices in the MR environment
- Goal is to review the relevant physics and provide an overview of some established guidelines and procedures useful for determining device MR safety conditions
- Endgame is to connect these technical conditions to MRI scanner specifications and scanning protocols as well as present some specific case examples of how to assess conditions for on-label scanning



Implants in MRI: Challenges & Changes

- More patients with implants scheduled for MRI
 - Increased number of MR systems
 - Increased number of indications for MR in diagnosis & therapy
 - Increased number of MR conditional medical implants
- Challenges due to MRI and medical devices
 - Increased number of 3T MRI (7T recently cleared)
 - Short and/or wide bore impact on spatial field gradients
 - Increased number of advanced procedures that utilize high end hardware capabilities (increased SAR, dB/dt, multichannel transmit, etc)
 - Increased number of MR conditional medical implants with complex conditions requiring expert technical knowledge
 - Evolving conditions confusing to technologists
 - Lack of physician understanding of MR conditional implants
 - Poor documentation in patient EMR and lack of centralized information on MR conditions



Medical Physicist as MR Safety Expert (MRSE)

- Scientific and technical expertise of MR physicist/scientist serving as a resource for MR faculty and staff
 - medical education & training not expected/required (i.e., <u>not</u> a "medical device expert")
 - no expected expertise in safety of prescription medications or other non-MR medical procedures (i.e., contrast agents, anesthetics, sedatives/anxiolytics, etc.)

• Expected role to provide expert consultation & <u>advice on</u>

- engineering, scientific, & administrative aspects of safe use of MR equipment
- development & continuing evaluation of safety framework for MR environment
- development of local rules & procedures to ensure safe use of MR equipment
- modification of MR protocols (including diagnostic effectiveness linked to safety)
- non-routine MR procedures for individual subjects and specific subjects groups (including diagnostic effectiveness linked to safety)
 - includes advice regarding safety related to implanted devices, metallic foreign bodies, tattoos, & other similar issues
- choice of MR Safety & Quality Assurance programs (including evaluation/audit)

Inter-Society Working Group on MR Safety. "<u>Recommended responsibilities for management of MR safety</u>." J Magn Reson Imaging 2016. European Federation of Organisations for Medical Physics Policy Statement No 14: the role of the Medical Physicist in the management of safety within the magnetic resonance imaging environment: EFOMP recommendations. Phys Med 2013.

Medical Physicist as MR Safety Expert (MRSE)

- Must be able to clearly communicate impact of technical nuance on risks in MRI environment to aid MR faculty and staff in making effective patient management decisions
- Does <u>not</u> make medical decisions (such as to move forward with scanning a specific patient)
 - does not 'clear' devices to scan
 - does advise on technical conditions for scanning on label
- May be asked to advise on approaches to scanning offlabel and associated risks

Inter-Society Working Group on MR Safety. "<u>Recommended responsibilities for management of MR safety</u>." J Magn Reson Imaging 2016. European Federation of Organisations for Medical Physics Policy Statement No 14: the role of the Medical Physicist in the management of safety within the magnetic resonance imaging environment: EFOMP recommendations. Phys Med 2013.



Medical Devices & Implants in MRI Environment

- Active Implanted Medical Devices (AIMD)
 - CIED (pacemakers, ICD)
 - Stimulators (deep brain, vagal nerve, spinal, bone and bladder)
 - Pumps (pain, drug, insulin)
 - Cochlear implants
 - Cardiac loop recorders
- Passive implants & retained foreign objects
 - Neurological (aneurysm clips & coils, shunts)
 - Orthopedic (prosthetics, rods, screws)
 - Cardiovascular and Vascular (stents, coils & filters)
 - Breast (implants, tissue expanders)
 - Retained foreign objects (i.e., metal in orbits, bullet fragments, etc)
- External objects and devices
 - <u>On body injectors</u>
 - Permanent makeup, tattoos, piercings, etc



MRI Safety Screening

Everyone entering Zone III must be screened!

Patient Record i	Patient, MDA # Date	
	DOB FC SEX	
Please help us prepare for your exam by an E:Out PT/IN PT RMs:Ando Storr Chart avail. No PATIENT INFORMATION Vest Home Cli	Iswering the questions in the shaded area(s). WC Stretcher Exam Time Time of Arrivat: Meterdica MD MRI PATIENT CHECKLIST	
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you have any PAIN now on a scale of 0 to 107 and syour weight and syour weight your cocive instructions about your test? your have a history of: Yes you have a history of: Yes you have a history of:	Heart pacemaker or detoriliator Yes Cerebral anoursin clips Yes Bar Implants Yes Spinal Cord stimulator Yes Implanted infusion pump Yes Have you ever had any metal in your eyes? Yes	No No No No No
anna Constipution / Diarrhea Constipution / Diarrhea Constipution / Diarrhea Constipution / Diarrhea Constitution / Diarrhea C	If you answered NO to all the above, please continue Brain Clips Yes No Denture Yes Adric clips Yes No Denture Yes Heart Valves Yes No Bectrodes Yes Heart Valves Yes No Built fragments Yes VC filter (untbrella) Yes No Built fragments Yes Shunts/stents Yes No Strappel Yes Joint reglecoments Yes No Strappel Yes	5 No 5 No 6 No 6 No 5 No 5 No 5 No
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id you receive any medication for the reaction? Yes No	List any other metal or biomedical devices:	
hat medications are you taking?		
PATIENT CHECKLIST Have you had CT scan before? When No Yes Have you had barium in the last 6 DAYS Barium Sould with the standing	Can you lie flat and remain still? Yet Does being in an enclosed space make you nervous or fearlul? Yet How can we make your scan more pleasant/tolerable? Patient Signature: Family/S0 screened according to above criteria Signature of MRI Representative/Title:	s 🗌 No s 🗌 No s 🗌 No
Have you had blod work done in the last two days? Are you on radiation thrangy? If yes, Specify 0. Do you have colostomy/lieostomy/urinary diversion? No Yes	Information given by Interpreter Needed: D No D Yes If yes, Interpreter Name:	

If you have any of the following - STOP and alert the staff now 🗌 Yes 🗌 No Heart pacemaker or defibrillator 🗌 Yes 🗌 No Cerebral aneurysm clips Yes No Ear Implants Yes Spinal Cord stimulator 🗌 No ☐ Yes Implanted infusion pump □ No Have you ever had any metal in your eyes? ☐ Yes If you answered NO to all the above, please continue Yes No Denture ☐ Yes ☐ No Brain Clips Yes No Hearing Aid Yes No Aortic clips Yes No Electrodes Yes No Heart Valves Yes No Bullet fragments Yes No IVC filter (umbrella) Yes No Shrapnel Yes No Shunts/stents Yes No Hair pins/barrettes Yes No Joint replacements Yes No Permanent eyeliner 🗌 Yes 🗌 No Limb prosthesis Yes No Tattoos/piercings Rods/screws/plates Yes No Any other metal Yes No Metal mesh Yes No Are you a metal worker? Yes No Metal tracheostomy 🗌 Yes 🗌 No Yes No Existing IV catheter Penile Implants Yes No Port/Port-a-Cath Yes No IUD List any other metal or biomedical devices:

MRI PATIENT CHECKLIST

*Adult and pediatric patient anxiolysis, sedation, analgesia, and anesthesia for any reason should follow established standards set by: American College of Radiology (ACR); American Society of Anesthesiologists (ASA); Joint Commission standards

List your SURGERIES:

Overview: MRI environment and medical devices



⁽Adapted from Wolbarst, Physics of Radiology)



Overview: MRI environment and medical devices

Source	Primary Safety Concern(s)
Static Magnetic Field (B_0) - Spatial field gradient (∇B_0)	Translation projectile "missile" hazards Transient bioeffects at high fields
Radiofrequency Field (B ₁ ⁺) - B ₁ ⁺ _{rms} - Specific Absorption Rate (SAR) - Specific Energy Deposition (SED) - Exposure time and/or temperature	Local tissue and whole body heating
Pulsed Gradient Magnetic Field (G) - Slew rate (T/m/s) - Max dB/dt (T/s)	Peripheral nerve stimulation Acoustic noise

Overview: MRI environment and medical devices

Source	Primary Safety Concern(s)	
Static Magnetic Field (B ₀)	Translation projectile "missile" hazards Transient bioeffects at high fields	
Medical devices on/in patient:	Displacement Disruption Damage	
Radiofrequency Field (B ₁ ⁺)	Local tissue and whole body heating	
Medical devices on/in patient:	Heating Unintended stimulation Disruption Damage	
Pulsed Gradient Magnetic Field (G)	Peripheral nerve stimulation Acoustic noise	
Medical devices on/in patient:	Heating Vibration Unintended stimulation Disruption Damage	
Reconstructed Image		
Medical devices on/in patient:	Artifacts	

MR Site Safety Issues / Access Control: 'Zone Defense'



(ACR Guidance – Section B.1)

The Joint Commission Diagnostic Imaging Requirements Elements of Performance for EC.02.01.01 - A.14

*Access to any space contained in the 5 G (0.5 mT) fringe field MUST have controlled access and appropriate signs posted

Zone I

 \bullet

- General public
- Zone II
 - Patient preparation and holding
- Zone III
 - >5 G possible*
 - Screening before entry
 - Non-MR personnel restriced
- Zone IV*
 - MR scan room
 - Restricted access & screening for personnel & ferromagnetic objects
 - Level 2 oversight & direct monitoring

Preventing missile effect in Zone IV:

- Appropriate signage of all Zone III & IV areas
- Before entering, check for magnetic objects concealed on transport equipment.
- Perform thorough written & verbal screening of all patients or visitors prior to entering
- Engage in ongoing MRI safety training & review MRI safety policies & procedures

Forces and torques on objects in static magnetic fields

- Objects in static field can be magnetized
 - Ferromagnetic objects saturate between 0.3-2.2T
 - Saturation likely near scanner face, less likely in fringe
 - Paramagnetic objects not often saturated in this range
- Torque (L) on an object in magnetic field $L \propto m \times B_0 \Rightarrow L \propto V \cdot B_0^2 \cdot \sin \theta \longrightarrow$

$$L_{max} \propto V \cdot M_s^2$$

(saturated material near isocenter)

Translational force on object in magnetic field

$$F \propto \nabla (m \cdot B_0) \Rightarrow F_{max} \propto V \cdot B_0 \nabla B_0 \longrightarrow$$

$$F_{max} \propto V \cdot M_s \cdot \frac{\partial B_0}{\partial z} \bigg|_{max}$$

MRI bore

(saturated material near bore face)

m = magnetic moment V = material volume M_s = saturated magnetization

Panych LP, Madore B, J Magn Reson Imaging. 2018; 47(1):28-43 Nyenhuis JH, et al, IEEE Trans Dev Mat. Rel. 2005; 5(3):467-79

Testing medical devices for torque and displacement

- Torque¹
 - measure at magnetic isocenter
 - device on holder w/ torsion spring
 - rotate 360° for each principle axis
 - record angular deflection of holder
 - calculate torque as function of angle
 - τ_{max}< F_{gravity}*L_{max}



Woods TO, JMRI 26:1186–1189 (2007)

- Displacement Force²
 - suspend device by thin string
 - position for largest displacement
 - likely off-isocenter @ bore face
 - measure deflection
 - <45° with F || B0
 - F_{max} < F_{gravity}



Shellock, Kanal, Gilk, AJR, 196:1-4 (2011)

¹ASTM F2213: Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the MR Environment ²ASTM F2052: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the MR Environment



Displacement Force Test & "Spatial Field Gradient"

- Often mistaken to indicate the value of pulsed imaging gradients
- Device manufacturers have measured at location of highest deflection accessible to patient
- Vendors provide access to maps and values in the system operator manual
- In the past, values tabulated by some MR vendors not useful for determining conditions
 - locations not accessible by patient
 - likely to exceed device manufacturer value





Shellock, Kanal, Gilk, AJR, 196:1–4 (2011) Nyenhuis JH, et al, IEEE Trans Dev Mat. Rel. 5(3):467-79 (2005). c

C.

Summary: MR static magnetic field concerns for implants



 Access to any space contained in the 5 G (0.5 mT) fringe field <u>MUST</u> have controlled access and appropriate signs posted



Radiofrequency fields and the patient

- dB₁/dt => local E-field (Faraday's Law)
 - Specific Absorption Rate (SAR) = $\sigma E^2/2\rho = (\sigma/2\rho) \cdot (\pi f B_p R)^2 (W/kg)$
 - σ = conductivity; R = radius; f = frequency
 - 1 W/kg => ~1°C/hr heating in an insulated tissue slab
 - 15 minutes @ 4 W/kg => 1°C

SAR $\propto B_0^2 \cdot (\text{flip angle})^2 \cdot (\text{RF duty cycle}) \cdot (\text{Patient Size})$

- Tissue heating greatest at periphery and least in center
 - head phantom: $\Delta T \leq 2^{\circ}C$ and ≤ 4 cm deep (30 min @ 1-2.5 W/kg)
- Poorly perfused tissue require particular attention
 - Examples: orbits; thermoregulatory compromised (fever)



Pennes Bioheat Equation: A simple model



Essentially, just the heat equation modified for perfusion at body temperature (T_a) :

HEAT SOURCE :

P = Power absorbed (W m⁻³) = SAR*ρ

HEAT CONDUCTION (diffusion):

T = temperature (Kelvin) *c* = specific heat of material (J kg⁻¹ °C⁻¹)

<u>HEAT CONVECTION</u> (effects of perfusion): $\rho_b = blood density (kg m^{-3})$ *V* = volume flow rate per unit volume (s⁻¹) ρ = density (kg/m³) k = thermal conductivity of tissue (W m⁻¹ °C⁻¹)

 C_b = specific heat of blood (J kg⁻¹ °C⁻¹) κ = dimensionless convection scale factor



IEC Operating Modes & Patient Temperature

- Primary goal of SAR management is avoiding temperature induced heat stresses in patient
- Recommendations must ALWAYS be interpreted in context to patient & ambient room conditions
- T_{core}>39°C scanned in Normal Mode
- T_{core}>39.5°C not be scanned at all
- Compromised thermoregulatory system or inability to communicate heat stress not scanned in First Mode
- T_{room}>25°C => SAR derated until 2W/kg

Mode	Core T _{max} (C°)	Local T _{max} (C°)	Core ∆T _{max} (C°)
Normal	39	39	<u><</u> 0.5
First ⁺	40	40	<u><</u> 1
Second*	>40	>40	>1

*requires medical supervision
*requires IRB approval (a.k.a. "research mode")





Thermal "Dose" & Risk Assessment

- Thermal damage is cumulative effect (exposure)
 - Isotherm characterization of bioeffects limited
- Many isoeffects can be modeled thermodynamically, $_{\Delta T}$ or more simply as an Arrhenius rate process (Ω)

$$\Omega = A \int_{0}^{t} e^{\frac{-E_{a}}{RT(\tau)}} d\tau$$

- R = Universal Gas ConstantA = Frequency Factor $(3.1 \times 10^{98} \text{ s}^{-1})$ E_a = Activation Energy $(6.3 \times 10^5 \text{ J})$ (Henriques FC, Arch Pathol, 1947; 43: p. 489.)
- Cumulative Equivalent minutes @ 43°C (CEM₄₃)
 - derived empirically from low temperature isoeffects:

$$\operatorname{CEM}_{43}(t_n) = \sum_{t=0}^{n \cdot \Delta t} \mathbb{R}^{(43-T_n)} \cdot \Delta t, \text{ with } \mathbb{R} = \begin{cases} 0.25 \ T_n < 43^{\circ}C \\ 0.50 \ T_n \ge 43^{\circ}C \end{cases}$$

(Sapareto SA, Dewey WC Int. J. Rad. Onc. Bio. Phys. 10: 787-800, 1984.)

- being considered in conjunction with models of SAR induced heating for future IEC standards (IEC 60601-2-33)





30°C

5°C

Normal Canine Brain



 $\frac{\text{isodose models}}{\Omega \ge 1}$ $T \ge 57^{\circ}C$ $CEM_{43} \ge 240 \text{ min}$



SAR Standards (IEC 60601-2-33)

IEC 2010 SAR Limits for Volume Coils (6 minute average)			
Operating Mode	Whole Body SAR (W/kg)	Partial Body SAR (W/kg)	Head (modeled mass) SAR (W/kg)
Normal	2	2-10	3.2
First ⁺	4	4-10	3.2
Second*	>4	>4-10	>3.2

Note that long term volume coil scanning now has a specific absorbed energy (SAE) limit: SAE < 14.4 kJ/kg (240 min*W/kg)

IEC 2010 SAR Limits for Local Transmit Coils (6 minute average over 10g mass)			
Operating Mode	Head SAR (W/kg)	Trunk SAR (W/kg)	Extremities SAR (W/kg)
Normal	10	10	20
First ⁺	20	20	40
Second*	>20	>20	>40

Note that for <u>both</u> volume and local transmit coils limits:

(SAR averaged over 10sec) < 2*(SAR limit for 6 min average)

*requires medical supervision *requires IRB approval (a.k.a. "research mode")



Heating in passive medical implants

- Mount implant in gel phantom with similar electrical/thermal properties of the body
- Expose to SAR > 2 W/kg averaged over the volume of the phantom for 15 min
- Measure with and w/o device
- Worst case configurations measured
- Heating danger increased when the "critical length" reached
 - $L_{device} \sim n_{odd}^* \lambda_{tissue}/2$
 - permittivity & conductivity => reduced λ_{tissue}
 - L ~ 25 cm @ 1.5T
 - L ~ 12 cm @ 3.0T



Nordbeck P, et al, MRM 61:570-578 (2009)



ASTM F2182: Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging FDA Assessment of Radiofrequency- Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices

Spatial Distribution of SAR

- IEC 60601-2-33 standard guidance suggests providing spatial information on RF power distribution (B_1^+) in addition to static and pulsed gradient fields to users
 - some vendors provide this information in their owner manual
- SAR \propto (B₁⁺)² => plot below tracks with normalized SAR
 - <1% maximum SAR @ 30 cm from isocenter (3T wide bore)</p>
 - useful for prospective planning or retrospective assessments





MRI Safety Zones: Zone IV





AIMD: RF heating and "Head Only" conditions

- Many implants (often stimulators) do not have conditions that allow the system body transmit coil to be used
- These may specify a 'head or extremity only' transmit-receive coil
 - local transmit limits the RF energy delivery beyond the coil volume
 - system body coil with array receive coil off-label
- Caveats
 - many technologists do not know the difference between a T/R head or extremity coil versus phased-array "only" receive coil
 - many modern protocols may need to be modified for T/R coil only acquisitions (i.e., lower SNR, no parallel imaging, etc)
 - expect timing IQ issues with EPI based studies (DTI, DSC, BOLD, etc), especially at higher fields, as well as 3D techniques (FSE, GRE, CSI)



Issues associated with vendor SAR and devices

- Estimated SAR differs across vendors/scanners
 - SAR on scanners "conservative"
 - potential problem with reporting medical device test results
 - measure SAR via calorimetry during device testing
- FDA & ASTM MR interlaboratory comparison
 - concerns over excessive device heating in normal mode
 - concerns over how to capture "worst case scenario"
- Synergistic integration of models of SAR induced implant heating
 - help better plan phantom testing for reporting
 - phantom testing can also provide feedback to refine models
 - possibly provide patient specific modeling in future
- SAR induced by implants proportional to B1_{rms}
 - New display standard to aid in medical device performance reporting

Managing SAR in the patient via the pulse sequence

 Largest SAR concern with fast spin echo and fast imaging sequences (high density of refocusing pulses) and fast sequences utilizing large flip angle pulses (balanced steady state free precession, magnetization transfer angiography, etc)

	Examples of Modifications	Potential Tradeoff
Reduce nu	Imber of k-space views reduced phase encodes rectangular field of view parallel imaging acquisition	resolution loss not amenable to all anatomy SNR loss and potential artifacts; reduced ETL benefits
Modify RF	pulse shape or flip angle reduced flip excitation pulses (bSSFP) reduced flip 180° refocusing pulses pulse amplitude/width modulation	SNR loss and contrast changes SNR loss and contrast changes SNR loss versus sequence timing
Scan less spacing	efficiently reduce echo train or increase echo increase TR increase concatenations less slices	longer acquisition times longer acquisition times longer acquisition times loss of volume coverage or slice resolution
Avoid saturation/suppression pulses		contrast changes; artifacts
Coil Selec	tion Local transmit/receive coils	coverage, uniformity, availability



Sample of MR implant safety standards & guidance

FIENT

- IEC 60601-2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
- ASTM F2052: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2213: Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- ASTM F2182: Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2119: Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- ASTM F2503–05: Standard practice for marking medical devices and other items for safety in the magnetic resonance environment
- FDA: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment Guidance for Industry and Food and Drug Administration Staff
- FDA: Assessment of Radiofrequency- Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices
- AIMD

PASSIVE IMPL

- ISO TS 10974: Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device
- ACR: Guidance Document on MR Safe Practices

AIMD Safety (ISO TS 10974)

Table 1 — Potential patient hazards and corresponding test methods

General hazard	Test method	Clause
Heat	RF field-induced heating of the AIMD	<u>8</u>
	Gradient field-induced device heating	9
Vibration	Gradient field-induced vibration	<u>10</u>
Force	B ₀ -induced force	11
Torque	B ₀ -induced torque	<u>12</u>
Unintended stimulation	Gradient field-induced lead voltage (extrinsic electric potential)	<u>13</u>
	RF field-induced rectified lead voltage	<u>15</u>
Malfunction	B_0 field-induced device malfunction	<u>14</u>
	RF field-induced device malfunction	<u>15</u>
	Gradient field-induced device malfunction	<u>16</u>
	Combined fields test	17



Pulsed gradient field safety issues

- Induced voltages from the rapid switching of the imaging gradients can produce painful nerve stimulation
- Auditory sound pressure levels produced by bucking of coils as current ramped in static field require hearing protection
- Gradients interfere with patient monitoring equipment used in MRI
- In conducting implants the rapid switching of gradients can lead to
 - device heating (induced eddy currents)
 - power $\propto \sigma \cdot V \cdot dB/dt_{normal}$
 - device vibration (via B₀ interaction and Lenz's Law)
 - $L \propto \sigma \cdot V \cdot (B_0 X dB/dt)$
 - unintended patient stimulation (induced lead voltages), and
 - device malfunctions (such as device resets via electrical interference)
 - $V_{emf} \sim A_{loop} \cdot dB/dt$



Pulsed gradient induced nerve stimulation

- Gradients reach their maximum amplitude away from isocenter
 - this is where induced voltages in the conductive tissues/objects is greatest
- Maximum dB/dt usually limited by vendor to limit PNS
- Effects on devices within these limits of concern



Mode	dB/dt * (T/s)	Isoeffect
Normal	<u><</u> 45	none
First ⁺	<u><</u> 56	none
Second*	60 90 900 3600	peripheral nerve stimulation threshold painful nerve stimulation threshold respiratory stimulation threshold cardiac stimulation threshold

+requires medical supervision

*requires IRB approval (a.k.a. "research mode")

$$dB/dt_{\rm max} = f r \left(1 + \frac{c}{d}\right)$$

*dB/dt modeled as hyberbolic function:

d = effective stimulus duration (see graph)

r = rheobase (20T/s) is minimal strength needed to stimulate

c = chronaxie (0.36 ms) is stimulated nerve time constant

f = operating mode dependent fraction (Normal = 0.8; First = 1)



Spatial distribution of pulsed gradient field

- Maximum gradient switching rate happens away from isocenter
- Device guidance may recommend IEC Normal Operating Mode to limit dB/dt
- Further limitations require consideration of device placement with respect to isocenter





Labeling of items that may go in Zone IV



- Item that poses no known hazards in all MR environments
- Nonconducting, nonmagnetic items (plastic Petri dish)
- Items may be determined to be MR Safe by providing a scientifically based rationale rather than test data

NOTE: Items in Zone III (control room) that may be taken into Zone IV (procedure room) should be appropriately labeled in order to minimize the potential for an MR accident.



Labeling of items that may go in Zone IV



NOTE: Items in Zone III (control room) that may be taken into Zone IV (procedure room) should be appropriately labeled in order to minimize the potential for an MR accident.

(ASTM F2503 & ACR Guidance Section - B.5)



Labeling of items that may go in Zone IV



- Demonstrated to pose no known hazards in a <u>specified</u> <u>MR environment</u> with <u>specified</u> <u>conditions of use</u>
- Additional conditions in addition to field and spatial gradient may include dB/dt, RF field specification and/or SAR

• Specific configurations of the item, may also be required.

 Most devices (and implants) are MR Conditional

NOTE: Items in Zone III (control room) that may be taken into Zone IV (procedure room) should be appropriately labeled in order to minimize the potential for an MR accident.





Non-clinical testing has demonstrated the *(insert device name)* is MR Conditional. It can be scanned safely under the following conditions:

- static magnetic field of <u>Tesla</u>
- spatial field gradient of <u>Gauss/cm</u>
- maximum whole body averaged specific absorption rate (SAR) of __W/kg for __minutes of scanning.
- Normal operating mode or first level controlled operating mode

In non-clinical testing, the *(insert device name)* produced a temperature rise of less than __°C at a maximum whole body averaged specific absorption rate (SAR) of ___ W/kg, as assessed by calorimetry for ___ minutes of MR scanning in a *(field strength__)* (*model__)* (*manufacturer__*) (*software version __*) MR scanner.

ASTM F2503-05 Standard Practice for *Marking Medical Devices and Other Items for Safety* in the Magnetic Resonance Environment Shellock FG, Woods TO, Crues JV, Radiology, 253(1):26-30 (2009).


AIMD MRI conditions

- Static field (B₀)
 - Maximum (static) spatial field gradient (∇B_0)
 - 1 T/m = 100 G/cm
- Pulsed imaging gradients (G)
 - Slew rate (T/m/s)
 - Maximum dB/dt (T/s)
- Radiofrequency excitation (B₁⁺)
 - Whole body or Head SAR (and/or $B_1^+_{rms}$)
 - Anatomical and positioning restrictions
 - Transmit coil type (full body vs local T/R)
 - Transmit coil mode (Quadrature vs multi-channel)
 - Exposure time
 - Temperature rise under given conditions of testing
 - Active scan time (within a specific window)
- Image artifacts





AIMD in MRI: Managing both device & patient

Action	Device	Scanner & Protocol	Patient
Assess	Identify & Characterize - obtain vendor guidance - learn MR conditions - device eligibility/status - risks to the device? Document Artifacts (guidance)	MR condition conformance - Field: strength & SFG - Gradients: slew rate and dB/dt - RF: SAR, B1, coil/mode, pulse sequences and exam time limits Artifacts (management)	Risk vs Benefit- indication- anatomical region- patient eligibility/condition- other implants- alternative imaging- modified appropriatenessArtifacts (impact on benefit)
Prepare	Follow vendor guidance MR modes of operation Record/save settings Secure/immobilize Device specialist scheduling if needed	Appropriate scanner available RF coil selection IEC Operator Mode Modified protocol for - RF coil & mode - SAR - Time - Gradient limitations - Artifacts	Inform patient Communication plan Positioning Monitoring Cooling Consent if needed
Scan	Follow vendor guidance	Conform to MR conditions Monitor SAR or B1 ⁺ _{rms} Monitor active scan time Monitor artifacts	Appropriate monitoring Frequent communication
Follow-up	Follow vendor guidance Return to normal status		Assess for pain or injury



Managing the MR conditional implant device

Assess the device

- Identify the device
 - patient implant card, medical record, implanting physician, x-ray
 - AIMD vendor, patient AIMD programmer
- Obtain MR conditions <u>AND</u> procedures
 - vendor guidance document (always get most current), patient implant card
 - MR Safety, published literature or consensus statements
 - hospital policies and procedures
- Document device eligibility and status
 - EHR, patient eligibility form, patient programmer, device specialist assessment
 - Check all components of AID (IPG, leads, extenders)
 - Caution: abandoned devices; broken, abandoned or test leads
- Identify risks to the device?

Prepare AIMD device for MRI

- FOLLOW VENDOR GUIDANCE
 - Device charged and ready? Programming device available if needed?
 - Record/save settings or data
 - Secure/immobilize/position
 - MR mode or device interrogation with patient programmer

• Following MRI

- FOLLOW VENDOR GUIDANCE
 - Perform device check & return device to normal status if needed

Managing the MR conditional implant patient



Assess patient

- <u>Risk</u> vs Benefit taking into account indication, anatomical region and potential artifacts, patient eligibility and current condition and ability to undergo procedure, presence of other implants and the availability of alternative imaging in light of a risk modulated appropriateness criteria
- Risk to device, patient and patient dependence on device (CIED, drug delivery, etc)
- FOLLOW VENDOR GUIDELINES

Prepare patient for MRI

- Inform patient and consent if needed
- Have a communication & monitoring plan
- Positioning and managing considerations (i.e., patient cooling, sedation, etc)
- During exam
 - Provide appropriate monitoring and frequent communication
- Following exam
 - Assess for pain or injury



Medical Devices & Implants in MRI Environment

- Active Implanted Medical Devices (AIMD)
 - CIED (pacemakers, ICD)
 - Stimulators (deep brain, vagal nerve, spinal, bone and bladder)
 - Pumps (pain, drug, insulin)
 - Cochlear implants
 - Cardiac loop recorders
- Passive implants & retained foreign objects
 - Neurological (aneurysm clips & coils, shunts)
 - Orthopedic (prosthetics, rods, screws)
 - Cardiovascular and Vascular (stents, coils & filters)
 - Breast (implants, tissue expanders)
 - Retained foreign objects (i.e., metal in orbits, bullet fragments, etc)
- External objects and devices
 - On body injectors
 - Permanent makeup, tattoos, piercings, etc



Cardiac Implantable Electronic Devices (CIED)

- <u>Pacemaker (PM)</u>: implanted device for delivering treatment and managing bradyarrhythmia (slow heart rate; <60 bpm)
- Internal Cardiac Defibrillator (ICD): implanted device for treatment and management of tachyarrhythmia (fast heart rate; >100 bpm)
- <u>Cardiac Resynchronization Therapy (CRT)</u>: implanted devices for systolic dysfunction with conduction delays (<50% ejection fraction; CRT-P or CRT-M devices).
- <u>Implantable Loop Recorder (ILR)</u>: subcutaneous implanted devices that have no leads & store recordings of the heart rhythm and data derived from the cardiac rhythm in device memory. ILR DO NOT control cardiac therapies, have their own MR conditions, and are not part of the CIED MRI policy.



Cardiac Implantable Electronic Devices (CIED)

- During MRI of CIED patients bradyarrythmia/tachyarrythmia therapy is temporarily modified or discontinued for scanning
- Patient risks dominate and proper patient evaluation and device preparation is crucial for MRI conditional or nonconditional scanning
 - Risk increased with amount of time device is programmed to be in MR environment
 - Monitoring by qualified personnel during time that CIED is reprogrammed is crucial
- No CIED patient should undergo MRI without appropriate monitoring.



CIED Procedure

The presence of an implanted cardiac pacemaker or implantable cardioverter defibrillator (ICD) is considered a relative contraindication for MR examinations unless the *device is established to be MR conditional*. In agreement with general and specific recommendations of the ACR Guidance, this policy dictates that MR examinations of a patient with an implanted cardiac pacemakers or ICD proceed *if and only if*:

- There is a documented risk-benefit ratio analysis that favors the MR procedure over any other Diagnostic Imaging procedure,
- the patient signs an informed consent that clearly outlines potential complications of the examination including death,
- normal operation and reasonable remaining battery life of the device is confirmed,
- there is an appropriately trained, qualified, equipped and credentialed member of the medical staff present to monitor the patient and the implanted cardiac pacemaker or implantable cardioverter defibrillator for the duration of the MR examination,
- pulse oximetry and cardiac monitoring is used to continuously monitor the patient during the MR examination and an appropriately prepared crash cart is nearby,
- the MR exam can be completed without the administration of drugs (analgesia/anesthesia) and
- the patient is communicative.
- The risk-benefit ratio analysis and approval of the MR procedure must be documented by a Level 2 MR Personnel-designated attending Radiologist.



CIED Procedure

- Physics may be called to help identify if implanted system is conditional/non-conditional
 - radiologist decision to proceed to schedule cardiology appointment vs alternative imaging
 - cardiology appointment
 - device check & appropriateness
 - patient check & appropriateness
 - If radiologist decides appropriate in light of cardiology and MRI team input, exam is scheduled
 - Physics may assist with
 - exam modifications needed to comply with MR conditions
 - Work with radiology to optimize active scan time



Cardiac Implantable Electronic Devices (CIED)

- CIED (pacemaker/defibrillator) is a *system*
 - Pulse generator
 - Leads/electrodes
 - All components and conditions must be met to be considered MR conditional and on-label
- Physicist may be contacted to help assess if implanted system is MR conditional for scheduling/assessing risk by radiologist
 - Off-label: alternative imaging first consideration
- Identify components with serial numbers
 - call manufacturer if needed
 - must identify if implanted system is MR conditional
- Communicate conditionality, conditions & details

HRS expert consensus statement on MRI in patients with CIED. Heart Rhythm. 2017



CIED evaluation example: Abbott PM/ICD/CRT-D

MRI Scan Parameters for St. Jude Medical MR Conditional Systems

When performing an MRI scan on a patient with a St. Jude Medical[™] MR Conditional system, the following scan parameters must be followed.

Table 2. MRI scan parameters

Scan parameters	Settings
Scanner type	Cylindrical-bore magnet, horizontal field orientation
Magnet strength	1.5 Tesla/64 MHz excitation frequency (hydrogen atom only)
Spatial field gradient	≤30 T/m (3000 G/cm)
MR operating mode	Normal Operating Mode
Whole body SAR (Specific Absorption Rate)	≤2 W/kg
Head SAR	≤3.2 W/kg
Gradient slew rate	≤200 T/m/s-per axis
Scan region	Full-body

The following RF coil types may be used when performing an MRI scan:

- 1. Full-body RF transmit coil with any receive coil in Normal Operating Mode
- 2. Local RF transmit-receive coil in Normal Operating Mode:
 - RF transmit-receive Head coil (quadrature only)
 - RF transmit-receive Lower extremity coil (quadrature only)
 - RF transmit-receive Upper extremity coil (quadrature only)

WARNING: Use of local RF transmit coils placed directly over the device is untested.

CAUTION: Multiple leads can be connected to an MR Conditional device. Not all lead lengths are MR Conditional. Each lead needs to be checked for MRI compatibility and individual scan parameters. The device/lead combination tables list the MR Conditional lead lengths (page 3).



St. Jude Medical MR Conditional Systems Device/Lead Combinations

Pacemakers

Table 3. St. Jude Medical MR Conditional System device/lead combinations for Accent MRI™ pacemakers

Device model	Lead model (lengths)	RF Power (SAR)	Scan region
Accent MRI PM1224 PM2218	Tendril MRI™ LPA1200M (46 cm, 52 cm, 58 cm)	Normal Operating Mode	Full-body

ICDs

Table 5. St. Jude Medical MR Conditional System device/lead combinations for Ellipse™ ICDs

Device model	Lead model (lengths)	RF Power (SAR)	Scan region
Ellipse CD1311-36Q CD1411-36Q	Durata™ 7120Q (58 cm, 65 cm) 7122Q (58 cm, 65 cm)	Normal Operating Mode	Full-body
CD1411-36QC CD2311-36Q CD2411-36Q	Optisure™ LDA220Q (58 cm, 65 cm) LDA210Q (58 cm, 65 cm)		
UD2411-30QU	Tendril MRI™ LPA1200M (46 cm, 52 cm)	-	

CRT-Ds

Table 7. St. Jude Medical MR Conditional System device/lead combinations for Quadra Assura™ and Quadra Assura MP™ CRT-Ds

Device model	Lead model (lengths)	RF Power (SAR)	Scan region
Quadra Assura CD3365-40Q CD3365-40QC	Quartet™ 1456Q (86 cm) 1457Q (86 cm)	Normal Operating Mode	Full-body
Quadra Assura MP CD3369-40Q	1458Q (86 cm) 1458QL (86 cm)	If the nati	ent has a
CD3369-40QC	Durata™ 7120Q (58 cm, 65 cm) 7122Q (58 cm, 65 cm)	lead combination	
	Optisure™ LDA210Q (58 cm, 65 cm) LDA220Q (58 cm, 65 cm)	not listed, MR condit	it is non-
	Tendril MRI™ LPA1200M (46 cm, 52 cm)		



CIED evaluation example: Adverse MRI Conditions

- System not implanted in left/right pectoral region
- Combination of leads & device not listed as MR Conditional
- System modifications (i.e., lead extenders/adapters, abandoned leads, etc)
- Broken/intermittently functioning leads*
- Lead impedance measurements not within limits*
- Device at end-of-life
- Patients with unstable capture thresholds



- Capture threshold >2.5 V @ 0.5 ms pulse width for RA & RV leads
- Capture threshold >2.0 V @ 0.5 ms pulse width for the LV lead
- Diaphragmatic stimulation at pacing output of 5.0 V or 7.5 V & 1ms pulse width in patients requiring asynchronous pacing mode when MRI Settings are enabled
- ICD/CRT-D: capacitor hasn't been prepared for MRI scan
- Patient has elevated body temperature or compromised thermoregulation at time of scan

*NOTE: Lead fractures or other damage to the leads may cause changes in the electrical properties of the MR Conditional system that makes the system unsafe for an MRI scan. Patients with damaged leads may be harmed if an MRI scan is performed.





CIED: Implanted Loop Recorders (ILP) Example

Reveal XT

- Patients must wait 6 weeks post-insertion before having an MRI scan.
- Closed bore, cylindrical magnet with static magnetic field must be 1.5 T or 3.0 T.
- Whole body gradient systems with gradient slew rate specification must be ≤200 T/m/s.
- Whole body Specific Absorption Rate (SAR) as reported by the MRI equipment must be ≤2.0 W/kg; head SAR as reported by the MRI equipment must be ≤3.2 W/kg.
- The uninterrupted duration of active scanning (when radio frequency (RF) and gradients are on) over the chest during MRI must not exceed 30 min.
- If additional chest scans beyond 30 min are necessary, a waiting period of at least 10 min is required.

Reveal LINQ

- Horizontal cylindrical bore magnet, clinical MRI systems with a static magnetic field of 1.5 Tesla (T) or 3.0 T must be used.
- Hydrogen proton MRI equipment must be used.
- Maximum spatial gradient of the static magnetic field specification must be ≤25 T/m (2500 gauss/ cm).
- Whole body gradient systems with gradient slew rate specification must be ≤200 T/m/s per axis.
- The Whole Body Specific Absorption Rate (WB-SAR) as reported by the MRI equipment must be \leq 4.0 W/kg; the head SAR as reported by the MRI equipment must be \leq 3.2 W/kg.
- Do not use local transmit coils on the chest, trunk, or shoulder region.
- There are no restrictions on the placement of receive-only coils, and there are no restrictions on the use of local transmit or receive coils for imaging of the head or extremities.



In all cases, patients encouraged to download/backup data prior to MRI and clear system post-MRI to avoid erroneous recordings.



Deep Brain Stimulators (DBS)

• Deep Brain Stimulation consists of two electrodes implanted in the thalamus or globus pallidus to manage patients with motion disorders. An implanted pulse generator (IPG) sends electrical signals into the brain.



 Because of the sensitive location and sensitivity to RF heating, serious permanent injury or death can result from improper scanning of DBS patients.

Implanted neurostimulation systems include the following components:

- 1. Lead
- 2. Extension
- 3. Pocket adaptor (not present in all implanted systems)
- 4. Implanted neurostimulator

Lead-only systems include the following component implanted in one of two ways:

- 1. Lead
 - Fully-implanted, also called internalized (under the skin)
 - Partially-implanted, also called externalized (exits the skin)

Deep Brain Stimulators (DBS)

- Identify implanted device
- Obtain MRI eligibility information from patient clinician
- Assess MR conditions of device
- Assess medical necessity of MRI
- Inform MRMD, MRI administration, MR Physics
- Schedule patient
- Physics: modify & test MRI protocol to conform to MR conditions of vendor
- On day of scan
 - Vendor on site to manage device (eligibility form)
 - Radiology consent of patient
 - Direct physics oversight

Obtain the latest MRI guidelines labeling

Always obtain the latest MRI guidelines. Refer to the contact information at the back of this manual, or go to www.medtronic.com/mri.



Deep Brain Stimulators (DBS)

MRI and Medtronic DBS Therapy



MR Conditional – Non-clinical testing has demonstrated that Medtronic DBS Systems have been found to be MR Conditional. If this patient is implanted with a Medtronic DBS System, MRI examinations of the head only or the entire body may be safely performed depending on the DBS system components implanted.

Medtronic DBS Systems that are eligible for MRI scans of the entire body (ie, full-body eligible) must be scanned under the following conditions:

- 1.5-tesla (T) horizontal closed bore
- Maximum spatial gradient of 19 T/m (1900 gauss/cm)
- RF transmit/receive body coil (built-in) or RF transmit/receive head coil
- Maximum RF power of 2.0 µT B1+rms (B1+ root mean squared)
- If B1+rms is not available, a maximum RF power of 0.1 W/kg (0.05 W/lb) whole body and head SAR (specific absorption rate). Using a SAR setting may result in a more restrictive MRI scan.
- Gradient slew rate limited to 200 T/m/s

Medtronic DBS Systems that are eligible for MRI scans of the head only must be scanned under the following conditions:

- 1.5-tesla (T) horizontal closed bore
- RF transmit/receive head coil only
- Maximum RF power of 0.1 W/kg (0.05 W/lb) head SAR
- Gradient slew rate limited to 200 T/m/s



DBS: Model & Config Matters!

Contraindication

Certain MRI procedures - Use of a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area is contraindicated for patients with the following implanted DBS systems or system components:

- Soletra Model 7426 Neurostimulator
- Kinetra Model 7428 Neurostimulator
- Activa SC Model 37602 Neurostimulator
- Model 64001 and Model 64002 pocket adaptors implanted with any DBS system

Tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis, or death, can occur if a contraindicated MRI scan is performed on a patient with these DBS systems.

Warnings

Read and fully understand guidelines before conducting MRI scan - Do not conduct an MRI examination on a patient with any implanted Medtronic DBS System component until you read and fully understand all the information in this manual. Failure to follow all warnings and guidelines related to MRI can result in serious and permanent injury including coma, paralysis, or death.



DBS: MRSE recommended

Assess neurostimulator implant location for full-body eligible DBS systems - MRI scans using the full-body eligible MRI scan conditions on patients with a neurostimulator implanted in locations other than the pectoral and abdominal regions are untested and may cause unintended stimulation, device damage, or excessive heating, which can result in serious and permanent injury including coma, paralysis, or death.

Avoid exposure to unapproved MRI parameters - In-vitro testing has shown that exposure of the Medtronic DBS System to MRI at parameters other than those described in this guideline can induce significant heating at the lead electrodes or at breaks in the conductor wire (in the lead, extension, or pocket adaptor). Excessive heating may occur even if the lead and/or extension are the only part of the Medtronic DBS System that is implanted. Excessive heating can result in serious and permanent injury including coma, paralysis, or death.

Consider alternative diagnostic methods - MRI examinations of patients with an implanted Medtronic DBS System should only be done if absolutely needed and then only if these guidelines are followed. MRI should not be considered for Medtronic DBS patients if other potentially safer diagnostic methods such as CT, x-ray, ultrasound, or other methods will provide adequate diagnostic information.

Ensure appropriate supervision - A responsible individual with expert knowledge about MRI, such as an MRI radiologist or MRI physicist, must ensure all procedures in this guideline are followed and that the MRI scan parameters, especially RF specific absorption rate (SAR), B1+rms, and gradient parameters, comply with the recommended settings, both for the prescan (tuning) and during the actual MRI examination. The responsible individual must verify that parameters entered into the MRI system meet the guidelines in this manual.



DBS Potential MR interactions

- **Heating:** RF field induces voltages onto the lead system that can produce significant heating at lead-electrode-tissue interface or at the location of any breaks in the neurostimulator lead system. Component heating most serious risk from MRI exposure.
- Magnetic field interactions: Magnetic material of an implanted system may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner. Patients may feel a mild tugging or vibration sensation at the site of the device implant. Patients being scanned with recent implant incisions should be monitored for any surgical wound discomfort.
- Induced stimulation Gradient & RF fields produced by MRI induce energies onto an implanted lead system that could potentially cause
- unintended stimulation, which may result in uncomfortable stimulation or unusual sensations. Induced stimulation can occur even if only a lead or extension is implanted.
- Effects on neurostimulator function Static, gradient, and RF fields may affect the neurostimulator operation and programming. The static magnetic field may cause the neurostimulator to turn on or off if the neurostimulator uses a magnetically controlled switch. MRI RF, static, and gradient fields may temporarily affect or disable other functions, such as telemetry or stimulation pulses. Parameters will need to be reprogrammed if the MRI causes a POR (power-on-reset) of the neurostimulator.
- Image artifacts



DBS: Multiple, complex device combinations

DBS systems that are full-body eligible:

Neurostimulator models	37612 Activa RC, 37603 Activa SC, 37601 Activa PC
Pocket adaptor	No pocket adaptor can be implanted with the DBS system.
Lead-only systems	Fully-implanted leads (ie, leads that are internalized and capped)
System integrity	No open or short circuits

DBS systems that do not satisfy full-body eligible conditions are considered headonly eligible systems.

DBS systems that are head-only eligible:		
Neurostimulator models	37602 Activa SC, 7428 Kinetra, 7426 Soletra	
Pocket adaptor	Any DBS system that is implanted with a pocket adaptor. ^a	
Lead-only systems	Partially-implanted leads (ie, leads that are externalized)	
System integrity	No open or short circuits	

Warning: Confirm the implanted neurostimulator model number(s) and record the model number(s) on the MRI eligibility sheet. Misidentification of neurostimulator model number(s) may result in exposure to MRI parameters not approved for the DBS system, which can induce significant heating. Excessive heating can result in serious and permanent injury including coma, paralysis, or death.



DBS: Compromised system is a hard stop

7. System integrity — Section 7 of the MRI eligibility sheet

- a. If the patient does not have an implanted neurostimulation system, check the box that indicates that this section is not applicable.
- b. If the patient has an implanted neurostimulation system:
 - Perform impedance measurements to determine the integrity of the patient's DBS system (ie, whether open or short circuits are detected). For instructions on performing impedance measurements, refer to step 1 under "Prepare the patient for an MRI scan" on page 19.
 - (2) If no open or short circuits are detected, check the box that indicates that system integrity has been verified.
 - (3) If an open or short circuit is verified, check the box that indicates that the system is compromised. If the system is compromised, an MRI scan should not be performed.

Note: If the clinician programmer cannot communicate with the device or if the device has reached its end of service, MRI scan eligibility cannot be determined and an MRI scan should not be performed.



DBS: Complex scan settings

Table 2. Recommended neurostimulator settings (for all programs) for MRI	
System type	Settings
37612, 37603, 37601	Unipolar configuration ^a — Turn therapy off.
(no pocket adaptor implanted)	Bipolar configuration ^b — Keep therapy on or turn therapy off.
37612, 37603, 37601	Turn therapy off.
(with pocket adaptor implanted)	
37602	Turn therapy off.
7428	Turn therapy off.
	Disable magnetic (reed) switch.
	Disable day cycling.
7426	Turn therapy off.
	Set to bipolar configuration.
	Set amplitude to 0 volts.

This is why prefer to have the vendor onsite if not managed by clinician with device expertise

Cautions:

Complex patient preparation for different configurations

- The decision to turn off a patient's implanted neurostimulator in order to perform medical diagnostic or therapeutic procedures should be carefully considered based on the patient's underlying medical condition.
 Consultation with the appropriate medical professional (prescribing or implanting clinicians) is recommended.
- Carefully weigh any decision to perform MRI examinations on patients who require the neurostimulator to control tremor. Image quality during MRI examinations may be reduced, because the tremor may return when the neurostimulator is turned off.
- If the patient has a lead-only system, prepare the lead before conducting the MRI scan.

For fully-implanted leads (full-body eligible):

- a. Cap and internalize the lead(s). For instructions on capping the lead, refer to the appropriate lead implant manual.
- △ Caution: For lead-only systems, ensure that the lead is capped before it is internalized if an MRI scan will be performed after surgery. Failure to cap the lead may result in unintended stimulation during an MRI scan.

For partially-implanted leads (head-only eligibile):

- a. Wrap the external portion of the lead(s)/percutaneous extension(s) with thermally and electrically insulating material.
- Keep the external portion of the lead(s)/percutaneous extension(s) out of contact with the patient.
- c. Keep the external lead(s)/percutaneous extension(s) straight, with no loops, and running down the center of the head coil.



DBS: Use only the field strengths listed/tested!

Full-body eligible – MRI equipment and scan requirements

Table 3. Full-body eligible – MRI equipment and scan requirements

Radio-frequency (RF) coils	 Transmit coil: body transmit/receive (built-in), quadrature only. head transmit/receive, quadrature only.
	▲ Warning: Do not use RF transmit coils other than a body transmit/receive (built-in) quadrature coil or a head transmit/receive quadrature coil. Other transmit/receive coils (eg, linear coils) have not been tested and could cause excessive heating, which can result in serious and permanent injury including coma, paralysis, or death.
	Receive-only coil: any type.
MRI system type	1.5-T horizontal closed bore with maximum spatial gradient of 19 T/m (1900 gauss/cm).
	Warning: Only use 1.5-T horizontal closed bore MRI systems. Other MRI systems (such as 0.6-T or 3.0-T, and open bore machines) have not been tested and could cause device damage and excessive heating, which can result in serious and permanent injury including coma, paralysis or death.

DBS: Careful attention to protocol RF (B_1^+)

Table 3. Full-body eligible – MRI equipment and scan requirements (continued)	
RF power	B1+rms (B1+ root mean squared): ■ B1+rms must be ≤ 2.0 µT as reported by the MRI equipment.
	If a B1+rms setting is not available on the MRI equipment, a SAR setting may be used. Using a SAR setting may result in a more restrictive MRI scan.
	 SAR (specific absorption rate): Use MRI examination parameters that limit the displayed average whole body and head SAR to 0.1 W/kg (0.05 W/lb) or less for all RF pulse sequences unless the applied SAR is known. If known, an applied SAR up to 0.1 W/kg (0.05 W/lb) may be used.
	To determine whether patient weight will affect the RF power setting, refer to "Full-body eligible – Pre-MRI scan operations and considerations" on page 30.



DBS: Expert knowledge of scanner operation

Warnings:

- If using B1+rms, do not exceed 2.0 µT. If B1+rms is not available and SAR must be used, do not exceed an average whole body and head SAR of 0.1 W/kg (0.05 W/lb). Exceeding these power limits may cause excessive heating, which can result in serious and permanent injury including coma, paralysis, or death.
- If MRI parameters must be manually adjusted after the initial automatic MRI prescan, do not make any adjustments that will increase the SAR value. Some MRI machines may not automatically update the displayed SAR value if manual adjustments are made. This may lead to higher than expected temperature increases in the Medtronic DBS System, particularly at the lead electrodes.



DBS: Normal Operator Mode for Gradients

Operating mode	Use Normal Operating Mode.
Ĩ	 Warning: Do not conduct MRI scans in the following modes: First Level Controlled Operating Mode Second Level Controlled Operating Mode (ie, research mode)
	These modes allow higher gradient levels, which could cause increased risk of unintended stimulation or heating of the neurostimulator.
Gradients	Gradient systems with a maximum gradient slew rate performance per axis of 200 T/m/s or less.
	Warning: Do not use gradient systems producing gradient slew rates greater than 200 T/m/s because they have not been tested and could cause increased risk of unintended stimulation or heating of the neurostimulator.



DBS: Active scan time limits

- Many active implants have active scan time limits
- This along with other restrictions limits protocol
- Example of a standard below

Active scan time limits	MRI scan durations should not exceed a total of 30 minutes of active scan time within a 90-minute window (within every 90-minute window should be a total of 60 minutes of nonscan time).	
i. k .i	▲ Warning: Do not exceed a total of 30 minutes of active scan time within a 90-minute window. Exceeding the active scan time duration increases the risk of tissue heating.	
Landmark (isocenter location)	No restrictions. All anatomical locations can be scanned.	



DBS: Abandoned systems

 Active implant systems 'no longer in use' can present alterations in MR conditions

Full-body eligible – Preparing the patient before the MRI scan

Table 4. Full-body eligible – Preparing the patient before the MRI scan

Abandoned systems	Do not conduct a full-body MRI scan on a patient with an abandoned system. Abandoned systems are complete neurostimulation systems or partially-explanted systems (eg, neurostimulator, lead, extension, or lead-extension fragment) that no longer provide therapy to the patient.
	The presence of an abandoned system can be confirmed with x-ray imaging, referring to the patient records, or consulting with the clinician managing the patient's neurostimulation system.
	For more information on the effects of MRI on abandoned systems, refer to "Precautions" on page 10.



DBS: Artifacts may impact decision to scan

Table 5. Full-body eligible – Pre-MRI scan operations and considerations
(continued)

Consider image artifacts and distortion	Image artifacts and distortion resulting from the presence of the device, the leads, and any other DBS system components within the field of view must be considered when selecting the field of view and imaging parameters. Careful choice of pulse sequence parameters, location of the angle, and location of the imaging plane may minimize MR image artifacts. For more information on minimizing artifacts and distortion caused by DBS systems, refer to "Image artifacts and distortion" on page 12
	△ Caution: MRI images may be severely distorted or image target areas can be completely blocked from view near the implanted Medtronic DBS System components, especially near the neurostimulator. If the MRI targeted image area is near the neurostimulator, it may be necessary to move the neurostimulator and lead(s) to obtain an image, or use alternate imaging techniques.

DBS: Patient considerations

Core body temperature	Fever
Ĩ	▲ Warning: Do not perform an MRI scan if the patient's body temperature is above 38 °C (100 °F). Elevated body temperature in conjunction with tissue heating caused by an MRI scan increases the risk of excessive tissue heating, which could cause tissue damage.
	No blankets
	Warning: Do not cover the patient with blankets or heated blankets. Blankets raise the patient's body temperature and increase the risk of tissue heating, which could cause tissue damage.
Patient weight, minimum	No restrictions.
Sedation	No restrictions.
	△ Caution: If possible, do not sedate the patient so that the patient can provide feedback of any problems during the examination.
Patient position within the bore	Position the patient in a prone or supine position in the MRI bore.
	Marning: Do not position the patient in other positions, eg, on his or her side (called the lateral decubitus position) within the MRI bore. Scanning patients in positions other than prone or supine is untested and could cause excessive tissue heating during an MRI scan.

C.

DBS: Patient considerations

Table 6. Full-body eligible – During the MRI scan	
Keep track of active scan time	Keep track that the active scan time is within a 90-minute window. See "Active scan time limits" in Table 3.
n Monitor the patient	△ Caution: Monitor the patient during the MRI examination. Verify that the patient is feeling normal and is responsive between each individual scan sequence of the MRI examination. Discontinue the MRI immediately if the patient becomes unresponsive to questions or experiences any heating, pain, shocking sensations, uncomfortable stimulation, or unusual sensations.
Patient comfort	Heating may be felt at the neurostimulator site during the MRI scan. If the heating causes the patient discomfort, stop the MRI scan immediately. Consider applying an ice pack or cold compress to the location after the scan is stopped.
Neurostimulator tugging, vibration	During the MRI scan, the patient may feel tugging and/or vibration of the neurostimulator. If the tugging or vibration causes the patient considerable discomfort, stop the MRI scan.
	If the neurostimulator is close to the MRI bore wall, consider using a pillow to keep the neurostimulator away from the bore wall to minimize vibration.



DBS: Post-MRI

Table 7. Full-body eligible – Post-MRI scan	
Patient feedback	Verify that the patient has not experienced adverse effects as a result of the MRI. Contact Medtronic to report any adverse effects.
Turn therapy back on or return therapy to original parameter settings	After the scan has been completed, instruct the patient to see the clinician managing the patient's neurostimulation system to have the therapy turned back on or program therapy to the original settings.
	Or, if the patient has brought a patient control device to the MRI appointment, instruct the patient (outside of the scanner room) to turn therapy back on or program therapy to the original settings using the patient control device.
	Notes:
	 To turn on or adjust therapy, tell the patient to hold the patient control device over the neurostimulator and
	press the Check local key. Then the patient can turn on or adjust therapy.
	 If the patient control device cannot synchronize with the neurostimulator, or cannot turn therapy back on, or displays a screen with the letters "POR" on it, instruct the patient to see the clinician managing the patient's neurostimulation system. Contact Medtronic to report the POR event.



DBS: Head-only considerations

Head-only eligible – MRI equipment and scan requirements

Table 8. Head-only eligible – MRI equipment and scan requirements

Radio-frequency (RF)	Transmit/receive head coil only .
coils	 Important: Do not use an RF transmit body coil, a receive-only head coil, or a head transmit coil that extends over the chest area. If you are unsure if your MRI system has RF transmit/ receive head coil capability, consult the MRI manufacturer.
	 Warnings: An MRI examination of the head only (no other part of the body) can be conducted safely using an RF transmit/ receive head coil when all instructions in this head-only eligible section are followed. If the patient's neurostimulation system has a broken conductor wire (in the lead, extension, or pocket adaptor), higher than normal heating may occur at the break or lead electrodes. Excessive heating can cause serious and permanent injury including coma, paralysis, or death.



DBS: Head-only considerations

Head-only eligible – Preparing the patient before the MRI scan

Table 9. Head-only eligible – Preparing the patient before the MRI scan

Abandoned systems	Confirm that no abandoned systems are within 0 cm of the transmit/receive head coil. Abandoned systems are complete neurostimulation systems or partially-explanted systems (eg, neurostimulator, lead, extension, or lead-extension fragment) that no longer provide therapy to the patient.
	The presence of an abandoned system can be confirmed with x-ray imaging, referring to the patient records, or consulting with the clinician managing the patient's neurostimulation system.
	For more information on the effects of MRI on abandoned systems, refer to "Precautions" on page 10.

Table 9. Head-only eligible – Preparing the patient before the MRI scan (continued)

Core body temperature	Fever
ïΥï	No restrictions.
L.X.I	Blankets
	No restrictions.


Spine Stimulators: complex conditions for SAR

Warning: The Precision Montage MRI SCS System can be "Full Body MR Conditional" only when exposed to the MRI environment under the specific conditions defined in this manual.

Table 1. Components that are eligible for Precision Montage MRI System with ImageReady MRI Full Body Technology

Component	Description	Model Number(s)	MRI System Settings
IPG	Precision Montage MRI 16 Contact Implantable Pulse Generator (IPG)	SC-1200	Follow the MRI System Settings used with the implanted lead(s).
Percutaneous Leads	Avista™ MRI Percutaneous Leads, 56 cm	SC-2408-56	Normal Operating Mode (See "Radiology" on page 6, MRI System Settings, 4a)
	Avista MRI Percutaneous Leads, 74 cm	SC-2408-74	
	Linear™ Percutaneous Leads, 50 cm	SC-2158-50, SC-2138-50	Normal Operating Mode with B1+RMS limits (See "Radiology" on page 6, MRI System Settings, 4b)
	Linear Percutaneous Leads, 70 cm	SC-2158-70, SC-2138-70	
	Linear ST Percutaneous Leads, 50 cm	SC-2218-50, SC-2208-50	
	Linear ST Percutaneous Leads, 70 cm	SC-2218-70, SC-2208-70	
	Linear 3-4 Percutaneous Leads, 50 cm	SC-2352-50	
	Linear 3-4 Percutaneous Leads, 70 cm	SC-2352-70	
	Linear 3-6 Percutaneous Leads, 50 cm	SC-2366-50	
	Linear 3-6 Percutaneous Leads, 70 cm	SC-2366-70	
	Infinion™ CX Percutaneous Leads, 50cm	SC-2317-50	
	Infinion CX Percutaneous Leads, 70cm	SC-2317-70	
Surgical Leads	Artisan™ MRI Surgical Leads, 50 cm	SC-8416-50	
	Artisan MRI Surgical Leads, 70 cm	SC-8416-70	
	Artisan Surgical Leads, 50 cm	SC-8216-50, SC-8120-50, SC-8116-50	
	Artisan Surgical Leads, 70 cm	SC-8216-70, SC-8120-70, SC-8116-70	
Surgical Accessories	IPG Port Plugs	SC-4401	Surgical Accessories should follow the MRI System Settings used with the associated implanted lead(s).
	Clik Anchor	SC-4316	
	Clik X Anchor	SC-4318	
	Clik™ X MRI Anchor	SC-4319	
	Silicone Suture Sleeves	N/A, included in kit	
	Med-A	SC-4320	

Note: The system must be fully implanted and must include both an IPG and a lead(s), at a minimum, to be MR Conditional. The lead(s) should be connected to the IPG, no extensions, splitters, and adapters are allowed. Leads implanted without the IPG are not MR Conditional.

- 1. MRI systems that meet the following criteria:
 - MRI magnet strength of 1.5T only, in a horizontal closed bore system (no vertical-field, standing, or extremity systems).
 - Gradient systems with a maximum gradient slew rate per axis less than or equal to 200 T/m/s.
 - Maximum spatial field gradient less than or equal to 40 T/m (4000 gauss/cm).
- 2. MRI coil setup:
 - Transmit coil: 1.5T Full Body transmit/receive, Head transmit/receive, or Extremity transmit/ receive. RF quadrature¹ only.
 - · Receive-only coil: Any type.
 - Hydrogen/proton imaging only.
- 3. Patient status and positioning:
 - · The patient is in supine or prone position only.
 - · The lead implant location is epidural.
 - · The IPG is implanted in the upper buttock or the lower flank.
 - Confirm with the patient that their IPG is fully charged (IPG charge shown as three (3) bars on the Remote Control).
 - · The patient has turned stimulation "Off" using their Remote Control.
- 4. MRI system settings:
 - a. Only for Patients Implanted with Precision Montage MRI IPG and Avista MRI Leads: Scanner operation at or below Normal Operating Mode limits for RF and gradient exposure: Whole body SAR must be ≤ 2.0 W/kg, Head SAR must be ≤ 3.2 W/kg
 - b. For Patients Implanted with Precision Montage MRI IPG and any other leads listed in Table 1:

Scan sequence throughout the scan must have B1+rms less than or equal to (≤) 2.0 μT

If B1+rms is not available then scan sequence must have Whole body and head SAR less than or equal to (\leq) 0.2 W/kg

Note: Using the SAR value may result in a more restrictive MRI scan.

Warning: Apply the required B1+rms (or SAR) limit in the Normal Operating Mode. Do not conduct MRI scans in the First Level and Second Level Controlled Operating Modes as it may increase the risk of unintended stimulation and excessive heating.

- 5. Monitoring:
 - · The patient must be under continuous audio/visual monitoring during the MRI.





Spine Stimulators: device & patient

SCS Implant System Conditions

Appendix A, "ImageReady MRI Full Body Patient Eligibility," contains a form that may be used by the physician managing the patient's SCS system to confirm the patient meets the SCS Implant System Conditions for MRI Scans as described in this manual.

 The patient is implanted with a Precision Montage MRI SCS System composed only of components listed in "Table 1. Components that are eligible for Precision Montage MRI System with ImageReady MRI Full Body Technology" on page 2 of this manual.

Note: Full body MRI leads should be connected directly into the IPG. Patient should not be implanted with lead extensions, splitters, or adapters.

- 2. The lead implant location is epidural
- The patient has no abandoned leads or IPGs (i.e. leads or IPGs that are not connected to the functioning Precision Montage MRI System).
- 4. The IPG is implanted in the upper buttock or the lower flank.
- 5. No evidence of fractured leads or compromised IPG-lead system integrity.
- 6. The patient has been informed of what to do or expect in preparation for their MRI scan:
 - a. Prior to arrival at the MRI Center, the patient should ensure that the IPG is fully charged (IPG charge shown as three (3) bars on the Remote Control) for the MRI scan. The patient should bring the Charger (in case charging is necessary) to the MRI center. *The Charger is MR Unsafe and must not be brought into the MRI Scanner Room.*
 - b. At the MRI Center, prior to entering the scanner room, the patient should turn the stimulation "off" using the Remote Control. *The Remote Control is MR Unsafe and must not be brought into the MRI Scanner Room.*
- c. The patient should be aware of the potential perceptible effects of undergoing MRI with an SCS System, which are as follows: vibration or tugging (moving) sensation in the IPG pocket, warming of the implanted system, and sensation of stimulation. The patient should be directed to immediately notify the MRI personnel if any of these effects become uncomfortable or intolerable. Refer to the "Potential Interactions with MRI Environment" in the Safety Information section of this manual for additional information.

Medtronic Precision Montage



Drug Infusion Pumps: Prometra Programmable Pump

WARNING: FAILURE TO EMPTY THE PUMP PRIOR TO EXPOSURE TO MRI ENVIRONMENT COULD RESULT IN DRUG OVERDOSE THAT COULD LEAD TO SERIOUS PATIENT INJURY OR DEATH.

IF AN MRI PROCEDURE IS NECESSARY, THE PUMP MUST BE EMPTIED of drug solution, not refilled and the PUMP PROGRAMMED TO 0.0 MG/DAY DRUG FLOW RATE prior to entering the environment of the MRI. Strong magnetic fields, such as those created in Magnetic Resonance Imaging (MRI) devices, may cause the valves of the pump to open, resulting in the immediate discharge of the contents of the drug reservoir and catheter into the patient.

Prior to initiating the MRI procedure, the physician should determine if the patient could safely be deprived of pain medication for the length of the procedure. If pain medication is needed, then alternate means of drug delivery (such as I.V. administration) should be employed for the duration of the MRI procedure.

Prior to scheduling an MRI scan and upon its completion, pump status should be confirmed by inquiring the pump to verify pump operation and settings.

Non-clinical testing has demonstrated the Prometra Programmable Pump is MR Conditional. It can be scanned safely under the following conditions:

- The pump's reservoir is completely emptied by following the procedures for emptying the reservoir in the Refill Kit Instructions for Use.
- The pump is programmed to 0.0 mg/day flow prior to MRI exposure and throughout the scanning sequence.
- A static magnetic field of 1.5 Tesla
- A maximum spatial gradient field of 410 Gauss/cm
- A maximum whole body averaged specific absorption rate (SAR) of 2W/kg for 20 minutes of scanning in the Normal Operating Mode.

In non-clinical testing, the Prometra Pump produced a maximum temperature rise of 1.5°C during 20 minutes of continuous MR scanning in the Normal Operation Mode at a maximum whole-body averaged specific absorption rate (SAR) of 2 W/kg.

Drug Infusion Pumps: Prometra Programmable Pump

Post MRI Procedures

- 1. Confirmation of Pump Operational Status
 - a) Pump Inquiry

Upon the completion of an MRI procedure, inquire the pump with the programmer to verify pump operation and settings. Confirm that settings are unchanged from the Pre-MRI settings, e.g., flow rate must be 0.0 mg/day.

Warning: If pump status cannot be properly confirmed, <u>DO NOT</u> proceed since the pump is not operating properly and should be explanted and replaced.

- b) Pump Aspiration
 - Once the pump status and flow rate is confirmed to be 0.0 mg/day via inquiry, attempt to aspirate the pump reservoir through the refill port.
 - To aspirate, attach the 22G non-coring needle (available in Refill Kit) to a sterile syringe.
 - Advance needle through center refill septum until needle tip resides completely inside the drug refill reservoir.
 - Pull a vacuum with the syringe for approximately 10 to 30 seconds.

Warning: If any significant volume (>1ml) is retrieved, it may be indicative that the pump valves are open, providing direct access to the catheter/cerebral spinal fluid; If so, <u>DO NOT</u> proceed with the refill since the pump is not operating properly and should be explanted and replaced.

2. Refill Procedure

After confirming that the pump is operating properly, proceed to refill the pump in accordance with the refill procedures defined in the Refill Kit Instructions for Use.

Warning: A period of observation should follow the Refill Procedure to closely monitor patients for clinical symptoms of underdose or overdose based upon Infumorph's prescribing information.



Drug Infusion Pumps: Medtronic Synchromed

MRI information for Model 8637-20 and 8637-40 SynchroMed II pumps

MR Conditional: If the patient is implanted with a Medtronic SynchroMed II pump, MRI examinations of the entire body may be safely performed under the following conditions:

- 1.5-Tesla (T) and 3T horizontal closed bore
- Maximum spatial gradient of 19T/m (1900 gauss/cm)
- Maximum gradient slew rate: 200 T/m/s
- Maximum RF field intensity: First level controlled operating mode defined in IEC 60601-2-33

SynchroMed II Filmp performance has not been established using other types of MRI scanners such as open-sided or standing MRI.

Temporary motor stall and stall recovery

The magnetic field of the MRI scanner will temporarily stop the rotor of the SynchroMed II pump motor and suspend drug infusion for the duration of the MRI exposure. The pump should resume normal operation upon termination of MRI exposure; however, there is the potential for an extended delay in pump recovery after exiting the MRI magnetic field because exposure to the MRI magnetic field may cause the motor gears within the pump to bind temporarily without permanent damage. This is caused by the potential for

backward rotation of the pump rotor magnet when it aligns with the MRI magnetic field. This temporary binding may delay the return of proper infusion after the pump is removed from the MRI magnetic field. While extended delays in pump recovery are unlikely, reports have indicated that there is the potential for a delay of 2 to 24 hours to return to proper drug infusion after completion of an MRI scan.

Warning: Patients receiving intrathecal baclofen therapy (eg, Lioresal Intrathecal) are at higher risk for adverse events, as baclofen withdrawal can lead to a life threatening condition if not treated promptly and effectively. For complete product information, refer to the Liorecce Intrathecal (baclofen injection) Package Insert. For information on other drugs, ple ase refer to the product labeling for the drug being administered.

Time required for stall and recovery detection

The SynchroMed II pump detects motor stall and motor stall recovery. Medtronic does not recommend programming the SynchroMed II pump to "stopped pump mode" prior to an MRI because of the possibility of an increased delay in the detection of an extended motor stall.

Motor stall events are recorded in the Amp event log and can be reviewed using the clinician programmer. A motor stall will also cause the pump alarm to sound (two-tone alarm). The slower the programmed delivery rate, the longer it may take for the stall detection algorithm to log motor stall and motor stall recovery. For pumps programmed to deliver at least 0.048 mL/day, the motor stall detection (with audible alarm) should occur within 20 minutes of exposure to the MRI magnetic field. Stall recovery detection should occur within 20 minutes of exiting the MRI magnetic field. The detection of a motor stall and detection of motor stall recovery may each take up to 90 minutes if the pump is programmed to minimum rate mode (0.006 mL/day).



Cochlear Implants

- "Cochlear" implants are electronic devices for restoring hearing bypassing damaged portions of the ear and directly stimulate the auditory nerve
- Recently, the FDA cleared MRI conditional labeling for a large variety of Cochlear models
- These models vary significantly in their risk and discomfort profile as well as their technical MRI conditions
 - some conditions require surgical magnet removal, some do not
 - some require significant SAR reductions, some do not
- A search of the FDA MAUDE database from Jan-Aug 2018 resulted in 23 of these devices requiring revision procedure/surgery post-MRI
 - about 3 of these inferred issue was with patient management during the MRI
 - procedure was associated with a lot of pain in those cases



Cochlear Implant: Example of MR conditions

CI512 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 36.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg.

Under the scan conditions defined above, the CI512 cochlear implant is expected to produce a maximum temperature rise of less than 3.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI512 cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:



CI512 cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg.
 Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI512 cochlear implant is expected to produce a maximum temperature rise of less than 3.7 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI512 cochlear implant when imaged with a gradient echo pulse gequence scan for 3 minutes and 20 seconds is as follows:



5.7 cm (2.2 in.)



Cochlear Implant: Example of MR conditions

MRI safety information for CI 11+11+2M cochlear implants

A Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI 11+11+2M cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant. MRI safety information for ABI24M auditory brainstem implants

A Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow patients with an ABI24M auditory brainstem implant to be in the room where an MRI scanner is located except under the following special circumstances.

The ABI24M auditory brainstem implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher. If the ABI24M auditory brainstem implant magnet is in place, it must be removed surgically before the patient undergoes an MRI procedure.

The patient must take off the speech processor and headset before entering a room where an MRI scanner is located.

If the implant magnet is still in place, tissue damage may occur if the recipient is exposed to MRI. Once the magnet is surgically removed, the metal in the ABI24M auditory brainstem implant will affect the quality of the MRI. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, resulting in loss of diagnostic information in the vicinity of the implant.

ABI24M auditory brainstem implants have removable magnets. Once the magnet has been removed, MRI can be performed. The headset can be held in place on the recipient's head by a stick-on retainer disk.



Summary

- MR physicists act as MR safety experts
- Primary role is to advise, it is inappropriate to make medical decisions
- Active implant MR conditions are becoming increasingly complex and include more than technical assessment of the MRI hardware and software
 - Device function during and after examination important
 - Latest vendor U.S. guidelines should be downloaded and consulted in order to provide requested advice



How to find balance with implants in the equation?







THE UNIVERSITY OF TEXAS MDAnderson Cancer Center

Thank you for your time!

Email: jstafford@mdanderson.org

