



# Therapeutic Radiation

The guidance provided in this letter is for healthcare providers and Medtronic representatives, and it applies to the following devices types:

**IPG** – Implantable Pulse Generators (Pacemakers)

**ICD** – Implantable Cardioverter Defibrillators

**CRT-P** – Cardiac Resynchronization Therapy Pacemakers

**CRT-D** – Cardiac Resynchronization Therapy Defibrillators

**ICM** – Implantable Cardiac Monitors

This letter addresses the following concerns related to cancer radiotherapy (RT) and devices:

1. Device Interference leading to pauses in pacing therapy or inadvertent shocks in defibrillator patients
2. Device Operational Errors (Memory Errors)
3. Permanent Device damage

## Device Interference

If a patient undergoes radiotherapy, the device may inappropriately sense direct or scattered radiation as cardiac activity for the duration of the procedure. Average dose rates at the device of less than 1 cGy/min (centigray per minute) are unlikely to produce device interference. Decreasing the dose rate (for example, by increasing the distance between the device and the beam) decreases the risk of interference.

The programmer can be utilized to determine if there is device interference during the initial therapy. The device marker channels can be monitored for interference. If no interference is reflected in the marker channel, it is unlikely to occur with future treatments provided there are no changes in the therapy.

Device evaluation is recommended when all therapies are complete.

The following precautions can minimize complications if oversensing is noted:

- Suspend tachyarrhythmia detection using a magnet, or disable tachyarrhythmia detection using the programmer. After the radiotherapy procedure is complete, remove the magnet or use the programmer to enable tachyarrhythmia detection.
- Pacemaker patients who can tolerate asynchronous operation may have a magnet secured over their pacemaker or have the pacing mode programmed to an asynchronous pacing mode such as DOO, VOO or AOO.

Remove the magnet or program the device parameters to the original setting after each radiotherapy session is complete.

How to contact U.S. CRDM Technical Services:

Pacemakers: (800) 505-4636, ICDs: (800) 723-4636, Instruments: (800) 638-1991. Email: [tshelp@medtronic.com](mailto:tshelp@medtronic.com)

This information is verified for devices approved in the U.S. and may differ by country.  
For product-specific information on device operation and indications for use, reference the appropriate product labeling.

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## Device Operational Errors (Memory Errors)

Exposing the device to direct or scattered neutrons may cause electrical reset, errors in device functionality, errors in diagnostic data, partial loss of diagnostic data or complete loss of diagnostic data.

The use of photon beams less than or equal to 10 MV will greatly reduce the neutron flux and, consequently, the probability of any of these errors occurring. Photon beams at 6 MV or electron beams that do not produce neutrons cannot cause these errors. The use of conventional x-ray shielding during radiotherapy does not protect the device from the effects of the neutrons.

Device interrogation at the conclusion of all treatment is recommended.

An electrical reset does not indicate damage to the device; however, a reset requires device interrogation. In rare cases, a device reset may be delayed for several days following neutron exposure.

Electrical resets should be reported to Technical Services. If a device programmer is available a Save-to-Disk file containing the device's memory image should be included with the report.

### *Evaluating a defibrillator for a device reset*

A magnet may be used to check whether an electrical reset occurred for defibrillator (ICD and CRT-D) patients. Place the magnet over the device and listen for the Patient Alert tone from the device. Note the following:

1. If there is no tone or a steady tone, then an electrical reset did not occur.
2. If the tone is high/low, like a European police siren, then an electrical reset occurred and the device must be checked.

### *Evaluating a pacemaker for a device reset*

Place a magnet over the device. A pacing rate of 65 bpm indicates a reset has occurred.

## Permanent Device Damage

Do not expose the device to high doses of direct or scattered radiation. All currently manufactured devices use a type of circuitry that can be affected by radiation. An accumulated dose of radiation exceeding the recommended values to the device circuits may damage the device; however, the damage may not be immediately apparent. If a patient requires radiation therapy from any source, do not expose the device to a radiation dose exceeding the recommended values. Consider the accumulated dose to the device from previous exposures for patients undergoing multiple courses of radiation treatment.

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If it is not possible to meet the device's recommended dose limit then it may be moved to an alternate location to reduce the dose. Pacing and defibrillation lead extenders may be used to extend the existing lead to the new implant location. The lead and lead extenders will not be damaged by the radiation.

Tests on Medtronic devices have demonstrated radiation damage at doses exceeding their listed tolerance that may affect device operation. We are unable to predict the operation of devices that have been exposed to doses greater than their listed tolerance. Devices exposed above their tolerance should be monitored after each radiation treatment and should be considered for replacement. An intensified follow-up schedule for these devices following the completion of all therapy should also be considered. The dose tolerance for all Medtronic pacemakers (IPG and CRT-P devices) and implantable cardiac monitors (ICM) is 500 cGy. Some older models of Medtronic defibrillators (ICD and CRT-D devices) have had a lower radiation tolerance. The radiation tolerances for all devices are listed in the following table.

Device Type	Device Family	Model Numbers	Dose Limit
ICD	AT500, GEM, GEM DR, GEM II DR, GEM III AT, GEM III VR, Insync ICD, Jewel, MicroJewel, Onyx VR	7221, 7223, 7227, 7229, 7231, 7250, 7271, 7272, 7273, 7275, 7276, 7290, 7253	100 cGy
ICD	Concerto, Virtuoso	D154AWG, C154DWK, D154VWC, D164VWC, D164AWG, C164AWK, C174AWK	300 cGy
ICD	All ICD families not listed above	All ICD models not listed above	500 cGy
CRT-D	All CRT-D families	All CRT-D models	500 cGy
IPG	All IPG families	All IPG models	500 cGy
CRT-P	All CRT-P families	All CRT-P models	500 cGy
ICM	All ICM families	All ICM models	500 cGy

## Additional Information

- Technical questions: For further guidance on radiation that are not addressed in this letter, contact Medtronic CRDM Technical Services (see contact information below) or contact your Medtronic representative.
- Device labeling: For device-specific guidance, consult the labeling associated with the device, which is available on the Medtronic Manual Library website at [www.medtronic.com/manuals](http://www.medtronic.com/manuals).
- Patient questions: Patients who have questions can contact Medtronic Heart Rhythm Patient Services at 1-800-551-5544 or see [www.medtronic.com/rhythms](http://www.medtronic.com/rhythms) for a variety of resources.

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