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Tech Note

Date: November 26, 2008

To: All Field Personnel

From: Biotronik Technical Services

Re: Computed Tomography (CT) Scans and Biotronik Implantable Devices

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Background

A computed tomography (CT) scan delivers x-ray radiation from multiple angles to create a cross-sectional image of the patient's body. The CT scan can also be called computed axial tomography, or CAT scan. Recent reports[1] and studies[2,3] have suggested that when CT x-rays are delivered directly over an implantable cardiac device, it is possible for the radiation to cause the device to sense non-physiologic changes in voltage. These sensed voltages may lead to transient inhibition of pacing output, safety pacing, tracking at high rates, or inappropriate arrhythmia detection and therapy. In rare cases where a high radiation dose is applied directly to the pulse generator, the implanted cardiac device may revert to a backup mode.

Based upon the cited references (please refer to page 2), Biotronik recommends the precautions described below. There have been no reports to suggest that these precautions are unique to Biotronik devices; the recommendations are derived from research that is applicable to devices across the industry.

Recommendations

If the pulse generator will not enter the x-ray beam, there is a very low possibility for interference and the CT scan may be performed as usual.

If the pulse generator will enter the x-ray beam, the CT scan should be planned to minimize both the time that the generator will be under the beams, and the peak radiation dosage delivered to the device. The patient ECG should be monitored, and cardiac emergency equipment should be available during the procedure. Clinicians should be aware of potential for transient changes to the pacing/defibrillation functions of the implanted device. If there is any indication that abnormal device function persists after concluding the scan, the device should be interrogated to ensure normal operation.

The patient's following physician should be contacted to determine if device reprogramming is necessary prior to the CT scan and what type of reprogramming is suggested. Studies have indicated that the potential for interference with the implanted device only exists when the x-ray beam is directly over the device. Given this, the physician may consider the time the x-ray beam will be applied to the device, as well as the patient's condition and device settings, to determine if any programming changes are necessary. Programming changes may include disabling tachycardia detection and therapy in ICDs, or using an asynchronous pacing mode in pacemakers. Any programming changes should be returned to the original parameters after the CT scan is completed.

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References

1. "FDA Preliminary Public Health Notification: Possible malfunction of Electronic Medical Devices Caused by Computed Tomography (CT) Scanning." CDRH Medical Device Safety Public Health Notifications: www.fda.gov/cdrh/safety/071408-ctscanning.html. (2008).

2. "Effects of CT Irradiation on Implantable Cardiac Rhythm Management Devices." McCollough, C., et al. Radiology 243(3): 766-774 (2007).

3. Does High-Power Computed Tomography Scanning Equipment Affect eh Operation of Pacemakers?" Yamaji, S., et al. Circulation Journal 70: 190-197 (2006).

Please contact Technical Services for additional questions: 1-800-284-6689