

**Applicant:**

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**Test report no.:**

230520-AU01+W02

**for:**

eResearchTechnology GmbH  
Spirometer  
iSpiro Ultrasonic Sensor

**according to:**

47 CFR Part 2  
RSS-102



**Accreditation:**

FCC test firm accreditation expiration date: 2024-05-17  
MRA US-EU, FCC designation number: DE0010  
Test firm registration number: 997268  
FCC Registration Number (FRN): 0032245045  
BNetzA-CAB-02/21-02/7 Valid until 2028-11-26

Recognized until 2025-03-16 by the  
Department of Innovation, Science and Economic Development Canada (ISED)  
as a recognized testing laboratory  
CAB identifier: DE0011  
Company number: 3472A

**Location of Testing:**

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The technical accuracy is guaranteed through the quality management of  
Element Materials Technology Straubing GmbH.

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## 1 Summary of test results

### 1.1 FCC standard

<i>FCC standard</i>	<i>Requirement</i>	<i>Result</i>	<i>Page</i>
47 CFR Part 2, § 2.1093	SAR test exclusion, except WPT	Passed	8

### 1.2 IC standard

<i>IC standard</i>	<i>Requirement</i>	<i>Result</i>	<i>Page</i>
RSS-102 Issue 6, section 6.3	SAR test exclusion, except 3 kHz – 10 MHz	Passed	11

Straubing, February 15, 2024



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Tested by  
Konrad Graßl  
Department Manager Radio



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Approved by  
Christian Kiermeier  
Reviewer

## 2 Test regulations

### 2.1 FCC standards

<i>Standard</i>	<i>Title</i>
Part 1, Subpart I, Section 1.1307 October 2023	Actions that may have a significant environmental effect, for which Environmental Assessment (EAs) must be prepared.
Part 1, Subpart I, Section 1.1310 October 2023	Radiofrequency radiation exposure limits
Part 1, Subpart 2, Section 2.1093 October 2023	Radiofrequency radiation exposure evaluation: portable devices.
KDB 447498 D04 v01 November 29, 2021	RF Exposure Procedures and Equipment Authorization Policies for Mobile and Portable Devices

### 2.2 IC standards

<i>Standard</i>	<i>Title</i>
RSS-102 Issue 6 (December 15, 2023)	Spectrum Management and Telecommunications Radio Standards Specification Radio Frequency (RF) Exposure Compliance of Radio communication Apparatus (All Frequency Bands)

### 3 Equipment under Test

#### 3.1 General information

Product type:	Spirometer		
Model name:	iSpiro Ultrasonic Sensor		
Serial number(s):	S202300053		
Manufacturer:	eResearchTechnology GmbH		
Hardware version:	N0		
Software version:	1.5.1		
Short description:	The product is a portable spirometer that is capable of pairing via Bluetooth with smart devices to perform a spirometry test. The iSpiro Ultrasonic Sensor detects the volume and flow moving through the device to record spirometry data. The device is powered by standard 2 x AAA Alkaline batteries. The iSpiro Ultrasonic Sensor is used in combination with the SpiroWay® mouthpiece.		
Additional modifications:	None		
FCC ID:	2AAUFISPIRO1		
IC registration number:	11335A-ISPIRO1		
Designation of emissions:	1M05F7D--		
Power supply:	Battery supply		
	Nominal voltage:	3.0 V	
Device type:	<input checked="" type="checkbox"/> Portable	<input type="checkbox"/> Mobile	<input type="checkbox"/> Fixed

### 3.2 Radio specifications

System type (Note 1):	Digital transmission system (DTS)		
Application frequency band:	2400.0 MHz - 2483.5 MHz		
Number of RF channels:	40		
Nominal bandwidth:	2 MHz		
Modulation(s):	GFSK		
Antenna:	Type:	Small size 2.4 GHz PCB antenna	
	Gain:	5.3 dBi (maximum) (see note 2)	
	Connector:	<input type="checkbox"/> external	<input type="checkbox"/> internal
		<input type="checkbox"/> temporary	<input checked="" type="checkbox"/> none (integral antenna)

Note(s):

1. "DTS" is the equipment class for digital transmission systems, "DSS" for all other Part 15 spread spectrum transmitters as used for equipment authorization system form 731.
2. The data was taken from the document "Application Note AN043" of Texas Instruments, which was provided by the customer.

### 3.3 Human exposure specifications

Exposure tier:	Limbs
Separation distance:	≤ 20 cm
Evaluated against exposure limits:	General public use
Simultaneous transmissions:	no

### 3.4 Photographs of EUT

See Annex B of test report 230520-AU01+W01 of test laboratory Element Materials Technology Straubing GmbH.

## 4 Test results

This clause gives details about the test results as collected in the summary of test results on page 4.

### 4.1 FCC

#### 4.1.1 SAR test exclusion, except WPT

Requirement: Part 2, §2.1093  
Reference: KDB 447498 D04 v01

Performed by:	Konrad Graßl	Date of test:	February 15, 2024
Result:	<input checked="" type="checkbox"/> Limits kept	<input type="checkbox"/> Limits not kept	

##### 4.1.1.1 Requirements and limits for separation distance $\leq 20$ cm

According to §2.1093(b):

For purposes of this section, the definitions in §1.1307(b)(2) of this chapter shall apply. A portable device is defined as a transmitting device designed to be used in other than fixed locations and to generally be used in such a way that the RF source's radiating structure(s) is/are within 20 centimeters of the body of the user.

According to §2.1093(c)(1):

Evaluation of compliance with the exposure limits in §1.1310 of this chapter, and preparation of an EA if the limits are exceeded, is necessary for portable devices having single RF sources with more than an available maximum time-averaged power of 1 mW, more than the ERP listed in Table 1 to §1.1307(b)(3)(i)(C), or more than the  $P_{th}$  in the following formula, whichever is greater. The following formula shall only be used in conjunction with portable devices not exempt by §1.1307(b)(3)(i)(C) at distances from 0.5 centimeters to 20 centimeters and frequencies from 0.3 GHz to 6 GHz.

Note:

1. According to the TCB Workshop on April 27, 2022  $P_{th}$  can be calculated to the extended frequency range 100 kHz to 6 GHz. The formulas in the presentation of the TCB workshop beginning at slide 17 were used in addition to the KDB 447498 D04 v01.



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

Where

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

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

Table 1: Formula for calculation P<sub>th</sub>

d = the minimum separation distance (cm) in any direction from any part of the device antenna(s) or radiating structure(s) to the body of the device user.

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> .

Table 2: Table 1 to §1.1307(b)(3)(i)(C)—Single RF Sources Subject to Routine Environmental Evaluation

#### 4.1.1.2 Process to determine RF Exposure Compliance

According to Appendix A of KDB 447498 D04 Interim General RF Exposure Guidance V01: Generally, the sequence to apply for single portable RF sources includes the following steps:

- 1) Determination of 1 mW exemption
- 2) Determination of exemption according to Table 2
- 3) Determination of exemption according to formula in Table 1

### 4.1.1.3 Results

The following data are based on applicants document: Test report 230520-AU01+W01 of the test laboratory Element Materials Technology Straubing GmbH.

Application: Bluetooth low energy  
 Operation frequency band: 2400 MHz to 2483.5 MHz  
 Antenna gain: 5.3 dBi  
 Maximum conducted output power: 0.7 dBm at 2402 MHz

Information related to Exposure:

Tune-up tolerance (according to the manufacturer): 0 dB  
 Separation distance: < 5 mm  
 Exposure tier: general public and limb-worn  
 Power averaging over time: not applied  
 Applied determination process: Step 3 of clause 4.1.1.2

<i>Separation distance (mm)</i>	<i>Channel frequency (MHz)</i>	<i>ERP + tolerance (dBm)</i>	<i>ERP + tolerance (mW)</i>	<i>Limit (mW)</i>	<i>Ratio of limit</i>	<i>Result</i>
<5	2402	3.85	2.4	2.8	0.86	Passed

Table 3: Result of SAR test exclusion

ERP = EIRP – 2.15 dB

## 4.2 Canada

### 4.2.1 SAR test exclusion, except 3 kHz – 10 MHz

Requirement: RSS-102 Issue 6, section 6.3

Reference: n/a

Performed by:	Konrad Graßl	Date of test:	February 15, 2024
Result:	<input checked="" type="checkbox"/> Limits kept	<input type="checkbox"/> Limits not kept	

#### 4.2.1.1 Exemption Limits for Routine Evaluation – SAR Evaluation

According RSS 102, section 6.3:

Devices operating at or below the applicable output power levels (adjusted for tune-up tolerance) specified in Table 4, based on the separation distance, are exempt from SAR evaluation. The separation distance, defined as the distance between the user and/or bystander and the antenna and/or radiating element of the device or the outer surface of the device, shall be less than or equal to 20 cm for these exemption limits to apply.

Frequency (MHz)	≤ 5 mm (mW)	10 mm (mW)	15 mm (mW)	20 mm (mW)	25 mm (mW)	30 mm (mW)	35 mm (mW)	40 mm (mW)	45 mm (mW)	>50 mm (mW)
≤ 300	45	116	139	163	189	216	246	280	319	362
450	32	71	87	104	124	147	175	208	248	296
835	21	32	41	54	72	96	129	172	228	298
1900	6	10	18	33	57	92	138	194	257	323
2450	3	7	16	32	56	89	128	170	209	245
3500	2	6	15	29	50	72	94	114	134	158
5800	1	5	13	23	32	41	54	74	102	128

Table 4: Power limits for exemption from routine SAR evaluation based on the separation distance

The exemption limits in Table 4 are based on measurements and simulations of half-wave dipole antennas at separation distances of 5 mm to 50 mm from a flat phantom, which provides a SAR value of approximately 0.4 W/kg for 1 g of tissue.

For limb-worn devices where the 10 gram of tissue applies, the exemption limits for routine evaluation in Table 4 are multiplied by a factor of 2.5.

For controlled-use devices where the 8 W/kg for 1 gram of tissue applies, the exemption limits for routine evaluation in Table 4 are multiplied by a factor of 5.

When the operating frequency of the device is between two frequencies located in Table 4, linear interpolation shall be applied for the applicable separation distance. If the separation distance of the device is between two distances located in Table 4, linear interpolation may be applied for the applicable frequency. Alternatively, the limit corresponding to the smaller distance may be employed. For example, in case of a 7 mm separation distance, either use the exception value for a 5 mm separation distance or interpolate between the limits corresponding to 5 mm and 10 mm separation distances.

For implanted medical devices, the exemption limit for routine SAR evaluation is set at an output power of 1 mW, regardless of frequency.

The SAR levels from exempted transmitters shall be included in the compliance assessment and the determination of the TER. Detailed guidance is included in sections 7.1.8 and 8.2.2.1 of RSS-102.

#### 4.2.1.2 Results

The following data are based on applicants document: Test report 230520-AU01+W01 of the test laboratory Element Materials Technology Straubing GmbH.

Application:	Bluetooth low energy
Operation frequency band:	2400 MHz to 2483.5 MHz
Antenna gain:	5.3 dBi
Maximum conducted output power:	0.7 dBm at 2402 MHz

Information related to Exposure:

Tune-up tolerance (according to the manufacturer):	0 dB
Separation distance:	< 5 mm
Exposure tier:	general public and limb-worn
Power averaging over time:	not applied

<i>Separation distance (mm)</i>	<i>Channel frequency (MHz)</i>	<i>Output power + tolerance (dBm)</i>	<i>Output power + tolerance (mW)</i>	<i>Limit (mW)</i>	<i>Ratio of limit</i>	<i>Result</i>
<5	2402	0.7	1.2	7.5	0.16	passed

Table 5: Result of SAR test exclusion, exposure to the limbs

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## 5 Revision history

<i>Revision</i>	<i>Date</i>	<i>Issued by</i>	<i>Description of modifications</i>
0	2024-02-15	Konrad Graßl	First edition

Template: RF\_FCC\_IC\_Human Exposure\_V1.8