



EMI – TEST REPORT

- Human Exposure -

Type / Model Name : AudioLink (market name), Wireless Relay (internal development name)

Product Description : Audio streaming accessory for MED-EL audio processors including a
2.4 GHz proprietary transceiver and Bluetooth classic

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. : **T44784-00-01KS**

27. May 2019

Date of issue



Deutsche
Akkreditierungsstelle
D-PL-12030-01-01
D-PL-12030-01-02

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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IC: 11986A-AL

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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 1, Subpart 2, Section 2.1091 Radiofrequency radiation exposure evaluation: mobile devices.

Part 1, Subpart 2, Section 2.1093 Radiofrequency radiation exposure evaluation: **portable devices**.

KDB 447498 D01 v06 Mobile and portable devices RF Exposure procedures and equipment authorisation policies, October 23, 2015.

KDB 865664 D01 v01r04 SAR Measurement Requirements for 100 MHz to 6 GHz, August 7, 2015.

ANSI C95.1: 2005 IEEE Standard for Safety Levels with respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz

ETSI TR 100 028 V1.3.1: 2001-03, Electromagnetic Compatibility and Radio Spectrum Matters (ERM);
Uncertainties in the Measurement of Mobile Radio Equipment
Characteristics—Part 1 and Part 2

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2 EQUIPMENT UNDER TEST

2.1 Photo documentation of the EUT – See ATTACHMENT A

2.2 Equipment type, category

2.4 GHz transceiver, Bluetooth classic device, portable equipment.

2.3 Short description of the equipment under test (EUT)

The AudioLink is a multifunctional battery powered body worn accessory to the MED-EL CI System that provides wireless connectivity options for MED-EL CI systems. It communicates over a proprietary low power 2.4 GHz link to supported MED-EL audio processors (e.g. SONNET & SONNET 2) and has a Bluetooth classic module integrated for connectivity to common mobile devices. From such Bluetooth devices the AudioLink can receive audio signals which are streamed to the MED-EL audio processor or control data like remote control commands e.g. from the FineTuner App. It also provides a user interface, a USB charging connector and an audio jack.

SN EUT	CBA	RF Transceiver FW	Main Controller FW	Tests
#1	AL-000066	rev. 1.0.0	rev. 1.0.0	Conducted measurements MB, CPC, SEC
#2	AL-000077	rev. 1.0.0	rev. 1.0.0	Conducted measurements MB, CPC, SEC
#3	AL-000080	rev. 1.0.0	rev. 1.0.0	Radiated measurements MB, SER3, SER2, DC
#4	AL-000081	rev. 1.0.0	rev. 1.0.0	Radiated measurements MB, SER3, SER2, DC

2.4 Variants of the EUT

None.

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2.5 Operation frequency and channel plan

The operating frequency band is 2400 MHz to 2483.5 MHz.

2.6 Transmit operating modes

The equipment under test was operated during the measurement under the following conditions:

- 2.4 GHz transceiver: cont. TX at CH1, CH19 and CH39 (the EUT uses GFSK and provides following data rate:

2 Mbps)

- BT: cont. TX at 2401MHz, 2441 MHz and 2480 MHz (the EUT uses GFSK and provides following data rate:

1 Mbps; modulation type DH1, frequencies were supplied by the manufacturer)

2.7 Antennas

The following antennas shall be used with the EUT:

Module	Number	Characteristic	Type	Plug	Frequency range (GHz)	Gain (dBi)
Prop. 2.4 GHz transceiver	1	Omni	PCB	None	2.4	1.0
BT	1	Omni	Chip antenna	None	2.4	0.0

2.8 Power supply system utilised

Power supply voltage, V_{nom} : 3.2 VDC – 4.2 VDC Battery powered
 Power supply voltage (alternative) : 5 VDC USB powered

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3 TEST RESULT SUMMARY

Operating in the 2400 MHz – 2483.5 MHz band:

FCC Rule Part	RSS Rule Part	Description	Result
15.247(i)	RSS 102, 2.5.2	MPE	not applicable
KDB 447498	RSS 102, 2.5.1	SAR exclusion consideration	passed
OET Bulletin 65	RSS102, 3.2	Co-location, Co-transmission	passed

The mentioned RSS Rule Parts in the above table are related to:
RSS 102, Issue 5, March 2015

3.1 Final assessment

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

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

Testing commenced on : 01 February 2019

Testing concluded on : 08 March 2019

Checked by:

Tested by:

Klaus Gegenfurtner
Teamleader Radio

Hermann Smetana
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 acc. to CISPR 16-4-2 / 11.2003 „Uncertainties, statistics and limit modelling – Uncertainty in EMC measurements“ and is documented in the quality system acc. to DIN EN ISO/IEC 17025. For all measurements shown in this report, the measurement uncertainty of the test laboratory, CSA Group Bayern GmbH, is below the measurement uncertainty as defined by CISPR. Therefore, no special measures must be taken into consideration with regard to the limits according to CISPR. 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.

Measurement Type	Range	Confidence Level	Calculated Uncertainty
AC power line conducted emissions	0.15 MHz to 30 MHz	95%	± 3.29 dB
EBW and OBW	2400 MHz to 30000 MHz	95%	$\pm 2.5 \times 10^{-7}$
Output power ERP, radiated	1000 MHz to 7000 MHz	95%	± 2.71 dB
Field strength of the fundamental	1000 MHz to 7000 MHz	95%	± 2.71 dB
Power spectral density	2400 MHz to 3000 MHz	95%	± 0.62 dB
Spurious Emissions, conducted	9 kHz to 10000 MHz	95%	± 2.15 dB
Spurious Emissions, conducted	10000 MHz to 40000 MHz	95%	± 3.47 dB
Spurious Emissions, radiated	9 kHz to 30 MHz	95%	± 3.53 dB
Spurious Emissions, radiated	30 MHz to 1000 MHz	95%	± 4.44 dB
Spurious Emissions, radiated	1000 MHz to 30000 MHz	95%	± 2.34 dB
Spurious Emissions, radiated	30000 MHz to 40000 MHz	95%	± 5.13 dB

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5 HUMAN EXPOSURE

5.1 Maximum permissible exposure (MPE)

Remarks: Not applicable, because the distance between the user and the device is below 20 cm, therefore
the SAR test exclusion consideration is applicable.

5.2 SAR test exclusion considerations

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 device which is handled by hand. This distance is assumed to be ≤ 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:

$[(\text{max. power of channel, including tune-up tolerance, mW})/(\text{min. test separation distance, mm})] \cdot [\sqrt{f(\text{GHz})}] \leq 7.5;$

The max conducted power is according the equipment (proprietary 2.4 GHz transceiver):

Rated output power:	3.0 mW	4.7 dBm
Tune-up tolerance:	3.50 dB	
Maximum output power:	8.2 dBm	6.6 mW
Antenna gain max:	1 dBi	

Maximum EIRP:	9.2 dBm	8.3 mW
Minimum distance r:	5.0 mm	

Channel frequency (MHz)	A (mW)	Threshold level	Limit 1g	Limit 10g	Margin 1g	Margin 10g
2404	6.6	2.1	3.0	7.5	-1.0	-5.5
2440	6.6	2.1	3.0	7.5	-0.9	-5.4
2480	6.6	2.1	3.0	7.5	-0.9	-5.4

Conclusion: The threshold level is much lower than the limit, SAR measurement is NOT necessary.

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The max conducted power is according the equipment (WT32i **Bluetooth classic**):

Rated output power:	0.25 mW	-6.0 dBm
Tune-up tolerance:	1.00 dB	
Maximum output power:	-5.0 dBm	0.32 mW
Antenna gain max:	0.0 dBi	
Maximum EIRP:	-5.0 dBm	0.32 mW
Minimum distance r:	5.0 mm	

Channel frequency (MHz)	A (mW)	Threshold level	Limit 1g	Limit 10g	Margin 1g	Margin 10g
2480	0.32	0.10	3.0	7.5	-2.9	-7.4

Conclusion: The threshold level is much lower than the limit, SAR measurement is NOT necessary.

5.2.3 Determination of the SAR test exclusion threshold for simultaneous transmission

When both modules are active the max threshold level has to be summed and the total threshold level is determined.

Level module 1 + level module 2 \leq 18.75;

$$2.1 + 0.1 = 2.6 \leq 18.75$$

Conclusion: The Threshold level is smaller than the limit, SAR measurement is NOT necessary. Bluetooth classic and the proprietary 2.4 GHz transceiver can be co-located without exceeding SAR limits.

The requirements are **FULFILLED**.

Remarks:

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5.3 Exemption limits for routine evaluation - SAR evaluation

5.3.1 Applicable standard

According to RSS-102, item 2.5.1:

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 Table 1.

Result of SAR exemption evaluation (proprietary 2.4 GHz transceiver):

Channel frequency (MHz)	EIRP Peak (dBm)	EIRP Peak (mW)	duty cycle	EIRP AV (mW)	Limit 1-g SAR (mW)	Margin 1g
2404	9.2	8.3176	0.2880	2.3955	4.0	-1.6
2440	9.2	8.3176	0.2880	2.3955	4.0	-1.6
2480	9.2	8.3176	0.2880	2.3955	4.0	-1.6

Result of SAR exemption evaluation (Bluetooth classic):

Channel frequency (MHz)	EIRP Peak (dBm)	EIRP Peak (mW)	duty cycle	EIRP AV (mW)	Limit 1-g SAR (mW)	Margin 1g
2480	-5.0	0.3162	0.3200	0.1012	4.0	-3.7

Table 1: SAR evaluation – Exemption limits for routine evaluation based on frequency and separation distance 4, 5

Frequency (MHz)	Exemption Limits (mW)				
	At separation distance of ≤5 mm	At separation distance of 10 mm	At separation distance of 15 mm	At separation distance of 20 mm	At separation distance of 25 mm
≤ 300	71 mW	101 mW	132 mW	162 mW	193 mW
450	52 mW	70 mW	88 mW	106 mW	123 mW
835	17 mW	30 mW	42 mW	55 mW	67 mW
1900	7 mW	10 mW	18 mW	34 mW	60 mW
2450	4 mW	7 mW	15 mW	30 mW	52 mW
3500	2 mW	6 mW	16 mW	32 mW	55 mW
5800	1 mW	6 mW	15 mW	27 mW	41 mW

4 The exemption limits in Table 1 are based on measurements and simulations of half-wave dipole antennas at separation distances of 5 mm to 25 mm from a flat phantom, providing a SAR value of approximately 0.4 W/kg for 1 g of tissue. For low frequencies (300 MHz to 835 MHz), the exemption limits are derived from a linear fit. For high frequencies (1900 MHz and above), the exemption limits are derived from a third order polynomial fit.

5 Transmitters operating between 0.003-10 MHz, meeting the exemption from routine SAR evaluation, shall demonstrate compliance to the instantaneous limits in Section 4.

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Maximum average output power at 2480 MHz (proprietary 2.4 GHz transceiver), **2.4 mW** is < 4 mW;

Maximum average output power at 2480 MHz (BT classic), **0.1 mW** is < 4 mW;

For the EUT SAR measurement is NOT necessary

5.3.3 Determination of the SAR test exclusion for simultaneous transmission

When both modules are active, the maximum output power level has to be summed.
The total power level is determined with the following formula:

Level module 1 + level module 2 \leq 3.9 mW at 2480 MHz

$2.4 \text{ mW} + 0.1 \text{ mW} = \mathbf{2.5 \text{ mW}} \leq 3.9 \text{ mW}$

5.3.4 Conclusion according RSS-102 for simultaneous transmission

Maximum output power transmitter 1 + transmitter 2 = $\mathbf{2.5 \text{ mW}} \leq 3.9 \text{ mW}$;

Conclusion: The output power level is smaller than the exemption limit, SAR measurement is NOT necessary. Bluetooth classic and the proprietary 2.4 GHz transceiver can be co-located without exceeding SAR limits.

The requirements are **FULFILLED**.

Remarks:

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