Medtronic
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Standard Letter
CRDM Technical Services U.S.
Minneapolis, MN
Brady (800) 505-4636
Tachy (800) 723-4636
Instruments (800) 638-1991

HYPERBARIC CHAMBER TREATMENTS

PACEMAKER (IPG – IMPLANTABLE PULSE GENERATOR)

DEFIBRILLATOR (ICD – IMPLANTABLE CARDIOVERTER DEFIBRILLATOR)

Medtronic has performed hyperbaric chamber testing on several pacemakers and defibrillators to determine the maximum safe pressure for hyperbaric chamber therapy. This testing was performed at selected pressures up to 165 feet of seawater or 6 Atmospheric Pressure Absolute (ATA). The devices used for this testing included Thera i™, Prodigy™, and Elite II™. These devices exhibit rate response and were chosen because they are representative of current models with respect to mechanical susceptibility to external pressure.

No loss or degradation of output operation was observed in any of the devices tested, however, rate responsive pacing began to diminish at pressures in excess of 66 feet of seawater (3 ATA) which caused the devices to pace at the programmed lower rate. The loss of rate responsive pacing was observed to be temporary; activity pacing returned at lesser pressures. It was also noted that pressures approaching 132 feet of seawater (5 ATA) began to significantly deform the titanium shield.

Following the hyperbaric chamber testing, all devices were analyzed for final functional and activity performance. Each device performed within specification.

In summary, Medtronic devices similar to the Medtronic pacemakers and defibrillators tested should operate normally up to 49.5 feet of seawater (2.5 ATA), and will begin to significantly deform at pressures near 132 feet of seawater (5 ATA).

Based on results of this testing, similar Medtronic pacing devices should not be exposed to pressures in excess of 49.5 feet of seawater (2.5 ATA). It is the responsibility of the physician to determine the safety concerns for these pacemaker patients and make the final decision concerning the use of hyperbaric chamber treatments when indicated.

Although we are not aware of any reported incidences of ICD shock triggered ignition, and do not believe this to be of significant risk, it may be advisable to disable defibrillation therapies, pending further study to the contrary, while patients are undergoing hyperbaric treatments. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present while device therapies are programmed off should the patient require external rescue.