



Standard Letter  
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## ELECTROMAGNETIC COMPATIBILITY (EMC) ELECTROMAGNETIC INTERFERENCE (EMI)

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**IPG – IMPLANTABLE PULSE GENERATOR (PACEMAKER)**

**ICD – IMPLANTABLE CARDIOVERTER DEFIBRILLATOR**

**ILR – IMPLANTABLE LOOP RECORDER**

Medtronic pacemakers, defibrillators, and loop recorders have been designed and tested to operate normally during a patient's exposure to the electromagnetic fields commonly encountered in the work and home environments. The patient, physician and employer together need to consider the ability of the patient to resume work after receiving a device.

The following are three principal types of interference

- **Conducted interference** occurs when the patient is in direct contact with the electrical source. The most risk and actual accounts have occurred from poorly maintained electrical equipment. Conducted currents should be avoided.
- **Radiated fields** are those signals which propagate through the air and may potentially induce current that can be detected by the implanted device. Common sources of these fields include high-voltage power lines, radio transmission towers, or two-way wireless communication equipment.
- **Static magnetic fields** are those produced by a permanent or direct current (DC) electro-magnet.

Typical Response by each type of device (effects are typically temporary):

Source	IPG	ICD	ILR
Conducted Interference -OR- Radiated Electric/Magnetic Fields	Inhibition, Reversion or high rate pacing	Inhibition, Shock or high rate pacing	False Episode Activation
Static Magnetic Fields (DC)	Asynchronous pacing	Suspend Detection (pacing unaffected)	No effect

Interference to a device from electromagnetic fields is unlikely, but has been known to occur in some instances.

## ELECTROMAGNETIC COMPATIBILITY (EMC)

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### ELECTROMAGNETIC FIELDS—THRESHOLDS

The following are field intensity limits for Medtronic IPGs and ICDs. The following limits are stated relative to where the patient's torso may be located:

EMI Source	Field Intensity Limit
Power Frequency (50/60 Hz)	6,000 volts per meter
High Frequency (150 KHz & up)	100 volts per meter
Static Magnetic Fields (DC)	5 Gauss
Modulated Magnetic Fields	80 Amps/meter (1 Gauss) up to 10 KHz and 1 Amp/meter for greater than 10 KHz

Although Medtronic does not provide on-site environmental testing, technical assistance can be provided to the environmental consultant or employer in interpreting test results. Medtronic Technical Services can answer questions regarding EMC and possible device interactions.

End of Document

## EMI in the Workplace Environment

Medical devices have become very sophisticated since the introduction of the first implantable pacemaker in the late 1950's. Similarly, technology of items found in the home and workplace environments have become very sophisticated to the point where interaction between some products and implanted devices can occur. Mechanical and electrical shielding designed into pacemakers and implantable cardioverter-defibrillators (ICDs), has, in most cases, enabled these medical devices to be immune to external electromagnetic interference (EMI). Most of the common home and workplace items that can generate EMI typically do not interfere with normal operation of implantable medical devices.

There are instances where equipment in a home, workplace or other environment may produce levels of electromagnetic interference capable of interfering with an implantable pacemaker or ICD. When interference is encountered, there are various device responses (some of which are listed below) that can occur and are usually temporary until the source of the EMI is removed or the patient moves outside the EMI field. If interference is encountered, once the patient is no longer exposed to the EMI field, normal device function usually returns. In the event that an EMI source strong enough to affect an implanted device is encountered, one or more of the potential responses listed in Table 1 below may occur.

Table 1 – Potential device responses.

Response A description of each is outlined in the bullets below.	Pacemakers	ICDs
Asynchronous pacing/ Magnet mode operation	Possible	Possible
Inhibition of pacing	Possible	Possible
Tracking up to programmed Maximum Rate	Possible	Possible
Inappropriate shocks/ATP	N/A	Possible
Inhibition of High Voltage/ATP therapy	N/A	Possible
Device Damage	Unlikely	Unlikely

- Asynchronous pacing due to electrical noise is a safety feature that forces pacing regardless of the patient's own rhythm. Magnet mode will also cause asynchronous pacing in response to a magnetic field in pacemakers.
- Inhibition of pacing (pauses in pacing) may occur at the onset of noise or with continued noise.
- In dual chamber devices noise detected on the atrial channel may result in temporary increased ventricular paced rates within the programmed limits.
- Noise could inhibit or trigger high voltage/Anti-Tachycardia Pacing (ATP) therapy.
- The presence of a static magnetic field may inhibit shock therapy.
- An external high voltage shock may result in device damage. This type of interference is not specified in the Field Strength Test Limits table below.

The susceptibility of an implanted device being affected by the environment or an external source of EMI is influenced by many factors including the patient body mass,

the implanted device configuration and programmed settings, the proximity and orientation to the EMI field as well as the EMI field strength.

For patients who work in, or frequent locations that may expose them to high levels of electromagnetic interference, specific testing of an environment should be undertaken if a medical professional deems there is sufficient risk to the patient based on the patient's medical history.

St. Jude Medical does not provide field testing of potential sources of interference. Patients who work at facilities where EMI sources may be present should consider advising their employer that they have an implanted medical device and that environmental testing may be in order. This type of assessment can be performed by a trained EMI testing consultant at the employer's request. Testing typically includes the work areas the employee would encounter, but may include the entire facility as the employer and tester deem necessary. A list of some potential EMI test consultants is provided to help facilitate this testing. St. Jude Medical does not recommend any particular consultant nor do we ensure the quality of the EMI testing performed. EMI field strengths encountered above those listed in Table 2 may cause device interference with an undesired device response.

Table 2 - Field Strength Test Limits

EMI Source	Field type	Field strength limit
High Voltage Power Lines (50/60 Hz)	E-field	6000 V/m peak
Continuous Wave and/or Modulated Magnetic Fields (50/60 Hz)	H-field	80 A/m peak
Static Magnetic Field	B-field	5 Gauss (0.5 mT) peak

The above mentioned H-field limit will vary depending on the frequency of the EMI. Further standards may be reviewed for other frequencies in the International Non-Ionizing Radiation Protection (ICNIRP) recommendations for reference levels for general public exposure to time-varying electric and magnetic fields.

- The H-field limit is useful in ensuring that a time varying magnetic field will not induce electrical voltages or currents in the lead-device-tissue loop area. Any induced electrical signals should be below the device sensing threshold, and well below the capture threshold just as for an E-field.
- The B-field limit is useful in ensuring that the device magnet mode (using the GMR – Giant MagnetoResistive sensor) will not activate. The formal standard is that a device shall not detect environmental fields less than or equal to 10Gauss (1 milliTesla). The clinical field magnets are much stronger, about 125Gauss at one inch distance to ensure properly activating the sensor when desired.
- Some commercially available measuring instruments may switch between H units (Amperes/meter or Oersteds) and B units (Gauss or Tesla). Different equipment is needed to measure H- or B-fields. H-fields require frequency and area to be accounted for. Therefore different probes (antenna) will be required to make the measurements.

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St. Jude Medical pacemakers and ICDs are designed to meet the electromagnetic compatibility requirements described in the following standards:

European Standard EN 45502-2-1

Active Implantable Medical Devices Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (Cardiac pacemakers).

European Standard EN 45502-2-2

Active Implantable Medical Devices, Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators).

2007 American National Standard ANSI/AAMI PC69, 2<sup>nd</sup> edition  
Implantable Medical Devices – Electromagnetic compatibility.

St. Jude Medical does not provide recommendations regarding a patient's ability to return to work because we can not account for every variable or unique condition in the workplace environment. Technical Services can provide technical assistance to the employer or testing consultant in interpreting test results related to various EMI sources and potential responses.

If you have any questions on this topic please contact CRM Technical Services.

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