

SPINE SAFETY CAUTIONARY NOTICE:

Information for Healthcare Professionals: Preliminary Public Health Notification (FDA): Possible Malfunction of Electronic Medical Devices Caused by Computer Tomography (CT) Scanning

According to a preliminary public health notice issued by the FDA on Monday, July 14th, health care professionals are being advised of the possibility that x-rays used during CT exams may cause some implanted and external electronic medical devices to malfunction. The notice also provides recommendations to reduce the potential risk.

Most patients with electronic medical devices undergo CT scans without any adverse consequences. However, FDA has received a small number of reports of adverse events in which CT scans may have interfered with electronic medical devices, including pacemakers, defibrillators, neurostimulators, and implanted or externally worn drug infusion pumps. There have been similar reports in the literature. It is possible that this interference is being reported more frequently now because of the increased utilization of CT, the higher dose-rate capability of newer CT machines, an increase in the number of patients with implanted and externally worn electronic medical devices, and better reporting systems.

Adverse events

In the reports received by FDA, the following adverse events were likely to have been caused by x-rays from CT scans:

- Unintended “shocks” (i.e., stimuli) from neurostimulators
- Malfunctions of insulin infusion pumps
- Transient changes in pacemaker output pulse rate

Note that malfunctions of this kind, which can result from direct exposure of the medical device to the high x-ray dose rates generated by some CT equipment, are different from those related to MRI scanning, which are caused by strong electric and magnetic fields.

Recommendations

Before beginning a CT scan, the operator should use CT scout views to determine if implanted or externally worn electronic medical devices are present and if so, their location relative to the programmed scan range.

For CT procedures in which the medical device is in or immediately adjacent to the programmed scan range, the operator should:

- Determine the device type;
- If practical, try to move external devices out of the scan range;
- Ask patients with neurostimulators to shut off the device temporarily while the scan is performed;
- Minimize x-ray exposure to the implanted or externally worn electronic medical device by:
 - Using the lowest possible x-ray tube current consistent with obtaining the required image quality; and

- Making sure that the x-ray beam does not dwell over the device for more than a few seconds;

Important note: For CT procedures that require scanning over the medical device continuously for more than a few seconds, as with CT perfusion or interventional exams, attending staff should be ready to take emergency measures to treat adverse reactions if they occur.

After CT scanning directly over the implanted or externally worn electronic medical device:

- **Have the patient turn the device back on if it had been turned off prior to scanning.**
- Have the patient check the device for proper functioning, even if the device was turned off.
- Advise patients to contact their healthcare provider as soon as possible if they suspect their device is not functioning properly after a CT scan.

FDA is continuing to investigate this issue while working with device manufacturers and raising awareness in the healthcare community. To date, no patient deaths have been reported from CT scanning of implanted or externally worn electronic medical devices.

Additional background information related to this issue and instructions for reporting adverse events to the FDA can be found at:

<http://www.fda.gov/cdrh/safety/071408-ctscanning.html>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.