RF – TEST REPORT

- Human Exposure -

Type / Model Name	:	FineTuner Echo (product name)
		Ma010201 (product code)
Product Description	:	Remote Control for compatible MED-EL audio processors
Applicant	:	MED-EL Elektromedizinische Geraete GmbH
Address	:	Fuerstenweg 77a
		6020 INNSBRUCK, AUSTRIA
Manufacturer	:	MED-EL Elektromedizinische Geraete GmbH
Address	:	Fuerstenweg 77a
		6020 INNSBRUCK, AUSTRIA

Test Result according to the standards listed in clause 1 test standards:	**POSITIVE**

Test Report No. : 80202871-03 Rev_0	26. April 2024 Date of issue

Deutsche Akkreditierungsstelle
D-PL-12030-01-03
D-PL-12030-01-04

The test report merely corresponds to the test sample. It is not permitted to copy extracts of these test results without the written permission of the test laboratory.

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ATTACHMENT A as separate supplement

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1 TEST STANDARDS

The tests were performed according to following standards:

FCC Rules and Regulations Part 1, Subpart I - Procedures Implementing the National Environmental Policy Act of 1969	
Part 1, Subpart I, Section 1.1310	Radiofrequency radiation exposure limits
Part 2, Subpart J, Section 2.1093	Radiofrequency radiation exposure evaluation: portable devices.
KDB 447498 D01 V06	RF Exposure procedures and equipment authorisation policies for mobile and portable devices, April 20, 2021.
RSS-102, Issue 6	**Radio Frequency (RF) Exposure Compliance of Radiocommunication Apparatus (All Frequency Bands)**

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2 EQUIPMENT UNDER TEST

2.1 Information provided by the Client

Please note, we do not take any responsibility for information provided by the client or his representative which may have an influence on the validity of the test results.

2.2 Sampling

The customer is responsible for the choice of sample. Sample configuration, start-up and operation is carried out by the customer or according his/her instructions.

2.3 General remarks

The EUT contains a 2.4 GHz proprietary transceiver and a BLE transceiver with one antenna being used by both transceivers.

This test report only covers the BLE part of the EUT. For the proprietary 2.4 GHz transceiver please refer to test report T44781-00-00KS issued by CSA Group Bayern GmbH.

2.4 Photo documentation of the EUT – See ATTACHMENT A

2.5 Equipment type, category

BLE device, portable equipment.

2.6 Short description of the equipment under test (EUT)

The FineTuner Echo is a further development of the existing FineTuner and is intended to be used as a remote control for patients with a compatible MED-EL audio processor. The device allows the user to vary certain audio processor parameters within the limits set be the audiologist during fitting. It communicates over a proprietary low power 2.4 GHz link or Bluetooth Low Energy.

Number of tested samples	:	1 (radiated sample)	1 (conducted sample)
Serial number	:	140860	084537
Firmware number	:	PF24-0124 (Rev 2.0)	PF24-0124 (Rev 2.0)

2.7 Variants of the EUT

There are no variants.

2.8 Operation frequency and channel plan

The operating frequency is 2400 MHz to 2483.5 MHz.

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Channel plan:

Channel	Frequency (MHz)	Channel	Frequency (MHz)
37	2402	18	2442
0	2404	19	2444
1	2406	20	2446
2	2408	21	2448
3	2410	22	2450
4	2412	23	2452
5	2414	24	2454
6	2416	25	2456
7	2418	26	2458
8	2420	27	2460
9	2422	28	2462
10	2424	29	2464
38	2426	30	2466
11	2428	31	2468
12	2430	32	2470
13	2432	33	2472
14	2434	34	2474
15	2436	35	2476
16	2438	36	2478
17	2440	39	2480

Note: the marked frequencies are determined for final testing.

2.9 Transmit operating modes

The EUT uses GFSK and provides following data rate:

- 1 Mbps (Mbps = *Megabits per second)*

2.10 Antennas

The following antennas shall be used with the EUT:

Number	Characteristic	Type	Plug	Frequency range (GHz)	Gain (dBi)
1	Omni	PCB	-	2.4 – 2.4835	4.3

2.11 Power supply system utilised

Power supply voltage, V_{nom} : 3.0 V/DC (battery – CR2032)

2.12 Peripheral devices and interface cables

The following peripheral devices and interface cables are connected during the measurements:

- Serial interface and power supply cable Model : Supplied by manufacturer, modification only used for RF measurements

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2.13 Determination of worst-case conditions for final measurement

Preliminary tests are performed in all three orthogonal axes of the EUT to locate at which position and at what setting of the EUT produce the maximum of the emissions.

For the final test the following channels and test modes are selected:

Radio	Available channel	Tested channels	Power setting	Modulation	Modulation type	Data rate
BLE	0 to 39	37, 17, 39	P_{def}	GFSK	digital	1 Mbps

2.13.1 Test jig

No test jig is used.

2.13.2 Test software

The EUT has a special firmware that allows enabling the Direct Test Mode.

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3 TEST RESULT SUMMARY

BLE device using digital modulation and operates in the 2400 MHz – 2483.5 MHz band:

FCC Rule Part	RSS Rule Part	Description	Result
KDB 447498, 7.1	RSS-102, 6.6	MPE	not applicable[1]
KDB 447498, 4.3.1	RSS-102, 6.3	SAR exclusion consideration	passed
KDB 447498, 7.2	RSS-102, 7.1.5	Co-location, Co-transmission	not applicable[2]

Note [1]: Not applicable, EUT is portable
Note [2]: Not applicable, EUT has only one transmitter

3.1 Revision history of test report

Test report No	Rev.	Issue Date	Changes
80202871-02	0	26 April 2024	Initial test report

The test report with the highest revision number replaces the previous test reports.

3.2 Final assessment

The equipment under test fulfils the requirements cited in clause 1 test standards.

Date of receipt of test sample : acc. to storage records

Testing commenced on : 16 April 2024

Testing concluded on : 16 April 2024

Checked by:

Klaus Gegenfurtner
2024.04.26
11:56:02 +02'00'

Klaus Gegenfurtner
Teamleader Radio

Tested by:

Sabine Kugler
2024.04.26
11:16:43 +02'00'

Sabine Kugler
Radio Team

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4 TEST ENVIRONMENT

4.1 Address of the test laboratory

CSA Group Bayern GmbH
Ohmstrasse 1-4
94342 STRASSKIRCHEN
GERMANY

4.2 Environmental conditions

During the measurement the environmental conditions were within the listed ranges:

Temperature:	15 - 35 °C
Humidity:	30 - 60 %
Atmospheric pressure:	86 - 106 kPa

4.3 Statement of the measurement uncertainty

The data and results referenced in this document are true and accurate. It is noted that the expanded measurement uncertainty corresponds to the measurement results from the standard measurement uncertainty multiplied by the coverage factor k = 2. The true value is located in the corresponding interval with a probability of 95 %. The measurement uncertainty was calculated for all measurements listed in this test report on basis of the ETSI Technical Report TR 100 028 Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics; Part 1 and Part 2. The results are documented in the quality system acc. to DIN EN ISO/IEC 17025. Furthermore, component and process variability of devices similar to that tested may result in additional deviation. The manufacturer has the sole responsibility of continued compliance of the device.

4.4 Conformity Decision Rule

The applied conformity decision rule is based on ILAC G8:09/2019 clause 4.2.1 Binary Statement for Simple Acceptance Rule (w = 0).
Details can be found in the procedure CSA_B_V50_29.

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5 HUMAN EXPOSURE

5.1 SAR test exclusion considerations

5.1.1 Applicable standard

According to RF exposure guidance:
Systems operating under the provisions of this section shall be operated in a manner that the public is not exposed to radio frequency energy levels in excess of the Commission's guidelines.

5.1.2 Determination of the standalone SAR test exclusion threshold

The minimum separation distance results from the application of the EUT which is handled by hand. This distance is assumed to ≤ 5 mm from antenna to the hand of the user.
The hand of the user is the nearest extremity of a human being therefore the threshold for 10-g is determined.

The formula under 4.3.1 1) for 100 MHz to 6 GHz for standalone equipment is used:
[(*max. power of channel, including tune-up tolerance, mW*)/(*min. test separation distance, mm*)]*[√f(GHz)] ≤ 7.5;

The max EIRP including tune-up tolerance is according to the equipment:

Channel frequency (MHz)	Peak EIRP (dBm)	Tune-up tolerance (dB)	max. EIRP (mW)	Threshold level	Limit 10g	Margin 10g
2402	3.6	4.0	5.8	1.78	7.5	-5.7
2440	3.5	4.0	5.6	1.76	7.5	-5.7
2480	3.0	4.0	5.0	1.58	7.5	-5.9

Conclusion: The threshold level is below 10g limit, SAR measurement is NOT necessary.

The requirements are **FULFILLED.**

Remarks: For EIRP measurement please refer to test report 80202871-02 Rev_0 issued by CSA Group Bayern GmbH.

As worst case the EIRP measurements are not averaged.

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5.2 Exemption limits for routine evaluation - SAR evaluation

5.2.1 Applicable standard

According to RSS-102, section 6.3:
Devices operating at or below the applicable output power levels (adjusted for tune-up tolerance) specified in table 11, 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.

Table 11: Power limits for exemption from routine SAR evaluation based on the separation distance

Frequency (MHz)	**Exemption Limits (mW)**				
	≤5 mm	10 mm	15 mm	20 mm	25 mm
300	45	116	139	163	189
450	32	71	87	104	124
835	21	32	41	54	72
1900	6	10	18	33	57
2450	3	7	16	32	56
3500	2	6	15	29	50
5800	1	5	13	23	32

Frequency (MHz)	**Exemption Limits (mW)**				
	30 mm	35 mm	40 mm	45 mm	≥50 mm
≤ 300	216	246	280	319	362
450	147	175	208	248	296
835	96	129	172	228	298
1900	92	138	194	257	323
2450	89	128	170	209	245
3500	72	94	114	134	158
5800	41	54	74	102	128

The exemption limits in table 11 Table 11 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 11 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 11 are multiplied by a factor of 5.

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5.2.2 Cunclusion according RSS-102.

Measured Peak EIRP:	3.6	dBm
Tune-up tolerance:	4.0	dBm
Maximum EIRP:	7.6	dBm
Maximum EIRP (mW):	5.8	mW
Minimum distance r:	5.0	mm

Maximum output power (EIRP) at 2450 MHz, **5.8 mW** is < 7.5 mW;

For the EUT SAR measurement is NOT necessary

The requirements are **FULFILLED.**

Remarks: For EIRP measurement please refer to test report 80202871-02 Rev_0 issued by CSA Group Bayern GmbH.

- End of test report -

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