

RF-TEST REPORT

- FCC Part 15B -

Type / Model Name : c-med° alpha

Product Description : Medical wearable for continuous vital signs

measurement

Applicant : Cosinuss GmbH

Address : Kistlerhofstraße 60

81379 München, GERMANY

Manufacturer : Cosinuss GmbH

Address : Kistlerhofstraße 60

81379 München, GERMANY

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

POSITIVE

Test Report No. : T47140-01-01LH 15. July 2021

Date of issue







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1 TEST STANDARDS

The tests were performed according to following standards: FCC Rules and Regulations Part 15 Subpart B - Unintentional Radiators (September 2020) Part 15, Subpart B, Section 15.109 Radiated emission, general requirements Class B device Class A device ANSI C63.4: 2014 Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz. CISPR 16-4-2: 2011 + A1: 2014 Uncertainty in EMC measurement EN 55016-4-2: 2011 ISED Canada Rules and Regulations - Information Technology Equipment (Including Digital Apparatus) ICES-003, Issue 7, October 15, 2020 Radiated emission Class B device Class A device ANSI C63.4: 2014 Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz.





2 SUMMARY

2.1 General remarks

2.2 Summary for all EMC tests

FCC Rule Part	ISED Standard	Description
15.107	ICES-003/RSS-Gen	AC power line conducted emissions
15.109	ICES-003/RSS-Gen	Radiated Emissions

	Type of test	Test result
Emis	ssion:	
A4	Conducted emission (AC mains power / DC power)	not applicable*
A5	Radiated emission (< 1 GHz)	passed
SER	3 Radiated emission (> 1 GHz)	passed

^{*} The EUT is battery powered, therefore AC power line conducted emissions is not applicable.

17 March 2021

2.3 Final assessment

Testing concluded on

Checked by:

Date of receipt of test sample	: acc. to storage records
Testing commenced on	: 10 March 2021

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

Klaus Gegenfurtner
Teamleader Radio
Lukas Scheuermann
Radio Team

Tested by:

CSA Group Bayern GmbH Ohmstrasse 1-4 · 94342 STRASSKIRCHEN · GERMANY Tel.:+49(0)9424-94810 · Fax:+49(0)9424-9481440 File No. **T47140-01-01LH**, page **4** of **17**

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3 EQUIPMENT UNDER TEST

3.1 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.

3.2 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.

3.3 Photo documentation of the EUT - Detailed photos see ATTACHMENT A

3.4 Power supply system utilised

Power supply voltage : 3.7 V_{DC} Battery

3.5 Highest internal frequency

Highest internal frequency : - BLE module: 2.4 GHz

- System clock μC: 64 MHz

3.6 Short description of the Equipment under Test (EUT)

The EUT is a Bluetooth 5.0 Low Energy wireless device for continuous vital signs measurements. A single PCB antenna is used within the system. The EUT has only one integrated antenna, no temporary connector and no external antenna can be connected.

The radiated test samples is specially prepared to be connected to a PC and set into test mode by a set of commands in a terminal program.

Number of tested samples: 1 radiated Type: MS01

Serial number: PCB ID 6001501A.002019
Firmware version: special testing firmware

3.7 EUT operation mode

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

- The EUT is set into RX (receive mode) by test software.



3.8 EUT configuration

(The CDF filled by the applicant can be viewed at the test laboratory.)

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

-	Device1	Model:	Raspberry Pi 3B+
-	WLAN Router	Model:	FRITZ!Box 4020
-	Laptop	Model:	MS-16GD
-	UART-USB Converter	Model:	DLP-USB232R
_	USB Mini Cable	Model:	-
_	2x Ethernetcable	Model:	
_	USB Micro Cable	Model:	-

Modifications during the EMC test: None



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 / 2011 + A1 / 2014 "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.

4.4 Conformity Decision Rule

The conformity decision rule is based on the ILAC G8 published at the time of reporting.

4.5 Measurement protocol for FCC and ISED

4.5.1 General information

CSA Group Bayern GmbH is recognized as wireless testing laboratory under the CAB identifier:

FCC: DE 0011 ISED: DE0009

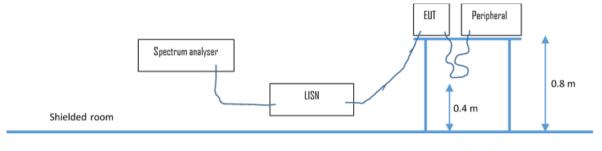
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4.5.2 Details of test procedures

4.5.2.1 Conducted emission

Test setup according ANSI C63.4



Non-conducted support

Description of measurement

The final level, expressed in $dB\mu V$, is arrived at by taking the reading directly from the Spectrum analyser. This level is compared to the limit.

To convert between $dB\mu V$ and μV , the following conversions apply:

 $dB\mu V = 20(log \mu V)$ $\mu V = log(dB\mu V/20)$

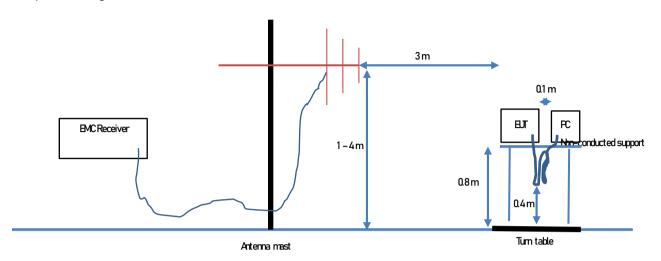
Conducted emissions on the 50 Hz and/or 60 Hz power interface of the EUT are measured in the frequency range of 150 kHz to 30 MHz. The measurements are performed using a receiver, which has CISPR characteristic bandwidth and quasi-peak detection and a Line Impedance Stabilization Network (LISN) with 50 Ω / 50 μ H (CISPR 16) characteristics. The receiver is protected by means of an impedance matched pulse limiter connected directly to the RF input. Table top equipment is placed on a non-conducting table 80 centimetres above the floor and is positioned 40 centimetres from the vertical ground plane (wall) of the screen room. If the minimum limit margin appears to be less than 20 dB with a peak mode measurement, the emission is re-measured using a tuned receiver with quasi-peak and average detection and recorded on the data sheets.



4.5.2.2 Radiated emission

4.5.2.2.1 OATS1 test site (30 MHz - 1 GHz)

Test setup according ANSI C63.4



Description of measurement

Spurious emission from the EUT is measured in the frequency range of 30 MHz to 1000 MHz using a tuned receiver and appropriate broadband linearly polarized antennas. Measurements between 30 MHz and 1000 MHz are made with 120 kHz/6 dB bandwidth and quasi-peak detection. Table top equipment is placed on a 1.0 X 1.5 metre non-conducting table 80 centimetres above the ground plane. Floor standing equipment is placed directly on the turntable/ground plane. The setup of the equipment under test is established in accordance with ANSI C63.4. The interface cables that are closer than 40 centimetres to the ground plane are bundled in the centre in a serpentine fashion so that they are at least 40 centimetres from the ground plane. Cables to simulators/testers (if used in this test) are routed through the centre of the table and to a screened room located outside the test area.

The antenna is positioned 3 or 10 metres horizontally from the EUT. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 metres, measurement scans are made with both horizontal and vertical antenna polarization planes and the EUT is rotated 360 degrees.

The final level is calculated in a calculation sheet by taking the reading from the EMI receiver (Level $dB\mu V$) and adding the correction factors and cable loss factor (Factor dB) on to it. The limit is subtracted from this result in order to provide the limit margin listed in the measurement protocols.

Example:

Frequency	Reading	+	Correction*	=	Level	-	Limit	=	Dlimit
(MHz)	(dBµV)		(dB/m)		(dBµV/m)		(dBµV/m)		(dB)
719.0	75.0	+	32.6	=	107.6	-	110.0	=	-2.4

*Correction Factor = Antenna Factor + Cable Attenuation = 30 dB/m + 2.6 dB = 32.6 dB/m

The resolution bandwidth during the measurement is as follows:

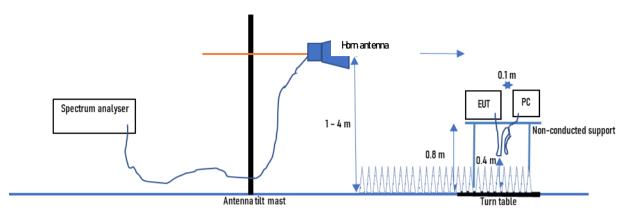
30 MHz – 1000 MHz: RBW: 120 kHz

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4.5.2.2.2 Anechoic chamber 1, 1000 MHz - 18000 MHz

Test setup according ANSI C63.4



Description of measurement

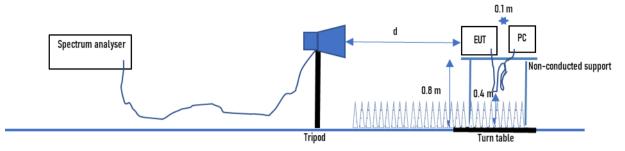
Radiated emission from the EUT are measured in the frequency range of 1 GHz to the maximum frequency as specified in 47 CFR Part 15 Subpart A section 15.33, using a tuned receiver (spectrum analyser) and appropriate linearly polarized antennas. Table top equipment is placed on a 0.65 X 1.0 metre non-conducting table 80 centimetres above the ground plane. The turntable is fully covered with the appropriate absorber (Type VHP-12).

The interface cables that are closer than 40 centimetres to the ground plane are bundled in the centre in a serpentine fashion, so they are at least 40 centimetres from the ground plane. Measurements are made in both the horizontal and vertical polarization planes in a fully anechoic room using a spectrum analyser set to a peak detector function and a RBW= 1 MHz and VBW = 3 MHz. All tests are performed at a test distance of 3 metres. Hand-held or bodyworn devices are rotated around three orthogonal axes in order to determine the position, angle and configuration having the maximum emission. The antenna height is then adjusted from 1 m to 4 m maximizing the measured value. The antenna is mounted to a boresight axis, so the antenna centre always points to the EUT. The turntable is rotated 360° until the spectrum analyser displays the maximum level at the observed frequency. The antenna height is then adjusted from 1 m to 4 m maximizing the measured value. The turntable is re-adjusted to re-affirm the maximum emission value which is then recorded. This procedure is repeated for all frequencies of interest.



4.5.2.2.3 Anechoic chamber 1, 18 GHz - 40 GHz

Test setup according ANSI C63.4

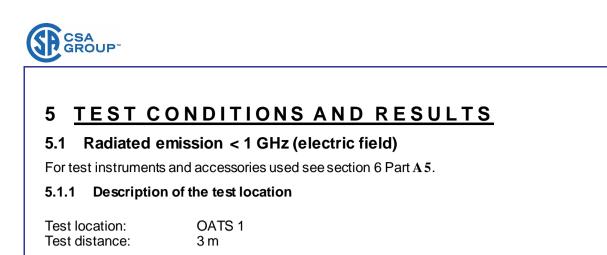


Description of measurement

Radiated emission from the EUT are measured in the frequency range of 1 GHz to the maximum frequency as specified in 47 CFR Part 15 Subpart A section 15.33, using a tuned receiver (spectrum analyser) and appropriate linearly polarized antennas. Table top equipment is placed on a 0.65 X 1.0 metre non-conducting table 80 centimetres above the ground plane. The turntable is fully covered with the appropriate absorber (Type VHP-12).

The interface cables that are closer than 40 centimetres to the ground plane are bundled in the centre in a serpentine fashion, so they are at least 40 centimetres from the ground plane. Measurements are made in both the horizontal and vertical polarization planes in a fully anechoic room using a spectrum analyser set to a peak detector function and an RBW= 1 MHz and VBW = 3 MHz. All tests are performed at a test distance of 3 metres. Hand-held or bodyworn devices are rotated around three orthogonal axes in order to determine the position, angle and configuration having the maximum emission. The turntable is rotated 360° until the spectrum analyser displays the maximum level at the observed frequency, the maximum emission value is then recorded. This procedure is repeated for all frequencies of interest.

Where appropriate in frequency range 18 GHz - 40 GHz, the test distance may be reduced to 1 m in order to reduce the noise level to hold a minimum distance between noise level and limit. The limit will be adopted to the measurement distance.



5.1.2 Photo documentation of the test setup

Open area test site





5.1.3 Test result

Frequency range: 30 MHz - 1000 MHz

Min. limit margin 16.6 dB

The requirements are FULFILLED.

Remarks: For detailed results, please see the following page(s).

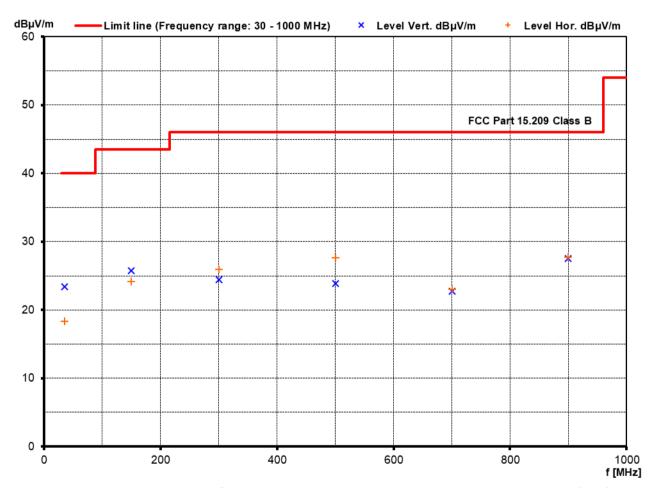
For description of the measurement see 4.5.2.

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



5.1.4 Test protocol

Frequency (MHz)	Reading Vert. (dBµV)	Reading Hor. (dBµV)	Correct. Vert. (dB)	Correct. Hor. (dB)	Level Vert. (dBµV/m)	Level Hor. (dBµV/m)	Limit (dBµV/m)	Dlimit (dB)
35.00	10.2	4.2	13.2	14.2	23.4	18.4	40.0	-16.6
150.00	9.3	8.	16.5	15.7	25.8	24.1	43.5	-17.7
300.00	7.2	8.2	17.2	17.7	24.4	25.9	46.0	-20.1
500.00	1.1	4.6	22.7	23.1	23.8	27.7	46.0	-18.3
700.00	-3.9	-4.3	26.7	27.3	22.8	23.0	46.0	-23.0
900.00	-2.3	-2.5	29.8	30.2	27.5	27.7	46.0	-18.3



Note: No emissions below 1 GHz were detected. Results above show noise values of the OATS.



5.2 Radiated emission > 1 GHz (electric field)

For test instruments and accessories used see section 6 Part SER 3.

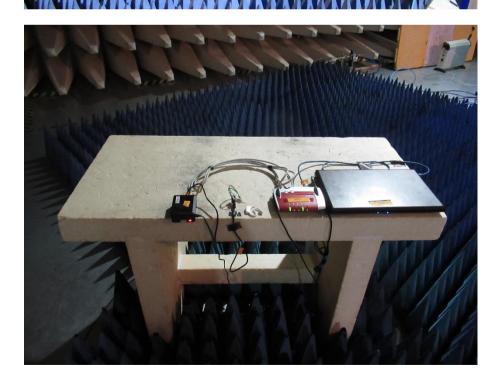
5.2.1 Description of the test location

Test location: Anechoic chamber 1

Test distance: 3 m

5.2.2 Photo documentation of the test setup







5.2.3 Test result

Frequency range: 1 GHz – 12.5 GHz Min. limit margin 3.67 dB @ 12.47 GHz

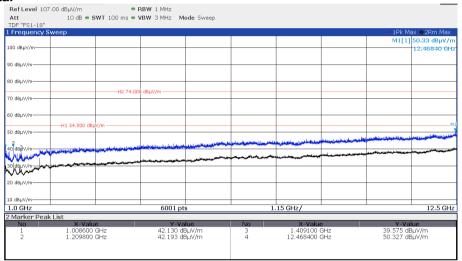
The requirements are **FULFILLED**.

Remarks: For detailed results, please see the following page(s).

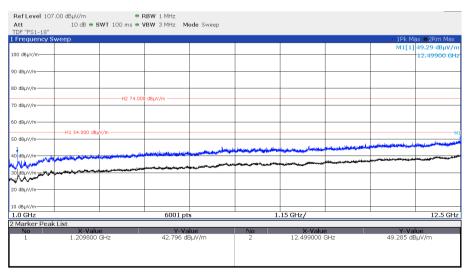
For description of the measurement see 4.5.2.

5.2.4 Test protocol

Antenna horizontal



Antenna vertical





6 USED TEST EQUIPMENT AND ACCESSORIES

All test instruments used, in addition to the test accessories, are calibrated and verified regularly.

Test ID	Model Type	Kind of Equipment	Manufacturer	Equipment No.	Next Calib.	Last Calib.	Next Verif. Last Verif.
A5	ESVS 30	EMI Test Receiver	Rohde & Schwarz München	02-02/03-05-006	15/07/2021	15/07/2020	
	VULB 9168	Trilog Broadband Antenn	Schwarzbeck Mess-Elektron	102-02/24-05-005	18/12/2021	18/12/2020	
	NW-2000-NB	RF Cable	Huber + Suhner	02-02/50-05-113			
	KK-EF393/U-16N-21N20 n	nRF Cable 20m	Huber + Suhner	02-02/50-12-018			
	KK-SD_7/8-2X21N-33,0M	RF Cable 33 m	Huber + Suhner AG	02-02/50-15-028			
SER 3	FSW43	Spectrum Analyser	Rohde & Schwarz München		02/04/2021	02/04/2020	
	AMF-6D-01002000-22-10F	•	MITEQ, Inc.	02-02/17-15-004			
	LNA-40-18004000-33-5P	Amplifier 18-40 GHz	0	02-02/17-20-002			
	3117	Horn Antenna 1 - 18 GH		02-02/24-05-009	18/06/2021	18/06/2020	
	BBHA 9170	SHF-EHF Horn Antenna	Schwarzbeck Mess-Elektron	102-02/24-05-013	19/05/2023	19/05/2020	04/02/2022 04/02/2021
	18N-20	Coax Attenuator 20dB	Tactron Elektronik	02-02/50-17-003			
	BAM 4.5-P	Antenna Mast	maturo GmbH	02-02/50-17-024			
	NCD	Controller for Antenna M	maturo GmbH	02-02/50-17-025			
	KK-SF106-2X11N-6,5M	RF Cable	Huber + Suhner	02-02/50-18-016			
	KMS116-GL140SE-KMS11	6 Cable DC-40GHz	GigaLane Co., Ltd.	02-02/50-20-026			
	BAT-EMC 3.19.1.24	Nexio Software	EMCO Elektronik GmbH	02-02/68-13-001			

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7 <u>Detailed measurement uncertainty</u>

7.1 Overview

Measurement instrumentation uncertainty shall be taken into account when determining compliance or non-compliance with a disturbance limit.

The measurement instrumentation uncertainty for a test laboratory shall be evaluated. The standard uncertainty u(x) in decibels and the sensitivity coefficient c_i shall be evaluated for the estimate x_i of each quantity. The combined standard uncertainty $u_c(y)$ of the estimate y of the measurand shall be calculated as

$$u_{\rm c}(y) = \sqrt{\sum_i c_i^2 \ u^2(x_i)}$$

The expanded measurement instrumentation uncertainty U_{lab} for a test laboratory shall be calculated as $U_{lab} = 2 u_{c}(y)$

$$U_{\text{lab}} = 2 u_{\text{c}}(y)$$

Compliance or non-compliance with a disturbance limit shall be determined in the following manner:

If U_{lab} is less than or equal to U_{cispr} in the table below, then:

- compliance is deemed to occur if no measured disturbance exceeds the disturbance limit;
- non-compliance is deemed to occur if any measured disturbance exceeds the disturbance limit.

If Ulab is greater than Ucisprin the table below, then:

- compliance is deemed to occur if no measured disturbance, increased by (Ulab Ucispr), exceeds the
 disturbance limit.
- non-compliance is deemed to occur if any measured disturbance, increased by (*U*_{lab} *U*_{cispr}), exceeds the disturbance limit.

7.2 Definitions and symbols

Xi Input quantity xi estimate of Xi

u(xi) standard uncertainty of xici sensitivity coefficient

 $u_c(y)$ (combined) standard uncertainty of y

Y result of a measurement, (the estimate of the measured), corrected for all recognised significant

systematic effects expanded uncertainty of y

7.3 Measurement uncertainty

Measurement	<i>U</i> _{lab} [dB]
Conducted disturbance	+ 2.53 / - 2.77
Radiated disturbance (electric field)	
 10 m test distance 	+ 3.16 / - 3.22
- 3 m test distance	+ 3.16 / - 3.22
 Frequency range: 30 MHz – 200 MHz 	
Radiated disturbance (electric field)	
 10 m test distance 	+ 4.51 / - 4.51
- 3 m test distance	+ 4.51 / - 4.51
 Frequency range: 200 MHz – 1000 MHz 	
Radiated disturbance (electric field)	
- 3 m test distance	+ 5.07 / -3.70
- Frequency range: 1 GHz – 30 GHz	

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