



# Test report

N°: 137359-676558E

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

**Issued to** SORIN  
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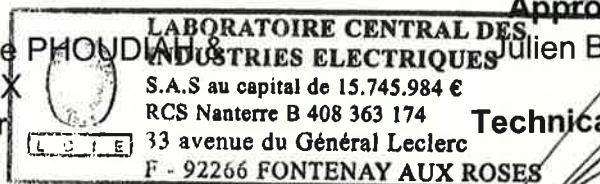
**Apparatus under test**

↪ Product Platinum IS4 Implantable Cardioverter Defibrillateur  
↪ Trade mark Sorin Group  
↪ Manufacturer Sorin Group Italia S.r.l  
↪ Model PLATINIUM 4LV SonR CRT-D 1844  
↪ Serial number J38DF043  
↪ FCC ID YSGCRTDSOR1844  
↪ IC ID 10270A-CRTDSOR1844  
↪ IC Site number OATS 6230B

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

**Modification of the last version** -  
**Document issued on** 2016/05/12

**Written by :**  
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Laurent DENEUX  
**Tests operator**



**Approved by :**  
Julien BOUTAUD  
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## SUMMARY

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## 1. TEST PROGRAM

- References**

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

- Requirements:**

| Clause (FCC Part 95l) Test Description  | TEST RESULT - Comments  |
|---|---|
| FCC § 95.627(e) & RSS-243 § 5.3 – Frequency error   | <input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL <input type="checkbox"/> NA <input type="checkbox"/> NP (Limited Program)  |
| FCC § 95.633(e) & RSS-243 § 5.1 – Emission bandwidth  | <input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL <input type="checkbox"/> NA <input type="checkbox"/> NP (Limited Program)  |
| RSS-Gen § 6.6 – Occupied bandwidth  | <input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL <input type="checkbox"/> NA <input type="checkbox"/> NP (Limited Program)  |
| FCC § 95.639(f) & RSS-243 § 5.4 – Transmitter output power  | <input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL <input type="checkbox"/> NA <input type="checkbox"/> NP (Limited Program)  |
| FCC § 15.207(d) & RSS-Gen § 8.8 – AC conducted emissions  | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input checked="" type="checkbox"/> NA <input type="checkbox"/> NP (Limited Program)  |
| FCC § 95.635(d) & RSS-243 § 5.5 – Transmitter unwanted emission                                       | <input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL <input type="checkbox"/> NA <input type="checkbox"/> NP (Limited Program)  |
| FCC 15.109 & RSS-243 § 5.6 – Receiver spurious emissions  | <input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL <input type="checkbox"/> NA <input type="checkbox"/> NP (Limited Program)  |
| FCC 95.627 (a)(3) & RSS-243 § 5.7.1 – LBT threshold power level                                       | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input checked="" type="checkbox"/> NA (MICS Communication session initiated by ULP-AMI-P only) <input type="checkbox"/> NP (Limited Program) |
| FCC 95.627 (a)(1) & RSS-243 § 5.7.2 – Monitoring system bandwidth                                     | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input checked="" type="checkbox"/> NA (MICS Communication session initiated by ULP-AMI-P only) <input type="checkbox"/> NP (Limited Program) |
| FCC 95.627 (a)(2) & RSS-243 § 5.7.3 –Monitoring system scan cycle time                                | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input checked="" type="checkbox"/> NA (MICS Communication session initiated by ULP-AMI-P only) <input type="checkbox"/> NP (Limited Program) |
| FCC 95.627 (a)(2) & RSS-243 § 5.7.4 –Minimum channel monitoring period                                | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input checked="" type="checkbox"/> NA (MICS Communication session initiated by ULP-AMI-P only) <input type="checkbox"/> NP (Limited Program) |
| FCC 95.627 (a)(4) & RSS-243 § 5.7.5 – Channel access  | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input checked="" type="checkbox"/> NA (MICS Communication session initiated by ULP-AMI-P only) <input type="checkbox"/> NP (Limited Program) |
| FCC 95.627 (a)(4) & RSS-243 § 5.7.6 – Discontinuation of MICS session                                 | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input checked="" type="checkbox"/> NA (MICS Communication session initiated by ULP-AMI-P only) <input type="checkbox"/> NP (Limited Program) |
| FCC 95.627 (a)(5) & RSS-243 § 5.7.7 – Use of pre-scanned alternative channel                          | <input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input checked="" type="checkbox"/> NA (MICS Communication session initiated by ULP-AMI-P only) <input type="checkbox"/> NP (Limited Program) |
| SAR Evaluation  | <input checked="" type="checkbox"/> PASS <input type="checkbox"/> FAIL <input type="checkbox"/> 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 SonR CRT-D 1844 , SN: J38DF043 is Compliant according to FCC part 95l & 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 SonR CRT-D 1844 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):





- **Auxiliary equipment (AE) used for testing:**
  - 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) |
|----------------|-----------------|
| <b>Cmin: 0</b> | 402.15          |
| <b>1</b>       | 402.45          |
| <b>2</b>       | 402.75          |
| <b>3</b>       | 403.05          |
| <b>4</b>       | 403.35          |
| <b>Cnom:5</b>  | 403.65          |
| <b>6</b>       | 403.95          |
| <b>7</b>       | 404.25          |
| <b>8</b>       | 404.55          |
| <b>Cmax: 9</b> | 404.85          |



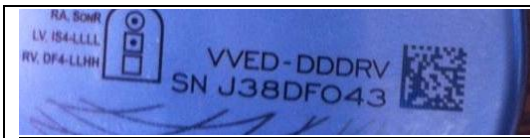
### 2.3. RUNNING MODE

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 : 2016/02/16  
Ambient temperature : 21°C  
Relative humidity : 37%

#### 3.2. TEST SETUP

- The Equipment under Test is installed:

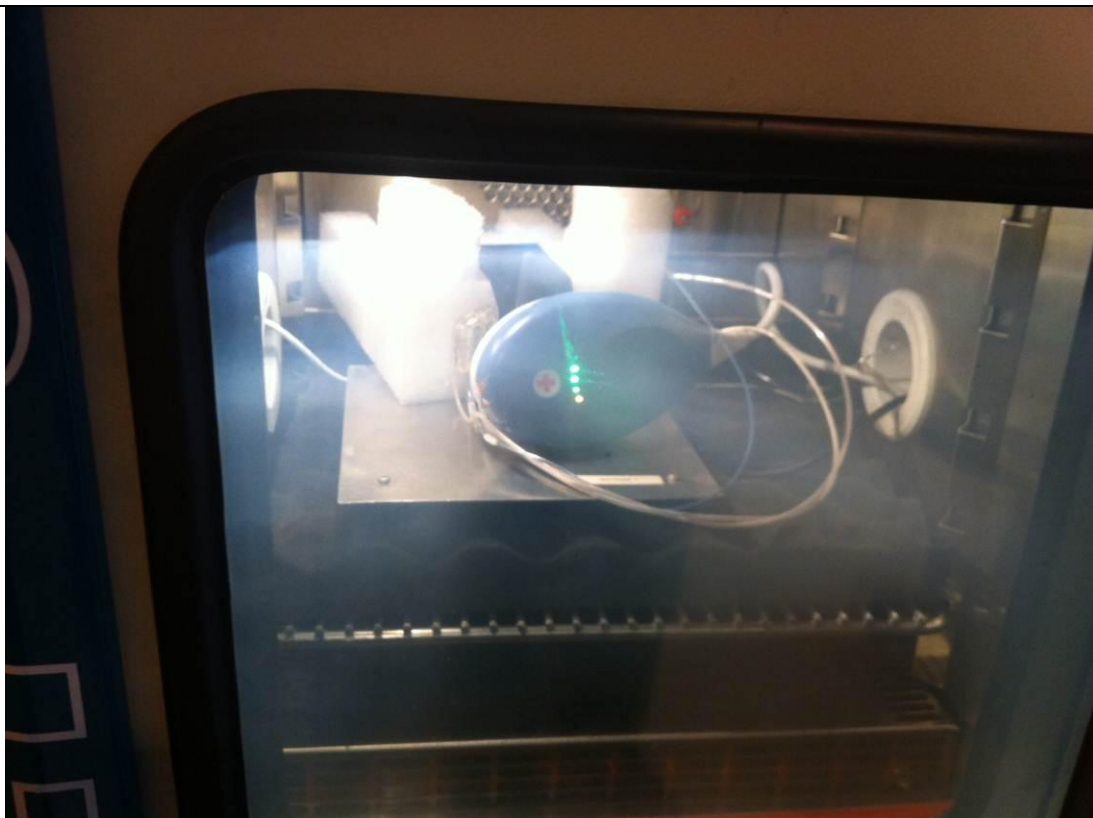
- In the climatic chamber
- On a table
- In an anechoic chamber

-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  $\pm 100$  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                          |

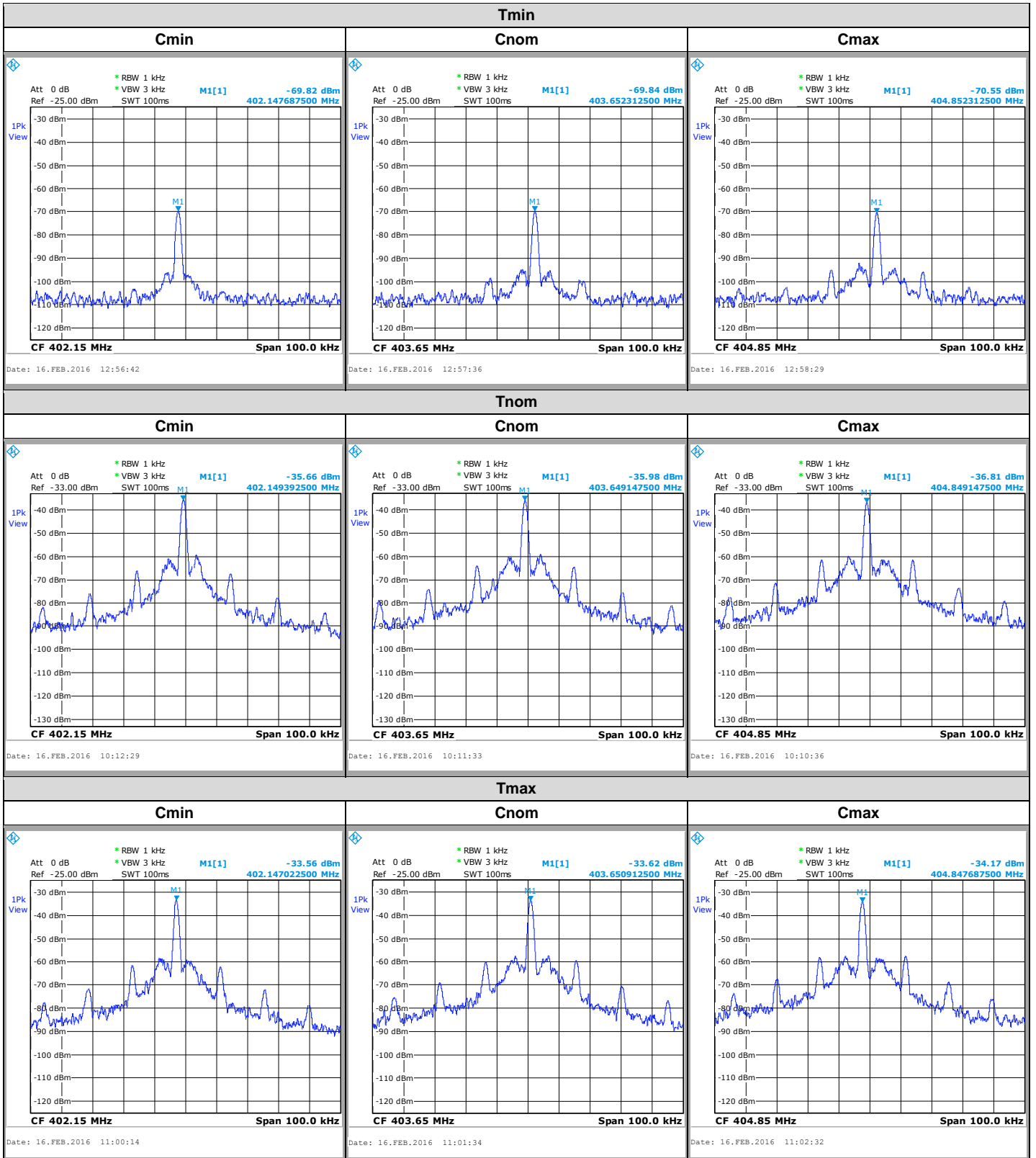
### 3.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION

None

Divergence:



### 3.6. GRAPHICS & RESULTS





| Temperature           | Tmin     |          |          | Tnom     |          |          | Tmax     |          |          |
|-----------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| Voltage               | Vnom     |          |          |          |          |          |          |          |          |
| Channel               | Cmin     | Cnom     | Cmax     | Cmin     | Cnom     | Cmax     | Cmin     | Cnom     | Cmax     |
| Frequency (MHz)       | 402,1477 | 403,6523 | 404,8523 | 402,1494 | 403,6491 | 404,8491 | 402,1470 | 403,6509 | 404,8477 |
| Frequency error (ppm) | -4,2     | 7,8      | 7,8      | REF      | REF      | REF      | -5,9     | 4,4      | -3,6     |

### 3.7. CONCLUSION

The product Sorin Group PLATINIUM 4LV SonR CRT-D 1844 , SN:J38DF043, 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 : 2016/02/16  
Ambient temperature : 21°C  
Relative humidity : 37%

### 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                          |

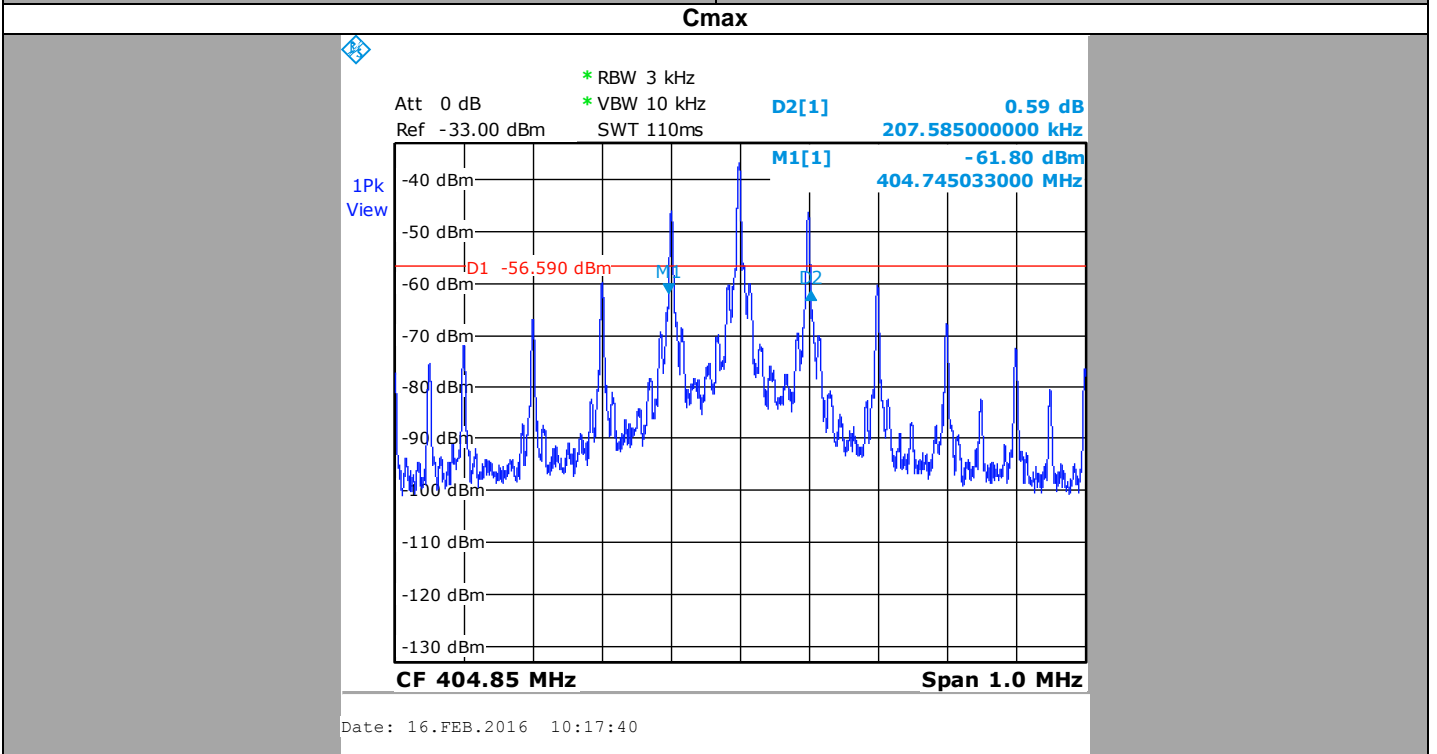
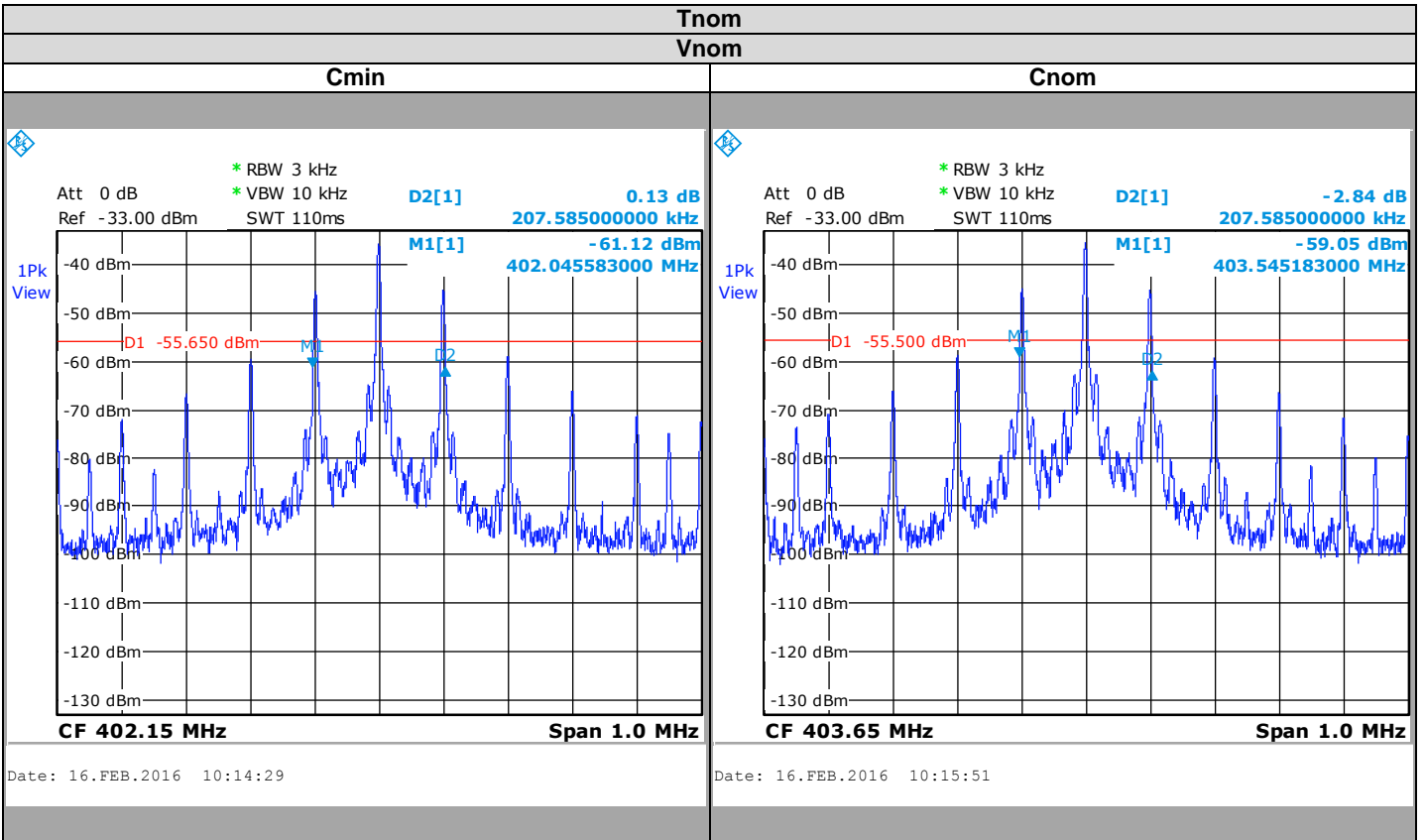
#### 4.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION

None

Divergence:



#### 4.6. GRAPHICS & RESULTS





| 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 SonR CRT-D 1844 , SN:J38DF043, 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 : 2016/02/16  
Ambient temperature : 21°C  
Relative humidity : 37%

### 5.2. TEST SETUP

- The Equipment under Test is installed:

- In the climatic chamber
- On a table
- In an anechoic chamber

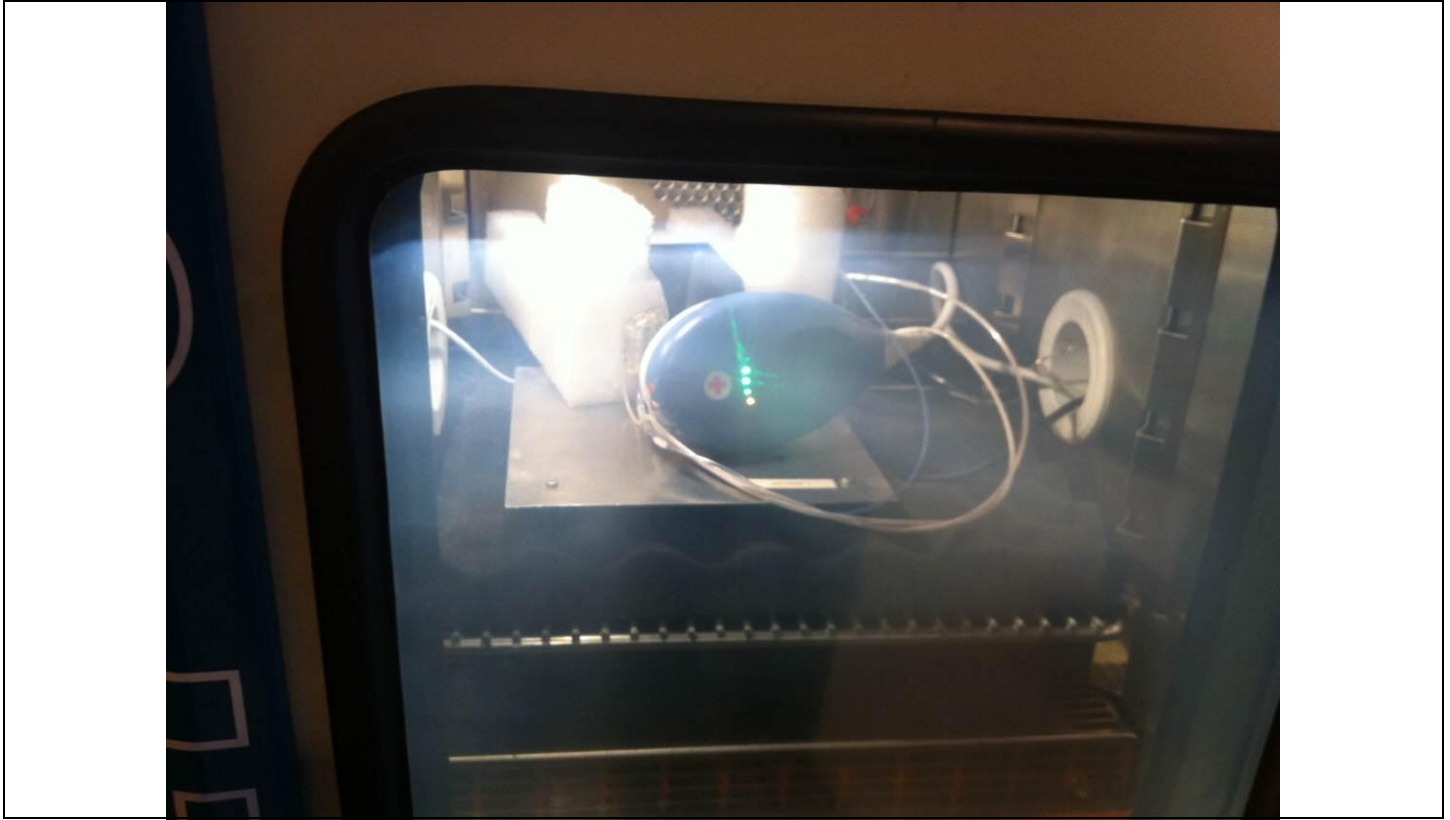
-Measurement is performed with a spectrum analyzer

- 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                          |

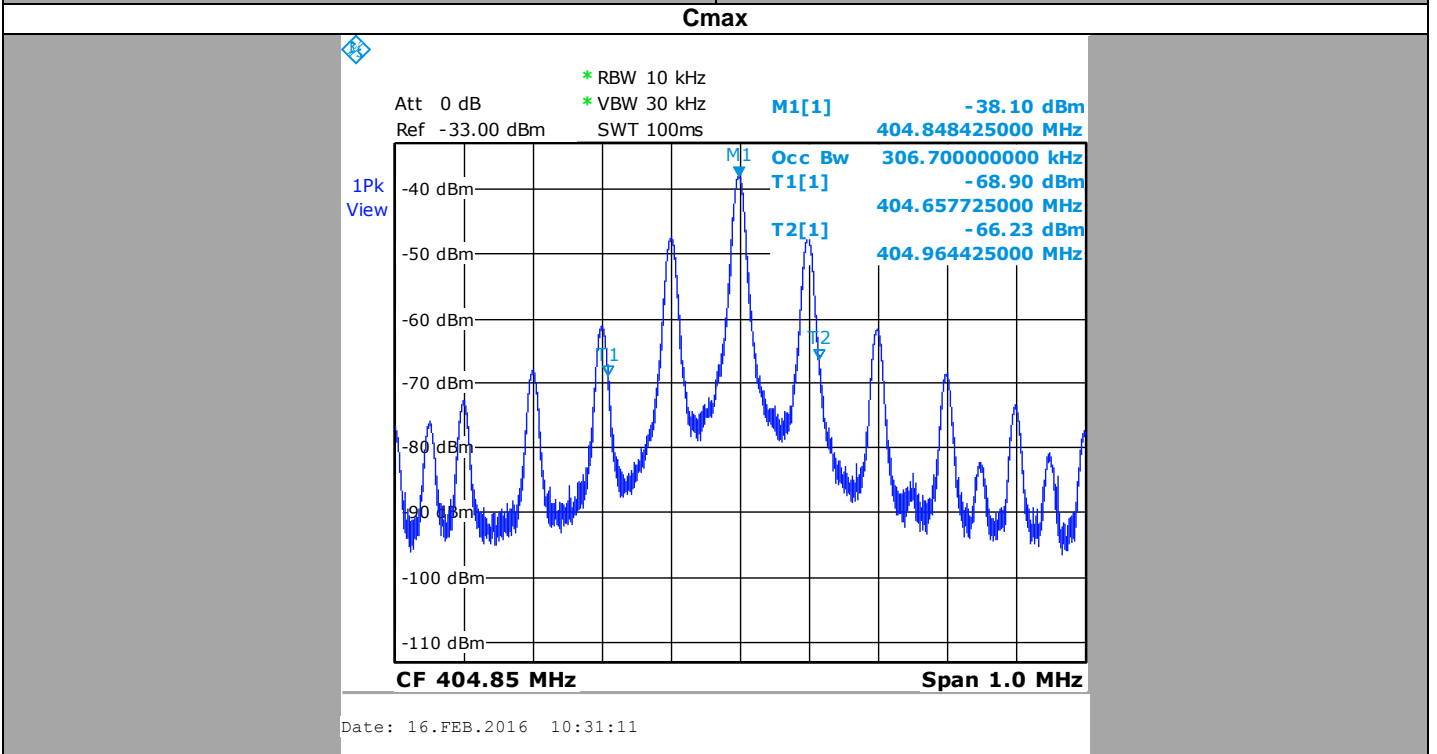
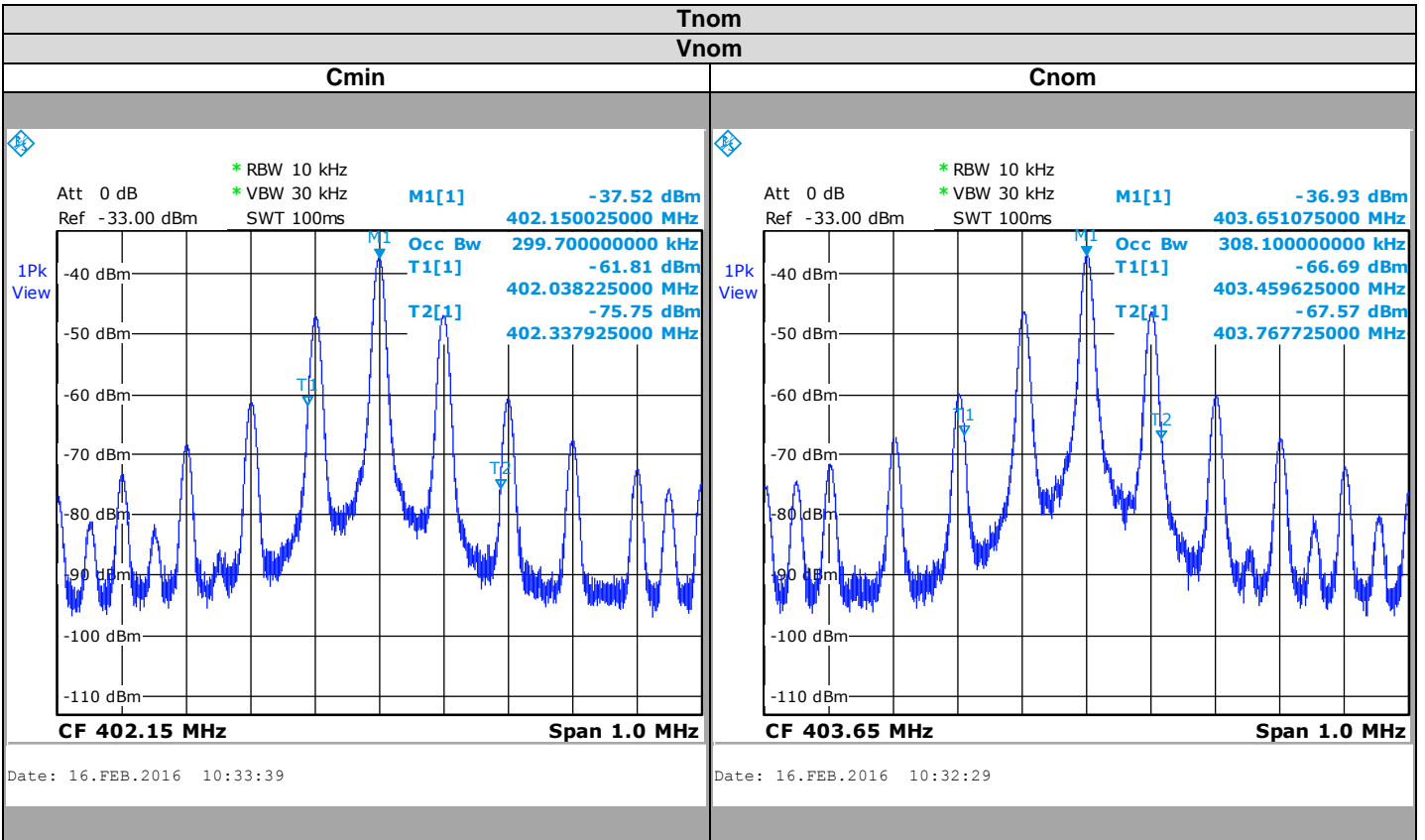
Note: In our system quality, calibration due is more & less 2 month.

**5.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION**

None       Divergence:



5.6. GRAPHICS & RESULTS





| Temperature              | Tnom  |       |       |
|--------------------------|-------|-------|-------|
| Voltage                  | Vnom  |       |       |
| Channel                  | Cmin  | Cnom  | Cmax  |
| Occupied Bandwidth (kHz) | 299,7 | 308,1 | 306,7 |

## 5.7. CONCLUSION

The product Sorin Group PLATINIUM 4LV SonR CRT-D 1844 , SN:J38DF043, 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  $\mu$ W.

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 | -46                   | 2,4       | 3,8                | -44,6      | 0,035    |
| 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 SonR CRT-D 1844 , SN:J38DF043, 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





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 ( $\mu\text{V}/\text{m}$ ) | Limit at 3m ( $\mu\text{V}/\text{m}$ ) | Limit at 3m ( $\mu\text{V}/\text{m}$ ) |
|-------------------|---|--|--|
| 30MHz to 88MHz    | 29.55dB $\mu\text{V}/\text{m}$ QPeak    | 40dB $\mu\text{V}/\text{m}$ QPeak      | 100 $\mu\text{V}/\text{m}$ QPeak       |
| 88MHz to 216MHz   | 33.05dB $\mu\text{V}/\text{m}$ QPeak    | 43.5dB $\mu\text{V}/\text{m}$ QPeak    | 150 $\mu\text{V}/\text{m}$ QPeak       |
| 216MHz to 960MHz  | 35.55dB $\mu\text{V}/\text{m}$ QPeak    | 46dB $\mu\text{V}/\text{m}$ QPeak      | 200 $\mu\text{V}/\text{m}$ QPeak       |
| 960MHz to 1000MHz | 43.45dB $\mu\text{V}/\text{m}$ QPeak    | 53.9dB $\mu\text{V}/\text{m}$ QPeak    | 500 $\mu\text{V}/\text{m}$ QPeak       |
| Above 1000MHz     | 63.45dB $\mu\text{V}/\text{m}$ Peak     | 73.9dB $\mu\text{V}/\text{m}$ Peak     | 5000 $\mu\text{V}/\text{m}$ Peak       |
|                   | 43.45dB $\mu\text{V}/\text{m}$ Average  | 53.9dB $\mu\text{V}/\text{m}$ Average  | 500 $\mu\text{V}/\text{m}$ 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.



**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<br>B4041042 |         |
| Thermometer       | AOIP                | TM 6630   | B4041042 | 2014/12                                      | 2016/06 |

**7.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION**

None

Divergence:



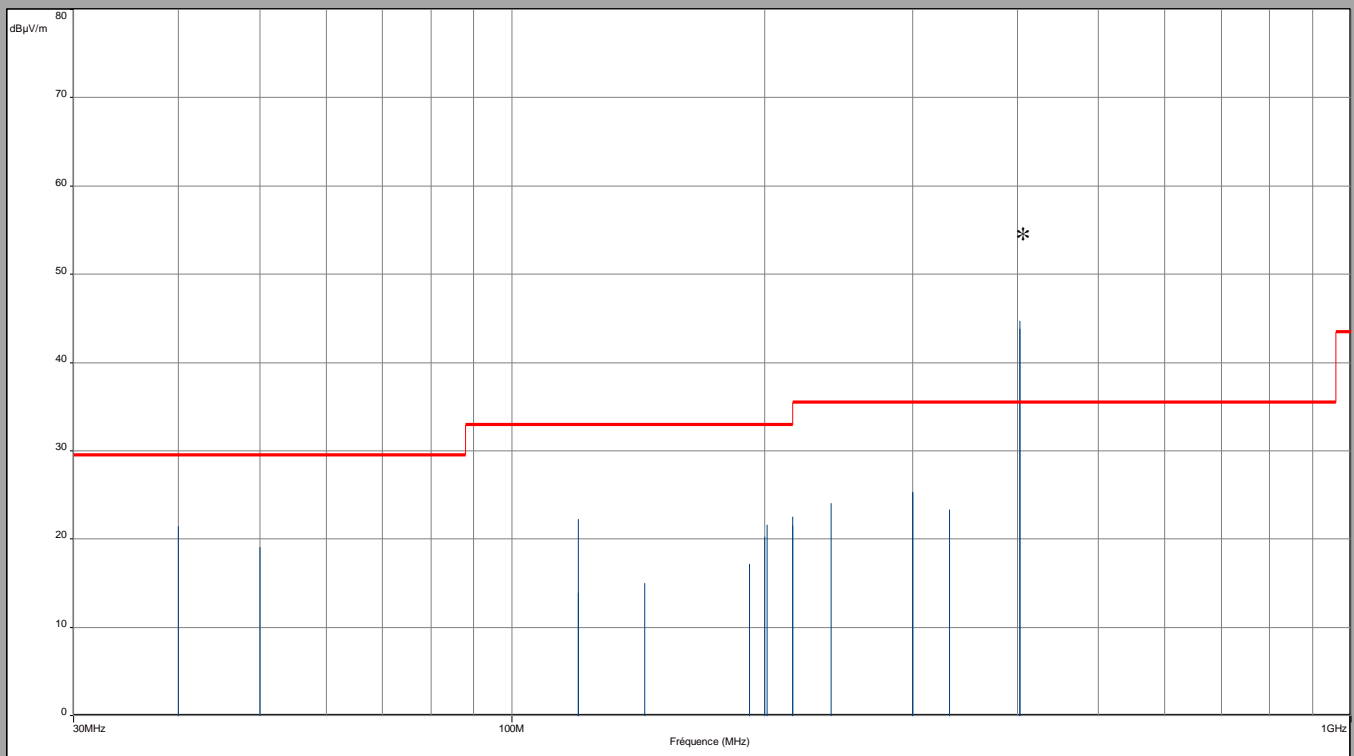
7.6. GRAPHICS & RESULTS

Out of band transmitter unwanted emissions ( below 1GHz)

400 Tx mode

Quasi peak measurement

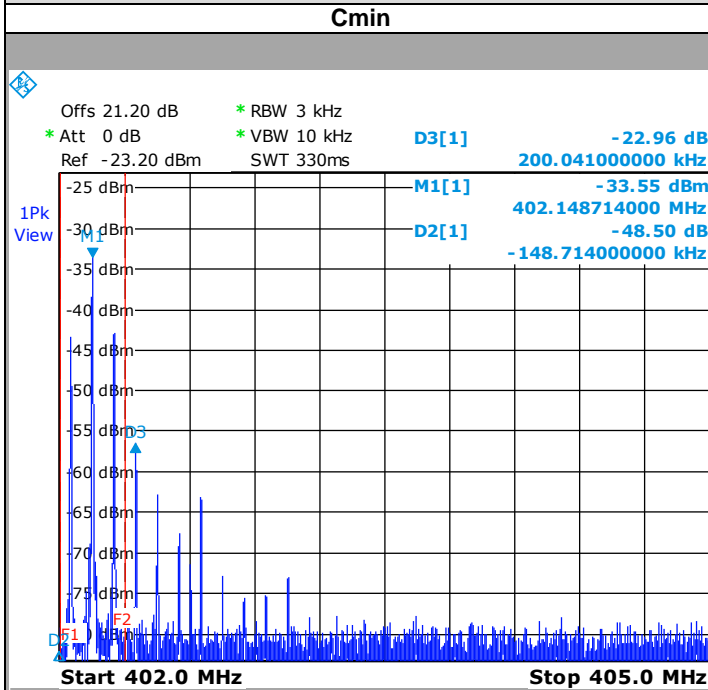
— FCC Part 15 (intentional radiator) §209 - Classe- - QCrête/10.0m/  
— Mes. Q-Peak (Horizontale)  
— Mes. Q-Peak (Verticale)  
— Mes. Q-Peak (Horizontale)  
— Mes. Q-Peak (Verticale)



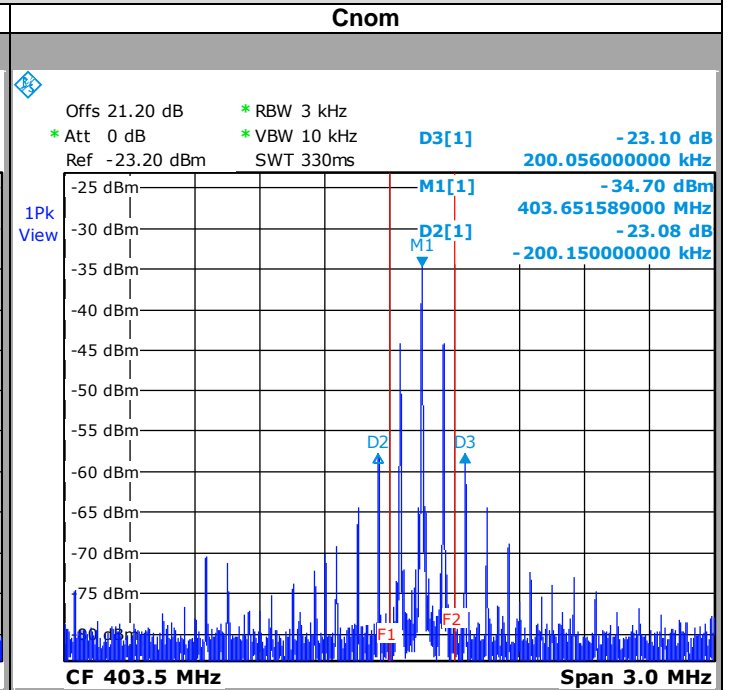
\* Transmitter frequency



**Tnom**  
**Vnom**  
**In band transmitter unwanted emissions**

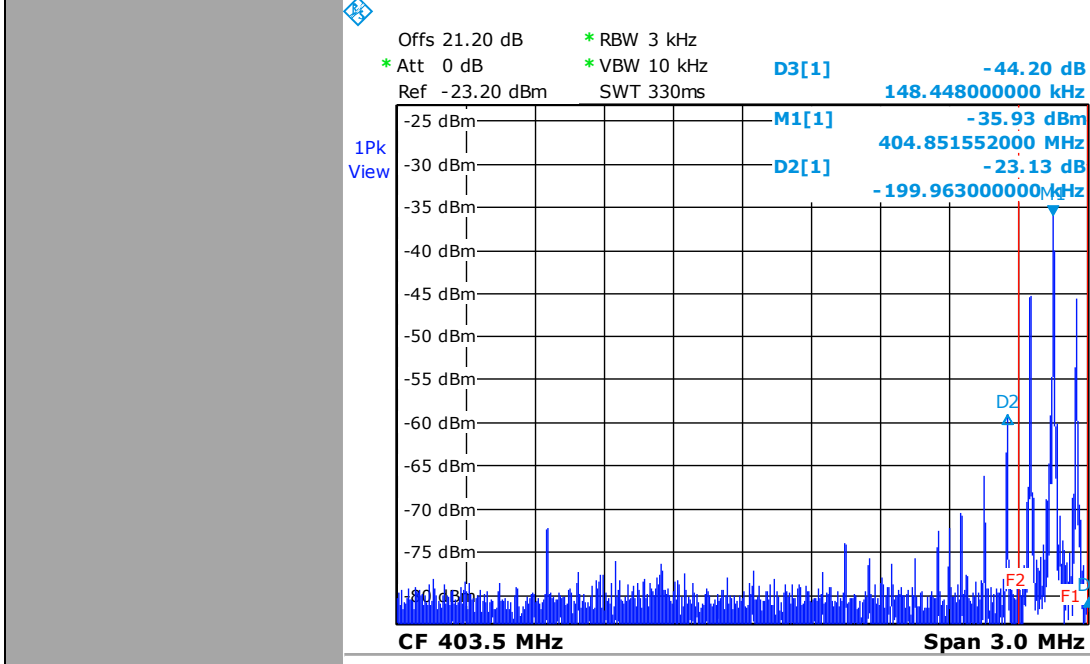


Date: 2.MAR.2016 14:38:55



Date: 2.MAR.2016 14:41:16

**Cmax**

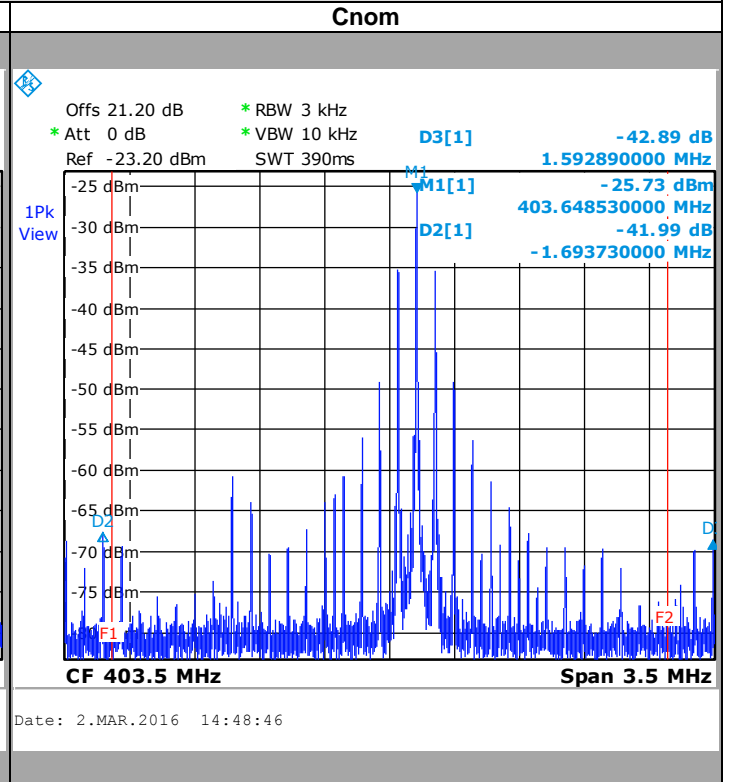
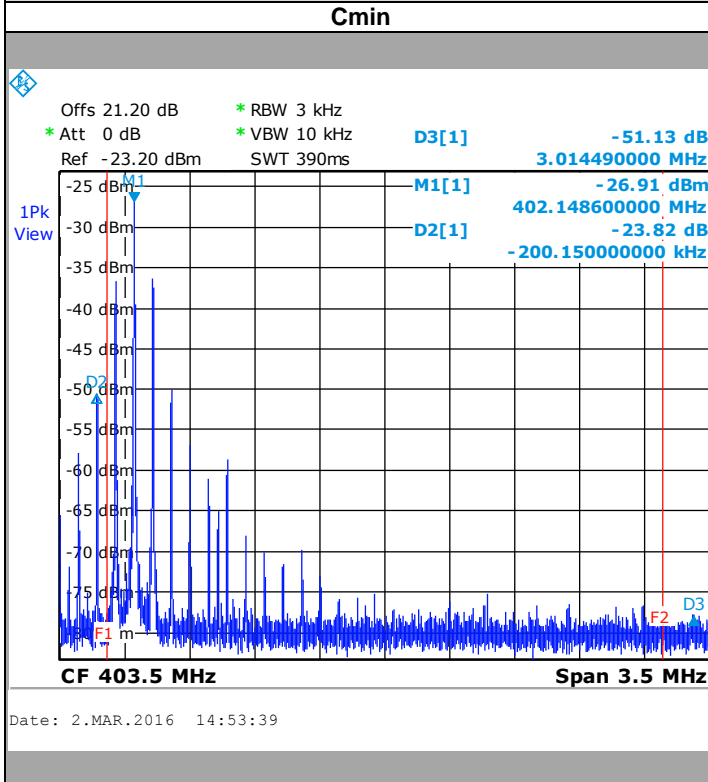


Date: 2.MAR.2016 14:42:52

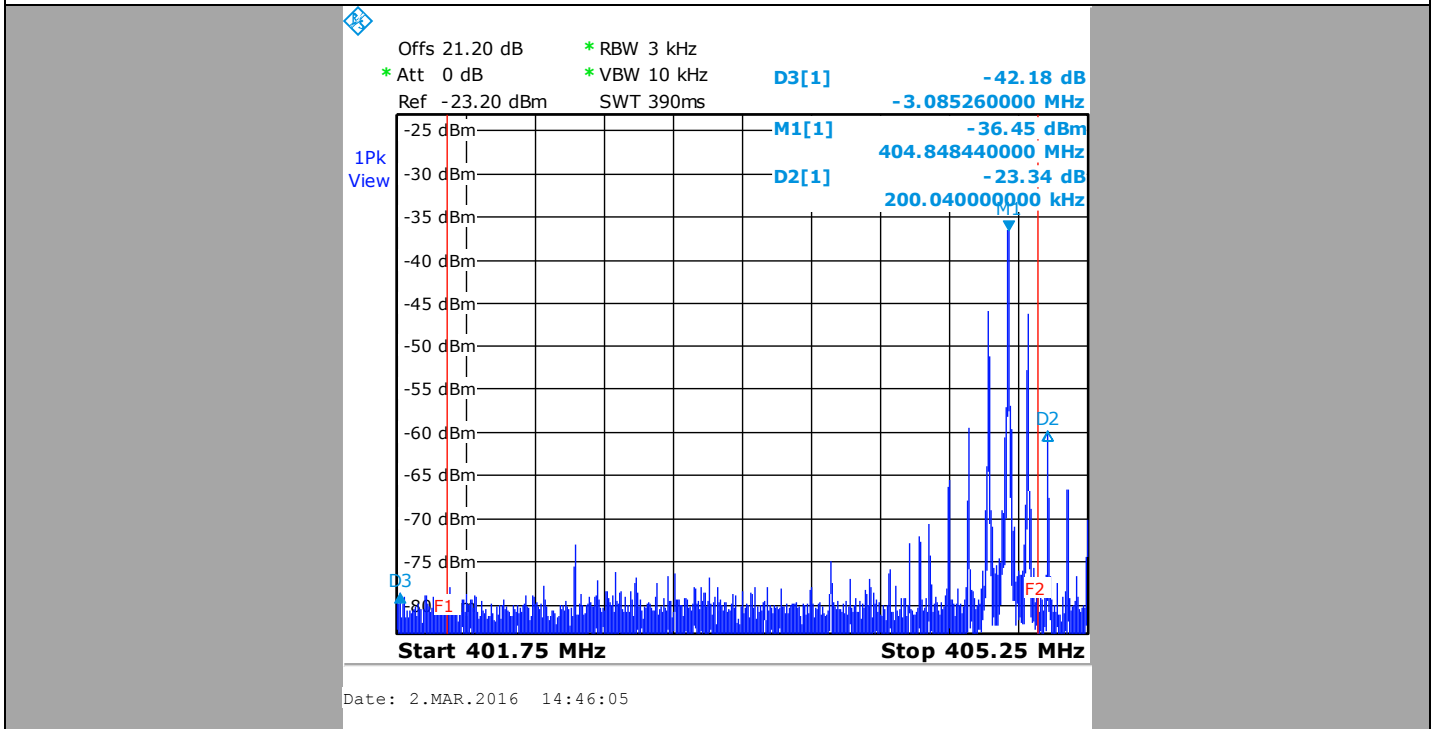


**Tnom**  
**Vnom**

**Out of band transmitter unwanted emissions +/-250kHz**



**Cmax**





**Out of band transmitter unwanted emissions**

**Below 1GHz**

| Polarization | Frequencies (MHz) | Quasi-Peak Level (dB $\mu$ V/m) | Quasi-Peak Limit (dB $\mu$ V/m) |
|--------------|-------------------|---------------------------------|---------------------------------|
| Vertical     | 40                | 21,4                            | 29.5                            |
| Vertical     | 50                | 19                              | 29.5                            |
| Vertical     | 120               | 22,3                            | 33                              |
| Vertical     | 144               | 15                              | 33                              |
| Vertical     | 192               | 17,2                            | 33                              |
| Vertical     | 199,9             | 20,3                            | 33                              |
| Vertical     | 216               | 22,6                            | 33                              |
| Vertical     | 240               | 24,1                            | 35.5                            |
| Vertical     | 300               | 25,3                            | 35.5                            |
| Vertical     | 332               | 23,4                            | 35.5                            |
| Horizontal   | 120               | 13,95                           | 33                              |
| Horizontal   | 201,3             | 21,65                           | 33                              |
| Horizontal   | 216               | 21,59                           | 33                              |
| Horizontal   | 300               | 25,33                           | 35.5                            |



Detector peak

| <b>Out of band +/-250kHz transmitter unwanted emissions</b> |                    |                    |             |
|---|--------------------|--------------------|-------------|
| Channel   | Level (dB) at Fmin | Level (dB) at Fmax | Limit (dB)  |
| Cmin  | 23,82              | 51,13              | At least 20 |
| Cnom  | 41,99              | 42,89              | At least 20 |
| Cmax  | 42,18              | 23,34              | At least 20 |

Detector peak

| <b>In band transmitter unwanted emissions</b> |                    |                    |             |
|---|--------------------|--------------------|-------------|
| Channel                                       | Level (dB) at Fmin | Level (dB) at Fmax | Limit (dB)  |
| Cmin  | 48,5               | 22,96              | At least 20 |
| Cnom  | 23,08              | 23,10              | At least 20 |
| Cmax  | 23,13              | 44,20              | At least 20 |

## 7.7. CONCLUSION

The product Sorin Group PLATINIUM 4LV SonR CRT-D 1844 , SN:J38DF043, 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 : 2016/02/02  
Ambient temperature : 18°C  
Relative humidity : 47%

### 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: 29.5dB $\mu$ V/m QPeak  
 88MHz to 216MHz: 33dB $\mu$ V/m QPeak  
 216MHz to 960MHz: 35.5dB $\mu$ V/m QPeak  
 960MHz to 1000MHz: 43.5dB $\mu$ V/m QPeak  
 Above 1000MHz: 63.5dB $\mu$ V/m Peak  
 43.5dB $\mu$ V/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:

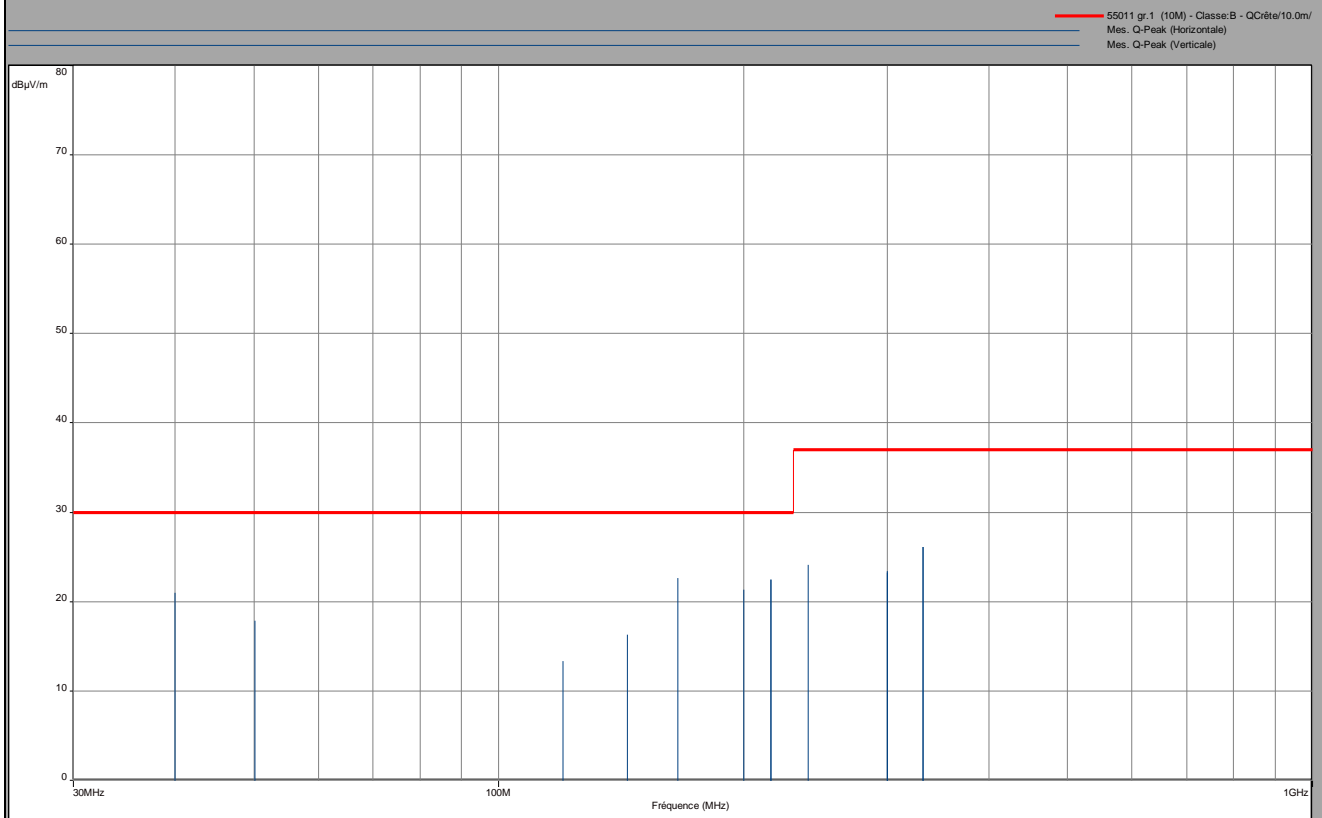


### 8.6. GRAPHICS & RESULTS

#### Out of band transmitter unwanted emissions ( below 1GHz)

400 Rx and 2.4 Rx mode

Quasi peak measurement





| <b>Out of band transmitter unwanted emissions</b> |                          |                                  |                                  |
|---|--------------------------|----------------------------------|----------------------------------|
| <b>Below 1GHz</b>                                 |                          |                                  |                                  |
| <b>Polarization</b>                               | <b>Frequencies (MHz)</b> | <b>Quasi-Peak Level (dBµV/m)</b> | <b>Quasi-Peak Limit (dBµV/m)</b> |
| Vertical  | 40                       | 21                               | 29.5                             |
| Vertical  | 50,1                     | 17,9                             | 29.5                             |
| Vertical  | 120                      | 13,4                             | 33                               |
| Vertical  | 166                      | 22,7                             | 33                               |
| Vertical  | 200                      | 21,4                             | 33                               |
| Vertical  | 216                      | 22,5                             | 33                               |
| Vertical  | 300                      | 23,4                             | 35.5                             |
| Vertical  | 332                      | 26,1                             | 35.5                             |
| Horizontal  | 144                      | 16,35                            | 33                               |
| Horizontal  | 216                      | 22,52                            | 33                               |
| Horizontal  | 240                      | 24,19                            | 35.5                             |
| Horizontal  | 300                      | 23,29                            | 35.5                             |

## **8.7. CONCLUSION**

The product Sorin Group PLATINIUM 4LV SonR CRT-D 1844 , SN:J38DF043, 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

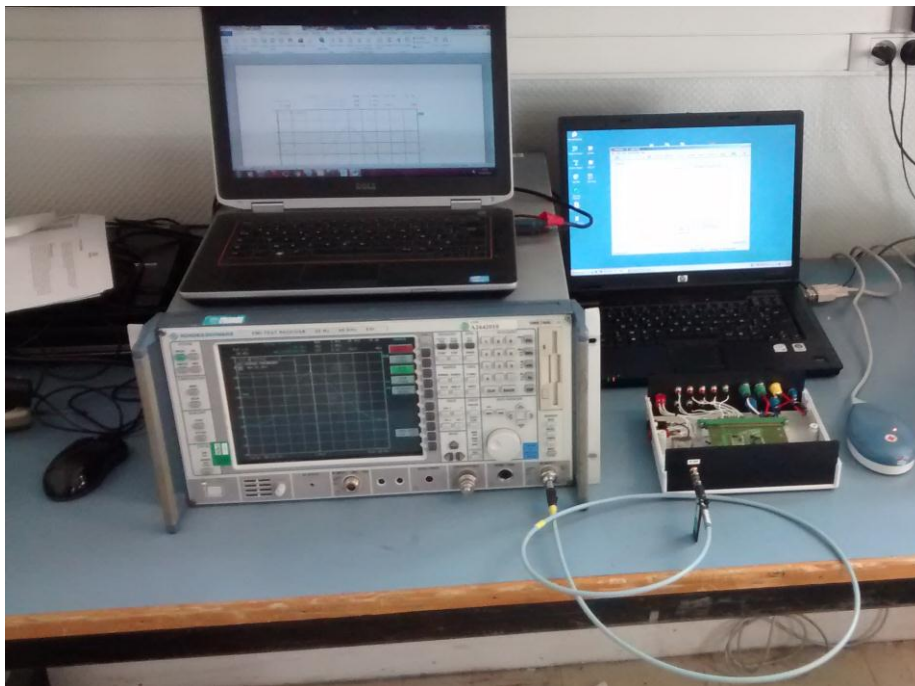
- The Equipment under Test is installed:

- 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  $\leq 1.0$  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

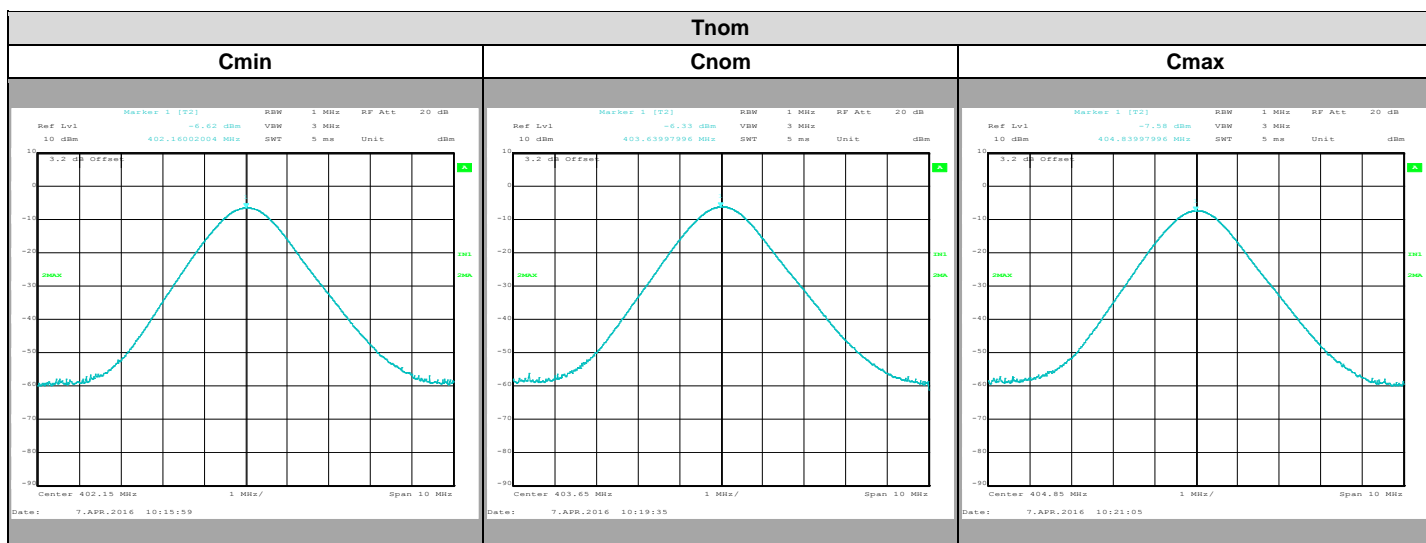
| DESCRIPTION           | MANUFACTURER             | MODEL                    | N° LCIE  | Cal_Date | Cal_Due |
|-----------------------|--------------------------|--------------------------|----------|----------|---------|
| EMI receiver          | ROHDE & SCHWARZ          | ESI40 1088<br>740K40   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

### 9.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION

None

Divergence:

### 9.6. GRAPHICS & RESULTS





| 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)                      | -44.6    | -46.6    | -45.6    |
| EIRP (mW)                       | 0.000035 | 0.000022 | 0.000028 |

## 9.7. CONCLUSION

The product Sorin Group PLATINIUM 4LV SonR CRT-D 1844 , in configuration and description presented in this test report, is excluded of SAR evaluation.



**10. UNCERTAINTIES CHART**

| Kind of test  | Measurement uncertainties<br>(k=2) $\pm x(\text{dB}) / (\text{Hz})$ | Limit for uncertainties<br>$\pm y(\text{dB})$ |
|---|---|---|
| <b>REQUIREMENTS</b>   |   |   |
| RF output power, conducted  | $\pm 0.6 \text{ dB}$  | $\pm 1,5 \text{ dB}$                          |
| Power Spectral Density, conducted   | $\pm 0.6 \text{ dB}$  | $\pm 1,5 \text{ dB}$                          |
| Unwanted Emissions, conducted   | $\pm 0.6 \text{ dB}$  | $\pm 1,5 \text{ dB}$                          |
| Radiated emissions <ul style="list-style-type: none"> <li>• Frequency &lt; 1000 MHz</li> <li>• Frequency &gt; 1000 MHz</li> </ul> | $\pm 3.9 \text{ dB}$<br>$\pm 3.1 \text{ dB}$                        | $\pm 6 \text{ dB}$                            |
| Temperature   | $\pm 0.5^\circ\text{C}$   | $\pm 1^\circ\text{C}$                         |
| Humidity  | $\pm 2.5 \%$  | $\pm 5 \%$                                    |