

Medtronic Inc.

CARELINK ENCORE™ 29901

Report No. MDTR0119.2 Rev 01

Report Prepared By



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MPE Estimate



22975 NW Evergreen Parkway
Suite 400
Hillsboro, Oregon 97124

Certificate of Evaluation
Medtronic Inc.
Model: CARELINK ENCORE™ 29901

Emissions			
Test Description	Specification	Test Method	Pass/Fail
Maximum Permissible Exposure	FCC 2.1091:2012	OET Bulletin 65, Supplement C Ed 01-01	Pass

Approved By:

Donald Facteau, IS Manager

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
01	Corrected EUT product name	5/4/12	2
01	Corrected details on datasheet	5/4/12	8

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. The scope includes radio, ITE, and medical standards from around the world. See: <http://www.nwemc.com/accreditations/>

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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

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Singapore

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Vietnam

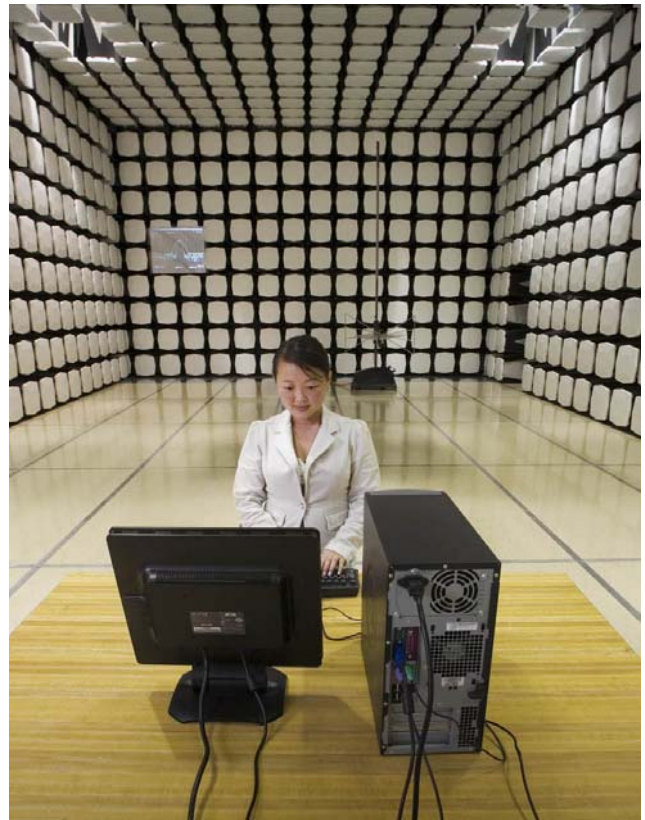
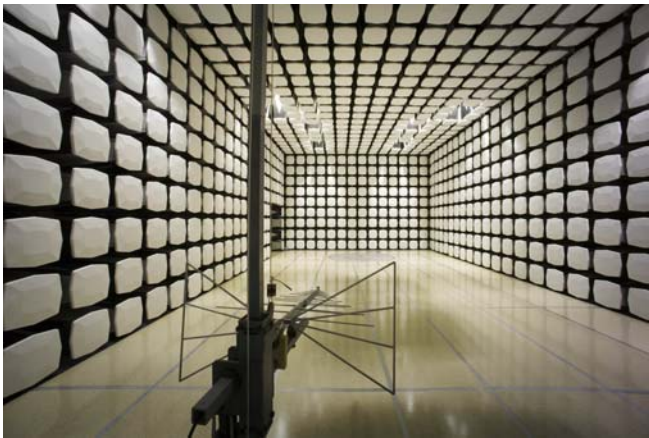
MIC – Recognized by MIC as a CAB for the acceptance of test data.

Russia

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



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VCCI				
C-1071, R-1025, G-84, C-2687, T-1658, R-2318	R-1943, G-85, C-2766, T-1659, G-548		R-3125, G-86, G-141, C-3464, T-1634	R-871, G-83, C-3265, T-1511
Industry Canada				
2834D-1, 2834D-2	2834B-1, 2834B-2, 2834B-3		2834E-1	2834C-1



Party Requesting the Evaluation

Company Name:	Medtronic Inc.
Address:	8200 Coral Sea Street N.E.
City, State, Zip:	Mounds View, MN 55112
Test Requested By:	Janet Gavidia
Models:	CARELINK ENCORE™ 29901
Date of Evaluation:	May 3, 2012

Information Provided by the Party Requesting the Evaluation**Functional Description of the EUT (Equipment Under Test):**

The Programmer is used to interrogate and program selected Medtronic implantable devices. It contains 802.11a/b/g/n and Bluetooth radio modules.

Objective:

To demonstrate compliance 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 Mobile Portable RF Exposure V04

The WiFi and Bluetooth radio transceivers are mobile transmitters that each operate through their own antenna. They can transmit simultaneously.

"KDB 447498 D01 Mobile Portable RF Exposure v04" provides the procedures, requirements, and authorization policies for mobile and portable devices. Item #8 best fits the exposure condition described in this report. Since these mobile devices are categorically excluded from routine evaluation; per footnotes 1 and 33 of KDB 447498, 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 for simultaneous transmission at a 20 cm boundary.

FCC LIMITS FOR MPE

Limits for General Population /Uncontrolled Exposure: 47 CFR 1.1310

Frequency Range (MHz)	Strength (V/m)	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

METHOD OF EVALUATION

The exposure level at a 20 cm distance from the EUT's transmitting antenna is calculated 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 summarized in the following table:

NORTHWEST EMC		Maximum Permissible Exposure (MPE)		XMIT 2008.12.29	
EUT:	CARELINK ENCORE 29901	Work Order:	MDTR0119		
Serial Number:	none	Date:	05/03/12		
Customer:	Medtronic Inc.	Temperature:	n/a		
Attendees:	None	Humidity:	n/a		
Project:	None	Barometric Pres.:	n/a		
Evaluated by:	Greg Kiemel	Power:	n/a	Job Site:	EV06
SPECIFICATIONS		Method			
FCC 2.1091:2012		OET Bulletin 65, Supplement C Ed 01-01			
COMMENTS					
None					
DEVIATIONS FROM TEST STANDARD					
No Deviations					
		Signature 			

MPE Estimates for Individual Devices

Radio	Antenna Type	Antenna Manufacturer	Antenna Part No. ³	Transmit Frequency (MHz)	Max Peak Conducted Output Power ¹ (mW)	Duty Cycle	Duty Cycle Corrected Output Power (mW)	Antenna Gain ² (dBi)	Minimum Antenna Cable Loss (dB)	Power Density @ 20 cm (mW/cm ²)	General Population Exposure Limit from 1.1310 (mW/cm ²)	Ratio of Power Density to the Exposure Limit
WiFi Radio	PIFA		631-1330 & 631-1331	2400	628.46	1	628.46	6.99	0	0.625	1	0.62518
				5200	50.05	1	50.05	8.65	0	0.073	1	0.07297
				5300	243.61	1	243.61	8.67	0	0.357	1	0.35680
				5600	175.03	1	175.03	7.43	0	0.193	1	0.19268
				5800	739.19	1	739.19	7.01	0	0.739	1	0.73873
Bluetooth Radio	Integral	PCB Etch	N/A	2400	2.1	1	2.1	1.87	0	0.001	1	0.00064

Note 1: Conducted output power listed on FCC Grant for PPD-AR5BxB92-H for Wi-Fi and QDS-BRCM1043 for Bluetooth.

Note 2: Antenna gain from FCC filings for radios. For the Wi-Fi, it is the log sum of the two MIMO antennas

Note 3: Antenna information from FCC filings for radios

Worst Case Co-located Exposure Conditions

Both radios transmitting at the exact same instant

Per Note 24 shown below, the Sum of Worst Case Power Ratios cannot exceed 1.0

WiFi Worst Case Ratio of Power Density to the Exposure Limit	Bluetooth Worst Case Ratio of Power Density to the Exposure Limit	Sum of Worst Case Ratios (Power Density to the Exposure Limit)	FCC Limit for Sum of Worst Case Ratios
0.73873	0.00257	0.74130	1.0

PASS

The results shown in the above table are equivalent to the Sum of the EIRP of the Co-located Transmitters (EIRP TX1 + EIRP TX2) compared to the exposure limit. The benefit of this method, is that accounts for transmitters operating at different frequencies against different exposure limits.

Excerpts from TCB Training, April 3, 2002, "Mobile Transmitters", Slide 6:

"Devices operating in multiple frequency bands

When RF exposure evaluation is required for TCB approval

o Separate antennas – estimated minimum separation distances may be considered for the frequency bands that do not require evaluation or TCB approval, however, the estimated distance should take into account the effect of co-located transmitters. (Note 24)

Note 24 According to multiple frequency exposure criteria, the ratio of field strength or power density to the applicable exposure limit at the exposure location should be determined for each transmitter and the sum of these ratios must not exceed 1.0 for the location to be compliant."

The sum of the ratios (power density to the exposure limit) does not exceed 1.0; therefore, the exposure condition is compliant with FCC rules.