



# element

**Hinge Health**

**Enso 2**

**FCC 1.1307:2022**

**Bluetooth Low Energy**

**Report: HING0001.3, Issue Date: April 5, 2022**



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

*EAR-Controlled Data - This document contains technical data whose export and reexport/retransfer is subject to control by the U.S. Department of Commerce under the Export Administration Act and the Export Administration Regulations. The Department of Commerce's prior written approval may be required for the export or re-export/retransfer of such technical data to any foreign person, foreign entity or foreign organization whether in the United States or abroad.*



# CERTIFICATE OF EVALUATION

Last Date of Evaluation: April 4, 2022  
Hinge Health  
EUT: Enso 2

## RF Exposure Evaluation

### Standards

Specification	Method
FCC 1.1307:2022	FCC 1.1307:2022

### Results

Method Clause	Description	Applied	Results	Comments
(b)(3)(i)(B)	Exemption From RF Exposure Evaluation	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** - 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.

---

## 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.

---

## 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:

[California](#)

[Minnesota](#)

[Oregon](#)

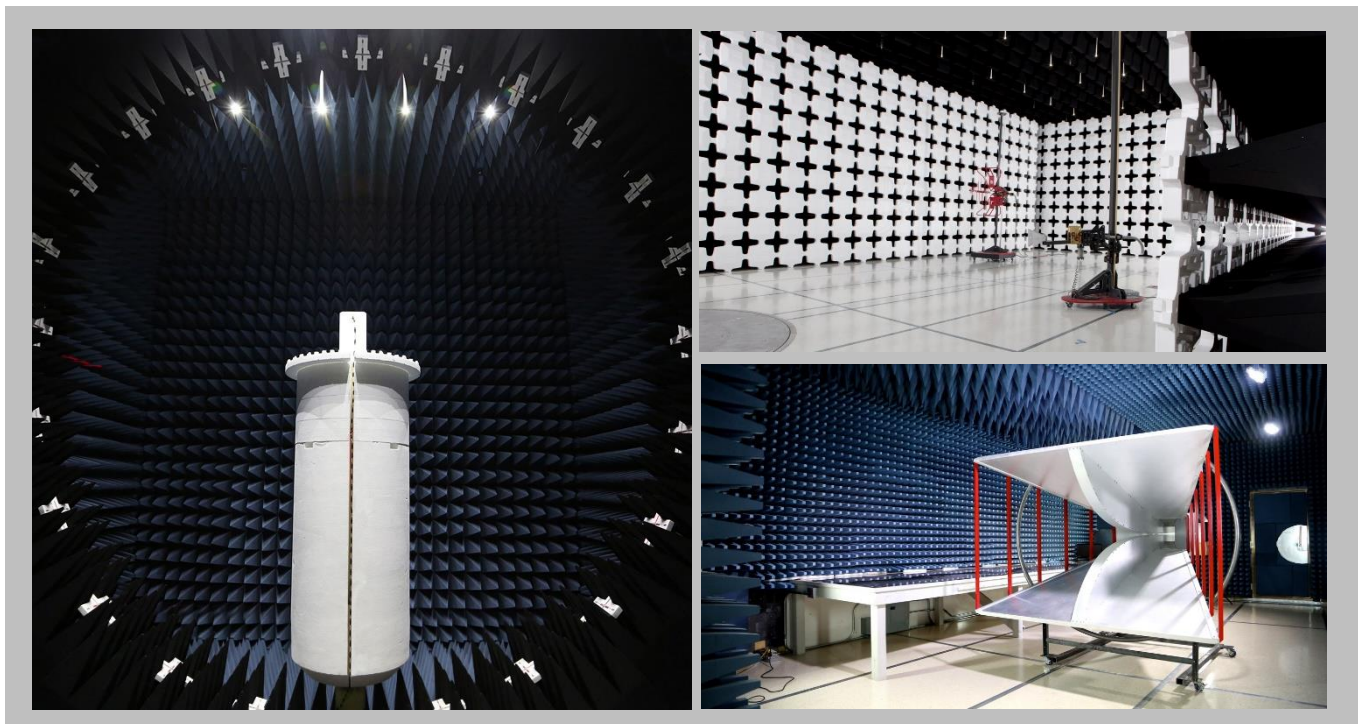
[Texas](#)

[Washington](#)

# FACILITIES



<b>California</b> Labs OC01-17 41 Tesla Irvine, CA 92618 (949) 861-8918	<b>Minnesota</b> Labs MN01-11 9349 W Broadway Ave. Brooklyn Park, MN 55445 (612)-638-5136	<b>Oregon</b> Labs EV01-12 6775 NE Evergreen Pkwy #400 Hillsboro, OR 97124 (503) 844-4066	<b>Texas</b> Labs TX01-09 3801 E Plano Pkwy Plano, TX 75074 (469) 304-5255	<b>Washington</b> Labs NC01-05 19201 120 <sup>th</sup> Ave NE Bothell, WA 98011 (425)984-6600
<b>A2LA</b>				
Lab Code: 3310.04	Lab Code: 3310.05	Lab Code: 3310.02	Lab Code: 3310.03	Lab Code: 3310.06
<b>Innovation, Science and Economic Development Canada</b>				
2834B-1, 2834B-3	2834E-1, 2834E-3	2834D-1	2834G-1	2834F-1
<b>BSMI</b>				
SL2-IN-E-1154R	SL2-IN-E-1152R	SL2-IN-E-1017	SL2-IN-E-1158R	SL2-IN-E-1153R
<b>VCCI</b>				
A-0029	A-0109	A-0108	A-0201	A-0110
<b>Recognized Phase I CAB for ISED, ACMA, BSMI, IDA, KCC/RRA, MIC, MOC, NCC, OFCA</b>				
US0158	US0175	US0017	US0191	US0157



# PRODUCT DESCRIPTION



## Client and Equipment Under Evaluation Information

<b>Company Name:</b>	Hinge Health
<b>Address:</b>	465 California Street 14th Floor
<b>City, State, Zip:</b>	San Francisco, CA 94104
<b>Evaluation Requested By:</b>	Samuel House
<b>EUT:</b>	Enso 2
<b>Date of Evaluation:</b>	April 4, 2022

## Information Provided by the Party Requesting the Evaluation

### Functional Description of the Equipment:

The Enso 2 is a wearable pain management device containing a Bluetooth Low Energy radio.

The nRF52832 SoC that is included in the product uses Bluetooth LE for wireless communications. It uses 1 Mbit/s LE 1M by default and supports switching to 2M. The SoC does not support any of the other BLE PHYs.

BLE is the only wireless protocol used by the product. Other protocols (such as ANT and NFC) are not implemented in firmware, and the product has no ability to use them.

The firmware hardcodes the device transmit power to 0 dBm. This value is never changed.

The maximum dimensions of the device are:

L = 39mm  
W = 39mm  
H = 10mm

### Objective:

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

# RF Exposure Condition



<b>The following RF Exposure conditions were used for the assessment documented in this report:</b>	
Intended Use	Portable
Location on Body (if applicable)	Head/Torso
How is the Device Used	The Enso 2 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	Optional metallic tape 4 mm thick
Environment	General Population/Uncontrolled Exposure



# EXEMPTION FROM RF EXPOSURE EVALUATION



## OVERVIEW

With respect to the limits on human exposure to RF emissions provided in 47 CFR §1.1310, if equipment can be shown to qualify for an exemption pursuant to 47 CFR §1.1307(b)(3), an evaluation is not required.

## 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:

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

Where

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

And

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

- (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  $\lambda/2\pi$ , where  $\lambda$  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  $\lambda/4$  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 <sup>2</sup> .
1.34-30	3,450 R <sup>2</sup> /f <sup>2</sup> .
30-300	3.83 R <sup>2</sup> .
300-1,500	0.0128 R <sup>2</sup> f.
1,500-100,000	19.2R <sup>2</sup> .



# EXEMPTION FROM RF EXPOSURE EVALUATION



(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 in 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  $\lambda/2\pi$  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



## 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)	Limit (mW)	Compliant
BTLE	2480	0 dBm	4.0	100.0%	1	0.5	1.9	2.5	2.7	Yes

The information in the table above was obtained from:

The rated value was used in these calculations. Customer supplied information and Element report HING0001 Rev.1 were used.

Evaluator: Jay Whitworth

End of Test Report