MRI Guidelines

Enterra® Therapy
Gastric Electrical Stimulation System

Physician's Guide

Rx only

Note: This document contains information related to Magnetic Resonance Imaging (MRI) use with the Enterra Therapy® Gastric Electrical Stimulation (GES) System. Refer to the product manuals for more detailed information about non-MRI aspects of implantation, programming, charging, and use of the components of the Enterra System.

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Glossary

MR Conditional - An item with demonstrated safety in the MR environment within defined conditions, including conditions of the static magnetic field, the switched gradient magnetic field and the radio frequency fields. Additional conditions, including specific configurations of the item, may be required.

MR Unsafe - An item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.

ACR Zone - Zones of an MR site that denote areas with various MR safety levels, as defined by the American College of Radiology.

MRI - Magnetic Resonance Imaging.

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1. MRI Safety Information 

The Enterra System is **MR Conditional**. This means that patients with the Enterra System can safely have MRI examinations of some body parts under certain conditions. The conditions for MRI scans will vary with the type of MRI coil.

Always obtain the latest MRI guidelines. Refer to the contact information on the last page of this manual or go to **www.enterramedical.com/hcp/manuals**.

1.1. MR Conditional Devices 

Non-clinical testing has demonstrated that the Enterra II 37800 Neurostimulator with two Enterra Therapy 4351 35 cm unipolar leads are **MR Conditional**.

Patients with these devices can be safely scanned in an MR system meeting the conditions described in the following section.

1.2. For MRI examinations using a detachable head, upper extremity, or lower extremity RF transmit/receive volume coil

A patient implanted with the Enterra Therapy System may be safely scanned at the head or upper/lower extremity at 1.5T MRI under the following conditions. Failure to follow these conditions may result in injury to the patient.

MRI Safety Information

A person with the Enterra Medical Enterra II System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Enterra II
Device Configuration	Stimulation OFF
Static Magnetic Field Strength (Bo)	1.5T
MR Scanner Type	Cylindrical
Bo Field Orientation	Horizontal
Maximum Spatial Field Gradient	20 T/m (2,000 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Head or Extremity Coils Only
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg
Maximum Head SAR	3.2 W/kg
Scan Duration	Scan for up to 60 minutes of continuous RF (a sequence or back to back series/scan without breaks).
Scan Regions	Only head or extremity scanning allowed.
MR Image Artifact	The presence of this implant may produce an image artifact.

Please consult your doctor and the MRI technologist to make sure that the specific conditions above are met before MRI examination.

1.3. MR unsafe devices

The external components of the Enterra System, including the Model 8840 Clinician Programmer, are **MR Unsafe.** These devices must **NOT** be taken into the MR scanner room (ACR Zone IV).

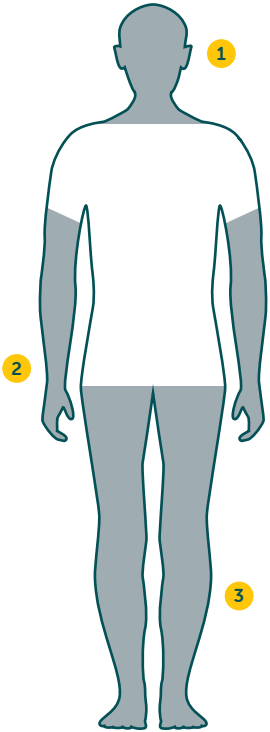

Figure: MRI scan* using detachable 1 head, 2 upper extremity, or 3 lower extremity RF transmit coil.

*Illustrated in Figure are typical use scenarios of detachable RF transmit/receive volume coil. Other scanning scenarios are also permissible according to MR scanner/coil manuals. For example, an MRI scan of the ankle with a detachable lower extremity RF transmit/receive volume coil or an MRI scan of the upper arm with a detachable lower extremity RF transmit/receive volume coil in the superman posture is permissible given the aforementioned scan conditions are met.

1.3. MR unsafe devices

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2. Possible Risks of MRI with the Enterra System

Non-clinical testing has shown that patients with the Enterra System can safely have MRI when the conditions for safe MRI described in this document are followed. However, there may be some risks of performing MRI when the patient has an implanted Enterra System. Possible risks include:

- Heating of the implant
- Unintended stimulation
- Image distortion and artifacts
- Magnetic field interactions
- Device malfunction or damage

2.1. Heating of the implant

MRI may cause the implant to become hot. However, if the conditions for safe MRI are followed, this heating is minimal. If the specific MRI conditions are not followed, heating of the implant could damage surrounding tissue. If the site of the patient's implant feels hot during MRI, the patient must inform the MRI technologist immediately and then contact their doctor.

2.2. Unintended stimulation

MRI may cause unintended stimulation from the implant. This unintended stimulation may be uncomfortable (the patient may feel a tingling, shocking, or jolting sensation). However, if the conditions for safe MRI are followed, such stimulations may not happen. If the patient experiences any uncomfortable stimulations during MRI, the patient must inform the MRI technologist immediately and then contact their doctor.

2.3. Image distortion and artifacts

No image distortion or artifacts should be visible from an MRI head and extremity scans.

2.4. Magnetic field interactions

The magnets used in MRI may cause the Neurostimulator to shift or move slightly within the implant pocket. This may cause stress to tissues and/or the lead. As a result, the patient may feel a slight tugging sensation at the site of the implant. If the patient feels uncomfortable while in the MRI, the patient must inform the MRI technologist immediately.

2.5. Device malfunction or damage

Tests in various MRI systems were conducted. These tests did not cause any damage to, or malfunction of, the implant. If the implant malfunctions or becomes damaged, it may result in nerve damage and other associated problems. If the patient feels any stimulation or discomfort during MRI, the patient must inform the MRI technologist immediately and then contact their doctor.

3. MRI Guidelines

The guidelines for MRI scans are based on non-clinical tests conducted on the Enterra System. Precautions are to be taken before, during, and after MRI scan. Talk to your MRI technologist or your doctor should you have any questions or concerns.

3.1. Before starting MRI scan

- Consult your doctor and MRI technologist to determine if you are eligible for MRI scan.
- Inform your doctor and MRI technologist if you have multiple Enterra GES devices or any other medical device(s) implanted, such as a pacemaker, drug pump, hip prosthesis, stent, etc.
- Inform your doctor and MRI technologist if you think you have any the following conditions with your device: a broken lead fragment, lead disconnection from the neurostimulator, a partially implanted lead, a malfunctioning neurostimulator, a neurostimulator implanted at an area other than abdomen, or a system with open or low impedances (indicating a short circuit) on any electrodes. Consult with your physician for MRI eligibility if any of these conditions apply.
- Your MRI technologist may also give you MRI Patient Guides and Instructions. Make sure that you fully comply with those. Discuss with your MRI technologist or your doctor if you have any concerns.
  - Bring the most up-to-date patient ID card to all MRI appointments.

- For MRI using detachable head, upper extremity, or lower extremity RF transmit/receive volume coils, make sure that the Neurostimulator stimulation is turned OFF.
- Make sure you remove any external metallic objects before entering the MRI room.

3.2. During MRI scan

- You may feel slight tugging, vibration, warming, and/or tapping in the area where the Neurostimulator is located during the MRI scan. If those feelings cause discomfort, you should let the MRI technologist know immediately.
- If you are not feeling well for any other reasons prior to or at the time of MRI scanning, please inform your MRI technologist.

3.3. After MRI Scan

- After the MRI scan, have the stimulation turned back on.
- If you feel any changes in stimulation after an MRI, you should contact your doctor, if uncomfortable.

4. Patient MRI Eligibility Checklist

This checklist is provided as an optional resource to support MRI centers in conducting an MRI of a patient implanted with the Enterra System.

Prior to performing a scan, verify all information with the patient's pain management physician, the referring medical facility, the implanting physician or a Enterra Medical representative.

Patient Name: _____

☐ **Step 1: Confirm that the patient has brought their patient ID card.**

☐ **Step 2: Verify model numbers of implanted Enterra System components.**

Component	Model Number	Head/Neck & Extremity Eligible (1.5T)
Enterra II IPG	37800	☐
Enterra Unipolar Leads	4351-35	☐

☐ **Step 3: Check if the patient has any other medical device implants.**

The most restrictive MRI exposure requirements must be used if the patient has multiple medical device implants. For patients with other implanted devices in addition to the Enterra System, consult the appropriate device manufacturers for MRI eligibility of those devices.

☐ **Step 4: Confirm that all implanted leads are connected to the IPG.**

☐ **Step 5: Document the patient's current amplitude, frequency (rate), on/off time, and pulse width.**

Amplitude	Frequency (rate)	On/off	Pulse width

☐ **Step 6: Perform an impedance check using the Model 8840 programmer.**

Note, the Model 8840 programmer is not MRI safe. **Do NOT** perform an MRI scan if any impedance is out of range.

☐ **Step 7: Stimulation is turned off using the 8840 programmer.**

☐ **Step 8: Verify the following MR scanner requirements and perform scans per the table below.**

Monitor the patient both visually and audibly. Discontinue the MRI examination immediately if the patient reports any problems.

MRI Safety Information

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Device Name	Enterra II
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Static Magnetic Field Strength (Bo)	1.5T
MR Scanner Type	Cylindrical
Bo Field Orientation	Horizontal
Maximum Spatial Field Gradient	20 T/m (2,000 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Head or Extremity Coils Only
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg
Maximum Head SAR	3.2 W/kg
Scan Duration	Scan for up to 60 minutes of continuous RF (a sequence or back to back series/scan without breaks).
Scan Regions	Only head or extremity scanning allowed.
MR Image Artifact	The presence of this implant may produce an image artifact.

☐ **Step 9: After scan is completed, turn stimulation back on using the 8840 programmer.**

Ensure the settings are the same as recorded in step 5. Verify that the patient has not experienced any adverse effects as a result of the MRI. Contact Enterra Medical, Inc. if the patient has experienced any adverse effects.

Manufacturer

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800-00938-001 Rev C 2023-11

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