



# RF - TEST REPORT

## - Human Exposure -

**Model Name** : AudioLink 2 (internal development name);

AudioLink XT (market name)

HVIN: Ma070304

**Product Description** : Audio streaming accessory for MED-EL audio  
processors including BLE

**Applicant** : MED-EL Elektromedizinische Geraete GmbH

**Address** : Fuerstenweg 77a  
6020 INNSBRUCK, AUSTRIA

**Manufacturer** : MED-EL Elektromedizinische Geraete GmbH

**Address** : Fuerstenweg 77a  
6020 INNSBRUCK, AUSTRIA

|  |                 |
|--|-----------------|
| <b>Test Result</b> according to the standards listed in clause 1 test standards: | <b>POSITIVE</b> |
|--|-----------------|

|   |   |
|---|---|
| <b>Test Report No. :</b> <u>80136971-04 Rev_2</u> | <u>09. September 2024</u><br><u>Date of issue</u> |
|---|---|



Deutsche  
Akkreditierungsstelle  
D-PL-12030-01-00

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ATTACHMENTS A, B as separate supplements

## **1 TEST STANDARDS**

The tests were performed according to following standards:

### **FCC Rules and Regulations (June 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<br>Radiocommunication Apparatus (All Frequency Bands) |
|------------------|---|

## 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 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)

AudioLink 2 is an audio streaming accessory for MED-EL audio processors equipid with Bluetooth Low Energy technology. Streaming is based on the Google ASHA (Audio Streaming for Hearing Aids) BLE profile using GFSK modulation with a data rate of 1 Mbit/s and 2 Mbit/s. The deceive contains one single hard-wired PCB antenna (inverted F) without temporary connector. No external antenna can be connected to the device.

|                           |   |  |
|---------------------------|---|--|
| Number of tested samples: | 1 (radiated sample)                       | 1 (normal sample)  |
| Serial number:            | 000140                                    | 000122   |
| Firmware number:          | FW Rev. PF23-0047_10_<br>AL2_hci_app_6dbm | FW Rev. 0.0.36777_<br>20230130.3 (ref. SP135673<br>Rev. 0.1) |
| HVIN:                     | Ma070304                                  |  |
| FCC ID:                   | VNP-ALXT                                  |  |
| IC ID:                    | 11986A-ALXT                               |  |

| 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 (max)          |
| Antenna type     | PCB                    |

## 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

A single integrated PCB antenna is used with the EUT, no other antenna can be used with the device.

All measurements were performed radiated, for additional photo documentation of the antenna please refer to Attachment A.

## 2.9 Power supply system utilised

Power supply voltage,  $V_{\text{nom}}$  : 3.7 V/DC (battery pack)  
 Alternative power supply voltage : 5.0 V/DC (switching power adaptor)

## 2.10 Peripheral devices and interface cables

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

- Notebook Model : Latitude 5480, DELL
- UART-USB adapter Model : Custom-built
- - Model : -

## 2.11 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 further measurement the EUT is set in X and Y position.

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    |

Note: Advertising channels (37, 38, 39) are not available for 2 Mbps data rate.

### 2.11.1 Test jig

No test jig is used.

### 2.11.2 Test software

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

### 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 |
| 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   |
|----------------|------|-------------------|---|
| 80136971-04    | 0    | 23 March 2023     | Initial test report                                   |
| 80136971-04    | 1    | 05 June 2024      | Update RSS-102 Issue 6                                |
| 80136971-04    | 2    | 09 September 2024 | 5.2.2 / 5.3.2: 10 gram limit replaced by 1 gram limit |

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 : 01 March 2023

Testing concluded on : 01 March 2023

Checked by:

Tested by:

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Klaus Gegenfurtner  
Teamleader Radio

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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/cm<sup>2</sup>)

$P_{out}$  = 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.

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## 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 handled by hand or worn on the body. This distance is assumed to be  $\leq 5$  mm from antenna to 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:  
 $\{(max. power of channel, including tune-up tolerance, mW)/(min. test separation distance, mm)\} * [\sqrt{f(GHz)}] \leq 3.0$   
for 1-g SAR;

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

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

Maximum conducted output power  $A_{max}$ :

|                              |       |     |     |    |
|------------------------------|-------|-----|-----|----|
| Measured A:                  | 5.4   | dBm | 3.5 | mW |
| Tune-up tolerance:           | 1.5   | dB  |     |    |
| Maximum $A_{max}$ :          | 6.9   | dBm | 4.9 | mW |
| DC correction factor:        | -15.6 | dB  |     |    |
| Time-averaged $A_{AV,max}$ : | -8.7  | dBm | 0.1 | mW |
| Minimum distance r:          | 5.0   | mm  |     |    |

**Conclusion: The maximum power level of 0.1 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**.

|                 |   |
|-----------------|---|
| <b>Remarks:</b> | <u>For conducted peak power measurement please refer to test report 80136971-03 issued by</u> |
|                 | <u>CSA Group Bayern GmbH.</u>   |
|                 | <u>For determination of Duty Cycle correction factor please refer to 5.5.</u>                 |

## 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    |
| <b>2450</b>     | <b>3</b>              | 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.

### 5.3.2 Conclusion according to RSS-102.

Maximum peak power  $EIRP_{max}$ :

|                                 |       |     |     |    |
|---------------------------------|-------|-----|-----|----|
| Measured EIRP:                  | 6.3   | dBm | 4.3 | mW |
| Tune-up tolerance:              | 1.5   | dB  |     |    |
| Maximum $EIRP_{max}$ :          | 7.8   | dBm | 6.0 | mW |
| DC correction factor:           | -15.6 | dB  |     |    |
| Time-averaged $EIRP_{AV,max}$ : | -7.8  | dBm | 0.2 | mW |
| Minimum distance $r$ :          | 5.0   | mm  |     |    |

**Conclusion: The maximum EIRP level of 0.2 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 80136971-03 issued by CSA Group Bayern

GmbH.

For determination of Duty Cycle correction factor please refer to 5.5.

## 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

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## 5.5 Correction for pulse operation (duty cycle)

For test instruments and accessories used see section 6 Part **DC**.

### 5.5.1 Description of the test location

Test location: Shielded Room S6

### 5.5.2 Photo documentation of the test set-up

See Attachment B for detailed photo documentation of the test set-up.

### 5.5.3 Description of Measurement

The duty cycle factor (dB) is calculated applying the following formula:

$$K_E = 20 \log (T_{on} / T_{conn})$$

$K_E$ : pulse operation correction factor

$T_{on}$ : on air duration

$T_{conn}$ : connection interval duration

### 5.5.4 Test result

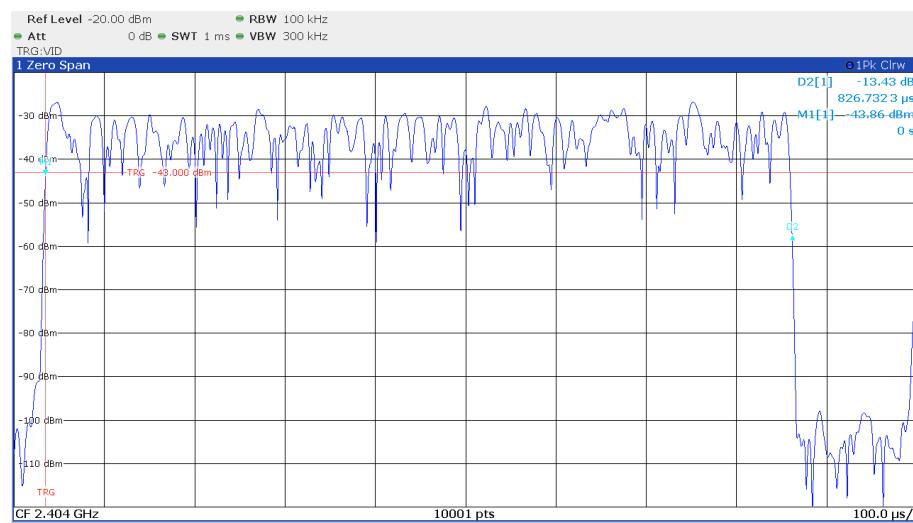
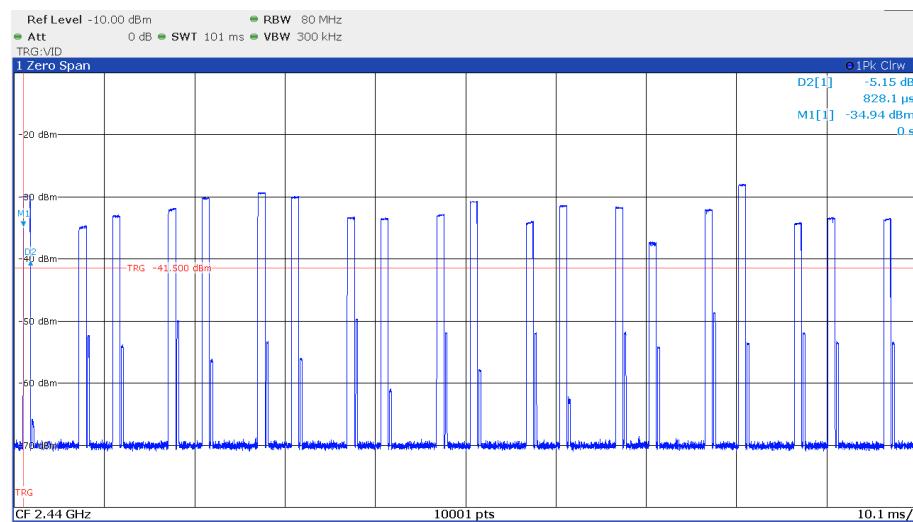
In a time interval of  $T_{conn} = 100$  ms a max. number of 20 pulses of  $T_{on} = 827$   $\mu$ s can be observed over all channels:

$$K_E = 20 \log ((0.827*20) / 100) = K_E = 20 \log (0.165) = -15.6 \text{ dB}$$

**Remarks:** Worst case scenario: EUT is in streaming mode with two audio processors.

For detailed test results please see the following test protocol.

### 5.5.5 Test protocol



## **6 USED TEST EQUIPMENT AND ACCESSORIES**

All test instruments used are calibrated and verified regularly. The calibration history is available on request.

| <b>Test ID</b> | <b>Model Type</b> | <b>Equipment No.</b> | <b>Next Calib.</b> | <b>Last Calib.</b> | <b>Next Verif.</b> | <b>Last Verif.</b> |
|----------------|-------------------|----------------------|--------------------|--------------------|--------------------|--------------------|
| DC             | FSW43             | 02-02/11-21-001      | 16/05/2023         | 16/05/2022         |                    |                    |

- End of test report -