Diagnostic Radiation and Implantable Cardiac Rhythm Devices

Diagnostic X-rays are waves of electromagnetic radiation used to create images of organs and other structures inside the body. As they penetrate the body, they are absorbed in different amounts by different body tissues. For example, bones are dense and absorb X-rays very well, but soft tissues (skin, fat, muscle) allow more X-rays to pass through. The result is an X-ray shadow on a film or fluorescent screen, where images of bones appear white, while shadows of soft tissues appear as various shades of gray. This technology encompasses many forms including (but not limited to) fluoroscopy, CT scans, mammography and traditional film X-ray imaging.

These diagnostic sources emit signals that, although very unlikely, have the potential to interfere with implanted cardiac rhythm devices. The potential interference would be transient, and could occur only when the X-ray signal is present. St. Jude Medical devices are designed to minimize the potential for effects in operation and function as a result of being exposed to these sources of radiation. Standard X-rays (chest X-rays, etc., which typically last less than 1 second) have not been reported to, and are not expected to, interfere with St. Jude Medical implantable pacemakers or ICDs.

CT scans, due to their increased power levels and longer exposure times, have the remote possibility to interfere with implanted devices. Testing has shown that for devices which incorporate an accelerometer for rate responsive, activity-based pacing, if the activity sensor is programmed "on" while continuous diagnostic X-ray exposure (e.g. CT scanning) is performed if the beam of energy is directly over the implanted device, there may be a temporary increase in pacing rate during the exposure. The pacing rate will return to baseline pacing after the X-ray exposure is terminated. If increased rates occur, the pacing rate will be limited to the programmable Maximum Sensor Rate which is generally determined by the patient's physician as the safe maximum rate to be achieved during exercise. To prevent any potential transient rate increase, the clinician may want to consider programming the rate responsive sensor to Passive or OFF, if appropriate, prior to the X-ray procedure and then reprogram the parameter as desired after the diagnostic imaging is completed.

Continuous X-ray beams may also have a temporary affect on the sensing circuitry of an implantable device. Although not reported as a field event, in-vitro testing identified that there is a remote possibility for a device to intermittently oversense while the CT scanning beam is directly over the implanted device. The oversensing observed during the in-vitro testing occurred with the devices programmed to their maximum sensitivity settings. For patients undergoing a CT scan, the potential for this interaction can occur when the CT scanning beam is directly over the implanted device. Testing has shown that when the CT scan beam is greater than 2 cm from the implanted device, neither of the aforementioned interactions were observed.

If you need additional information or would like to discuss the subject further, please call Technical Services at 1-800-722-3774.

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