Cardiac Rhythm Management
4100 Hamline Avenue North
St. Paul, MN 55112-5798
www.bostonscientific.com

8/12/2009

Subject: **Exposing Boston Scientific implantable devices to elevated pressure**

Reference:

Device family:	PULSAR®, INSIGNIA® AVT, INSIGNIA Entra, INSIGNIA Ultra, INSIGNIA Plus, PULSAR MAX, PULSAR MAX II, DISCOVERY®, DISCOVERY II, MERIDIAN®
Model number:	0470/0476/0481/0870/0970/0972/0976/0981/1170/1171/1172/1174/1175/1176/1180/1181/1184/1185/1186/11871270/1272/1273/1274/1275/1276/1280/1283/1284/1285/1286/0482/0484/0485/0882/0982/0985/09861190/1192/1194/1195/1198/1290/1291/1292/1294/1295/1296/1297/1298

Dear Customer:

Thank you for contacting our company regarding the impact of elevated pressure on Boston Scientific implantable pacemakers and defibrillators, including pressures encountered during hyperbaric oxygen therapy (HBOT) or recreational SCUBA diving. The information provided in this letter is a summary of pressure testing completed by Boston Scientific; it should not be viewed as and is not an endorsement of HBOT treatment or SCUBA diving activities.

During laboratory testing of the device family referenced above, all devices in the test sample (statistically significant) continued to function as designed when exposed to more than 1000 cycles at a pressure up to 5.0 ATA. Pressure for each test cycle began at ambient/room pressure, increased to a high pressure level, and then returned to ambient pressure. Although dwell time (the amount of time under elevated pressure) may have an impact on human physiology, testing indicated it did not impact device performance.

Since our pressure testing was conducted in a laboratory environment, it did not characterize the impact of elevated pressure on physiological response or device performance while implanted in a human body. **Prior to engaging in activities such as HBOT or SCUBA diving, a patient should consult their attending cardiologist or electrophysiologist to fully understand the potential consequences of these activities relative to their specific health condition.**

Refer to the table below for pressure value equivalencies.

ATA	Sea Water* Depth (feet)	Sea Water* Depth (meters)	Pounds per Square Inch Absolute (psia)	Pounds per Square Inch Gauge (psig)†	Bar	kPa Absolute
5.0	130	40	72.8	58.8	5.0	500

*All pressures derived assuming sea water density of 1030 kg/m^3

†Pressure as read on a gauge or dial (psia = psig + 14.7 psi)

If you have additional questions, please contact your local Boston Scientific CRM representative or CRM Technical Services – U.S. at 1.800.CARDIAC (227.3422) or Technical Services – Europe at +32 2 416 7222.

Sincerely,

Technical Services
Cardiac Rhythm Management
Boston Scientific