ST. JUDE MEDICAL

Technical Services
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Radiation

Pacemakers built prior to the early 1970's used discrete bipolar transistors which were found to be highly resistant to therapeutic radiation. Today's technology uses complimentary metal oxide semiconductors (CMOS) for their integrated circuits. Low current consumption CMOS circuits were a breakthrough in the pacemaker industry but were found to be more susceptible to therapeutic doses of radiation. The damage occurs to the silicone and silicone oxide insulators within the transistors. Diagnostic radiation, on the other hand, appears to have no effect on pacemakers manufactured today. Leads may be irradiated without risk.

Therapeutic radiation therapy is frequently used as a treatment in many types of cancer. There are three typical ways this radiation may be administered. These include radioactive cobalt, linear accelerators, and betatrons. The linear accelerators and betatrons produce radiation as well as a strong electromagnetic field.

The modes of failures are random. Some of the possible effects are loss of sensing, slight or sudden loss of output, runaway or increased rates, or inhibition. The effects are usually permanent, but may be temporary and resolve within 24 hours. Obviously, this is more likely to happen if the pulse generator is situated within the therapeutic field. The dose delivered to a pulse generator is cumulative. Meaning, you must add all the doses a particular unit has received in its lifetime to determine how much radiation it has received.

No exact amount of radiation has been determined relative to causing malfunction. The range has been as low as 2,000 rads in rare cases and as high as 15,000 rads. Individual St. Jude Medical - Pacesetter units from the Programalith® III, Phoenix®, Paragon®, Synchrony®, Trilogy®, Tempo™, Affinity®, Entity™, Integrity™ and Identity™ series have been tested to 3,000 rads, without any adverse effects. 2,000 rads is seldom encountered when the pacemaker is situated outside the irradiated field.

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St. Jude Medical's Recommendation

Do not subject pacemakers to therapeutic doses of radiation. If you must expose a pulse generator, please follow these guidelines:

Patient Evaluation Prior to Initiation of X-ray Therapy:

Assess pacemaker function. This includes an interrogation, evaluation of pacing, sensing, stimulation thresholds and diagnostic measurements (e.g. battery and lead impedance).

If radiation is to be applied directly over the pacemaker site, evaluation for pacemaker repositioning should be considered especially in the dependent patient.

Patient Management during Therapy:

The patient's vital signs should be obtained before and after each treatment. Should new symptoms develop during the course of therapy, vital signs and a thorough evaluation of the pacemaker operation should be performed.

In the pacemaker dependent patient, at least for the first therapeutic encounter, there should be continuous ECG monitoring to assess whether or not the electrical fields produced by the X-ray therapy equipment will interfere with the pacemaker. If there is no problem during this first treatment or the patient was previously determined not to be pacemaker dependent, subsequent ECG monitoring during each therapy period would not be required.

If inhibition occurs during the procedure the device can either be temporarily programmed to VOO/DOO mode or a magnet applied during subsequent treatments. Activity driven rate responsive pacemakers should have the sensor programmed Off during therapy to prevent transient rate increases. If the sensor is left On, the device may pace up to the maximum sensor rate during therapy and gradually returned to baseline after therapy is ended. The pacemaker should be shielded with a piece of lead apron to minimize the amount of radiation scatter.

If a change is noted, more intensive monitoring/evaluation is recommended to identify the extent of the CMOS damage. The pacemaker dependent patient should undergo a detailed evaluation of the pacing system once or twice during the course of therapy and after each treatment once the maximum cumulative dose (2,000-3,000 rads) reached. A change in the capture or sensing threshold may reflect an early problem with the pulse generator.

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Patient Evaluation Following Completion of Radiation Therapy:

Following completion of the course of therapeutic radiation, a detailed pacing system evaluation, similar to that obtained prior to the initiation of therapy, should be performed. A system demonstrating abnormal function, such as a rise in capture threshold or a rise in sensing threshold may:

- Reflect a local myocardial problem associated with the patient's endogenous disease.
- Be caused by radiation damage to the heart.
- Reflect a problem in the pulse generator. More detailed and frequent surveillance of the system would then be appropriate.