Standard Letter
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THERAPEUTIC RADIATION

PACEMAKER (IPG – IMPLANTABLE PULSE GENERATOR)
DEFIBRILLATOR (ICD – IMPLANTABLE CARDIOVERTER DEFIBRILLATOR)
REVEAL (ILR – INSERTABLE LOOP RECORDER)

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 ICD patients
2. Device Operational Errors (Memory Errors)
3. Permanent Device damage

1. 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.

2. Device Operational Errors (Memory Errors)

Exposing the device to direct or scattered neutrons may cause the following:

- electrical reset of the device
- errors in device functionality
- errors in diagnostic data
- loss of diagnostic data

Use photon beam energies less than or equal to 10 MV to deliver radiotherapy treatment in order to reduce the chance of any of the above memory errors and resets. 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. Electron beam treatments that do not produce neutrons do not cause electrical reset of the device.

An electrical reset does not necessarily indicate damage to the device; however, a reset requires device interrogation.

In rare cases, a device reset may be delayed for several days due to memory errors. Electrical resets should be reported to Technical Services followed by sending a Save-to-Disk file.

Evaluating for a device reset

ICD

A magnet may be used to check whether an electrical reset occurred for defibrillator (ICD) patients. Place the magnet over the ICD and listen for the Patient Alert tone. 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 police siren, then an electrical reset occurred and the device must be checked.

IPG

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

3. Permanent Device Damage

Do not expose the device to high doses of direct or scattered radiation. All currently manufactured Pacemakers (IPGs) and Insertable Loop Recorders (ILRs) use a type of circuitry that is 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 radiation exceeding the recommended values. Consider the accumulated dose to the device from previous exposures for patients undergoing multiple courses of radiation treatment.

If it is not possible to miss the device with the beam, the device should be moved to an alternate location since direct exposure or scattered radiation will often result in excessive amounts of radiation to the device. Pacing and defibrillation lead extenders may be used to extend the existing lead to the new implant location. The lead or extenders will not be damaged by the radiation.

Device tolerances for IPGs and ILRs are 500 cGy

Tests on Medtronic pacemakers have revealed minor radiation damage at accumulated dosages over 500 cGy (centigray) so we are unable to predict the operation of devices that have been exposed to more than 500 cGy. Devices that fall into this category should be monitored after each radiation treatment and should be considered for replacement.

Defibrillators (ICD – Implantable Cardioverter Defibrillator)

The following dose limits apply to Medtronic Antitachyarrhythmic Devices*:*

100 cGy

- **Device Families:** AT500, GEM, GEM DR, GEM II DR, GEM II VR, GEM III AT, GEM III VR, Insync ICD, Jewel, MicroJewel, Onyx VR
- **Model Numbers:** 7221, 7223, 7227, 7229, 7231, 7250, 7271, 7272, 7273, 7275, 7276, 7290, 7253

300 cGy

- **Device Families:** Concerto,Virtuoso
- **Model Numbers:** D154AWG, C154DWK, D154VWC, D164VWC, D164AWG, C164AWK, C174AWK

500 cGy

- **Device Families:** Consulta, Entrust, Insync Marquis, Insync II Marquis, Insnyc Maximo, InSync II Protect, InSync Sentry, Intrinsic, Intrinsic 30, Marquis DR, Marquis VR, Maximo DR, Maximo VR, Maximo II, Secura DR, Secura VR
- **Model Numbers:** 7230, 7232, 7274, 7277, 7278, 7279, 7287, 7288, 7289, 7295, 7297, 7298, 7299, 7303, 7304, D153ATG, D153VRC, D154ATG, D154VRC, D224DRG, D224VRC, D224TRK, D284TRK, D284DRG, D284VRC