Masimo Corporation

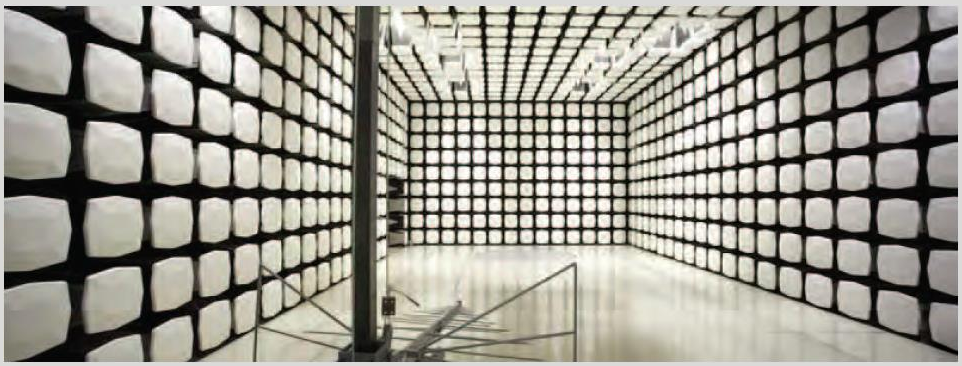
MightySat

FCC 1.1307:2025

FCC 2.1093:2025

Bluetooth Low Energy

Report: MASI0927.1 Rev. 1, Issue Date: April 3, 2025



This report must not be used to claim product certification, approval, or endorsement by A2LA, NIST, or any agency of the U.S. Government. This Report shall not be reproduced, except in full without written approval of the laboratory.

TABLE OF CONTENTS

Section	Page Number

Certificate of Evaluation 3
Revision History 4
Accreditations.....5
Facilities 6
Product Description.....7
Exposure Condition.....9
Exemption from RF Exposure Evaluation 10
End of Report.....12

CERTIFICATE OF EVALUATION

Last Date of Evaluation: April 3, 2025
Masimo Corporation
EUT: MightySat

RF Exposure Evaluation

Standards

Specification	Method
FCC 1.1307:2025 FCC 2.1093:2025	FCC 1.1307:2025

Results

Method Clause	Description	Applied	Results	Comments
(b)(3)(i)(B)	Exemption From RF Exposure Evaluation	Yes	Compliant	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
01	Reassessed using the measured power from MASI0927.0 Rev. 1. The reduction in reported power led to a decrease in exposure value. Consequently, the ratio to the limit at the minimum separation distance easily complied with the head/torso limit. Therefore, the assessment against the limb limits was removed.	2025-04-04	1-12

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 - Each laboratory is accredited by A2LA to ISO / IEC 17025, and as a product certifier to ISO / IEC 17065 which allows Element to certify transmitters to FCC and IC specifications.

FDA - Recognized by the FDA as an Accreditation Scheme for Conformity Assessment (ASCA)-accredited testing laboratory for basic safety and essential performance.

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 – Recognized as an EU Notified Body validated for the EMCD and RED Directives.

United Kingdom

BEIS – Recognized by the UK as an Approved Body under the UK Radio Equipment and UK EMC Regulations.

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.

SCOPE

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

California Minnesota Oregon Washington

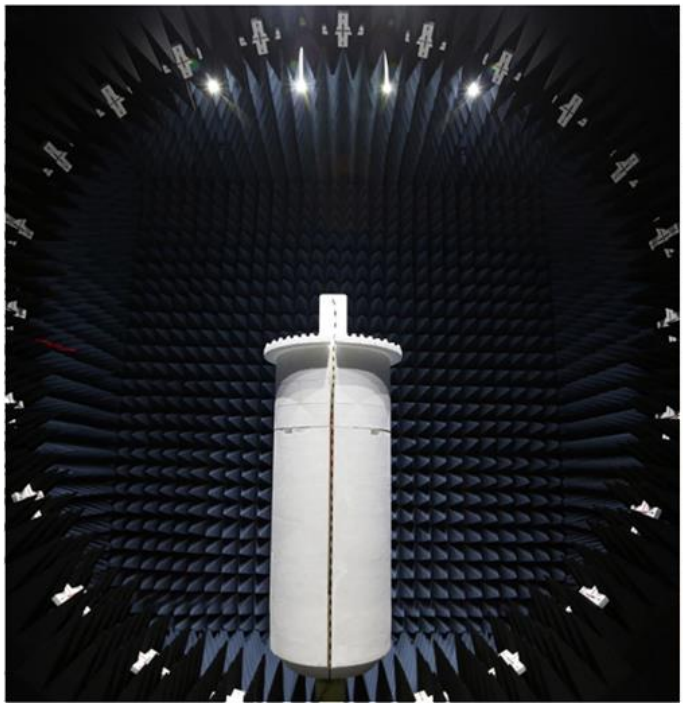
FACILITIES

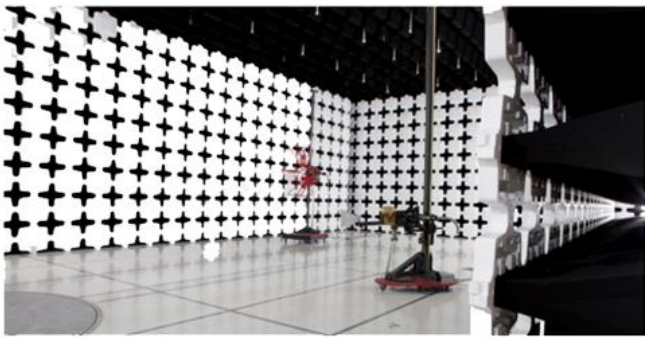
Testing was performed at the following location(s)

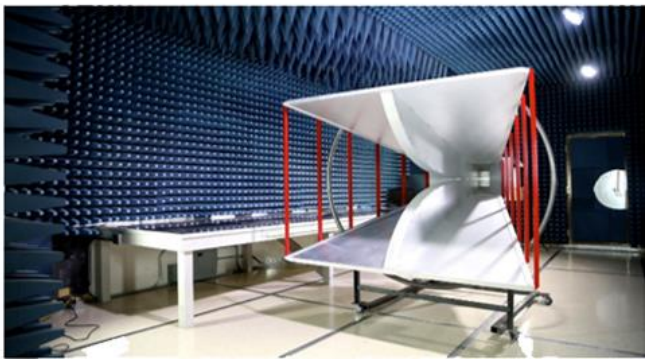
	Location	Labs (1)	Address	A2LA (2)	ISED (3)	BSMI (4)	VCCI (5)	CAB (6)	FDA (7)
☐	California	OC01-17	41 Tesla Irvine, CA 92618 (949) 861-8918	3310.04	2834B	SL2-IN-E-1154R	A-0029	US0158	TL-55
☐	Minnesota	MN01-11	9349 W Broadway Ave. Brooklyn Park, MN 55445 (612) 638-5136	3310.05	2834E	SL2-IN-E-1152R	A-0109	US0175	TL-57
☒	Oregon	EV01-12	6775 NE Evergreen Pkwy #400 Hillsboro, OR 97124 (503) 844-4066	3310.02	2834D	SL2-IN-E-1017	A-0108	US0017	TL-56
☐	Washington	NC01-05	19201 120th Ave NE Bothell, WA 98011 (425) 984-6600	3310.06	2834F	SL2-IN-E-1153R	A-0110	US0157	TL-67
☐	Offsite	N/A	See Product Description	N/A	N/A	N/A	N/A	N/A	N/A

See data sheets for specific labs

(1) The lab designations denote individual rooms within each location. (OC01, OC02, OC03, etc.)
(2) A2LA Certificate No.
(3) ISED Company No.
(4) BSMI No.
(5) VCCI Site Filing No.
(6) CAB Identifier. Recognized Phase I CAB for ISED, ACMA, BSMI, IDA, KCC/RRA, MOC, NCC, OFCA
(7) FDA ASCA No.







PRODUCT DESCRIPTION

Client and Equipment Under Evaluation Information

Company Name:	Masimo Corporation
Address:	52 Discovery
City, State, Zip:	Irvine, CA 92618
Evaluation Requested By:	Anami Joshi
EUT:	MightySat
Date of Evaluation:	4/3/2025

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:

MightySat is a stand-alone fingertip pulse oximeter that combines the functionality of an instrument, sensor, and technology board into a single portable instrument that fits on user's finger. The device will be capable of calculating functional oxygen saturation (SpO2), pulse rate(PR), perfusion index(PI), Pleth Respiration rate (RRp), Respiratory Effort Index(REi), waveform, and output this information via a display screen or wireless over a Bluetooth link. MightySat will be powered by 2 disposable AAA batteries and be used as a spot-check instrument, and as such will not contain alarm functionality.

The MighySat Fingertip Pulse Oximeter is indicated for noninvasive spot-checking of functional oxygen saturation of arterial hemoglobin(SpO2), Pulse Rate(PR), Perfusion Index(PI), Pleth Respiration rare(RRp), and Respiratory Effort Index(REi).

The MighySat Fingertip Pulse Oximeter is intended for spot-checking on people>30kg(66 lbs) during no motion and motion condition, and for people who are well or poorly perfused. This device is suitable for use in hospital, hospital-type facilities, mobile, and home environment.

Objective:

To demonstrate compliance with FCC Requirements for RF exposure for 1.1307 RF exempt devices

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 MightySat is used at a distance of less than 20 cm from the user.
Radios Contained in the Same Host Device	Bluetooth Low Energy
Simultaneous Transmitting Radios	None
Body Worn Accessories	None
Environment	General Population/Uncontrolled Exposure

EXEMPTION FROM RF EXPOSURE EVALUATION

element
EXRPT.2024.05.10.0

OVERVIEW

Section 1.3 of KDB 44798 D04 v01 states that, "Under the new rules, all radio services and operations are subject to Routine Evaluation [§§ 1.1307(b)(1), 2.1033(f), etc.], unless shown to qualify under the exemptions provided in the rules and OET Lab policies for equipment authorization."

The glossary of KDB 447498 D04 v01 specifies that an exempt RF device is defined "solely from the obligation to perform a routine environmental evaluation to demonstrate compliance with the RF exposure limits in § 1.1310; it is not exemption from the equipment authorization procedures described in 47 CFR Part 2, not exemption from general obligations of compliance with the RF exposure limits in § 1.1310 of this chapter, and not exemption from determination of whether there is no significant effect on the quality of the human environment under § 1.1306." Compliance with the exemption criteria defined in 1.1307(b) confirm compliance with the limits in § 1.1310.

COMPLIANCE WITH FCC 1.1310

Per 1.1307(b)(3), (i) For single RF sources (*i.e.,* any single fixed RF source, mobile device, or portable device, as defined in paragraph (b)(2) of this section): A single RF source is exempt if:

(A) The available maximum time-averaged power is no more than 1 mW, regardless of separation distance. This exemption may not be used in conjunction with other exemption criteria other than those in paragraph (b)(3)(ii)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(ii)(A);

(B) Or the available maximum time-averaged power or effective radiated power (ERP), whichever is greater, is less than or equal to the threshold P_{th} (mW) described in the following formula. This method shall only be used at separation distances (cm) from 0.5 cm to 40 cm and at frequencies from 0.3 GHz to 6 GHz (inclusive). P_{th} is given by:

$$P_{th}(mW) = \begin{cases} ERP_{20\,cm}(d/20\,cm)^x & d \le 20\,cm \\ ERP_{20\,cm} & 20\,cm < d \le 40\,cm \end{cases}$$

Where

$$x = -\log_{10}\left(\frac{60}{ERP_{20\,cm}\sqrt{f}}\right) \; and\; f\; is\; in\; GHz\,;$$

And

$$ERP_{20\,cm}(mW) = \begin{cases} 2040f & 0.3\,GHz \le f < 1.5\,GHz \\ 3060 & 1.5\,GHz \le f \le 6\,GHz \end{cases}$$

(C) Or using Table 1 and the minimum separation distance (R in meters) from the body of a nearby person for the frequency (f in MHz) at which the source operates, the ERP (watts) is no more than the calculated value prescribed for that frequency. For the exemption in Table 1 to apply, R must be at least λ/2π, where λ is the free-space operating wavelength in meters. If the ERP of a single RF source is not easily obtained, then the available maximum time-averaged power may be used in lieu of ERP if the physical dimensions of the radiating structure(s) do not exceed the electrical length of λ/4 or if the antenna gain is less than that of a half-wave dipole (1.64 linear value).

TABLE 1 TO §1.1307(b)(3)(i)(C)—SINGLE RF SOURCES SUBJECT TO ROUTINE ENVIRONMENTAL EVALUATION

RF Source frequency (MHz)	Threshold ERP (watts)
0.3-1.34	1,920 R^2.
1.34-30	3,450 R^2/f^2.
30-300	3.83 R^2.
300-1,500	0.0128 R^2f.
1,500-100,000	19.2R^2.

(ii) For multiple RF sources: Multiple RF sources are exempt if:

(A) The available maximum time-averaged power of each source is no more than 1 mW and there is a separation distance of two centimeters between any portion of a radiating structure operating and the nearest portion of any other radiating structure in the same device, except if the sum of multiple sources is less than 1 mW during the time-averaging period, in which case they may be treated as a single source (separation is not required). This exemption may not be used in conjunction with other exemption criteria other than those is paragraph (b)(3)(i)(A) of this section. Medical implant devices may only use this exemption and that in paragraph (b)(3)(i)(A).

(B) in the case of fixed RF sources operating in the same time-averaging period, or of multiple mobile or portable RF sources within a device operating in the same time averaging period, if the sum of the fractional contributions to the applicable thresholds is less than or equal to 1 as indicated in the following equation.

$$\sum_{i=1}^{a} \frac{P_i}{P_{th,i}} + \sum_{j=1}^{b} \frac{ERP_j}{ERP_{th,j}} + \sum_{k=1}^{c} \frac{Evaluated_k}{Exposure\ Limit_k} \leq 1$$

Where:

a = number of fixed, mobile, or portable RF sources claiming exemption using paragraph (b)(3)(i)(B) of this section for P_{th}, including existing exempt transmitters and those being added.

b = number of fixed, mobile, or portable RF sources claiming exemption using paragraph (b)(3)(i)(C) of this section for Threshold ERP, including existing exempt transmitters and those being added.

c = number of existing fixed, mobile, or portable RF sources with known evaluation for the specified minimum distance including existing evaluated transmitters.

P_i = the available maximum time-averaged power or the ERP, whichever is greater, for fixed, mobile, or portable RF source *i* at a distance between 0.5 cm and 40 cm (inclusive).

$P_{th,i}$ = the exemption threshold power (P_{th}) according to paragraph (b)(3)(i)(B) of this section for fixed, mobile, or portable RF source *i.*

ERP_j = the ERP of fixed, mobile, or portable RF source *j.*

$ERP_{th,j}$ = exemption threshold ERP for fixed, mobile, or portable RF source *j,* at a distance of at least λ/2π according to the applicable formula of paragraph (b)(3)(i)(C) of this section.

$Evaluated_k$ = the maximum reported SAR or MPE of fixed, mobile, or portable RF source *k* either in the device or at the transmitter site from an existing evaluation at the location of exposure.

$Exposure\ Limit_k$ = either the general population/uncontrolled maximum permissible exposure (MPE) or specific absorption rate (SAR) limit for each fixed, mobile, or portable RF source *k,* as applicable from §1.1310

The relationship between EIRP and ERP is:

$$ERP\ (dBm) = EIRP\ (dBm) - 2.14\ dB$$

Where EIRP is the sum of the conducted power (dBm) and the antenna gain (dBi).

EXEMPTION FROM RF EXPOSURE EVALUATION

element
EXRPT.2024.05.10.0

ASSESSMENT

The exemption from RF exposure evaluation is summarized in the following table(s):

Radio	Transmit Frequency (MHz)	Conducted Output Power	Power Tolerance (dB)	Duty Cycle	Antenna Assembly Gain (dBi)	Minimum Separation Distance (cm)	Calculated Radiated Exposure Power (mW) ERP	Calculated Conducted Exposure Power (mW dBm)	Limit (mW)	Compliant
Bluetooth Low Energy	2402 - 2480	2.496 dBm	1.0	100.0%	0.79	0.5	1.6	2.2	2.7	yes

The information in the table above was obtained from:

A measured value was used in these calculations. This assessment is based on customer supplied information and Element report MASI0927.0 Rev. 1.

Evaluator: Jay Whitworth

End of Test Report