

# **Test report**

N°: 131328-664446ECr2015-08-04

Subject

Radio spectrum Matters (ERM) tests according to standards:

47 CFR Part 95I & RSS-243 & RSS-Gen, Issue 4

Issued to

SORIN

Parc d'Affaires NOVEOS 4 avenue Réaumur

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Apparatus under test

♥ Product

Platinium implantable cardioverter defibrillator

♦ Trade mark

SORIN Group

Manufacturer

Sorin CRM S.r.I — Italy

♥ Model

DR 1540

Serial number

128DB027

**♥ FCC ID** 

YSGDR1540

& IC ID

10270A-DR1540

6230B

**Test date** 

2014/10/03 to 2014/10/07 & 2015/01/14 & 2015/01/15

**Test location** 

Ecuelles Fontenay Aux Roses

Test performed by

Laurent DENEUX & Mathieu CERISIER

**Composition of document** 

40 pages

Modification of the last version

Document issued on

2015/08/04 2015/03/11

Written by:
Laurent DENEUX & Mathieu CERISIER

**Tests operator** 

Approved by:
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INDUSTRIES ELECTRIQUES

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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 claus	e of this test report for detail.

The product SORIN Group DR 1540, SN: 128DB027 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

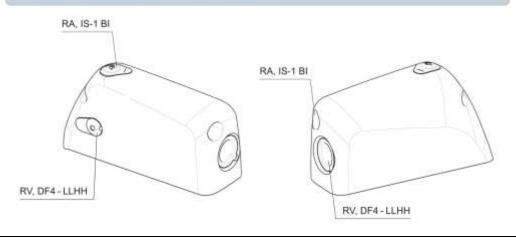
The SORIN Group PLATINIUM DR 1540 is an implantable dual-chamber cardioverter defibrillator. It is equipped with an accelerometer to allow adaptation of pacing to suit the patient's activity.

# 2.2. HARDWARE & SOFTWARE IDENTIFICATION DECLARED BY THE MANUFACTURER

# **Equipment under test (EUT):**



# Leads connection - 1540 model





# • Auxiliary equipment (AE) used for testing: -Inductive Head -Personal Computer





<ul><li>Input/output:</li></ul>
---------------------------------

- none

•	Softw	are	iden	tificat	<u>tion:</u>
-Sof	ftware	vers	sion:	ROM	V2

-Software version: RON						
<ul> <li>Equipment inform</li> <li>Modulation: 2FSK</li> <li>Transmit operating modulation</li> </ul>		<ul><li>☐ Multiples ar</li><li>☑ Single anter</li></ul>				
- Number of transmit ch	nains:	⊠ 1 □ 2				
- Number of receiver ch	nains:	⊠ 1 □ 2				
- Antenna type:			☐ External			
- Type of the equipmen	t:	⊠ Stand-alone	e equipment	☐ Plug-in radio d	evice  Combined equipment	İ
- Temperature range:	Tmin: Tnom:	☐ -20°C ⊠ 37°C	□ 0°C	⊠ 25°C		
	Tmax:	☐ +35°C	☐ 55°C	⊠ 45°C		
- Test source voltage:	Vmin: Vnom: Vmax:	☐ 207V/50Hz ☐ 230V/50Hz ☐ 253V/50Hz				
- Type of power source	:	Battery (Lith     □ External port     □		☐ Internal power ☐ Car Charger	supply	
- Test sequence/test so	ftware ι			maritta mt. dv.tv.	l Cantinuana an anatian	
<ul><li>Duty Cycle:</li><li>Equipment type:</li></ul>		<ul><li></li></ul>	duty Inte	rmittent duty nodel Pre-pro	Continuous operation oduction model	



- Operating frequency range:

Frequency Band (MHz)							
2400MHz to 2483,5MHz	$\boxtimes$						
5150MHz to 5350MHz							
5470MHz to 5725MHz							
402MHz to 405MHz	$\boxtimes$						

-Channel plan:

Criainioi piani						
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					



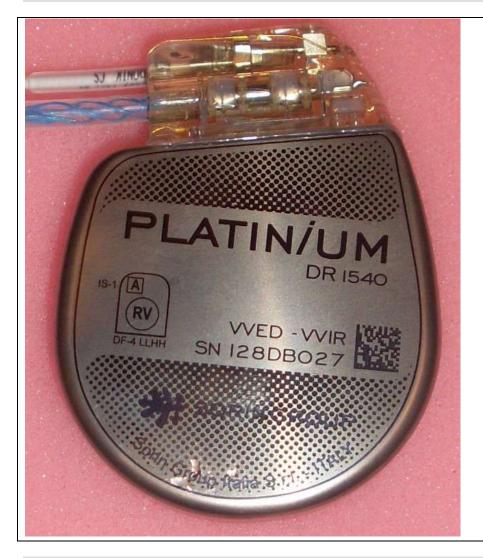
# 2.3. RUNNING MODE

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 MISC2723A 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 : 2015/01/14

Ambient temperature : 25°C

Relative humidity : 29%

#### 3.2. TEST SETUP

	Tha		inmont	under	Toot	io	installed:	
-	1110	$\Box$ UU	шинен	unaei	1651	1.5	msianeo	

In the climatic chamber

On a table

In an anechoic chamber

-Measurement is performed with a spectrum analyzer

On the EUT conducted access

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
				Verified with	Verified with
Climatic Chamber	SECASI	SLT34	D1024029	Temperature	Temperature
				Sensor	Sensor
EMI receiver	ROHDE & SCHWARZ	ESI40	A2642010	2014/02	2015/02
Temperature Sensor	AOIP	TM6630	B4041042	2014/12	2015/12

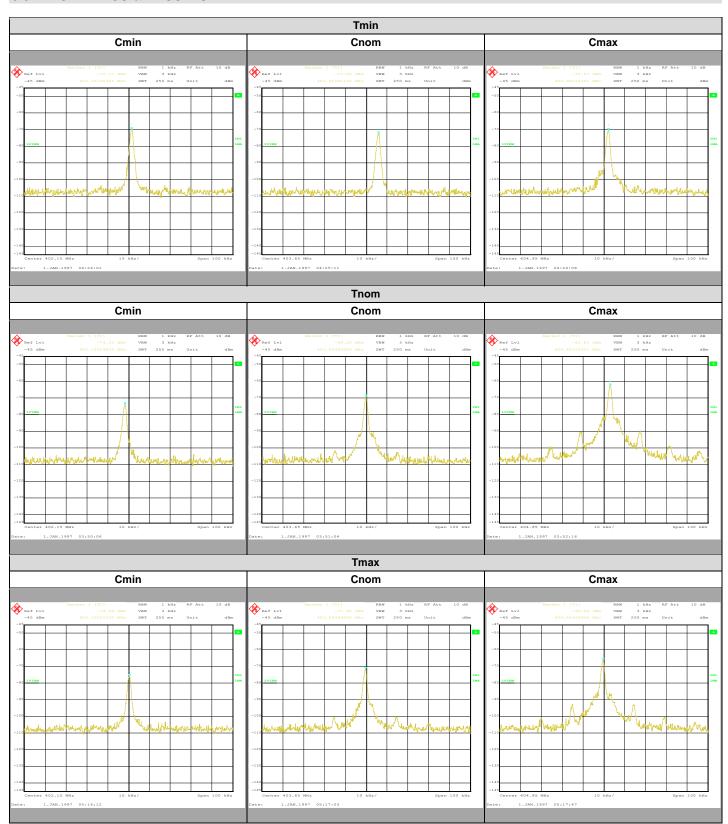
Note: In our system quality, calibration due is more & less 2 month.

3.5.	DIVERGENCE	ADDITION OR	SUPPRESSION (	ON THE TEST	SPECIFICATIO

o.o. Diverselled, Application on our recording the record of control	
⊠None □Divergence:	



# 3.6. GRAPHICS & RESULTS





Temperature	Tmin			Tnom			Tmax		
Voltage	Vnom								
Channel	Cmin	Cnom	Cmax	Cmin	Cnom	Cmax	Cmin	Cnom	Cmax
Frequency (MHz)	402,1515	403,6559	404,8523	402,1482	403,6498	404,8531	402,1505	403,6496	404,8496
Frequency error (ppm)	8,2	15,1	-2,0	REF	REF	REF	5,7	-0,5	-8,6

# 3.7. CONCLUSION

The product SORIN Group DR 1540, SN:128DB027, in configuration and description presented in this test report, complies with the frequency error measurement of FCC  $\S$  95.627(e) & RSS-243  $\S$  5.3.



# 4. EMISSION BANDWIDTH

# 4.1. TEST CONDITIONS

Test performed by : Mathieu CERISIER

Date of test : 2015/01/15 Ambient temperature : 25°C Relative humidity : 29%

# 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

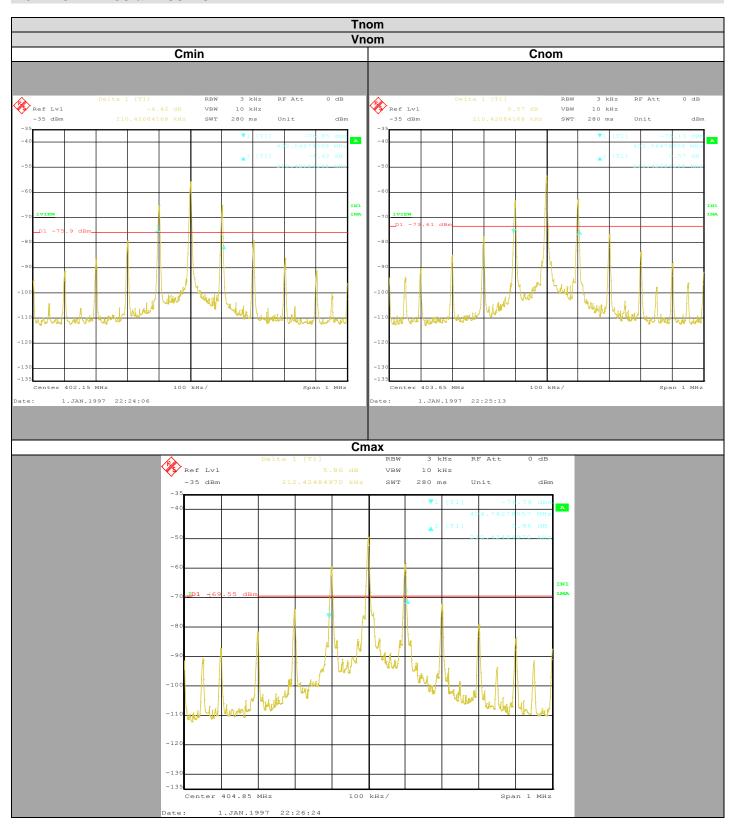
DESCRIPTION	MANUFACTURER	MODEL	N° LCIE	Cal_Date	Cal_Due
				Verified with	Verified with
Climatic Chamber	SECASI	SLT34	D1024029	Temperature	Temperature
				Sensor	Sensor
EMI receiver	ROHDE & SCHWARZ	ESI40	A2642010	2014/02	2015/02
Temperature Sensor	AOIP	TM6630	B4041042	2014/12	2015/12

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

<i>4.5.</i>	DIVERGENCE,	ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION
⊠Non	e	Divergence:



# 4.6. GRAPHICS & RESULTS





Temperature	Tnom			
Voltage	Vnom			
Channel	Cmin	Cnom	Cmax	
Emission bandwidth (kHz)	210.420	210.420	212.424	

# 4.7. CONCLUSION

The product SORIN Group DR 1540, SN:128DB027, in configuration and description presented in this test report, complies with the emission bandwidth measurement of FCC  $\S$  95.633(e) & RSS-243  $\S$  5.1.



#### 5. **OCCUPIED BANDWIDTH**

#### 5.1. **TEST CONDITIONS**

Test performed by : Mathieu CERISIER

Date of test : 2015/01/15 Ambient temperature : 25°C

#### **TEST SETUP** 5.2.

Relative humidity

- The Equipment under Test is installed:  $\begin{tabular}{l} \begin{tabular}{l} \begin{t$ 

On a table

☐ In an anechoic chamber

-Measurement is performed with a spectrum analyzer

: 29%

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
Climatic Chamber	SECASI	SLT34	D1024029	Verified with Temperature Sensor	Verified with Temperature Sensor
EMI receiver	ROHDE & SCHWARZ	ESI40	A2642010	2014/02	2015/02
Temperature Sensor	AOIP	TM6630	B4041042	2014/12	2015/12

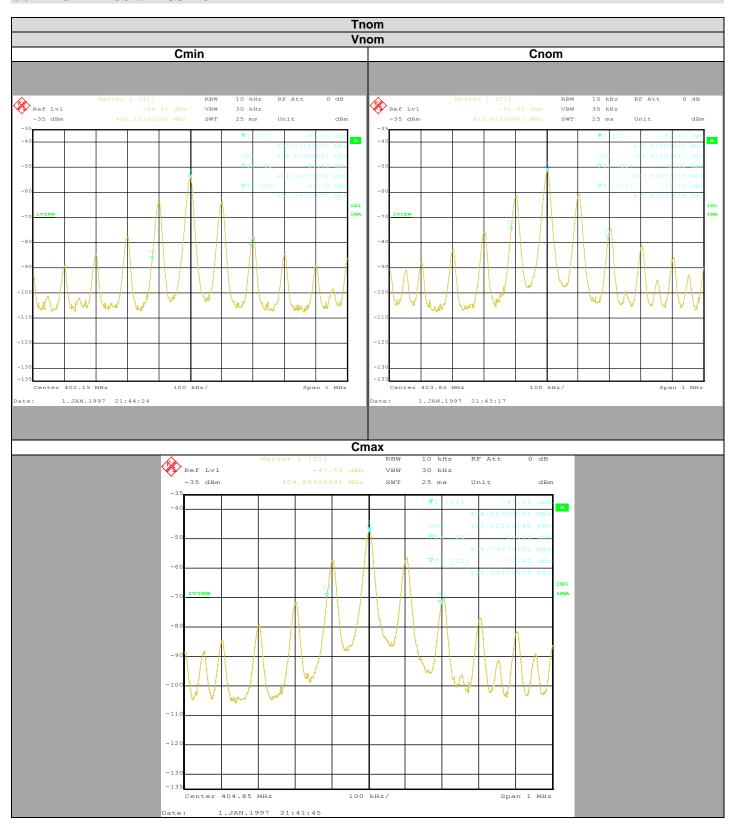
Note: In our system quality, calibration due is more & less 2 month.

5.5. DIVER	RGENCE. A	ADDITION	OR S	SUPPRES	SSION	ON TI	HE T	EST S	SPECIF	ICA	JIO	N
------------	-----------	----------	------	---------	-------	-------	------	-------	--------	-----	-----	---

⊠None	Divergence:



# 5.6. GRAPHICS & RESULTS





Temperature	Tnom			
Voltage	Vnom			
Channel	Cmin	Cnom	Cmax	
Occupied Bandwidth (kHz)	314.629	308.617	310.621	

# 5.7. CONCLUSION

The product SORIN Group DR 1540, SN:128DB027, in configuration and description presented in this test report, complies with the occupied bandwidth measurement of RSS-Gen § 6.6.



_			
ĸ.	TRANSMITTER		DOWED
U-	IKANSIVIIIIEK	COLPUL	PUVVER

6.1. TEST CONDIT	TIONS				
Test performed by Date of test Ambient temperature Relative humidity	: Laurent DENEUX : November 27th, 2014 : 18°C : 47%				
6.2. TEST SETUP					
- The Equipment Unde ☐ FAR ☐ SAR ☑ OATS	er Test is installed:				
- 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					
equipment under test.	The substitution antenna is powered by signal generator through RF cables. The input signal on 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	Туре	Registration number	Cal_Date	Cal_Due
EMI receiver	ROHDE & SCHWARZ	ESI40 1088 740K40	A2642010	2014/02	2015/02
Bilog antenna	CHASE	CBL 6112A	C2040040	2014/04	2015/04
Logperiodic antenna	ROHDE & SCHWARZ	HL 023 A2	C2040001	2014/05	2015/05
Signal Generator	ROHDE & SCHWARZ	SMY02	A5442014	2014/04	2015/04
Cable	-	-	A5329449	2014/09	2015/09
Cable	-	-	A5329368	2014/04	2015/04
cable	-	=	A5329444	2014/09	2015/09
Cable	-	-	A5329362	2014/03	2015/03
Cable	-	-	A5329442	2014/09	2015/09
OATS	L.C.I.E.	-	F2000400	2014/06	2015/06

6.5.	DIVERGENCE	, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION
⊠Non	e	Divergence:
6.6.	RESULTS	

Tnom					
Vnom					
Frequency	Generator level (dBm)	Loss (dB)	Antenna gain (dBi)	EIRP (dBm)	EIRP(μW)
402.15MHz	-48.0	2.4	5.1	-45,26	0,030
403.66MHz	-46.0	2.4	5.2	-43,26	0,047
404.85MHz	-49.0	2.4	5.2	-46,26	0,024

# 6.7. CONCLUSION

The product SORIN Group DR 1540, SN:128DB027, in configuration and description presented in this test report, complies with the transmitter output power measurement of FCC  $\S$  95.639(f) & RSS-243  $\S$  5.4.



# 7. TRANSMITTER UNWANTED EMISSIONS

#### 7.1. TEST CONDITIONS

Test performed by : Laurent DENEUX & Mathieu CERISIER Date of test : 2014/10/06 & 2014/08/19 to 2014/12/16

Ambient temperature : 18°C & 23°C Relative humidity : 51% & 43%

#### 7.2. TEST SETUP

	The	Equi	pment	under	Test	is	instal	lled:
--	-----	------	-------	-------	------	----	--------	-------

□SAR ⊠OATS

- Distance between EUT and the measuring antenna is:

□3m ⊠10m

- Choice of measuring antenna below 1GHz:

- 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.





# *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.



# 7.4. TEST EQUIPMENT LIST

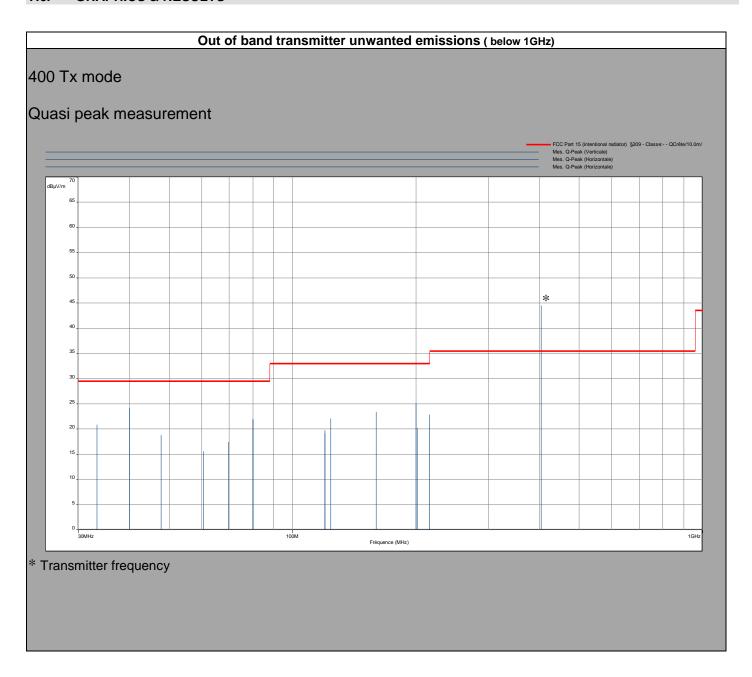
DESCRIPTION	MANUFACTURER	MODEL	N° LCIE	Cal_Date	Cal_Due
EMI receiver	ROHDE & SCHWARZ	ESI40 1088 740K40	A2642010	2014/02	2015/02
Bilog antenna	CHASE	CBL 6112A	C2040040	2014-04	2015-04
Cable	-	ı	A5329449	2014-09	2015-09
Cable	-	ı	A5329368	2014-03	2015-03
Cable	-	-	A5329444	2014-09	2015-09
Cable	-	-	A5329542	2014-01	2015-01
OATS	L.C.I.E.	-	F2000400	2014-06	2015-06
Horn Antenna	EMCO	3115	C2042016	2014-04	2015-04
Preampli	HEWLETT PACKARD	8449B	A4069002	2014-04	2015-04
Climatic Chamber	MPC	F65/350L	D1025035	2013/12	2014/12
EMI receiver	ROHDE & SCHWARZ	FSIQ7	A4060040	2013/11	2014/11
Temperature Sensor	HP	34970A	A6440070	2014/01	2016/01

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

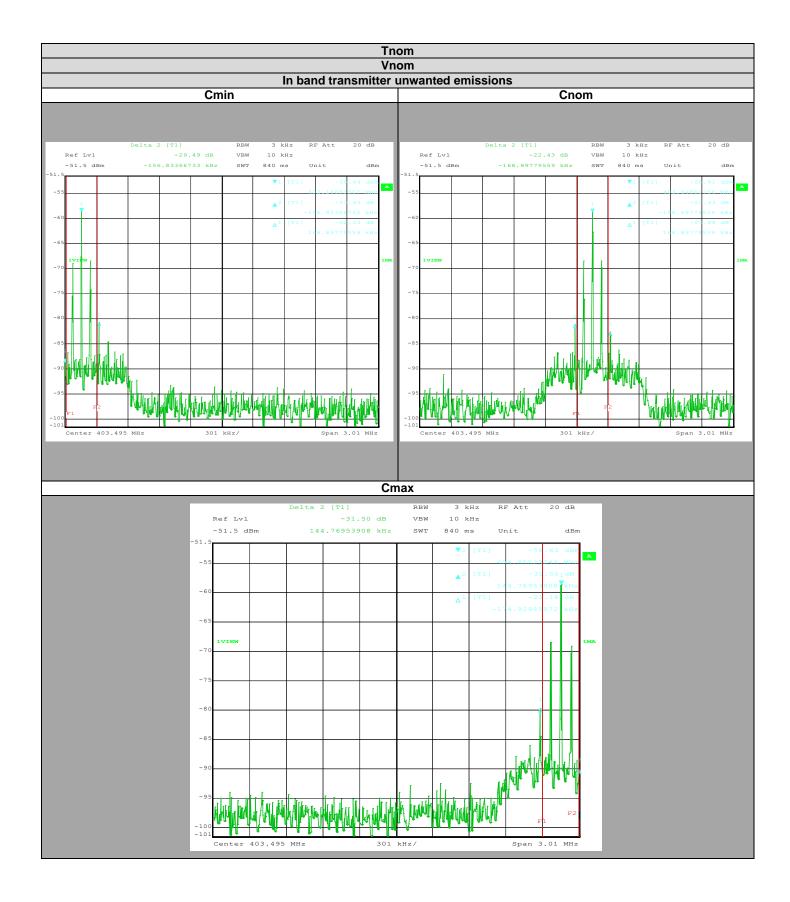
<i>7.5.</i>	DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION
⊠Non	Divergence:



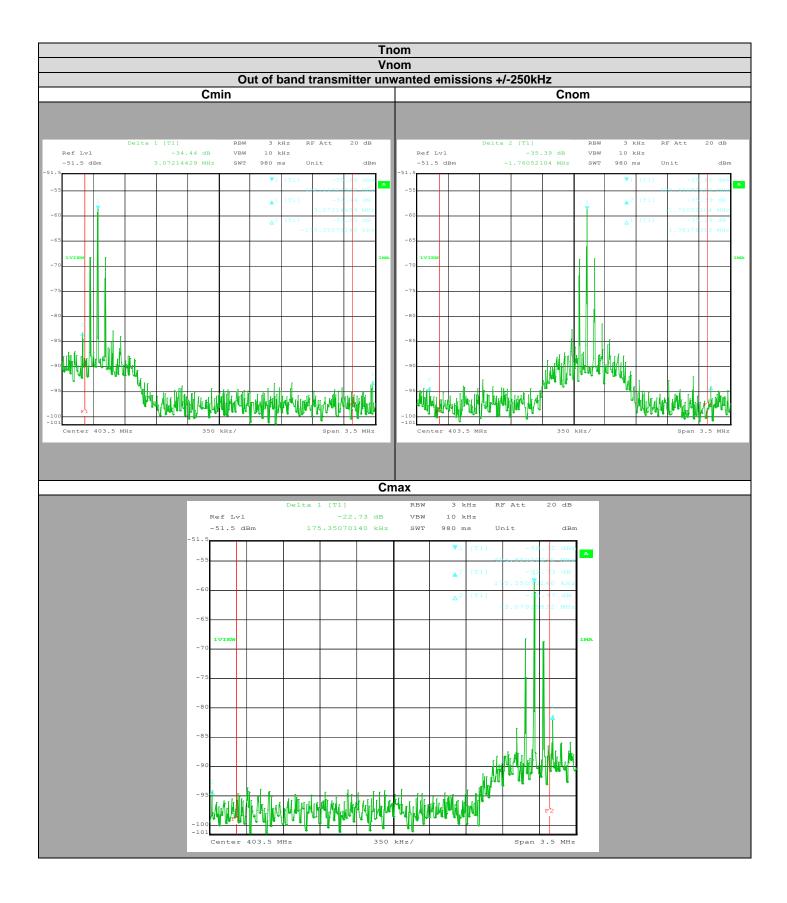
# 7.6. GRAPHICS & RESULTS













Out of band transmitter unwanted emissions						
Below 1GHz						
Polarization	Frequencies (MHz)	Quasi-Peak Level (dBµV/m)	Quasi-Peak Limit (dBµV/m)			
Vertical	33.3	20.85	29.5			
Vertical	40	24.25	29.5			
Vertical	47.8	18.88	29.5			
Vertical	60.6	15.62	29.5			
Vertical	69.7	17.45	29.5			
Vertical	80	22.02	29.5			
Vertical	120	19.18	33			
Vertical	160	23.45	33			
Vertical	200	25.17	33			
Vertical	216	22.91	33			
Horizontal	80	21.85	33			
Horizontal	120	19.83	33			
Horizontal	123.8	22.09	33			
Horizontal	201.3	20.25	33			
Horizontal	216	20.95	33			



# Detector peak

Out of band +/-250kHz transmitter unwanted emissions					
Channel	Level (dB) at Fmin	Level (dB) at Fmax	Limit (dB)		
Cmin	24,60	34,44	At least 20		
Cnom	35,39	35,29	At least 20		
Cmax	35,47	22,73	At least 20		

# Detector peak

In band transmitter unwanted emissions					
Channel Level (dB) at Fmin Level (dB) at Fmax Limit (dB)					
Cmin	29,49	22,23	At least 20		
Cnom	23,38	22,43	At least 20		
Cmax	21,18	31,50	At least 20		

# 7.7. CONCLUSION

The product SORIN Group DR 1540, SN:128DB027, in configuration and description presented in this test report, complies with the Unwanted Emission into Restricted Bands measurement of FCC  $\S$  95.635(d) & RSS-243  $\S$  5.5.



8.	DECENTED	CDUDIOUS	ENJUCCIONIC
ο.	RECEIVER	SPURIOUS	EMI22ION2

#### 8.1. TEST CONDITIONS

Test performed by : Laurent DENEUX
Date of test : 2014/11/27
Ambient temperature : 18°C

Relative humidity : 51%

8.2.	TEST	SETH	D
O.Z.	IESI	<b>JEIU</b>	г

<ul> <li>The Equipment under Test is installed</li> </ul>
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□SAR ⊠OATS

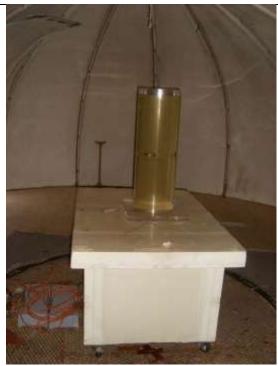
- Distance between EUT and the measuring antenna is:

- Choice of measuring antenna below 1GHz:

- 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



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Receiver spurious emissions shall not exceed value below:

 $\begin{array}{lll} 30 \text{MHz to } 88 \text{MHz:} & 29.5 \text{dB}\mu\text{V/m QPeak} \\ 88 \text{MHz to } 216 \text{MHz:} & 33 \text{dB}\mu\text{V/m QPeak} \\ 216 \text{MHz to } 960 \text{MHz:} & 35.5 \text{dB}\mu\text{V/m QPeak} \\ 960 \text{MHz to } 1000 \text{MHz:} & 43.5 \text{dB}\mu\text{V/m QPeak} \\ \text{Above } 1000 \text{MHz:} & 63.5 \text{dB}\mu\text{V/m Average} \\ \end{array}$ 

# 8.4. TEST EQUIPMENT LIST

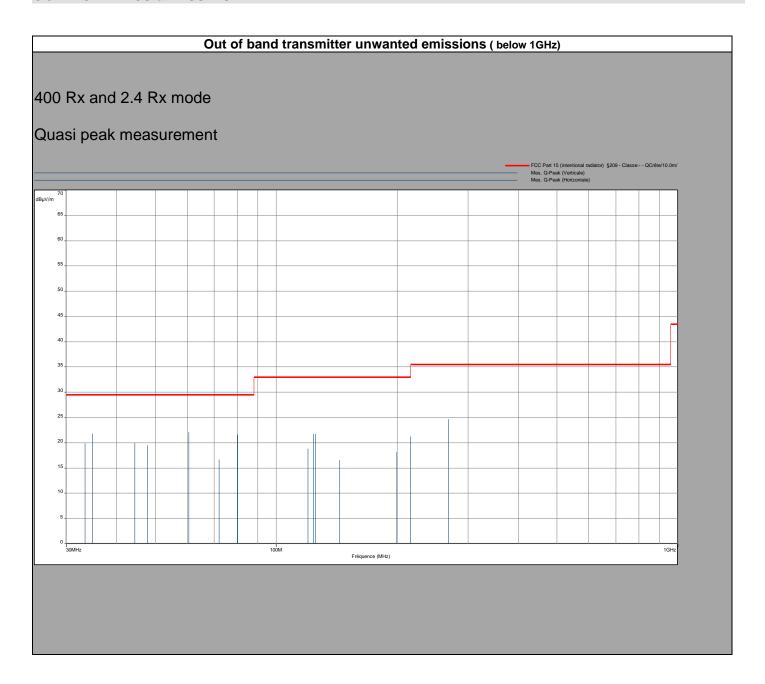
DESCRIPTION	MANUFACTURER	MODEL	N° LCIE	Cal_Date	Cal_Due
EMI receiver	ROHDE & SCHWARZ	ESI40 1088 740K40	A2642010	2014/02	2015/02
Bilog antenna	CHASE	CBL 6112A	C2040040	2014-04	2015-04
Cable	-	-	A5329449	2014-09	2015-09
Cable	-	-	A5329368	2014-03	2015-03
Cable	-	-	A5329444	2014-09	2015-09
Cable	-	-	A5329542	2014-01	2015-01
OATS	L.C.I.E.	-	F2000400	2014-06	2015-06
Horn Antenna	EMCO	3115	C2042016	2014-04	2015-04
Preampli	HEWLETT PACKARD	8449B	A4069002	2014-04	2015-04

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

8.5.	DIVERGENCE,	ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION
⊠None	е	Divergence:



# 8.6. GRAPHICS & RESULTS





Out of band transmitter unwanted emissions					
	Below 1GHz				
Polarization	Frequencies (MHz)	Quasi-Peak Level (dBµV/m)	Quasi-Peak Limit (dBµV/m)		
Vertical	33.4	19.91	29.5		
Vertical	34.9	21.81	29.5		
Vertical	44.4	19.96	29.5		
Vertical	47.8	19.51	29.5		
Vertical	60.6	22.1	29.5		
Vertical	72	16.74	29.5		
Vertical	80	21.52	29.5		
Vertical	120	18.84	33		
Vertical	123.6	21.78	33		
Vertical	144	16.54	33		
Vertical	199.4	18.19	33		
Horizontal	80	21.68	33		
Horizontal	125	21.73	33		

# 8.7. CONCLUSION

The product SORIN Group DR 1540, SN:128DB027, 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 : Mathieu CERISIER

Date of test : 2015/07/31

Ambient temperature : 26 Relative humidity : 32%

# 9.2. TEST SETUP

- The Equipment unde	er Test is installed:
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☐ In the climatic chamber

On a table

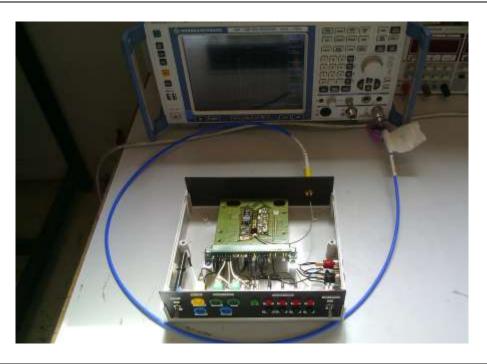
☐ In an anechoic chamber

# -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.

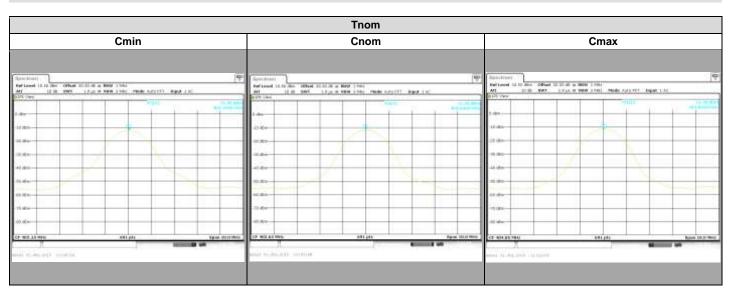
#### 9.4. TEST EQUIPMENT LIST

DESCRIPTION	MANUFACTURER	MODEL	N° LCIE	Cal_Date	Cal_Due
EMI test receiver	R&S	ESR	A2642023	03/2015	03/2016
RF cable & Attenuator	Télédyne & MINI CIRCUITS	920-0202-024 & FW-20+	A5329674	10/2014	10/2015

# 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)	-11,98	-11,59	-11,4	
RF conducted output power (mW)	0,063	0,069	0,072	
EIRP (dBm)	-45.26	-43.26	-46.26	
EIRP (mW)	0.000030	0.000047	0.000024	

# 9.7. CONCLUSION

The product SORIN Group DR 1540, 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	±3.9 dB	±6 dB
Frequency > 1000 MHz	±3.1 dB	
Temperature	±0.5°C	±1°C
Humidity	±2.5 %	±5 %