Title: Technical challenges and safety of magnetic resonance imaging with *in situ* neuromodulation from spine to brain

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Abstract

This review summarises the need for MRI with *in situ* neuromodulation, the key safety challenges and how they may be mitigated, and surveys the current status of MRI safety for the main categories of neuro-stimulation device, including deep brain stimulation, vagus nerve stimulation, sacral neuromodulation, spinal cord stimulation systems, and cochlear implants.

When neuro-stimulator systems are introduced into the MRI environment a number of hazards arise with potential for patient harm, in particular the risk of thermal injury due to MRI-induced heating. For many devices however, safe MRI conditions can be determined, and MRI safely performed, albeit with possible compromise in anatomical coverage, image quality or extended acquisition time.

The increasing availability of devices conditional for 3Tesla MRI, whole-body transmit imaging, and imaging in the on-stimulation condition, will be of significant benefit to the growing population of patients benefitting from neuromodulation therapy, and open up new opportunities for functional imaging research.

Key Words

neuromodulation; neurostimulation; MRI; MR Imaging; Safety

1.1 Introduction

Neuromodulation and magnetic resonance imaging (MRI) both rely at a fundamental level on interactions between electromagnetic fields and tissue. It is not surprising therefore that there can exist significant electromagnetic interactions between implanted neuromodulation apparatus and the MRI scanner. These interactions may disrupt the imaging process, degrading image quality, or, more importantly, cause loss of therapeutic neurostimulation, damage to the neuromodulation equipment, or injury to the patient. Nevertheless, MRI and neuromodulation devices may coexist safely under specific, controlled circumstances, if the necessary device-specific conditions for safe MRI can be defined and satisfied.

This article reviews the need for MRI with *in situ* neuromodulation, summarises the key safety issues and how they may be mitigated, and surveys the current status of MRI safety for the main categories of neuro-stimulation device. Recent developments are discussed which promise to make MRI

available to increasing numbers of patients previously contraindicated for MRI on account of their implants, and open new avenues for functional-imaging research.

Neuro-stimulation systems typically consist of metallic electrode contacts, either paddle-type electrodes or small arrays of cylindrical electrodes, at the end of insulated flexible leads, connected, via subcutaneous extension cables, to an implantable pulse generator (IPG) containing the pulse-generating electronics and a power cell.

Systems with this basic configuration have found clinical application in treating a range of conditions[1], for instance deep brain stimulation (DBS) is established as a treatment for Parkinson's disease or dystonia[2]; vagus nerve stimulation (VNS) has been shown to decrease seizure frequency in patients with medically refractory epilepsy[3]; occipital nerve stimulation (ONS)[4] has shown benefit in a variety of headache disorders; spinal cord stimulation (SCS) is valuable in the management of intractable pain syndromes[5] and sacral neuromodulation (SNM) has been advocated for the treatment of bladder and bowel dysfunction[6,7]. The same general physical hazards in the MRI environment are common across the devices delivering these therapies, although the precise conditions under which MRI may be safely performed, if existing, are device-model specific. As paediatric neuro-stimulation therapy continues to increase in importance[8], the need for devices engineered to better withstand the MRI environment, with rigorously defined conditions for safe MRI will become even more pressing. Cochlear implants (CIs), although differing in their design and function from the more generic types of neuro-stimulator listed above, are an important class of device frequently deployed in children[9], with specific MRI safety management issues which will be discussed in a separate section below.

1.2 The need for MRI with *in situ* neuromodulation

There are three broad motivations for undertaking MRI in patients with *in situ* neuromodulation devices: firstly, in many centres, MRI is an enabling technology in the workflow for neuro-stimulator implantation and therapy management. For instance intra- or post-operative MRI to verify anatomic electrode contact positions, and if necessary guide positional adjustment, as well as to assess for haemorrhagic complications, may be valuable in DBS implantation surgery[10–13]. Even if alternative methods to verify lead location, such as electrophysiological recordings or post-operative CT images fused to pre-operative MRI[14] are employed, MRI in subjects with pre-implanted electrode leads and IPGs may be necessary if implantation of one or more additional electrode leads, or revision of pre-existing lead position is indicated to achieve more effective therapy.

Secondly, functional magnetic resonance imaging (fMRI) testing the influence of the 'on' and 'off' stimulation conditions upon cerebral activation networks is becoming an important tool to elucidate the neurophysiological mechanisms underlying the success of neuro-stimulation therapy, or to explore the unique opportunity of controlled neuro-modulation as an experimental model[15]. Published fMRI studies involving conventional implanted neuro-stimulation systems include examples with DBS[16–20], VNS[21,22],SNM [23] and SCS[24].

Thirdly, as a result of the success of neuro-stimulation therapy across a wide range of clinical conditions, significant numbers of individuals now have implantable pulse generators and electrode leads *in situ*: very many of these patients are likely to require MRI later in life, possibly for indications not directly related to their neuro-stimulation therapy. For instance approximately 82-84% of SCS-implanted patients are expected to need at least 1 MRI within 5 years of implantation[25]. In many centres MRI safety concerns have led to patients with implanted neuro-stimulators being disbarred

from MRI on safety grounds[26], or, a sufficiently strong indication for MRI may have caused consideration of device explantation[27].

1.3 Potentially hazardous MRI-implant interactions

Since MRI avoids the use of ionizing radiation for image formation, it is generally considered a highly safe modality, appropriate for repeated examinations even in the paediatric population. However, there are additional hazards when active implantable medical devices (AIMDs) such as neuro-stimulator systems are introduced into the MRI environment which may compromise the AIMD function or create risk of significant patient injury.

The hazards arising during MRI with *in situ* neuro-stimulators are reviewed in a number articles[1,28,29]. In brief, the scanner main magnetic field ($\mathbf{B_0}$), required to align a sufficient majority of the microscopic nuclear magnetic moments to generate detectable bulk magnetisation, typically lies in the range 1.5-7.0 tesla for human scanning, i.e. up to 100,000 times greater than the earth's magnetic field. This field is permanently switched on, and can exert upon ferrous or electrically conducting components magnetic displacement or rotational forces, with risk of device displacement. The imaging process also requires switched spatially- and rapidly time-varying magnet gradient fields, with a rate of change of field strength ($d\mathbf{B}/dt$) sufficient to induce voltages in neuro-stimulator circuits, which *in extremis* may interfere with therapeutic stimulation delivery, produce parasitic stimulation, or damage the IPG circuitry. Finally, MRI signals are generated by exciting the nuclear magnetization with low amplitude, short duration pulses of a magnetic field ($\mathbf{B_1}$) rotating at radio-frequencies (RF pulses). In subjects with no implanted devices, RF pulses applied during scanning ordinarily elicit small increases in tissue temperature, largely by dielectric energy absorption, which safety restrictions act to limit to less than 1^{o}C for routine scanning[30]. However, extended electrically-conducting structures, such as neuro-stimulator leads, can amplify and focus the $\mathbf{B_1}$ field, causing local tissue energy deposition many times higher than that which would occur in the absence of the implant. The resulting local temperature elevation may be sufficient to cause thermal injury under MRI conditions that would otherwise be perfectly safe in an implant-free individual. This generates a significant heating hazard at neuro-stimulator electrode contacts where the impedance between the stimulator circuit and tissue is low. It is this MRI-induced heating that presents a particular concern in practice[31,32], and which has been historically an obstacle to establishing safe MRI conditions for AIMDs. Since the rotational frequency of $\mathbf{B_1}$ is directly proportional to $\mathbf{B_0}$, frequency-dependent RF interactions, and hence the risk of injurious heating for specific implant configurations, may vary with scanner main field strength.

1.4 The need for caution

While the design of contemporary neuromodulation systems to a great extent mitigates hazards arising from the main static and time varying magnetic gradient fields, the risk of thermal injury due to RF-induced heating during MRI remains a concern. This is not just a theoretical risk: numerous studies have demonstrated significant temperature rises at electrode contacts during MRI of *in vitro* tissue models (e.g.[33–35]), and there have been, e.g. for DBS systems, a number of reports of adverse events where MRI was undertaken outside of prescribed safe conditions[36,37].

1.5 Device Categories

To avoid ambiguity in discussing the safety of items in the MRI environment, three categories of device are defined in ASTM international standard F2503-13[38], namely:

MR Unsafe

'an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.'

MR Safe

'MR Safe—an item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic'

MR Conditional

'an item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.'

No neuro-stimulation devices can be categorised as "MR safe", since they all contain electrically conductive materials. Some systems may be categorised as "MR unsafe", meaning MRI is completely contraindicated; this might be because the devices have been tested and shown to be unsafe in the MR environment, or because there is available no test data adequate to establish safe MRI conditions. Neuro-stimulator devices are more commonly classed as "MR conditional" – safe MRI is possible under predetermined safe operating conditions. These conditions are specific to the model of neuro-stimulator and its configuration, and may include limitations on the $\mathbf{B_o}$ field strength, the strength and slew rate of imaging field gradients (d**B**/dt), the $\mathbf{B_o}$ spatial gradients within and beyond the scanner magnet bore, the positioning and electrical configuration of the neuro-stimulator circuit, and the degree of exposure to $\mathbf{B_1}$ RF energy during the imaging procedure. There may also be conditions relating to patient positioning and the need for monitoring during scanning. The device function may need to be verified before and after MRI, and the IPG set to a specific mode for scanning. Abnormal electrode impedance readings, or any evidence of broken electrode leads are generally contraindications to MRI. MRI safety conditions may differ between fully implanted systems and situations when the leads are externalised, for instance at the surgical stage following electrode lead implantation but prior to subcutaneous lead-extension routing and IPG positioning.

MRI RF exposure is conventionally quantified in terms of the specific absorption ratio (SAR), which is the rate of energy absorption per unit mass of tissue, with units Watts.kg^{-1}. The pulse sequence SAR depends upon the duration, magnitude and number per unit time of the RF pulses. The numerical relationship between the actual tissue local SAR, and the pulse-sequence parameters is not straightforward to obtain: scanner manufacturers each use their own proprietary mathematical models to estimate this, and thus scanner-reported SAR values may vary between scanner models even for nominally identical pulse sequences[39]. The numerical models used obviously do not account for the possible presence of $\mathbf{B_1}$-field focussing items within the tissue, and thus the true local tissue SAR close to neuro-stimulator electrode contacts may markedly exceed the scanner-estimated head, or whole-body, average SAR, with concomitant risk of local thermal injury. For these reasons SAR limitations have previously been specified quite conservatively in device MRI conditions[32].

1.6 MR conditional devices: safe MRI conditions in practice

There are essentially three sources of information regarding AIMD MRI safe operating conditions: device manufacturers' product labelling, the peer reviewed scientific literature and local testing and risk assessment. Websites, such as www.mrisafety.com or http://www.magresource.com/ are useful

compendia of information, but when available the latest available product information should be obtained direct from the device manufacturer, as MRI safety conditions are regularly updated.

1.6.1 Defining safe conditions for MRI

To define safe MRI conditions for an AIMD, it is necessary to assess the magnetic field interactions causing displacement, twisting forces, or interference with electro-mechanical function, the possibility of voltages induced in the AIMD circuit by the switched magnetic field gradients, the potential for $\mathbf{B_1}$ RF related heating, and the severity of image artefacts caused by the device.

To obtain regulatory approval for a device with respect to the use of MRI, the device manufacturer must document tests performed to determine the conditions under which a patient with that implant can safely undergo MRI. These tests must be sufficient to characterize the behaviour of the device in the MR environment, and the results used to specify parameters affecting safety and describe any condition that is known to produce an unsafe situation. These MRI Conditions are listed in the device labelling, including approved instructions for use, package inserts, operator manuals, patient information cards, and information pamphlets.

Principles and procedures for medical device testing and labelling with respect to MRI are described in a serious of standards[40], representing consensus guidance from regulatory bodies, device manufacturers and the scientific and medical communities. An important recent advance has been the development of a test specification specifically related to the MRI safety of AIMDs[38]. This specification includes a comprehensive 4-tier assessment of RF heating risk involving computational modelling with *in vitro* test validation, with body shape models including children. Adoption of this specification is likely to lead to a significant reduction in the uncertainty margin when assessing a particular device, meaning that the final MRI conditions may be less restrictive while still maintaining the same overall uncertainty budget.

If device manufacturer-defined conditions are unavailable, or cannot be satisfied by the required radiologically-indicated MRI protocol, then either the device must be considered a contraindication to MRI, or, subject to the local institutional regulations for clinical risk management, on-site testing and risk assessment may be appropriate if the necessary expertise is available. While it is generally beyond the resources of a local hospital or clinical research facility to achieve rigorous testing to meet the exacting requirements of [38], nevertheless, local in vitro testing of MRI-induced heating using in gel-filled test objects using fibre-optic temperature probes, according to the general principles outlined in the full standards[38,41] may be helpful to inform local risk assessment. In such a case it is important to assume a wide, conservative error margin regarding permissible RF exposure limits, and to adopt extreme caution before extrapolating the results to device and scanner configurations different from the specific arrangement tested.

While compliance with device manufacture-supplied MRI guidelines in the preferred operating situation, as will be detailed below, “off label” MRI of subjects with implanted neuro-stimulators has been apparently safely performed in various clinical and research contexts. This practice however should always involve a thorough safety assessment, risk-benefit analysis focussed on patient safety, and consideration of the need for informed consent.

1.7 Designing conditionally-safe MRI protocols

Once the MRI conditions for a particular AIMD have been established, it is assumed that the MRI manufacturer has designed the MRI instrument such that the necessary parameters may be accurately defined, controlled and measured, according to the relevant international standard[30].

It is then finally contingent on the MRI operator to specify user-selectable scanning parameters, including the scanner field strength (where the choice between different scanner models exists), the specific pulse-sequence and sequence parameters, and the specific RF coils used for excitation and reception, to ensure compliance with the conditions. RF exposure can be controlled in two ways, often used in combination: by appropriate parameter choices to limit the pulse sequence SAR, or by selecting a transmit coil that limits the area of the neuro-stimulator circuit exposed to the RF field.

1.7.1 Sequence parameter choices to limit RF exposure

The RF exposure limits stipulated in AIMD device conditions are frequently below the maximum levels permitted in routine MRI in the absence of implants[30]. Thus modification of conventional acquisition protocols may be required to achieve compliance, possibly involving compromise in terms of reduced image quality or extended acquisition time. In the simplest case the sequence repetition time may be increased to reduce SAR while increasing the examination duration, or for 2D scans, the number of slices excited per repetition cycle can be reduced with the compromise of reduced anatomical coverage. Alternative strategies to SAR reduction include specifying the use of longer amplitude RF pulses, or replacing an intrinsically high SAR acquisition method, for instance the fast spin-echo method routinely used in diagnostic brain imaging, with alternative pulse sequences, such as 2D or 3D gradient echo sequences with intrinsically lower SARs on account of the lower excitation flip angles used in these methods. Protocols modified to accommodate device MR conditions have been described for SCS[42], VNS[43] and DBS[10].

1.7.2 Choice of RF transmit coil to limit RF exposure

A common practice has been to reduce the area of the neuro-stimulator circuit exposed to the scanner transmit field, and hence minimize induced currents and consequent heating, by using a head-only transmit coil. Contemporary MRI systems conventionally use a “body transmit coil” to apply $\mathbf{B_1}$ RF pulses across the entire volume of the scanner bore. The MRI signals are then detected by arrays of smaller receiver coils, usually restricted to and conforming closely to the anatomical region of interest. The advantage of this arrangement is that whole body transmission yields a relatively uniform RF excitation, and multi-channel receive coils provide optimal signal-to-noise ratio with the option of time-saving image acceleration using partially parallel reconstruction methods[44]. If brain imaging only is required however, specialist head-only transmit-receive coils are available, usually as a special order, which perform the dual function of signal excitation and reception, with the advantage that the area of the stimulator circuit exposed to the RF is significantly reduced in cases when the IPG is located in the subclavicular region, as for DBS, vagal nerve, or occipital nerve stimulators, and eliminated entirely in the case of lower body neuro-stimulators such as sacral nerve or spinal stimulators. The principal disadvantage is that the signal-to-noise or acquisition acceleration benefits of multi-channel receiver arrays are lost.

1.7.3 Operational safety management

Once the conditions for safe MR for a specific device have been determined, and an appropriate MRI acquisition designed, it is vital that standard operating procedures for imaging specific devices are established and disseminated to the radiography staff, that requests for MRI examinations with active devices are specifically protocolled, that the device manufacturer and model number are confirmed and recorded before the examination, and that scan-time records of the RF exposure are maintained. A multi-disciplinary approach to MRI safety, combining scientific, radiological and radio-graphical expertise is key to safely managing MRI with complex implants.

1.8 MRI Conditions for specific classes of device

1.8.1 Deep brain stimulation systems

Of all of the neuromodulation systems in clinical use, DBS systems have received the most attention with respect to MRI safety. Numerous in vitro safety investigations have been described[19,33,35,39,45-52] and reports of patient series[10,20,53–56] with few or no adverse incidents directly attributable to exposure to the MRI environment. Medtronic first released MRI guidelines for their DBS devices in 2002, with requirements including head-coil only transmit and SAR restricted to 0.4W/kg. In 2005 the conditions were revised with a more conservative SAR limit of 0.1 W/kg[32]. In practice many centres found this limit too stringent to permit effective MRI, and either ceased offering MRI to this patient group, or proceeded, following local risk assessment, with less restrictive "off-label" MRI protocols. Reports of safe scanning outside of the manufactures product label guidelines[10,19,54,57–61], combined with the previously cited *in vitro* studies suggested that the manufacturer's guidelines may in fact have erred too far to the conservative side. In April 2015 the company announced extended labelling for eligible DBS devices with less restrictive RF power limits defined in terms of $\mathbf{B_{1,rms}}$, and the possibility of using body-coil transmit[62]. St Jude Medical have also in the past released MRI conditions for their Libra DBS product, quoted in[29&10].

1.8.2 Sacral neuromodulation systems

For a number of years following the introduction of clinical SNM, consistent with device manufacturer's then guidelines, SNM was widely considered a total contraindication to MRI, although two pioneering studies suggested that under appropriate conditions MRI could be safely performed[63,64]. Current SNM system MRI conditions for the Medtronic InterStim SNM systems permit head-only transmit coil MRI at 1.5T[65].

1.8.3 Spinal Cord Stimulation systems

Following an early case study in 3 individuals[66] safe MRI in patients with implanted SCS systems has been demonstrated in 2 patient series[67], one with a reduced SAR protocol [42], and fMRI studies at 1.5T[68] and 3T[24]. There are currently a number of SCS systems available with approved MRI Conditions from St Jude Medical[69], Medtronic[70], Boston Scientific[71] for 1.5T head-transmit only scanning, and for the latter two companies more recent systems eligible for whole-body transmit MRI[70,72] at 1.5T.

1.8.4 Vagus nerve stimulation systems

An early report of 25 patients scanned at 1.5T with a head transmit/receive coil with no permanent adverse effects[73], subsequent *in vitro* measurements[74] and further patient series scanned at 3T again with a head transmit/receive coil[75, 76, 43] support the view that under controlled conditions MRI is safe with the Cyberonics VNS Therapy system. Current approved MRI conditions for this device permit imaging at either 1.5T or 3T with a head-only transmit coil[77].

1.8.5 Cochlear implants

These devices generally consist of an external component, a unit to detect and process sound from the environment and generate electromagnetic signals received by an internally implanted element which directly stimulates the cochlear via an embedded electrode array to create the sensation of hearing. The external headpiece is held in place by magnetic attraction to an internal receiver placed under the skin behind the ear[78]. In addition to the MRI environmental hazards discussed above in relation to generic neuro-stimulator systems, the presence of the implanted magnetic creates additional risks due to the possibility of displacement, demagnetisation or polarity reversal when

introduced into the scanner $\mathbf{B_0}$ field, and gross artefacts on MRI images[79]. Cis were originally considered a contraindication to MRI but now 1.5T and increasingly 3T conditional labelling is available for many cochlear implants [79],[80]. Nevertheless, there remain recent reports of potential complications, in particular internal magnet movement[81], despite conformance with manufacturers' MRI conditions[82]. Under controlled conditions, MRI can be successfully performed in patients without the need for cochlear implant magnet removal; although the risk of internal magnet movement may remain significant, even with the recommended tight supportive head-wrap application[83], and there have been reports of adverse events and discomfort during MRI[84,85].

1.9 Recent developments in MR Conditional labelling

1.9.1 $B_{1,rms}$ as a measure of RF exposure

Inter-vendor variations in the method for determining scanner-reported sequence SAR resulting in inter-scanner variations in implant heating for the same nominal SAR[49] have driven suggestions for alternative metrics to limit RF exposure for implant safety.

Since the local tissue SAR can be theoretically related to the time average of the $\mathbf{B_1}$ RF field amplitude, it has been proposed that $\mathbf{B_{1,rms}}$ given by

$$B_{1,rms} = \sqrt{\frac{\int_0^{t_x}(B_1(t))^2 dt}{t_x}}$$

where t_x is the measurement period, specified as 10s[38] to be may be of value to limit the allowable RF power deposition in implant manufacturer labelling. If the scanner $\mathbf{B_1}$ amplitudes are correctly calibrated during the routine pre-scan adjustments, then $B_{1,rms}$ may be directly calculated for a given acquisition without numeral approximation. The resulting values are directly comparable between pulse sequences on different scanners. Clinical MRI systems from each of the main vendors now provide a user-display of the currently active pulse sequence of $B_{1,rms}$ alongside SAR estimates, enabling the user to readily confirm if a specific sequence meets the required $B_{1,rms}$ restriction.

The availability of this more open and specific RF exposure metric may lessen the need for highly conservative RF limits compared with those defined in terms of more ambiguous scanner-reported SARs. It is expected that this approach will be increasingly adopted by AIMD manufacturers in their labelling; In 2015 Medtronic adopted this approach in their extended labelling for their Activa DBS product line, specifying a maximum $B_{1,rms}$ of 2μT for eligible devices[86].

1.9.2 Permitting body coil transmit

As detailed above, head-only transmit coil operation has been a specified condition for many AIMDs to reduce the area of the RF-exposed neuro-stimulator circuit to minimize heating risk; In vitro tests for DBS equipment have indicated that for an otherwise identical experimental arrangement, body coil transmission does indeed produce an increase in RF heating relative to head coil transmission[52], although with appropriate control of the sequence SAR temperature increases can remain within safe limits[46]. More rigorous manufacturer device testing in line with[38], and the adoption of $B_{1,rms,}$ as a metric to limit RF exposure is expect to allow MRI conditions to be established which permit the use of whole-body coil transmission with a number of benefits: firstly, head-only transmit coils are not available at all MRI installations and may represent an additional expense. More fundamentally body-coil transmit

permits the use of multi-channel array receive coils, providing improved image signal-to-noise ratio, and the possibility of acquisition acceleration by partially parallel acquisition[44]. Another major advantage is that operating in whole-body transmit mode permits scanning of lower body regions, making e.g. spine or abdominal MRI available to implanted patients for the first time. Examples of recent approved labelling permitting whole-body MRI for specific eligible devices are available for the Medtronic Activa DBS system[86] and SCS systems from Medtronic[70] and Boston Scientific[72].

1.9.3 MRI 'on stimulation'

Manufacturer's guidance, and common practice in most centres, has been to require that the IPG output is set to "off" or "0V output" during MRI procedures. There are potential advantages to being able to scan "on stimulation": to avoid loss of the benefit of neuromodulation during the MRI procedure, reducing patient discomfort and minimizing the risk of image degradation due to subject motion. Also research functional imaging comparing "on" and "off" stimulation conditions requires scanning with active stimulation by definition.

While *In vitro* tests monitoring the IPG output during MRI with previous DBS devices reported IPG toggling between on and off state[20], and occasional delayed pulses [45], a similar investigation of a more recent DBS product suggested that MRI had no apparent effect upon the stimulator pulse output, and while small differences in RF-induced heating between the 'on' and 'off' stimulation state were seen, overall heating remained within safe limits (45). Numerous papers reporting successful fMRI studies involving neuro-stimulators in the 'on' condition[16,17,19–24,34,68] suggest that 'on' stimulation scanning can be safe, at least under certain conditions. MRI conditional labelling for a small number of devices now allows 'on' stimulation scanning with certain restrictions[86]; it is expected that the range of devices thus labelled will increase as device designs and safety testing continues to improve.

1.9.4 3T and higher vs. 1.5T

Many of the current approved label MRI conditions are based on measurements performed on 1.5T MRI systems and permissible scanning is limited to that field strength only. Clinical MRI systems operating at 3T and above are increasing available, offering higher sensitivity and greater soft-tissue contrast, driving a need to establish safe MRI conditions for neuro-stimulator devices at these fields. While technical specification TS 10974[38] currently specifically addresses testing limited to 1.5T, *in vitro* results suggests have tested RF heating at higher fields. Results suggest that for the devices tested, while a nominally identical acquisition sequence played out at 3T versus 1.5T produces slightly higher temperature increases, the overall temperature increases remained within reasonable safe limits, with no device malfunction reported, for DBS[19,45,46] and VNS[75] arrangements. These findings have been corroborated with *ex vivo* animal implantation models [87,88] at 3T, and a number of published 3T patient studies with no report of adverse incidents[19,75]. Current labelling for the Cyberonics VNS Stimulation System permits 3T scanning with a head-only transmit coil[77] and again it is expected that labelling permitting 3T MRI will become available for further devices in the near future.

1.10 Summary and Conclusions

Safe MRI of many neuro-stimulation devices is possible, but it remains essential to determine the specific conditions for safe scanning for a given device, and ensure that the necessary radiology and MRI physics expertise is available to ensure compliance. While some devices remain classified as MR unsafe, there are encouraging developments from the medical device industry which are extending

the availability of MRI to increasing numbers of patients with active implants for whom MRI was previously contraindicated. The moves towards whole-body eligible MRI conditions and 3T conditionally-safe devices will extend the clinical benefits of MRI for patients with neuro-stimulators, and provide an improved platform for functional-imaging based neuromodulation research.

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1.12 References

1. Adams A., Shand-Smith J., Watkins L., McEvoy AW., Elneil S., Zrinzo L., et al. Neural stimulators: A guide to imaging and postoperative appearances. *Clin Radiol* 2014;**69**(10):993–1003. Doi: 10.1016/j.crad.2014.03.005.
2. Oluigbo CO., Salma A., Rezai AR. Deep Brain Stimulation for Neurological Disorders. *IEEE Rev Biomed Eng* 2012;**5**:88–99. Doi: 10.1109/RBME.2012.2197745.
3. Uthman BM., Reichl AM., Dean JC., Eisenschenk S., Gilmore R., Reid S., et al. Effectiveness of vagus nerve stimulation in epilepsy patients A 12-year observation. *Neurology* 2004;**63**(6):1124–6. Doi: 10.1212/01.WNL.0000138499.87068.C0.
4. Trentman TL., Zimmerman RS. Occipital Nerve Stimulation: Technical and Surgical Aspects of Implantation. *Headache J Head Face Pain* 2008;**48**(2):319–27.
5. Kumar K., Hunter G., Demeria D. Spinal Cord Stimulation in Treatment of Chronic Benign Pain: Challenges in Treatment Planning and Present Status, a 22-Year Experience: *Neurosurgery* 2006;**58**(3):481–96. Doi: 10.1227/01.NEU.0000192162.99567.96.
6. Kessler TM., Fowler CJ. Sacral neuromodulation for urinary retention. *Nat Rev Urol* 2008;**5**(12):657–66. Doi: 10.1038/ncpuro1251.
7. Wöllner J., Hampel C., Kessler TM. Sacral neuromodulation. *BJU Int* 2012;**110**(1):146–59. Doi: 10.1111/j.1464-410X.2012.10906.x.
8. Kotagal P. Neurostimulation: Vagus Nerve Stimulation and Beyond. *Semin Pediatr Neurol* 2011;**18**(3):186–94. Doi: 10.1016/j.spen.2011.06.005.
9. Balkany TJ., Hodges AV., Eshraghi AA., Butts S., Bricker K., Lingvai J., et al. Cochlear Implants in Children–A Review. *Acta Otolaryngol (Stockh)* 2002;**122**(4):356–62. Doi: 10.1080/00016480260000012.
10. Zrinzo L., Yoshida F., Hariz MI., Thornton J., Foltynie T., Yousry TA., et al. Clinical safety of brain magnetic resonance imaging with implanted deep brain stimulation hardware: Large case series and review of the literature. *World Neurosurg* 2011;**76**(1–2):164–72.
11. Aviles-Olmos I., Kefalopoulou Z., Tripoliti E., Candelario J., Akram H., Martinez-Torres I., et al. Long-term outcome of subthalamic nucleus deep brain stimulation for Parkinson's disease using an MRI-guided and MRI-verified approach. *J Neurol Neurosurg Psychiatry* 2014;**85**(12):1419–25. Doi: 10.1136/jnnp-2013-306907.
12. Foltynie T., Zrinzo L., Martinez-Torres I., Tripoliti E., Petersen E., Holl E., et al. MRI-guided STN DBS in Parkinson's disease without microelectrode recording: efficacy and safety. *J Neurol Neurosurg Psychiatry* 2011;**82**(4):358–63. Doi: 10.1136/jnnp.2010.205542.
13. Schönecker T., Gruber D., Kivi A., Müller B., Lobsien E., Schneider G-H., et al. Postoperative MRI localisation of electrodes and clinical efficacy of pallidal deep brain stimulation in cervical dystonia. *J Neurol Neurosurg Psychiatry* 2015;**86**(8):833–9. Doi: 10.1136/jnnp-2014-308159.
14. Barnaure I., Pollak P., Momjian S., Horvath J., Lovblad KO., Boëx C., et al. Evaluation of electrode position in deep brain stimulation by image fusion (MRI and CT). *Neuroradiology* 2015;**57**(9):903–8. Doi: 10.1007/s00234-015-1547-z.

15. Alhourani A., McDowell MM., Randazzo MJ., Wozny TA., Kondylis ED., Lipski WJ., et al. Network effects of deep brain stimulation. *J Neurophysiol* 2015;**114**(4):2105–17. Doi: 10.1152/jn.00275.2015.
16. Kahan J., Mancini L., Urner M., Friston K., Hariz M., Holl E., et al. Therapeutic Subthalamic Nucleus Deep Brain Stimulation Reverses Cortico-Thalamic Coupling during Voluntary Movements in Parkinson's Disease. *PLoS ONE* 2012;**7**(12):e50270. Doi: 10.1371/journal.pone.0050270.
17. Kahan J., Urner M., Moran R., Flandin G., Marreiros A., Mancini L., et al. Resting state functional MRI in Parkinson's disease: the impact of deep brain stimulation on "effective" connectivity. *Brain* 2014. Doi: 10.1093/brain/awu027.
18. Jech R., Mueller K., Urgošík D., Sieger T., Holiga Š., Růžička F., et al. The Subthalamic Microlesion Story in Parkinson's Disease: Electrode Insertion-Related Motor Improvement with Relative Cortico-Subcortical Hypoactivation in fMRI. *PLOS ONE* 2012;**7**(11):e49056. Doi: 10.1371/journal.pone.0049056.
19. Phillips MD., Baker KB., Lowe MJ., Tkach JA., Cooper SE., Kopell BH., et al. Parkinson Disease: Pattern of Functional MR Imaging Activation during Deep Brain Stimulation of Subthalamic Nucleus—Initial Experience. *Radiology* 2006;**239**(1):209–16. Doi: 10.1148/radiol.2391041990.
20. Rezai AR., Lozano AM., Crawley AP., Joy MLG., Davis KD., Kwan CL., et al. Thalamic stimulation and functional magnetic resonance imaging: localization of cortical and subcortical activation with implanted electrodes. *J Neurosurg* 1999;**90**(3):583–90. Doi: 10.3171/jns.1999.90.3.0583.
21. Chae J-H., Nahas Z., Lomarev M., Denslow S., Lorberbaum JP., Bohning DE., et al. A review of functional neuroimaging studies of vagus nerve stimulation (VNS). *J Psychiatr Res* 2003;**37**(6):443–55. Doi: 10.1016/S0022-3956(03)00074-8.
22. Bari AA., Pouratian N. Brain imaging correlates of peripheral nerve stimulation. *Surg Neurol Int* 2012;**3**(Suppl 4):S260–8. Doi: 10.4103/2152-7806.103016.
23. Kavia R., DasGupta R., Critchley H., Fowler C., Griffiths D. A functional magnetic resonance imaging study of the effect of sacral neuromodulation on brain responses in women with Fowler's syndrome. *BJU Int* 2010;**105**(3):366–72. Doi: 10.1111/j.1464-410X.2009.08819.x.
24. Deogaonkar M., Sharma M., Oluigbo C., Nielson DM., Yang X., Vera-Portocarrero L., et al. Spinal Cord Stimulation (SCS) and Functional Magnetic Resonance Imaging (fMRI): Modulation of Cortical Connectivity With Therapeutic SCS. *Neuromodulation Technol Neural Interface* 2016;**19**(2):142–53. Doi: 10.1111/ner.12346.
25. Desai MJ., Hargens LM., Breitenfeldt MD., Doth AH., Ryan MP., Gunnarsson C., et al. The Rate of Magnetic Resonance Imaging in Patients With Spinal Cord Stimulation: *Spine* 2015;**40**(9):E531–7. Doi: 10.1097/BRS.0000000000000805.
26. Tagliati M., Jankovic J., Pagan F., Susatia F., Isaias IU., Okun MS. Safety of MRI in patients with implanted deep brain stimulation devices. *NeuroImage* 2009;**47 Suppl 2**:T53-57. Doi: 10.1016/j.neuroimage.2009.04.044.
27. Moeschler SM., Sanders RA., Hooten WM., Hoelzer BC. Spinal Cord Stimulator Explantation for Magnetic Resonance Imaging: A Case Series. *Neuromodulation Technol Neural Interface* 2015;**18**(4):285–8. Doi: 10.1111/ner.12254.
28. Manker SG., Shellock FG. MRI Safety Issues and Neuromodulation systems. *MRI: Bioeffects, Safety and Patient Management*. 1st ed. Los Angeles, CA: Biomedical Research Publishing Company; 2013. p. 424–60.
29. Shellock FG. Chapter 20 - MRI Safety and Neuromodulation Systems. In: Rezai ESKHPR, editor. *Neuromodulation*. San Diego: Academic Press; 2009. p. 243–81.
30. IEC., IEC, 3, rue de Varembe´, P.O. Box 131, CH-1211Geneva 20, Switzerland. IEC 60601-2-33: Particular requirements for the basic safety and essential performance of Magnetic Resonance Diagnostic Equipment n.d.

31. Nyenhuis JA., Sung-Min Park., Kamondetdacha R., Amjad A., Shellock FG., Rezai AR. MRI and implanted medical devices: basic interactions with an emphasis on heating. *IEEE Trans Device Mater Reliab* 2005;**5**(3):467–80. Doi: 10.1109/TDMR.2005.859033.
32. Gupte AA., Shrivastava D., Spaniol MA., Abosch A. MRI-Related Heating near Deep Brain Stimulation Electrodes: More Data Are Needed. *Stereotact Funct Neurosurg* 2011;**89**(3):131–40. Doi: 10.1159/000324906.
33. Finelli DA., Rezai AR., Ruggieri PM., Tkach JA., Nyenhuis JA., Hrdlicka G., et al. MR Imaging-Related Heating of Deep Brain Stimulation Electrodes: In Vitro Study. *Am J Neuroradiol* 2002;**23**(10):1795–802.
34. Jech R., Urgošík D., Tintěra J., Nebuželský A., Krásenský J., Liščák R., et al. Functional magnetic resonance imaging during deep brain stimulation: A pilot study in four patients with Parkinson's disease. *Mov Disord* 2001;**16**(6):1126–32. Doi: 10.1002/mds.1217.
35. Rezai AR., Finelli D., Nyenhuis JA., Hrdlicka G., Tkach J., Sharan A., et al. Neurostimulation systems for deep brain stimulation: in vitro evaluation of magnetic resonance imaging-related heating at 1.5 tesla. *J Magn Reson Imaging JMRI* 2002;**15**(3):241–50.
36. Henderson JM., Tkach J., Phillips M., Baker K., Shellock FG., Rezai AR. Permanent Neurological Deficit Related to Magnetic Resonance Imaging in a Patient with Implanted Deep Brain Stimulation Electrodes for Parkinson???s Disease: Case Report. *Neurosurgery* 2005;**57**(5):E1063. Doi: 10.1227/01.NEU.0000180810.16964.3E.
37. Spiegel J., Fuss G., Backens M., Reith W., Magnus T., Becker G., et al. Transient dystonia following magnetic resonance imaging in a patient with deep brain stimulation electrodes for the treatment of Parkinson disease. Case report. *J Neurosurg* 2003;**99**(4):772–4. Doi: 10.3171/jns.2003.99.4.0772.
38. International Organization for Standardization ISO/TS 10974:2012 - Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device. Available at http://www.iso.org/iso/catalogue_detail.htm?csnumber=46462. Accessed August 19, 2015.
39. Baker KB., Tkach JA., Nyenhuis JA., Phillips M., Shellock FG., Gonzalez-Martinez J., et al. Evaluation of specific absorption rate as a dosimeter of MRI-related implant heating. *J Magn Reson Imaging JMRI* 2004;**20**(2):315–20. Doi: 10.1002/jmri.20103.
40. Delfino JG., Woods TO. New Developments in Standards for MRI Safety Testing of Medical Devices. *Curr Radiol Rep* 2016;**4**(6):1–9. Doi: 10.1007/s40134-016-0155-y.
41. ASTM ASTM F2182 Standard Test Method for Measurement of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging, ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428. Available at http://www.nature.com/sc/journal/v50/n4/pdf/sc2011135a.pdf. Accessed August 17, 2015.
42. Mutter UM., Bellut D., Porchet F., Schuknecht B. Spinal magnetic resonance imaging with reduced specific absorption rate in patients harbouring a spinal cord stimulation device - A single-centre prospective study analysing safety, tolerability and image quality. *Acta Neurochir (Wien)* 2013;**155**(12):2327–32. Doi: 10.1007/s00701-013-1885-8.
43. Rösch J., Hamer HM., Mennecke A., Kasper B., Engelhorn T., Doerfler A., et al. 3T-MRI in patients with pharmacoresistant epilepsy and a vagus nerve stimulator: A pilot study. *Epilepsy Res* 2015;**110**:62–70. Doi: 10.1016/j.eplepsyres.2014.11.010.
44. Heidemann RM., Ozsarlak O., Parizel PM., Michiels J., Kiefer B., Jellus V., et al. A brief review of parallel magnetic resonance imaging. *Eur Radiol* 2003;**13**(10):2323–37. Doi: 10.1007/s00330-003-1992-7.
45. Carmichael DW., Pinto S., Limousin-Dowsey P., Thobois S., Allen PJ., Lemieux L., et al. Functional MRI with active, fully implanted, deep brain stimulation systems: Safety and experimental confounds. *NeuroImage* 2007;**37**(2):508–17.
46. Kahan J., Papadaki A., White M., Mancini L., Yousry T., Zrinzo L., et al. The Safety of Using Body-Transmit MRI in Patients with Implanted Deep Brain Stimulation Devices. *PLoS ONE* 2015;**10**(6):e0129077. Doi: 10.1371/journal.pone.0129077.

47. Georgi J-C., Stippich C., Tronnier V m., Heiland S. Active deep brain stimulation during MRI: A feasibility study. *Magn Reson Med* 2004;**51**(2):380–8. Doi: 10.1002/mrm.10699.
48. Baker KB., Nyenhuis JA., Hrdlicka G., Rezai AR., Tkach JA., Shellock FG. Neurostimulation systems: assessment of magnetic field interactions associated with 1.5- and 3-Tesla MR systems. *J Magn Reson Imaging JMRI* 2005;**21**(1):72–7. Doi: 10.1002/jmri.20224.
49. Baker KB., Tkach J., Phillips MD. In vitro studies of MRI-related heating of neurostimulation systems. *Magn Reson Imaging* 2006;**24**(5):677-679-680. Doi: 10.1016/j.mri.2005.08.001.
50. Bhidayasiri R., Bronstein JM., Sinha S., Krahl SE., Ahn S., Behnke EJ., et al. Bilateral neurostimulation systems used for deep brain stimulation: in vitro study of MRI-related heating at 1.5 T and implications for clinical imaging of the brain. *Magn Reson Imaging* 2005;**23**(4):549–55. Doi: 10.1016/j.mri.2005.02.007.
51. Uitti RJ., Tsuboi Y., Pooley RA., Putzke JD., Turk MF., Wszolek ZK., et al. Magnetic resonance imaging and deep brain stimulation. *Neurosurgery* 2002;**51**(6):1423-1428-1431.
52. Sharan A., Rezai AR., Nyenhuis JA., Hrdlicka G., Tkach J., Baker K., et al. MR safety in patients with implanted deep brain stimulation systems (DBS). In: Katayama PY, editor. *Neurosurgical Re-Engineering of the Damaged Brain and Spinal Cord*. Springer Vienna; 2003. p. 141–5.
53. Starr PA. Placement of deep brain stimulators into the subthalamic nucleus or Globus pallidus internus: technical approach. *Stereotact Funct Neurosurg* 2002;**79**(3–4):118–45. Doi: 70828.
54. Larson PS., Richardson RM., Starr PA., Martin AJ. Magnetic resonance imaging of implanted deep brain stimulators: experience in a large series. *Stereotact Funct Neurosurg* 2008;**86**(2):92–100. Doi: 10.1159/000112430.
55. Kovacs N., Nagy F., Kover F., Feldmann A., Llumiguano C., Janszky J., et al. Implanted deep brain stimulator and 1.0-Tesla magnetic resonance imaging. *J Magn Reson Imaging* 2006;**24**(6):1409–12. Doi: 10.1002/jmri.20779.
56. Starr PA., Martin AJ., Ostrem JL., Talke P., Levesque N., Larson PS. Subthalamic nucleus deep brain stimulator placement using high-field interventional magnetic resonance imaging and a skull-mounted aiming device: technique and application accuracy. *J Neurosurg* 2010;**112**(3):479–90. Doi: 10.3171/2009.6.JNS081161.
57. Vasques X., Tancu C., Cif L., Biolsi B., Maldonado I., Bonafe A., et al. Cerebral magnetic resonance imaging feasibility in patients with implanted neurostimulation system for deep brain stimulation. *Open Magn Reson J* 2008;**1**(1):1–8.
58. Chhabra V., Sung E., Mewes K., Bakay RAE., Abosch A., Gross RE. Safety of magnetic resonance imaging of deep brain stimulator systems: a serial imaging and clinical retrospective study. *J Neurosurg* 2010;**112**(3):497–502. Doi: 10.3171/2009.7.JNS09572.
59. Fraix V., Chabardes S., Krainik A., Seigneuret E., Grand S., Le Bas J-F., et al. Effects of magnetic resonance imaging in patients with implanted deep brain stimulation systems. *J Neurosurg* 2010;**113**(6):1242–5. Doi: 10.3171/2010.1.JNS09951.
60. Nazzaro JM., Lyons KE., Wetzel LH., Pahwa R. Use of brain MRI after deep brain stimulation hardware implantation. *Int J Neurosci* 2010;**120**(3):176–83. Doi: 10.3109/00207450903389156.
61. Weise LM., Schneider GH., Kupsch A., Haumesser J., Hoffmann KT. Postoperative MRI examinations in patients treated by deep brain stimulation using a non-standard protocol. *Acta Neurochir (Wien)* 2010;**152**(12):2021–7. Doi: 10.1007/s00701-010-0738-y.
62. Medtronic, Inc. MRI Eligibility and Guidelines. Available at https://professional.medtronic.com/europe/clinicians/mri-eligibility-guidelines/index.htm#.V08wMeSuO6M. Accessed June 1, 2016.
63. Elkelini MS., Hassouna MM. Safety of MRI at 1.5Tesla in patients with implanted sacral nerve neurostimulator. *Eur Urol* 2006;**50**(2):311–6. Doi: 10.1016/j.eururo.2006.02.011.
64. Chermansky CJ., Krlin RM., Holley TD., Woo HH., Winters JC. Magnetic resonance imaging following interstim®: An institutional experience with imaging safety and patient satisfaction. *Neurourol Urodyn* 2011;**30**(8):1486–8. Doi: 10.1002/nau.21147.

65. Medtronic, Inc. MRI Guidelines for InterStim Therapy neurostimulation systems 2012-02. Available at http://manuals.medtronic.com/wcm/groups/mdtcom_sg/@emanuals/@era/@neuro/documents/documents/contrib_214172.pdf. Accessed August 17, 2015.
66. Liem LA., van Dongen VCPC. Magnetic resonance imaging and spinal cord stimulation systems. *Pain* 1997;**70**(1):95–7. Doi: 10.1016/S0304-3959(96)03298-8.
67. De Andres J., Valía JC., Cerda-Olmedo G., Quiroz C., Villanueva V., Martinez-Sanjuan V., et al. Magnetic resonance imaging in patients with spinal neurostimulation systems. *Anesthesiology* 2007;**106**(4):779–86. Doi: 10.1097/01.anes.0000264776.17533.06.
68. Kiriakopoulos ET., Tasker RR., Nicosia S., Wood ML., Mikulis DJ. Functional magnetic resonance imaging: a potential tool for the evaluation of spinal cord stimulation: technical case report. *Neurosurgery* 1997;**41**(2):501–4.
69. St Jude Medical. MRI Procedure Information For St. Jude Medical MR Conditional Neurostimulation Systems; Clinician's Manual; St. Jude Medical 2015. Available at https://manuals.sjm.com/Search-Form?re=Europe&cc=GB&ln=all&cat=171340ad-f11e-497f-b034-b0bc02f96e79&seg=f213a464-9b89-4313-9b00-d587f2c44d16&ipp=10. Accessed June 3, 2016.
70. Medtronic Inc. MRI guidelines for Medtronic neurostimulation systems for chronic pain. Available at http://manuals.medtronic.com/wcm/groups/mdtcom_sg/@emanuals/@era/@neuro/documents/documents/contrib_171957.pdf. Accessed June 3, 2016.
71. Boston Scientific. ImageReady™ MRI Guidelines for Precision Spectra™ Spinal Cord Stimulator System; 2014 Boston Scientific Corporation. Available at http://hcp.controlyourpain.com/hcp/assets/File/90894518_ImagerReady%20MRI%20Guidelines.pdf. Accessed June 3, 2016.
72. Boston Scientific. Precision Montage™ MRI Spinal Cord Stimulator System. Available at http://www.bostonscientific.com/en-US/products/spinal-cord-stimulator-systems/precision_montage.html. Accessed June 3, 2016.
73. Benbadis SR., Nyhenhuis J., Tatum IV WO., Murtagh FR., Gieron M., Vale FL. MRI of the brain is safe in patients implanted with the vagus nerve stimulator. *Seizure* 2001;**10**(7):512–5. Doi: 10.1053/seiz.2001.0540.
74. Shellock FG., Begnaud J., Inman DM. Vagus nerve stimulation therapy system: in vitro evaluation of magnetic resonance imaging-related heating and function at 1.5 and 3 tesla. *Neuromodulation J Int Neuromodulation Soc* 2006;**9**(3):204–13. Doi: 10.1111/j.1525-1403.2006.00061.x.
75. Gorny KR., Bernstein MA., Watson RE. 3 tesla MRI of patients with a vagus nerve stimulator: Initial experience using a T/R head coil under controlled conditions. *J Magn Reson Imaging* 2010;**31**(2):475–81. Doi: 10.1002/jmri.22037.
76. de Jonge JC., Melis GI., Gebbink TA., de Kort GAP., Leijten FSS. Safety of a dedicated brain MRI protocol in patients with a vagus nerve stimulator. *Epilepsia* 2014;**55**(11):e112–5. Doi: 10.1111/epi.12774.
77. Cyberonics. VNS Therapy® System Physician's Manual; Cyberonics, Feb 2016. Available at http://dynamic.cyberonics.com/manuals/emanual_download.asp?lang=English-US&docid={FBDBD88D-3168-4B65-8931-E964A7D5768B}. Accessed June 3, 2016.
78. Zeng FG., Rebscher S., Harrison W., Sun X., Feng H. Cochlear Implants: System Design, Integration, and Evaluation. *IEEE Rev Biomed Eng* 2008;**1**:115–42. Doi: 10.1109/RBME.2008.2008250.
79. Broomfield SJ., Cruz MD., Gibson WPR. Cochlear implants and magnetic resonance scans: A case report and review. *Cochlear Implants Int* 2013;**14**(1):51–5. Doi: 10.1179/1754762811Y.0000000027.

80. Azadarmaki R., Tubbs R., Chen DA., Shellock FG. MRI Information for Commonly Used Otologic Implants Review and Update. *Otolaryngol -- Head Neck Surg* 2014;**150**(4):512–9. Doi: 10.1177/0194599813518306.
81. Hassepass F., Stabenau V., Arndt S., Beck R., Bulla S., Grauvogel T., et al. Magnet Dislocation: An Increasing and Serious Complication Following MRI in Patients with Cochlear Implants. *RöFo - Fortschritte Auf Dem Geb Röntgenstrahlen Bildgeb Verfahr* 2014;**186**(7):680–5. Doi: 10.1055/s-0033-1356238.
82. Hassepass F., Stabenau V., Maier W., Arndt S., Laszig R., Beck R., et al. Revision Surgery Due to Magnet Dislocation in Cochlear Implant Patients: An Emerging Complication. *Otol Neurotol* 2014;**35**(1):29–34. Doi: 10.1097/MAO.0b013e3182a5d2c5.
83. Carlson ML., Neff BA., Link MJ., Lane JI., Watson RE., McGee KP., et al. Magnetic Resonance Imaging With Cochlear Implant Magnet in Place: Safety and Imaging Quality. *Otol Neurotol* 2015;**36**(6):965–71. Doi: 10.1097/MAO.0000000000000666.
84. Kim B, Kim J, Park J, Kim S, Kim H, Choi J ADverse events and discomfort during magnetic resonance imaging in cochlear implant recipients. *JAMA Otolaryngol Neck Surg* 2015;**141**(1):45–52. Doi: 10.1001/jamaoto.2014.2926.
85. Kanal E Magnetic resonance imaging in cochlear implant recipients: Pros and cons. *JAMA Otolaryngol Neck Surg* 2015;**141**(1):52–3. Doi: 10.1001/jamaoto.2014.2932.
86. Medtronic Inc. MRI guidelines for Medtronic deep brain stimulation systems. Available at http://manuals.medtronic.com/wcm/groups/mdtcom_sg/@emanuals/@era/@neuro/documents/documents/contrib_228155.pdf. Accessed June 3, 2016.
87. Gorny KR., Presti MF., Goerss SJ., Hwang SC., Jang D-P., Kim I., et al. Measurements of RF heating during 3.0-T MRI of a pig implanted with deep brain stimulator. *Magn Reson Imaging* 2013;**31**(5):783–8. Doi: 10.1016/j.mri.2012.11.005.
88. Shrivastava D., Abosch A., Hughes J., Goerke U., DelaBarre L., Visaria R., et al. Heating induced near deep brain stimulation lead electrodes during magnetic resonance imaging with a 3 T transceive volume head coil. *Phys Med Biol* 2012;**57**(17):5651–65. Doi: 10.1088/0031-9155/57/17/5651.
89. ASTM International, West Conshohocken, PA,. ASTM F2503-13, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment 2013. Doi: 10.1520/F2503.