



element

Inspire Medical Systems

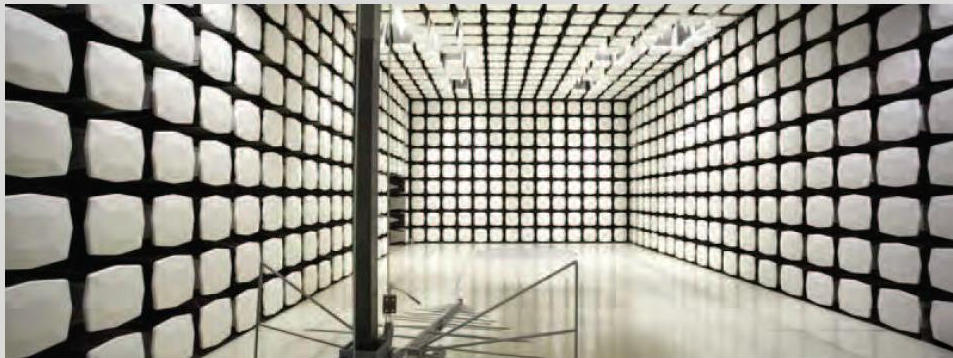
Inspire Remote Model 2580

FCC 2.1093:2021

Bluetooth LE Radio

Inductive Radio

Report: INSP0027.8, Issue Date: June 2, 2021



NVLAP LAB CODE: 200630-0



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CERTIFICATE OF EVALUATION

Last Date of Evaluation: Friday, May 21, 2021
Inspire Medical Systems
EUT: Inspire Remote Model 2580

RF Exposure Evaluation

Standards

Specification	Method
FCC 2.1093:2021	FCC 1.1307:2021 FCC 680106 D01 RF Exposure Wireless Charging Apps v03r01

Results

Method Clause	Description	Applied	Results	Comments
(b)(3)(ii)(B)	RF Exposure Exemption for Multiple RF Sources	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 – 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.

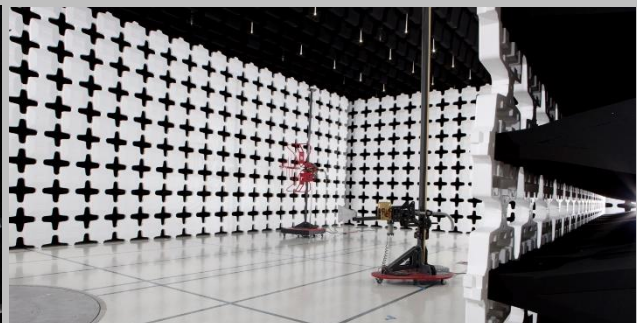
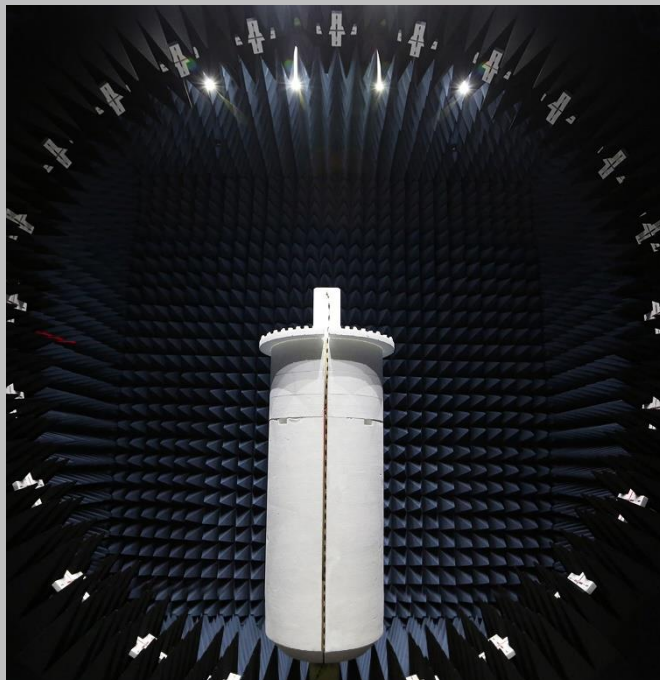
SCOPE

For details on the Scopes of our Accreditations, please visit:
<https://www.nwemc.com/emc-testing-accreditations>

FACILITIES



California Labs OC01-17 41 Tesla Irvine, CA 92618 (949) 861-8918	Minnesota Labs MN01-11 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 120 th 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



PRODUCT DESCRIPTION



Client and Equipment Under Evaluation Information

Company Name:	Inspire Medical Systems
Address:	5500 Wayzata Blvd., Suite 1600
City, State, Zip:	Golden Valley, 55416
Evaluation Requested By:	Charles Steaderman
EUT:	Inspire Remote Model 2580
Date of Evaluation:	Friday, May 21, 2021

Information Provided by the Party Requesting the Evaluation

Functional Description of the Equipment:

The Inspire Model 2580 Patient Remote is a battery-powered (two AA) handheld "Remote" device used to start/stop/configure sleep apnea therapy sessions of an implantable device (in the upper chest area of a patient). The Remote is intended for in-home use by a patient. The radio for data communications with the implantable device is low duty cycle 175kHz near-field inductive and the Remote must be held over the patient's implant during this communication. The Remote device will communicate with a patient's smartphone over Bluetooth Low Energy (BLE) to retrieve/configure diagnostic information.

Largest product dimension: 12 cm.

Objective:

To demonstrate compliance with FCC RF exposure requirements for 2.1093 portable 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 Inspire Model 2580 is used at a distance of less than 20 cm from the user.
Radios Contained in the Same Host Device	Bluetooth LE Inductive
Simultaneous Transmitting Radios	Bluetooth LE, Inductive
Body Worn Accessories	None
Environment	General Population/Uncontrolled Exposure

Duty Cycle Information for the Bluetooth LE Radio:

The following information was provided by Ryan Striker, Electrical Engineer and consultant to Inspire Medical Systems.

The BLE radio transmits a maximum 328 bits at a minimum of every 15 ms. The data rate is 1 Mbps; duty cycle is less than 2.2%

Duty Cycle Information for the Inductive Radio:

The following information was provided by Ryan Striker, Electrical Engineer and consultant to Inspire Medical Systems.

The inductive radio radiates at most 13.2 ms every 250 ms.

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 2.1093

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 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 $\lambda/4$ 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	$1,920 R^2$.
1.34-30	$3,450 R^2/f^2$.
30-300	$3.83 R^2$.
300-1,500	$0.0128 R^2 f$.
1,500-100,000	$19.2 R^2$.

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_m , 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).

$P_{m,i}$ = the exemption threshold power (P_m) 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 .

$ERP_{m,j}$ = 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

EXEMPTION FROM RF EXPOSURE EVALUATION



ASSESSMENT

The only assessment option available for a device operating at 175 kHz is the 1 mW exemption found in 1.1307(b)(3). This is based upon the maximum time averaged power delivered to the matched radiating structure. The near-field measurement of electric and magnetic field strength at the use distance is used here as a measure of the maximum level of RF energy delivered to the user.

An FCC inquiry was submitted to apply the approach outlined in 1.1307(b)(3)(ii)(B), using the field strength measurement approach. In this case, the BTLE radio maximum time averaged power is compared to the SAR exemption threshold and the inductive radio peak magnetic and peak electric field strength values are compared to the field strength limits shown in FCC KDB 660106 D01 v03 r01 section 3.(a)(2.).

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

Radio	Transmit Frequency (MHz)	Rated Output Power + Manufacturing Tolerance	Duty Cycle	Antenna Assembly Gain (dBi)	Minimum Separation Distance (mm)	Maximum Time Averaged Power	Limit (mW)	Ratio
BTLE	2480	7 dBm	2.2%	2.5	5	1.20 mW erp	2.79	0.430
Max Ratio								0.430

The information in the table above was obtained from:

Customer supplied information and Element test report # INSP0027. A 1 dB tolerance was added to the rated power.

Radio	Transmit Frequency (MHz)	Measured Field Strength	Duty Cycle	Minimum Separation Distance (mm)	Limit	Ratio
Inductive	0.175	1.88 A/m	5.3%	5.0	80 A/m	0.0235
Inductive	0.175	1.97 V/m	5.3%	5.0	93 V/m	0.0212
Max Ratio						0.0235

The information in the table above was obtained from:

Customer supplied information and test data from the attached Appendix A. The measured value is considered the maximum field strength, including manufacturing tolerances.

Sum of Maximum Ratios	Limit	Compliant
0.454	1	Yes

Field Strength Measurements



XMIT 2020.12.30.0

Testing was performed using the mode(s) of operation and configuration(s) noted within the report. The individuals and/or the organization requesting the test provided the modes, configurations and settings used to complete the evaluation. The actual test parameters are specified in the test data, this includes items such as investigated frequency range (scanned) and test levels. The testing methods and performance specifications, as well as the test site used for the evaluation are indicated in the test data.

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Cal. Due
Probe	WaveControl, Inc.	WP400	IPU	2019-04-06	2022-04-06
Meter - Magnetic/Electric Field	WaveControl, Inc.	SMP2	MFG	2019-04-06	2022-04-06

TEST DESCRIPTION

Field strength probes capable of 3-axis measurements of both electric and magnetic fields were placed at the distances away from the transmitter specified in the data sheet. The distances were chosen based on how the manufacturer specifies the transmitter is used. Although not required, the measurement was done in a semi-anechoic chamber to minimize ambient noise.

The transmitter was then rotated so a different face of the transmitter was facing the probe for all 6 faces of the device. The highest overall value of each distance across all of the 6 faces was recorded. This process was performed for both electric and magnetic fields. A reading of the ambient noise was also taken and documented.

The values were compared against the limit specified in FCC KDB 660106 D01 v03 r01 section 3.(a)(2.).

Field Strength Measurements



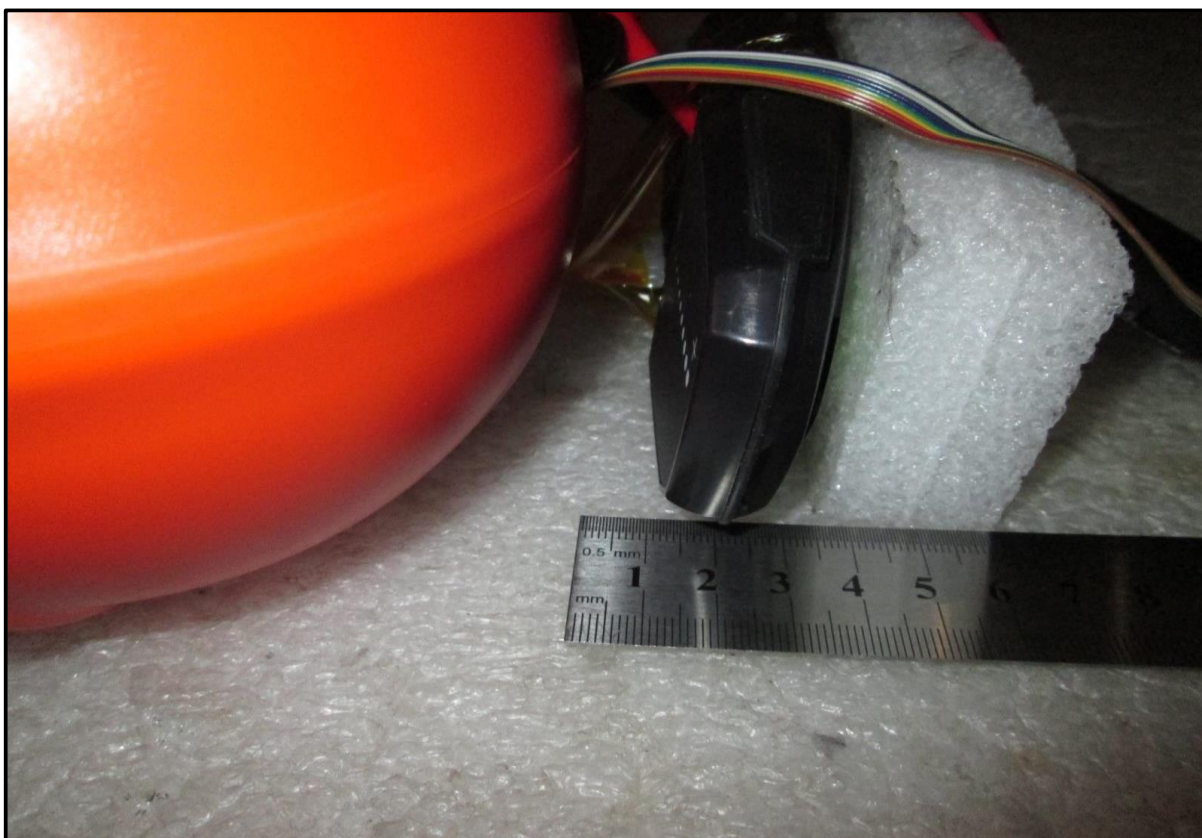
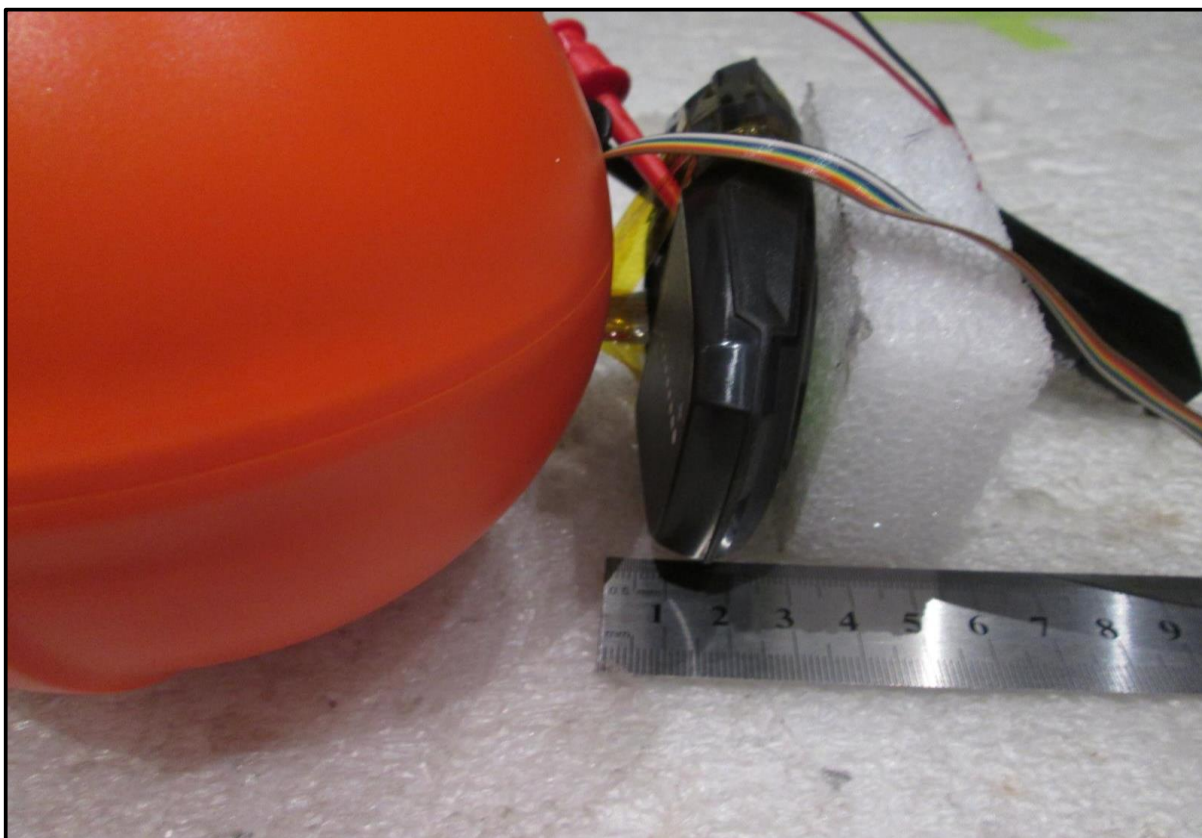
XMH 2020.12.30.0

EUT: Inspire Remote Model 2580		Work Order: INSP0035	
Serial Number: REM000098		Date: 19-May-21	
Customer: Inspire Medical Systems		Temperature: 21.9 °C	
Attendees: Tom Haider		Humidity: 53.6% RH	
Project: None		Barometric Pres.: 1018 mbar	
Tested by: Chris Patterson		Power: Battery	
Job Site: MN05			
TEST SPECIFICATIONS			
FCC 2.1093:2021		Test Method	
		FCC KDB 680106 D01	
COMMENTS			
EUT Transmitting at 175 kHz, measurements taken in worst case orientation. The ruler in the test setup photos was included for reference only and was not present during the actual measurements. Photos were taken at 3 cm separation distance for reference purposes.			
DEVIATIONS FROM TEST STANDARD			
None			
Configuration #	1	Signature <i>CE PTH</i>	
		Highest Measurement	Highest Measurement
		A/m	V/m
		Limit	Limit
		Result	Result
5 cm Separation		1.88	90
1 cm Separation		1.34	90
3 cm Separation		0.51	90
10 cm Separation		0.16	90
Ambient		0.001	N/A

Field Strength Measurements



XMit 2020.12.30.0



Field Strength Measurements



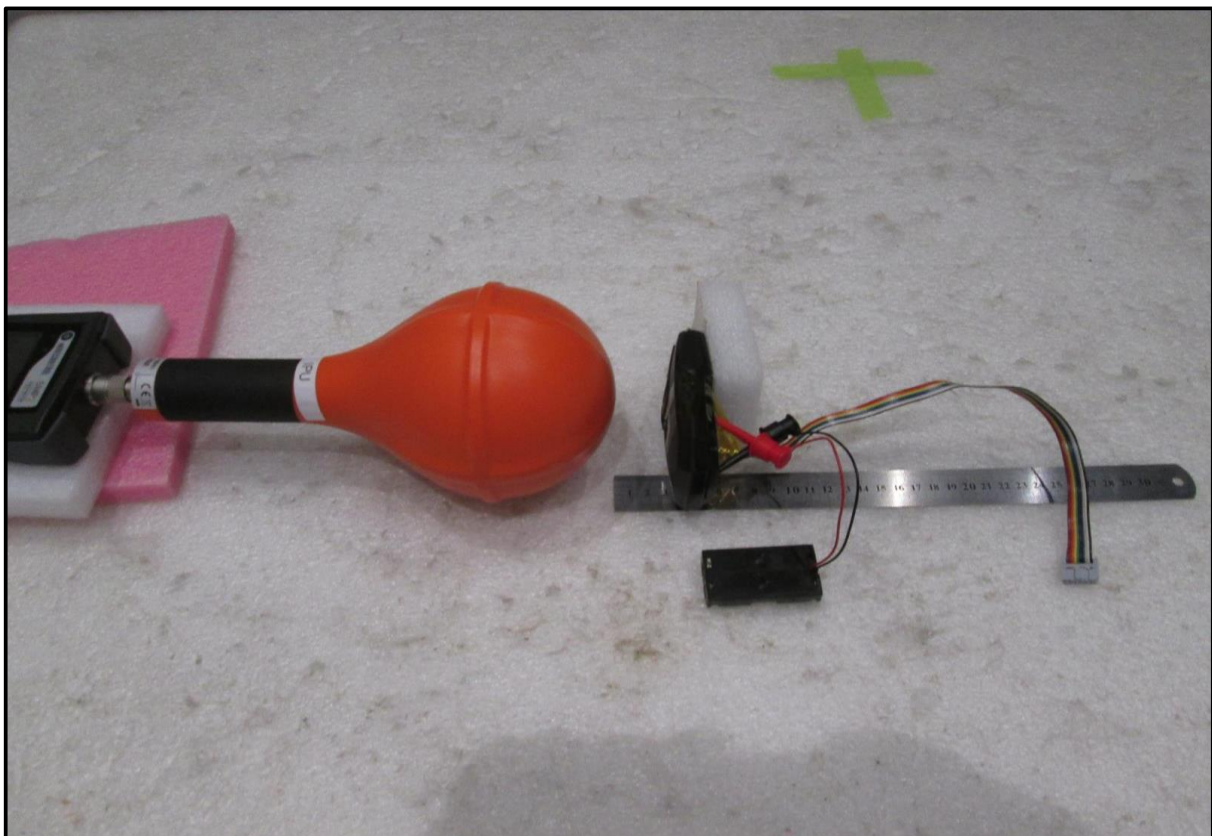
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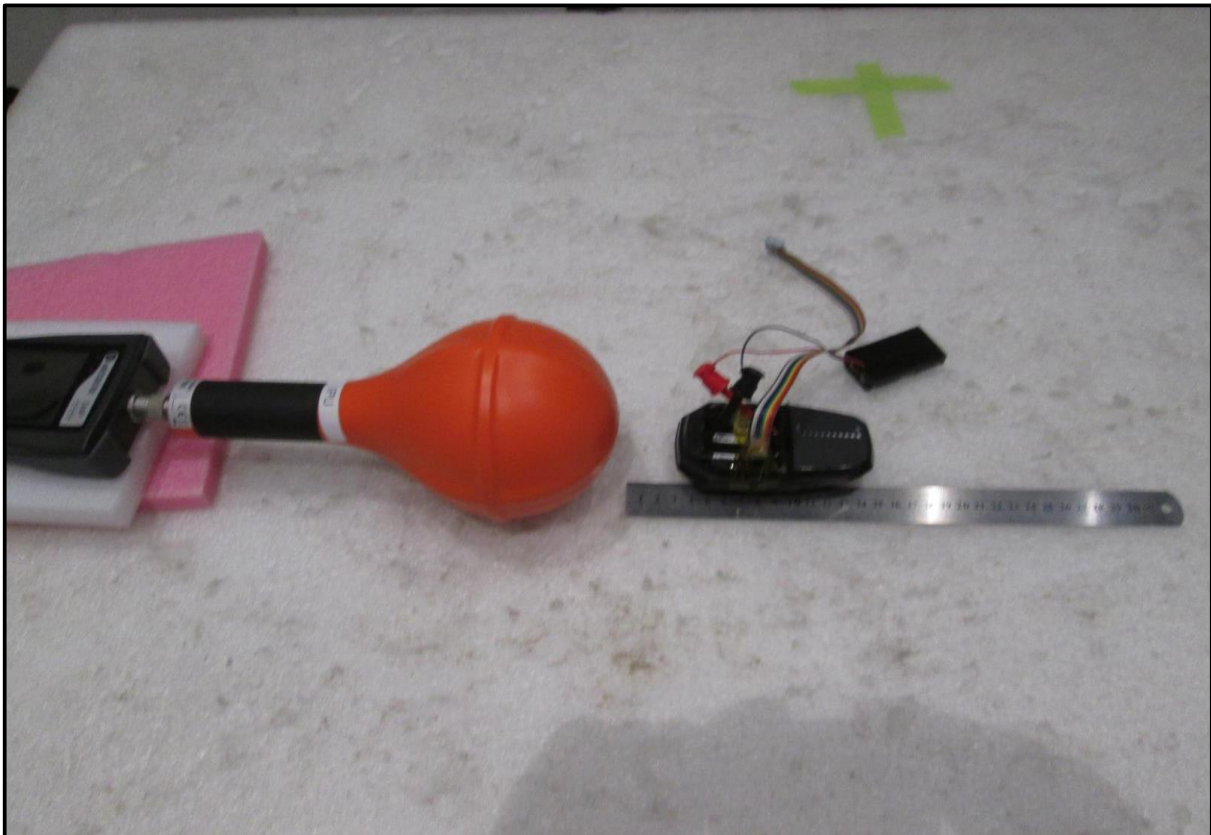
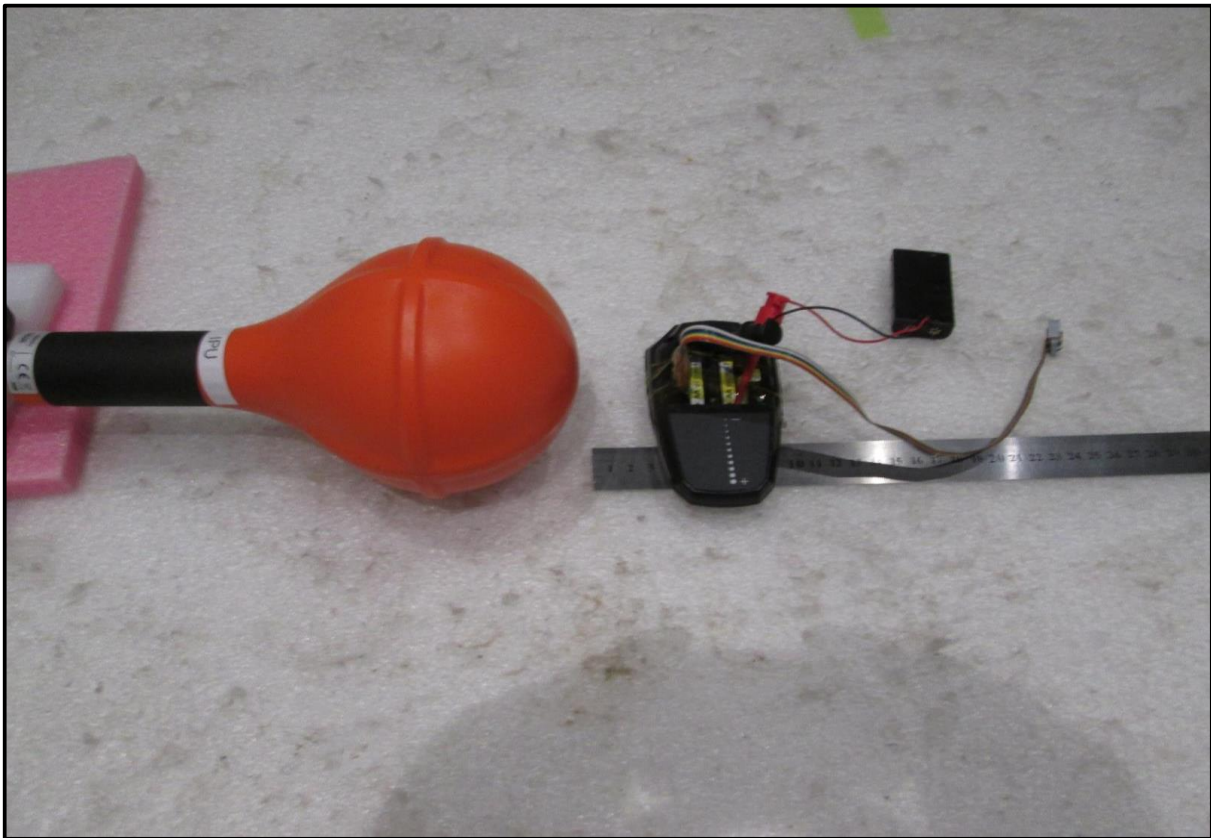
Field Strength Measurements



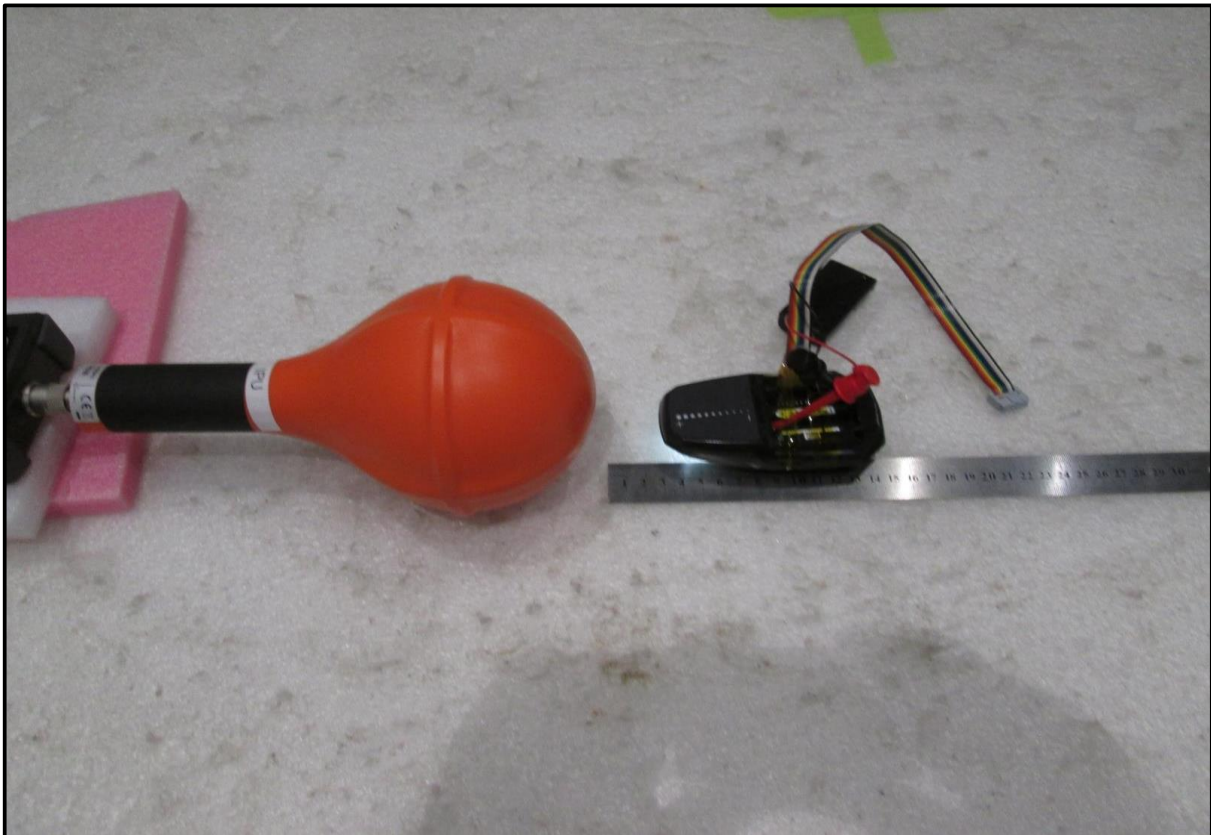
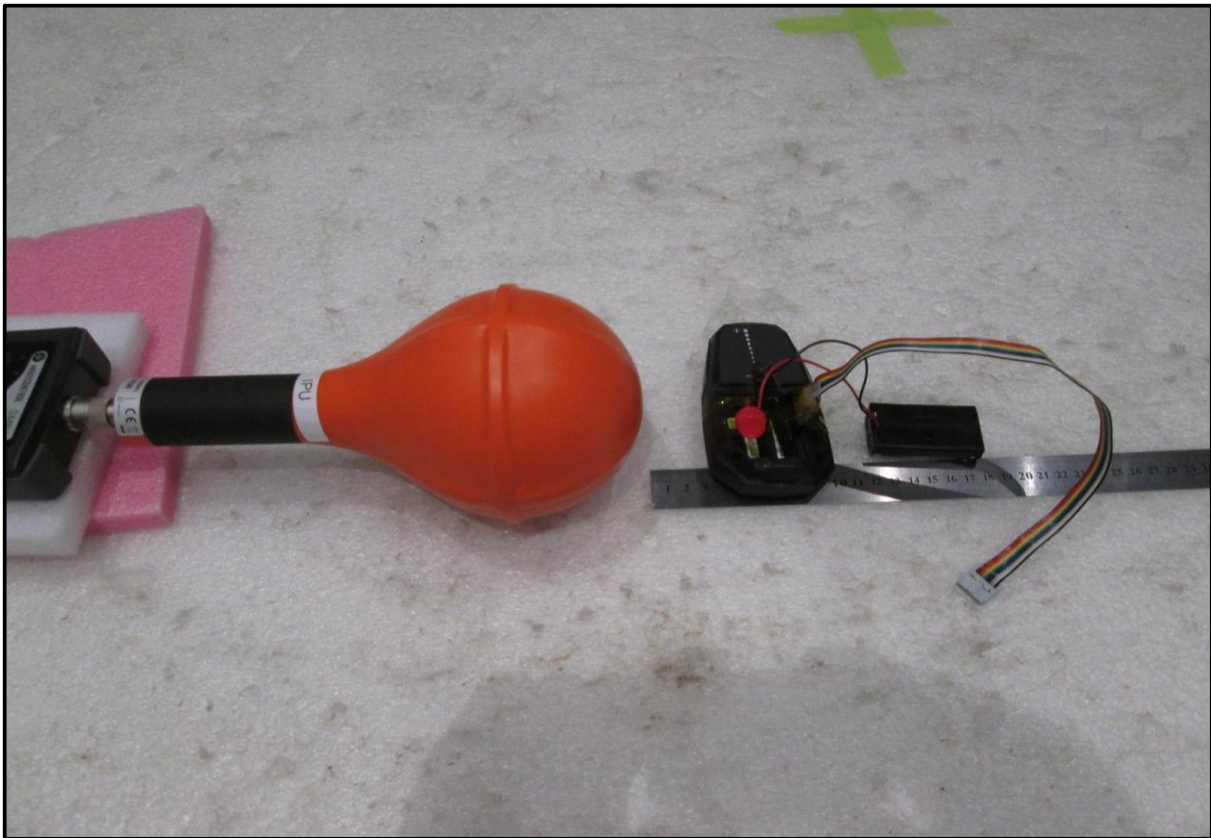
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Field Strength Measurements



Field Strength Measurements



CONFIGURATIONS



Configuration INSP0035- 1

EUT			
Description	Manufacturer	Model/Part Number	Serial Number
Inspire Remote	Inspire Medical Systems	2580	REM000098

Peripherals in test setup boundary			
Description	Manufacturer	Model/Part Number	Serial Number
Battery Pack	Unknown	None	None

Cables					
Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
Battery Leads (x2)	No	0.1m	No	Battery Pack	Inspire Remote

End of Test Report