

Test report

N°: 131328-664445FCr2015-08-04

Subject

Radio spectrum Matters (ERM) tests according to standards:

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

Issued to

SORIN CRM

Parc d'Affaires NOVEOS

4 avenue Réaumur 92143 Clamart cedex

Apparatus under test

♥ Product

Platinium implantable cardioverter defibrillator

♦ Trade mark

SORIN Group

Manufacturer

Sorin CRM S.r.l — Italy

♥ Model

VR 1210

Serial number

125D1071

♥ FCC ID

YSGVR1210

♥ IC ID

10270A-VR1210

6230B

Test date

2014/11/04 to 2014/11/20

Test location

Ecuelles Fontenay Aux Roses

Test performed by

Laurent DENEUX & Mathieu CERISIER

Composition of document

39 pages

Modification of the last version 2015/08/04

Document issued on

2015/03/11

Written by: Laurent DENEUX & Mathieu CERISIER **Tests operator**





Technical manager DES S.A.S au capital de 15.745.984 €

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A-01



SUMMARY

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1	TEST	PROGRA	м

References

Standards:

-47 CFR FCC Part 95I

-RSS-243 -RSS-Gen -FCC 15.207 -FCC 15.109

· Requirements:

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	e of this test report for detail.

The product SORIN Group VR 1210, SN: 125D1071 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

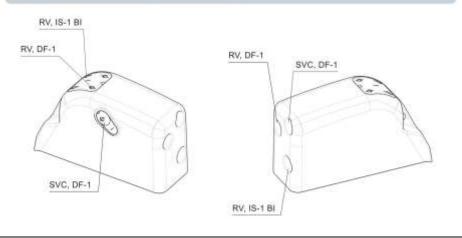
The SORIN Group PLATINIUM VR 1210 is an implantable single-chamber cardioverter defibrillator. It is equipped with an accelerometer to allow adaptation of pacing to suit the patient's activity.

2.2. HARDWARE & SOFTWARE IDENTIFICATION DECLARED BY THE MANUFACTURER

Equipment under test (EUT):



Leads connection - 1210 model



Photograph of EUT



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





•	ln	pu	<u>t/o</u>	ut	<u>put:</u>	

- none

- NOTIC						
	Software identification: Software version: ROM V2					
 Equipment information: Modulation: 2FSK Transmit operating mode: 			ltiples an gle anter			
- Number of transmit ch	nains:	⊠ 1	_ 2			
- Number of receiver ch	nains:	⊠ 1	□ 2			
- Antenna type:		⊠ Inte	egral	☐ External		
- Type of the equipmen	t:	⊠ Sta	nd-alone	equipment	☐ Plug-in radio device	e Combined equipment
- Temperature range:	Tmin: Tnom: Tmax:	☐ -20 ☑ 37 ☐ +35	°C	□ 0°C □ 55°C	 25°C 45°C	
- Test source voltage:	Vmin: Vnom: Vmax:	<u> </u>	V/50Hz V/50Hz V/50Hz	∑ 2.5Vdc∑ 2.62Vdc∑ 3.24Vdc		
- Type of power source:		=	• `	aline/Lithium-lor wer supply	n/Lead acid/Other)	☐ Internal power supply ☐ Car Charger
Test sequence/test softwareDuty Cycle:Equipment type:			ntinuous			ntinuous operation tion model



- Operating frequency range:

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

-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 MISC2723A document

2.4. EQUIPMENT LABELLING



2.5. EQUIPMENT MODIFICATION

\times	No equipment modification has been necessary during t	testing.
	Modification applied for following tests:	



3. FREQUENCY ERROR

3.1. TEST CONDITIONS

Test performed by : Mathieu CERISIER

Date of test : 2014/11/04 Ambient temperature : 22°C Relative humidity : 42%

3.2. TEST SETUP

_	Tho	Fauinmen	tundar	Tact ic	inetallad	•

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 and marker peak functions are 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

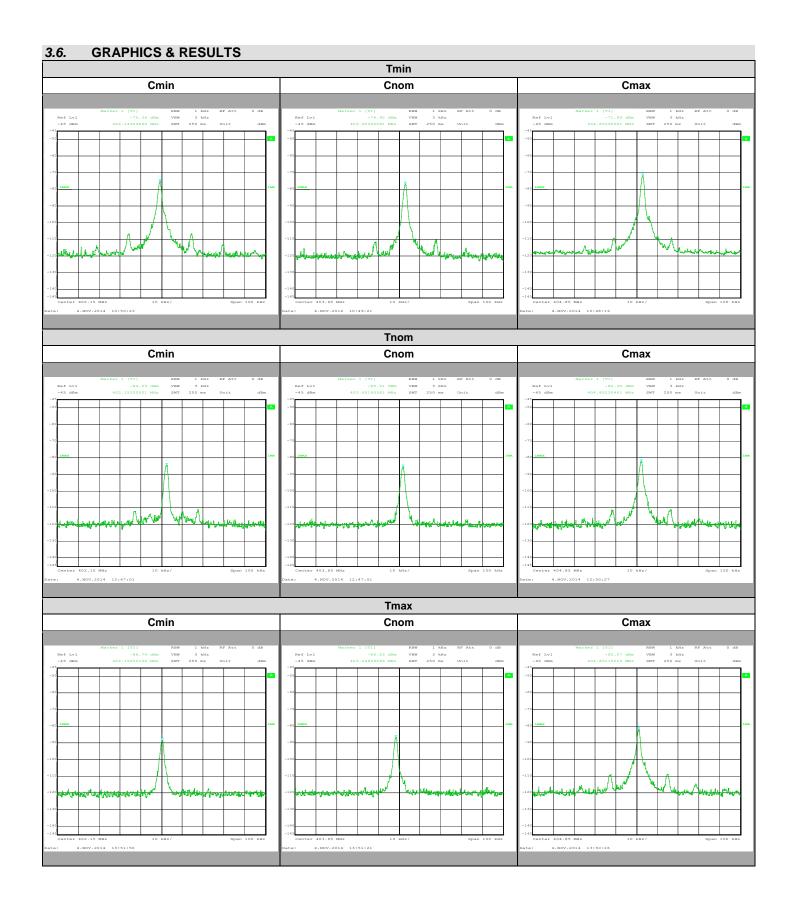
DESCRIPTION	MANUFACTURER	MODEL	N° LCIE	Cal_Date	Cal_Due
Climatic Chamber	MPC	F65/350L	D1025035	2013/12	2014/12
EMI receiver	ROHDE & SCHWARZ	FSIQ7	A4060040	2013/11	2014/11
Temperature Sensor	HP	34970A	A6440070	2014/01	2016/01

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

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

5.5.	DIVERSELIES, ADDITION OR SOLI RESOLON ON THE LEST OF ESTIMATION
⊠Non	e Divergence:







Temperature	Tmin		Tnom		Tmax				
Voltage		Vnom							
Channel	Cmin	Cnom	Cmax	Cmin	Cnom	Cmax	Cmin	Cnom	Cmax
Frequency (MHz)	402.1492	403.6529	404.8529	402.1525	403.6519	404.8523	402.1505	403.6484	404.8511
Frequency error (ppm)	-8.2	2.5	1.5	REF	REF	REF	-5.0	-8.7	-3.0

3.7. CONCLUSION

The product SORIN Group VR 1210, SN:125D1071, 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 : 2014/11/05 Ambient temperature : 22°C Relative humidity : 42%

4.2. TEST SETUP

- The Equipment under Test is installed:

In the climatic chamber

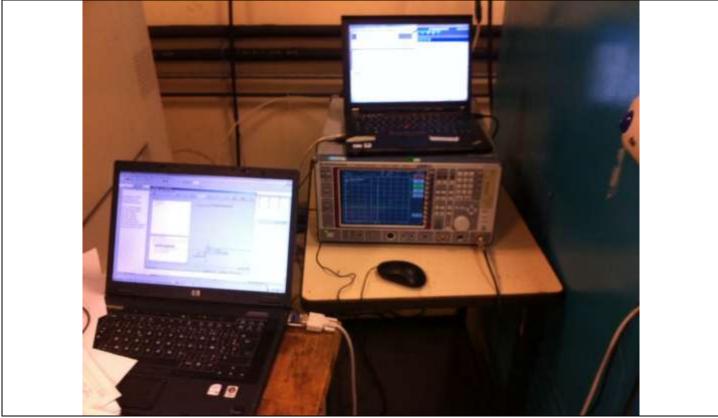
On a table

☐ In an anechoic chamber

-Measurement is performed with a spectrum analyzer

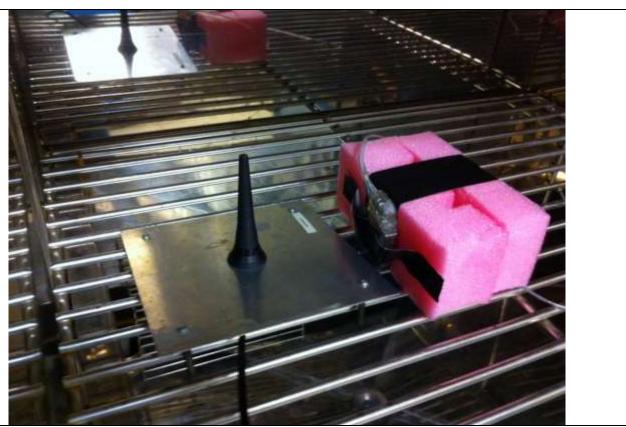
☐ On the EUT conducted access

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

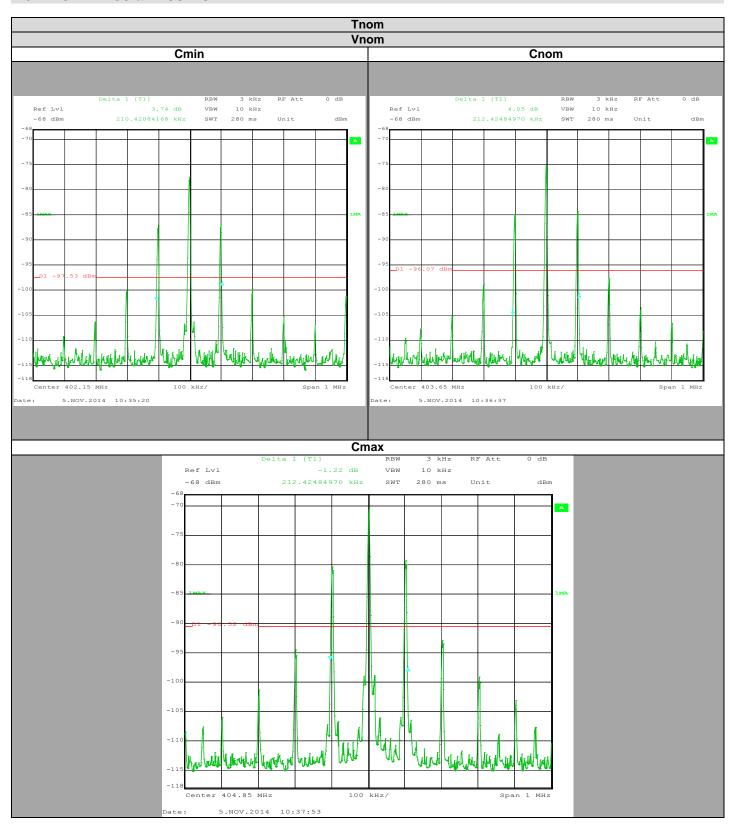
DESCRIPTION	MANUFACTURER	MODEL	N° LCIE	Cal_Date	Cal_Due
Climatic Chamber	MPC	F65/350L	D1025035	2013/12	2014/12
EMI receiver	ROHDE & SCHWARZ	FSIQ7	A4060040	2013/11	2014/11
Temperature Sensor	HP	34970A	A6440070	2014/01	2016/01

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

<i>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)	212,421	212,425	212,425	

4.7. CONCLUSION

The product SORIN Group VR 1210, SN:125D1071, 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 : 2014/11/05 Ambient temperature : 22°C Relative humidity : 42%

5.2. **TEST SETUP**

- 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

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	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

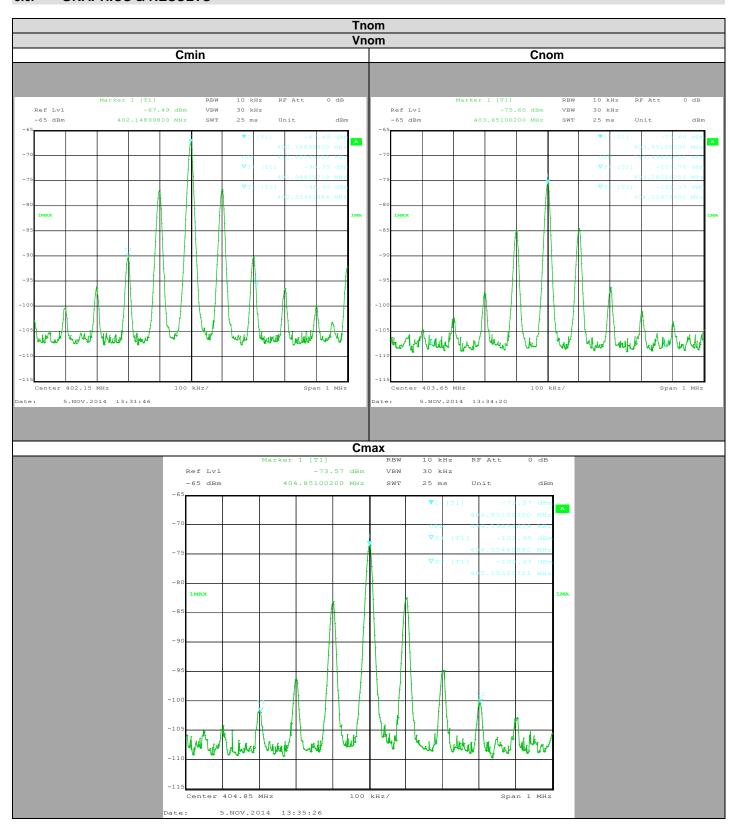
Note: In our system quality, calibration due is more & less 2 month.

5.5.	DIVERGENCE	ADDITION OR	SUPPRESSION (ON THE TEST	SPECIFICATION
11-11-	DIVERGENGE.		OUTER EGGIUN I	JIN THE LEGI	OFECIFICATION

None	Divergence:		



5.6. GRAPHICS & RESULTS





Temperature	Tnom			
Voltage	Vnom			
Channel	Cmin	Cnom	Cmax	
Occupied Bandwidth (kHz)	410,822	749,499	599,198	

5.7. CONCLUSION

The product SORIN Group VR 1210, SN:125D1071, in configuration and description presented in this test report, complies with the occupied bandwidth measurement of RSS-Gen § 6.6.



6.	TRANSMITTER	CUITDUIT	DOWED
O.	IKANSMILIER	OUTPUL	PUWER

6.1. TEST CONDITI	ONS				
Date of test Ambient temperature	: Laurent DENEUX : 2014/11/20 : 18°C : 47%				
6.2. TEST SETUP					
- The Equipment Under ☐ FAR ☐ SAR ☑ OATS	Test is installed:				
- Distance between EUT and the measuring antenna is: ☐ 3m ☐ 10m					
the EUT is found by the With measurement a	ove the ground reference plane on an isolating table and the maximum emitted power value from rotation of the 360°turntable and: antenna height at 1.5m from the ground reference plane surement antenna height between 1m and 4m from the ground reference plane				
equipment under test. The substitution antenna Mean power at the output	na is in vertical and then in horizontal polarization. The substitution antenna replaces the The substitution antenna is powered by signal generator through RF cables. The input signal on a is adjusted in order to obtain the same value found in the maximum emitted power search. put of the transmitter and product antenna gain (A+G) are deduced after correction due to the 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
⊠Nor	ne	Divergence:
6.6.	RESULTS	

		Tnom			
		Vnom			
Frequency	Generator level (dBm)	Loss (dB)	Antenna gain (dBi)	EIRP (dBm)	EIRP(µW)
402.15MHz	-45	2,4	5,1	-42,3	0,059
403.66MHz	-46	2,4	5,2	-43,2	0,048
404.85MHz	-46	2,4	5,2	-43,2	0,048

6.7. CONCLUSION

The product SORIN Group VR 1210, SN:125D1O71, 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 : 2014/11/20 & 2014/11/05

Ambient temperature : 18°C & 22°C Relative humidity : 47% & 42%

7.2. TEST SETUP

□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

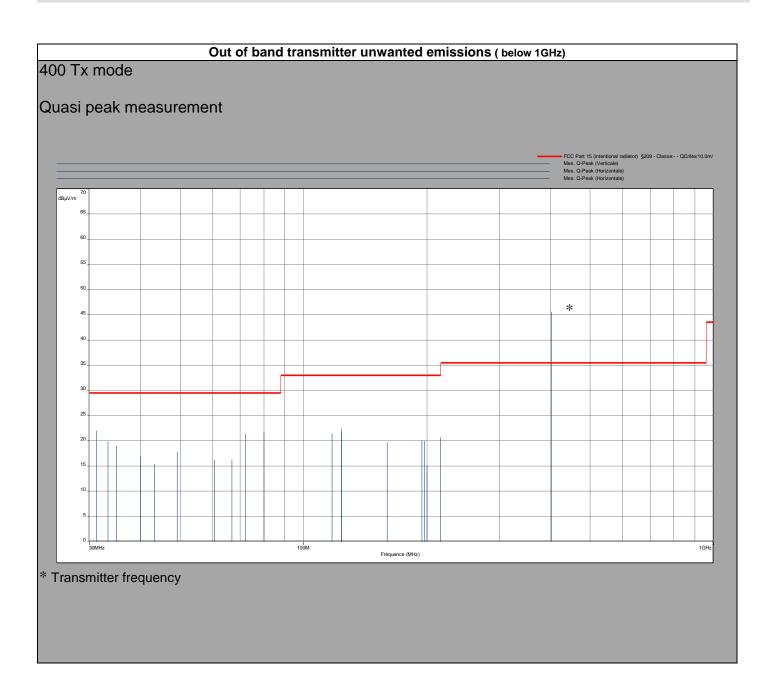
Apparatus	Trade Mark	Туре	Registration number	Cal_Date	Cal_Due
EMI receiver	ROHDE & SCHWARZ	ESI40 1088 740K40	A2642010	2014/02	2015/02
Bilog antenna	CHASE	CBL 6112A	C2040040	2014-04	2015-04
Cable	-	=	A5329449	2014-09	2015-09
Cable	-	=	A5329368	2014-03	2015-03
Cable	-	=	A5329444	2014-09	2015-09
Cable	-	=	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
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.

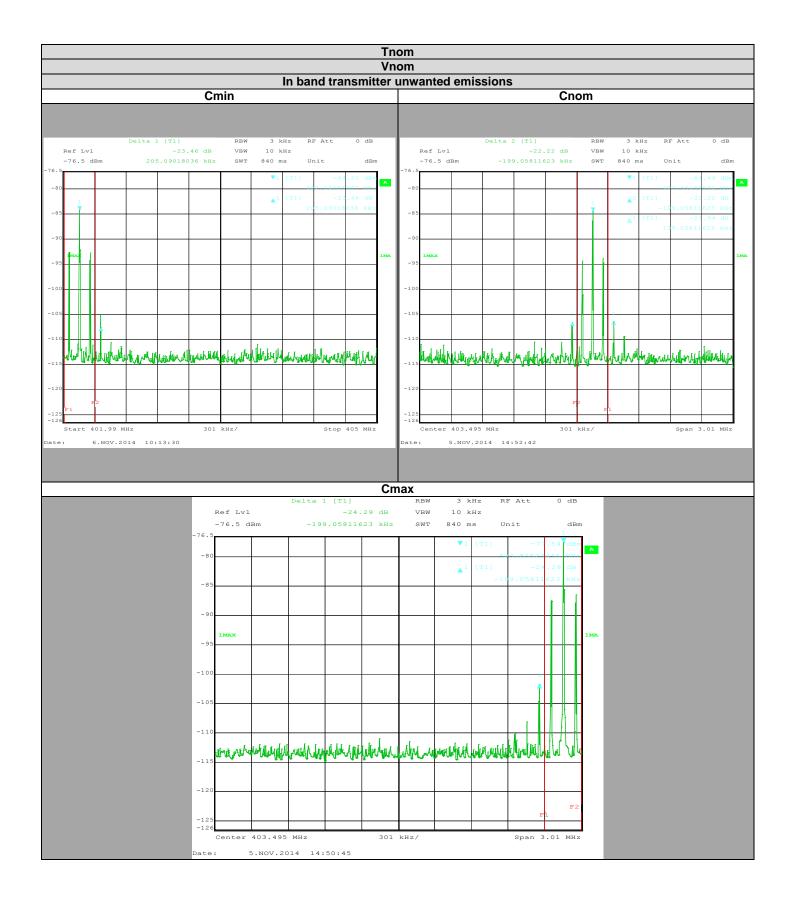
<i>7.5.</i>	DIVERGENCE, A	ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION
None	е [Divergence:



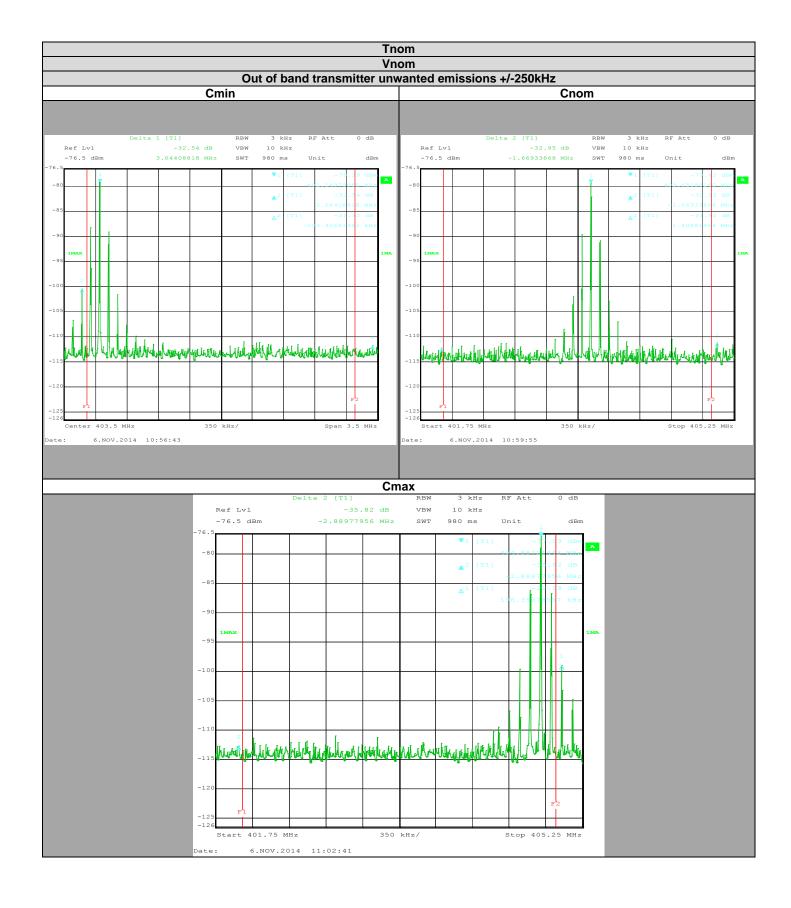
7.6. GRAPHICS & RESULTS













	Out of band transr	mitter unwanted emis	ssions
	В	elow 1GHz	
Polarization	Frequencies (MHz)	Quasi-Peak Level (dBµV/m)	Quasi-Peak Limit (dBµV/m)
Vertical	31.3	22.02	29.5
Vertical	33.3	19.88	29.5
Vertical	35	18.98	29.5
Vertical	40	16.91	29.5
Vertical	43.3	15.46	29.5
Vertical	49.2	17.82	29.5
Vertical	60.6	16.21	29.5
Vertical	66.8	16.28	29.5
Vertical	72.2	21.43	29.5
Vertical	80	21.76	29.5
Vertical	117.4	21.53	33
Vertical	123.6	22.51	33
Vertical	160	19.74	33
Vertical	194.3	20.07	33
Vertical	200	15.16	33
Horizontal	123.7	21.77	33
Horizontal	197	20.01	33
Horizontal	216	20.73	33



Detector peak

Out of ba	and +/-250kHz trans	smitter unwanted er	missions
Channel	Level (dB) at Fmin	Level (dB) at Fmax	Limit (dB)
Cmin	21,32	32,54	At least 20
Cnom	32,95	31,90	At least 20
Cmax	35,82	22,08	At least 20

Detector peak

İr	n band transmitter (unwanted emission	S
Channel	Level (dB) at Fmin	Level (dB) at Fmax	Limit (dB)
Cmin	30,12	23,46	At least 20
Cnom	22,22	21,94	At least 20
Cmax	24,29	31,17	At least 20

7.7. CONCLUSION

The product SORIN Group VR 1210, SN:125D1071, 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.	DECEIVED	CDUDIOUS	EMISSIONS
ο.	RECEIVER	SPURIOUS	FINISSIONS

⊠Horn

8.1. **TEST CONDITIONS** Test performed by : Laurent DENEUX : 2014/11/20 Date of test 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:

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



.3.			П

Receiver spurious emissions shall not exceed value below:

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

43.5dBµV/m Average

8.4. 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
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
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

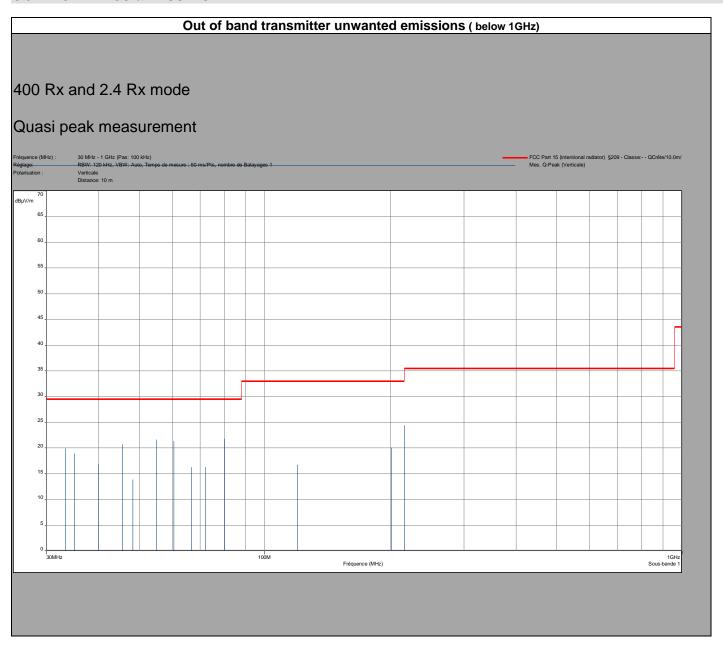
Note: In our system quality, calibration due is more & less 2 month.

8.5. DIVERGENCE, ADDITION OR SUPPRESSION ON THE TEST SPECIFICATION

None Divergence:
Zivene Estrengenee.



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	33.3	19.92	29.5		
Vertical	35	18.9	29.5		
Vertical	40	16.89	29.5		
Vertical	45.6	20.75	29.5		
Vertical	48.3	13.93	29.5		
Vertical	55	21.66	29.5		
Vertical	60.6	21.42	29.5		
Vertical	66.7	16.3	29.5		
Vertical	72.2	16.31	29.5		
Vertical	80	21.78	29.5		
Vertical	120	16.73	33		
Vertical	201.3	20.08	33		
Vertical	216.3	24.42	33		
Horizontal	123.6	16.8	33		
Horizontal	194.3	20	33		
Horizontal	200	19.75	33		

8.7. CONCLUSION

The product SORIN Group VR 1210, SN:125D1071, 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**

TEST CONDITIONS 9.1.

Test performed by : Mathieu CERISIER

Date of test : 2015/07/31

Ambient temperature : 26 Relative humidity : 32%

TEST SETUP 9.2.

_	The	Faui	oment	under	Test	is	installed	١.
	1110	Lyui		unuci	1 001	ı	II IStance	4.

☐ In the climatic chamber

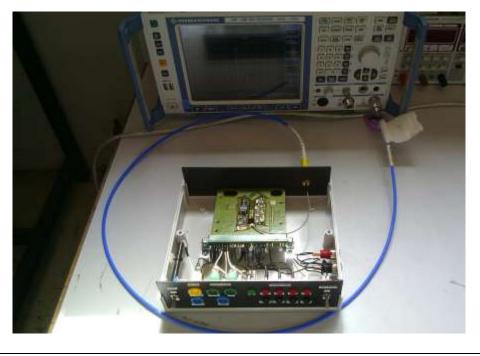
On a table

☐ 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. RESULTS

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	Э	Divergence:

9.6. GRAPHICS & RESULTS

	Tnom		
Cmin	Cmin Cnom Cma		
September 1 (1.1) de Chart (1.1) de propi (1.1) de			
27 SQ 3.5 May	20 周世 20 周世 21 成年 (日 南世 12 成年 (日 南世 12 (日 中 (元)(14) (14) (14) (14) (14) (14) (14) (14)	## ### ### ### ### #### ##############	



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)	-42,3	-43,2	-43,2	
EIRP (mW)	0.000059	0.000048	0.000048	

9.7. CONCLUSION

The product SORIN Group VR 1210, 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 %