

Report on the FCC and IC Testing of the
eResearchTechnology GmbH
Ultrasonic Spirometer
Model: iSpiro Pro
In accordance with FCC 47 CFR Part 1 I
and ISSED RSS-102



Product Service

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Prepared for: eResearchTechnology GmbH
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FCC ID: 2AAUFISPP01
IC: 11335A-ISPP01

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Date: 2025-04-02

Document Number: TR-713368494-04 | Revision 0

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Signatures in this approval box have checked this document in line with the requirements of TÜV SÜD Product Service document control rules.

Engineering Statement:

This measurement shown in this report were made in accordance with the procedures described on test pages.

All reported testing was carried out on a sample equipment to demonstrate limited compliance with with FCC 47 CFR Part 15 C and ISSED RSS-247 and RSS-GEN.

The sample tested was found to comply with the requirements defined in the applied rules.

RESPONSIBLE FOR	NAME	DATE	SIGNATURE
Testing	Martin Steindl	2025-04-02	 SIGN-ID 1032617

Laboratory Accreditation
DAkkS Reg. No. D-PL-11321-11-02
DAkkS Reg. No. D-PL-11321-11-03

Laboratory recognition
Registration No. BNetzA-CAB-
16/21-15

Industry Canada test site registration
3050A-2

Executive Statement:

A sample of this product was tested and found to be compliant with FCC 47 CFR Part 15 C:2024 and ISSED RSS-247:2023 and RSS-GEN:2018 + Amd.2:2021



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Trade Register Munich
HRB 85742
VAT ID No. DE129484267
Information pursuant to Section 2(1)
DL-InfoV (Germany) at
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1 Report Summary

1.1 Modification Report

Alternations and additions of this report will be issued to the holders of each copy in the form of a complete document.

Revision	Description of changes	Date of Issue
0	First Issue	2025-04-02

Table 1: Report of Modifications

1.2 Introduction

Applicant	eResearchTechnology GmbH Sieboldstr. 3 97230 Estenfeld, Germany
Manufacturer	eResearchTechnology GmbH
Model Number(s)	iSpiro Pro
Serial Number(s)	S409900030
Hardware Version(s)	V0
Software Version(s)	N/A
Number of Samples Tested	1
Test Specification(s) / Issue / Date	FCC 47 CFR Part 15 C : 2024 ISED RSS-247, Issue 3 : 2023 ISED RSS-GEN, Issue 5 + Amendment 2 : 2021
Test Plan/Issue/Date	N/A
Order Number	25000779
Date	
Date of Receipt of EUT	2025-03-05
Start of Test	2025-03-11
Finish of Test	2025-03-20
Name of Engineer(s)	M. Steindl
Related Document(s)	ANSI C63.10:2013



1.3 Brief Summary of Results

A brief summary of the tests carried out in accordance with FCC 47 CFR Part 1 I, is shown below.

<i>Section</i>	<i>Specification Clause</i>	<i>Test Description</i>	<i>Result</i>
2.1	1.1307 15.247(i)	RF Exposure	Pass

Table 2: Results according to FCC 47 CFR

A brief summary of the tests carried out in accordance withISED RSS-102, is shown below.

<i>Section</i>	<i>Specification Clause</i>	<i>Test Description</i>	<i>Result</i>
2.1	6.3	RF Exposure	Pass

Table 3: Results according to RSS-Gen



1.4 Product Information

1.4.1 Technical Description

Frequency Band: 2400.0 MHz – 2483.5 MHz

Nominal cond. power: 0 dBm

Antenna gain: 5.3 dBi

Supply Voltage: 3.0 V

Supply Frequency: DC battery supply

*Highest clock frequency
(non-radio part):* 24 MHz



Label



1.4.2 List of Antennas

<i>Manufacturer</i>	<i>Model</i>	<i>Antenna im- pedance</i>	<i>Antenna Type</i>	<i>Antenna gain</i>
eResearchTechnology	N/A	N/A	Integrated antenna on printed board	+5.2 dBi

Table 4: List of antennas

1.4.3 EUT Ports / Cables identification

Port	Max Cable Length specified	Usage	Type	Screened
Not applicable	---	---	---	---

Table 5

1.5 Test Configuration

The EUT was configured as stand alone device

1.6 Modes of Operation

The applicant provided a test software for configuring test modes. The tests were performed on lowest (CH37), a middle (CH17) and highest (CH39) BLE channels with five BLE 5 modes (physical layers) with a nominal conducted output power of 0 dBm:

Mode 1:

1M PHY

Mode 2:

1M PHY, Bluetooth 4.x compatible mode

Mode 3:

Coded PHY, S=2

Mode 4:

Coded PHY, S=8

Mode 5:

2M PHY



1.7 EUT Modifications Record

The table below details modifications made to the EUT during the test programme.
The modifications incorporated during each test are recorded on the appropriate test pages.

Modification State	Description of Modification still fitted to EUT	Modification Fitted By	Date Modification Fitted
0	As supplied by the customer	Not Applicable	Not Applicable

Table 6

1.8 Test Location

TÜV SÜD Product Service conducted the following tests at our Straubing test laboratory:

Test Name	Name of Engineer(s)
RF Exposure	M. Steindl

Office Address:

Äußere Frühlingstraße 45
94315 Straubing
Germany



2 Test Details

2.1 RF Exposure

2.1.1 Specification Reference

FCC 47 CFR Part 15 C, Clause 15.247(i)
FCC 47 CFR Part 2 J, Clause 2.1093
KDB 447498 D01 V06, section 4.3.1
ISED RSS-Gen, Clause 3.4
ISED RSS-102, Clause

2.1.2 Equipment under Test and Modification State

iSpiro Pro; S/N S409900030; Modification state 0

2.1.3 Date of Test

2025-03-14

2.1.4 Environmental Conditions

Ambient Temperature	23 °C
Relative Humidity	32 %

2.1.5 Test Method

The test is based on radiated emission tests of the device. See test report TR-713368494-02 for details. Maximum output was calculated through following equation:

$$P = \frac{(E \cdot d)^2}{30 \cdot G}$$

P: Maximum output power (in W)
E: Electric field strength (in V/m)
d: Distance to antenna (in m)
G: Linear antenna gain (= 1)



2.1.6 Specification Limits

47 CFR, Part 1, § 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 radiate 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

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

where

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

and

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

d = the test separation distance (cm);

- (C) Or using the table below 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 described for that frequency. For the exemption in the table 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).

RF source frequency (MHz)	Threshold ERP (Watts)
0.3 – 1.34	$1920 R^2$
1.34 – 30	$3450 R^2 / f^2$
30 – 300	$3.83 R^2$
300 – 1500	$0.0128 R^2 f^2$
1500 – 100000	$19.2 R^2$

- (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 2 cm 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 case of fixed RF sources operating in the same time-averaging period, or of multiple or portable RF sources within a device 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:

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



RSS-102, section 6.3

SAR evaluation is required if the separation distance between the user and/or bystander and the antenna and/or radiating element of the device is less than or equal to 20 cm, except when the device operates at or below the applicable output power level (adjusted for tune-up tolerance) for the specified separation distance defined in the table below:

<i>f</i> (MHz)	<i>Exemption Limits (mW) at separation distance of</i>									
	<i>≤ 5 mm</i>	<i>10 mm</i>	<i>15 mm</i>	<i>20 mm</i>	<i>25 mm</i>	<i>30 mm</i>	<i>35 mm</i>	<i>40 mm</i>	<i>45 mm</i>	<i>≥ 50 mm</i>
<i>≤ 300</i>	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

Output power level shall be the higher of the maximum conducted or equivalent isotropically radiated power (e.i.r.p.) source-based, time-averaged output power. For controlled use devices where the 8 W/kg for 1 gram of tissue applies, the exemption limits for route evaluation are multiplied by a factor of 5. For limb-worn devices where the 10 grams value applies, the exemption limits for routine evaluation are multiplied by a factor of 2.5. If the operating frequency of the device is between two frequencies located, linear interpolation shall be applied for the applicable separation distance. For test separation distance less than 5 mm, the exemption limits for a separation distance of 5 mm can be applied to determine if a routine evaluation is required.

For medical implants devices, the exemption limit for routine evaluation is set at 1 mW. The output power of a medical implant device is defined as the higher of the conducted or e.i.r.p. to determine whether the device is exempt from the SAR evaluation.



2.1.7 Test Results

Mode: 2M PHY

47 CFR, Part 1, § 1.1307(b)(3)

The carrier in the 2.4 GHz frequency band is evaluated acc. to § 1.1307(b)(3)(i)(A).

Frequency (MHz)	E-Field (dBµV/m)	Distance (m)	Maximum output power (mW)	Exemption limit (mW)	Evaluation
2402	80.71	3	0.035	1.0	Pass
2440	79.23	3	0.025	1.0	Pass
2480	77.77	3	0.018	1.0	Pass

No evaluation for multiple frequencies, since exemption acc. to § 1.1307(b)(3)(i)(A), is exempt from this evaluation.

RSS-102, section 6.3

Frequency (MHz)	E-Field (dBµV/m)	Distance (m)	Maximum output power (mW)	Exemption limit (mW)	Evaluation
2402	80.71	3	0.035	3.26	Pass
2440	79.23	3	0.025	2.84	Pass
2480	77.77	3	0.018	2.97	Pass

Worst case at 2402 MHz with maximum output power being 1.01% of limit.

No calculation regarding multiple output frequencies applicable.



3 Measurement Uncertainty

For a 95% confidence level, the measurement uncertainties for defined systems are:

<i>Radio Interference Emission Testing</i>		
<i>Test Name</i>	<i>kp</i>	<i>Expanded Uncertainty</i>
Conducted Voltage Emission		
9 kHz to 150 kHz (50Ω/50μH AMN)	2	± 3.8 dB
150 kHz to 30 MHz (50Ω/50μH AMN)	2	± 3.4 dB
100 kHz to 200 MHz (50Ω/5μH AMN)	2	± 3.6 dB
Discontinuous Conducted Emission		
9 kHz to 150 kHz (50Ω/50μH AMN)	2	± 3.8 dB
150 kHz to 30 MHz (50Ω/50μH AMN)	2	± 3.4 dB
Conducted Current Emission		
9 kHz to 200 MHz	2	± 3.5 dB
Magnetic Fieldstrength		
9 kHz to 30 MHz (with loop antenna)	2	± 3.9 dB
9 kHz to 30 MHz (large-loop antenna 2 m)	2	± 3.5 dB
Radiated Emission		
30 MHz to 300 MHz	2	± 4.9 dB
300 MHz to 1 GHz	2	± 5.0 dB
1 GHz to 6 GHz	2	± 4.6 dB
Test distance 10 m		
30 MHz to 300 MHz	2	± 4.9 dB
300 MHz to 1 GHz	2	± 4.9 dB
The expanded uncertainty reported according to CISPR16-4-2: 2011 + A1 + A2 + Cor1 is based on a standard uncertainty multiplied by a coverage factor of $k_p = 2$, providing a level of confidence of $p = 95.45\%$		

Table 7 Measurement uncertainty based on CISPR 16-4-2



<i>Radio Interference Emission Testing</i>		
<i>Test Name</i>	<i>kp</i>	<i>Expanded Uncertainty</i>
Occupied Bandwidth	2	± 5 %
Conducted Power		
9 kHz ≤ f < 30 MHz	2	± 1.0 dB
30 MHz ≤ f < 1 GHz	2	± 1.5 dB
1 GHz ≤ f ≤ 40 GHz	2	± 2.5 dB
1 MS/s power sensor (TS8997)	2	± 1.5 dB
Occupied Bandwidth	2	± 5 %
Power Spectral Density	2	± 3.0 dB
Radiated Power		
25 MHz – 6 GHz	1.96	±4.4 dB
1 GHz – 18 GHz	1.96	±4.7 dB
18 GHz – 40 GHz	1.96	±4.9 dB
40 GHz – 325 GHz	1.96	±6.1 dB
Conducted Spurious Emissions	2	± 3.0 dB
Radiated Spurious Emissions	2	± 6.0 dB
Voltage		
DC	2	± 1.0 %
AC	2	± 2.0 %
Time (automatic)	2	± 5 %
Frequency	2	± 10 ⁻⁷
The expanded uncertainty reported according to ETSI TR 100 028:2001 is based on a standard uncertainty multiplied by a coverage factor of kp = 2, providing a level of confidence of p = 95.45%		

Table 8 Measurement uncertainty based on ETSI TR 100 028

The measurement uncertainty in the laboratory is less than or equal to the maximum measurement uncertainty according to CISPR16-4-2: 2011 + A1 + A2 + Cor1 (U_{CISPR}) and as specified in the test report below. This normative regulation means that the measured value is also the value to be assessed in relation to the limit value.



Test Name	Expanded Uncertainty
Occupied Bandwidth	±5 %
Conducted Power	
9 kHz ≤ f < 30 MHz	±1.0 dB
30 MHz ≤ f < 1 GHz	±1.5 dB
1 GHz ≤ f ≤ 40 GHz	±2.5 dB
1 MS/s power sensor (2.4 / 5 GHz band)	±1.5 dB
Power Spectral Density	±3.0 dB
Radiated Power	
25 MHz – 26.5 GHz	±6.0 dB
26.5 GHz – 66 GHz	±8.0 dB
40 GHz – 325 GHz	±10.0 dB
Conducted Spurious Emissions	±3.0 dB
Radiated Field Strength 9 kHz – 40 GHz	±6.0 dB
Voltage	
DC	± 1.0 %
AC	± 2.0 %
Time (automatic)	± 5 %
Frequency	± 10 ⁻⁷

Table 9 Decision Rule: Maximum allowed measurement uncertainty

End of Test Report