

## **Statement of the SCBT-MR Regarding the FDA Notification on CT Causing Electronic Device Malfunction**

On July 14th, 2008, the FDA issued a Public Health Notification regarding possible malfunction of electronic medical devices caused by CT. We have attached that Notice as a pdf file and have reproduced an excerpt below. The direct link to this notice is:

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

While we agree that CT scanning can affect the function (behavior) of such devices, most often very transiently, we also believe that medical professionals and the public should know that, in general, it is safe for patients with these devices to undergo CT examinations in which the device moves briefly (less than 3 seconds) through the x-ray beam as occurs in most clinical CT examinations. About 60,000,000 CT scans are performed in the USA every year and many of these implantable cardiac rhythm management devices have been in use for several years and yet there have been no reported deaths or life-threatening clinical adverse consequences from this effect of which we are aware. The effects of CT on devices have been carefully studied in a phantom model for only one manufacturer and the occasional effects encountered were transient and unlikely to be symptomatic. Reference citations are found in the FDA notification.

We believe that medical professionals should become aware of this effect and how to recognize it and we recommend that incidents be reported to the FDA. Such reporting will improve knowledge about the frequency and nature of events, and information about which devices are affected. Hopefully, with widespread compliance with reporting, the resulting information will lead to establishing appropriate safety guidelines, and will also assist manufacturers in modifying or designing products to be less sensitive to ionizing radiation, if necessary.

The FDA notification includes the following possible adverse consequences of CT radiation:

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

The FDA recommends the following actions:

"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."

The basis of this effect is ionization within the electronic components of this device during radiation exposure, which generates a small electrical current. However, because this effect has only been recently appreciated, such effects may have been largely unrecognized up to now.

As stated in the notice, other than temporarily disabling the device, a method to decrease the probability of the effect is to minimize the radiation dose rate and exposure time to the device itself. Additionally, the dwell time of the radiation is relevant because the effect lasts only during the radiation exposure to the device itself and only can be symptomatic if it lasts 3 seconds or more. Even then, symptoms are unlikely to occur.

Therefore, the FDA's recommends limiting tube current and minimizing dwell time over the device, it should be emphasized that the risk occurs not from the total radiation exposure to the device, but the radiation dose RATE the device experiences. Therefore, in addition to decreasing the tube current (mA), the following methods may be employed to reduce risk:

Increase the helical pitch to decrease the dwell time over the device without increasing tube output,

Avoid using single-location dynamic scanning, perfusion scanning or CT fluoroscopy directly over the device because this prolongs radiation exposure to it,

Place a Bismuth shield directly over the device. Bismuth may decrease local dose up to about 25-30% (J. Geleijns J, Artells MS, Veldkamp WJH, Tortosa ML, Cantera AC. Quantitative assessment of selective in-plane shielding of tissues in computed tomography through evaluation of absorbed dose and image quality. Eur Radiol 2006 16: 2334–2340).

In summary, we believe that any event that is recognized should be reported to the FDA. Employing methods to decrease the probability of a symptomatic event may be prudent, but those who perform CT examinations should be aware that based on our current knowledge, the risk of an adverse clinical event is remote.

Board of Directors, SCBT-MR