NeuroControl FREEHAND® System
MRI Information Sheet

Safety information for the use of magnetic resonance imaging (MRI) procedures (i.e., imaging, angiography, functional imaging, spectroscopy, etc.) pertains to shielded or unshielded MR systems with a static magnetic field of 1.5T only and a maximum spatial gradient of 450 gauss/cm or less, gradient magnetic fields of 20 Tesla/second or less, and a maximum whole body averaged specific absorption rate (SAR) or 1.1 W/kg for 30 minutes of imaging. The effects of performing MRI procedures using different MR systems under conditions above these levels have not been determined. The use of Transmit Coils other than the scanner’s Body Coil or a Head Coil is prohibited.

Testing of the FREEHAND System in a 1.5 Tesla scanner with a maximum spatial gradient of 450 gauss/cm or less, exposed to an average Specific Absorption Rate (SAR) of 1.1 W/kg, for a 30 minute duration resulted in localized temperature rises no more than 2.7°C in a gel phantom (without blood flow). The device may affect image quality depending on the pulse sequence that is used and the imaging area of interest relative to the position of the FREEHAND System.

Magnetic resonance imaging (MRI) procedures must only be performed according to the following guidelines:

Functional testing of each implanted electrode must be conducted prior to the MRI examination to verify that there are no broken leads present. If this cannot be reliably determined, then the potential risks and benefits to the patient requiring the MRI examination must be carefully assessed in consideration of the possibility of excessive heat developing in any such broken leads of the device.

The patient must be continuously observed during the MRI procedure and instructed to report any unusual sensations including any feelings of warming, burning, or neuromuscular excitation or stimulation. If an unusual sensation occurs, the MRI procedure must be discontinued, immediately.

Static Magnetic Field: A patient with a FREEHAND System may undergo an MRI procedure using a shielded or unshielded MR system with a static magnetic field of 1.5 Tesla only (i.e.; no other MR system with a higher or lower static magnetic field may be used) and a maximum spatial gradient of 450 gauss/cm or less. During exposure to a shielded 1.5 Tesla MR system with a maximum spatial gradient of 450 gauss/cm or less, the FREEHAND System does not
exhibit substantial magnetic field interactions with respect to translational force (a deflection angle of 3 degrees was determined for this device using a 1.5 Tesla MR system; maximum spatial gradient of 450 gauss/cm, corresponding to less force than a 3 gram mass) or torque (0.063 N-cm corresponding to a restraining force of 1.6 gF on each of two sutures, significantly less than the weight of the device). Therefore, there is no risk to a patient with a FREEHAND System with respect to movement or dislodgment of this device in association with exposure to a 1.5 Tesla MR system with a maximum spatial gradient of 450 gauss/cm or less.

**Gradient Magnetic Fields:** Pulse sequences (e.g., echo planar imaging technique or other rapid imaging pulse sequence), specialized gradient coils, or other techniques or procedures that exceed exposure to gradient magnetic fields of 20 Tesla/sec (i.e., non-standard pulse sequences or techniques) must not be used for an MRI procedure in a patient with a FREEHAND System. Unconventional or non-standard MRI techniques have not been assessed for safety and, therefore, must not be used.

**Radiofrequency (RF) Fields of MR Systems:** MRI procedures must not exceed exposures to RF fields greater than a whole body averaged specific absorption rate (SAR) of 1.1 W/kg for more than 30 minutes of imaging in a patient with a FREEHAND System. Unconventional or non-standard MRI techniques have not been assessed for safety and, therefore, must not be used.

**MRI Artifacts:** Artifacts for the FREEHAND System have been characterized using a 1.5 Tesla MR system with a maximum spatial gradient of 450 gauss/cm and various pulse sequences. Based on this information, MR imaging quality may be compromised if the area of interest is in the same area or relatively close to the position of the FREEHAND Implantable Receiver-Stimulator. Artifact size is dependent on a variety of factors including the type of pulse sequence used for imaging (e.g., larger for gradient echo pulse sequences and smaller for spin echo and fast spin echo pulse sequences), the direction of the frequency encoding direction relative to the device (larger if the frequency encoding direction is perpendicular to the device and smaller if it is parallel to the device), and the size of the field of view used for imaging. The use of fast spin echo pulse sequences will minimize the amount of artifact associated with the presence of metallic implant, such as the FREEHAND System, compared to the use of other pulse sequences. Contact NeuroControl Corporation for any additional information about performing MRI procedures in patients with an implanted FREEHAND System.
<table>
<thead>
<tr>
<th>Technical Bulletin Number:</th>
<th>TB00-004</th>
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<tbody>
<tr>
<td>Affected Product:</td>
<td>FREEHAND® Neuroprosthetic System</td>
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<tr>
<td>Effective Date:</td>
<td>May 4, 2000</td>
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<tr>
<td>Subject:</td>
<td>MRI scanning of FREEHAND System Users</td>
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<tr>
<td>Distribution:</td>
<td>All FREEHAND Clinicians</td>
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<tr>
<td>For further information contact:</td>
<td>Customer Service (800.378.6955) or your local NeuroControl representative.</td>
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NeuroControl has completed testing and has received FDA approval to allow MRI scanning of FREEHAND System recipients. Testing of the effects of scanning on device/tissue heating, device movement, device function, and image artifact was conducted. The testing has shown that, within indicated limits of scanning hardware and exposure, patients and implanted hardware can be safely scanned using MRI.

The FREEHAND Package Insert, FREEHAND Clinician Manual, and FREEHAND User Manual have been amended to eliminate the MRI warning and to add precautionary technical information. A FREEHAND MRI Information Sheet is also being provided for the Radiologist or MRI Technician (attached) to provide detailed information regarding the testing conducted by NeuroControl and the instructions for safe scanning. The following summarizes the key points of the MRI precautionary technical information, however, the FREEHAND MRI Information Sheet must be referenced for complete information.

**Before Scanning:**

- The function of each electrode should be tested prior to MRI scanning by "Profiling" each electrode to ensure no leads are broken. Imaging a patient with a broken implanted lead may result in excessive heating around the break in the lead. This potential risk of scanning a patient with a broken implanted lead would have to be considered on a case-by-case basis against the benefits of scanning.
MRI scanning conditions: MRI scanning can be performed on individuals implanted with the FREEHAND System only under the following conditions:

- Only a 1.5T (Tesla) scanner with a spatial gradient of 450 gauss/cm or less can be used (this covers the majority of MRI scanners used in the US today)
- The imaging mode used must not load the patient with an average Specific Absorption Rate (SAR) of more than 1.1 W/kg for a scan of 30 minutes duration.
- Unconventional or non-standard MRI modes must not be used.
- The use of Transmit Coils other than the scanner’s Body Coil or a Head Coil is prohibited.

During MRI Scanning:
- Patients must be closely monitored during scanning and asked to report any unusual sensations or muscle activity

MRI Image Quality:
- MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the FREEHAND Implantable Receiver-Stimulator. See the MRI Information Sheet for more information on image artifact.

Any additional questions may be addressed to Customer Service at NeuroControl 216.912.0101 or 800.378.6955.