

TEST REPORT

No. AR18-0032697-01

performed in accordance with

FCC Rules: Code of Federal Regulations (CFR) no. 47
Part 15 Subpart C Section 15.207 and 15.209

PRODUCT	Physiological Signal Based Seizure Monitoring System
MODEL TESTED	EMBRACE (VARIANT EM2-FP-S)
TYPE REFERENCE	EMBRACE2
FCC ID	2AGGH-EMB
TRADE MARK(s)	EMPATICA

APPLICANT	EMPATICA S.r.l. – Via Stendhal 36, 20144 Milano - IT
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Tested by	Luigi Panzeri [Laboratory Technician]	 cosign
Approved by	Di Turi Giovanni [Laboratory manager]	 cosign

Revision Sheet

Release No.	Date	Revision Description
Rev. 0	2018-11-13	First edition: Digital signed - AR18-0032697-01_EMPATICA_Physiological Monitoring System _EMBRACE EM2-FP-S_FCC 47 section 15.207 and 15.209
Rev. 1	2018-12-06	Second edition: <i>The EUT's block diagram has been removed from the test report (see page 2 "REMARKS").</i> Digital signed - AR18-0032697-01_Rev.1_EMPATICA_Physiological Monitoring System _EMBRACE EM2-FP-S_FCC 47 section 15.207 and 15.209

The results of tests and checks reported in this Test Report refer exclusively to the samples tested and described in the Report itself.
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1. GENERAL DATA

SAMPLE		
Samples received on	2018-11-07	(Item(s) sampled and sent by applicant)
IMQ reference samples	BEM	93130
Samples tested No.	1	
Object under analysis recognition	Not carried out Except where stated, characteristics of products were taken from client description and were not verified by the laboratory	
Date of acceptance of test item	2018-11-07	
TEST LOCATION		
Testing dates	2018-11-13	
Testing laboratory.	IMQ S.p.A. - Via Quintiliano, 43 – I-20138 Milano	
Testing site	Via Quintiliano, 43 – I-20138 Milano	
Date of acceptance of test item	2018-11-07	
ENVIRONMENTAL CONDITIONING		
Parameter	Measured	
Ambient Temperature	25 ÷ 35 °C	
Relative Humidity	50 ÷ 60 %	
Atmospheric Pressure	900 ÷ 1000 mbar	
The laboratory is monitored by a continuous environmental conditions measurements system. Temperature, humidity and pressure data are recorded on a weekly basis and stored in local archive.		
REMARKS		
Throughout this report a point is used as the decimal separator. The ability or reliability of this product to perform its intended function in a particular application has not been investigated. Unless otherwise specified, warnings, installation instruction and/or user manual provided with the sample have been checked in Italian or English version only. IMQ declines any responsibility derived from missing or wrong information provided aside by the applicant. <i>Revision 1:</i> <i>The original test report AR18-0032697-01 dated 2018-11-13 was modified on date 2018-12-06 in order to delete the EUT's block diagram from page 4.</i>		

2. REFERENCE DOCUMENT

	DOCUMENT	DATE	TITLE
☒	47 CFR Part 15	2015	Radio Frequency 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
☒	ANSI C63.10	2013	American National Standard for Testing Unlicensed Wireless Devices

3. UNIT UNDER TEST (EUT) DETAILS

GENERAL DATA

MODEL (basic)	Description
EMBRACE (VARIANT EM2-FP-S) - s/n 2KKV11111L -	Medical device to monitoring physiological signals (smartwatch). The product is a wearable biosensor device that can capture, store, and wirelessly transmit sensor data via Bluetooth to a paired remote device. The device runs an on-board algorithm to continuously process sensor data and make a decision about whether the data might indicate a generalized tonic-clonic seizure (GTCS). When a likely GTCS is detected, the device sends a message to the Alert smartphone application, which initiates calls and texts to summon the attention of designated caregivers. Embrace2 represents a little evolution of the previous version, that introduces the following modifications: - cosmetic modification to the front face: the logo is engraved instead of printed, and hour dots are added - introduction of a battery connector, that replaces manual wire soldering - introduction of a battery gauge to estimate battery charge in a more reliable way - minor circuit modification that reduced power consumption - increase in battery charging current
VARIANTS (derived)	Description
EMBRACE (VARIANT EM2-MB-S _ EM2-BB-S _ EM2-SG-S _ EM2-SB-S)	As EMBRACE (VARIANT EM2-FP-S) with different color case and stretchable band (see ANNEX A for details)

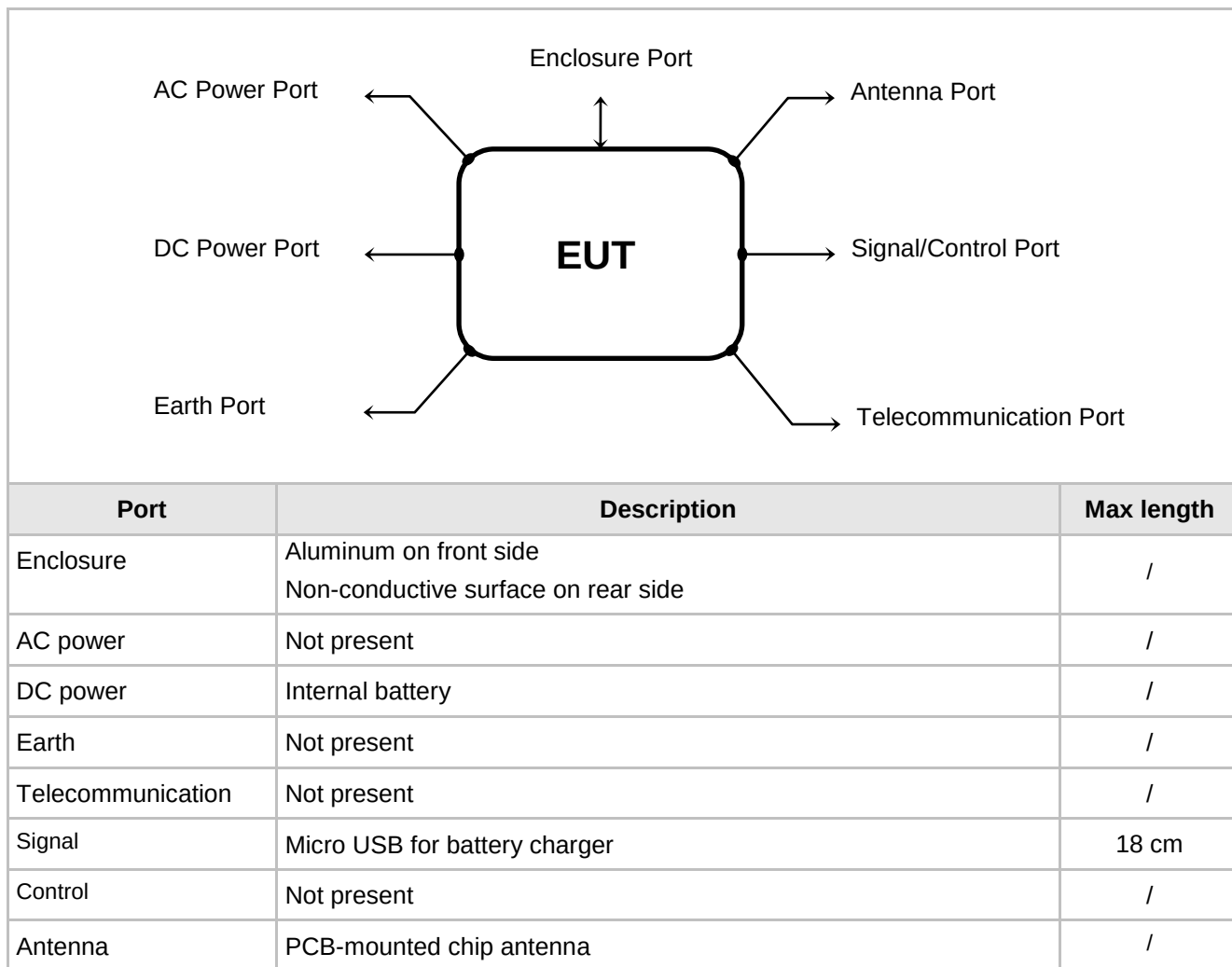
FCC ID	2AGGH-EMB
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Manufacturer	EMPATICA S.r.l. – Via Stendhal 36, 20144 Milano - IT
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Type of equipment	Medical equipment with Bluetooth Radio module
Operating frequency	2402 ÷ 2480 MHz
Max RF radiated power	dBµV/m @3m
Modulation	GFSK
Channel	40 channel, 2MHz spaced from 2402 to 2480MHz
Antenna	TDK - ANT016008LCS2442MA2 (Dedicated)
Interfaces	Micro USB for battery charger (18 cm)
Power supply type :	DC 3.7V (internal battery)

4. TEST CONFIGURATION OF UNIT UNDER TEST

EUT PORTS



STATE OF THE EUT DURING TESTS

Ref.	Mode	Description
#1	Operating	Data communication from device to smartphone
#2	Charging	EUT connected via Micro USB to portable Personal Computer

SUPPORT EQUIPMENT

Defined as equipment needed for correct operation or loading of the EUT, but not considered as tested:

Equipment	Manufacturer	Model
Personal Computer	TOSHIBA	SATELLITE PRO L770-11F

ELECTROMAGNETICALLY RELEVANT COMPONENTS

Component	No.	Manufacturer	Model
U12 (Microcontroller with RF Bluetooth module)	1	Toshiba	TZ1031MBG
ANT1 (antenna)	1	TDK	ANT016008LCS2442MA2
X1	1	/	12.000 MHz quartz
X2	1	/	26.000 MHz quartz

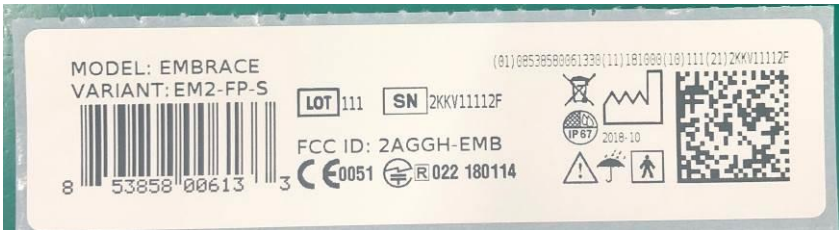
EMI PROTECTION DEVICES

Component	No.	Manufacturer	Model
DLM11GN601SD2D	1	MURATA	Common Mode Choke Coil
BLM15PD121SN1D	2	MURATA	CHIP FERRITE BEAD
ESD9R3.3ST5G	3	ONSEMI	Transient Voltage Suppressors
ESD9X5.0ST5G	1	ONSEMI	Transient Voltage Suppressors
ESD9X7.0ST5G	1	ONSEMI	Transient Voltage Suppressors

OSCILLATOR FREQUENCIES

Frequency (MHz)	Description	Frequency (MHz)	Description
26	Main Board	0.032768	Main Board
12	Main Board	/	/

EUT TECHNICAL DOCUMENTATION

Document	Reference
Labels	
	
	
	
	

5. METHODS OF MEASUREMENT

All compliance measurements have been carried out using the procedures described in the standard ANSI C63.4:2014, ANSI C63.10:2013 and Section 15.31 of CFR47 Part 15 – Subpart A (General).

Additional test requirements have been adopted according to the reference Section indicated in the § 6 of this test report.

FREQUENCY RANGE INVESTIGATED

Conducted emission tests : from 150 kHz to 30 MHz.

Radiated emission tests: from 9 kHz to tenth harmonic of fundamental

6. SUMMARY OF TEST RESULTS

POSSIBLE TEST CASE VERDICTS:	
Test object meets the requirement	PASS
Test object does not meet the requirement	FAIL
Test case does not apply to the test object	N.A.
Test not performed	N.P.

CFR47 Part 15	TITLE	RESULT
§ 15.207	Conducted emission	PASS
§ 15.209	Radiated disturbances	PASS

Note 1	/
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7. TEST RESULTS

7.1 CONDUCTED EMISSION

TEST REQUIREMENT	
Test setup	ANSI C63.4
Frequency range	150 kHz ÷ 30 MHz
IF bandwidth	9 kHz
EMC class	B
EUT operating condition	#2
Remark	Operating conditions #2; Test performed at AC Mains of Toshiba Personal Computer.
Testing dates	2018-11-13

TEST RESULT
The EUT meets the requirements of sections 15.207.

Port	Frequency (MHz)	Limit for Class B	Results
AC mains	0.15 ÷ 0.5	66 ÷ 56 dB(μV/m) Quasi-Peak ^(*)	PASS
		56 ÷ 46 dB(μV/m) Average ^(*)	PASS
	0.5 ÷ 5	56 dB(μV/m) Quasi-Peak	PASS
		46 dB(μV/m) Average	PASS
	5 ÷ 30	60 dB(μV/m) Quasi-Peak	PASS
		50 dB(μV/m) Average	PASS

^(*) limit decreases linearly with Log. Frequency

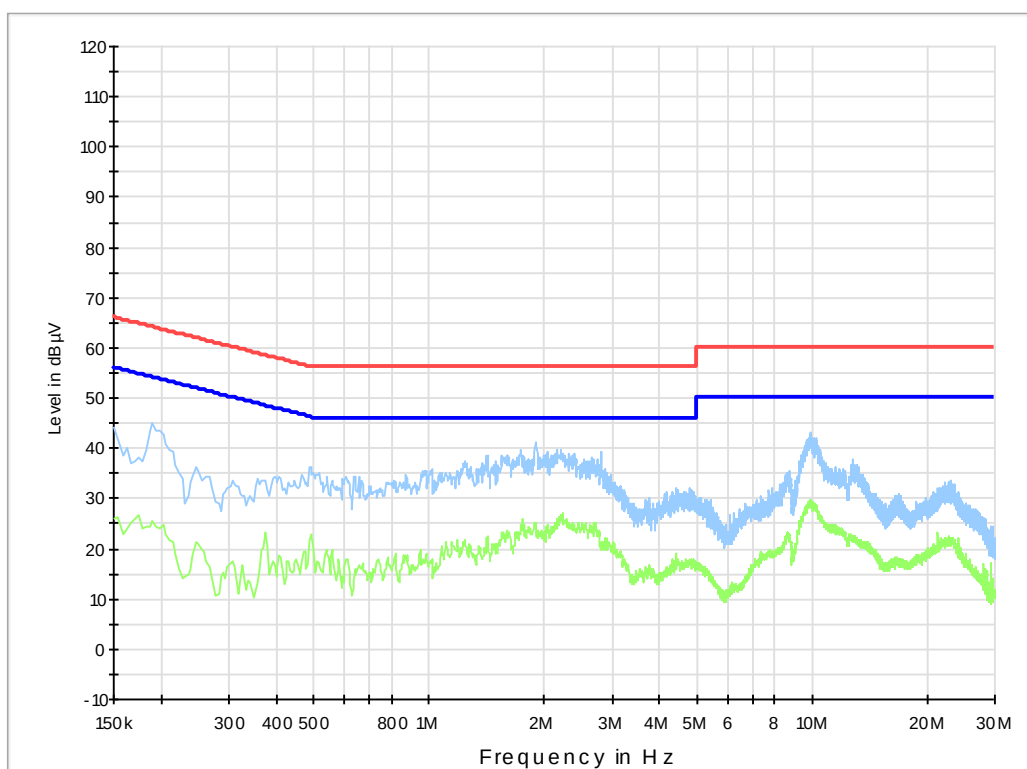
TEST PROCEDURE

- 1) The EUT was placed on a wooden table of size, 80 cm by 80 cm, raised 80 cm in which is located 40 cm away from the vertical wall the shielded room.
- 2) Each EUT power cord input cord was individually connected through a 50 Ω /50 μ H LISN to the input power source.
- 3) Exploratory measurements were made to identify the frequency of the emission that had the highest amplitude relative to the limit by operating the EUT in a range of typical modes of operation, cable position, and with a typical system equipment configuration and arrangement. Based on the exploratory tests of the EUT, the one EUT cable configuration and arrangement and mode of operation that had produced the emission with the highest amplitude relative to the limit was selected for the final measurement.
- 4) The final test on all current-carrying conductors of all of the power cords to the equipment that comprises the EUT (but not the cords associated with other non-EUT equipment is the system) was then performed over the frequency range of 0.15 MHz to 30 MHz.
- 5) The measurements were made with the detector set to PEAK and AVERAGE amplitude within a bandwidth of 10 kHz during the measurements.
- 6) The measurements with Quasi-Peak detector are performed only for frequencies for which the Peak values are $\geq$ (Q.P. limit - 6 dB).

MEASUREMENTS RESULTS

Port: AC MAINS POWER PORT OF PERSONAL COMPUTER

Line: PHASE



7.2 RADIATED DISTURBANCES

TEST REQUIREMENT	
Test setup	ANSI C63.4
Test facility	Semi-anechoic chamber
Test distance	3 meters
Frequency range	9 kHz to tenth harmonic of fundamental
IF bandwidth (below 30 MHz)	9 kHz
IF bandwidth (below 1,000 MHz)	120 kHz
IF bandwidth (above 1,000 MHz)	1 MHz
Deviation to test procedure	None
Limits	sections 15.209 (a)
EUT operating condition	#1, #2
Remark	(*) In accordance with part 15.31 (f) (2), where the measurement distance was specified to be 30 or 300 meters, a correction factor was applied in order to permit measurement to be performed at a separation distance. The applied formula for limits at 3 meter is: Extrapolation (dB) = $40\log(300\text{meter} / 3\text{meter}) = +80\text{db}$ Extrapolation (dB) = $40\log(30\text{meter} / 3\text{meter}) = +40\text{db}$
Testing dates	2018-11-13

LIMITS		
Band of operations	Peak (dBμV/m)	Average Limit (dBμV/m)
Restricted bands (§ 15.205)	74	54
Other bands	According to 15.209 or fundamental −20dB (which is greater)	According to 15.209 or fundamental −20dB (which is greater)

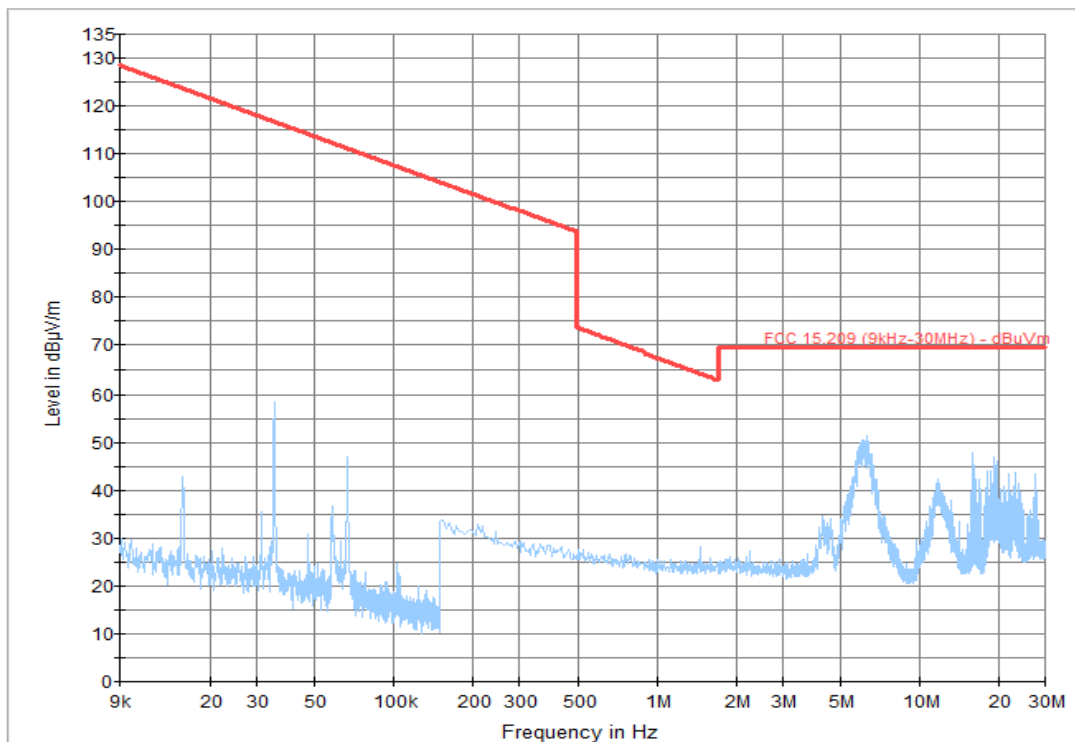
TEST PROCEDURE
1) The EUT was placed on turntable which is 0.8 m above the ground plane 2) The turntable shall rotate from 0° to 360° degrees to determine the position of maximum emission level. 3) The EUT is positioned 3 m away from the receiving antenna which varied from 1 to 4 m to find the highest emission. 4) The measurements were made with the detector set to PEAK and AVERAGE amplitude within a bandwidth of 100 kHz below 1000 MHz and 1 MHz above 1000 MHz. 5) The receiving antenna was positioned in both horizontal and vertical polarization. 6) The measurements with Quasi-Peak detector, below 1000 MHz are performed only for frequencies for which the Peak values are $\geq$ (Q.P. limit − 6 dB).

TEST RESULT
The EUT meets the requirements of sections 15.209.

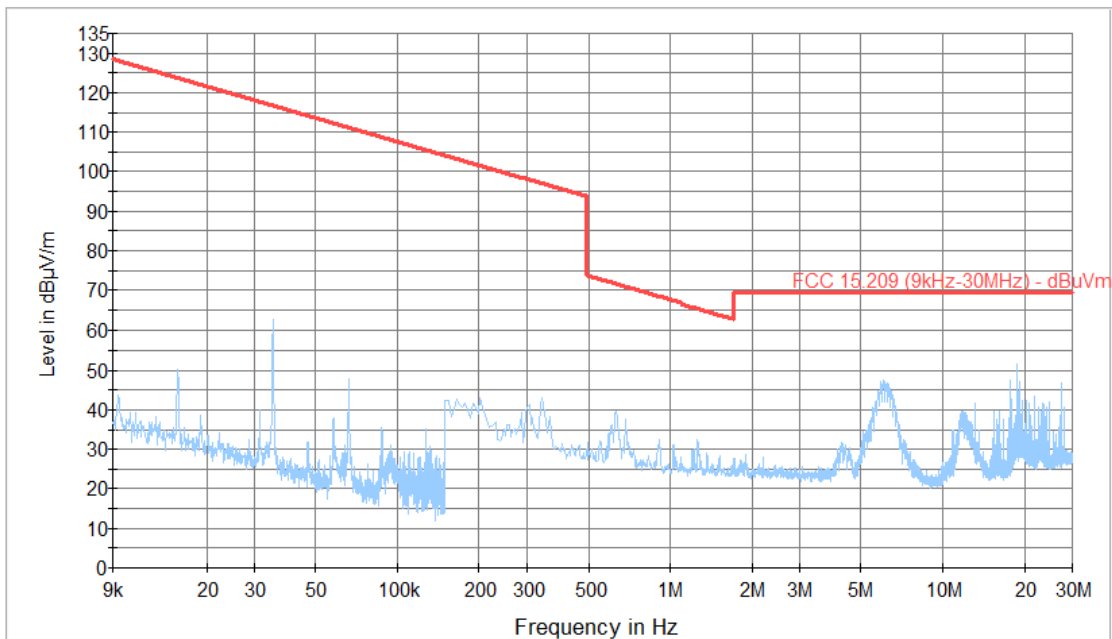
MEASUREMENTS RESULTS

Range: 9KHz ÷ 30 MHz

Operating mode #1

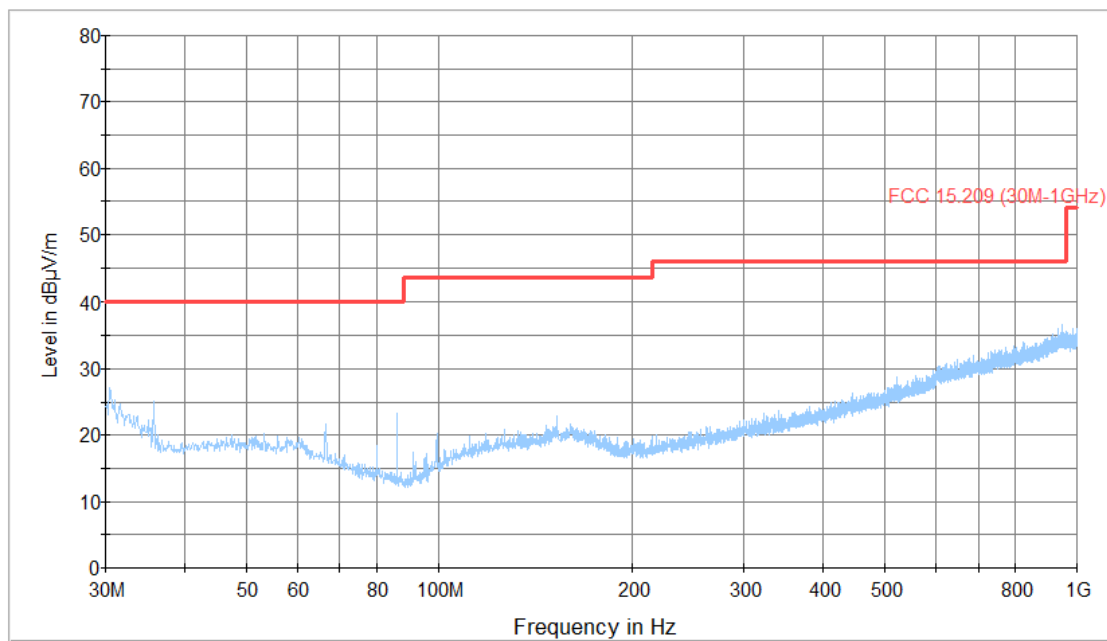


Operating mode #2

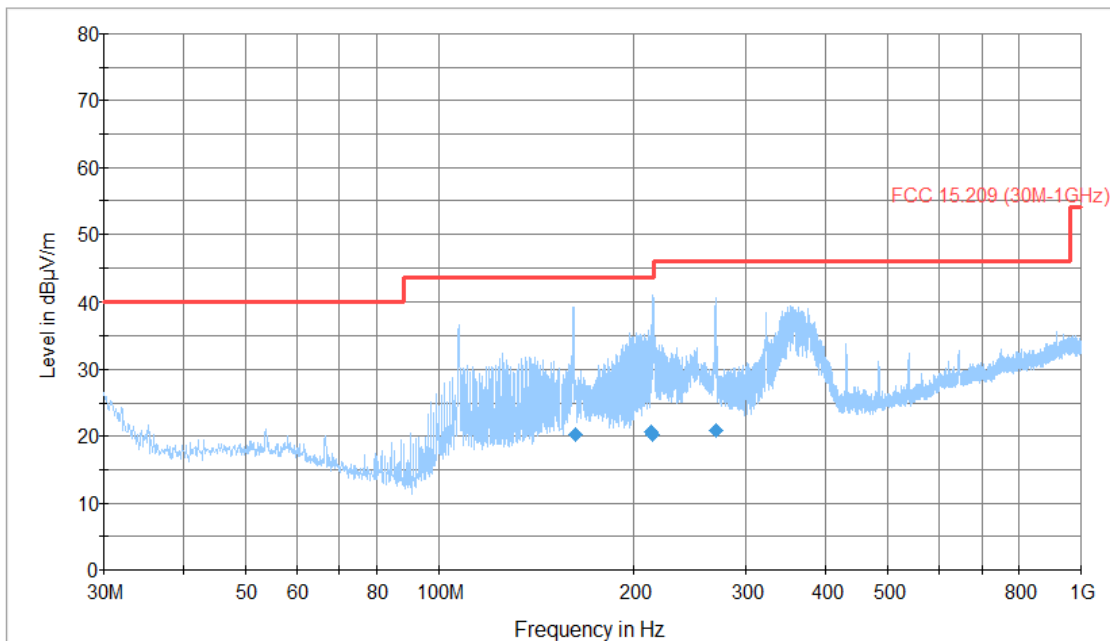


Range: 30 ÷ 1000 MHz

Operating mode #1



Operating mode #2



Frequency MHz	QuasiPeak dBµV/m	Meas. Time ms	Bandwidth kHz	Height cm	Polarization	Azimuth deg	Corr. dB	Margin dB	Limit dBµV/m
162.420500	20.2	1000.0	120.000	150.0	H	274.0	15.0	23.30	43.50
162.460500	20.2	1000.0	120.000	150.0	H	265.0	15.0	23.30	43.50
213.877250	20.7	1000.0	120.000	99.9	H	112.0	12.7	22.80	43.50
214.877250	20.2	1000.0	120.000	99.9	H	98.0	12.8	23.30	43.50
269.774250	20.8	1000.0	120.000	99.9	H	85.0	14.9	25.20	46.00

Worst case measurement result > 1 GHz

PEAK RESULT (RBW=1MHz; VBW=3MHz)						
Frequency	Reading value	Correction Factor	Correct reading	PK Limit (AV + 20dB)		Margin
(MHz)	(dBμV)	(dB)	(dBμV/m)	(μV/m)	(dBμV/m)	(dB)
2413	81.5	-7.3	88.80	---	---	
4826	49.15	-0.7	49.85	5000	74	24.15
7239	47.90	7.5	40.40	5000	74	33.60
9652	53.25	11.9	41.35	5000	74	32.65
f>9652	No significant values were found			5000	74	---

AVERAGE RESULT (RBW=1MHz; VBW=10Hz)						
Frequency	Reading value	Correction Factor	Correct reading	AV Limit		Margin
(MHz)	(dBμV)	(dB)	(dBμV/m)	(μV/m)	(dBμV/m)	(dB)
2413	43.00	-7.3	50.30	---	---	
4826	35.62	-0.7	36.32	500	54	17.68
7239	34.84	7.5	27.34	500	54	26.66
9652	38.65	11.9	26.75	500	54	27.25
f>9652	No significant values were found			500	54	---

8. MEASUREMENTS AND TESTS UNCERTAINTY

Unless otherwise stated the uncertainties for the tests and measurements are evaluated in according to IMQ Operational Instruction IO-LAB-001 and IO-LAB-004. and requirement of NIST Technical Note 1297 and NIS 81:1994 "The Treatment of Uncertainty in EMC Measurements"

The expanded uncertainty was calculated for all measurements and tests listed in this test report according to CISPR 16-4-2 "Specification for radio disturbance and immunity measuring apparatus and methods – Part 4-2: Uncertainty in EMC Measurements", with UKAS document LAB 34 and is documented in the quality system accordance to ISO/IEC 17025.

Internal Procedure PG-037 ensures that the requirements for traceability of calibrations, of all test equipment requiring calibration, and calibration intervals are met.

Methods/Standard	Parameter	Expanded Uncertainty	Unit	Confidence level
Continuous disturbance	QP detector 9 – 150 kHz	2.47	dB	95%
	QP detector 150 k – 30 MHz	2.61	dB	95%
	QP detector using Voltage Probe	2.45	dB	95%
	QP detector using ISN	3.15	dB	95%
	QP detector using Current Probe	2.15	dB	95%
Radiated disturbance	QP detector (30 MHz - 100 MHz) H polarization	4.33	dB	95%
	QP detector (30 MHz - 100 MHz) V polarization	4.22	dB	95%
	QP detector (100 MHz - 200 MHz) H polarization	3.40	dB	95%
	QP detector (100 MHz - 200 MHz) V polarization	4.76	dB	95%
	QP detector (200 MHz - 1000 MHz) H polarization	3.91	dB	95%
	QP detector (200 MHz - 1000 MHz) V polarization	3.82	dB	95%
	P detector 1-6 GHz	4.77	dB	95%
	P detector 6 – 18 GHz	5.14	dB	95%
	P detector 18 – 26 GHz	4.95	dB	95%
	P detector 26 – 40 GHz	5.20	dB	95%

9. LIST OF MEASURING EQUIPMENT AND CALIBRATION INFORMATION

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
EMI Receiver	ROHDE & SCHWARZ	ESCI 3	IMQ No. S-04355	2018-09-14	2019-09-30
Pulse limiter	ROHDE & SCHWARZ	ESH3-Z2	IMQ No. S-02153	2018-07-13	2019-07-31
LISN	ROHDE & SCHWARZ	ESH2-Z5	IMQ No. S-00554	2018-07-10	2019-07-31
Supplementary information: None					

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
EMI Receiver	ROHDE & SCHWARZ	ESCI 7	IMQ No. S-05563	2018-07-03	2019-07-31
Log-periodic antenna	SCHWARZBECK	VULB9160	IMQ No. S-06463	2016-04-15	2019-04-30
Loop antenna	ROHDE & SCHWARZ	HFH2-Z2	IMQ No S-02508	2018-07-30	2019-07-31
Horn antenna	SCHWARZBECK	BBHA 9120D (4GHz-6GHz)	IMQ No.S-04272	2017-07-21	2020-07-31
System controller mast antenna and turntable	FRANKONIA	FCTAM-01	IMQ No. P-02486 IMQ No. P-02488	/	/
Shielded semianechoic chamber	SIDT EUROPE	/	IMQ No. P-01709	/	/
Supplementary information: None					

10. PHOTOGRAPHIC DOCUMENTATION

EUT IDENTIFICATION

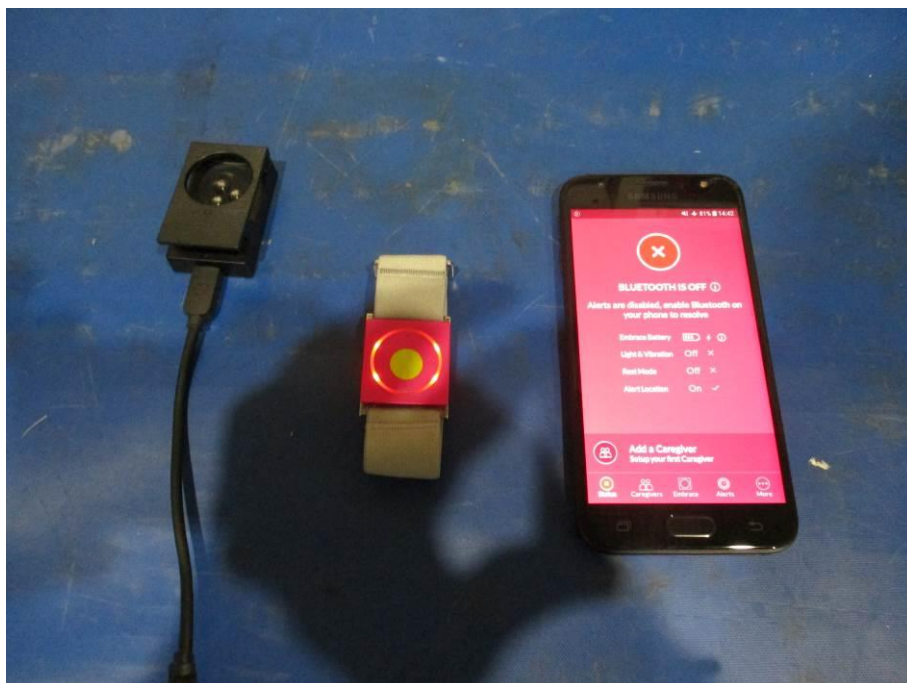
EMBRACE2 front view



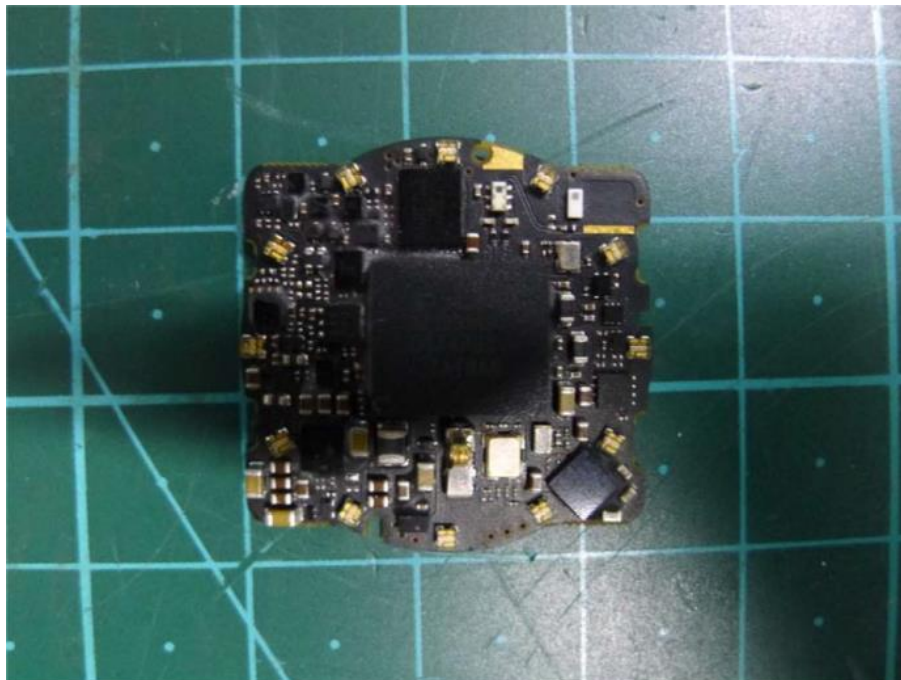
EMBRACE2 rear view



EMBRACE2 charging mode



EMBRACE2 inside front view



EMBRACE2 inside rear view



SET-UP

Test set-up conducted emission test



Test set-up Radiated emission test

9KHz ÷ 30 MHz



30 ÷ 1000 MHz



>1,000 MHz



ANNEX A

Variants of EMBRACE

	Embrace Variants				
					
Model	EM2-MB-S	EM2-BB-S	EM2-SG-S	EM2-FP-S	EM2-SB-S
Color	Milanese Black	Boston Blue	Seoul Gray	Flamingo Pink	Sky Blue

END OF TEST REPORT