SETPOINT SYSTEM

MAGNETIC RESONANCE IMAGING (MRI)

SAFETY INFORMATION MANUAL

Read all instructions, warnings and cautions carefully.

Failure to do so may damage the SetPoint System,
cause it to malfunction or perform poorly, and could result in injury.

If you have any questions about the information contained in the **SetPoint System Magnetic Resonance Imaging (MRI) Safety Information Manual**, please **contact SetPoint Medical**.

All SetPoint System Instructions for Use (IFUs) are available on the SetPoint Medical website.

If you experience any incident or problem related to the SetPoint System that may pose a safety risk, report it to SetPoint Medical immediately.

Contact

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Caution: Federal law restricts this device to sale by or on the order of a physician.

Table of Contents

Introduction

This MRI Safety Information Manual describes important safety requirements which need to be considered prior to conducting or recommending an MRI examination on a user implanted with the SetPoint System.

The table below shows the SetPoint System model numbers for the parts of the system that are described in this manual.

Device Name	Model Number
Implant	M01
Charger	E04
Docking Station	C01

Table 1 - Device Names and Model Numbers

SetPoint System Description

The SetPoint System includes:

- The Implant (A) which is placed within a Pod (B) and implanted on the left vagus nerve in the neck (C)
- A Charger (D) with a Docking Station (F)
- A Programmer (E)

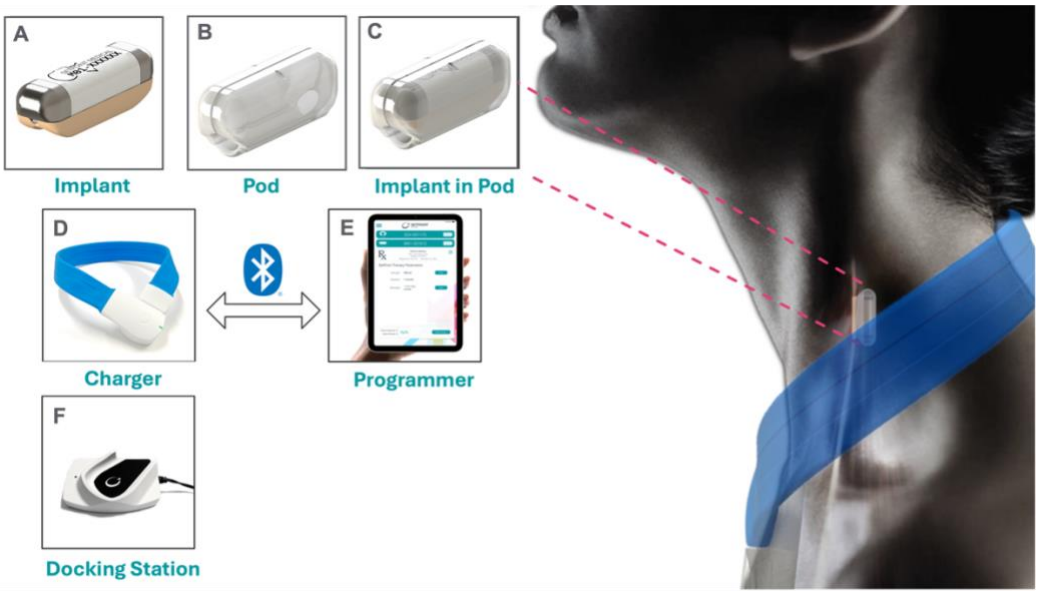

Figure 1 – SetPoint System and Components

The Implant is an integrated neurostimulation device. It is used to electrically stimulate the vagus nerve for 1 minute, every day. It is about 1 in (2.5 cm) long and weighs about 0.1 oz (3 g). Both the Charger and Docking Station are intended to be used at home for Implant charging. The Programmer is a software application on an Apple® iPad that is used to program the stimulation parameters of the Implant. The Programmer is intended to be used in the clinic.

Magnetic Resonance Imaging Safety

A magnetic resonance imaging scan, often referred to as an MRI, is a type of medical imaging that uses electromagnetic fields to create an internal view of the body for diagnostic purposes. An MRI scan performed outside the guidelines presented in this MRI Safety Information Manual may result in these electromagnetic fields interacting adversely with the implantable portion of the SetPoint System, potentially injuring the patient and/or damaging the device. Due to the risks of using MRI with a patient with any active implanted medical device, it is important to read, understand, and comply with all instructions to prevent potential harm or injury to the patient and/or damage to the device.

Implant

Non-clinical testing as well as safety outcomes from clinical studies of the SetPoint System have demonstrated that the implantable portions of the SetPoint System, specifically the Implant and Pod, are MR Conditional.

Figure 2 – MR Conditional

Patients with a SetPoint Implant may be safely scanned anywhere in the body at 1.5 T or 3.0 T two weeks following implantation under the conditions outlined in this section. Failure to follow these conditions may result in injury.

Parameter	Condition
Earliest MRI Scan	2 weeks after implantation
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
Type of Nuclei	^{1}H (hydrogen)
MR Scanner Type	Cylindrical, closed-bore
B_0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	30 T/m (3,000 G/cm)
Maximum Gradient Slew Rate Per Axis	200 T/m/s
RF Excitation	Circularly polarized (CP), (e.g., quadrature birdcage coils)
RF Transmit Coil Type	Integrated whole-body transmit coil or any detachable local RF transmit coil EXCEPT when imaging head and neck, (e.g., no transmit/receive head coil)
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
RF Conditions	Whole body average specific absorption rate (SAR) ≤ 2.0 W/kg
Scan Duration	Up to 1 hour of continuous scanning in Normal Operating Mode without a cooling period
Scan Regions	Any landmark is acceptable, with restrictions on RF Transmit Coil Type in the head and neck region as discussed in the section RF Excitation
Image Artifact	Significant image artifacts can result from MR imaging of the Implant or surrounding area. In non-clinical testing, the maximum artifact size as

	seen on the gradient echo pulse sequence extends approximately 45 mm from the Implant*.

*When scanned using spin echo and gradient echo sequences in a 3 T/128 MHz, Ingenia, Phillips Healthcare, self-shielded, horizontal field MR system with a whole body transmit coil.

Under the scan conditions defined above, the SetPoint System is not expected to experience any temperature rise after 15 minutes of continuous gradient field exposure at a maximum whole body average SAR of 2.0 W/kg.

Scanner

A horizontal field, cylindrical, closed-bore MR system with a static magnetic field strength of 1.5 T or 3.0 T operated in a Normal Operating Mode with a proton MRI imaging modality should be used for scanning the patient.

Cylindrical, closed-bore MR systems with 1.5 T or 3.0 T static magnetic field strengths are the most commercially prevalent systems. These types of systems all have horizontal field orientations. Permanent and dipolar magnets (other scanner configurations) can have either horizontal or vertical orientations. These wide bore MRI, open MRI, extremity MRI or other novel scanner configurations are not authorized for use. Neither are other field strengths, even if they are lower than 1.5 T.

Normal Operating Mode is the "routine" level at which most clinical MRI today is performed, being considered safe for all patients, regardless of their condition. First and Second level controlled operating modes may cause physiologic stress (such as peripheral nerve stimulation or tissue heating) and require active medical supervision. Only Normal Operating Mode is authorized.

Proton MRI (hydrogen nuclei) is the standard diagnostic imaging modality because of the abundance of hydrogen nuclei in water and fat. This allows the MRI to use the body's natural magnetic properties to produce detailed images from any part of the body. Sodium and potassium MRI (as well as the more exotic multinuclear MRI) are used for specialty imaging applications and in research contexts. Only proton MRI is authorized for use.

Gradient Slew Rate

In MRI, gradient coils are used to generate magnetic fields that vary linearly across the imaging volume. These fields are superimposed on the main magnetic field and allow for spatial encoding of the signals, which is essential for image reconstruction. The gradient slew rate is a measure of how quickly these gradient magnetic fields can be changed, and it has a significant impact on the speed and quality of imaging. While the actual gradient slew rate varies over the scanner volume, in MRI, the value at the geometric center of the imaging region is referred to as the “gradient slew rate” for a given gradient coil, at a particular coil current. This value cannot exceed 200 T/m/s per axis. Since all three axes may be driven at the maximum gradient slew rate simultaneously, the resulting maximum, combined gradient slew rate is 346 T/m/s.

Spatial Gradient Magnetic Field

The term “spatial gradient magnetic field” is unrelated to the gradient slew rate. It refers to the rate at which the static magnetic field strength changes over space or distance per unit of length and is a property of the static magnetic field strength of the scanner as well as the design of the shielding.

The attractive force experienced by the Implant in the field of the scanner is dependent on the spatial gradient. The larger the spatial gradient, the larger the force on the Implant.

The maximum spatial gradient is the place of maximum change. In general, the highest spatial gradient magnetic field is located off-axis, at a side wall, and near the opening of the bore of the scanner.

The maximum spatial gradient magnetic field cannot exceed 30 T/m (3,000 G/cm). This value is higher than the maximum spatial gradient magnetic field of all commercially available MR scanners on the market as of the release of this document.

RF Excitation

The earliest RF-coils for MR imaging were all linearly polarized (LP). In this configuration, both transmission and reception of electro-magnetic radiation took place along a single axis. In the transmit mode, LP coils are inefficient in that half their power does not contribute to the MR signal and therefore contributes only to undesirable heating of the patient. In the receiver mode they are incapable of extracting full phase information from the MR signal. By adding a second set of coils perpendicular to the first and driving them with sinusoidal current phase shifted by 90°, a pure rotating B1 field can be created. This is known as circularly polarized (CP) or quadrature transmission. Circularly polarized is the standard for modern, clinical use MRI systems. Older, linearly polarized systems are not authorized for use and are largely restricted to use in very small animal imaging and spectroscopy applications.

An integrated whole-body coil can be used for imaging any landmark. Alternatively, a detachable local RF transmit/receive coil can be used on any extremity except when imaging the head and neck. For head and neck imaging, either the integrated whole-body coil can be used for transmit/receive, or it can be used for transmit with a local receive only coil. Using the integrated whole-body coil for transmit with any local receive only extremity, spine, or torso coil is also acceptable. Example configurations are presented in the following figures.

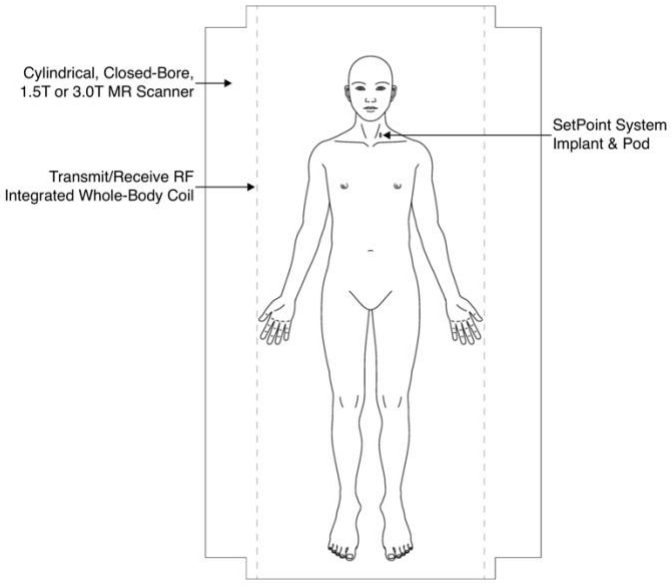

Figure 3 - ✅ Permitted Scan Using Integrated Whole-Body Coil Only

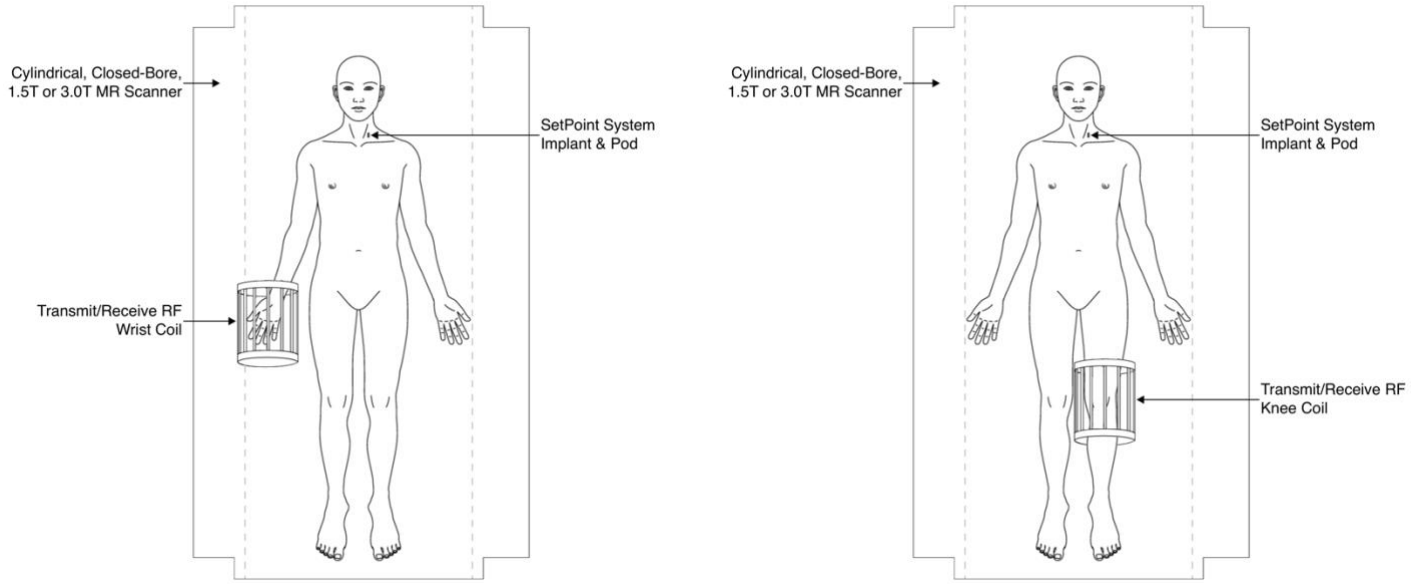

Figure 4 - ✅ Example Permitted Scans of the Wrist and Knee Using Transmit/Receive RF Peripheral Coil

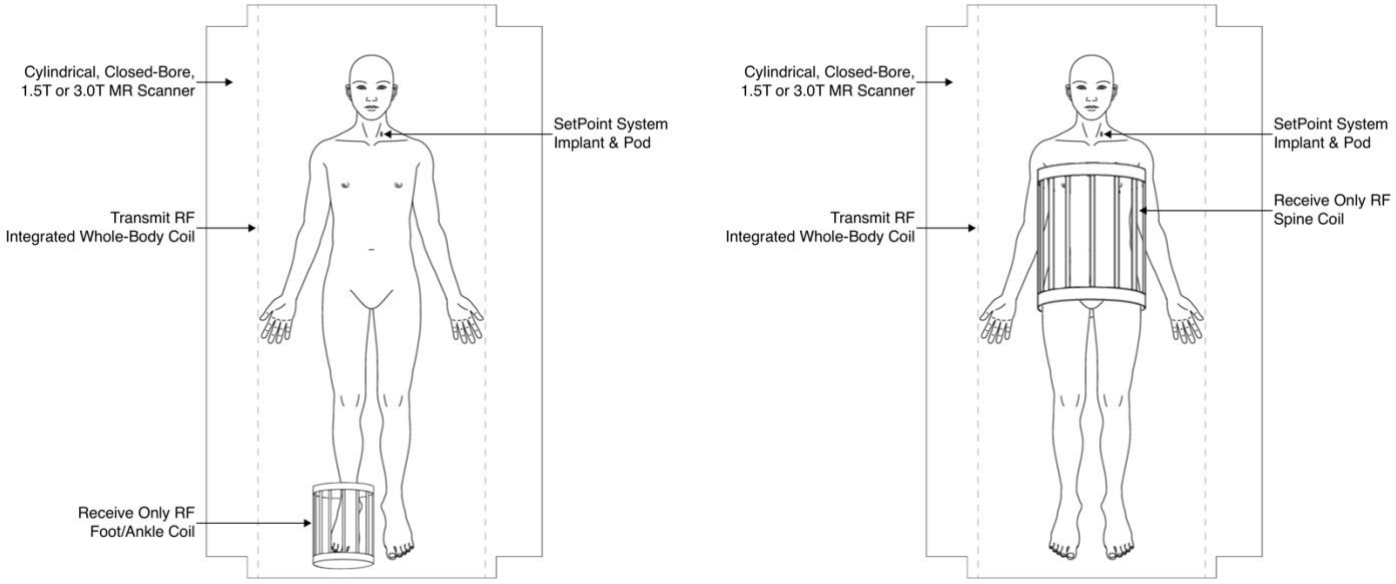

Figure 5 - ✅ Example Permitted Scans of the Foot/Ankle and Spine Using Integrated Whole-Body Coil for Transmit and Receive Only Peripheral Coil

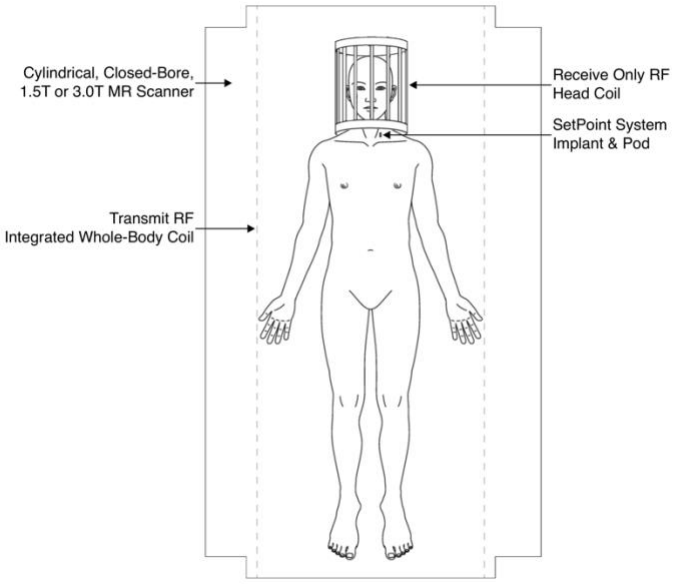

Figure 6 - ✅ Permitted Scan of the Head or Neck Using Integrated Whole-Body Coil for Transmit and Receive Only RF Head Coil

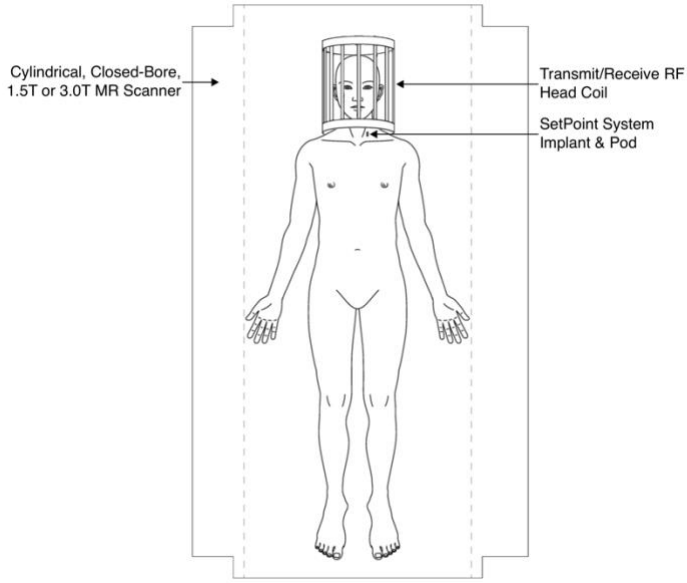

Figure 7 - 🚫 Prohibited Scan of the Head or Neck Using Transmit/Receive RF Head Coil

Image Artifacts

Significant image artifacts can result from MR scans of the Implant or surrounding area. In non-clinical testing, the maximum artifact size as seen on the gradient echo pulse sequence extends approximately 45 mm from the Implant. Image artifacts or distortion resulting from the presence of the Implant must be considered when selecting MR imaging parameters and field of view, and when interpreting MR images.

Externals

The external portions of the SetPoint System, specifically the Charger and Docking Station, are MR Unsafe.

Figure 8 – MR Unsafe

⚠ **Warning:** Do not bring the Charger or the Docking Station into the MRI scanner magnet room (Zone IV as defined by the American College of Radiology).

Appendix A – Explanation of Symbols Used on Packaging and Devices

Symbol	Title	Reference	Description
ASTM F2503			
	Magnetic Resonance (MR) Conditional	Fig. 5	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
	Magnetic Resonance (MR) Unsafe	Fig. 9	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment
ISO 7010			
	General Warning Sign	W001	To signify a general warning

Applicable Standards and Regulations

ASTM F2503 – 23 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

ISO 7010:2019 Graphical symbols – Safety colors and safety signs – Registered safety signs