

On July 14, the U.S. Food and Drug Administration issued a preliminary public health notification alerting healthcare professionals of the possibility that x-rays delivered during diagnostic computed tomography scanning could cause some electronic medical devices to malfunction (<http://www.fda.gov/cdrh/safety/071408-ctscanning.html>). This notification was prompted by a small number of clinical reports linking adverse events with implanted and external electronic medical devices with exposure to x-rays during computed tomography (CT) scanning. Adverse events included unintended "shocks" from neurostimulators, insulin pump malfunctions, and transient changes in pacemaker output pulse rate. The FDA also noted similar reports in the literature (1, 2, 3). Although there is not yet a comprehensive understanding of the potential risks, the FDA recommends precautionary steps be taken before using CT to image patients with cardiac pacemakers, implantable cardiac defibrillators, neurostimulators, drug infusion pumps (including insulin pumps), cochlear implants, and retinal implants. The following potential risks were identified: 1) generation of spurious signals, including cardiac defibrillation pulses, 2) misinterpretation of signals produced by the x-rays as actual biological signals, 3) missed detection of actual biological signals, 4) resetting or reprogramming of device settings.

The potential for radiation-induced malfunction of life-supporting implantable cardiac rhythm management devices (ICRMDs) such as pacemakers and defibrillators has long been recognized. X-rays interfere with such devices by inducing current within the electronic circuitry. X-ray induced malfunction is more likely with both higher instantaneous exposures to the device and higher cumulative exposures. These in turn are influenced by the amount of attenuating tissue between the x-ray source and the device

and the dwell time of the x-ray beam over the device. Subsequently, adverse events are known to occur if ICRMDs are in the therapeutic field during radiation therapy, but have not been a clinical concern during diagnostic CT exams, which are associated with much lower radiation dose levels.

However, in a recent ex-vivo study by McCollough et al (2), radiation-induced disruption of normal ICRMD function was detected even at clinical radiation doses. Twenty-one ICRMDs manufactured by Medtronic were exposed to ionizing radiation from typical and high dose cardiovascular CT scanning. Malfunctions occurred when the devices were in the primary x-ray beam and subject to the highest instantaneous exposure. The likelihood of malfunction increased with the dwell time of the x-ray beam over the device. The authors concluded that 1) the effects on the ICRMDs studied were largely temporary with a return of normal function after CT scanning and 2) the likelihood of permanent damage to the devices at standard radiation doses was low. The results confirmed earlier findings by Yamaji et al (1).

The recent FDA clinical adverse event report suggests that the interference of x-rays delivered during diagnostic CT examinations may be related to technical modifications of newer CT scanners and cardiac protocols. X-ray exposure has gradually increased for cardiovascular imaging in response to shortening gantry rotation times and shrinking x-ray detector element size and as a consequence of increased x-ray tube power. Further, exposure to ICRMDs has significantly increased with the increase in the number of cardiovascular CT scans performed because the devices are within the scan range and subject to direct, rather than scattered, radiation. Additionally, lower helical pitch values contribute to an increase in the dwell time of the x-ray beam over the device.

The device malfunctions may also stem from modifications to newer electronic medical devices leaving them more vulnerable to x-ray interference as well as the increasing number of patients with devices such as ICRMDs. Another plausible explanation for the apparent increase in occurrence of adverse events may simply be that effects were not noticed and/or reported previously. Further evaluation is necessary.

In the meantime, the FDA still recommends CT scanning for patients with these devices but urges implementation of precautionary safety measures that include

- Examination of the localizer image to confirm the presence or absence of an implanted or externally worn electronic medical device.
- Determination of the device type.
- Turning off non-life supporting devices such as neurostimulators during CT scanning.
- Relocating external devices outside the scan field to the extent possible.
- Modifying the diagnostic scan range to exclude implanted devices to the extent possible.
- Minimizing radiation exposure to the device by using the lowest possible tube current and tube voltage allowable to obtain a diagnostic image.
- Insuring the dwell time of the x-ray beam over the device is less than three seconds by increasing the pitch of a helical scan or increasing the detector collimation. If this cannot be accomplished (e.g., for CT perfusion scanning or interventional CT procedures), prepare for emergency measures.

The SCCT endorses these safety measures and supports comprehensive evaluation of available devices from other ICRMD manufacturers and additional CT scanner models and protocols (McCollough et al systematically evaluated ICRMDs manufactured only by Medtronic and only using two scanner models). However, concern about interference, and also patient radiation dose in general, should be balanced with efforts to obtain diagnostic image quality. X-ray interference with ICRMDs may result in arrhythmia during data acquisition and cardiac motion artifacts in the reconstructed image. Appropriate CT scanning of patients with arrhythmia often requires helical versus axial data acquisition, lower helical pitch, and wider full tube current window with ECG-based tube current modulation during helical scanning. However, such actions result in increases in radiation exposure and the dwell time of the x-ray beam over the device in direct contradiction to the precautionary measures outlined by the FDA. Given the low risk to patient safety, though, the FDA recommendation to minimize direct irradiation to ICRMDs may need to be tempered in the interest of obtaining diagnostic cardiovascular images with CT. However, in such situations, attending staff should be aware of the risk and verify the return to pre-CT scan heart rhythm and proper functioning of the device at the conclusion of scanning.

1. “Does High-Power Computed Tomography Scanning Equipment Affect the Operation of Pacemakers?,” Yamaji, S., et al., *Circulation Journal* 70:190-197 (2006).
2. “Effects of CT Irradiation on Implantable Cardiac Rhythm Management Devices,” McCollough, C., et al., *Radiology* 243 (3):766-774 (2007).

3. “Hazard Report—CT Scans Can Affect the Operation of Implanted Electronic Devices,” ECRI Institute Problem Reporting System, *Health Devices* 36 (4):136-138 (2007).