SUMMARY

Hyperbaric Oxygen Therapy (HBOT) is the medical use of oxygen at a level higher than atmospheric pressure using a pressure chamber and an oxygen-delivery system.

SCUBA (Self Contained Underwater Breathing Apparatus) is equipment used to breathe underwater while swimming or diving at elevated pressures (SCUBA diving).

This article includes a summary of Boston Scientific's elevated pressure testing of our implantable medical devices. It is not an endorsement of HBOT or SCUBA diving for patients with these implantable devices.

Products Referenced

CDs, CRT-Ds, S-ICDs, Pacemakers, and CRT-Ps listed in Tables 2 and 4.

For comprehensive information on device operation, reference the full instructions for use or found at: www.bostonscientific-elabeling.com.

CAUTION: The law restricts this device to sale by or on the order of a physician.

Products referenced herein may not be approved in all geographies. Information is for the use in countries with applicable Health Authority product registrations.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator
S-ICD: Subcutaneous Implantable Defibrillator

Contact Information

www.bostonscientific.com

Americas

Technical Services
LATITUDE™ Customer Support
1.800.CARDIAC (227.3422)
+1.651.582.4000

Patient Services
1.866.484.3268

Europe, Middle East, Africa

Technical Services
+32 2 416 7222
intltechservice@bsci.com

LATITUDE Customer Support
latitude.europe@bsci.com

Japan

Technical Services
japantechservice@bsci.com

LATITUDE Customer Support
japan.latitude@bsci.com

Asia Pacific

Technical Services
+61 2 8063 8299
aptechservice@bsci.com

LATITUDE Customer Support
latitude.asiapacific@bsci.com

Elevated Pressure (HBOT/SCUBA) and Implanted Medical Devices

The International Standards Organization (ISO) has not approved a standardized pressure test for implantable pulse generators that are exposed to hyperbaric oxygen therapy (HBOT) or SCUBA diving. However, Boston Scientific developed a test protocol to evaluate device performance upon exposure to elevated atmospheric pressures (Table 1).

During laboratory testing of products listed in Table 2, all devices in a statistically significant sample continued to function as designed when exposed to more than 1,000 test cycles at pressures up to 5.0 atmospheres (ATA). Devices of the model listed in Table 3 continued to function as designed when exposed to 300 test cycles at pressures up to 3.0 ATA. 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 dwell time did not impact performance of the implanted device.

CAUTION: Excessive pressure due to HBOT or SCUBA diving may damage the pulse generator. Laboratory testing did not characterize the impact of elevated pressure on pulse generator performance or physiological response while implanted in a human body.

Prior to SCUBA diving or starting an HBOT program, the patient's attending cardiologist or electrophysiologist should be consulted to assess the potential consequences relative to the patient's specific health condition. A Dive Medicine Specialist may also be consulted prior to SCUBA diving. In addition, more frequent device follow-up may be warranted in conjunction with HBOT or SCUBA diving. Evaluate pulse generator operation following high pressure exposure. The extent, timing, and frequency of this evaluation relative to the high pressure exposure are dependent upon current patient health.

If you would like information on Boston Scientific product families not listed in Tables 2 and 3, or have additional questions regarding the test protocol or test results specific to HBOT or SCUBA diving, please contact Boston Scientific Technical Services.

Table 1. 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	58.1	5.0	500
3.0	62	20	42.7	28	2.9	290

Table 2. Testing Applicable to Boston Scientific Product Families and Models Listed

Please note that not all models are approved in all geographies. All devices continued to function as designed when exposed to more than 1,000 test cycles at pressures up to 5.0 atmospheres. ‡

Product Type	Product Family	Model Numbers beginning with
Pacemakers	ACCOLADE™, ACCOLADE™ MRI, PROPONENT™, PROPONENT™ MRI, ESSENTIO™, ESSENTIO™ MRI, ALTRUA™ 2, FORMIO™, FORMIO™ MRI, VITALIO™, VITALIO™ MRI, INGENIO™, INGENIO™ MRI, ADVANTIO™, ADVANTIO™ MRI, EQUIO™, ALTRUA®‡	J, K, L, S
CRT-Ps	VISIONIST™, VISIONIST™ X4, VALITUDE™, VALITUDE™ X4, INVIVE®, INTUA™, INLIVEN™	U, V, W
ICDs and CRT-Ds	AUTOGEN™, DYNAGEN™, INOGEN™, ORIGEN™, INCEPTA®, PUNCTUA®, ENERGEN™, TELIGEN®, COGNIS®	D, E§, F§, G, N, P

* 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)

‡ IALTRUA Instructions for Use have not yet been updated to reflect engineering pressure test results.

§ Testing described herein is not applicable to CONFIENT® Models E030/F030.

Table 3. Testing Applicable to Boston Scientific Product Family and Model Listed

Please note that not all models are approved in all geographies. All devices continued to function as designed when exposed to up to 300 test cycles at pressures up to 3.0 atmospheres.

Product Type	Product Family	Model Numbers beginning with
S-ICD	EMBLEM™	A209

* 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)