



RF - TEST REPORT

- Human Exposure -

Model Name : SONNET 3 EAS (market name), Me1720 (product
code), OPUS 4++ (internal development name)

Product Description : Audio processor for cochlear implant including a
2.4 GHz transceiver with integral antenna

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. : **80208700-01 Rev_0**

03. June 2024

Date of issue



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

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ATTACHMENT A as separate supplement

1 TEST STANDARDS

The tests were performed according to following standards:

FCC Rules and Regulations (May 2024):

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	General RF Exposure Guidance

ISED Canada Rules and Regulations:

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 to his/her instructions.

2.3 Photo documentation of the EUT – See ATTACHMENT A

2.4 Equipment type, category

Bluetooth Low Energy (BLE) device,
portable equipment.

2.5 Short description of the equipment under test (EUT)

The EUT is an audio processor for a MED-EL cochlear implant including a 2.4 GHz transceiver with integral antenna.

Market names: SONNET 3 / SONNET 3 EAS

Product codes: Me1710, Me1711, Me1712, Me1713 / Me1720, Me1721, Me1722, Me1723*.

The EUT is a medical device similar to a hearing aid. It is worn behind the ear, converts acoustic signals and drives an implanted MED-EL cochlear implant which – based on the information from the audio processor – directly stimulates the acoustic nerve in the inner ear to evoke auditory sensations.

The 2.4 GHz transceiver can receive commands or data from external devices (e.g., remote control, remote programmer, streaming device, etc.). Additionally, it can transmit responses to external devices (external devices are not part of this testing).

Number of tested samples:	1 (radiated sample)	1 (conducted sample)
Serial number:	000068	000070
Firmware number:	hci_2dBm	hci_2dBm
Type:	Me1720	Me1720
HVIN:	Me172	Me172
FCC ID:	VNP-ME1700	
IC ID:	11986A-ME1700	

Items	Description
BT type	5.2 Low Energy
BT chipset type	onsemi RSL10
Modulation	GFSK
Frequency range	2400 MHz to 2483.5 MHz
Channel numbers	40
Data rate (Mbps)	1, 2
Power setting	Default (2 dBm)
Antenna type	PCB

*According to the customer the only difference between the devices with the product code Me172x (x = 0, 1, 2, or 3) and the devices with the product code Me171x is that the devices with the product code Me171x do not contain acoustic hearing aid functionality, i.e., do not contain an acoustic only output ("loudspeaker"). The devices with the product code Me172x are referred to as EAS (electric acoustic stimulation) devices.

The sub variants Me1710, Me1711, Me1712, and Me1713 do not differ in hardware and / or firmware, they just differ in product code. The same is true for the sub variants Me1720, Me1721, Me1722, and Me1723, i.e. they do not differ in hardware and / or firmware, they just differ in product code. These different sub variants are only introduced for marketing and sales purposes.

2.6 Operation frequency and channel plan

The operating frequency is 2400 MHz to 2483.5 MHz.

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.

2.7 Transmit operating modes

The EUT uses GFSK modulation and may provide following data rates:

- 1 Mbps
- 2 Mbps

(Mbps = Megabits per second)

2.8 Antennas

The following antennas shall be used with the EUT:

Characteristic	Model number	Plug	Frequency range (GHz)	Gain (dBi)
Omni	PCB antenna	-	2.4 – 2.4835	-8.0

2.9 Power supply system utilised

Power supply voltage, V_{nom} : 2.2 V/DC (2 x zinc-air batteries type 675)

2.10 Peripheral devices and interface cables

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

- Battery pack _____ Model : SONNET battery pack (Ma060106) _____

2.11 Final measurement conditions

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:

BLE V5	Available channel	Tested channels	Power setting	Modulation	Modulation type	Data rate
802.15.1	0 - 39	37, 17, 39	P_{def}	DSSS	GFSK	1 Mbps
802.15.1	0 - 36	0, 17, 36	P_{def}	DSSS	GFSK	2 Mbps

Packet payload length: 255 octets; Packet payload: PRBS9

2.11.1 Test jig

No test jig is used.

2.11.2 Test software

The EUT provides the Bluetooth Low Energy Direct Test Mode (DTM) via HCI (V2 commands) as specified in the Bluetooth Core Specification 5.2 Vol 6 Part F. The DTM firmware in the EUT was the BLE Direct Test Mode (DTM) firmware hci_2dBm specified in the MED-EL document PF21-0529 Rev 4.0.

3 TEST RESULT SUMMARY

Operating 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
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

3.1 Revision history of test report

Test report No	Rev.	Issue Date	Changes
80208700-01	0	03 June 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 : 24 May 2024

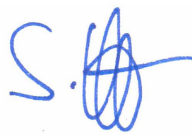
Testing concluded on : 24 May 2024

Checked by:


 Klaus
 Gegenfurtner
 2024.06.03
 14:21:14 +02'00'

 Klaus Gegenfurtner
 Teamleader Radio

Tested by:


 Sabine Kugler
 2024.06.03
 11:31:29
 +02'00'

 Sabine Kugler
 Radio Team

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.

5 HUMAN EXPOSURE

5.1 Maximum permissible exposure (MPE)

5.1.1 Applicable standard

According to FCC Part 15, Section 15.247(i):

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 Description of Determination

The maximum rated output power conducted included the tune up tolerance is used to calculate the EIRP. Through the Friis transmission formula, the known maximum gain of the antenna and the maximum power, can be calculated the MPE in a defined distance away from the product.

Friis transmission formula:

$$P_d = \frac{P_{out} * G}{4 * \pi * r^2}$$

Where:

P_d = power density (mW/cm²)

P_{out} = output power to antenna (mW)

G = gain of antenna (linear scale)

r = distance between antenna and observation point (cm)

Remarks: Not applicable, EUT is portable equipment.

5.2 SAR test exclusion consideration according to FCC

5.2.1 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.

5.2.2 Determination of the standalone SAR test exclusion threshold

The minimum separation distance results from the application of the EUT which is worn behind the ear. This distance is assumed to be ≤ 5 mm from antenna to the head of the user. The threshold for 1-g is determined.

The formula under 4.3.1 a) for 100 MHz to 6 GHz for standalone equipment is used:

$\{[(\text{max. power of channel, including tune-up tolerance, mW})/(\text{min. test separation distance, mm})] \cdot [\sqrt{f(\text{GHz})}]\} \leq 3.0$
for 1-g SAR;

Power allowed at *numeric threshold* for **5 mm** separation distance:

max. power = $\{3.0 / \sqrt{f(\text{GHz})} [\text{min. test separation distance (mm)}]\}$ mW
= $\{3.0 / \sqrt{2.480 \cdot 5.0}\}$ mW
= **9.5 mW**

Maximum conducted output power A_{max} :

Measured A:	1.7 mW	2.2 dBm
Tune-up tolerance:	1.5 dB	
Maximum A_{max} :	3.7 dBm	2.3 mW
Minimum distance r:	5.0 mm	

Conclusion: The maximum power level of 2.3 mW is lower than the allowed power of 9.5 mW at a separation distance of 5 mm, thus SAR measurement is NOT necessary.

The requirements are **FULFILLED**.

Remarks: For conducted peak power measurement please refer to test report 80208700-00 issued by
CSA Group Bayern GmbH.

5.3 Exemption limits for routine evaluation according to ISED

5.3.1 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 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.

5.3.2 Conclusion according to RSS-102.

Maximum peak power EIRP_{max}:

Measured EIRP:	0.3 mW	-5.8 dBm
Tune-up tolerance:	1.5 dB	
Maximum EIRP _{max} :	-4.3 dBm	0.4 mW
Minimum distance r:	5.0 mm	

Conclusion: The maximum EIRP level of 0.4 mW is lower than the Exemption Limit of 3 mW at a separation distance of 5 mm, thus SAR measurement is NOT necessary.

The requirements are **FULFILLED**.

Remarks: For EIRP measurement please refer to test report 80208700-00 issued by CSA Group Bayern GmbH.

5.4 Co-location and Co-transmission

Applicable standard:

OET Bulletin 65, Edition 97-01, Section 2: Multiple-transmitter sites and Complex Environments

The FCC's MPE limits vary with frequency. Therefore, in mixed or broadband RF fields where several sources and frequencies are involved, the fraction of the recommended limit (in terms of power density or square of the electric or magnetic field strength) incurred within each frequency interval should be determined, and the sum of all fractional contributions should not exceed 1.0, or 100 % in terms of percentage.

Remarks: Not applicable, EUT has only one transmitter.

- End of test report -

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.