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ReActiv8®

Implantable Electrical Stimulation System

ReActiv8® System Magnetic Resonance Imaging (MRI) Guidelines

English

FOR EU/UK USE ONLY

Mainstay Medical

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Mainstay Medical Limited
Clonmel House
Forster Way
Swords, Co. Dublin, K67F2K3, Ireland

Internet: www.mainstaymedical.com
E-mail: contact@mainstaymedical.com
Tel.: +353 766 801428

UK Responsible Person:
ICON (LR) Limited
500 South Oak Way
Green Park, Reading RG2 6AD
United Kingdom

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Contents

Symbols and Terms

Explanation of symbols and terms used in this document.

Symbols

	MR Conditional
	MRI Unsafe
	Caution
	Warning
	Refer to instruction manual/booklet (Mandatory)

Terms

MRI	Magnetic Resonance Imaging
Magnetic Resonance (MR) Environment *	The three-dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.50 mT field contour (5 gauss (G) line). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories.
MR Conditional *	An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields, and the radiofrequency fields.
MR Unsafe *	An item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
Specific Absorption Rate (SAR) *	Radio frequency power absorbed per unit of mass (W/kg).

* ASTM F2503-20, "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment"

1 Introduction

The ReActiv8® Implantable Pulse Generator (IPG) and implantable leads are **MR Conditional** devices with demonstrated safety in the MR environment only within the defined conditions specified in this document.

This document is a supplement to the *ReActiv8 Implant and Programming Manual* and *ReActiv8 User Manual.* The intended audience for this document is healthcare providers. This includes physicians and other healthcare professionals (HCP) prescribing and/or implanting ReActiv8, as well as those providing continuing care after implantation. This document is also intended for radiologists and other HCPs responsible for prescribing and/or performing magnetic resonance imaging (MRI) scans on ReActiv8 patients.

Obtain the Latest MRI Guidelines

This document may be updated periodically. The latest version of these guidelines may be obtained at **www.mainstaymedical.com/resources** or through Mainstay Medical with the contact information provided at the beginning of this document.

2 Warnings and Cautions

Reading this document completely prior to any MRI exam is required for safety. If there are any questions about the information in this document, contact Mainstay Medical.

WARNING: Failure to understand and comply with the guidelines in this document for MRI exams may result in severe patient injury and/or device malfunction.

WARNING: The risks associated with ReActiv8 in the MR environment under any conditions that contradict those specified in this document are unknown. Deviating from the specified conditions may result in severe patient injury and/or device malfunction.

WARNING: If removal of the ReActiv8 neurostimulator is under consideration for the purposes of an MRI exam, ALL implantable components must be completely removed. Severe patient injury may occur if components not fully implanted as a connected system are left in the body during an MRI scan.

CAUTION: The risks associated with ReActiv8 in the MR environment when the patient is implanted with other medical devices are unknown. If a patient has multiple medical device implants, consult with the manufacturers of all implanted devices, and discuss with the patient's physician and radiology/imaging team prior to any MRI exam. The most restrictive MRI conditions of the implanted medical devices must be considered. Do not conduct an MRI exam if any implants are contraindicated for MRI.

CAUTION: The radiologist and/or other HCPs responsible for prescribing and/or performing magnetic resonance imaging (MRI) scans on the patient must know the model numbers of the ReActiv8 components implanted completely within the patient's body. Not knowing this information prior to the MRI exam may result in delayed treatment.

CAUTION: Potential interactions between the MR environment and the MR Conditional ReActiv8 system components may be perceived by the patient during an MRI exam. This includes force or torque exerted on the implantable components due to MRI magnetic fields, heating of the implanted components due to MRI fields, and energy from the MRI scan induced into implanted leads. These interactions could result in unusual sensations and/or patient discomfort during the exam.

CAUTION: Thermoregulation should be accounted for during the MRI scan. Compromised thermoregulation could lead to higher heating of implanted ReActiv8 components.

3 ReActiv8 System Components Approved for MR Conditional Use

Table 1 — ReActiv8 System components approved for MR Conditional Use

	**MR Conditional Approved Components**	**Model**
	ReActiv8 Implantable Pulse Generator (IPG)	5100
	ReActiv8 Implantable Stimulation Lead, 45 cm length	8145

WARNING: The ReActiv8 components specified above are approved for MR Conditional use only within the conditions defined in this document when **fully implanted with the following configurations:**

1) The Model 5100 IPG with two (2) properly and directly connected Model 8145 (45 cm) leads.

Important Note: Leads implanted without the IPG or disconnected from an implanted IPG are NOT APPROVED for MR Conditional use.

Additional conditions required for MR Conditional use are described throughout this document.

WARNING: ReActiv8 Implantable Stimulation Lead Model 8165 (65 cm length) is NOT APPROVED FOR USE in a Magnetic Resonance (MR) environment.

WARNING: ReActiv8 Implantable Stimulation Lead Models 8000-45 (45 cm length, Discontinued 2017) and Model 8000-65 (65 cm length, Discontinued 2017) are NOT APPROVED FOR USE in a Magnetic Resonance (MR) environment.

MR UNSAFE COMPONENTS		
		WARNING: All other components of the ReActiv8 System are NOT APPROVED FOR USE in a Magnetic Resonance (MR) environment. **DO NOT** bring any other ReActiv8 System components into the MR scanning room.

4 Conditions for Safe Use in the MR Environment

The conditions specified in this section must be followed for safe use of ReActiv8 in the MR environment.

4.1 Read First — MRI Exam Workflow

As stated in *2 Warnings and Cautions*, reading this document completely prior to any MRI exam is required for safety. The required **4-step workflow** for an MRI exam is summarized below:

▶ **Step 1:** Confirm the ReActiv8 patient is eligible for an MRI exam by reviewing the requirements described in section *4.2 Patient Eligibility*.

> **Note:** Conditions for safe use vary based on the *Static Magnetic Field Strength (B0)* required. See *Section 4.6* for MR Conditions and restrictions.
>
> Confirming eligibility prior to scheduling an MRI exam is recommended.

▶ **Step 2:** Review the required steps in *4.3 Preparation before the MRI Exam* and *4.5 Instructions after the MRI Exam*. Preparation before and actions after the MRI exam require support from a trained Mainstay Medical employee. The preparation steps in section 4.3 should be performed prior to the MRI exam.

▶ **Step 3:** Ensure all required steps described in *4.4 Instructions during the MRI Exam* are followed.

▶ **Step 4:** Ensure all required steps described in *4.5 Instructions after the MRI Exam* are followed.

4.2 Patient Eligibility

⚠ **WARNING: Confirm the patient meets the following requirements.** **Note:** If there are any questions about the Patient Eligibility requirements, contact Mainstay Medical.	
1	The patient is implanted only with the ReActiv8 components approved for MR Conditional use listed in *Table 1*. **Important Note:** Leads implanted without the IPG or disconnected from an implanted IPG are not approved for MR Conditional use.
2	Confirm the conditions for safe use support the desired MRI scan sequence. Refer to *section 4.6*.
3	The IPG is implanted in the flank or upper buttock.
4	The IPG and leads are implanted consistent with the implant procedure instructions provided in the *ReActiv8 Implant and Programming Manual*.
5	The patient has no fractured leads or lead fragments in their body.
6	The patient's body temperature is not greater than 37°C at the time of the MRI exam. A patient implanted with ReActiv8 with an elevated body temperature should not undergo an MRI scan.
7	The patient can confirm that their implant battery level is adequate (e.g., not at "Battery End of Life") and can provide a therapy session normally, e.g., can be started/stopped as described in the *ReActiv8 User Manual*. If there is any evidence of compromised system integrity, contact Mainstay Medical.
8	The patient is in possession of their Patient ID card. If the card is not available, contact the patient's physician and/or Mainstay Medical to obtain and document the information on the card.
9	The patient has informed their physician and Mainstay Medical of the intended MRI exam. The IPG must be programmed to OFF mode prior to the scan and must remain in OFF mode for the duration of the MRI exam. This must be done by a trained Mainstay Medical employee. A trained Mainstay Medical employee must also be available following the MRI exam to turn the IPG back ON.

4.3 Preparation before the MRI Exam

1	Confirm the patient is implanted only with the ReActiv8 components approved for MR Conditional use listed in *Table 1.* **Important Note:** Leads implanted without the IPG or disconnected from an implanted IPG are not approved for MR Conditional use.
2	Confirm the healthcare professional(s) responsible for performing the MRI scan on the patient has fully read and understood and is able to comply with the conditions described in this document.
3	Confirm if the patient has any other medical device implants. ⚠ **CAUTION:** The risks associated with ReActiv8 in the MR environment when the patient is implanted with other medical devices are unknown. If a patient has multiple medical device implants, consult with the manufacturers of all implanted devices and discuss with the patient's physician and radiology team prior to any MRI exam. The most restrictive MRI conditions of the implanted medical devices must be considered. Do not conduct an MRI exam if any implants are contraindicated for MRI.
4	Immediately prior to the exam, confirm the patient's body temperature is not greater than 37°C. A patient implanted with ReActiv8 with an elevated body temperature should not undergo an MRI scan. Do not cover the patient with blankets or similar articles. These items can raise the patient's body temperature. ⚠ **CAUTION:** Thermoregulation should be accounted for during the MRI scan. Compromised thermoregulation could lead to higher heating of implanted ReActiv8 components.
5	**Note:** This step requires a trained Mainstay Medical employee. Interrogate the IPG and perform an impedance measurement. Confirm communication with the IPG and that both lead impedances are less than 12 kΩ. If there is any evidence of compromised system integrity, do not conduct an MRI exam.

6	**Note:** This step requires a trained Mainstay Medical employee. Document the current programming parameters, then confirm the IPG is programmed to OFF mode. The IPG must remain in OFF mode for the duration of the MRI exam.
7	If possible, do not sedate or anesthetize the patient. A sedated patient may not be able to report to the MRI staff any problems encountered or experienced during the exam.
8	During the MRI scan, the patient must be positioned in the supine position, arms straight and at the sides, and legs straight. The patient must also be centered within the bore prior to scanning. No other patient positions are permitted.
9	Inform the patient of the potential interactions between the MR environment and the implanted ReActiv8 components that could be perceived, possibly resulting in unusual sensations and/or discomfort (See *2 Warnings and Cautions*). Instruct the patient to report all unusual sensations and/or discomfort experienced during the MRI exam to the MRI staff.

4.4 Instructions during the MRI Exam

1	Monitor the patient visually and audibly throughout the MRI exam. Discontinue the exam if the patient becomes unresponsive to questions or experiences any discomfort or reports any other problems.

4.5 Instructions after the MRI Exam

1	**Note:** This step requires a trained Mainstay Medical employee. Verify that the IPG is configured with the programming parameters that were set prior to the MRI exam. Reconfigure the IPG to the parameters that were set prior to the MRI exam if the IPG is in Safe Mode. Program the IPG back to ON mode. Perform an Impedance measurement and confirm both lead impedances are less than 12 kΩ. Confirm there is no evidence of compromised system integrity.

4.6 MR Conditions for Patients Implanted with IPG Model 5100 and 45 cm Length Stimulation Leads (Model 8145) – Static Magnetic Field Strength (B0) 1.5T

Table 2 – Conditions for safe scanning: **IPG Model 5100 and 45 cm length Stimulation Leads (Model 8145)**

 **MRI Safety Information**	A person implanted with the ReActiv8 Implantable Neurostimulation System may be safely scanned at 1.5T under the following conditions. Failure to follow these conditions may result in injury.
Parameter	**Condition**
Device Name	ReActiv8 **IPG Model 5100** with ReActiv8 **Stimulation Lead 45 cm length, Model 8145**
Device Configuration	Mode: OFF
Static Magnetic Field Strength (B0)	1.5T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	40 T/m (4000 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Volume RF Body Coils ONLY *
Operating Mode	1.5T: Normal Operating Mode
RF Conditions	**For 1.5T: MR Scanner:** $B_{1+rms} \leq 3.0$ uT; for MRI scanners that do not report $B_{1+rms,}$ Maximum Whole-body SAR: 2 W/kg Maximum Head SAR: 3.2 W/kg
Scan Duration	24 minutes of continuous scanning
Scan Regions	No restrictions – Full Body scanning permitted
Image Artifact	The presence of the ReActiv8 system may produce an image artifact of 7.4 cm at the IPG and 1.4 cm at the distal lead. Some manipulation of scan parameters may be needed to compensate for the artifact.

* The required *RF Transmit Coil Type* of Volume RF Body Coil is also referred to as “Whole Body RF Transmit Coil”

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