FDA Preliminary Public Health Notification: Possible Malfunction of Electronic Medical Devices Caused by Computed Tomography (CT) Scanning

Date July 14, 2008

Dear Healthcare Professional:

This is to alert you to the possibility that the x-rays used during CT examinations may cause some implanted and external electronic medical devices to malfunction, and to provide 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.²⁻⁴

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.

We are 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.

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.

Background

Experimental studies with anthropomorphic phantoms have demonstrated the potential for high dose rate CT irradiation to affect implanted cardiac rhythm management devices. Some occurrences in patients, which involved neurostimulator and pacemaker devices, have also been reported to FDA and appear in the literature.

Electronic medical devices that theoretically could be affected by CT x-rays include, but are not limited to:

- cardiac pacemakers,
- implantable cardiac defibrillators,
- neurostimulators,
- drug infusion pumps, including insulin pumps,
- cochlear implants, and
- retinal implants.

While theoretically possible, reports of CT interference with cochlear implants and retinal implants have not been received to date.
Problems with electronic medical devices that might be caused by CT scanner interference include:

- generation of spurious signals, including cardiac defibrillation pulses
- misinterpretation of signals produced by the x-rays as actual biological signals
- missed detection of actual biological signals
- resetting or reprogramming of device settings

The type of effect, if any, is likely to depend on the device type, the manufacturer and the model.

**Reporting to FDA**

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of CT equipment, you should follow the reporting procedure established by your facility.

We also encourage you to report adverse events that do not meet the requirements for mandatory reporting. You can report directly to MedWatch, the FDA Safety Information and Adverse Event Reporting program. You may submit reports online at [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm), by phone 1-800-FDA-1088, or by returning the postage-paid FDA form 3500 which may be downloaded from [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) by mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787 or fax 1-800-FDA-0178.

**Getting More Information**

If you have questions about this Notification, please contact Issues Management Staff, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by Fax at 240-276-3356, or by e-mail at phann@cdrh.fda.gov. You may also leave a voicemail message at 240-276-3357 and we will return your call as soon as possible.

FDA medical device Public Health Notifications are available on the Internet at [http://www.fda.gov/cdrh/safety.html](http://www.fda.gov/cdrh/safety.html). You can also be notified through email on the day the safety notification is released by subscribing to our list server. To subscribe, visit: [http://service.govdelivery.com/service/subscribe.html?code=USFDA_39](http://service.govdelivery.com/service/subscribe.html?code=USFDA_39).

Sincerely yours,

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

1 CDRH Preliminary Public Health Notifications are intended to quickly share device-related safety information with healthcare providers when the available information and our understanding of an issue are still evolving. We will revise this Notification as new information merits and so encourage you to check this site for updates.


5 MedSun is the FDA's Medical Product Safety Network of 350 hospitals spread throughout the United States. Information from 132 of these facilities indicated that they have not experienced any CT medical device interference, while 3 have had from 1 to 3 events that may have been CT scan induced. Fifteen MedSun facilities indicated they take some precautionary steps when CT scanning patients who have electronic medical devices.

Updated July 14, 2008