Safety and Management of Implanted Epilepsy Devices for Imaging and Surgery

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Abstract

Permanently implanted devices that deliver electrical stimulation are increasingly used to treat patients with drug-resistant epilepsy. Primary care physicians, neurologists, and epilepsy clinicians may encounter patients with a variety of implanted neuromodulation devices in the course of clinical care. Due to the rapidly changing landscape of available epilepsy-related neurostimulators, there may be uncertainty related to how these devices should be handled during imaging procedures and perioperative care. We review the safety and management of epilepsy-related implanted neurostimulators that may be encountered during imaging and surgery. We provide a summary of approved device labeling and recommendations for the practical management of these devices to help guide clinicians as they care for patients treated with bioelectronic medicine.

Neuromodulation is a promising palliative approach to the treatment of patients with drug-resistant epilepsy who are not candidates for epilepsy therapy from resective or ablative surgeries. These implanted neurostimulators are generally more effective in reducing seizures and sudden death than additional antiseizure medications, but they rarely render patients seizure-free. Advantages of neuromodulation include a lack of systemic adverse effects, allergic reactions, and drug-drug interactions, all of which are typical for medications. The mechanisms of action for neurostimulators distinctly differ from those for antiseizure medications; the devices can improve compliance and day-to-day delivery of therapy, and stimulation can improve overall quality of life. However, there are associated surgical risks and adverse effects related to permanently implanted hardware. Furthermore, devices require ongoing care (eg, recharging or changing the battery).

Neuromodulation for epilepsy has advanced considerably in the past several decades. There are 3 US Food and Drug Administration (FDA)—approved stimulation approaches for the treatment of epilepsy: vagus nerve stimulation (VNS), responsive neurostimulation (RNS), and deep brain stimulation (DBS) of the anterior nucleus of the thalamus (Figure 1). Stimulation devices are increasingly used to treat patients with drug-resistant epilepsy. Patients receive an implantable pulse generator (IPG) that is connected to multiple intracranial electrodes (RNS or DBS) or vagus nerve electrodes (VNS). Electrical stimulation therapy is then typically adjusted via multiple parameters. For VNS and RNS, these settings are adjusted by clinician programmers only. For DBS, some parameter adjustments may be made by patient programmers.

Permanently implanted neurostimulators are increasingly used to treat epilepsy. More than 125,000 VNS devices have been implanted, and the number of DBS and RNS implants has increased dramatically in recent years. For this reason, neurostimulators are increasingly encountered during elective, urgent, and emergency medical procedures.
situations requiring imaging and surgery for neurologic and medical indications. The variety of devices can lead to uncertainty and confusion for physicians and care providers. Although there are significant data guiding practice in how devices are handled related to imaging, there is relatively more uncertainty in the perioperative period. The goal of this review is to provide background and rationale for device labeling, current recommendations, and the authors’ opinions regarding how epilepsy devices can be safely managed during imaging and surgery. Note that current recommendations and guidelines for safe device management are updated regularly, and the most recent information from device manufacturers should always be consulted.

**ARTICLE HIGHLIGHTS**

- Permanently implanted hardware that provides ongoing electrical stimulation is increasingly used to treat patients with epilepsy.
- Permanent neurologic injury may occur when electrical safety measures are not followed.
- Safely managing these devices in the setting of magnetic resonance imaging and surgical procedures requires unique considerations.

**FDA-APPROVED INVASIVE STIMULATION DEVICES FOR THE TREATMENT OF EPILEPSY**

The VNS (LivaNova PLC) was approved for use by the FDA in 1997 and is currently approved as adjunctive treatment for patients 4 years and older with drug-resistant focal epilepsy.1,7-9 Surgical risks of implantation, including infection, vascular damage (eg, to the carotid artery or jugular vein), and vocal cord paresis (∼1%), are rare.6 Stimulation-induced adverse effects include hoarseness, cough, shortness of breath, and paresthesia.9 The VNS IPG is typically placed in the upper left chest inferior to the clavicle7 because stimulation of the left vagus nerve is less likely to cause cardiac effects.10 Each IPG is powered by a single battery that requires replacement at the end of service, typically 3 to 8 years, depending on the device model and setting parameters. The most current model VNS uses a single subcutaneously placed lead wire tunneled to reach the left vagus nerve to provide bilateral stimulation that transmits an electrical current from the left vagus nerve to the brain on an ongoing basis as well as in response to patient or caregiver activation with a magnet swipe over the device. The most recent model includes a closed-loop system triggered by an increase in heart rate designed to precede seizure onset that has been associated with reduced seizure severity and further improvements in seizure frequency over the open-loop system.11-13 Surgery is minimally invasive and is performed in an outpatient setting. In contrast to DBS and RNS, VNS does not require cranial surgery.

Deep brain stimulation of the anterior nucleus of thalamus was FDA-approved in 2018 for use in adults for drug-resistant focal epilepsy (Medtronic Inc), after the SANTE (Stimulation of the Anterior Nucleus of the Thalamus) trial.14 Deep brain stimulation is more widely used for movement disorders such as essential tremor and Parkinson disease, with initial FDA approval for these indications in 1997,15 and there are now multiple manufacturers with device approvals. The DBS system consists of an IPG located in the chest, similar to that in VNS, with leads implanted into the brain and targeting the bilateral anterior nucleus of the thalamus.

Responsive neurostimulation (NeuroPace Inc) was FDA-approved in 2013 for the treatment of drug-resistant focal epilepsy in adults.16 Unlike VNS and DBS, in which the IPG is typically implanted in the chest with relatively long leads to their targets at the vagus nerve and thalamus, respectively, the IPG for RNS is cranially mounted with electrodes targeting seizure-related brain regions. The RNS system provides closed-loop stimulation such that stimulation is provided after electrographic activity is detected, eg, over the clinically determined seizure onset zone in the cortex. The goal is to stop seizures before progression to
generalization and to reduce seizure frequency. The RNS system is capable of providing real-time intracranial electrocorticography and post hoc recordings of detected events. Although intracranial activity is monitored continuously, limited amounts of data (~10 minutes) are stored on the neurostimulator; data are frequently uploaded to cloud-based storage.

These stimulation devices are typically considered to be adjunctive and palliative approaches for seizure control. Results for DBS and RNS show an approximate 50% reduction in seizures after 1 year for at least one-half of patients, with VNS typically considered to be somewhat less efficacious.\(^4,7,17\) For all these devices, seizure reduction tends to improve over time.

**IMAGING SAFETY**

Comprehensive guidelines determining when magnetic resonance (MR) imaging (MRI) can be safely performed with implanted stimulation devices have been published.\(^18\) We focus on approved conditions for safe MRI for neurostimulation systems designed to treat people with epilepsy (Table 1). Commonly used neurostimulators are designated as either MRI unsafe or MRI conditional. In fact, any metal-containing implanted device cannot, by definition, be considered MRI safe. Ferrous-containing implants are subject to attraction and torque related to the static magnetic field. Modern IPGs contain a small amount of ferromagnetic material, which is mostly contained in the battery. However, even nonferrous metals (eg, contained in the lead, lead extension, and IPG) pose a safety hazard insofar as they can serve as conductors with radiofrequency (RF) fields, leading to dangerous heating. Due to the Lenz effect,\(^19\) patients may experience a sense of “tugging” in the region of the IPG when moving relative to the static magnetic field, especially when crossing the bore of the magnet. Magnetic resonance conditional labeling indicates that the MRI examination can be performed safely if all the specific conditions for scanning are strictly adhered to. Essential MRI safety requires precise and accurate identification of the pulse

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**FIGURE 1.** A, Illustration of 3 different Food and Drug Administration—approved stimulation approaches for the treatment of epilepsy: deep brain stimulation (DBS), responsive neurostimulation (RNS), and vagus nerve stimulation (VNS). Approaches differ in their primary targets (seizure onset zone vs seizure node) and primary stimulation method (duty cycle/continuous or responsive). Images show the DBS (B), RNS (C), and VNS (D) devices. Part A used with permission of Mayo Foundation for Medical Education and Research, all rights reserved.
<table>
<thead>
<tr>
<th>Device</th>
<th>Model</th>
<th>Imaging Recommendations</th>
<th>Surgery Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>LivaNova VNS</td>
<td>Demipulse 103, AspireHC 105, AspireSR 106, SenTiva 1000</td>
<td>MRI 1.5T and 3T conditional if device is between C7 and T8 vertebrae; Interrogate and turn off stimulation and any optional features (including Magnet and AutoStim modes)</td>
<td>No transmit coil for C7-T8; Avoid electrocautery near the device; confirm generator functions as programmed after surgery; Device may remain on during surgical procedures with cardiac monitoring. Consider turning device off, especially for high-risk patients; electrocautery can damage the device or alter stimulation.</td>
</tr>
<tr>
<td>NeuroPace RNS</td>
<td>RNS-320</td>
<td>MRI 1.5T conditional; Place in MRI mode (no detection or stimulation provided); patient should be supine; active scan time limited to &lt;30 min per session</td>
<td>Time in MRI mode should be limited to &lt;2 d per year as it is energy intensive; no transmit head or extremity coils; If possible, stop device stimulation using a programmer; bipolar electrocautery recommended, &gt;2 cm from device, monopolar electrocautery should not be used; Device may remain on during surgical procedures; electrocautery can damage the device or alter stimulation.</td>
</tr>
<tr>
<td>Medtronic DBS</td>
<td>Activa PC 37601, Activa SC 37603, Activa RC 37612, Percept B35200</td>
<td>MRI 1.5T conditional, full-body eligible; Interrogate and MRI mode with therapy off or in bipolar configuration</td>
<td>Percept B35200 is MRI 3T conditional; If possible, turn off stimulator before electrocautery; bipolar electrocautery recommended; Device may remain on during surgical procedures; electrocautery can damage the device or alter stimulation.</td>
</tr>
</tbody>
</table>

DBS, deep brain stimulator; FDA, Food and Drug Administration; MRI, magnetic resonance imaging; RNS, responsive neurostimulator; VNS, vagus nerve stimulator.
generator and leads in the stimulator system, the physical location in the body of the device, any orphaned hardware, programming/settings of the IPG, the body region being imaged, and the type of MRI coil to be used. In addition, MRI uses 3 primary fields to create images that can interfere with implanted electronic components: a strong static magnetic field ($B_0$), a strong RF field ($B_1$), and rapidly changing gradient magnetic fields ($dB/dt$). Safe scanning requires knowing the static magnetic field strength ($B_0$), static magnetic spatial gradient ($dB/dx$), rate of change of time-varying magnetic fields ($dB/dt$), intensity of RF fields (such as $B_1 + \text{rms}$ or the associated specific absorption rate [SAR]), and duration of MRI scan. Radiofrequency waves are perhaps the most concerning because they can induce electrical currents, especially in long leads, and cause local heating and tissue damage. At present, commercial devices are approved only for 1.5T and 3T, and not for other field strengths such as 7T.

Although older devices were frequently overtly MR unsafe, increasingly implanted devices are being engineered with important modifications, such as RF shielding of leads and circuitry, that permit MRI conditional safe scanning. However, issues relating to devices and MRI are complex, and striking examples exist of what can go wrong (Figure 2).

Many previous studies of epilepsy-related device safety have focused on issues related to imaging as well as VNS-induced heart rate or breathing changes. From a historical perspective, early multicenter experience suggested that VNS devices could be imaged safely. Recent work ($n = 73$ patients) has supported safe use for 1.5T and 3T MRI. An additional study of 4 patients reported safety with VNS and 1.5T functional MRI with the device turned on. For Medtronic DBS systems FDA-approved for epilepsy, accepted imaging conditions include restricting stimulation to either bipolar stimulation or no stimulation and restrictions on the use

![FIGURE 2. Tissue damage to the left thalamus resulting from magnetic resonance imaging (MRI) and radiofrequency heating, seen in a computed tomography scan (A) and a T2-weighted fluid-attenuated inversion recovery MRI (B). The patient had a deep brain stimulation pulse generator permanently implanted in the abdomen and underwent lumbar spine MRI. From Neurosurgery, with permission.](image-url)
of transmit and receive body coils. Studies have supported imaging safety, and at times imaging may be safe outside of these restrictions, such as with monopolar stimulation at native settings. However, caveats remain. The authors of this last study concluded that routine 3T MRI protocols with T2-weighted sequences should be avoided but that transmit body multiarray receive coils may be safe. Furthermore, major adverse events have also been reported, such as a major thalamic hemorrhage leading to permanent deficits from an MRI not performed per approved safety protocols. Specifically, a lumbar 1.0T MRI was performed using the body transmit coil in a patient with an IPG in the abdomen due to patient preference with resulting tissue damage (Figure 2). In 2020, the FDA approved MRI conditional labeling of the NeuroPace RNS device. In general, implanted devices undergo rigorous testing to receive FDA approval and can be imaged safely under tested conditions.

SURGICAL SAFETY

Safety data related to non—device-related surgical procedures are largely limited to VNS devices. Although manufacturer labeling makes no recommendations regarding ongoing stimulation during anesthesia, VNS carries risks to breathing and heart rate control during surgery. Bradycardia and asystole have been seen intraoperatively during initial testing at the time of device implantation, during intraoperative lead testing with VNS, and with long-term stimulation. Lead placement and safety is typically tested intraoperatively by applying a 30- to 60-second pulse of current (1 mA, 500-microsecond pulse width, 20-30 Hz). Most patients with marked bradycardia or asystole during lead testing did not go on to receive a permanent implant and had a subsequent unremarkable cardiac evaluation, although 1 patient required intraoperative cardiopulmonary resuscitation. Several patients received a permanent implant and responded well to VNS therapy. More gradual increases in stimulation amplitude may avoid symptomatic effects. Overall, the risk of asystole has been estimated to be 0.1%, and very few cases of bradycardia have been reported. Even years after implant, VNS can induce symptomatic bradycardia or ventricular asystole for unclear reasons. At least in 1 patient, the new-onset symptoms were not present when stimulation amplitude was lowered. Finally, VNS has been noted to diminish airway patency and contribute to sleep apnea. Perioperative management of these patients may include reducing use of narcotics.

Clinical data are limited regarding specific safety concerns for other issues related to neurostimulation devices for epilepsy. Electrocautery, RF ablation, extracorporeal shock wave lithotripsy, and defibrillation or cardioversion could potentially cause malfunction or deprogramming of the device. Bipolar electrocautery leads to a reduced electromagnetic field compared with monopolar electrocautery and may carry less of a risk of damage to a neurostimulator device, although monopolar electrocautery has been used safely. A summary of recommendations is presented in Table 1 (and are subject to change).

RECOMMENDED CLINICAL WORKFLOW FOR IMAGING SAFETY

The general approach to ensure the safety of MRI for patients with implanted neurostimulators requires close collaboration of a multidisciplinary team. The workflow at Mayo Clinic includes the following key steps, which are performed by a senior MRI technologist, frequently an MRI safety officer:

1. Unambiguously identify the precise make and model of both the IPG and leads of the neurostimulator system, as well as the physical location in the body of the IPG and leads to determine whether the system is MRI unsafe or potentially MRI conditional.
2. Obtain the latest MRI safety guidelines for MRI conditional systems recommended by
the device manufacturer to determine whether the facility has the MRI scanner (ie, appropriate field strength), appropriate imaging coils, and other needed equipment to perform the MRI study safely. An MRI medical physicist may be consulted for clarification (eg, altering pulse sequences so that diagnostic-quality images can be obtained while continuing to satisfy the MRI conditions related to the different fields to ensure patient safety).

3. Pre-MRI device interrogation and programming of the neurostimulator to an “off” or “safe” mode.

4. Take a “time-out” before the MRI examination to ensure that all the safety checks have been completed and the safety conditions during the examination are clearly understood.

5. Radiology technologists should closely monitor the patient and maintain compliance of safety conditions during the MRI examination. The predicted RF intensity or RF energy deposition is checked before each sequence, and a medical physicist may be present to optimize the MRI parameters.

6. Post-MRI device interrogation and reprogramming of the neurostimulator if needed.

This workflow is captured as a site-specific step-by-step check list that accounts for variations in scheduling, staff, and equipment, and it should be repeated before each examination.

**IMAGING RECOMMENDATIONS**

**Vagus Nerve Stimulation**

Guidelines for the VNS system are listed in Table 2 (and are subject to change). LivaNova VNS devices can be categorized as newer devices (group A) and devices that require more restrictive parameters for safe imaging (group B). Device implant location can determine whether a device is in group A or B. For example, a model SenTiva 1000 device is in group A if implanted in the recommended location of the left chest above rib 4; it is in group B if it is implanted elsewhere. Imaging (eg, radiography) is obtained if there is any uncertainty as to the device location. Group B devices require the use of a local transmit and receive RF coil such as a transmit and receive head coil. In contrast, body transmit RF coils can be used with group A devices, which can lead to improved imaging quality. It is critical to avoid scanning a group B device using group A parameters.

For VNS, devices should be implanted between C7-T8. Devices implanted outside C7-T8 have not been evaluated for safety. A head or extremity transmit coil may be used if the placement of the entire coil is outside of C7-T8. For group A, the body transmit coil may be used if the isocenter — the center point of the magnetic field — is located outside of C7-L3. For group B, body transmit coils should not be used. Given more permissive conditions for Group A, lower body scans, eg, lumbar spine,
pelvic, or upper thigh imaging, may be obtained. When the body transmit coil is used for transmitting RF, local coils may be used for receiving. However, the MRI isocenter must still be excluded from C7-L3. When body transmit coil is used, there is also a limit of less than 15 minutes active scan time within a 30 minute window. The key point is that the VNS system must not be exposed to an RF field from a local transmit RF coil and energy from a body transmit coil must be limited.

For the newest devices implanted per manufacturer labeling, safe imaging parameters include a static magnetic field of 3.0T, a spatial field gradient of 30T/m or less, a gradient slew rate of 200T/m per second or less, and an average head SAR of 3.2 W/kg or less when using a head or extremity transmit RF coil. More generally, 1.5T and 3T images can be safely acquired using body and head coils per the specific conditions in the approved labeling. When a VNS IPG is explanted, sometimes the lead is transected and a portion of the lead is retained in the body. Lead anchors are typically left in place on the vagus nerve to prevent any nerve damage that could occur if

### TABLE 2. MRI Eligibility Criteria and Preparation Instructions for VNS Patients

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generator model</td>
<td>103, 105, 106, 1000, 8103</td>
<td>103, 105, 106, 1000, 8103</td>
</tr>
<tr>
<td>Generator location</td>
<td>Upper left chest at or above rib 4</td>
<td>Location other than upper left chest in C7-T8</td>
</tr>
<tr>
<td>Model</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All models</td>
<td>Interrogate and record settings for post-MRI restoration</td>
<td>Perform system diagnostics</td>
</tr>
<tr>
<td></td>
<td>Set normal output current: 0 mA; magnet current: 0 mA</td>
<td></td>
</tr>
<tr>
<td>106, 1000</td>
<td>Set detection: “OFF”; AutoStim output current: 0 mA</td>
<td></td>
</tr>
<tr>
<td>1000</td>
<td>Turn off other optional features</td>
<td></td>
</tr>
</tbody>
</table>

### MRI conditions of VNS patients

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scanner type</td>
<td>Horizontal, closed-bore, cylindrical MRI system</td>
<td>Models 100C and 101: ≤7.2T/m; models 102 through 1000 and 8103: ≤30T/m</td>
</tr>
<tr>
<td>Static magnetic field</td>
<td>1.5T or 3.0T</td>
<td></td>
</tr>
<tr>
<td>Spatial field gradient</td>
<td>≤30T/m</td>
<td></td>
</tr>
<tr>
<td>Gradient slew rate</td>
<td>≤200T/m per second</td>
<td></td>
</tr>
<tr>
<td>Transmit RF coil</td>
<td>Head or extremity coil</td>
<td>Circularly polarized body coil</td>
</tr>
<tr>
<td>SAR</td>
<td>Average head SAR ≤3.2 W/kg (normal mode)</td>
<td>Average whole-body SAR ≤2.0 W/kg (normal mode)</td>
</tr>
<tr>
<td>Active scan time or exposure time</td>
<td>No restriction</td>
<td>≤15 min within a 30-min window</td>
</tr>
</tbody>
</table>

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*MRI, magnetic resonance imaging; RF, radiofrequency; SAR, specific absorption rate; VNS, vagus nerve stimulator.

†The entire head coil must be outside of C7-T8.

‡Isocenter of scan must be outside of C7-L3.

lead anchors were removed, ie, the VNS lead is typically cut, and a portion of the lead remains. If the retained in situ lead is 2 cm or less, as assessed by radiography, scanning under group A conditions is permitted. If retained leads are greater than 2 cm, such as when the lead is not transected right next to the nerve, then a full-body MRI is not allowed and group B conditions apply to avoid dangerous heating.

Deep Brain Stimulation
Guidelines for the Medtronic DBS system are listed in Table 3 (and are subject change). In general, safe imaging parameters include a static magnetic field of 1.5T, a spatial field gradient of 19T/m or less, a gradient slew rate of 200T/m per second or less, and an average SAR of 0.1 W/kg or less (when \( B_1^{+} \) is not predicted by the scanner). The newest DBS system (model Percept B33005/B33015) is eligible for full-body scan at 3T as well as 1.5T. Due to reports of permanent neurologic injury, there had been an abundance of caution performing MRI in patients with DBS. However, the most recent DBS device systems manufactured by all 3 major DBS companies in the United States are now FDA-listed as MRI conditional. Some systems are approved for full-body scans, and others for head-only scans. Newer systems have an “MRI mode” that can be engaged to protect the system during a scan, and other guidelines designate specific settings for safe scanning. There are also guidelines regarding “lead-only” systems (eg, those where leads have been placed and capped but are not connected to the battery/pulse generator). Anchoring caps and covers do not add restrictions to the imaging protocol. Abandoned components are a contraindication for MRI, as are adapters. Implanted systems may simultaneously reduce the amount of time to scan (due to concerns for heating) while also prolonging the length of time the sequences take. During scanning, patients may feel heating at the neurostimulator site. If the heating causes patient discomfort, the MRI must be stopped immediately. Imaging artifacts from DBS leads are primarily related to susceptibility-induced distortions and signal loss. For most sequences, these artifacts are typically in the range of 0.2 to 1 cm in diameter surrounding the lead, which produces minimal obscuration of total brain volume (Figure 4).

Responsive Neurostimulation
Guidelines for the NeuroPace RNS systems are listed in Table 4 (and are subject to change). The original RNS device RNS-300M is considered MRI unsafe. The RNS-320 neurostimulator along with other implanted leads/strip electrodes/connectors are MRI conditional (Table 4). Conditions state that the leads can be connected to the device or not connected, they can be capped or not capped, and they can be cut or not cut while maintaining MRI eligibility. Per manufacturer labeling, leads must be implanted for a minimum of 10 days before MRI due to potential changes in characteristic impedances that could affect how the lead resonates in the RF field. Before MRI, it is important to verify that the neurostimulator battery is not at the end of service. The patient should be afebrile related to concerns of additional minor heating during imaging. Magnetic resonance scanners should have a horizontal field, closed bore (cylindrical system) with a static field strength of 1.5T. The spatial field gradient should be 30T/m or less and the gradient slew rate should be 200T/m per second or less per axis. The active scan time during 1 MRI session is limited to 30 minutes. The patient should be in the supine position for the scan.

For scanning, the neurostimulator should be turned on to MRI mode. The patient should be placed in the scanner in a supine position, and an RF whole-body transmit and receive coil should be used; no head or extremity coils should be used for scanning. If the scanner can predict \( B_1^{+} \)rms, then the RF power limits are less restricted and the \( B_1^{+} \)rms limits listed in Table 4 can be used as limits for the 3 body regions based on vertebral scan location. Otherwise, the average SAR should be
<table>
<thead>
<tr>
<th>Head-only</th>
<th>MRI eligibility of DBS patients¹¹</th>
<th>Full-body</th>
<th>MRI conditions of DBS patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Models 37602, 7428, 7426</td>
<td>Models 37612, 37603, 37601, B35200 with pocket adapter</td>
<td>Models 37612, 37603, 37601, B35200 without pocket adapter</td>
<td></td>
</tr>
<tr>
<td>Partially implanted lead-only system</td>
<td>Fully implanted lead-only system</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Preparation of DBS patient before MRI

<table>
<thead>
<tr>
<th>Model</th>
<th>Device settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>37612, 37603, 37601 (full-body eligible)</td>
<td>Therapy off in unipolar; on or off in bipolar</td>
</tr>
<tr>
<td>37612, 37603, 37601 (head coil—only eligible)</td>
<td>Off</td>
</tr>
<tr>
<td>B35200</td>
<td>MRI mode</td>
</tr>
<tr>
<td>37602</td>
<td>Off</td>
</tr>
<tr>
<td>7428</td>
<td>Off; Magnetic Switch disabled; Day Cycling disabled</td>
</tr>
<tr>
<td>7426</td>
<td>Off; bipolar; amplitude set to 0 V</td>
</tr>
</tbody>
</table>

### MRI conditions of DBS patients

<table>
<thead>
<tr>
<th>Eligibility</th>
<th>Field strength, T</th>
<th>Maximum spatial field gradient, T/m</th>
<th>Maximum gradient slew rate, T/m per second</th>
<th>Maximum scan time</th>
<th>RF coil</th>
<th>RF maximum power (B1+rms), μT</th>
<th>SAR limit (when B1+ rms not predicted), W/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head-only</td>
<td>1.5</td>
<td>19</td>
<td>200</td>
<td>No limit</td>
<td>Detachable head transmit and receive volume coil</td>
<td>NA</td>
<td>0.1 (for head SAR)</td>
</tr>
<tr>
<td>Full-body</td>
<td>1.5</td>
<td>19</td>
<td>200</td>
<td>30-min active scan in 90-min window</td>
<td>Any combination of whole-body, head, or extremity transmit and receive coils</td>
<td>2.0 (1.7 for abdomen implantation and B33005/B33015 leads)¹²</td>
<td>0.1</td>
</tr>
<tr>
<td>Full-body</td>
<td>3.0</td>
<td>20</td>
<td>200</td>
<td>30-min active scan in 90-min window</td>
<td>Any combination of whole-body, head, or extremity transmit and receive coils</td>
<td>2.5 (2.0 for B33005/B33015 leads)¹²</td>
<td>1.0</td>
</tr>
</tbody>
</table>

⁰DBS, deep brain stimulator; MRI, magnetic resonance imaging; NA, not available; RF, radiofrequency; SAR, specific absorption rate.

¹¹The integrity of the system should be verified with an impedance check (no open or short circuits) before performing MRI.

¹²No B1+rms limit for detachable lower extremity transmit and receive volume coils.

¹³B1+rms limit depends on the implant location and lead type.

limited as follows: (1) if the region of interest is superior to the T2 vertebra, scanning should be completed using a restricted mode with a head average SAR of 0.6 W/kg or less, (2) if scanning from T2-T8 vertebrae, scanning should proceed in the restricted mode with a whole-body average SAR of 1.0 W/kg or less, (3) if scanning inferior to the T8 vertebrae, scanning can be completed in normal operating mode with a whole-body average SAR of 2.0 W/Kg or less. Active scanning should be 30 minutes or less per session, with a 30-minute interval between sessions.52 Note that there will be notable imaging artifacts near the device, typically in the posterosuperior ipsilateral brain region (Figure 5). Because of this, subcortical structures will be imaged with less artifact than cortical structures on the side of neurostimulator implantation.

**INVESTIGATIONAL DEVICES**

Investigational devices and off-label uses of FDA-approved hardware are increasingly encountered in the imaging suite. For example, although 2 intracranial leads have typically been standard, there are now situations in which orphaned (or unconnected) leads are present, or there are 4 connected leads to a single or even multiple IPGs. In these cases, the types of leads and IPGs must be considered as well as relative locations of the hardware components. In these cases, whether to image may become a decision based on relative risks and benefits as determined by a multidisciplinary team that includes MR physicist safety experts.

**SURGICAL SAFETY**

Implanted neurostimulation devices are of concern during surgical procedures. The model, location, and settings of neurostimulation devices need to be verified before surgery. Consideration needs to be given as to the role of anesthesia and to the electromagnetic field, with a potential risk of device malfunction or change in delivered stimulation.

Device companies note that the following may damage the device or require the device to be turned off: electrocautery, electrostatic discharges, external defibrillation, extracorporeal shock wave lithotripsy, therapeutic radiation, or ultrasound. Therapeutic radiation could damage the generator’s circuitry, leading to malfunction.53 The primary concern during surgery is preventing damage to the device by electrocautery. Typically, surgically induced excessive stimulation to the brain is a lesser concern. Recommendations focus on avoiding electrocautery near the device, especially monopolar electrocautery, although in general...
Turning off the device provides maximal protection against device damage. For VNS, device labeling recommends interrogation of the device after surgery. For DBS, the recommendation of device labeling is to turn off the device to avoid electrocautery damage. For RNS, the device labeling recommends interrogating the device with the patient or physician programmer before and after surgery and turning off stimulation before the procedure if possible. For practical reasons and to avoid delays in resuming stimulation after surgery, at many centers, VNS, DBS, and RNS devices continue stimulation during surgical procedures. There is limited published evidence supporting a detrimental effect of VNS stimulation to cardiorespiratory function in the perioperative period for patients with chronically implanted VNS devices. Turning the device off before surgery may be considered, especially for high-risk patients.

Bipolar rather than monopolar electrocautery for hemostasis should be used during surgical procedures. Personal experience is that bipolar electrocautery can be used safely when it is performed distant from the device; monopolar electrocautery can have a yet broader field than bipolar electrocautery. For VNS, DBS, and RNS device implantation and battery replacements, we use bipolar electrocautery. If the VNS or DBS device is turned off for battery replacements, monopolar cautery can be used but is not recommended by the manufacturer. There is a low risk of arcing current on the device, which may require device replacement. In our experience, the RNS device is more sensitive to bipolar electrocautery used near the device.

### Table 4. MRI Eligibility Criteria and Preparation Instructions for RNS Patients

<table>
<thead>
<tr>
<th>MRI eligibility of RNS patients</th>
<th>RNS-320 (RNS-300M is magnetic resonance unsafe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth lead</td>
<td>CL-315-10, CL-325-10, CL-335-10</td>
</tr>
<tr>
<td>Cortical strip lead</td>
<td>CC-01, CP-01</td>
</tr>
<tr>
<td>Connector cover, connector plug</td>
<td>F-01, FC-01</td>
</tr>
<tr>
<td>Ferrule, ferrule clamp</td>
<td>LSR-01, LC-01, SS-01</td>
</tr>
</tbody>
</table>

#### Preparation of RNS patient before MRI

<table>
<thead>
<tr>
<th>Model</th>
<th>Device settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>RNS-320</td>
<td>Turn on MRI mode</td>
</tr>
</tbody>
</table>

**MRI Conditions of RNS patients**

<table>
<thead>
<tr>
<th>SAR or B1+ms</th>
<th>Average head SAR ≤0.6 W/kg (restricted mode) or B1+ms ≤2.95μT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superior of T2 vertebrae</td>
<td>T2-T8 vertebrae</td>
</tr>
<tr>
<td>Active scan time or expose time</td>
<td>≤30 min per session. Wait 30 min between sessions.</td>
</tr>
</tbody>
</table>

MRI, magnetic resonance imaging; RNS, responsive neurostimulation; SAR, specific absorption rate.

during a recent temporal lobectomy with the RNS device already in place, bipolar cautery was used near an intracranial electrode, and the device was subsequently found to be nonviable. Certainly, in emergency situations it is reasonable to proceed without turning off the device. Regardless, VNS, DBS, and RNS devices should be interrogated 1 to 3 days after any procedure to confirm that the device is functioning properly.

MISCELLANEOUS CONCERNS
In general, IPGs are susceptible to various forms of electromagnetic interference. Theft detectors, screening devices (such as found in airports), and even large loudspeakers have rarely been reported to produce patient-perceived stimulation “jolts” or cause devices to inactivate.54 Even unexpected sources of electromagnetic interference have been reported to lead to altered device function, such as a winter coat that had an inner pocket with magnetic closure.55 Per manufacturer labeling, any form of high-frequency electromagnetic radiation or currents, including diathermy and transcranial magnetic stimulation, should be avoided. Defibrillation from a cardiac pacemaker can damage a neurostimulator. Neurostimulation can also affect cardiac sensing, and manufacturer labeling typically recommends implanting devices on opposite sides of the body if possible, or at least 4 inches apart, and using bipolar neurostimulation. Finally, for dental procedures some physicians will recommend prophylactic antibiotics. For these issues, definitive data are typically lacking, and attention to the manufacturer labeling and careful consideration are advised.

CONCLUSION
Bioelectronic medicine is increasingly used to treat a variety of diseases, including epilepsy. Permanently implanted invasive stimulation devices are used to treat drug-resistant epilepsy. Health care clinicians are increasingly faced with questions relating to patient management with these devices as they undergo elective and urgent imaging and surgical procedures. Herein we summarized current information regarding the 3 FDA-approved devices used for neuromodulation in the treatment of patients with drug-resistant epilepsy and provided recommendations related to safe management of these devices. As technology evolves and knowledge advances, recommendations are updated; therefore, the most recent sources from each of the device manufacturers should be consulted. By understanding the
background and rationale for safe use of neurostimulators, clinicians are better able to make informed decisions that balance risks and benefits in the increasingly complex world of bioelectronic medicine.

**POTENTIAL COMPETING INTERESTS**

Drs Lundstrom and Van Gompel are named inventors for intellectual property licensed to Cadence Neuroscience Inc, which is co-owned by Mayo Clinic. Dr Lundstrom has waived contractual rights to royalties. Drs Lundstrom, Gregg, and Van Gompel are investigators for the Medtronic EPAS trial and Medtronic-supported National Institutes of Health grants UH3-NS95495 and UH3-NS112826. Dr Lundstrom is an investigator for the NeuroPace RNS System Responsive Stimulation for Adolescents with Epilepsy (RESPONSE) Study and Neuroelectrics tDCS for Patients with Epilepsy Study. Mayo Clinic has received consulting fees on behalf of Dr Lundstrom from Epiminder, Medtronic, NeuroPace, and Philips Neuro. Dr Lin is a member of the board of directors and treasurer of the American Board of Medical Physics. Dr Middlebrooks receives research support and consulting fees from Boston Scientific Corp and Varian Medical Systems and has received nonmonetary research support from NeuroPace. Dr Tatum receives a stipend as editor-in-chief of Epilepsy & Behavior Report; is a member of the editorial board of Journal of Clinical Neurophysiology; is a consultant for BioSerenity/DigiTrace Care Services Inc, Neu relis, and Zimmer Biomet; has patents held or pending (#62527896 and #62770362) for intraoperative monitoring sensor devices; receives royalties from Demos Publishers Inc and Springer Publishing; receives honoraria for speaking engagements from the American Academy of Neurology, American Epilepsy Society, and American Clinical Neurophysiology Society; and receives research support from Mayo Clinic, Martin Family Foundation, Esai Inc, LivaNova, Xenon Pharma, Cerevel Therapeutics, and McElvey Foundation. Dr Van Gompel owns stock in Neuro-One Inc. Dr Watson is chair of the American College of Radiology Committee on MR Safety and chair of the American Board of Magnetic Resonance Safety. The other authors report no competing interests.

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**Abbreviations and Acronyms:** DBS, deep brain stimulation; FDA, Food and Drug Administration; IPG, implantable pulse generator; MR, magnetic resonance; MRI, magnetic resonance imaging; RF, radiofrequency; RNS, responsive neurostimulation; SAR, specific absorption rate; VNS, vagus nerve stimulation

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