



element

Nuvectra Medical
Bridge Communicator 4110-US

FCC 2.1093:2019
Bluetooth and MED Radio

Report # NUVE0027.8



NVLAP Lab Code: 200630



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CERTIFICATE OF EVALUATION



Last Date of Evaluation: Monday, August 5, 2019
Nuvecra Medical
Model: Bridge Communicator 4110-US

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
4.3.2(b)	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

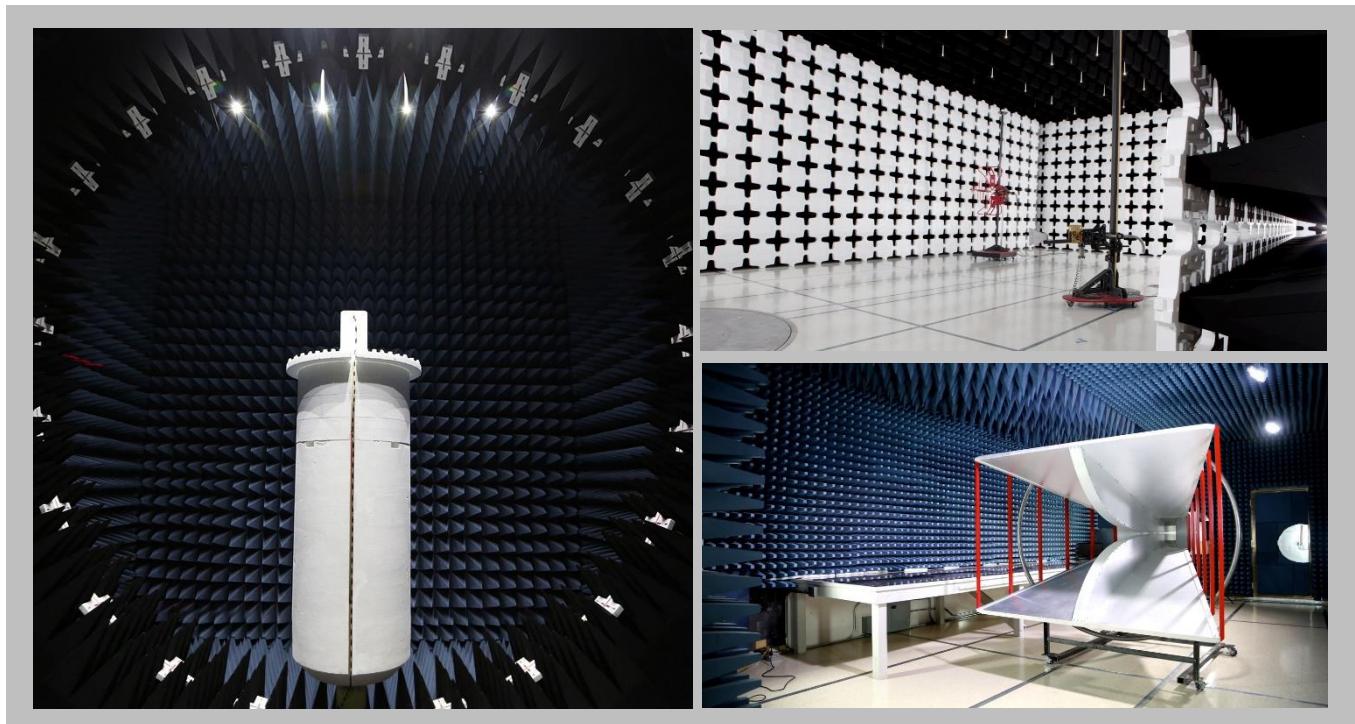
For details on the Scopes of our Accreditations, please visit:

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

FACILITIES



California Labs OC01-17 41 Tesla Irvine, CA 92618 (949) 861-8918	Minnesota Labs MN01-10 9349 W Broadway Ave. Brooklyn Park, MN 55445 (612) 638-5136	Oregon Labs EV01-12 6775 NE Evergreen Pkwy #400 Hillsboro, OR 97124 (503) 844-4066	Texas Labs TX01-09 3801 E Plano Pkwy Plano, TX 75074 (469) 304-5255	Washington 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: 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	2834D-1	2834G-1	2834F-1
BSMI				
SL2-IN-E-1154R	SL2-IN-E-1152R	SL2-IN-E-1017	SL2-IN-E-1158R	SL2-IN-E-1153R
VCCI				
A-0029	A-0109	A-0108	A-0201	A-0110
Recognized Phase I CAB for ISED, ACMA, BSMI, IDA, KCC/RRA, MIC, MOC, NCC, OFCA				
US0158	US0175	US0017	US0191	US0157



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	The pocket programmer is used as a Bluetooth bridge communicator with a clinician programmer. In addition to the Bluetooth radio, it uses a low power 2.45 GHz signal (15.249) to wake-up a pulse generator and then transmits and receives information with the pulse generator using the MICS protocol at 402- 405 MHz.
Radios Contained in the Same Host Device	Bluetooth MED Radio 2.45 GHz Radio (15.249)
Simultaneous Transmitting Radios	Bluetooth, MED Radio
Body Worn Accessories	N/A
Environment	General Population/Uncontrolled Exposure

PRODUCT DESCRIPTION

Client and Equipment Under Evaluation Information

Company Name:	Nuvectra Medical
Address:	10000 Wehrle Drive 11th Floor
City, State, Zip:	CLARENCE, TX 14031
Evaluation Requested By:	Peter Valentyik
Model:	Bridge Communicator 4110-US
Date of Evaluation:	Monday, August 5, 2019

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:

A MED radio transceiver (402- 405 MHz) is activated by a 2.45 GHz (15.249) wake-up signal. The MED Radio is co-located with a Bluetooth radio. The Bluetooth radio provides communications to a remote tablet.

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 is covered under section 4.3.1. Unless specifically required by the published RF exposure KDB procedures, standalone 1-g head or body and 10-g extremity SAR evaluation for general population exposure conditions, by measurement or numerical simulation, is not required when the corresponding SAR Test Exclusion Thresholds are met as shown in the Limits section below.

Simultaneous transmission SAR test exclusion is covered under section 4.3.2. SAR test exclusion is determined for each operating configuration and exposure condition according to the reported standalone SAR of each applicable simultaneously transmitting antenna. When the sum of 1-g or 10-g SAR of all simultaneously transmitting antennas in an operating mode and exposure condition combination is within the SAR limit, SAR test exclusion applies to that simultaneous transmission configuration.

SAR TEST EXCLUSION

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.

For 100 MHz to 6 GHz and test separation distances \leq 50 mm, the SAR test exclusion thresholds are 1-g for head and body SAR and 10-g SAR for extremity SAR.

ASSESSMENT

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

$[(\text{max. power of channel, including tune-up tolerance, mW}) / (\text{min. test separation distance, mm})] \cdot [\sqrt{f(\text{GHz})}] = 3.0$
 for 1-g SAR and = 7.5 for 10-g extremity SAR,
 where

- $f(\text{GHz})$ 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 \leq 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 – STANDALONE CONFIGURATION

The standalone SAR Test Exclusion Threshold for each radio is summarized in the following table.

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

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

Radio	Transmit Frequency (MHz)	Measured Conducted Output Power (mW)	Duty Cycle	Minimum Separation Distance (mm)	Exclusion Threshold	Limit	Compliant
MED Radio	403.35	1.168	1	5	0.148	3.0	Yes

The information in the table above was obtained from:

For the MED radio, the client provided information for this application and Element report # NUVE0019.1.

METHOD OF EVALUATION – SIMULTANEOUS TRANSMISSION CONFIGURATION

KDB 447498 D01 General RF Exposure Guidance v06, Section 4.3.2(b)

“When an antenna qualifies for the standalone SAR test exclusion of 4.3.1 and also transmits simultaneously with other antennas, the standalone SAR value must be estimated according to the following to determine the simultaneous transmission SAR test exclusion criteria:

SAR TEST EXCLUSION

1) $[(\text{max. power of channel, including tune-up tolerance, mW})/(\text{min. test separation distance, mm})] \cdot [\sqrt{f(\text{GHz})}/x]$, for test separation distances $\leq 50\text{mm}$;

where $x = 7.5$ for 1-g SAR and $x = 18.75$ for 10-g SAR.

2) 0.4 W/kg for 1-g SAR and 1.0 W/kg for 10-g SAR, when the test separation distance is $> 50 \text{ mm}$.

This SAR estimation formula has been considered in conjunction with the SAR Test Exclusion Thresholds to result in substantially conservative SAR values of $= 0.4 \text{ W/kg}$. When SAR is estimated, the peak SAR location is assumed to be at the feed-point or geometric center of the antenna, whichever provides a smaller antenna separation distance, and this location must be clearly identified in test reports. The estimated SAR is used only to determine simultaneous transmission SAR test exclusion; it should not be reported as the standalone SAR. When SAR is estimated, it must be applied to determine the sum of 1-g SAR test exclusion. When SAR to peak location separation ratio test exclusion is applied, the highest reported SAR for simultaneous transmission can be an estimated standalone SAR if the estimated SAR is the highest among the simultaneously transmitting antennas (see also KDB Publication 690783 D01). For situations where the estimated SAR is overly conservative for certain conditions, the test lab may choose to perform standalone SAR measurements, then use the measured SAR to determine simultaneous transmission SAR test exclusion. Estimated SAR values at selected frequencies, distances, and power levels are illustrated in Appendix D.

In the table below, the estimated stand-alone SAR for the MED radio has been estimated. The estimated value have been summed with the highest reported SAR value for the Bluetooth radio and compared to the SAR limit. The result of the calculation is well below the limit therefore the unit is excluded from simultaneous SAR evaluation and deemed compliant with FCC RF exposure requirements.

Radio	Transmit Frequency (GHz)	Test Separation (mm)	Output Power (mW)	Duty Cycle	Estimated Standalone SAR (W/kg)	Specification (W/kg)
Med Radio	0.40335	5	1.17	1	0.020	1.6

Radio	Highest Reported SAR (W/kg)	Specification (W/kg)
Bluetooth	0.22	1.6

Estimated Summed SAR (W/kg)	Specification (W/kg)
0.240	1.6

The information in the table above was obtained from:

For the MED radio, the client provided information for this application and Element report # NUVE0019.1. For the Bluetooth radio, SGS report # 287407-2-1 and Verkotan SAR Compliance Test Report dated 7/4/2017 for FCC ID: QOQ11.