



# element

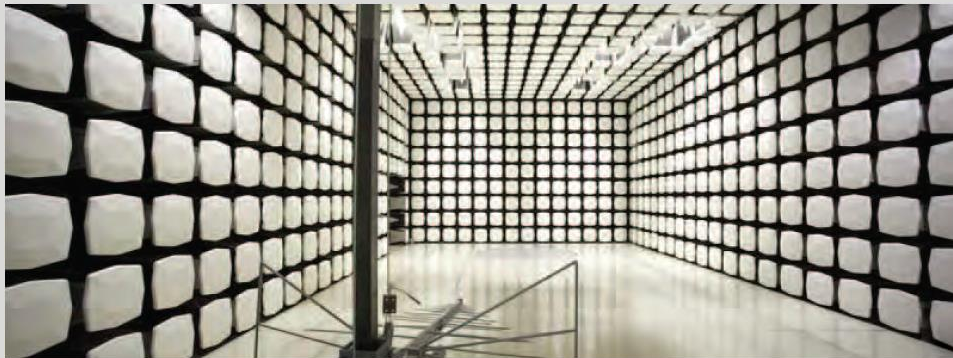
**Medtronic, Inc.**

**MyCareLink Relay Home Communicator 24960**

**FCC 2.1091:2018**

**802.11bgn, Bluetooth Low Energy, Cellular**

**Report # MDTR0649.20**



NVLAP Lab Code: 200630

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# CERTIFICATE OF EVALUATION

Last Date of Evaluation: Monday, November 19, 2018  
Medtronic, Inc.  
Model: MyCareLink Relay Home Communicator 24960

## RF Exposure Evaluation

### Standards

Specification	Method
FCC 2.1091:2018	FCC 447498 D01 General RF Exposure Guidance v06

### Results

Method Clause	Description	Applied	Results	Comments
7.2	Maximum Permissible Exposure	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



<b>The following RF Exposure conditions were used for the assessment documented in this report:</b>	
Intended Use	Mobile
Location on Body (if applicable)	NA
How is the Device Used	The MyCareLink Relay home communicator wirelessly transfers information between an implanted medical device and the Medtronic CareLink network. The wireless communication between the MyCareLink Relay and an implanted medical device is accomplished by means of a Bluetooth low energy (BLE) radio. The wireless communication between the MyCareLink Relay and an implanted medical device is accomplished by means of a Bluetooth low energy (BLE) radio whereas that between the MyCareLink Relay and the Medtronic CareLink network is accomplished by means of either a WiFi or cellular radio. The Wi-Fi radio supports 802.11b/g/n (2.4 GHz, 20 MHz bandwidth only) and the four variations of the cellular radio support some or all the 2G, 3G and 4G technologies.
Radios Contained in the Same Host Device	Cellular 802.11bg BTLE
Simultaneous Transmitting Radios	Cellular 802.11bg BTLE
Body Worn Accessories	NA
Environment	General Population/Uncontrolled Exposure

# REVISION HISTORY



Revision Number	Description	Date (yyyy-mm-dd)	Page Number
00	None		

# ACCREDITATIONS AND AUTHORIZATIONS



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## 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

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## 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.

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## European Union

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

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## Australia/New Zealand

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

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## Korea

**MSIT / RRA** - Recognized by KCC's RRA as a CAB for the acceptance of test data.

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## Japan

**VCCI** - Associate Member of the VCCI. Conducted and radiated measurement facilities are registered.

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## 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.

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## Singapore

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

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## Israel

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

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## Hong Kong

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

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## Vietnam

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

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## SCOPE

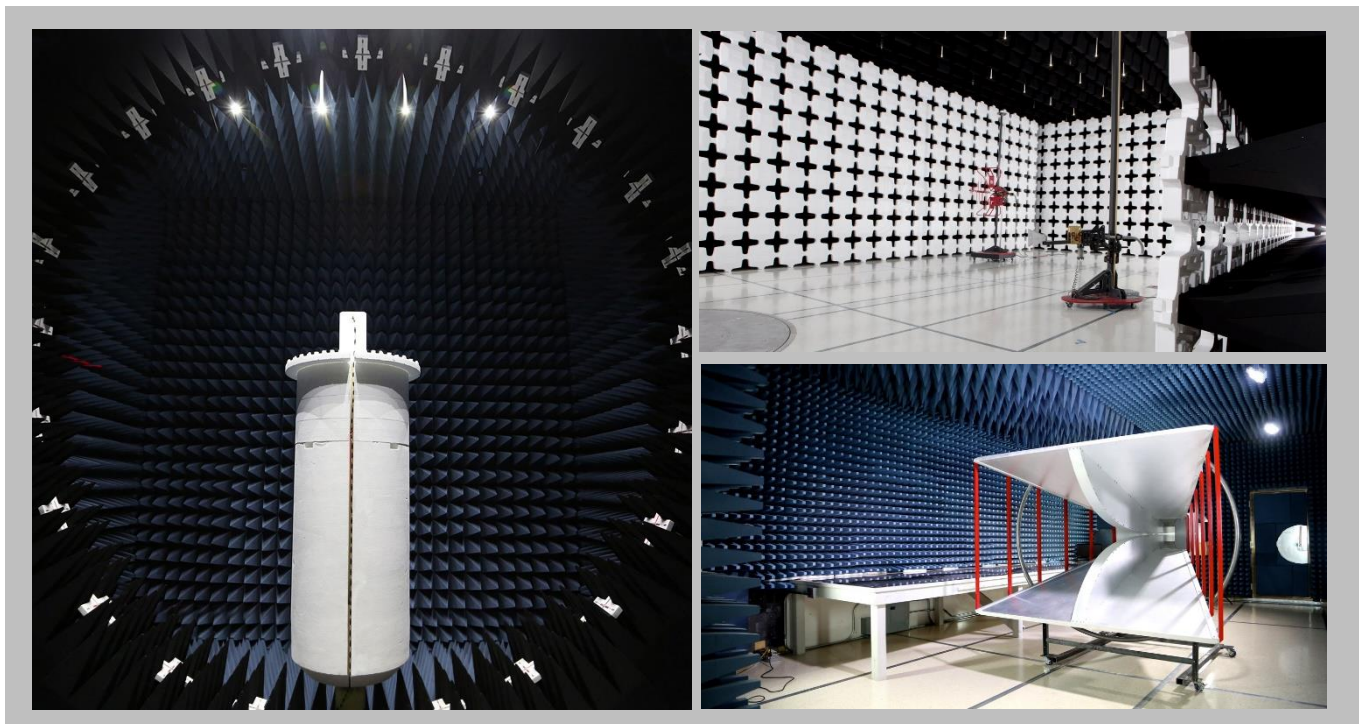
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# FACILITIES



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<b>NVLAP</b>					
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
<b>Innovation, Science and Economic Development Canada</b>					
2834B-1, 2834B-3	2834E-1, 2834E-3	N/A	2834D-1, 2834D-2	2834G-1	2834F-1
<b>BSMI</b>					
SL2-IN-E-1154R	SL2-IN-E-1152R	N/A	SL2-IN-E-1017	SL2-IN-E-1158R	SL2-IN-E-1153R
<b>VCCI</b>					
A-0029	A-0109	N/A	A-0108	A-0201	A-0110
<b>Recognized Phase I CAB for ACMA, BSMI, IDA, KCC/RRA, MIC, MOC, NCC, OFCA</b>					
US0158	US0175	N/A	US0017	US0191	US0157



# PRODUCT DESCRIPTION



## Client and Equipment Under Evaluation Information

<b>Company Name:</b>	Medtronic, Inc.
<b>Address:</b>	710 Medtronic Parkway
<b>City, State, Zip:</b>	Minneapolis, MN 55432
<b>Evaluation Requested By:</b>	Taylor Dowden
<b>Model:</b>	MyCareLink Relay Home Communicator 24960
<b>Date of Evaluation:</b>	Monday, November 19, 2018

## Information Provided by the Party Requesting the Evaluation

### Functional Description of the Equipment:

The MyCareLink Relay home communicator is a home health monitoring device to allow communication between an implanted medical device and the Medtronic CareLink network.

### Objective:

To demonstrate compliance with FCC requirements for RF exposure for 2.1091 mobile/fixed devices



# MAXIMUM PERMISSIBLE EXPOSURE (MPE)



## 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 <sup>2</sup> )	Averaging Time (minutes)
0.3 - 1.34	614	1.63	*(100)	30
1.34 - 30	824/f	2.19/f	*(180/f <sup>2</sup> )	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/cm<sup>2</sup>)

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 tables:

# MAXIMUM PERMISSIBLE EXPOSURE (MPE)



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 <sup>2</sup> )	Limit (mW/cm <sup>2</sup> )	Ratio
BTLE	2402	4.947	1	3.17	0	20	0.0020	1.0	0.0020
Max Ratio									0.0020

The information in the table above was obtained from:

The antenna gain is taken from the manufacturer's data sheet submitted as part of the certification application.

Conducted output power taken from Element Report MDTR0649.9

Radio	Transmit Frequency (MHz)	Measured Conducted Output Power (dBm)	Duty Cycle	Highest Antenna Gain (dBi)	Minimum Antenna Cable Loss (dB)	Minimum Separation Distance (cm)	Power Density (mW/cm <sup>2</sup> )	Limit (mW/cm <sup>2</sup> )	Ratio
802.11bg	2412	13.5	1	4.32	0	20	0.012	1.0	0.0120
Max Ratio									0.0120

The information in the table above was obtained from:

The antenna gain is taken from the manufacturer's data sheet submitted as part of the certification application.

Conducted output power taken from Element Report MDTR0649.5

Radio	Transmit Frequency (MHz)	Measured Radiated Output Power	Duty Cycle	Minimum Separation Distance (cm)	Power Density (mW/cm <sup>2</sup> )	Limit (mW/cm <sup>2</sup> )	Ratio
Cellular: UMTS 850	825.7	23.4 dBm EIRP	1	20	0.044	0.6	0.0791
Cellular: UMTS 1900	1851.8	26 dBm EIRP	1	20	0.079	1.0	0.0792
Cellular: UMTS 1700	1734.7	26.7 dBm EIRP	1	20	0.093	1.0	0.0931
Cellular: LTE Band 5	826.615	21.6 dBm EIRP	1	20	0.029	0.6	0.0522
Cellular: LTE Band 4	1725.855	22.9 dBm EIRP	1	20	0.039	1.0	0.0388
Cellular: LTE Band 2	1850.195	23.8 dBm EIRP	1	20	0.048	1.0	0.0477
Cellular: LTE Band 12	708.395	18.5 dBm EIRP	1	20	0.014	0.5	0.0298
Max Ratio							0.0931

The information in the table above was obtained from:

EIRP taken from Element Report MDTR0649

Sum of Maximum Ratios	Limit	Compliant
0.1071	1	Yes