



element[®]

Boston Scientific Corporation

Bluetooth Telemetry Module

FCC 2.1091:2017

Bluetooth Low Energy Radio

Report # BSTN0717.1



NVLAP Lab Code: 200881-0

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CERTIFICATE OF EVALUATION

Last Date of Evaluation: March 6, 2017
Boston Scientific Corporation
Model: Bluetooth Telemetry Module

Radio Equipment Evaluation

Standards

Specification	Method
FCC 2.1091:2017	FCC 447498 D01 General RF Exposure Guidance v06

Results

Method Clause	Evaluation Description	Applied	Results	Comments
7.1	Maximum Permissible Exposure	Yes	Pass	

Deviations From Evaluation Standards

None

Approved By:

Donald Facteau, Systems Architect

Product compliance is the responsibility of the client; therefore, the Evaluations and equipment modes of operation represented in this report were agreed upon by the client, prior to Evaluation. The results of this Evaluation pertain only to the sample(s) Evaluation. The specific description is noted in each of the individual sections of the Evaluation report supporting this certificate of Evaluation. This report reflects only those Evaluations from the referenced standards shown in the certificate of Evaluation. It does not include inspection or verification of labels, identification, marking or user information.

REVISION HISTORY



2017.1.25

Revision Number	Description	Date	Page Number
00	None		

ACCREDITATIONS AND AUTHORIZATIONS



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 17065 as a product certifier. This allows Element to certify transmitters to FCC and IC specifications.

NVLAP - Each laboratory is accredited by NVLAP to ISO 17025

Canada

ISED - Recognized by Innovation, Science and Economic Development Canada as a Certification Body (CB). Certification chambers and Open Area Test Sites are filed with ISED.

European Union

European Commission – Validated by the European Commission 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

MSIP / 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.

Israel

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

Hong Kong

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

Vietnam

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

SCOPE

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

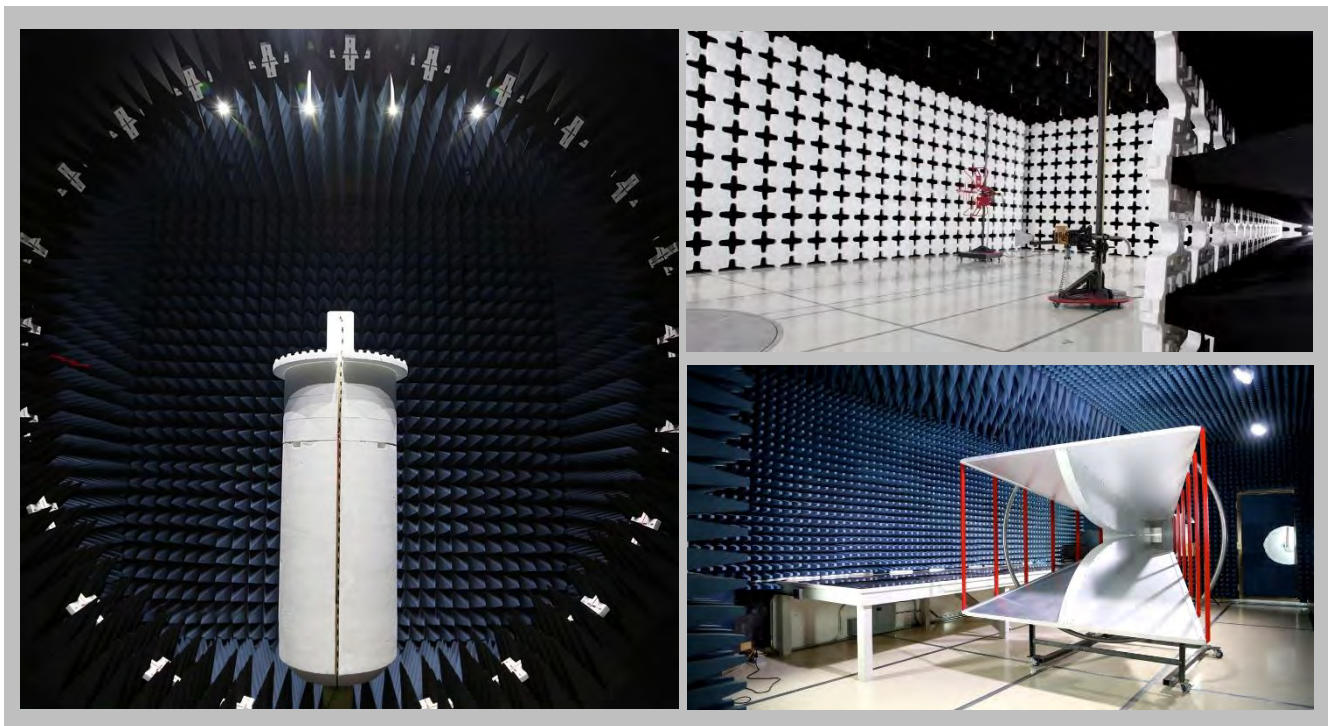
<http://portlandcustomer.element.com/ts/scope/scope.htm>

<http://gsi.nist.gov/global/docs/cabs/designations.html>

FACILITIES



California	Minnesota	New York	Oregon	Texas	Washington
Labs OC01-13 41 Tesla Irvine, CA 92618 (949) 861-8918	Labs MN01-08, MN10 9349 W Broadway Ave. Brooklyn Park, MN 55445 (612)-638-5136	Labs NY01-04 4939 Jordan Rd. Elbridge, NY 13060 (315) 554-8214	Labs EV01-12 22975 NW Evergreen Pkwy Hillsboro, OR 97124 (503) 844-4066	Labs TX01-09 3801 E Plano Pkwy Plano, TX 75074 (469) 304-5255	Labs NC01-05 19201 120 th Ave NE Bothell, WA 98011 (425)984-6600
NVLAP					
NVLAP Lab Code: 200676-0	NVLAP Lab Code: 200881-0	NVLAP Lab Code: 200761-0	NVLAP Lab Code: 200630-0	NVLAP Lab Code:201049-0	NVLAP Lab Code: 200629-0
Innovation, Science and Economic Development Canada					
2834B-1, 2834B-3	2834E-1	N/A	2834D-1, 2834D-2	2834G-1	2834F-1
VCCI					
A-0029	A-0109	N/A	A-0108	A-0201	A-0110
Recognized Phase I CAB for ACMA, BSMI, IDA, KCC/RRA, MIC, MOC, NCC, OFCA					
US0158	US0175	N/A	US0017	US0191	US0157





PRODUCT DESCRIPTION

Client and Equipment Under Evaluation Information

Company Name:	Boston Scientific Corporation
Address:	4100 Hamline Avenue North
City, State, Zip:	St. Paul, MN 55112-5798
Evaluation Requested By:	Pete Musto
Model:	Bluetooth Telemetry Module
First Date of Evaluation:	March 6, 2017

Information Provided by the Party Requesting the Evaluation

Functional Description of the equipment:
BLE radio module.
Objective:
To demonstrate compliance of the Bluetooth radio to FCC 2.1091 requirements.

MAXIMUM PERMISSIBLE EXPOSURE (MPE)



EXRPT.2017.02.13

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 C95.1:2005 + Amd 1:2010 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 FCC 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 device will only be used with a separation distance between the antenna and the body of the user or nearby persons as shown in the table below and can therefore be considered a mobile transmitter per 47 CFR 2.1091(b).

COMPLIANCE WITH FCC KDB 447498 D01 General RF Exposure Guidance v06

"KDB 447498 D01 General RF Exposure Guidance v06" provides the procedures, requirements, and authorization policies for mobile and portable devices.

Devices operating in standalone mobile device exposure conditions may contain a single transmitter or multiple transmitters that do not transmit simultaneously are covered in section 7.1.

Devices containing multiple transmitters capable of simultaneous transmissions are covered in section 7.2.

MAXIMUM PERMISSIBLE EXPOSURE (MPE)



LIMITS

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 - 100000			1	30

f = frequency in MHz

* = Plane-wave equivalent power density

ASSESSMENT

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. This level is then compared to the applicable limit for the transmit frequency. If limits were not met at the 20 cm boundary the evaluation distance is increased until the limit is met as shown in the table below.

For co-located radios, the ratio of the calculated level to the limit is determined. The ratios for each co-located radio are summed. If the sum is less than or equal to one, then the device is excluded from testing and is deemed compliant.

The standalone MPE and summed MPE ratios are summarized in the following table:

Radio	Transmit Frequency (MHz)	Measured Conducted Output Power (mW)	Duty Cycle	Highest Antenna Gain (dBi)	Minimum Antenna Cable Loss (dB)	Minimum Separation Distance (cm)	Power Density (mW/cm ²)	Limit (mW/cm ²)	Compliant
Bluetooth Low Energy	2402	2.127	1	2	0	20	0.00067	1.0	Yes