Test report

N°: 137359-676558B

Subject — **Radio spectrum Matters (ERM) tests according to standards: 47 CFR Part 95I & RSS-243 & RSS-Gen, Issue 4**

Issued to

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Apparatus under test

Product	Platinium IS4 Implantable Cardioverter Defibrillateur
Trade mark	Sorin Group
Manufacturer	Sorin Group Italia S.r.l
Model	PLATINIUM 4LV CRT-D 1744
Serial number	J38DE045
FCC ID	YSGCRTD1744
IC ID	10270A-CRTD1744
IC Site number OATS	6230B

Test date	2016/02/03 to 2016/04/07
Test location	Ecuelles Fontenay Aux Roses
Test performed by	Mathieu CERISIER
Composition of document	39 pages

Document issued on 2016/05/12

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SUMMARY

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1. TEST PROGRAM

- **References**

Standards: -47 CFR FCC Part 95I
-RSS-243
-RSS-Gen
-FCC 15.207
-FCC 15.109

- **Requirements:**

Clause (FCC Part 95I) Test Description	TEST RESULT - Comments
FCC § 95.627(e) & RSS-243 § 5.3 – Frequency error	☒PASS ☐FAIL ☐NA ☐NP (Limited Program)
FCC § 95.633(e) & RSS-243 § 5.1 – Emission bandwidth	☒PASS ☐FAIL ☐NA ☐NP (Limited Program)
RSS-Gen § 6.6 – Occupied bandwidth	☒PASS ☐FAIL ☐NA ☐NP (Limited Program)
FCC § 95.639(f) & RSS-243 § 5.4 – Transmitter output power	☒PASS ☐FAIL ☐NA ☐NP (Limited Program)
FCC § 15.207(d) & RSS-Gen § 8.8 – AC conducted emissions	☐PASS ☐FAIL ☒NA ☐NP (Limited Program)
FCC § 95.635(d) & RSS-243 § 5.5 – Transmitter unwanted emission	☒PASS ☐FAIL ☐NA ☐NP (Limited Program)
FCC 15.109 & RSS-243 § 5.6 – Receiver spurious emissions	☒PASS ☐FAIL ☐NA ☐NP (Limited Program)
FCC 95.627 (a)(3) & RSS-243 § 5.7.1 – LBT threshold power level	☐PASS ☐FAIL ☒NA (MICS Communication session initiated by ULP-AMI-P only) ☐NP (Limited Program)
FCC 95.627 (a)(1) & RSS-243 § 5.7.2 – Monitoring system bandwidth	☐PASS ☐FAIL ☒NA (MICS Communication session initiated by ULP-AMI-P only) ☐NP (Limited Program)
FCC 95.627 (a)(2) & RSS-243 § 5.7.3 –Monitoring system scan cycle time	☐PASS ☐FAIL ☒NA (MICS Communication session initiated by ULP-AMI-P only) ☐NP (Limited Program))
FCC 95.627 (a)(2) & RSS-243 § 5.7.4 –Minimum channel monitoring period	☐PASS ☐FAIL ☒NA (MICS Communication session initiated by ULP-AMI-P only) ☐NP (Limited Program)
FCC 95.627 (a)(4) & RSS-243 § 5.7.5 – Channel access	☐PASS ☐FAIL ☒NA (MICS Communication session initiated by ULP-AMI-P only) ☐NP (Limited Program)
FCC 95.627 (a)(4) & RSS-243 § 5.7.6 – Discontinuation of MICS session	☐PASS ☐FAIL ☒NA (MICS Communication session initiated by ULP-AMI-P only) ☐NP (Limited Program)
FCC 95.627 (a)(5) & RSS-243 § 5.7.7 – Use of pre-scanned alternative channel	☐PASS ☐FAIL ☒NA (MICS Communication session initiated by ULP-AMI-P only) ☐NP (Limited Program)
SAR Evaluation	☒PASS ☐FAIL ☐NA
This table is a summary of test report, see conclusion of each clause of this test report for detail.	

The product Sorin Group PLATINIUM 4LV CRT-D 1744 **, SN: J38DE045 is Compliant according to FCC part 95I & RSS-243 & RSS-Gen standards.**

PASS: EUT complies with standard's requirement
FAIL: EUT does not comply with standard's requirement
NA: Not Applicable
NP: Not Performed

2. EQUIPMENT DESCRIPTION

2.1. GENERAL DESCRIPTION

The Sorin Group PLATINIUM PLATINIUM 4LV CRT-D 1744 is an implantable dual-chamber cardioverter defibrillator. It is equipped with
an accelerometer to allow adaptation of pacing to suit the patient's activity.

2.2. HARDWARE & SOFTWARE IDENTIFICATION DECLARED BY THE MANUFACTURER

Equipment under test (EUT):

- **<u>Auxiliary equipment (AE) used for testing:</u>**

-Inductive Head
-Personal Computer

Photograph of AE

- **Input/output:**

- none

- **Software identification:**

-Software version: ROM V2Build 27

- **Equipment information:**

- Modulation: 2FSK
- Transmit operating mode: ☐ Multiples antenna ☒ Single antenna
- Number of transmit chains: ☒ 1 ☐ 2
- Number of receiver chains: ☒ 1 ☐ 2
- Antenna type: ☒ Integral ☐ External
- Type of the equipment: ☒ Stand-alone equipment ☐ Plug-in radio device ☐ Combined equipment
- Temperature range: Tmin: ☐ -20°C ☐ 0°C ☒ 25°C
  Tnom: ☒ 37°C
  Tmax: ☐ +35°C ☐ 55°C ☒ 45°C
- Test source voltage: Vmin: ☒ 2.5Vdc
  Vnom: ☒ 2.62Vdc
  Vmax: ☒ 3.24Vdc
- Type of power source: ☒ Battery (Lithium-Ion) ☐ Internal power supply ☐ External power supply ☐ Car Charger
- Test sequence/test software used: See 2.2. Running Mode
- Duty Cycle: ☒ Continuous duty ☐ Intermittent duty ☐ Continuous operation
- Equipment type: ☒ Representative production model ☐ Pre-production model

-Channel plan:

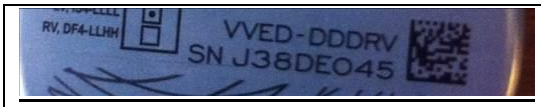
Channel	Frequency (MHz)
Cmin: 0	402.15
1	402.45
2	402.75
3	403.05
4	403.35
Cnom:5	403.65
6	403.95
7	404.25
8	404.55
Cmax: 9	404.85

2.3. RUNNING MODE

The EUT is set in the following modes during tests:
- Permanent emission with modulation on a fixed channel at the highest power
- Permanent emission without modulation on a fixed channel at the highest power
- Permanent reception

Following commands with the specific test software are used to set the product:
See MISC2723B document

2.4. EQUIPMENT LABELLING



2.5. EQUIPMENT MODIFICATION

☒ No equipment modification has been necessary during testing.
☐ Modification applied for following tests:

3. FREQUENCY ERROR

3.1. TEST CONDITIONS

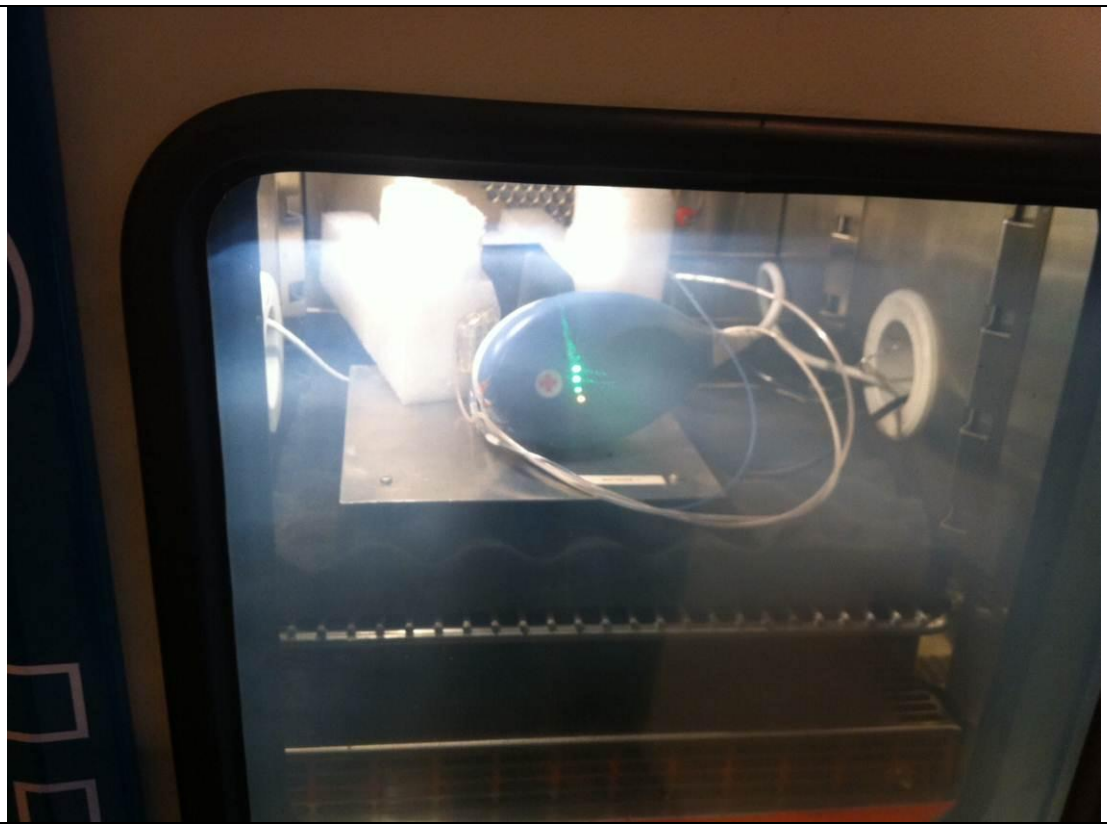
Test performed by : Mathieu CERISIER
Date of test : 2016/02/15
Ambient temperature : 22°C
Relative humidity : 32%

3.2. TEST SETUP

- The Equipment under Test is installed:
☒ In the climatic chamber
☐ On a table
☐ In an anechoic chamber

-Measurement is performed with a spectrum analyzer
☐ On the EUT conducted access
☒ With a test fixture

The spectrum analyzer counter or marker peak function is used to find the frequency error.
Detector peak



Photograph for Frequency Error

Photograph for Frequency Error

3.3. LIMIT

Frequency error for equipment operating in the 402 MHz to 405 MHz band shall not exceed ±100 ppm under normal, extreme or any intermediate set of conditions.

3.4. TEST EQUIPMENT LIST

DESCRIPTION	MANUFACTURER	MODEL	N° LCIE	Cal_Date	Cal_Due
Spectrum analyzer	ROHDE & SCHWARZ	FSL6	A4060032	2015/04	2017/04
Climatic chamber	SECASI Technologies	SLT-34	D1024029	Verified with Temperature Sensor	Verified with Temperature Sensor
Thermometer	AOIP	TM 6630	B4041042	2014/12	2016/06

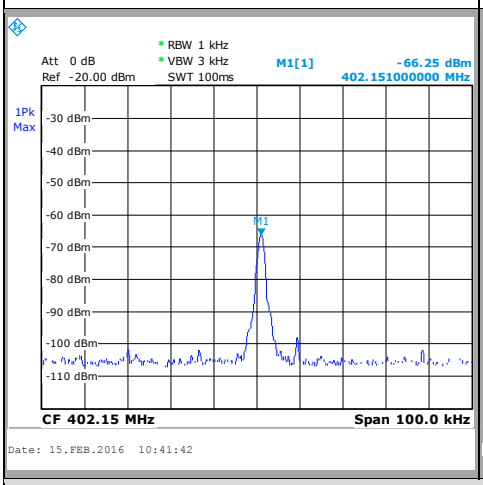
3.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION

☒None ☐Divergence:

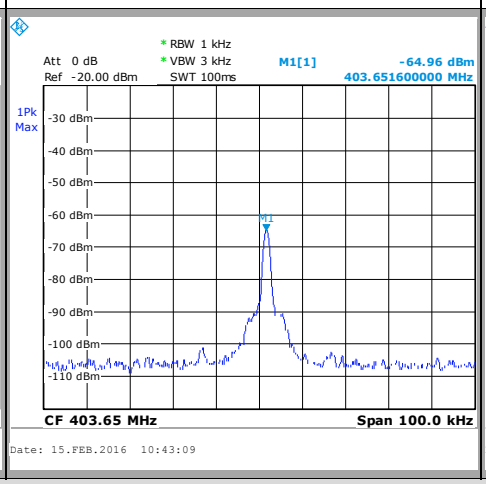
3.6. GRAPHICS & RESULTS

Tmin

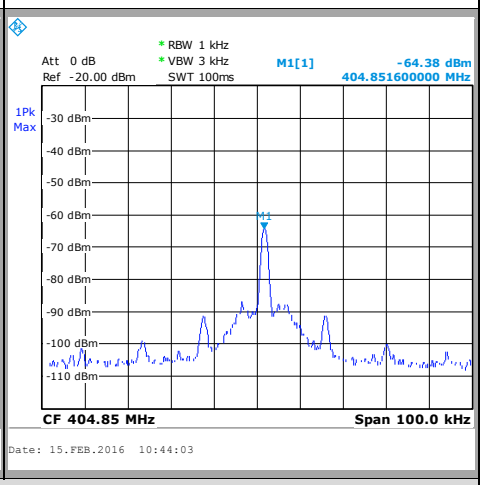
Cmin



Cnom

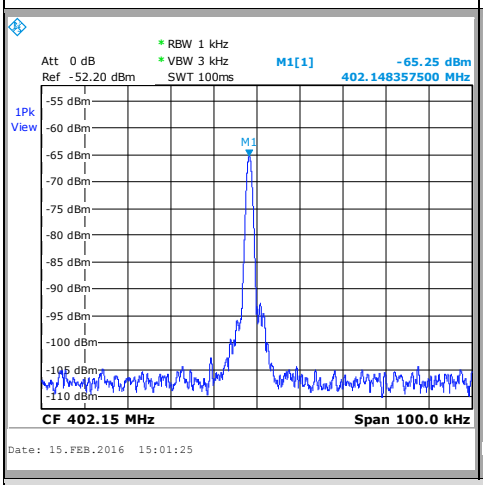


Cmax

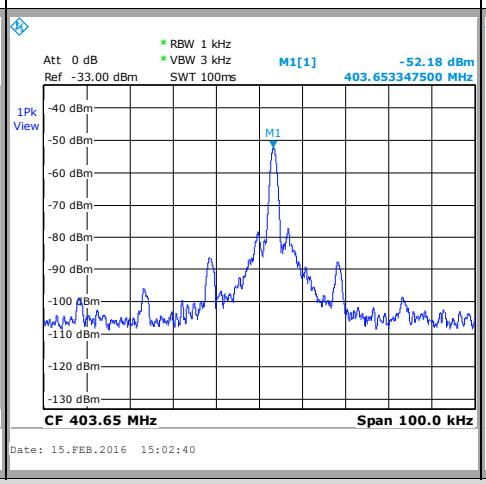


Tnom

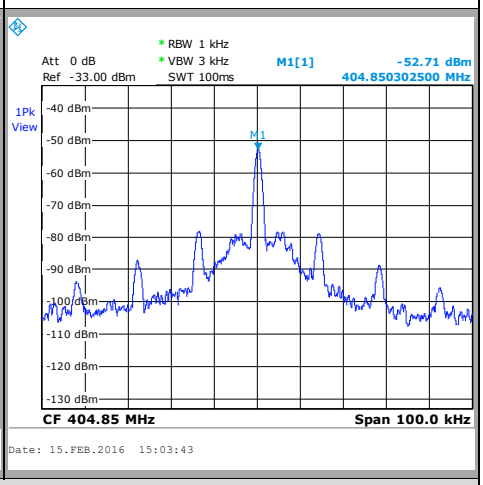
Cmin



Cnom

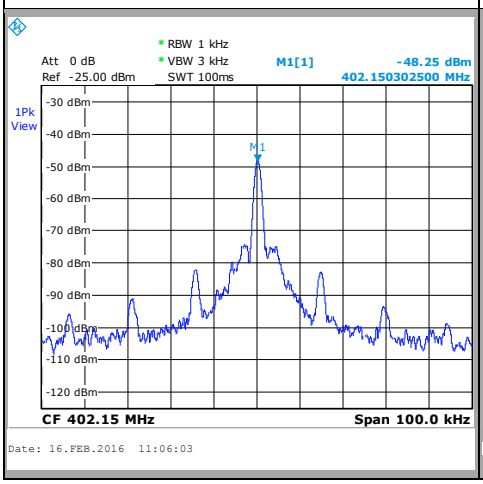


Cmax

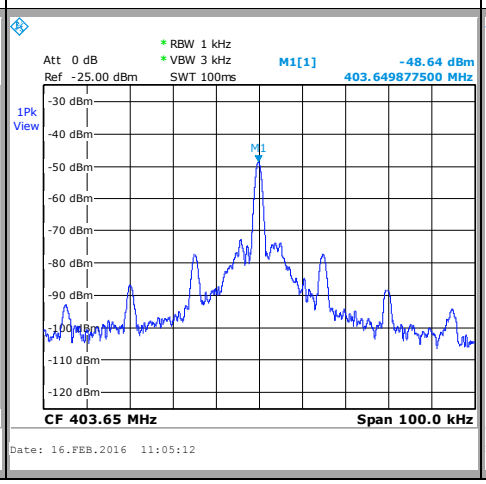


Tmax

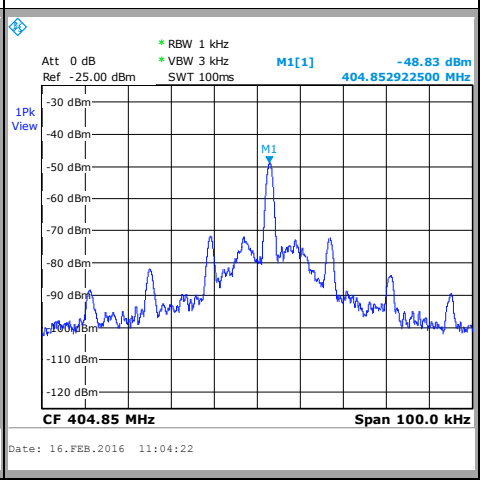
Cmin



Cnom



Cmax



Temperature	Tmin			Tnom			Tmax		
Voltage	**Vnom**								
Channel	Cmin	Cnom	Cmax	Cmin	Cnom	Cmax	Cmin	Cnom	Cmax
Frequency (MHz)	402,1510	403,6516	404,8516	402,1484	403,6533	404,8503	402,1503	403,6499	404,8529
Frequency error (ppm)	6,6	-4,3	3,2	REF	REF	REF	4,8	-8,6	6,5

3.7. CONCLUSION

The product Sorin Group PLATINIUM 4LV CRT-D 1744 , SN:J38DE045, in configuration and description presented in this test report, complies with the frequency error measurement of FCC § 95.627(e) & RSS-243 § 5.3.

4. EMISSION BANDWIDTH

4.1. TEST CONDITIONS

Test performed by : Mathieu CERISIER
Date of test : 2016/02/15
Ambient temperature : 22°C
Relative humidity : 42%

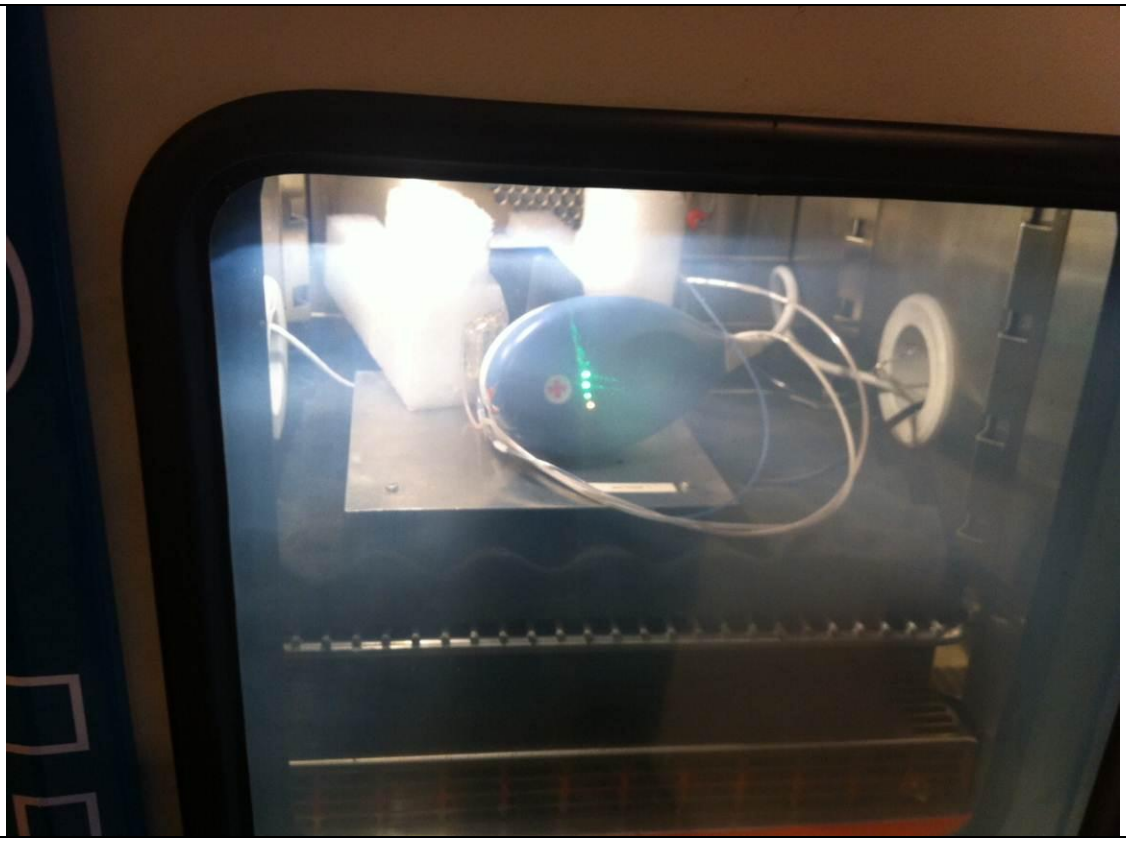
4.2. TEST SETUP

- The Equipment under Test is installed:
☒ In the climatic chamber
☐ On a table
☐ In an anechoic chamber

-Measurement is performed with a spectrum analyzer
☐ On the EUT conducted access
☒ With a test fixture

The spectrum analyzer is used to find the emission bandwidth.
Detector peak

Photograph for Emission Bandwidth



Photograph for Emission Bandwidth

4.3. LIMIT

Emission bandwidth shall not exceed 300 kHz. If two or more devices that operate in a given MICS communications session operate in different portions of the 402 MHz to 405 MHz band, their combined emission bandwidths shall not exceed 300 kHz. This limits spectrum usage to a maximum of 300 kHz in any single MICS communications session. The 300 kHz limitation may be exceeded briefly due to intermittent transmissions that may occur when operating channel acquisitions or changes are required to maintain a communications session.

All emissions from each device that fall outside its emission bandwidth but do fall within the 402 MHz to 405 MHz band shall be attenuated at least 20dB.

In addition, emissions from a device operating in the low duty cycle low power mode in the band 403,5MHz to 403,8MHz must be attenuated at least 20 dB at the band edges, 403,5MHz and 403,8MHz.

4.4. TEST EQUIPMENT LIST

DESCRIPTION	MANUFACTURER	MODEL	N° LCIE	Cal_Date	Cal_Due
Spectrum analyzer	ROHDE & SCHWARZ	FSL6	A4060032	2015/04	2017/04
Climatic chamber	SECASI Technologies	SLT-34	D1024029	Verified with Temperature Sensor	Verified with Temperature Sensor
Thermometer	AOIP	TM 6630	B4041042	2014/12	2016/06

4.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION

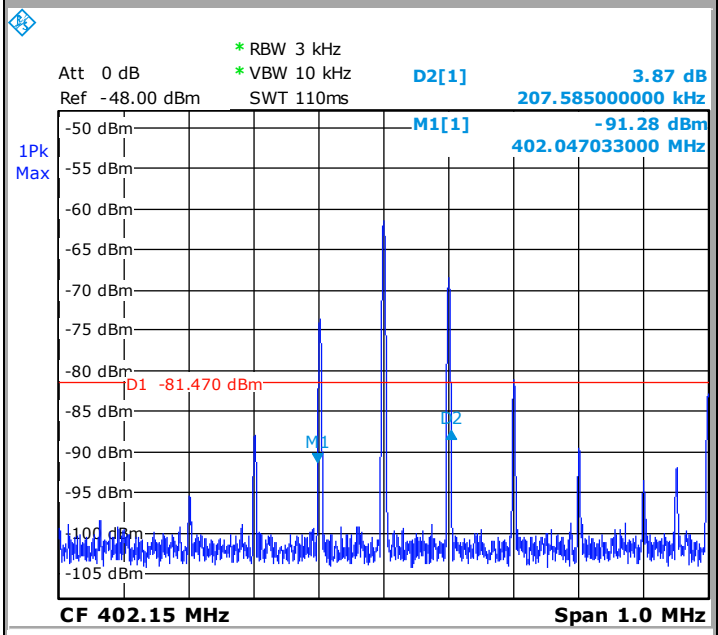
☒None ☐Divergence:

4.6. GRAPHICS & RESULTS

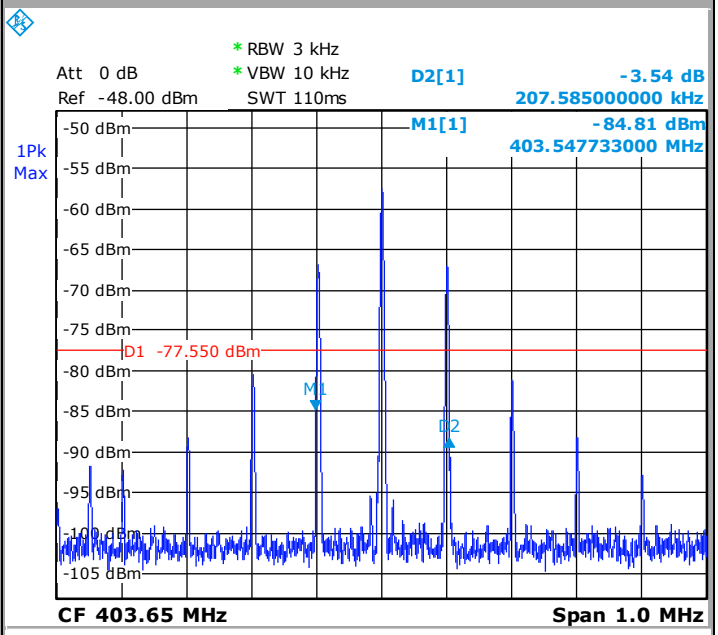
Tnom

Vnom

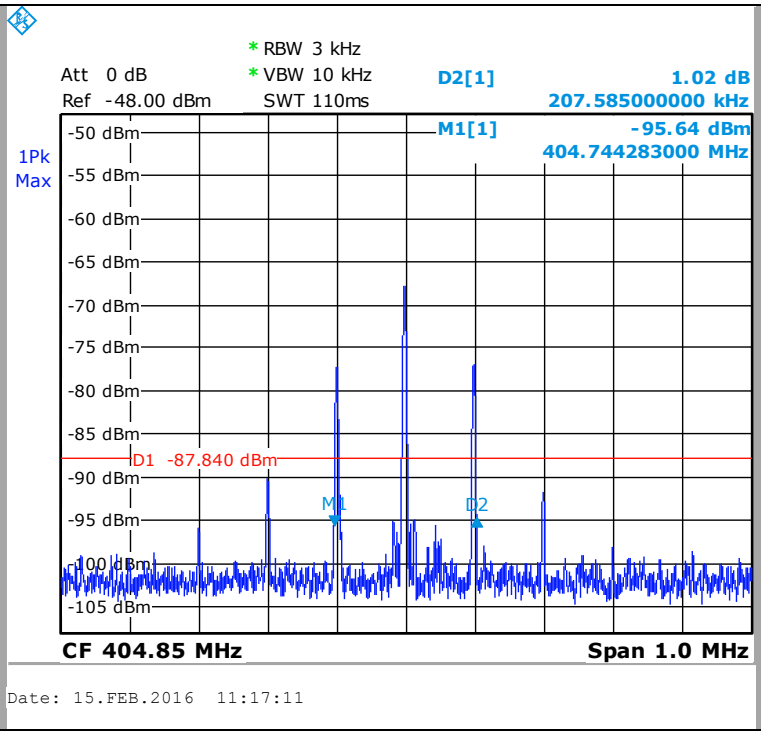
Cmin



Cnom



Cmax



Temperature	Tnom		
Voltage	**Vnom**		
Channel	Cmin	Cnom	Cmax
207,585	207,585	207,585	207,585

4.7. CONCLUSION

The product Sorin Group PLATINIUM 4LV CRT-D 1744 , SN:J38DE045, in configuration and description presented in this test report, complies with the emission bandwidth measurement of FCC § 95.633(e) & RSS-243 § 5.1.

5. OCCUPIED BANDWIDTH

5.1. TEST CONDITIONS

Test performed by : Mathieu CERISIER
Date of test : 2016/02/15
Ambient temperature : 22°C
Relative humidity : 42%

5.2. TEST SETUP

- The Equipment under Test is installed:
☒ In the climatic chamber
☐ On a table
☐ In an anechoic chamber

-Measurement is performed with a spectrum analyzer
☐ On the EUT conducted access
☒ With a test fixture

The product has been tested according to the RSS-GEN § 6.6 reference method.
Detector peak

Photograph for Occupied Bandwidth

Photograph for Occupied Bandwidth

5.3. LIMIT

No Limit

5.4. TEST EQUIPMENT LIST

DESCRIPTION	MANUFACTURER	MODEL	N° LCIE	Cal_Date	Cal_Due
Spectrum analyzer	ROHDE & SCHWARZ	FSL6	A4060032	2015/04	2017/04
Climatic chamber	SECASI Technologies	SLT-34	D1024029	Verified with Temperature Sensor	Verified with Temperature Sensor
Thermometer	AOIP	TM 6630	B4041042	2014/12	2016/06

5.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION

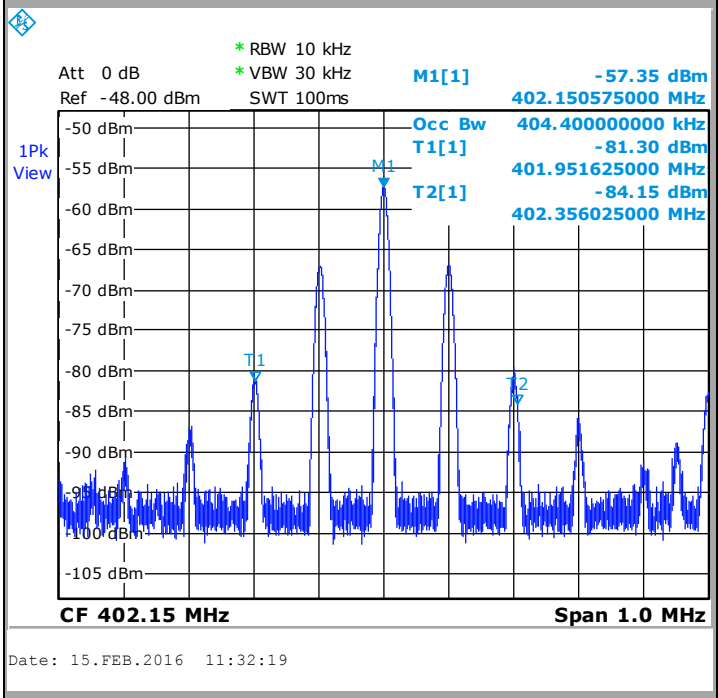
☒None ☐Divergence:

5.6. GRAPHICS & RESULTS

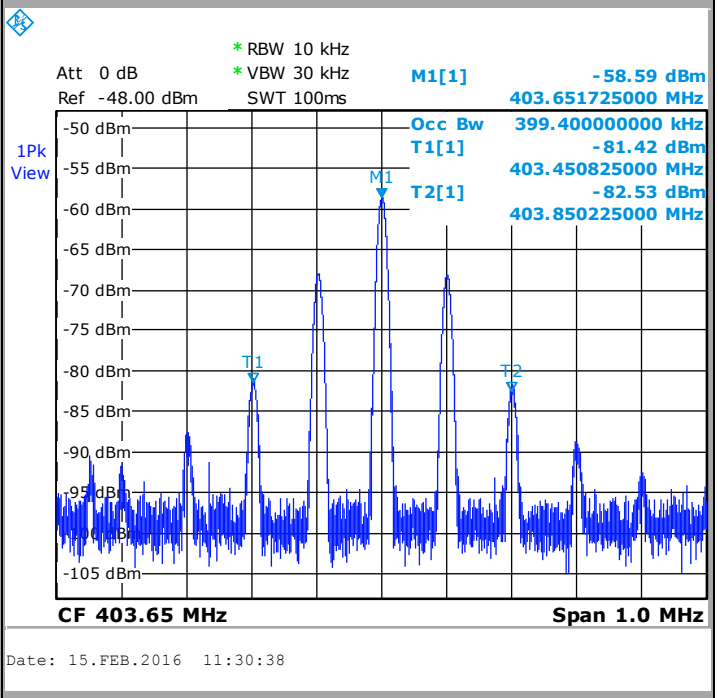
Tnom

Vnom

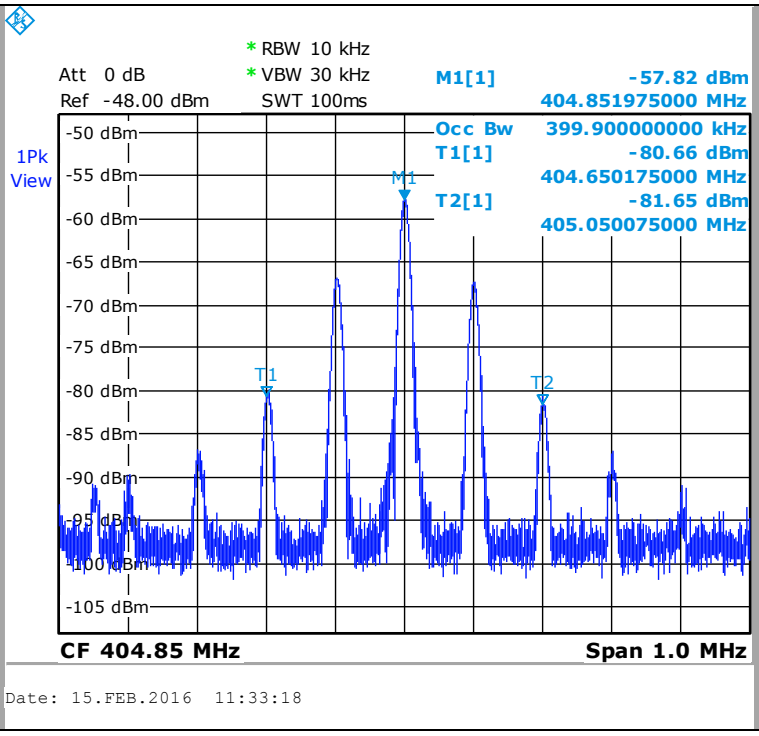
Cmin



Cnom



Cmax



Temperature	Tnom		
Voltage	**Vnom**		
Channel	Cmin	Cnom	Cmax
Occupied Bandwidth (kHz)	404,4	399,4	399,9

5.7. CONCLUSION

The product Sorin Group PLATINIUM 4LV CRT-D 1744 , SN:J38DE045, in configuration and description presented in this test report, complies with the occupied bandwidth measurement of RSS-Gen § 6.6.

6. TRANSMITTER OUTPUT POWER

6.1. TEST CONDITIONS

Test performed by : Laurent DENEUX
Date of test : 2016/02/03
Ambient temperature : 18°C
Relative humidity : 47%

6.2. TEST SETUP

- The Equipment Under Test is installed:
☐ FAR
☐ SAR
☒ OATS

- Distance between EUT and the measuring antenna is:
☐ 3m
☒ 10m

- The setup is 1.5 m above the ground reference plane on an isolating table and the maximum emitted power value from the EUT is found by the rotation of the 360°turntable and:
☐ With measurement antenna height at 1.5m from the ground reference plane
☒ By variation of measurement antenna height between 1m and 4m from the ground reference plane

The measuring antenna is in vertical and then in horizontal polarization. The substitution antenna replaces the equipment under test. The substitution antenna is powered by signal generator through RF cables. The input signal on the substitution antenna is adjusted in order to obtain the same value found in the maximum emitted power search. Mean power at the output of the transmitter and product antenna gain (A+G) are deduced after correction due to the gain of the substitution antenna and the RF cables loss between the signal generator and the substitution antenna

The Equivalent Isotropic Radiated Power (EIRP in dBm) is defined with the following formula:

EIRP = A+G
A (dBm): peak power at the output of the transmitter
G (dBi): product antenna gain
A+G: Measured in radiated by substitution method

Detector peak

Photograph for Transmitter output power

6.3. LIMIT

The EIRP of ULP-AMI and/or ULP-AMI-P equipment that operates as part of system that incorporates a monitoring system to select the frequency of operation using LBT and AFA shall not exceed 25 µW.

The EIRP of ULP-AMI transmitters operating on any frequency in the band 403,5 MHz to 403,8 MHz shall not exceed 100nW unless the frequency of operation in this band has been selected by a monitoring system using LBT and AFA. The duty cycle for any transmitter operating in the LDC mode is limited to 0,01%.

6.4. TEST EQUIPMENT LIST

Apparatus	Trade Mark	Type	Registration number	Cal_Date	Cal_Due
EMI receiver	ROHDE & SCHWARZ	ESIB	A2642021	2015/12	2016/12
Bilog antenna	CHASE	CBL 6112A	C2040040	2015/04	2016/04
Logperiodic antenna	ROHDE & SCHWARZ	HL 023 A2	C2040001	2016/01	2017/01
Signal Generator	ROHDE & SCHWARZ	SMY02	A5442014	2014/04	2016/04
Cable	-	-	A5329449	2015/10	2016/10
Cable	-	-	A5329368	2015/03	2016/03
cable	-	-	A5329444	2015/10	2016/10
Cable	-	-	A5329362	2015/03	2016/03
Cable	-	-	A5329442	2015/10	2016/10
OATS	L.C.I.E.	-	F2000400	2015/06	2016/06

6.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION

☒None ☐Divergence:

6.6. RESULTS

Tnom					
Vnom					
Frequency	Generator level (dBm)	Loss (dB)	Antenna gain (dBi)	EIRP (dBm)	EIRP(µW)
402.15MHz	-47	2.4	3.8	-45,6	0,028
403.66MHz	-48	2.5	3.9	-46,6	0,022
404.85MHz	-47	2.5	3.9	-45,6	0,028

6.7. CONCLUSION

The product Sorin Group PLATINIUM 4LV CRT-D 1744 , SN:J38DE045, in configuration and description presented in this test report, complies with the transmitter output power measurement of FCC § 95.639(f) & RSS-243 § 5.4.

7. TRANSMITTER UNWANTED EMISSIONS

7.1. TEST CONDITIONS

Test performed by : Laurent DENEUX & Mathieu CERISIER
Date of test : 2016/02/03 & 2016/03/02
Ambient temperature : 18°C & 23°C
Relative humidity : 51% & 43%

7.2. TEST SETUP

- The Equipment under Test is installed:
☐SAR ☒OATS

- Distance between EUT and the measuring antenna is:
☐3m ☒10m

- Choice of measuring antenna below 1GHz:
☒Bilog ☐Log periodic ☐Biconic ☐Dipole antenna

- Choice of measuring antenna above 1GHz:
☒Horn

The product has been tested according to ANSI C63.10 (2009). Test is performed in horizontal (H) and vertical (V) polarization. Measurement bandwidth was 120kHz below 1GHz and 1MHz above 1GHz. The level has been maximised by the turntable rotation of 360 degrees range on the 3 axis of EUT. Antenna height search was performed from 1 to 4m.

Photograph for Transmitter unwanted emissions

7.3. LIMIT

Transmitter unwanted emissions from MICS devices more than 250kHz outside of the 402-405 MHz band shall not exceed the field strength limits specified below:

Frequencies	Limit at 10m (µV/m)	Limit at 3m (µV/m)	Limit at 3m (µV/m)
30MHz to 88MHz	29.55dBµV/m QPeak	40dBµV/m QPeak	100µV/m QPeak
88MHz to 216MHz	33.05dBµV/m QPeak	43.5dBµV/m QPeak	150µV/m QPeak
216MHz to 960MHz	35.55dBµV/m QPeak	46dBµV/m QPeak	200µV/m QPeak
960MHz to 1000MHz	43.45dBµV/m QPeak	53.9dBµV/m QPeak	500µV/m QPeak
Above 1000MHz	63.45dBµV/m Peak	73.9dBµV/m Peak	5000µV/m Peak
	43.45dBµV/m Average	53.9dBµV/m Average	500µV/m Average

Transmitter unwanted emissions within the 402-405MHz MICS band which are more than 150kHz away from the centre frequency of the spectrum, and the transmissions that occupy up to 250kHz above and below the band shall be attenuated at least 20dB below the maximum transmitter output power.

Photograph for Transmitter unwanted emissions

7.4. TEST EQUIPMENT LIST

DESCRIPTION	MANUFACTURER	MODEL	N° LCIE	Cal_Date	Cal_Due
EMI receiver	ROHDE & SCHWARZ	ESIB	A2642021	2015/12	2016/12
Bilog antenna	CHASE	CBL 6112A	C2040040	2015/04	2016/04
Cable	-	-	A5329449	2015/10	2016/10
Cable	-	-	A5329368	2015/03	2016/03
Cable	-	-	A5329444	2015/10	2016/10
Cable	-	-	A5329542	2015/10	2016/10
OATS	L.C.I.E.	-	F2000400	2015/06	2016/06
Horn Antenna	EMCO	3115	C2042016	2015/04	2016/04
Preampli	HEWLETT PACKARD	8449B	A4069002	2016/01	2017/01
Spectrum analyzer	ROHDE & SCHWARZ	FSL6	A4060032	2015/04	2017/04
Climatic chamber	SECASI Technologies	SLT-34	D1024029	Verified with Temperature Sensor	Verified with Temperature Sensor
Thermometer	AOIP	TM 6630	B4041042	2014/12	2016/06

7.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION

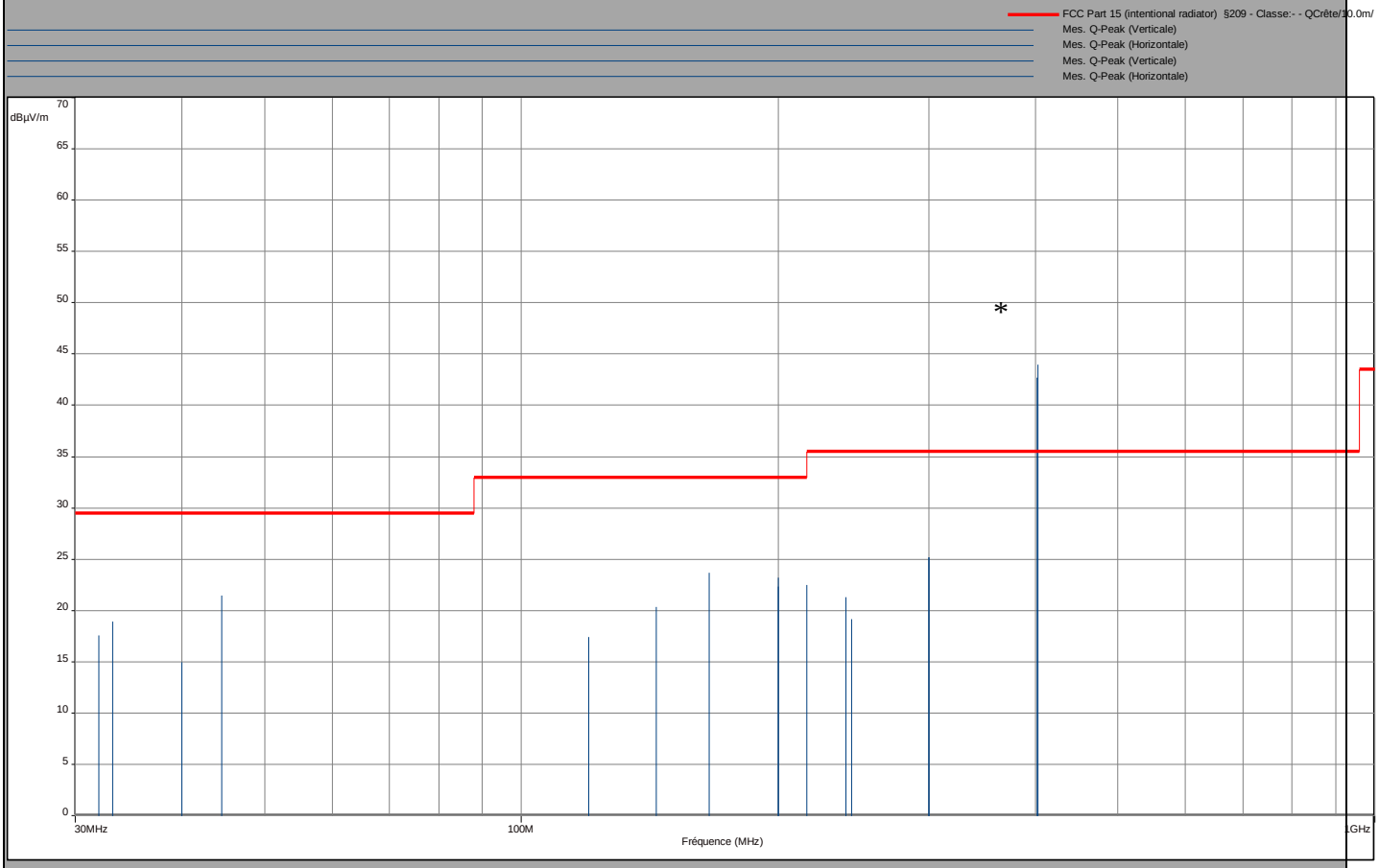
☒None ☐Divergence:

7.6. GRAPHICS & RESULTS

Out of band transmitter unwanted emissions (below 1GHz)

400 Tx mode

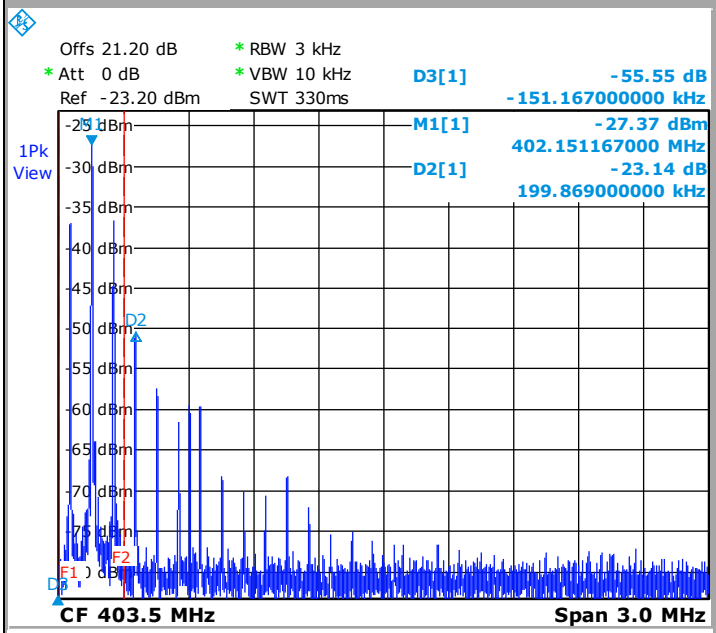
Quasi peak measurement



* Transmitter frequency

Tnom
Vnom
In band transmitter unwanted emissions

Cmin



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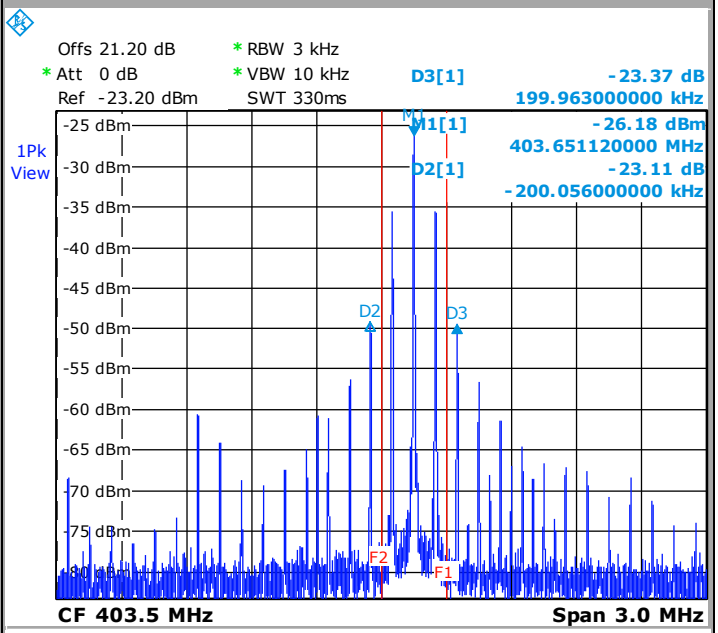
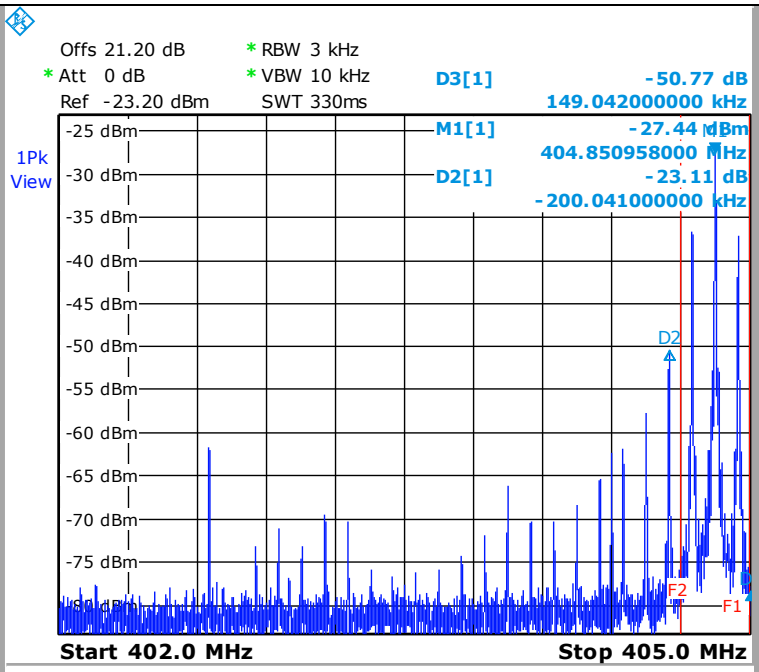
Cnom



Date: 2.MAR.2016 15:05:57

Cmax



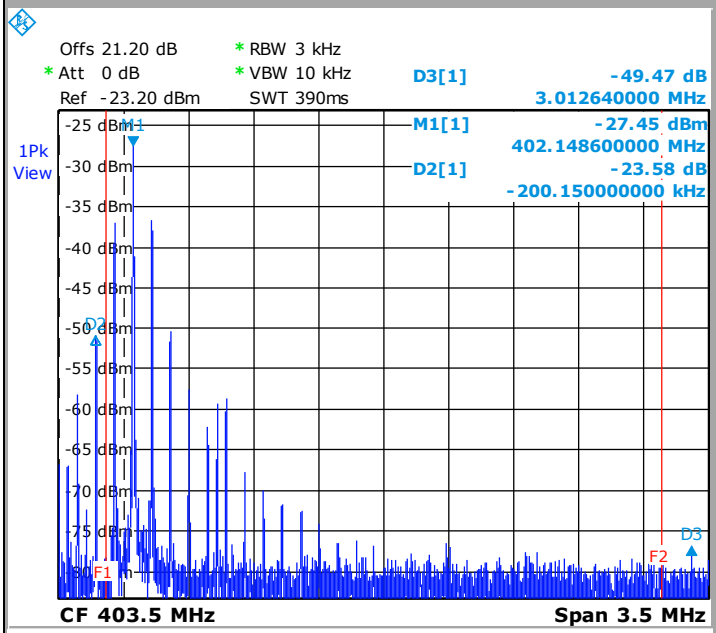
Date: 2.MAR.2016 15:04:32

Tnom

Vnom

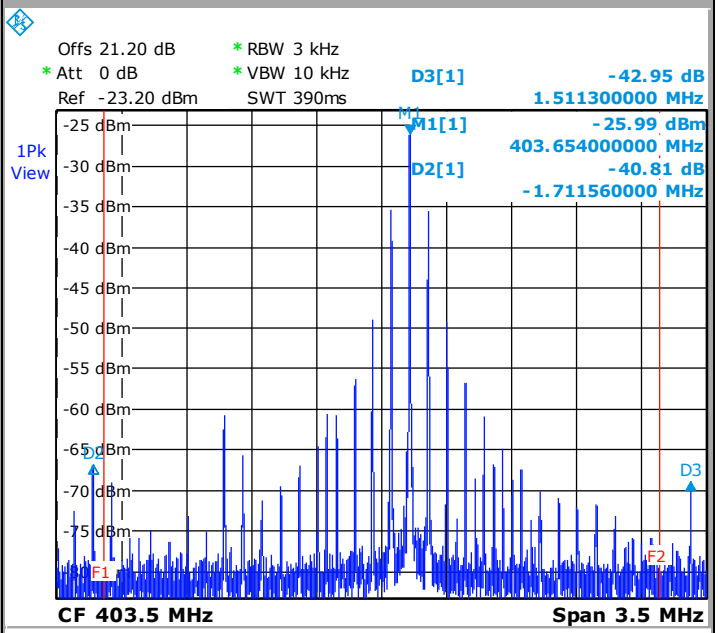
Out of band transmitter unwanted emissions +/-250kHz

Cmin



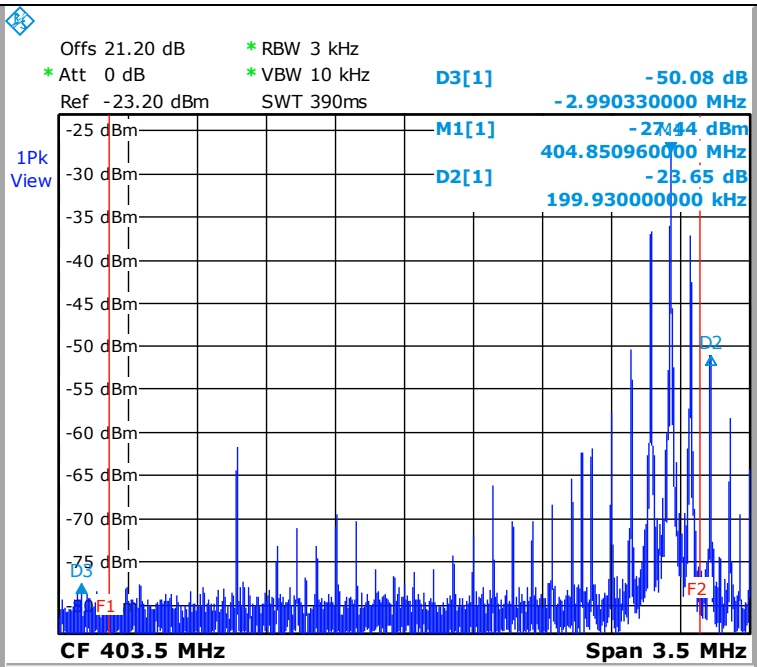
Date: 2.MAR.2016 14:59:59

Cnom



Date: 2.MAR.2016 15:01:36

Cmax



Date: 2.MAR.2016 15:03:19

Out of band transmitter unwanted emissions			
Below 1GHz			
Polarization	Frequencies (MHz)	Quasi-Peak Level (dBµV/m)	Quasi-Peak Limit (dBµV/m)
Vertical	32	17,6	29.5
Vertical	33,2	18,9	29.5
Vertical	40	15,0	29.5
Vertical	44,5	21,5	29.5
Vertical	120	17,4	33
Vertical	166	23,7	33
Vertical	200	23,2	33
Vertical	216	22,5	33
Vertical	240	21,4	35.5
Vertical	300	25,2	35.5
Horizontal	144	20,4	33
Horizontal	200	22,3	33
Horizontal	243,9	19,2	35.5
Horizontal	300	25,2	35.5

Detector peak

Out of band +/-250kHz transmitter unwanted emissions			
Channel	Level (dB) at Fmin	Level (dB) at Fmax	Limit (dB)
Cmin	23,58	49,47	At least 20
Cnom	40,81	42,95	At least 20
Cmax	50,08	23,65	At least 20

Detector peak

In band transmitter unwanted emissions			
Channel	Level (dB) at Fmin	Level (dB) at Fmax	Limit (dB)
Cmin	55,55	23,14	At least 20
Cnom	23,11	23,37	At least 20
Cmax	23,11	50,77	At least 20

7.7. CONCLUSION

The product Sorin Group PLATINIUM 4LV CRT-D 1744 , SN:J38DE045, in configuration and description presented in this test report, complies with the Unwanted Emission into Restricted Bands measurement of FCC § 95.635(d) & RSS-243 § 5.5.

8. RECEIVER SPURIOUS EMISSIONS

8.1. TEST CONDITIONS

Test performed by : Laurent DENEUX
Date of test : 2016/02/03
Ambient temperature : 18°C
Relative humidity : 51%

8.2. TEST SETUP

- The Equipment under Test is installed:
☐SAR ☒OATS

- Distance between EUT and the measuring antenna is:
☐3m ☒10m

- Choice of measuring antenna below 1GHz:
☒Bilog ☐Log periodic ☐Biconic ☐Dipole antenna

- Choice of measuring antenna above 1GHz:
☒Horn

The product has been tested according to ANSI C63.10 (2009). Test is performed in horizontal (H) and vertical (V) polarization. Measurement bandwidth was 120kHz below 1GHz and 1MHz above 1GHz. The level has been maximised by the turntable rotation of 360 degrees range on the 3 axis of EUT. Antenna height search was performed from 1 to 4m.

Photograph for Receiver spurious emissions

8.3. LIMIT

Receiver spurious emissions shall not exceed value below:

30MHz to 88MHz:	29.5dBµV/m QPeak
88MHz to 216MHz:	33dBµV/m QPeak
216MHz to 960MHz:	35.5dBµV/m QPeak
960MHz to 1000MHz:	43.5dBµV/m QPeak
Above 1000MHz:	63.5dBµV/m Peak
	43.5dBµV/m Average

8.4. TEST EQUIPMENT LIST

DESCRIPTION	MANUFACTURER	MODEL	N° LCIE	Cal_Date	Cal_Due
EMI receiver	ROHDE & SCHWARZ	ESIB	A2642021	2015/12	2016/12
Bilog antenna	CHASE	CBL 6112A	C2040040	2015/04	2016/04
Cable	-	-	A5329449	2015/10	2016/10
Cable	-	-	A5329368	2015/03	2016/03
Cable	-	-	A5329444	2015/10	2016/10
Cable	-	-	A5329542	2015/02	2016/02
OATS	L.C.I.E.	-	F2000400	2015/06	2016/06
Horn Antenna	EMCO	3115	C2042016	2015/04	2016/04
Preampli	HEWLETT PACKARD	8449B	A4069002	2016/01	2017/01

Note: In our system quality, calibration due is more & less 2 month.

8.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION

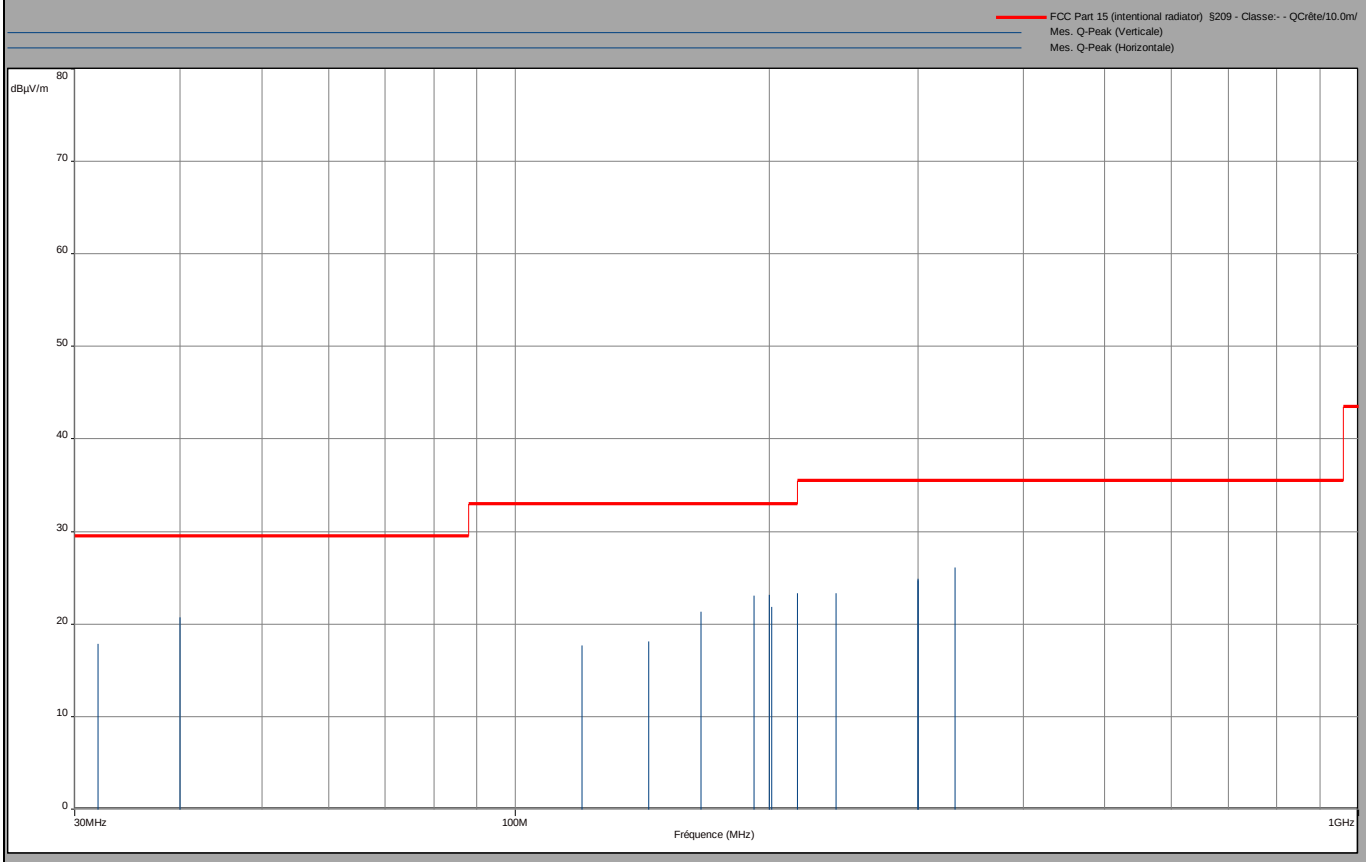
☒None ☐Divergence:

8.6. GRAPHICS & RESULTS

Out of band transmitter unwanted emissions (below 1GHz)

400 Rx and 2.4 Rx mode

Quasi peak measurement



Out of band transmitter unwanted emissions			
Below 1GHz			
Polarization	Frequencies (MHz)	Quasi-Peak Level (dBµV/m)	Quasi-Peak Limit (dBµV/m)
Vertical	32	17,9	29.5
Vertical	40	20,7	29.5
Vertical	120	17,8	33
Vertical	166	21,4	33
Vertical	192	23,1	33
Vertical	200	23,2	33
Vertical	216	23,4	33
Vertical	300	24,9	35.5
Vertical	332	26,1	35.5
Horizontal	144	18,2	33
Horizontal	201,3	21,9	33
Horizontal	240	23,4	35.5
Horizontal	300	24,8	35.5

8.7. CONCLUSION

The product Sorin Group PLATINIUM 4LV CRT-D 1744 , SN:J38DE045, in configuration and description presented in this test report, complies with the receiver spurious emissions measurement of FCC 15.109 & RSS-243 5.6.

9. SAR EVALUATION

9.1. TEST CONDITIONS

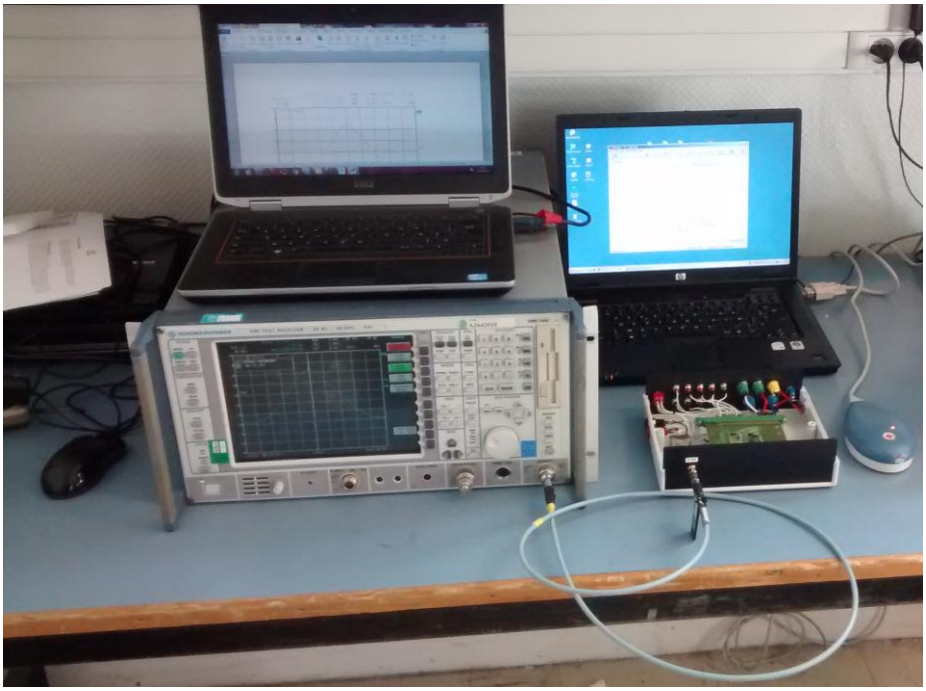
Test performed by : Stéphane PHOUDIAH
Date of test : 2016/04/07
Ambient temperature : 22°C
Relative humidity : 40%

9.2. TEST SETUP

- The Equipment under Test is installed:
☐ In the climatic chamber
☒ On a table
☐ In an anechoic chamber

-Measurement is performed with a spectrum analyzer
☒ On the EUT conducted access
☐ With a test fixture

The spectrum analyzer marker peak functions is used to find the maximum rf conducted output power
Detector peak



Photograph for RF conducted output power

9.3. LIMIT

RSS-102 Issue 5 March 2015:

2.5.1 Exemption Limits for Routine Evaluation – SAR Evaluation

For medical implants devices, the exemption limit for routine evaluation is set at 1 mW. The output power of a medical implants device is defined as the higher of the conducted or e.i.r.p to determine whether the device is exempt from the SAR evaluation.

FCC:

KDB 447498 section 4.2.4:

4.2.4. Transmitters implanted in the body of a user

When the aggregate of the maximum power available at the antenna port and radiating structures of an implanted transmitter, under all operating circumstances, is ≤ 1.0 mW, SAR test exclusion may be applied. The maximum available output power requirement and worst case operating conditions must be supported by power measurement results and fully justified in a SAR analysis report, in lieu of the SAR measurement or numerical simulation, according to design and implementation requirements of the device.

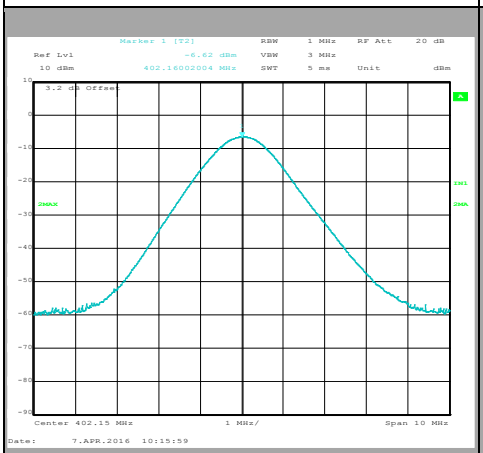
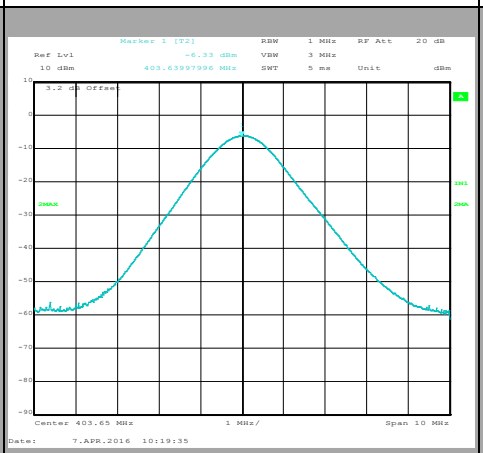
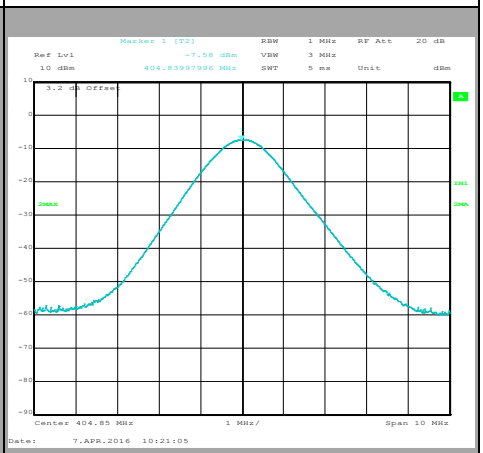
9.4. TEST EQUIPMENT LIST

DESCRIPTION	MANUFACTURER	MODEL	N° LCIE	Cal_Date	Cal_Due
EMI receiver	ROHDE & SCHWARZ	ESI40 1088 740K40	A2642010	2015/05	2016/05
RF cable & Attenuator	Télédyne & MINI CIRCUITS	920-0202-024 & FW-20+	A5329674	2015/10	2016/10

9.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION

☒None ☐Divergence:

9.6. GRAPHICS & RESULTS

Tnom		
Cmin	**Cnom**	**Cmax**
		

Temperature	Tnom		
Voltage	**Vnom**		
Channel	Cmin	Cnom	Cmax
RF conducted output power (dBm)	-6.62	-6.33	-7.58
RF conducted output power (mW)	0.22	0.23	0.17
EIRP (dBm)	-45.6	-46.6	-45.6
EIRP (mW)	0.000028	0.000022	0.000028

9.7. CONCLUSION

The product Sorin Group PLATINIUM 4LV CRT-D 1744 , in configuration and description presented in this test report, is excluded of SAR evaluation.

10. UNCERTAINTIES CHART

Kind of test	Measurement uncertainties (k=2) ±x(dB) / (Hz)	Limit for uncertainties ±y(dB)
REQUIREMENTS		
RF output power, conducted	±0.6 dB	±1,5 dB
Power Spectral Density, conducted	±0.6 dB	±1,5 dB
Unwanted Emissions, conducted	±0.6 dB	±1,5 dB
Radiated emissions • Frequency < 1000 MHz • Frequency > 1000 MHz	 ±3.9 dB ±3.1 dB	±6 dB
Temperature	±0.5°C	±1°C
Humidity	±2.5 %	±5 %