NORTHWEST EMC

Medtronic, Inc.

24967 CareLink SmartSync™ Device Manager Patient Connector

FCC 2.1093:2016

Bluetooth Radio Module

Report # MDTR0474

NVLAP TESTING

NVLAP Lab Code: 200881-0

CERTIFICATE OF EVALUATION

NORTHWEST EMC
2014-12-10

Last Date of Evaluation: July 28, 2016
Medtronic, Inc.
Model: 24967 CareLink SmartSync™ Device Manager Patient Connector

RF Exposure Evaluation

Standards

Specification	Method
FCC 2.1093:2016	FCC KDB 447498 D01 General RF Exposure Guidance v06

Results

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

Deviations From Standards

None

Approved By:

Donald Facteau, IT Manager

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 Evaluationing. The results of this Evaluation pertain only to the sample(s) Evaluationed. 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

NORTHWEST EMC
REV 2014.10.14

Revision Number	Description	Date	Page Number
00	None		

ACCREDITATIONS AND AUTHORIZATIONS

NORTHWEST EMC
REV 2016.3.22

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 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 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.

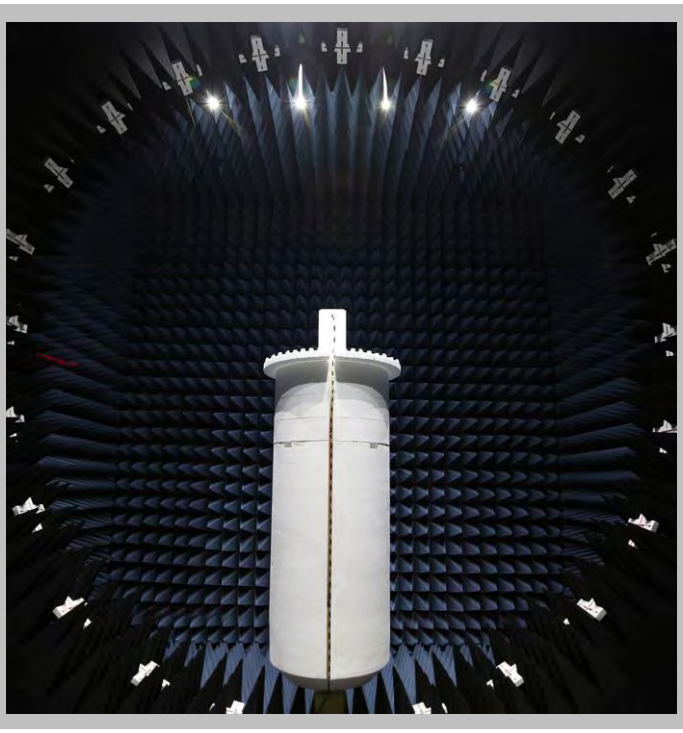
SCOPE

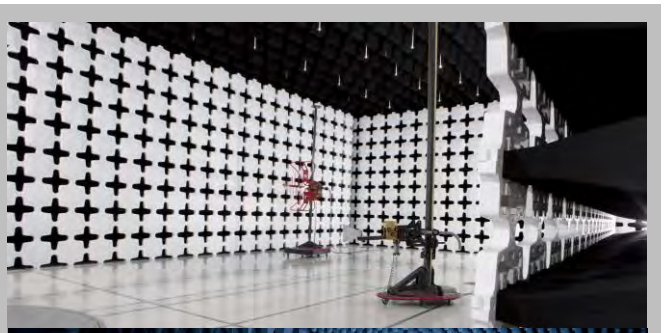
For details on the Scopes of our Accreditations, please visit:
http://www.nwemc.com/accreditations/
http://gsi.nist.gov/global/docs/cabs/designations.html

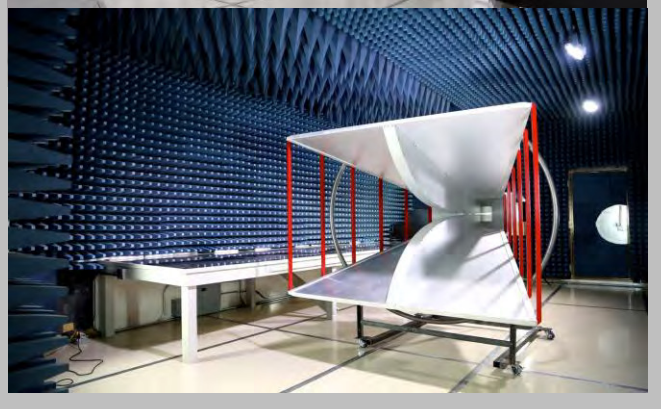
FACILITIES

NORTHWEST EMC
REV 2015.2.19

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 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
Industry Canada					
2834B-1, 2834B-3	2834E-1	N/A	2834D-1, 2834D-2	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

NORTHWEST EMC
2014-12-10

Client and Equipment Under Evaluation (EUT) Information

Company Name:	Medtronic, Inc
Address:	710 Medtronic Parkway
City, State, Zip:	Fridley, MN 55432
Evaluation Requested By:	Jay Axmann
Model:	24967 CareLink SmartSync™ Device Manager Patient Connector
First Date of Evaluation:	July 28, 2016

Information Provided by the Party Requesting the Evaluation

Functional Description of the EUT:
The Sirius system consists of the Handheld RF Head and the Base Station. The RF Head will only communicate to the base station via a wired connection. The RF Head will also include a 175 kHz Inductive H Field radio. The Hand held (RF Head) includes a Bluetooth radio that can operate as both a BLE radio when communicating to an implant and a classic Bluetooth radio when communicating to an external tablet.

Objective:
To demonstrate compliance of the RF head Bluetooth radio (BTLE/BR/EDR operation) with a new antenna to FCC 2.1093 requirements for a Class II Permissive Change to FCC ID: T7V1316.

SAR TEST EXCLUSION

NORTHWEST EMC
WTD.2014.12.17

OVERVIEW

The device is excluded from SAR evaluation and therefore deemed compliant with FCC RF exposure requirements as described below:

COMPLIANCE WITH FCC KDB 447498 D01 General RF Exposure Guidance v06

KDB 447498 D01 General RF Exposure Guidance v06, Section 4.3.1(a)

"For 100 MHz to 6 GHz and test separation distances ≤ 50 mm, the 1-g and 10-g SAR test exclusion thresholds are determined by the following:

[(max. power of channel, including tune-up tolerance, mW)/(min. test separation distance, mm)] · [√f(GHz)] ≤ 3.0 for 1-g SAR and ≤ 7.5 for 10-g extremity SAR,
where

- *f(GHz) is the RF channel transmit frequency in GHz*
- *Power and distance are rounded to the nearest mW and mm before calculation*
- *The result is rounded to one decimal place for comparison*
- *3.0 and 7.5 are referred to as the numeric thresholds in the step b below*

The test exclusions are applicable only when the minimum test separation distance is ≤ 50 mm and for transmission frequencies between 100 MHz and 6 GHz. When the minimum test separation distance is < 5 mm, a distance of 5 mm according to 4.1f) is applied to determine SAR test exclusion."

METHOD OF EVALUATION

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

Jay Axmann, Principal Engineer, Medtronic, Inc. attests that the conducted output power is 4.26 dBm (per the attached data), which is less than the level listed on the FCC grant. The lower value is set in firmware by Medtronic.

The result of the calculation is below the exclusion threshold of 3.0, therefore the unit is excluded from SAR evaluation and deemed compliant with FCC RF exposure requirements.

Transmit Frequency (GHz)	Test Separation (mm)	Output Power (mW)	Duty Cycle	Exclusion Threshold	Specification
2.441	5	2.7	1	0.8	<=3.0

SAR TEST EXCLUSION

NORTHWEST EMC
WTD.2014.12.17

CONDUCTED OUTPUT POWER DATA PROVIDED BY MEDTRONIC, INC.

The following is an excerpt from Medtronic's Internal Design Verification report for the BT/BLE radio:

Direct Measurement Confirmation

To confirm the datasheet inspection, a manufacturing equivalent Pilot base station (serial number SPM000113A, firmware HEAD_BS_TRR4(20160707) was modified by removing the chip antenna from the Bluetooth module and soldering a SMA socket in its place. This was connected through a 20 dB Agilent attenuator (no calibration required) and a 1 meter length of coaxial cable (measured loss of 1.02 dB) to an Agilent model E4404B spectrum analyzer (ID#145092, calibration due 21Oct2016) with a 1 MHz resolution bandwidth (the same bandwidth as the Bluetooth classic channel). There was enough "leakage" power to successfully allow two-way communication with a nearby tablet computer (Android Google Pixel C, 6.0.1 running CareLink SmartSync application ID 0000-881D-7104-8604) and measure the transmit power.

Agilent datasheet 5589-9815EN published August 4, 2014, page 13, shows the absolute frequency response of the E4404B from 9 kHz to 3 GHz is +/-0.46 dB. Overall amplitude accuracy is the absolute frequency response +/-0.54 dB, so the overall amplitude accuracy is +/-0.46 +/- 0.54 = +/-1.00 dB. That is, a "true" power of 4 dBm might be measured anywhere from 3 to 5 dBm, so the "pass" criterion is a measured power of 5 dBm or less.

Operator and Date	*Thomas Kelly 03August2016*					
Parameter	Measured Power. Max. (raw)	Add: 20 dB Attenuator	Add: 1.02 dB Cable Loss	Transmit Power (adjusted)	Transmit Power Limit	Pass/ Fail
Value	-16.76 dBm	+ 20 dB	+ 1.02 dB	4.26 dBm	5 dBm	Pass