



# element

## Boston Scientific Corporation

Bluetooth Low Energy Insertable Cardiac Monitor (ICM)

LUX-Dx

M301

FCC 2.1093:2019

Bluetooth Low Energy

Report # BSTN0975.7



NVLAP Lab Code: 200630

***This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the U.S. Government. This Report shall not be reproduced, except in full without written approval of the laboratory.***

***EAR-Controlled Data - This document contains technical data whose export and reexport/retransfer is subject to control by the U.S. Department of Commerce under the Export Administration Act and the Export Administration Regulations. The Department of Commerce's prior written approval may be required for the export or re-export/retransfer of such technical data to any foreign person, foreign entity or foreign organization whether in the United States or abroad.***

***More: <https://www.bis.doc.gov/index.php/forms-documents/regulations-docs/14-commerce-country-chart/fileT>***



# CERTIFICATE OF EVALUATION

Last Date of Evaluation: Friday, November 22, 2019  
Boston Scientific Corporation  
EUT: Bluetooth Low Energy ICM

## RF Exposure Evaluation

### Standards

Specification	Method
FCC 2.1093:2019	FCC 447498 D01 General RF Exposure Guidance v06

### Results

Method Clause	Description	Applied	Results	Comments
4.3.1	SAR Test Exclusion	Yes	Pass	None

### Deviations From Evaluation Standards

None

### Approved By:

Donald Facteau, Process Architect

*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. 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. This report reflects only those tests from the referenced standards shown in the certificate of test. It does not include inspection or verification of labels, identification, marking or user information. As indicated in the Statement of Work sent with the quotation, Element's standard process is to always use the latest published version of the test methods even when earlier versions are cited in the test specification. Issuance of a purchase order was de facto acceptance of this approach. Otherwise, the client would have advised Element in writing of the specific version of the test methods they wanted applied to the subject testing*

# REVISION HISTORY



Revision Number	Description	Date (yyyy-mm-dd)	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) and as a CAB for the acceptance of test data.

---

## European Union

**European Commission** – Within Element, we have a EU Notified Body validated for the EMCD and RED Directives.

---

## Australia/New Zealand

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

---

## Korea

**MSIT / 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

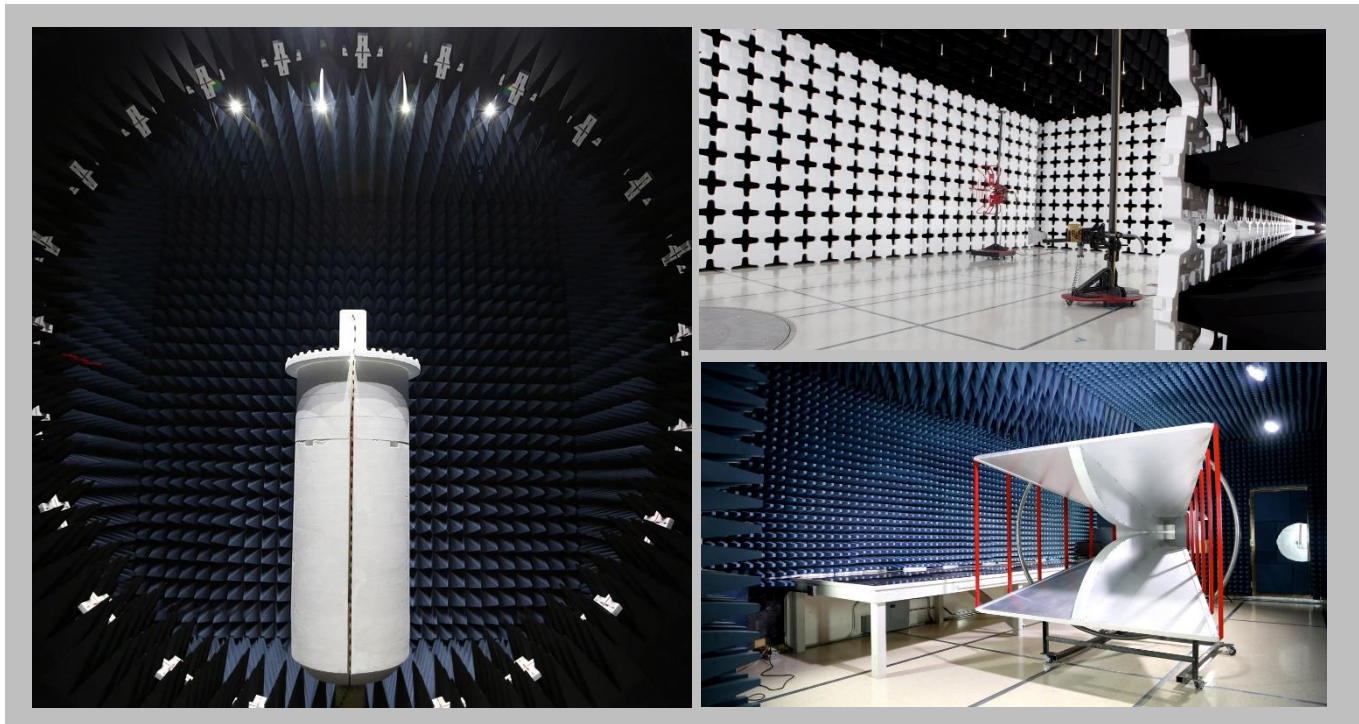
For details on the Scopes of our Accreditations, please visit:

<https://www.nwemc.com/emc-testing-accreditations>

# FACILITIES



<b>California</b> Labs OC01-17 41 Tesla Irvine, CA 92618 (949) 861-8918	<b>Minnesota</b> Labs MN01-10 9349 W Broadway Ave. Brooklyn Park, MN 55445 (612)-638-5136	<b>Oregon</b> Labs EV01-12 6775 NE Evergreen Pkwy #400 Hillsboro, OR 97124 (503) 844-4066	<b>Texas</b> Labs TX01-09 3801 E Plano Pkwy Plano, TX 75074 (469) 304-5255	<b>Washington</b> Labs NC01-05 19201 120 <sup>th</sup> Ave NE Bothell, WA 98011 (425)984-6600
<b>NVLAP</b>				
NVLAP Lab Code: 200676-0	NVLAP Lab Code: 200881-0	NVLAP Lab Code: 200630-0	NVLAP Lab Code:201049-0	NVLAP Lab Code: 200629-0
<b>Innovation, Science and Economic Development Canada</b>				
2834B-1, 2834B-3	2834E-1, 2834E-3	2834D-1	2834G-1	2834F-1
<b>BSMI</b>				
SL2-IN-E-1154R	SL2-IN-E-1152R	SL2-IN-E-1017	SL2-IN-E-1158R	SL2-IN-E-1153R
<b>VCCI</b>				
A-0029	A-0109	A-0108	A-0201	A-0110
<b>Recognized Phase I CAB for ISED, ACMA, BSMI, IDA, KCC/RRA, MIC, MOC, NCC, OFCA</b>				
US0158	US0175	US0017	US0191	US0157



# RF Exposure Condition



<b>The following RF Exposure conditions were used for the assessment documented in this report:</b>	
Intended Use	Portable
Location on Body (if applicable)	Head/Torso
How is the Device Used	The ICM sensor device is implanted in the user.
Radios Contained in the Same Host Device	Bluetooth Low Energy
Simultaneous Transmitting Radios	None
Body Worn Accessories	N/A
Environment	General Population/Uncontrolled Exposure

# PRODUCT DESCRIPTION



## Client and Equipment Under Evaluation Information

<b>Company Name:</b>	Boston Scientific Corporation
<b>Address:</b>	4100 Hamline Avenue North
<b>City, State, Zip:</b>	St. Paul, MN 55112-5798
<b>Evaluation Requested By:</b>	Daniel Landherr
<b>EUT:</b>	Bluetooth Low Energy ICM
<b>Date of Evaluation:</b>	Friday, November 22, 2019

## Information Provided by the Party Requesting the Evaluation

### Functional Description of the Equipment:

The ICM sensor device (called LUX-Dx™) is a subcutaneously-implanted sensor device for cardiac event data collection and transmission. Patient and device data are also collected and transmitted from the sensor device.

### Objective:

To demonstrate compliance with FCC RF exposure requirements for 2.1093 portable devices.

# SAR TEST EXCLUSION



## OVERVIEW

Human exposure to RF emissions from portable devices (47 CFR §2.1093) used with the radiating antenna closer than 20 cm to the user requires Specific Absorption Rate (SAR) to evaluate the environmental impact of human exposure to radiofrequency (RF) radiation.

## COMPLIANCE WITH FCC 2.1093

*“Portable devices that operate in the Cellular Radiotelephone Service pursuant to part 22 of this chapter; the Personal Communications Service (PCS) pursuant to part 24 of this chapter; the Satellite Communications Services pursuant to part 25 of this chapter; the Miscellaneous Wireless Communications Services pursuant to part 27 of this chapter; the Maritime Services (ship earth station devices only) pursuant to part 80 of this chapter; the Specialized Mobile Radio Service, the 4.9 GHz Band Service, and the 3650 MHz Wireless Broadband Service pursuant to part 90 of this chapter; the Wireless Medical Telemetry Service (WMTS) and the Medical Device Radiocommunication Service (MedRadio), pursuant to subparts H and I of part 95 of this chapter, respectively, unlicensed personal communication service, unlicensed NII devices and millimeter wave devices authorized under §§15.253(f), 15.255(g), 15.257(g), 15.319(i), and 15.407(f) of this chapter; and the Citizens Broadband Radio Service pursuant to part 96 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use. All other portable 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 portable transmitting devices subject to routine environmental evaluation must contain a statement confirming compliance with the limits specified in paragraph (d) of this section. Technical information showing the basis for this statement must be submitted to the Commission upon request.”*

**The EUT will be used with a separation distance of less than 20 centimeters between the radiating antenna and the body of the user or nearby persons and must therefore be considered a portable transmitter per 47 CFR 2.1093(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.

Standalone radio SAR test exclusion for an implanted transmitter is covered under section 4.2.4:

*“When the aggregate of the maximum power available at the antenna port and radiating structures of an implanted transmitter, under all operating circumstances, is  $\leq 1.0$  mW, SAR test exclusion may be applied.<sup>27</sup> The maximum available output power requirement and worst case operating conditions must be supported by power measurement results, based on device design and implementation requirements, and fully justified in a SAR analysis report according to KDB Publication 865664 D02, in lieu of SAR measurement or numerical simulation.*

*Footnote 27: Maximum conducted and radiated power should both be taken into consideration to establish the worst case aggregate maximum output power.”*

General guidance regarding maximum power is found in Section 4(b),

*“As required by §§ 2.1091(d)(2) and 2.1093(d)(5), RF exposure compliance must be determined at the maximum average power level according to source-based time-averaging requirements to determine compliance for general population exposure conditions. Unless it is specified differently in the published*



# SAR TEST EXCLUSION



RF exposure KDB procedures, these requirements also apply to test reduction and test exclusion considerations. Time-averaged maximum conducted output power applies to SAR”

**ASSESSMENT**

The time-averaged maximum conducted output power is summarized in the following table:

Radio	Transmit Frequency (MHz)	Measured Conducted Output Power (mW)	Duty Cycle	Time-averaged maximum conducted output power (mW)	Exclusion Threshold (mW)	Compliant
Bluetooth Low Energy	2402	0.82	1	0.82	≤ 1.0	Yes

The time-averaged maximum radiated output power is summarized in the following table:

Radio	Transmit Frequency (MHz)	Measured Radiated Output Power (mW)	Duty Cycle	Time-averaged maximum radiated output power (mW)	Exclusion Threshold (mW)	Compliant
Bluetooth Low Energy	2402	0.44	1	0.44	≤ 1.0	Yes

The aggregate (worst case) of the time averaged maximum conducted and radiated output powers are less than the exclusion threshold:

Conducted Output Power (mW)	Radiated Output Power (mW)	Exclusion Threshold (mW)	Compliant
0.82	0.44	≤ 1.0	Yes

The information in the table above was obtained from:

From client supplied information and Element report #BSTN0975.