



Boston Scientific Corporation
Model: 6280

Report No. BSTN0429.7



Report Prepared By Northwest EMC Inc.

NORTHWEST EMC – (888) 364-2378 – www.nwemc.com

California – Minnesota – Oregon – New York – Washington

Certificate of Evaluation

Date of Evaluation: August 24, 2013
Boston Scientific Corporation
Model: 6280

Emissions

Description of Evaluation	Specification	Evaluation Method	Pass/Fail
Maximum Permissible Exposure	FCC 2.1091:2013	OET Bulletin 65, Supplement C Ed 01-01	Pass

Approved By:



Don Facticeau, IS Manager



NVLAP Lab Code: 200630-0

This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government of the United States of America.

Product compliance is the responsibility of the client, therefore the tests and equipment modes of operation represented in this report were agreed upon by the client, prior to testing. This Report may only be duplicated in its entirety. The results of this test pertain only to the sample(s) tested. The specific description is noted in each of the individual sections of the test report supporting this certificate of test.

Revision Number	Description	Date	Page Number
00	None		

Barometric Pressure

The recorded barometric pressure has been normalized to sea level.

United States

FCC - Designated by the FCC as a Telecommunications Certification Body (TCB). Certification chambers, Open Area Test Sites, and conducted measurement facilities are listed with the FCC.

A2LA - Accredited by A2LA to ISO / IEC Guide 65 as a product certifier. This allows Northwest EMC to certify transmitters to FCC and IC specifications.

NVLAP - Each laboratory is accredited by NVLAP to ISO 17025

Canada

IC - Recognized by Industry Canada as a Certification Body (CB). Certification chambers and Open Area Test Sites are filed with IC.

European Union

European Commission – Validated by the European Commission as a Conformity Assessment Body (CAB) under the EMC directive and as a Notified Body under the R&TTE Directive.

Australia/New Zealand

ACMA - Recognized by ACMA as a CAB for the acceptance of test data.

Korea

KCC / RRA - Recognized by KCC's RRA as a CAB for the acceptance of test data.

Japan

VCCI - Associate Member of the VCCI. Conducted and radiated measurement facilities are registered.

Taiwan

BSMI – Recognized by BSMI as a CAB for the acceptance of test data.

NCC - Recognized by NCC as a CAB for the acceptance of test data.

Singapore

IDA – Recognized by IDA as a CAB for the acceptance of test data.

Hong Kong

OFTA – Recognized by OFTA as a CAB for the acceptance of test data.

Vietnam

MIC – Recognized by MIC as a CAB for the acceptance of test data.

Russia

GOST – Accredited by Certinform VNIINMASH, CERTINFO, SAMTES, and Federal CHEC to perform EMC and Hygienic testing for Information Technology products to GOST standards.

SCOPE

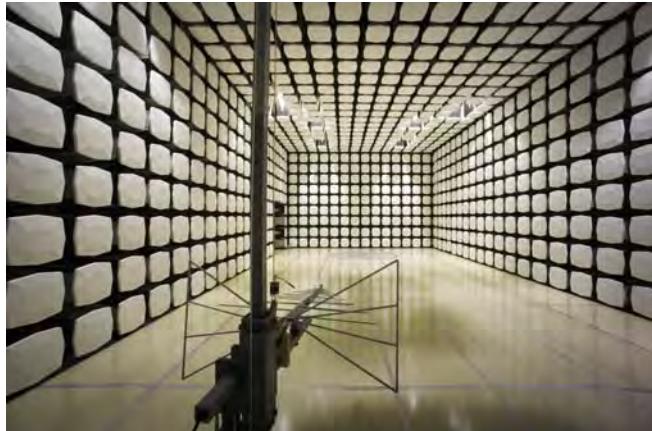
For details on the Scopes of our Accreditations, please visit:

<http://www.nwemc.com/accreditations/>

LOCATIONS



Oregon Labs EV01-12 22975 NW Evergreen Pkwy Hillsboro, OR 97124 (503) 844-4066	California Labs OC01-13 41 Tesla Irvine, CA 92618 (949) 861-8918	New York Labs NY01-04 4939 Jordan Rd. Elbridge, NY 13060 (315) 685-0796	Minnesota Labs MN01-08 9349 W Broadway Ave. Brooklyn Park, MN 55445 (763) 425-2281	Washington Labs NC01-05, SU02, SU07 19201 120 th Ave. NE Bothell, WA 98011 (425) 984-6600
VCCI				
A-0108	A-0029		A-0109	A-0110
Industry Canada				
2834D-1, 2834D-2	2834B-1, 2834B-2, 2834B-3		2834E-1	2834C-1
NVLAP				
NVLAP Lab Code: 200630-0	NVLAP Lab Code: 200676-0	NVLAP Lab Code: 200761-0	NVLAP Lab Code: 200881-0	NVLAP Lab Code: 200629-0



Product Description

Client and Equipment Under Test (EUT) Information

Company Name:	Boston Scientific Corporation
Address:	4100 Hamline Avenue North
City, State, Zip:	St. Paul, MN 55112
Test Requested By:	Pete Musto
Model:	6280
Date of Evaluation:	August 24, 2013

Information Provided by the Party Requesting the Test

Functional Description of the EUT (Equipment Under Test):

In-Home Patient Management System allows one to remotely follow most Boston Scientific device patients using the 902 MHz – 928 MHz ISM Band for use with radio frequency (RF) enabled BSC implantable pulse generators.

Objective:

To demonstrate compliance of the radio with FCC requirements for RF exposure for 2.1091 mobile devices.

OVERVIEW

Human exposure to RF emissions from mobile devices (47 CFR §2.1091) may be evaluated based on the MPE limits adopted by the FCC for electric and magnetic field strength and/or power density, as appropriate, since exposures are assumed to occur at distances of 20 cm or more from persons. ANSI C95.1-1992 specifies a minimum separation distance of 20 cm for performing reliable field measurements to determine adherence to MPE limits. If the minimum separation distance between a transmitter and nearby persons is more than 20 cm under normal operating conditions, compliance with MPE limits may be determined at such distance from the transmitter. When applicable, operation instructions and prominent warning labels may be used to alert the exposed persons to maintain a specified distance from the transmitter or to limit their exposure durations and usage conditions to ensure compliance. If the use of warning labels on a transmitter is not effective or desirable, the alternative of performing SAR evaluation with the device at its closest range to persons under normal operating conditions may be used. The field strength and power density limits adopted by the FCC are based on whole-body averaged exposure and the assumption of RF field levels relate most accurately to estimating whole-body averaged SAR. This means some local values of exposures exceeding the stated field strength and power density limits may not necessarily imply non-compliance if the spatial average of spatially averaged RF fields over the exposed portions of a person's body does not exceed the limits.

COMPLIANCE WITH 2.1091

“Mobile devices that operate in the Cellular Radiotelephone Service, the Personal Communications Services, the Satellite Communications Services, the General Wireless Communications Service, the Wireless Communications Service, the Maritime Services and the Specialized Mobile Radio Service authorized under subpart H of part 22 of this chapter, parts 24, 25, 26 and 27 of this chapter, part 80 of this chapter (ship earth stations devices only) and part 90 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use if they operate at frequencies of 1.5 GHz or below and their effective radiated power (ERP) is 1.5 watts or more, or if they operate at frequencies above 1.5 GHz and their ERP is 3 watts or more. Unlicensed personal communications service devices, unlicensed millimeter wave devices and unlicensed NII devices authorized under §§15.253, 15.255, and 15.257, and subparts D and E of part 15 of this chapter are also subject to routine environmental evaluation for RF exposure prior to equipment authorization or use if their ERP is 3 watts or more or if they meet the definition of a portable device as specified in §2.1093(b) requiring evaluation under the provisions of that section. All other mobile and unlicensed transmitting devices are categorically excluded from routine environmental evaluation for RF exposure prior to equipment authorization or use, except as specified in §§1.1307(c) and 1.1307(d) of this chapter. Applications for equipment authorization of mobile and unlicensed transmitting devices subject to routine environmental evaluation must contain a statement confirming compliance with the limits specified in paragraph (d) of this section as part of their application.”

The EUT will only be used with a separation distance of 20 centimeters or greater between the antenna and the body of the user or nearby persons and can therefore be considered a mobile transmitter per 47 CFR 2.1091(b). Per 47 CFR 1.1310, the EUT meets the General Population / Uncontrolled exposure limits listed in Table 1.

COMPLIANCE WITH FCC KDB 447498 D01 General RF Exposure Guidance V05

The 902 MHz - 928 MHz ISM band radio is a mobile transmitter that operates through its own antenna. It is not co-located with any other radio.

"KDB 447498 D01 General RF Exposure Guidance v05" provides the procedures, requirements, and authorization policies for mobile and portable devices. Section 7.1 best fits the exposure condition described in this report. Since this mobile device is categorically excluded from routine evaluation; simple calculations may be used to estimate the power density to demonstrate compliance with 47 CFR 1.1310 requirements. The attached estimate shows MPE limits are met at a 20 cm boundary.

FCC LIMITS FOR MPE

Limits for General Population /Uncontrolled Exposure: 47 CFR 1.1310

Frequency Range (MHz)	Electric Field Strength (V/m)	Magnetic Field Strength (A/m)	Power Density (mW/cm ²)	Averaging Time (minutes)
0.3 - 1.34	614	1.63	*(100)	30
1.34 - 30	824/f	2.19/f	*(180/f ²)	30
30 - 300	27.5	0.073	0.2	30
300 - 1500			f/1500	30
1500 - 1000000			1	30

f = frequency in MHz

* = Plane-wave equivalent power density

METHOD OF EVALUATION

The exposure level for the radio is evaluated at a 20 cm distance from the radio's transmitting antenna using the general equation:

$$S = \frac{P * G}{4 * \pi * R^2}$$

Where: S = power density (mW/cm²)

P = power input to the antenna (mW)

G = numeric power gain relative to an isotropic radiator

R = distance to the center of the radiation of the antenna (20 cm = limit for MPE estimates)

P*G = EIRP

Solving for S, the maximum power density 20 cm from the transmitting antenna is determined.

EUT:	6280	Work Order:	BSTM0429
Serial Number:	NA	Date:	8/24/13
Customer:	Boston Scientific Corporation	Temperature (°C):	NA
Attendees:	N/A	Rel. Humidity (%):	NA
Customer Project:	N/A	Bar. Pres. (mb):	NA
Evaluated By:	Rod Peloquin	Power:	NA
		Job Site:	EV

TEST SPECIFICATIONS

Specification:	Method:
FCC 2.1091:2013	OET Bulletin 65, Supplement C Ed 01-01

COMMENTS

See Product Description

DEVIATIONS FROM TEST STANDARD

None



Signature

MPE Estimates for Individual Devices

Radio	Antenna Type	Antenna Manufacturer	Antenna Part No.	Transmit Frequency (MHz)	Max Peak EIRP (mW)	Duty Cycle	Duty Cycle Corrected Output Power (mW)	Power Density @20 cm (mW/cm ²)	General Population Exposure Limit from 1.1310 (mW/cm ²)
902-928 MHz ISM	Inverted L PCB	Boston Scientific	None	916.515	0.703	1	0.703	0.00014	0.611