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Standard Letter CRDM Technical Services U.S. Mounds View, MN Brady (800) 505-4636 Tachy (800) 723-4636 Instruments (800) 638-1991

CT SCAN/CAT SCAN X-RAY EFFECTS ON MEDTRONIC PACEMAKERS & ICDs Rev B, 21-JUL-2008, Page 1 of 2

PACEMAKER (IPG – IMPLANTABLE PULSE GENERATOR)
DEFIBRILLATOR (ICD – IMPLANTABLE CARDIOVERTER DEFIBRILLATOR)

OVERVIEW

Medtronic has tested representative samples of their implantable pacemakers and ICD models, and predicted the expected effects of the following four methods of CT scanning:

- 1. Axial CT scan, also called Computed Axial Tomography (CAT) scan
- 2. Helical scan CT, also called Spiral scan CT
- 3. Dynamic scan CT
- 4. Cardiac gated scan CT

Results from this testing provides the following information:

- 1. X-rays from a CT scan and electrical interference from the CT scanner may interfere with the operation of an IPG or ICD. Interference will present as oversensing, possibly resulting in inhibition of the pacing function of IPGs or ICDs.
- 2. X-ray exposure from CT scans will not cause any permanent physical damage to an IPG or ICD system.
- 3. Electrical reset is possible. Operational parameters in devices which have been reset may be reprogrammed to pre-reset values with a Medtronic programmer.

CONSIDERATIONS

- 1. The risk of interference has been reported during the time of exposure when the implanted device (IPG or ICD only) is <u>directly in the X-ray beam</u>. The time of exposure varies with the type of CT scan.
- 2. Monitor the ECG of pacemaker and ICD patients during a CT scan.
- 3. If an electrical reset is suspected after a CT scan (e.g., the IPG rate is 65 ppm with magnet after scan), the device should be interrogated using a Medtronic programmer to determine if it experienced an electrical reset, and if so, reprogram it as needed.
- 4. If the duration of time directly in the beam is going to be longer than 4 seconds, consider appropriate measures for the patient, such as enabling an asynchronous mode for a pacemaker dependent patient, placement of an appropriate magnet, (Medtronic Model 9466T, part # 174105, or Smart Magnet Model 9322), or turning arrhythmia detections on an ICD to "OFF."

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CT SCAN / CAT SCAN EFFECTS ON PACEMAKERS & ICDs Rev B, 21-JUL-2008, Page 2 of 2

POTENTIAL EFFECTS OF CT SCAN X-RAY ON IPG'S AND ICD'S

If a patient undergoes a CT scan procedure and the device is not directly in the CT scan x-ray beam, the device will not be affected. When the device is directly in the CT scan x-ray beam, oversensing may occur for the duration of the time in the beam. The risk of interference has been reported only when the implanted device is directly in the CT scan x-ray beam. If the device has been directly in the field for more than 4 seconds, the device should be interrogated after the CT scan.

PACEMAKER (IPG - IMPLANTABLE PULSE GENERATOR)

Oversensing the CT scan x-ray beam may cause the following:

- Inhibition of pacing on one or both channels
- Reversion pacing. If oversensing occurs several times per second, it can cause reversion
 which causes the IPG to pace asynchronously at the programmed lower rate or sensorindicated rate.
- Extra ventricular pacing due to oversensing on the atrial channel. Ventricular pacing would be limited to the programmed upper rate limit during this time.
- Competing rhythms

The effects of oversensing in an IPG can be eliminated or modified by the application of an appropriate magnet over the implanted device or by programming the IPG to an asynchronous mode, such as DOO or VOO if the duration of time in the beam is more than 4 seconds. Application of a magnet or device reprogramming will NOT reduce the probability of an electrical reset..

DEFIBRILLATOR (ICD - IMPLANTABLE CARDIOVERTER DEFIBRILLATOR)

Oversensing the CT scan x-ray beam may cause the following:

- False detection of a VT/VF or AT/AF which may cause inappropriate therapy to be administered.
- Inhibition of pacing on one or both channels
- Extra ventricular pacing due to oversensing on the atrial channel. Ventricular pacing would be limited to the programmed upper rate limit during this time.
- Competing rhythms

The effects of false detection in an ICD can be eliminated by the application of an appropriate magnet or by programming detections to OFF if the duration of time directly in the beam is more than 4 seconds. Application of a magnet will NOT eliminate or modify the effects of oversensing on the bradycardia pacing and sensing operation of the ICD.