



RF - TEST REPORT

- FCC Part 15.249, RSS210 -

Type / Model Name : alfapump

Product Description : alfapump® System

Applicant : Sequana Medical NV

Address : Kortrijksesteenweg 1112

9051 SINT DENIJS WESTREM, BELGIUM

Manufacturer : Sequana Medical NV

Address : Technoparkstrasse 1

8005 ZÜRICH, SWITZERLAND

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

POSITIVE

Test Report No. : **80181315-00 Rev_0**

28. November 2024

Date of issue



Deutsche
Akkreditierungsstelle
D-PL-12030-01-00

FCC ID:2BDJN01473

IC ID:31649-01532

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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 15, Subpart A - General (September 2021)

Part 15, Subpart A, Section 15.31	Measurement standards
Part 15, Subpart A, Section 15.33	Frequency range of radiated measurements
Part 15, Subpart A, Section 15.35	Measurement detector functions and bandwidths

FCC Rules and Regulations Part 15, Subpart C - Intentional Radiators (September 2021)

Part 15, Subpart C, Section 15.203	Antenna requirement
Part 15, Subpart C, Section 15.204	External radio frequency power amplifiers and antenna modifications
Part 15, Subpart C, Section 15.205	Restricted bands of operation
Part 15, Subpart C, Section 15.207	Conducted limits
Part 15, Subpart C, Section 15.209	Radiated emission limits, general requirements
Part 15, Subpart C, Section 15.215	Additional provisions to the general radiated emission limitations
Part 15, Subpart C, Section 15.249	Operation within the bands 902 - 928 MHz, 2400 - 2483.5 MHz, 5725 - 5875 MHz, and 24.0 - 24.25 GHz

ANSI C63.10: 2013	Testing Unlicensed Wireless Devices
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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 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 General remarks

This report covers the emissions of the Module “CC1101” in combination with the host device “alfapump”.

Performed tests:

- RF output power, radiated
- Transmitter unwanted emissions, radiated

2.4 Photo documentation of the EUT – Detailed photos see attachment A

2.5 Equipment category

EUT is a short-range device.

2.6 Short description of the equipment under test (EUT)

Fully implantable, battery operated, medical device. It is programmable via the Smart Charger through wireless communication (TX frequency 907 MHz). The alfapump is designed to slowly and continuously transport ascites from the peritoneal cavity to the bladder, allowing the ascites to be eliminated from the body through normal urination. The ascetic fluid is transported according to a programmed schedule determined by the physician.

Number of tested samples: 1
 Serial number: 08563
 Firmware version: 11.00

EUT configuration:

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

2.7 Variants of the EUT

There are no variants.

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2.8 Operation frequency and channel plan

The operating frequency is 907 MHz.

2.9 Transmit operating modes

The EUT use GFSK and provide following data rate:

76.767 kbps (kbps = kilobits per second)

2.10 Antenna

The EUT has a customized antenna with no information of the Gain from the manufacturer.

2.11 Power supply system utilised

Power supply voltage, V_{nom} : 3.7V DC / Battery powered

2.12 Peripheral devices and interface cables

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

- _____ Model : - _____

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 further measurement the EUT is set in Y position.

2.13.1 Test jig

No test jig is used.

2.13.2 Test software

A special test software is used for setting TX continuous.



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3 TEST RESULT SUMMARY

FCC Rule Part	RSS Rule Part	Description	Result
15.205(a)	RSS-Gen, 8.10	Emissions in restricted bands	passed
15.207(a)	RSS-Gen, 8.8	AC power line conducted emissions	not applicable
15.215(c)	-	EBW	passed
-	RSS-Gen, 6.6	OBW	passed
15.249(a)	RSS-210, B10(a)	Field strength of fundamental	passed
15.249(d)	RSS-210, B10(b)	Out-of-band emission, radiated	passed
15.215	RSS-Gen, 8.11	Transmitter frequency stability	not applicable

The mentioned RSS Rule Parts in the above table are related to:
 RSS-Gen, Issue 5 + Amendment 1 + Amendment 2, March 2019
 RSS-210, Issue 11 June 2024

3.1 Revision history of test report

Test report No	Rev.	Issue Date	Changes
80181315-00	0	24 November 2023	Initial test report

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

3.2 Final assessment

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

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

Testing commenced on : 21 September 2023

Testing concluded on : 02 November 2023

Checked by:

Tested by:


 Klaus Gegenfurtner
 2024.11.28
 15:14:02 +01'00'

Klaus Gegenfurtner
 Teamleader Radio


 Laurin Roth
 2024.11.28 15:06:46
 +01'00'

Laurin Roth
 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:	<u>15 - 35 ° C</u>
Humidity:	<u>30 - 60 %</u>
Atmospheric pressure:	<u>86 - 106 kPa</u>

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.

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

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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.

4.5 Measurement protocol for FCC and ISCED**4.5.1 General information**

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

FCC: DE 0011
ISED: DE0009

4.5.2 General Standard information

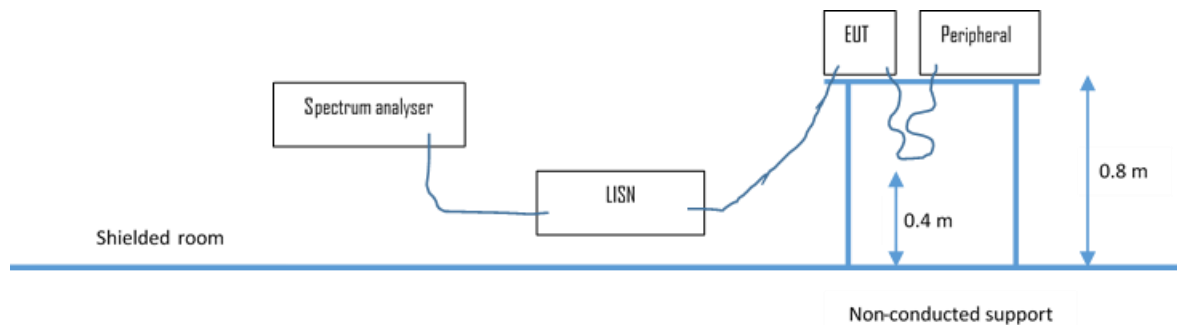
The test methods used comply with ANSI C63.10 - "Testing Unlicensed Wireless Devices".

4.5.2.1 Justification

The equipment under test (EUT) is configured in a typical user arrangement in accordance with the manufacturer's instructions.

4.5.3 Details of test procedures**4.5.3.1 Conducted emission**

Test setup according ANSI C63.10



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

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

$$\text{dB}\mu\text{V} = 20(\log \mu\text{V})$$

$$\mu\text{V} = \text{Inverse log}(\text{dB}\mu\text{V}/20)$$

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 $50 \Omega / 50 \mu\text{H}$ (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.

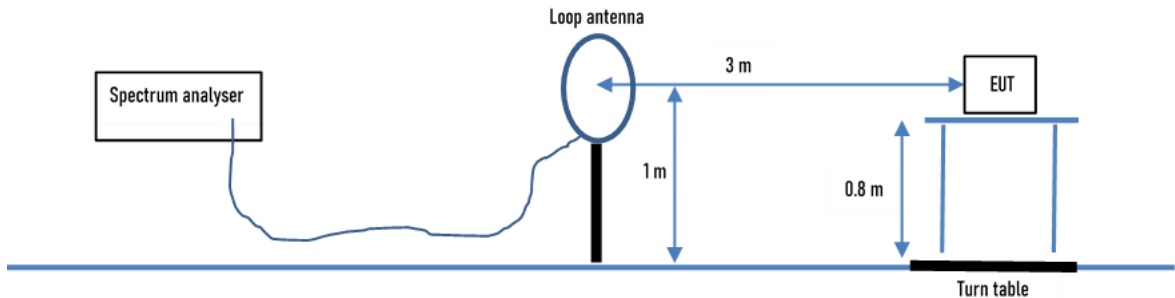
FCC ID:2BDJN01473

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4.5.3.2 Radiated emission

4.5.3.2.1 OATS1 test site (9 kHz - 30 MHz):

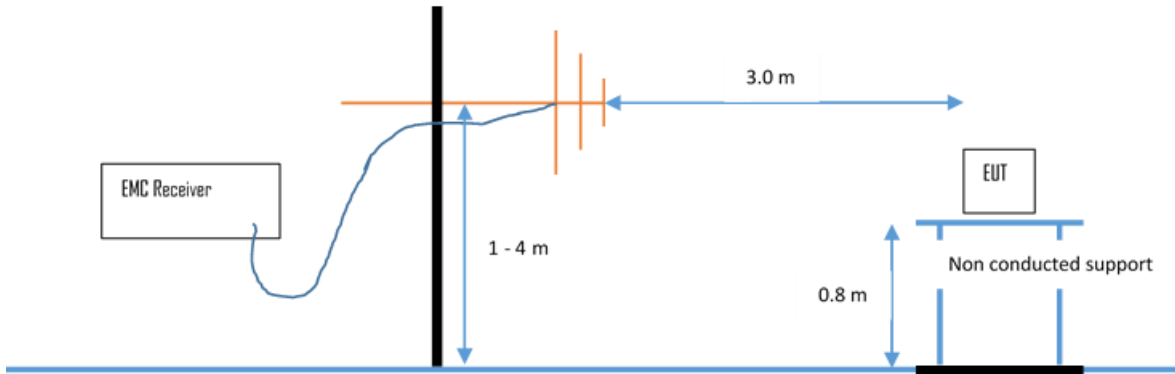
Test setup according ANSI C63.10



Emissions from the EUT are measured in the frequency range of 9 MHz to 30 MHz using a tuned receiver and a calibrated loop antenna. Table top equipment is placed on a 1.0 X 1.5 m non-conducting table 80 centimetres above 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, 10 or 30 metres horizontally from the EUT and is repeated vertically. To locate maximum emissions from the test sample the antenna is varied along the site axis and the EUT is rotated 360 degrees.

4.5.3.2.2 OATS1 test site (30 MHz - 1 GHz):

Test setup according ANSI C63.10.



Spurious emissions from the EUT are measured in the frequency range of 30 MHz to 1000 MHz using a tuned receiver and appropriate broadband linearly polarised 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 m non-conducting table 80 centimetres above the ground plane. Floor standing equipment is placed directly on the turntable/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. To locate maximum emissions from the test sample the antenna is varied in height from 1 to 4 metres and the EUT is rotated 360 degrees. The final level in dBµV/m is calculated by taking the reading from the EMI receiver (Level dBµV) and adding the correction factors and cable loss factor (dB). The FCC limit is subtracted from this result in order to provide the limit margin listed in the measurement protocol.

The resolution bandwidth setting:

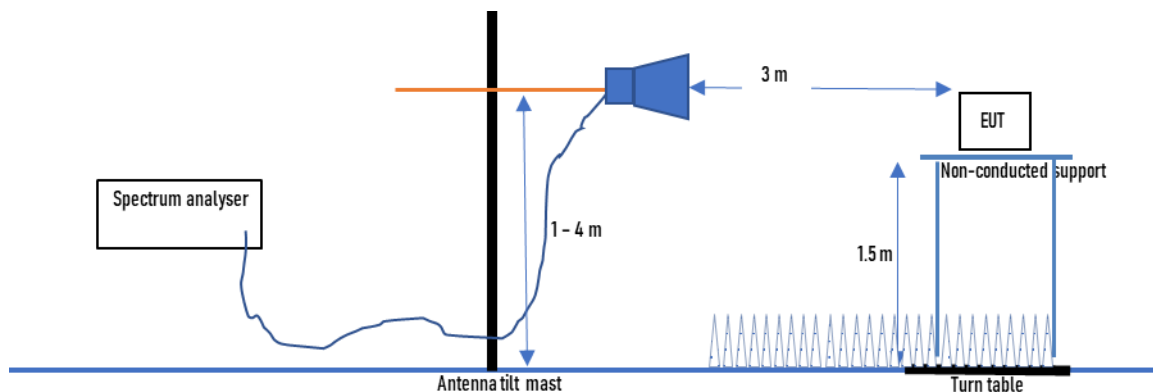
30 MHz – 1000 MHz: RBW: 120 kHz

Example:

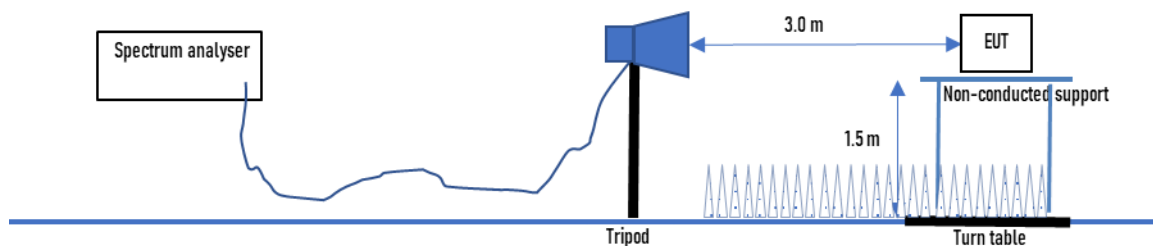
Frequency (MHz)	Level (dBµV)	+	Factor (dB)	=	Level (dBµV/m)	-	Limit (dBµV/m)	=	Delta (dB)
719.0	75.0	+	32.6	=	107.6	-	110.0	=	-2.4

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Test setup according to ANSI C63.10.



Radiated emissions from the EUT are measured in the frequency range 1 GHz up to 18 GHz as specified in 47 CFR Part 15, Subpart A, Section 15.33, using a spectrum analyser and appropriate linearly polarized antennas. Table top equipment is placed on a non-conducting table, 1.5 metre above the ground plane. The turntable is fully covered with the appropriate absorber (Type VHP-12). Any controlling device is positioned such that it does not significantly influence the measurement results. Interconnecting cables that hang closer than 40 cm to the ground plane are folded back and forth in the centre, forming a bundle 30 cm to 40 cm long. Measurements are made in three orientations of the EUT and the horizontal and vertical polarization planes of measurement antenna in a fully anechoic room. The measurement antenna is adjusted and the EUT orientated to permit the measurement of the maximum emission from the EUT. The conditions determined as worst-case will then be used for the final measurements.

4.5.3.2.4 Anechoic chamber 1 (18 GHz – 40 GHz)

Emissions from the EUT are measured in the frequency range 18 GHz up to 40 GHz as specified in 47 CFR Part 15, Subpart A, Section 15.33, using a spectrum analyser and appropriate linearly polarized antennas. Table top equipment is placed on a non-conducting table, 0.8 metre above the ground plane. The turntable is fully covered with the appropriate absorber (Type VHP-12). Any controlling device is positioned such that it does not significantly influence the measurement results. Interconnecting cables that hang closer than 40 cm to the ground plane are folded back and forth in the centre, forming a bundle 30 cm to 40 cm long. Measurements are made in three orientations of the EUT and the horizontal and vertical polarization planes of measurement antenna in a fully anechoic room. The measurement antenna is adjusted and the EUT orientated to permit the measurement of the maximum emission from the EUT. The conditions determined as worst-case will then be used for the final measurements. Where appropriate, the test distance may be reduced in order to detect emissions under better uncertainty. The limit is adopted.

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5 TEST CONDITIONS AND RESULTS

5.1 Field strength of fundamental

For test instruments and accessories used see section 6 Part **CPR 2**.

5.1.1 Description of the test location

Test location: OATS 1
Test distance: 3 m

5.1.2 Photo documentation of the test set-up: Detailed photos see attachment B

5.1.3 Applicable standard

According to FCC Part 15C, Section 15.249(a):

The field strength of emissions from intentional radiators operated within these frequency bands shall comply with the effective limits.

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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5.1.4 Description of Measurement

The radiated emission of the fundamental wave from the EUT is measured using a spectrum analyser and appropriate linear polarized antennas. The setup of the EUT and the measurement procedure is in accordance to ANSI C63.10, Item 6.5. The EUT is measured in TX continuous mode unmodulated under normal conditions with a Quasi-peak detector.

5.1.5 Test result

Frequency (MHz)	QP reading Vert. (dBµV)	QP reading Hor. (dBµV)	Correct. Vert. (dB)	Correct. Hor. (dB)	QP level Vert. (dBµV/m)	QP level Hor. (dBµV/m)	QP Limit (dBµV/m)	Dlimit (dB)
907,028	51,7	46,7	33,0	33,5	84,7	80,2	94,0	-9,3

Note: The correction factor includes cable loss and antenna factor.

Limit according to FCC Part 15C, Section 15.249(a):

Frequency (MHz)	Field strength of fundamental	
	(mV/m)	dB(µV/m)
902 - 928	50	94
2400 - 2483.5	50	94
5725-5875	50	94
24000 - 24250	250	108

The requirements are **FULFILLED**.

Remarks: None.

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For test instruments and accessories used see section 6 Part **SER1, SER 2, SER 3**.

5.2.1 Description of the test location

Test location: OATS 1
Test location: Anechoic chamber 1
Test distance: 3 m

5.2.2 Photo documentation of the test set-up: Detailed photos see attachment B

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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5.2.3 Applicable standard

According to FCC Part 15C, Section 15.249 (d):

Emission radiated outside of the specified frequency bands, except harmonics, shall be attenuated by at least 50 dB below the level of the fundamental or to the general radiated limit in FCC Part 15C, Section 15.209, whichever is the lesser attenuation.

5.2.4 Description of Measurement

The radiated emissions from the EUT are measured in the frequency range of 9 kHz to 1000 MHz using a tuned receiver and appropriate broadband linearly polarized antennas. The setup of the EUT and the measurement procedure is in accordance to ANSI C63.10, Item 6.3. In the frequency range above 1 GHz a spectrum analyser is used with appropriate linear polarized antennas. If the emission level in peak mode complies with the average limit testing is stopped and peak values will be reported, otherwise, the emission is measured in average mode again and reported. The EUT is measured in TX continuous mode unmodulated under normal conditions.

Instrument settings:

9 kHz – 150 kHz	RBW:	200 Hz
150 kHz - 30 MHz	RBW:	9 kHz
30 MHz – 1000 MHz:	RBW:	120 kHz
1000 MHz – 25 GHz	RBW:	1 MHz

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5.2.1 Test result f < 30 MHz

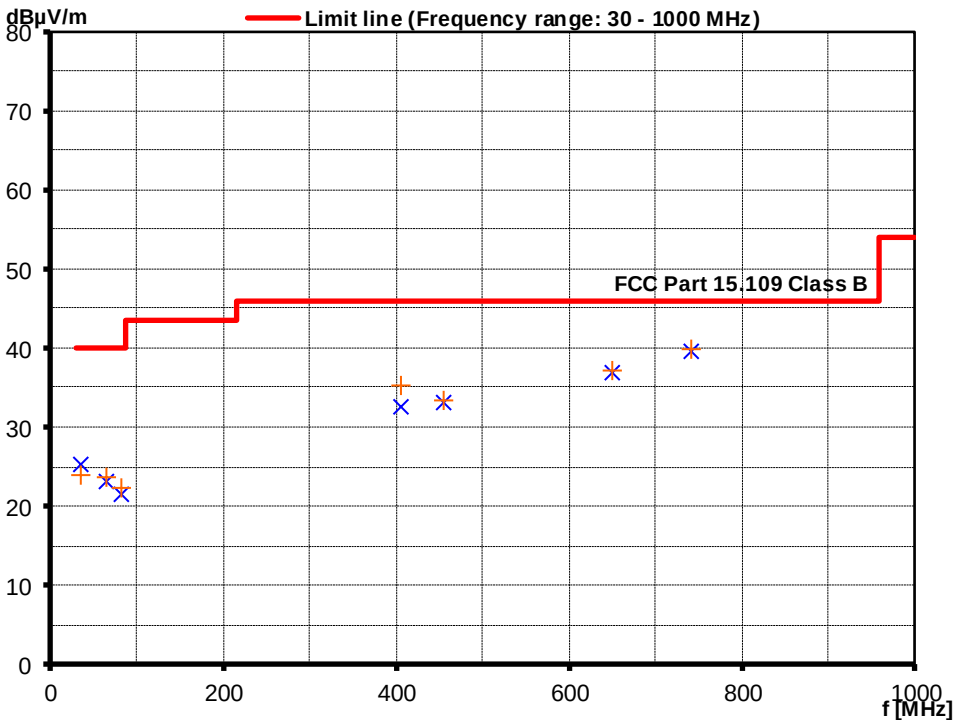
Note: In the frequency range 9 kHz to 30 MHz no emission could be detected. The frequencies mention the noise level. The measurement results from distance 3 m are extrapolated (D factor) to the specified distance.

f [kHz]	PK reading [dBμV]	QP reading [dBμV]	Duty cycle corr. [dB]	Ant. factor [dB]	Distance corr. [dB]	corr. AV level [dBμV/m]	QP level [dBμV/m]	Limit [dBμV/m]	Margin [dB]
10,000	46,7	40,7	0,0	20,0	-80,0	-13,3	-19,3	47,6	-60,9
50,000	37,5	35,3	0,0	20,0	-80,0	-22,5	-24,7	33,6	-56,1
200,000	40,2	39,1	0,0	20,0	-80,0	-19,8	-20,9	21,6	-41,4
5000,000	25,0	23,3	0,0	20,0	-40,0	5,0	3,3	29,5	-26,2
20000,000	20,3	19,9	0,0	20,0	-40,0	0,3	-0,1	29,5	-29,6

5.2.2 Test result f < 1 GHz

Note: In the frequency range 30 MHz to 1000 MHz no emission could be detected. The frequencies mention the noise level.

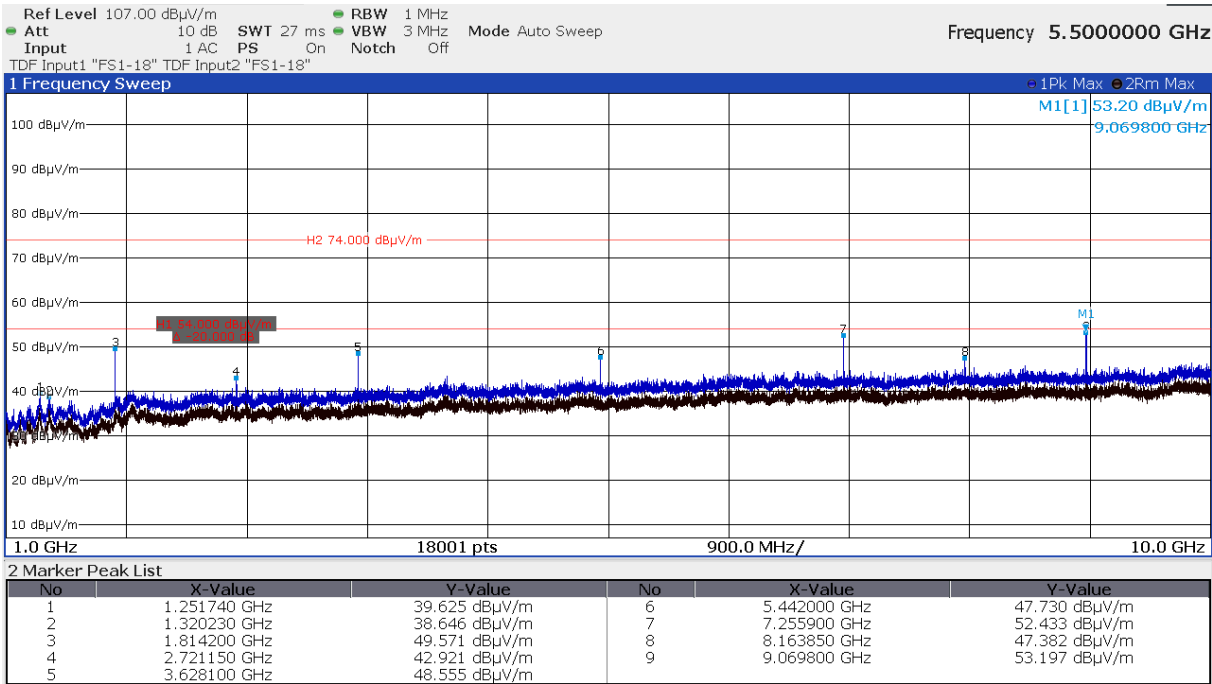
Frequency (MHz)	Reading Vert. (dBμV)	Reading Hor. (dBμV)	Correct. Vert. (dB)	Correct. Hor. (dB)	Level Vert. (dBμV/m)	Level Hor. (dBμV/m)	Limit (dBμV/m)	Dlimit (dB)
35,50	9,0	6,5	16,3	17,4	25,3	23,9	40,0	-14,7
65,50	6,6	6,5	16,4	17,1	23,0	23,6	40,0	-16,4
84,00	7,7	8,6	13,8	13,7	21,5	22,3	40,0	-17,7
408,00	9,1	11,4	23,5	23,8	32,6	35,2	46,0	-10,8
455,50	8,4	8,3	24,7	25,0	33,1	33,3	46,0	-12,7
652,00	7,8	7,7	29,1	29,5	36,9	37,2	46,0	-8,8
744,00	9,0	8,8	30,6	31,0	39,6	39,8	46,0	-6,2



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5.2.3 Test result f > 1 GHz



Limit according to FCC Part 15C, Section 15.209:

Frequency (MHz)	15.209 Limits (µV/m)	Measurement distance (m)
0.009 - -0.49	2400/f(kHz)	300
0.49 – 1.705	24000/f(kHz)	30
1.705 – 30.0	30	30
30 - 88	100	3
88 - 216	150	3
216 - 960	200	3
Above 960	500	3

Average limit according to FCC Part 15C, Section 15.249(a):

Fundamental frequency (MHz)	Field strength of harmonics	
	(µV/m)	dB(µV/m)
902 - 928	500	54
2400 - 2483.5	500	54
5725 - 5875	500	54
24000 - 24250	2500	68

The requirements are **FULFILLED**.

Remarks: The measurement was performed up to the 10th harmonic (10000 MHz). For detailed test result please refer to following test protocols.



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5.3 EBW and OBW

For test instruments and accessories used see section 6 Part MB.

5.3.1 Description of the test location

Test location: AREA4

5.3.2 Photo documentation of the test set-up : Detailed photos see attachment B

5.3.3 Applicable standard

According to FCC Part 15, Section 15.215(c):
Intentional radiators operating under the alternative provisions to the general emission limits, as contained in Section 15.217 through Section 15.257, must be designed to ensure that the 20 dB bandwidth of the emission is contained within the frequency band designated in the rule section under which the equipment is operated.

5.3.4 Description of Measurement

The bandwidth is measured at an amplitude level reduced from the reference level by a specified ratio of -20 dB (99%). The x-dB-down (OBW) function of the analyser is used. The measurement is performed with normal modulation in TX continuous mode.

Spectrum analyser settings:
RBW: 3 kHz, VBW: 10 kHz, Span: 500 kHz, Trace mode: max. hold, Detector: max. peak;

5.3.5 Test result

Operating frequency band (MHz)	20 dB Bandwidth (kHz)
907.028	87.21

Limit according to FCC Part 15C, Section 15.215(c):
If frequency stability is not specified in the regulations, it is recommended that the fundamental emission be kept within the central 80% of the permitted band in order to minimize the possibility of out-of-band operation. Due to the channelizing of the operating band into 16 channels with channel bandwidth of 5 MHz the limit central 80% of the permitted band cannot be applied. Therefore, the stability of the EUT will be shown staying within the central 80% of the operating channel.

The requirements are **FULFILLED**.

Remarks: For detailed test result please refer to following test protocols.
The OBW99 is measured for RSS only.



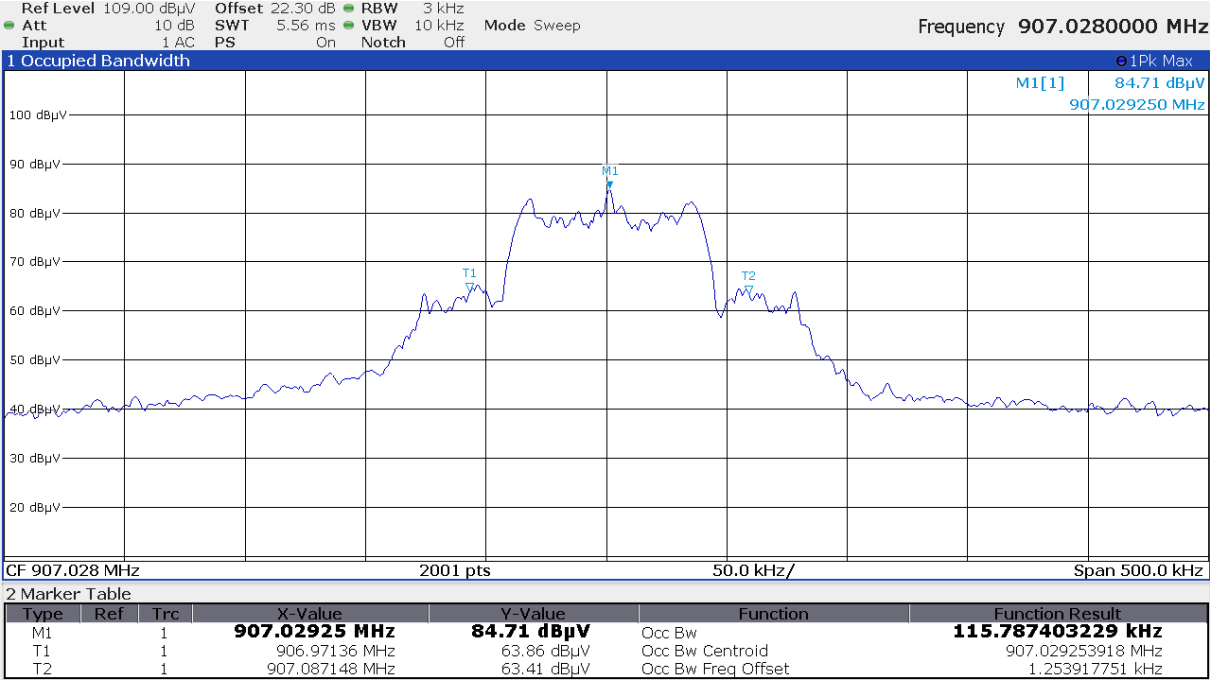
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5.3.6 Test protocols

20 dB bandwidth



OBW 99%



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5.4 Antenna application

5.4.1 Applicable standard

According to FCC Part 15C, Section 15.203(a):

An intentional radiator shall be designed to ensure that no antenna other than that furnished by the responsible party shall be used with the device. The use of a permanently attached antenna or of an antenna that uses a unique coupling to the intentional radiator shall be considered sufficient to comply with the provisions of this Section.

5.4.2 Result

The EUT use an integrated PCB antenna. No other antenna than that furnished by the responsible party or external power amplifier can be applied by a customer.

The antenna of the EUT meets the requirement of FCC Part 15C, Section 15.203 and 15.204.

The requirements are **FULFILLED**.

Remarks:



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6 USED TEST EQUIPMENT AND ACCESSORIES

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

Test ID	Model Type	Equipment No.	Next Calib.	Last Calib.	Next Verif.	Last Verif.
CPR 2	ESR 7	02-02/03-17-001	01/08/2024	01/08/2023		
	VULB 9168	02-02/24-05-005	20/04/2024	20/04/2023	03/05/2024	03/05/2023
	NW-2000-NB	02-02/50-05-113				
	KK-EF393/U-16N-21N20 m	02-02/50-12-018				
	KK-SD_7/8-2X21N-33,0M	02-02/50-15-028				
	50F-003 N 3 dB	02-02/50-21-010				
MB	FSW43	02-02/11-15-001	04/05/2024	04/05/2023		
SER 1	FSW43	02-02/11-15-001	04/05/2024	04/05/2023		
	HFH 2 - Z 2	02-02/24-05-020	01/06/2025	01/06/2022	05/09/2024	05/09/2023
	KK-EF393/U-16N-21N20 m	02-02/50-12-018				
	KK-SD_7/8-2X21N-33,0M	02-02/50-15-028				
SER 2	ESVS 30	02-02/03-05-006	27/07/2024	27/07/2023		
	VULB 9168	02-02/24-05-005	20/04/2024	20/04/2023	03/05/2024	03/05/2023
	NW-2000-NB	02-02/50-05-113				
	KK-EF393/U-16N-21N20 m	02-02/50-12-018				
	KK-SD_7/8-2X21N-33,0M	02-02/50-15-028				
	50F-003 N 3 dB	02-02/50-21-010				
SER 3	FSW43	02-02/11-15-001	04/05/2024	04/05/2023		
	AMF-6D-01002000-22-10P	02-02/17-15-004				
	3117	02-02/24-05-009	12/07/2024	12/07/2023		
	BAM 4.5-P	02-02/50-17-024				
	NCD	02-02/50-17-025				
	KK-SF106-2X11N-6,5M	02-02/50-18-016				
	BAT-EMC 2022.0.23.0	02-02/68-13-001				

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.