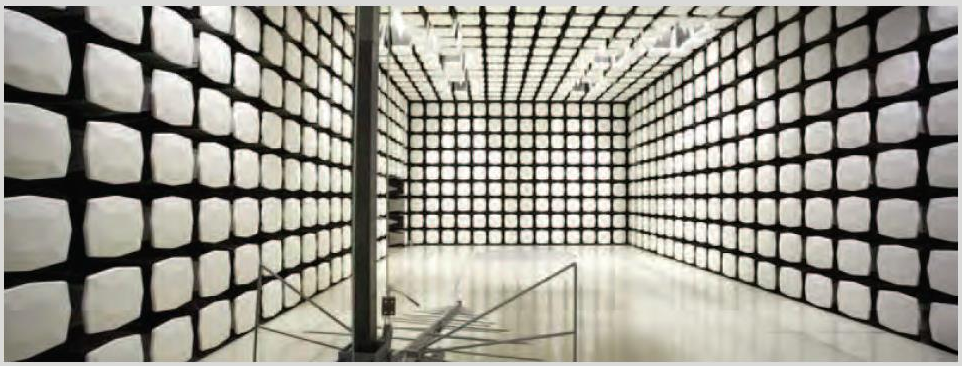
Medtronic, Inc.

EV ICD

FCC 2.1093:2018

MICS Radio

Report # MDTR0743



NVLAP Lab Code: 200630

CERTIFICATE OF EVALUATION

Last Date of Evaluation: Monday, December 31, 2018
Medtronic, Inc.
Model: EV ICD

RF Exposure Evaluation

Standards

Specification	Method
FCC 2.1093:2018	FCC 447498 D01 General RF Exposure Guidance v06

Results

Method Clause	Description	Applied	Results	Comments
4.3.1	SAR Test Exclusion	Yes	Pass	

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

RF Exposure Condition

The following RF Exposure conditions were used for the assessment documented in this report:	
Intended Use	Portable
Location on Body (if applicable)	Head/Torso
How is the Device Used	An extravascular implantable cardioverter defibrillator
Radios Contained in the Same Host Device	Inductive MICS
Simultaneous Transmitting Radios	None (Per FCC 1.1307 the inductive radio certified under FCC 15.209 is categorically exempt from RF Exposure evaluation)
Body Worn Accessories	N/A
Environment	General Population/Uncontrolled Exposure

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). Certification chambers and Open Area Test Sites are filed with ISED.

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

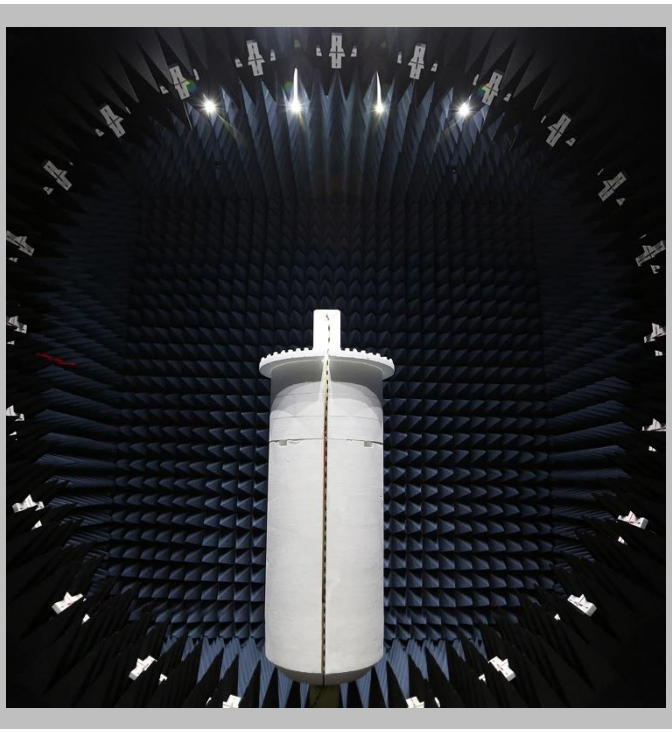
MIC – Recognized by MIC as a CAB for the acceptance of test data.

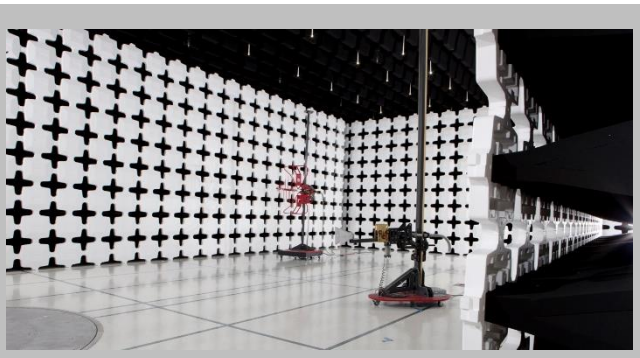
SCOPE

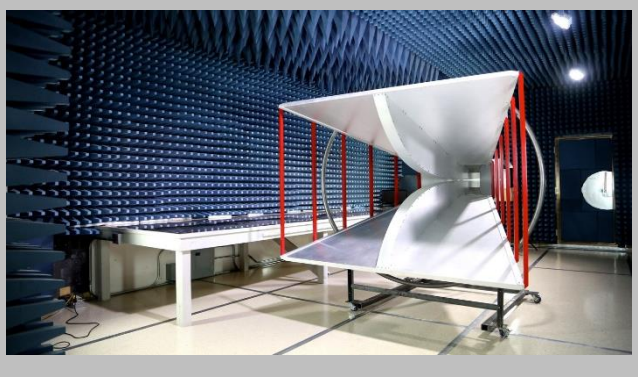
For details on the Scopes of our Accreditations, please visit:
https://www.nwemc.com/emc-testing-accreditations

FACILITIES

California	Minnesota	New York	Oregon	Texas	Washington
Labs OC01-17 41 Tesla Irvine, CA 92618 (949) 861-8918	Labs MN01-10 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 6775 NE Evergreen Pkwy #400 Hillsboro, OR 97124 (503) 844-4066	Labs TX01-09 3801 E Plano Pkwy Plano, TX 75074 (469) 304-5255	Labs NC01-05 19201 120th 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, 2834E-3	N/A	2834D-1	2834G-1	2834F-1
BSMI					
SL2-IN-E-1154R	SL2-IN-E-1152R	N/A	SL2-IN-E-1017	SL2-IN-E-1158R	SL2-IN-E-1153R
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:	Medtronic, Inc.
Address:	710 Medtronic Parkway
City, State, Zip:	Minneapolis, MN 55432
Evaluation Requested By:	Taylor Dowden
Model:	EV ICD
Date of Evaluation:	Monday, December 31, 2018

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:

The Medtronic EV ICD device is an extravascular implantable cardioverter defibrillator that provides fast ventricular tachyarrhythmia/fibrillation detection and defibrillation therapy. The device is built off the Evera MRI platform, with a device volume consistent with transvenous ICDs. The EV ICD device will have a DF4 connector and will support both 1.5T and 3T Conditional MRI.

The EV ICD device will be programmable and will have the capability of transmitting via telemetry the programmed values, measured and collected data, event markers, and real-time waveforms. The EV ICD system will utilize a commercially available Medtronic programmer for both the implant and in-office follow-up. Frequency bands contained in the product are inductive telemetry operating in 175 KHz and MICS frequency operating in 402-405 MHz.

The device automatically detects and records the occurrence of atrial fibrillation (AF) for diagnostic purposes. The devices also provide diagnostic and monitoring information that assists with system evaluation and patient care.

Objective:

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

SAR TEST EXCLUSION

element
EXRPT.2017.10.02

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 implanted in the body 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.

Per 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 ≤ 1.0 mW, SAR test exclusion may be applied.[27] 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."

SAR TEST EXCLUSION

element
EXRPT.2017.10.02

LIMITS

Limits for General Population /Uncontrolled Exposure: 47 CFR 1.1310 (c)

The SAR limits for general population/uncontrolled exposure are 0.08 W/kg, as averaged over the whole body, and a peak spatial-average SAR of 1.6 W/kg, averaged over any 1 gram of tissue (defined as a tissue volume in the shape of a cube). Exceptions are the parts of the human body treated as extremities, such as hands, wrists, feet, ankles, and pinnae, where the peak spatial-average SAR limit is 4 W/kg, averaged over any 10 grams of tissue (defined as a tissue volume in the shape of a cube). Exposure may be averaged over a time period not to exceed 30 minutes to determine compliance with general population/uncontrolled SAR limits.

ASSESSMENT

The SAR Test Exclusion Threshold is summarized in the following table:

Radio	Transmit Frequency (MHz)	Measured Conducted Output Power (mW)	Measured Radiated Output Power (mW) EIRP	Duty Cycle	Limit (mW)	Compliant
MICS	403.345	0.83618	0.000069	1	1.0	Yes

The information in the table above was obtained from:

Element Report No. MDTR0743.4