MAGNET OPERATION

CRHF Technical Services Standard Letter

Rev. 1.0, September 2016, © Medtronic, PLC 2016

The information provided in this letter is for healthcare providers and Medtronic representatives and applies to the following Medtronic device models:

All Medtronic **Implantable Pulse Generator (IPG)** and **Cardiac Resynchronization Pacemakers (CRT-P)** Models, both MR Conditional and non-MR Conditional, whose Instructions For Use (IFU) includes recommendations for application of a magnet to induce magnet operation - asynchronous pacing for specific clinical applications. The IFU may also suggest use of a magnet to inhibit sensing of electromagnetic interference (EMI) for specific medical procedures. Magnet application may also be used to check for elective replacement indicators (ERI) in IPG and CRT-P devices. Consult the appropriate individual device/clinician manual for specific guidance under which magnet operation is recommended. http://manuals.medtronic.com/manuals/main/region	All Medtronic **Implantable Cardioverter Defibrillators (ICD)** and **Cardiac Resynchronization Defibrillator (CRT-D)** Models, both MR Conditional and non-MR Conditional, whose Instructions For Use (IFU) includes recommendations for application of a magnet to inhibit detection of electromagnetic interference (EMI) for specific medical procedures. Magnet application on an ICD/CRT-D device will not initiate asynchronous pacing. Magnet application on an ICD/CRT-D device may be used to check device status alerts. Consult the appropriate individual device/clinician manual for specific guidance under which magnet operation is recommended. http://manuals.medtronic.com/manuals/main/region

This Standard Letter addresses Magnet Operation

This document is useful to health care professionals who perform medical procedures on patients with Medtronic implanted cardiac device systems and who consult with the patients' cardiologists.

OVERVIEW

The Model 9466 Patient Magnet is a blue coated, ring-shaped magnet.

MAGNET APPLICATION
Continued

Figure 1: 174105-2 Magnet

Magnet Description: Model 9466 or part number 174105, is a blue-coated, ring-shaped permanent ferrous magnet with minimum field strength of 90 Gauss when measured 1.5 inches from either flat side of the magnet (see Figure 1).

Storage and handling

- The magnet could damage some electronic devices if kept too close.
- Keep the magnet at least 15 cm (six inches) from electronic devices and recordings: VCRs, televisions, and videotapes; bank and credit cards, cordless and cellular telephones, computers, diskettes, calculators, etc.
- Keep the magnet at least 5 cm (two inches) from watches and clocks.
- If soiled, the magnet can be wiped clean with a soft cloth or a sponge, or washed with a non-abrasive cleanser. The magnet is not damaged by being submerged in water.

Shape	**Ring**
Size	**Approx. 75 mm (3") diameter x 16 mm (5/8") thick**
Materials	**Ferrous alloys coated with epoxy**
Minimum field strength	**90 gauss measured 40 mm (1.5") from magnet surface**

IPG or CRT-P MAGNET OPERATION

When a magnet is placed near the device, the pacing mode changes from the programmed mode to DOO, VOO, or AOO, and the pacing rate changes to 85 bpm or 65 bpm. Placing a magnet near the device suspends tachyarrhythmia detection. When the magnet is removed, the device returns to its programmed operation.

Note: Magnet operation does not occur if telemetry between the device and programmer is established or if MRI SureScan is on.

The pacing mode will be DOO when the programmed pacing mode is a dual chamber mode or an MVP mode (AAIR<=>DDDR, AAI<=>DDD), VOO when the programmed pacing mode is a single chamber ventricular mode, and AOO when the programmed pacing mode is a single chamber atrial mode.

IPG or CRT-P MAGNET OPERATION (Continued)

The pacing rate will be 85 bpm (700 ms) if the device conditions are normal and it will be 65 bpm (920 ms) if a Recommended Replacement Time (RRT) indicator or an electrical reset has occurred. Some pacemakers may deliver the first three beats of magnet response at 100 ppm, followed by pacing at a rate of 85 ppm. Others will only deliver a magnet response at 85 ppm*.

Magnet use for initiating asynchronous pacing in an IPG or CRT-P device:

1. *Locate the patient's implanted device by gently feeling for the device under the skin (typically in the left or right pectoral area)*
2. *Place the magnet directly over the device*

***** The magnet rate of older Medtronic pacemakers may be different than 85 ppm or 65 ppm. Please refer to the Medtronic Pacemaker and ICD Encyclopedia available on www.Medtronicacademy.com for the model's specified magnet and non-magnet response.

ICD or CRT-D MAGNET OPERATION

The Model 9466 Patient Magnet is used with certain Medtronic Implantable Cardioverter Defibrillators (ICDs) that provide a programmable Patient Alert™ monitoring feature.

If any Patient Alert condition (low battery voltage, lead impedance out of range, etc.) that is programmed On has occurred, these ICDs emit an audible Patient Alert™ tone. By placing the magnet over the ICD, the clinician or the patient can replay the Patient Alert™ tone.

The Patient Alert condition does not need to be present at the time of the replay. The tone indicates whether a programmed condition has *occurred* since the last device interrogation.

Warnings

The ICD suspends its tachyarrhythmia detection and therapy operations while the magnet is in place. Removing the magnet restores the ICD to its programmed operation. The magnet does not affect the ICD's bradycardia pacing operations.

To ensure tachyarrhythmia therapy if necessary, the patient should not carry, store, or leave the magnet positioned over the ICD. The patient should be careful to avoid sources of electromagnetic interference (EMI) while applying the magnet.

Directions for use

How to suspend or resume detection with a magnet

1. To suspend detection, place the magnet (such as the Model 9466 Tachy Patient Magnet) over the device.
2. To resume detection, remove the magnet from over the device.

   Note: The programming head contains a magnet. When the programmer is using wireless telemetry, you can suspend detection by placing the programming head over the device.

The Model 9466 Patient Magnet can be used whenever a Patient Alert™ tone has been announced.

Medtronic CareAlert events trigger patient alerts that are clinician-defined or system-defined and emit tones that can be differentiated using 2 levels of urgency:

- Clinician-defined alerts may be programmed as high-urgency or low-urgency and may be turned on or off.
- System-defined alerts are high-urgency, and they are always on.

High-urgency alerts emit a dual, high-low tone. Low-urgency alerts emit an intermittent on-off tone. High-urgency tones may indicate that there is a device problem that needs immediate attention. Alerts are displayed in the Observations window on the Quick Look II and Alert Events screens of the Medtronic programmer.

ICD or CRT-D MAGNET OPERATION (Continued)

When an alert is initiated, the device emits the tone pattern either at a selected time of day or at a fixed time interval. The tone then sounds each day at the selected time or interval until the alert is cleared (or until Device Tone is set to Off). **Active tones also sound when the patient magnet is placed over the device.** You can view alert details on a programmer during a patient session.

Instructing the patient

It is important that patients understand that they may hear alert tones emitted from implanted devices. They must know what to do when an alert sounds.

Warning: Make sure that patients understand that they must not carry, store, or leave the patient magnet positioned over the device. Device operation is temporarily impaired when the magnet is placed over the device and it must be moved away from the device to restore normal operation.

- Instruct patients to contact you immediately if they hear ANY tones from the device.
- Advise patients of the time of day that you have programmed an alert tone to sound. If a tone sounds, they should expect it to sound every day at that time until the alert is cleared (or until Device Tone is set to Off).
- For patients with a Medtronic patient monitor, advise them that if an alert is not successfully transmitted to the monitor within 72 hours, a high-urgency tone sounds each day at the programmed alert time.
- Make sure patients know that the alert time does not adjust for time zone changes.
- Advise patients that they may hear a steady test tone or any active alert tones if they are in the presence of a strong electromagnetic field, such as the field within a store theft detector. Advise patients that the device operation is temporarily impaired in these situations and that they should move away from the source of the interference to restore normal device operation.

Patients should also understand the purpose of the patient magnet and how and when to use it. Make sure that they know that current patient alerts sound when the patient magnet is placed over the device. Demonstrate how to place the patient magnet over the device to replay the alert tones, and review the patient magnet manual with them. Patients can use a folded patient magnet manual as a reference card.

The patient may wish to call the follow-up clinician and **use the magnet to replay the tone** over the telephone.

1. Call the follow-up clinician, using a conventional (not cellular) telephone*.
2. Hold the face of the magnet directly over the ICD (Figure 1).

* Mobile telephones, including cellular telephones and smartphones, are not likely to affect cardiac devices. However, some accessories for mobile telephones contain magnets, such as cases with magnetic clasps. Keep these accessories at least 15 cm (6 in) away from cardiac devices. If you wish to call the office using a cellular phone, place the phone to the ear on the opposite side of your implant site. When initiating the audible tone using a magnet, hold the phone at least 6 inches away from your implant site – the sound emitted from the device should be loud enough for your care giver to hear it.

ICD or CRT-D MAGNET OPERATION (Continued)

Figure 1. 9466 Magnet Application

3. After about a second, the ICD sounds one of three tones. If more than one Patient Alert™ condition has occurred since the last interrogation, the highest urgency tone is sounded.

Continuous tone	**No programmed Patient Alert™ condition has occurred**
Intermittent on/off tone	**A Low-Urgency condition has occurred**
Dual high/low tone	**A High-Urgency condition has occurred**

4. Move the magnet away from the ICD once the tone begins to sound.
5. The audible tone continues for at least two seconds (maximum of 30 seconds). The magnet can be applied again to retrigger the tone if necessary.
6. If a Patient Alert™ condition has occurred, the audible tone sounds automatically each day at the programmed time until the ICD is interrogated with a Medtronic programmer. At the time of interrogation, the clinician can retrieve a detailed report of the alert condition.
7. Refer to the applicable ICD or CRT-D technical manual for additional information.

Additional Labeling

Consult the appropriate individual device/clinician manual for specific guidance under which magnet operation is recommended.

http://manuals.medtronic.com/manuals/main/region

9466 Tachy Patient Magnet Technical Manual, for implantable cardioverter defibrillators and cardiac resynchronization therapy defibrillators. M940929A001C 197773001 Rev C 2005-01-28.

Medical Procedure and EMI Precautions, for implantable cardioverter defibrillators and cardiac resynchronization therapy defibrillators. M940929A001C 2014-03-10.

Medical Procedures and EMI Precautions, for MR Conditional Cardiac Implantable Electronic Devices. M955447A001 2015-04-30, and (non-MR Conditional) Cardiac Implantable Electronic Devices, M962179A001 A 2016-01-27, www.medtronic.com/manuals.

Additional comments

For further information please contact the following:

- **Technical questions:** Medtronic Technical Services can answer additional questions regarding these device operations. **Device labeling:** For additional device-specific guidance**,** consult the labeling associated with the device available on the Medtronic Manual Library website at www.medtronic.com/manuals.
- **Patient questions:** Patients who have questions can contact Medtronic Heart Rhythm Patient Services at 1-800-551-5544, Option 3, email at pshelp@medtronic.com, or see www.medtronic.com/rhythms for a variety of resources.