

## TEST REPORT

RADIO

Number

112624-622708-F-Cr2012-10-22

Composition of document

45 pages

Standards

ETSI EN 301 839-1 V1.2.1 ETSI EN 301 839-2 V1.3.1 FCC RULES PART 951 FCC RULES PART 15 FCC RYLES PART 2

IC RADIO STANDARDS RSS-243

Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1

of Certification Ordinance)

Issued to

SORIN CRM

Parc d'affaires NOVEOS 4. Avenue Réaumur

92140 Clamart Cedex, FRANCE

Mme DE JESO

Apparatus under test

Trade mark

Manufacturer

Type

Serial number

Syndeli RF implantable cardioverter defibrillator

SORIN Group

SORIN BIOMEDICA CRM

PARADYM RF — CRT-D model 9750

148YY028

Test date

2012/03/20 and 2012/03/26 to 2012/03/30

Tests performed by

Stéphane PHOUDIAH & Laurent DENEUX

Test site

Fontenay Aux Roses & Ecuelles

File issued on File corrected on File initialy issued on 2012/10/22 2012/10/22 2012/04/18

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## 1. Test Program

## • References

Standards: ETSI EN 301 839-1 V1.3.1

ETSI EN 301 839-2 V1.2.1 ERC Recommendation 70-03 FCC RULES PART 95I FCC RULES PART 15 FCC RULES PART 2

IC RADIO STANDARDS RSS-243

Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of Certification Ordinance)

## • Transmitter requirement:

Clause (FTS) FN 204 920 4)	TEST DESILIT Comments
Clause (ETSI EN 301 839–1)	TEST RESULT - Comments
Clause (FCC PART 95I)	
Clause (RSS 243)	
Clause (Specified low-power radio equipment (Item 8 of Article 2	
Paragraph 1 of Certification Ordinance))	
Test Description	D. 00
EN § 8.1 – Frequency error	PASS
FCC § 95.627 (e) – Frequency stability	PASS
FCC § 2.1055 – Measurements required: Frequency stability	PASS
RSS § 3.3 – Frequency stability	PASS
Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of	PASS
Certification Ordinance) –Tolerance of frequency	
EN § 8.3 – Effective radiated power of the fundamental emission	PASS
FCC § 95.639 (f) – Maximum transmitter power	PASS
FCC § 2.1046 – Measurements required: RF power output	PASS
RSS § 5.4 – Maximum transmitter power	PASS
Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of	PASS
Certification Ordinance) – Antenna gain	
EN § 8.2 – Emission bandwidth	PASS
FCC § 95.633 (e) – Emission bandwidth	PASS
FCC § 2.1049 – Measurements required: Occupied bandwidth	PASS
RSS § 3.2 – Occupied bandwidth	PASS
Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of	PASS
Certification Ordinance) – Tolerance of occupied bandwidth	
EN § 8.5 – Frequency stability under low voltage conditions	N/A (EUT hermetically sealed: See last
	paragraph in clause 5.2.2 of ETSI EN
	301 839-1 V1.3.1)
EN § 8.4 – Spurious emissions of transmitter	PASS
Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of	
Certification Ordinance) – Tolerance of unwanted emission intensity	PASS
FCC § 95.635 (d) – Unwanted radiation	PASS
FCC § 2.1053 – Measurements required: Field strength of spurious radiation	PASS
RSS § 3.4 – Unwanted radiation	PASS
Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of	
Certification Ordinance) – Limit of secondary radiated emission	
15.207 – Conducted emission	N/A (Equipment powered by battery)
FCC § 2.1047 – Measurements required: Modulation characteristics	PASS ( please refer to §2.1
3	Equipment information p.5)
FCC § 2.1057 – Frequency spectrum to be investigated	PASS (see §2.1
1 - 5 3 - 1 10 quelley opeoutain to be investigated	Equipment information p.5)
	Equipment information p.J)



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**Receiver requirement:** 

Clause (ETSI EN 301 839–1)	TEST RESULT -
Clause (FCC PART 15) (only for 400MHz receiver)	Comments
Clause (FCC PART 95I)	
Clause (RSS 243-243)	
Test Description	
EN § 9.1 – Spurious radiation of receivers	PASS
FCC § 2.1053 – Measurements required: Field strength of spurious radiation	PASS
FCC § 15.109 – Radiated emissions	PASS
RSS § 3.5 – Radiated emissions	PASS
EN § 10.1 – Monitoring system threshold power level	N/A
FCC § 95.627 (a)(3) – Monitoring system threshold power level	N/A
RSS § 5.7.1 – Monitoring system threshold power level	N/A
EN § 10.2 – Monitoring system bandwidth	N/A
FCC § 95.627 (a)(1) – Monitoring system bandwidth	N/A
RSS § 5.7.2 – Monitoring system bandwidth	N/A
EN § 10.3.1.1 & 10.3.3.1 – Scan cycle time	N/A
FCC § 95.627 (a)(2) – Scan cycle time	N/A
RSS § 5.7.3 – Scan cycle time	N/A
EN § 10.3.1.2 & 10.3.3.2 – Minimum channel monitoring period	N/A
FCC § 95.627 (a)(2) – Minimum channel monitoring period	N/A
RSS § 5.7.4 – Minimum channel monitoring period	N/A
EN § 10.4 – Channel access	N/A
FCC § 95.627 (a)(4) – Channel access	N/A
RSS § 5.7.5 – Channel access	N/A
EN § 10.5 – Discontinuation of MICS session	N/A
95.627 (a)(4) – Discontinuation of MICS session	N/A
RSS § 5.7.6 – Discontinuation of MICS session	N/A
Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of Certification	
Ordinance) – Transmission suspension function due to interruption of communications	N/A
EN § 10.6 – Use of pre-scanned alternate channel	N/A
FCC § 95.627 (a)(5) – Use of pre-scanned alternate channel	N/A
RSS § 5.7.7 – Use of pre-scanned alternate channel	N/A

PASS: EUT complies with standard's requirement FAIL: EUT does not comply with standard's requirement

N/A: Not Applicable N/P: Test Not Performed

Remark: The equipment is: - transmitter and receiver at 400MHz - only receiver at 2400 MHz.



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## 2. EQUIPMENT DESCRIPTION

#### 2.1. HARDWARE IDENTIFICATION

#### Equipment under test (EUT):



The EUT is housed in a single cabinet that cannot be readily opened because the enclosure is hermetically sealed.

#### Auxiliary equipment used for testing:

- -Human torso simulator
- -Fluid corresponding to human tissue characteristics at that frequency.
- -Lead IS-1 LV
- -Lead IS-1 A
- -Lead IS-1 RV
- -Lead DF-1 SVC
- -Lead DF-1 RV

## Equipment information:

- External antenna connector: No
- Frequency band allocated: 402MHz to 405MHz
- Frequency used for test: -Fmin: 402,15MHz

-Fnom: 403,65MHz -Fmax: 404,85MHz

Modulation: 2 FSKData rate: 200kb/sNumber of channel: 10Antenna type: Integral

- Equipment intended for use as a mobile station
- Equipment designed for continuous operation
- Stand By mode: No
- Extreme temperature range: -Tmin: 25°C

-Tnom: 37°C -Tmax: 45°C

- Extreme test source voltage: -Vnom: BOL: 3.25 V. ERI: 2.66 V. EOL: 2.5 V (Internal Battery)



#### 2.2. RUNNING MODE

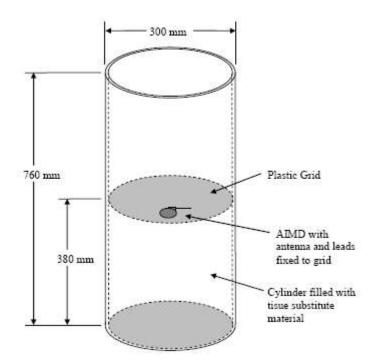
The EUT is set in the following modes during tests:

- -Permanent emission with modulation
- -Permanent emission without modulation
- -Permanent reception

#### 2.3. EQUIPEMENT SET UP AND TESTING CONFIGURATION

Equipment (ULP-AMIs) intended to be implanted in a human body shall be tested in a simulated man constructed as follows in order to simulate operation of the ULP-AMI under actual operation conditions as shown in figure A.2 of EN 301 489-1.

An appropriate simulator for testing ULP-AMI consists of a cylindrical acrylic container with an outside diameter of 300 mm, a sidewall thickness of 6 mm, and a fluid-filled height of 760 mm. It shall be filled with a material that is sufficiently fluid that it will flow around the AIMD without any voids. The dielectric and conductivity properties of this material shall match the dielectric and conductivity properties of human muscle tissue at 403,5 MHz (conductivity = 0,93 and relative permittivity = 57,2). Simple saline solutions do not meet the dielectric and conductivity requirements for use as a substitute for human tissue. All emissions measurements will be made using the above specification with the tissue substitute material at a nominal temperature between 22 °C and 38 °C.



For the testing, the equipment under test (EUT) was suspended in a Plexiglas torso simulator as specified above. The simulator used was constructed in accordance with FCC 95.627(g)(3)(i), EN 301 839-1 (A.113) and EN 301 489-27 annex B.

During the test, the EUT was centred vertically in Plexiglas cylinder. The torso simulator was filled with a fluid formulated is in accordance with the specification by using tissue material corresponding to human tissue characteristics at that frequency. The fluid temperature was maintained between 20° to 25° C. There are also the reference for simulator fluid (see annex 2).



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## 2.4. EQUIPEMENT LABELLING



## 2.5. EQUIPMENT MODIFICATIONS

No equipment modification has been necessary during testing.



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## 3. Frequency Error & Frequency Stability

## 3.1. TEST CONDITIONS

Test performed by : Stéphane PHOUDIAH

Date of test : 2012/03/27 Ambient temperature : 24°C Relative humidity : 32%

#### 3.2. TEST SETUP

FCC 95.627(e) RSS 243 §3.3

ETSI EN 301 839-1 §8.1

Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of Certification Ordinance)

The test is performed on EUT in permanent emission without modulation mode.

For measurement under normal and extreme test conditions, the Equipment Under Test is installed in the climatic chamber. A test fixture is created to perform the measurement.

## 3.3. RESULTS

Frequency: Fmin

Temperature	Tmin	Tnom	Tmax
Power voltage: Vnom			
Frequency (MHz)	402,1498	402,1512	402,1522
Frequency Drift (ppm)	-0,49732687	2,98396121	5,47059555

Frequency: Fnom

Temperature	Tmin	Tnom	Tmax
Power voltage: Vnom			
Frequency (MHz)	403,65399	403,6536	403,65
Frequency Drift (ppm)	9,88480119	8,91861761	0

Frequency: Fmax

Temperature	Tmin	Tnom	Tmax
Power voltage: Vnom			
Frequency (MHz)	404,85399	404,8516	404,8538
Frequency Drift (ppm)	9,85550204	3,95208102	9,38619242

## See graphics in annex 1

Result: PASS

**Limit:** → ± 100 ppm



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## 4. EFFECTIVE RADIATED POWER, MAXIMUM TRANSMITTER POWER & ANTENNA POWER

#### 4.1. TEST CONDITIONS

Test performed by : Stéphane PHOUDIAH

Date of test : 2012/03/26 Ambient temperature : 24°C Relative humidity : 28%

#### 4.2. TEST SETUP

FCC 95.639(f) RSS 243 §5.4

ETSI EN 301 839-1 §8.3

Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of Certification Ordinance)

The test is performed on EUT in permanent emission without modulation mode on vertically and horizontally position. The setup is 1.5m above the ground reference plane on a wooden table. Distance between measuring antenna and the

The setup is 1.5m above the ground reference plane on a wooden table. Distance between measuring antenna and the EUT is 3 meters. The measuring antenna is in vertical and then in horizontal polarization. Measurement bandwidth was 100kHz.Continuous linear turntable azimuth search was performed with 360 degrees range.

The substitution method is used to obtain the effective isotropic radiated power and effective radiated power. (KDB 412172 D01 Determining ERP and EIRP)

#### 4.3. RESULTS

#### Maximum values for both polarizations:

Frequency (MHz)	Generator (dBm)	Cables loss (dB)	Antenna Gain (dBi)	EIRP (dBm)	EIRP (µW)	ERP (dBm)	ERP (µW)
Fmin	-35,5	1,6	6,6	-40,5	0,089	-42,64	0,054
Fnom	-35,3	1,7	6,6	-40,2	0,095	-42,34	0,058
Fmax	-37,2	1,8	6,6	-42	0,063	-44,14	0,038

Result: PASS

**Limit:**  $\rightarrow$  25µW or -16dBm



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## 5. EMISSION BANDWIDTH & OCCUPIED BANDWIDTH

#### 5.1. TEST CONDITIONS

Test performed by : Stéphane PHOUDIAH

Date of test : 2012/03/28 Ambient temperature : 25°C Relative humidity : 30%

#### 5.2. TEST SETUP

FCC 95.633(e) RSS 243 §3.2

ETSI EN 301 839-1 §8.2

Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of Certification Ordinance)

The test is performed on EUT in permanent emission with modulation. the Equipment Under Test is installed in the climatic chamber. A test fixture is created to perform the measurement. RBW was 3kHz and VBW was 10kHz. The Emission Bandwidth is measured 20dB below the peak power.

## 5.3. RESULTS

Frequency (MHz)	Emission Bandwidth (kHz)	Occupied Bandwidth (kHz)
Fmin	206,9	219,88
Fnom	208,6	213,41
Fmax	208,6	206,95

#### See graphics in annex 1

Result: PASS

Limit: → Shall not exceed 300kHz



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#### 6. Spurious emissions of transmitter & Tolerance of unwanted emission intensity

#### 6.1. TEST CONDITIONS

Test performed by : Stéphane PHOUDIAH

Date of test : 2012/03/26 Ambient temperature : 23°C Relative humidity : 30%

#### 6.2. TEST SETUP

ETSI EN 301 839-1 §8.2

Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of Certification Ordinance)

The test is performed on EUT in permanent emission with modulation mode.

#### • Method of measurement

☐ Effective Radiated Power, cabinet radiation

□ Effective Radiated Power, cabinet and antenna radiation

#### Qualification measurements on an open test site (25MHz to 200MHz):

The setup is 1.5m above the ground reference plane.

Distance between measuring antenna and the EUT is 10meters for frequency 30MHz to 200MHz.

Test is performed in horizontal (H) and vertical (V) polarization with a bilog antenna below 1GHz and with a horn antenna above 1GHz. Measurement bandwidth was 100kHz.Continuous linear turntable azimuth search was performed with 360 degrees range. Vertical search was performed between 1m and 4m with the measuring antenna.

The Substitution Method is applied on the maximum values observed during the azimuth and vertical search in order to obtain the spurious radiated emission.

#### Qualification measurements in full anechoic chamber (200MHz to 4GHz):

The setup is 1.5m above the ground reference plane.

Distance between measuring antenna and the EUT is 3meters for frequency 200MHz to 4GHz.

Test is performed in horizontal (H) and vertical (V) polarization with a bilog antenna below 1GHz and with a horn antenna above 1GHz. Measurement bandwidth was 100kHz for measurement below 1GHz and 1MHz for measurement above 1GHz. Continuous linear turntable azimuth search was performed with 360 degrees range.

The Normalized Site Attenuation (NSA) is added to the maximum values observed during the azimuth search in order to obtain the spurious radiated emission.



## 6.3. RESULTS

## • Characterization on open test site (25MHz to 200MHz):

Vertical antenna

	Operating				
Frequency (MHz)	Measure E.R.P (dBm)	Limit (dBm)			
32.2	-62	-36			
33.3	-62	-36			
34.5	-65	-36			
35.3	-66	-36			
36.1	-65	-36			
37.4	-67	-36			
39	-66	-36			
40	-65	-36			
41.3	-70	-36			
44.7	-64	-36			
48	-62	-54			
49.9	-68	-54			
52.9	-67	-54			
60	-62	-54			
64	-65	-54			
67.1	-67	-54			
72	-64	-54			
77.1	-68	-36			
80	-65	-36			
116	-64	-54			
120	-64	-36			
144.4	-66	-36			
156.4	-67	-36			
166.6	-69	-36			
175.9	-65	-54			
199.8	-65	-54			



#### Horizontal antenna

Operating					
Frequency (MHz)	Measure E.R.P (dBm)	Limit (dBm)			
32.9	-62	-36			
40	-65	-36			
50.3	-68	-54			
59.3	-69	-54			
67.1	-65	-54			
74.5	-69	-36			
133	-66	-36			
144	-67	-36			
166	-69	-36			
200.3	-68	-54			

#### • Characterization in full anechoic chamber (200MHz to 4GHz):

Operating				
Frequency Measure (MHz) E.R.P (dBm)		Measure E.I.R.P (dBm)		
794,8	-71,63	-69,63		
3771,7	-47,75	-45,75		

Result: PASS

ETSI EN 301 839-1 §8.2

**Limit:** → 25MHz to

25MHz to 47MHz: -36dBm (operating)/ -57dBm (Standby) 47MHz to 74MHz: -54dBm (operating)/ -57dBm (Standby) 74MHz to 87,5MHz: -36dBm (operating)/ -57dBm (Standby) 87,5MHz to 118MHz: -54dBm (operating)/ -57dBm (Standby) 118MHz to 174MHz: -36dBm (operating)/ -57dBm (Standby) 174MHz to 230MHz: -54dBm (operating)/ -57dBm (Standby) 230MHz to 470MHz: -36dBm (operating)/ -57dBm (Standby) 470MHz to 862MHz: -54dBm (operating)/ -57dBm (Standby) 862MHz to 1GHz: -36dBm (operating)/ -57dBm (Standby) 1GHz to 4GHz: -30dBm (operating)/ -47dBm (Standby)

Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of Certification Ordinance)

Limit: → -36dBm (operating)

## See graphics in annex 1



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## 7. UNWANTED RADIATION

#### 7.1. TEST CONDITIONS

Test performed by : Laurent DENEUX
Date of test : 2012/03/20
Ambient temperature : 21°C

Relative humidity : 48%

#### 7.2. TEST SETUP

FCC 95.635(d) RSS 243 §3.4

The test is performed on EUT in permanent emission with modulation mode.

## Method of measurement

☐ Effective Radiated Power, cabinet radiation

Effective Radiated Power, cabinet and antenna radiation

The setup is 1.5m above the ground reference plane.

Distance between measuring antenna and the EUT is 10 meters for frequency 30MHz to 25GHz.

Test is performed in horizontal (H) and vertical (V) polarization with a bilog antenna below 1GHz and with a horn antenna above 1GHz. Measurement bandwidth was 100kHz and 1MHz for measurement above 1GHz. Continuous linear turntable azimuth search was performed with 360 degrees range. Vertical and horizontal search was performed between 1m and 4m with the measuring antenna.





## 7.3. RESULTS

#### **Out-Of-Band Emissions**

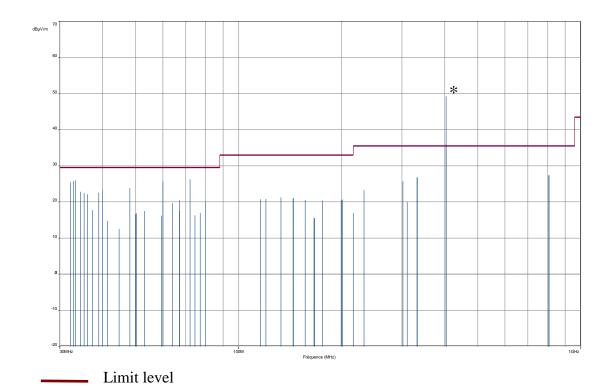
• Characterization on open test site (30MHz to 25GHz):

Fcc Part.15 CLASS B

SORIN IMPLANT

MODEL: PARADYM RF CRT D 9750

400 Tx



\* Transmitter frequency

Remark: During the Scan, no unwanted emission has been detected in the frequency range 1 GHz to 25 GHz.

Result: PASS

**Limit:** → 30MHz to 88MHz:  $29.5B\mu$ V/m or  $100\mu$ V/m

88MHz to 216MHz:  $33dB\mu V/m$  or  $150\mu V/m$  216MHz to 960MHz:  $35.5dB\mu V/m$  or  $200\mu V/m$  Above 960MHz:  $43.5dB\mu V/m$  or  $500\mu V/m$ 





#### **In-Band Emissions**

The "In band emission" is measured 20dB below the peak power. RBW=3kHz VBW=10kHz

Frequency (MHz)	Measure (kHz)	Limit (kHz)
Fmin	103,5	150
Fnom	103,5	150
Fmax	103,5	150

Result: PASS

**Limit:** → Emissions within the MEDRADIO band (402 – 405 MHz) more than 150 kHz away from the center frequency of the spectrum the transmission is intended to occupy will be attenuated below the transmitter output power by at least 20 dB

## See graphics in annex 1

## **Band-Edge Emissions**

The "In band emission" is measured 20dB below the peak power. RBW=3kHz VBW=10kHz

Frequency (MHz)	Measure (MHz)	Limit (MHz)	
Fmin	402,046	Above 401,75	
Fmax	404,95	Below 405,25	

Result: PASS

**Limit:** → Emissions 250 kHz or less that are above and below the MEDRADIO band (402 – 405 MHz) will be attenuated below the maximum permitted output power by at least 20 dB.

## See graphics in annex 1

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#### 8. RECEIVER SPURIOUS RADIATION & SECONDARY RADIATED EMISSION

#### 8.1. TEST CONDITIONS

Test performed by : Stéphane PHOUDIAH

Date of test : 2012/03/26 Ambient temperature : 23°C

Relative humidity : 30%

## 8.2. TEST SETUP

ETSI EN 301 839-1 §9.1

Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of Certification Ordinance)

The test is performed on EUT in reception mode.

#### Method of measurement

☐ Effective Radiated Power, cabinet radiation

☐ Effective Radiated Power, cabinet and antenna radiation

#### Qualification measurements on an open test site (25MHz to 200MHz):

The setup is 1.5m above the ground reference plane.

Distance between measuring antenna and the EUT is 10 meters for frequency 30MHz to 200MHz.

Test is performed in horizontal (H) and vertical (V) polarization with a bilog antenna below 1GHz and with a horn antenna above 1GHz. Measurement bandwidth was 100kHz. Continuous linear turntable azimuth search was performed with 360 degrees range. Vertical search was performed between 1m and 4m with the measuring antenna.

The Substitution Method is applied on the maximum values observed during the azimuth and vertical search in order to obtain the spurious radiated emission.

#### Qualification measurements in full anechoic chamber (200MHz to 4GHz):

The setup is 1.5m above the ground reference plane.

Distance between measuring antenna and the EUT is 3meters for frequency 200MHz to 4GHz.

Test is performed in horizontal (H) and vertical (V) polarization with a bilog antenna below 1GHz and with a horn antenna above 1GHz. Measurement bandwidth was 100kHz for measurement below 1GHz and 1MHz for measurement above 1GHz. Continuous linear turntable azimuth search was performed with 360 degrees range.

The Normalized Site Attenuation (NSA) is added to the maximum values observed during the azimuth search in order to obtain the spurious radiated emission.



## 8.3. RESULTS

## Characterization on open test site (25MHz to 200MHz):

## Vertical antenna

Operating				
Frequency (MHz)	Measure E.R.P (dBm)	Limit (dBm)		
32.2	-64	-57		
33.3	-65	-57		
34.5	-65	-57		
35.3	-66	-57		
36.1	-65	-57		
37.4	-67	-57		
39	-66	-57		
40	-65	-57		
41.3	-70	-57		
44.7	-67	-57		
48	-65	-57		
49.9	-68	-57		
52.9	-67	-57		
60	-62	-57		
64	-65	-57		
67.1	-67	-57		
72	-66	-57		
77.1	-68	-57		
80	-65	-57		
116	-64	-57		
120	-64	-57		
144.4	-66	-57		
156.4	-67	-57		
166.6	-69	-57		
175.9	-65	-57		
199.8	-65	-57		



#### Horizontal antenna

Operating				
Frequency (MHz)	Measure E.R.P (dBm)	Limit (dBm)		
32.9	-65	-57		
40	-64	-57		
50.3	-68	-57		
59.3	-69	-57		
67.1	-65	-57		
74.5	-69	-57		
133	-64	-57		
144	-64	-57		
166	-69	-57		
200.3	-64	-57		

## • Characterization in full anechoic chamber (200MHz to 4GHz):

Frequency (MHz)	Measure E.R.P (dBm)	Measure E.I.R.P (dBm)		
3966,7	-57,71	55,71		
3506,6	-58,70	-56,70		
986.9	-68.37	-66.37		

Limit: → -57dBm below 1000 MHz

-47dBm above 1000 MHz

Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of Certification Ordinance)

**Limit:** → -54dBm

Result: PASS

See graphics in annex 1



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## 9. RADIATION EMISSIONS

#### 9.1. TEST CONDITIONS

Test performed by : Laurent DENEUX Date of test : 2012/03/20

Ambient temperature : 21°C Relative humidity : 48%

#### 9.2. TEST SETUP

FCC 15.109 RSS 243 §3.5

The test is performed on EUT in reception mode.

## Method of measurement

☐ Effective Radiated Power, cabinet radiation

☐ Effective Radiated Power, cabinet and antenna radiation

#### • Qualification measurements on an open test site (30MHz to 25GHz):

The setup is 1.5m above the ground reference plane.

Distance between measuring antenna and the EUT is 10 meters for frequency 30MHz to 25GHz.

Test is performed in horizontal (H) and vertical (V) polarization with a bilog antenna below 1GHz and with a horn antenna above 1GHz. Measurement bandwidth was 100kHz and 1MHz for measurement above 1GHz. Continuous linear turntable azimuth search was performed with 360 degrees range. Vertical and horizontal search was performed between 1m and 4m with the measuring antenna.



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## TEST REPORT N° 112624-622708-F-Cr2012-10-22

## 9.3. RESULTS

## • Characterization on open test site (30MHz to 25GHz):

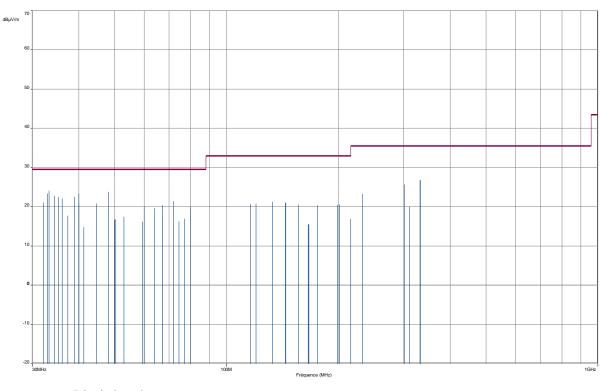
Fcc Part.15 CLASS B

SORIN IMPLANT

MODEL: PARADYM RF CRT D 9750

400 Rx

## Quasi peak measurement



\_\_\_\_\_ Limit level

Remark: During the Scan, no radiated emission has been detected in the frequency range 1 GHz to 25 GHz.

Result: PASS

**Limit:** → 30MHz to 88MHz:  $29.5B\mu$ V/m or  $100\mu$ V/m

88MHz to 216MHz:  $33dB\mu V/m$  or  $150\mu V/m$  216MHz to 960MHz:  $35.5dB\mu V/m$  or  $200\mu V/m$  Above 960MHz:  $43.5dB\mu V/m$  or  $500\mu V/m$ 





## 10. TEST EQUIPMENT LIST

Test	Apparatus	Trade Mark	Type	Registration number
	Effective Radiated Power Of The Fundamental	Emission, Maximum Transmit		
Х	Full anechoic chamber	SIEPEL	S36	D3044019
Х	Logperiodic antenna	AMPLIFIER RESEARCH	ATR80M6G	C2040149
Х	EMI Test Receiver	ROHDE & SCHWARZ	ESMI	A2642009
Χ	Signal Generator	ROHDE & SCHWARZ	SMIQ03b	A5442039
Χ	Logperiodic antenna	AMPLIFIER RESEARCH	AT1000	C2040002
Х	Substitution Cable	-	CNJ01	A5329393
Х	Substitution Cable	-	CNS1E 04	A5329434
Х	Horn Antenna	A.H. SYSTEMS	SAS-571	C2042041
Χ	Horn Antenna	EMCO	3117	C2042031
Х	Dipole Antenna	SCHWARZBECK	VHAP	C2040020
Χ	Dipole Antenna	SCHWARZBECK	UHAP	C2040022
	Emission Bandwidth, Occupied Bandw			
Х	Antenna	KATHREIN	-	-
X	Climatic Chamber	SECASI Technologies	SLT-34	D1024029
X	Spectrum Analyser	ROHDE & SCHWARZ	FSL	A4060032
		or & Frequency stability	1 02	711000002
Х	Spectrum Analyser	ROHDE & SCHWARZ	FSL	A4060032
X	Antenna	KATHREIN	-	-
X	Climatic Chamber	SECASI Technologies	SLT-34	D1024029
		missions & Unwanted Emission		D 102 1020
Х	Full anechoic chamber	SIEPEL	S36	D3044019
X	EMI Test Receiver	ROHDE & SCHWARZ	ESMI	A2642009
X	Preamplier	BONN Elektronik	BLNA 3018-8F30S	A7080053
X	Horn Antenna	A.H. SYSTEMS	SAS-571	C2042041
X	Logperiodic antenna	AMPLIFIER RESEARCH	ATR80M6G	C2040149
X	Signal Generator	ROHDE & SCHWARZ	SMR	A5444002
X	Signal Generator	ROHDE & SCHWARZ	SMIQ03b	A5442039
X	Dipole Antenna	SCHWARZBECK	VHAP	C2040020
X	Dipole Antenna	SCHWARZBECK	UHAP	C2040022
X	Open test site	LCIE	-	F2000400
X	EMI Test Receiver	ROHDE & SCHWARZ	ESU	A2642018
X	Preamplifier	HEWLETT PACKARD	8449B	A4069002
X	Bilog antenna	CHASE	CBL 6112A	C2040040
X	Dipole	ROHDE & SCHWARZ	HUF-Z1	C2040011
X	Logperiodic antenna	ROHDE & SCHWARZ	HL 023 A2	C2040001
X	Horn antenna	EMV	3115	C2040023
X	Horn antenna	AH SYSTEMS	SAS-572	C2042026
X	Horn antenna	EMCO	.3115	C2042016
X	Signal Generator	ROHDE & SCHWARZ	SMP02	B2163019
X	Signal Generator	ROHDE & SCHWARZ	SMY02	A5442014
,		nissions & Radiated Emissions		7.01.2011
Х	Full anechoic chamber	SIEPEL	S36	D3044019
Χ	EMI Test Receiver	ROHDE & SCHWARZ	ESMI	A2642009
X	Preamplier	BONN Elektronik	BLNA 3018-8F30S	A7080053
X	Horn Antenna	A.H. SYSTEMS	SAS-571	C2042041
X	Logperiodic antenna	AMPLIFIER RESEARCH	ATR80M6G	C2040149
X	Signal Generator	ROHDE & SCHWARZ	SMR	A5444002
X	Signal Generator	ROHDE & SCHWARZ	SMIQ03b	A5442039
X	Dipole Antenna	SCHWARZBECK	VHAP	C2040020
X	Dipole Antenna	SCHWARZBECK	UHAP	C2040022
X	Open test site	LCIE	-	F2000400
X	EMI Test Receiver	ROHDE & SCHWARZ	ESU	A2642018
X	Preamplifier	HEWLETT PACKARD	8449B	A4069002
X	Bilog antenna	CHASE	CBL 6112A	C2040040
X	Dipole	ROHDE & SCHWARZ	HUF-Z1	C2040011
	Dipoic	INDITION OF THE PROPERTY OF TH		020 <del>7</del> 0011
X	Logperiodic antenna	ROHDE & SCHWARZ	HL 023 A2	C2040001



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Χ	Horn antenna	AH SYSTEMS	SAS-572	C2042026
X	Horn antenna	EMCO	.3115	C2042016
Х	Signal Generator	ROHDE & SCHWARZ	SMP02	B2163019

# 11. UNCERTAINTIES CHART

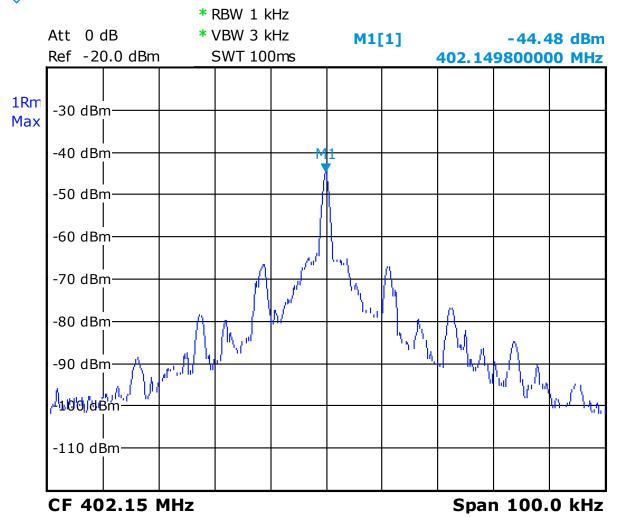
	Measurement uncertainties (k=2) ±x(dB) / (Hz)	Limit for uncertainties ±y(dB)
TRANSMITTER REQUIREMENTS		
Frequency Error	±2.10 <sup>-8</sup> Hz	±1.10 <sup>-7</sup> Hz
Modulation Bandwidth	± 100 kHz	-
Effective Radiated Power	±3.9 dB	±6 dB
Adjacent Channel Power	±1.6 dB	±3 dB
Spurious emissions		
<ul> <li>Frequency &lt; 1000 MHz</li> </ul>	±3.9 dB	±6 dB
<ul><li>Frequency &gt; 1000 MHz</li></ul>	±3.1 dB	
Conducted power	±0.6 dB	±1.5 dB
Spectral density in conduction	±0.6 dB	±1.5 dB
Spurious emissions in conduction	±1.6 dB	±3 dB
Temperature	±0.5°C	±1°C
Humidity	±2.5 %	±5 %
RECEIVER REQUIREMENTS		
Spurious emissions		
<ul> <li>Frequency &lt; 1000 MHz</li> </ul>	±3.9 dB	±6 dB
<ul><li>Frequency &gt; 1000 MHz</li></ul>	±3.1 dB	
Spurious emissions in conduction	±0.6 dB	±3 dB



## 12. ANNEX 1 (GRAPHS)

Frequency: Fmin Frequency error Temperature: Tmin Voltage: Vnom



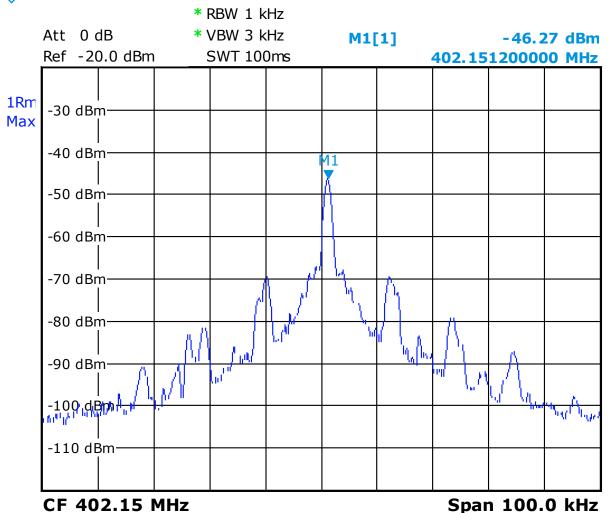


Date: 30.MAR.2012 10:48:10



Frequency: Fmin Frequency error Temperature: Tnom Voltage: Vnom



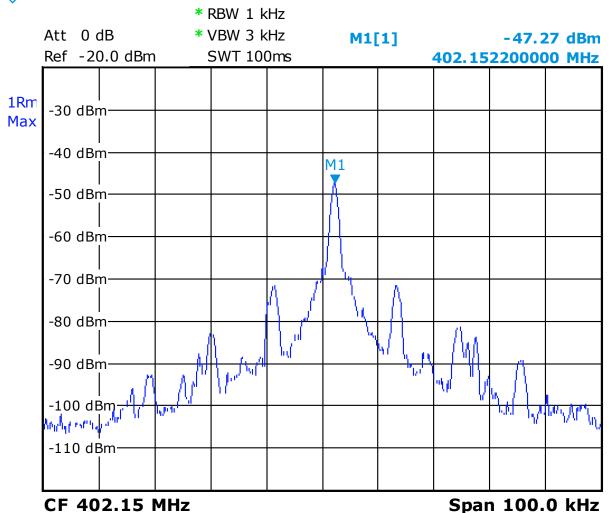


Date: 30.MAR.2012 14:57:10



Frequency: Fmin Frequency error Temperature: Tmax Voltage: Vnom



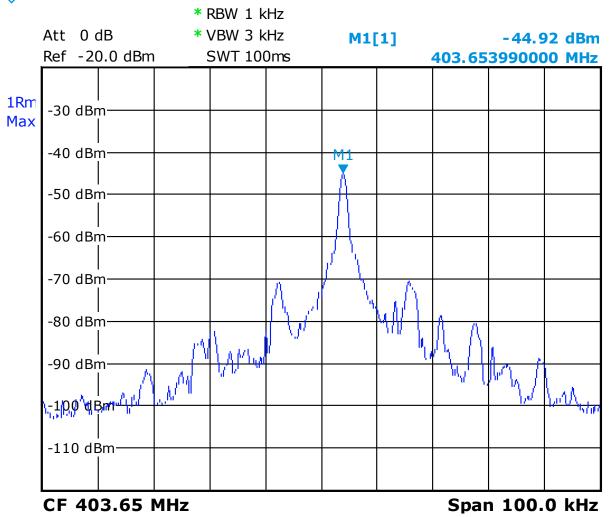


Date: 30.MAR.2012 16:45:40



Frequency: Fnom Frequency error Temperature: Tmin Voltage: Vnom



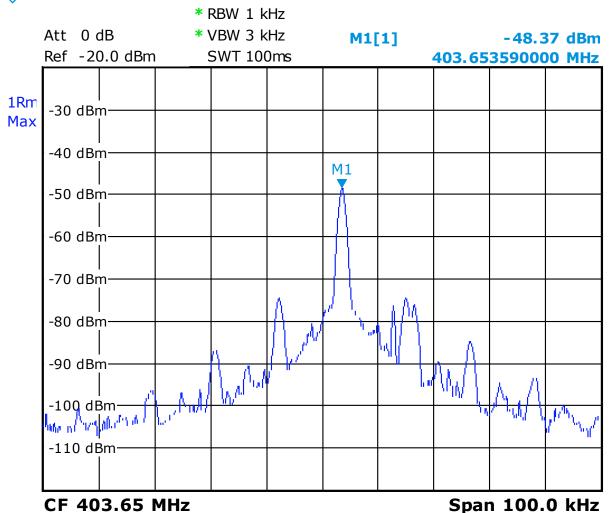


Date: 30.MAR.2012 10:51:37



Frequency: Fnom Frequency error Temperature: Tnom Voltage: Vnom



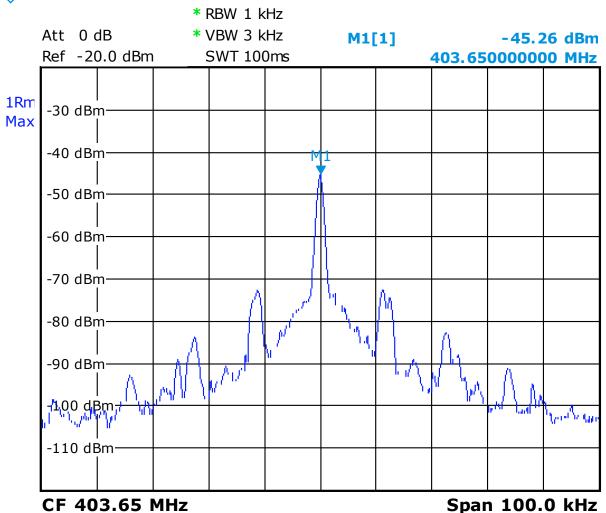


Date: 30.MAR.2012 14:59:23



Frequency: Fnom Frequency error Temperature: Tmax Voltage: Vnom



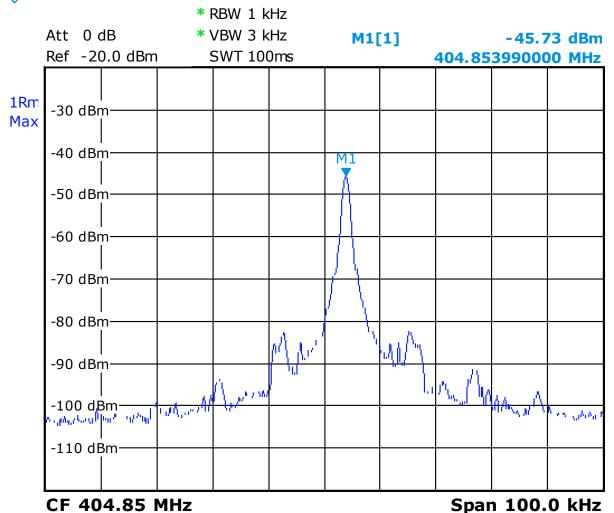


Date: 30.MAR.2012 16:44:30



Frequency: Fmax Frequency error Temperature: Tmin Voltage: Vnom



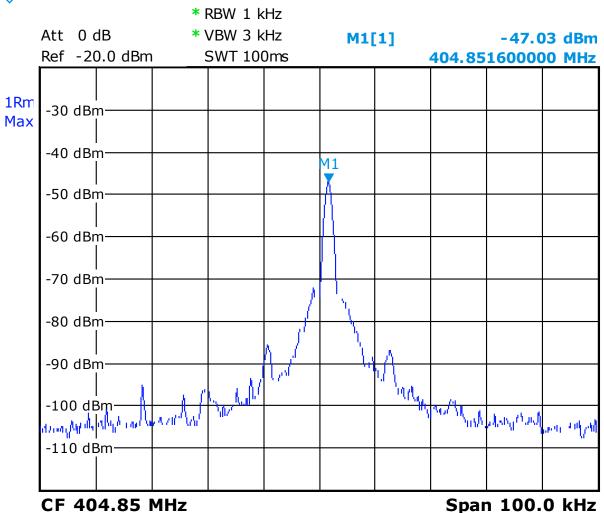


Date: 30.MAR.2012 10:54:06



Frequency: Fmax Frequency error Temperature: Tnom Voltage: Vnom



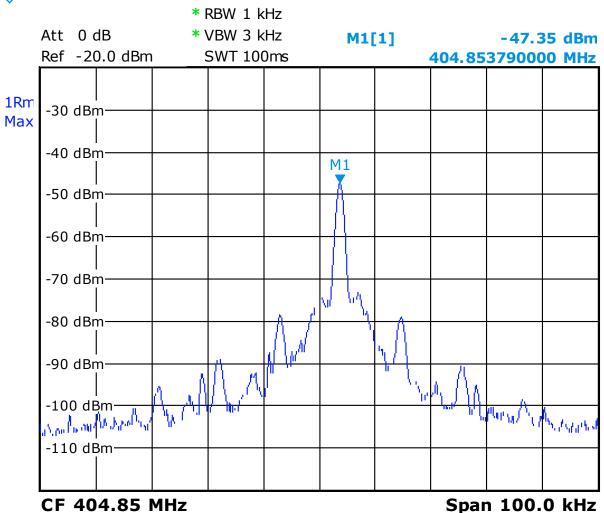


Date: 30.MAR.2012 15:01:46



Frequency: Fmax Frequency error Temperature: Tmax Voltage: Vnom

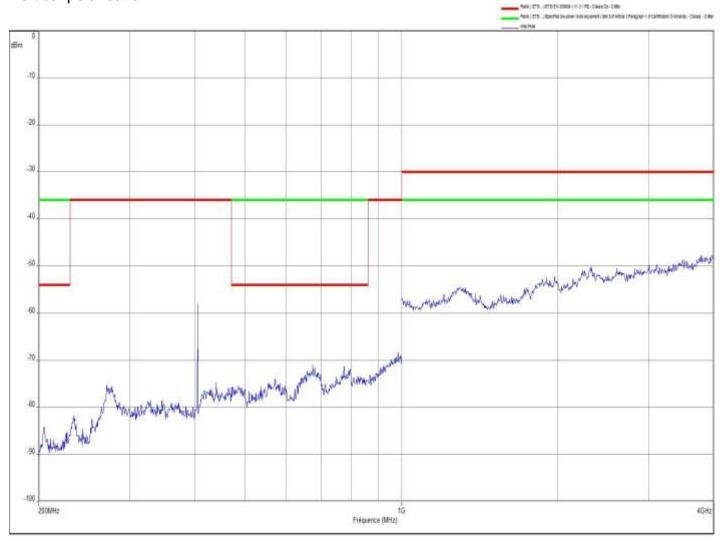




Date: 30.MAR.2012 16:49:36



Spurious emissions Operating mode Vertical polarisation





Spurious emissions Operating mode Horizontal polarisation



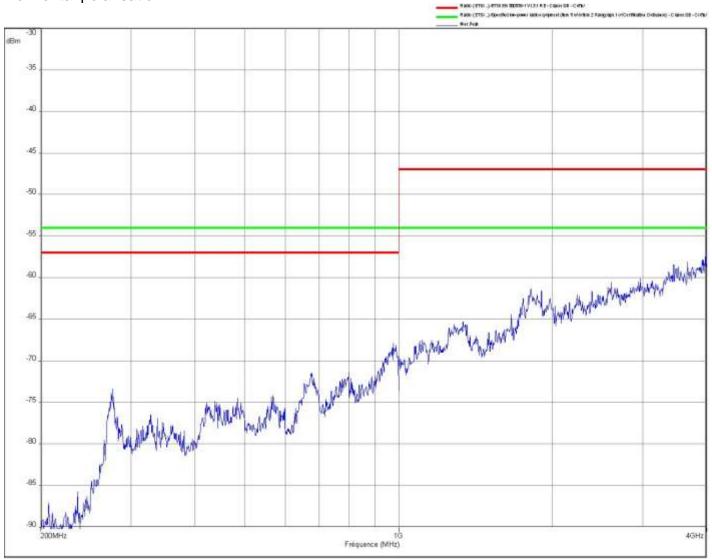


Spurious emissions Receiver mode Vertical polarisation





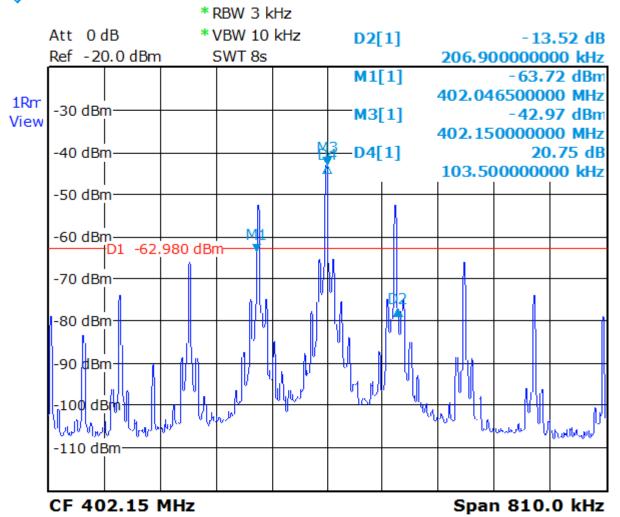
Spurious emissions Receiver mode Horizontal polarisation





Frequency: Fmin Emission Bandwidth Band-Edge Emissions In-Band Emissions



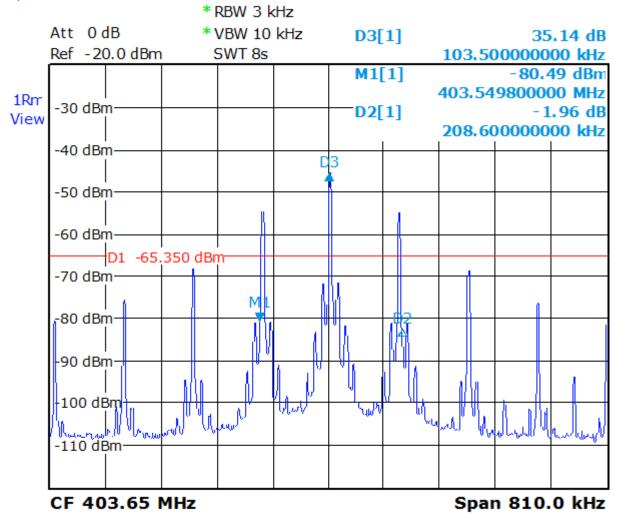


Date: 29.MAR.2012 11:39:59



Frequency: Fnom Emission Bandwidth In-Band Emissions



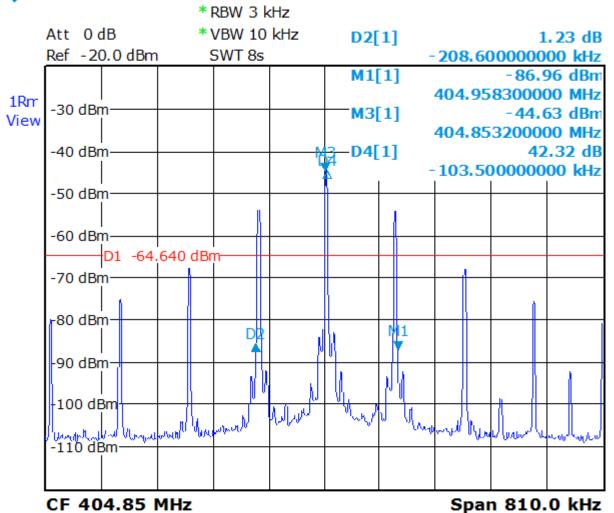


Date: 29.MAR.2012 12:49:02



Frequency: Fmax Emission Bandwidth Band-Edge Emissions In-Band Emission



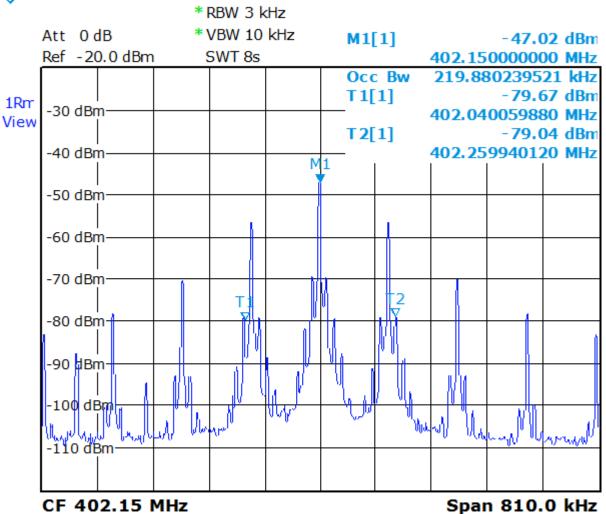


Date: 29.MAR.2012 12:41:20



# Frequency: Fmin Occupied Bandwidth



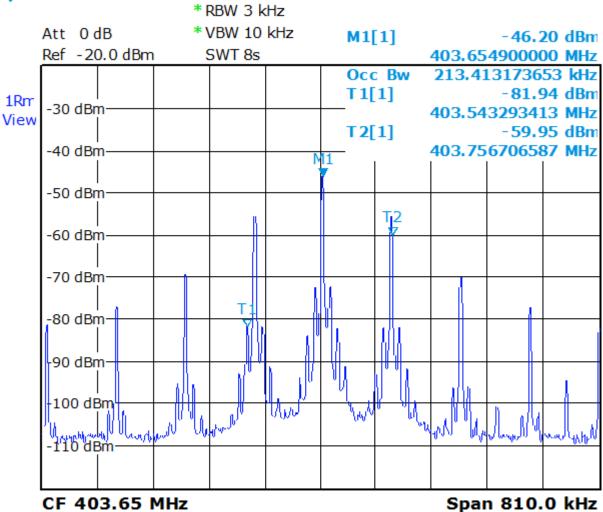


Date: 29.MAR.2012 11:28:04



# Frequency: Fnom Occupied Bandwidth



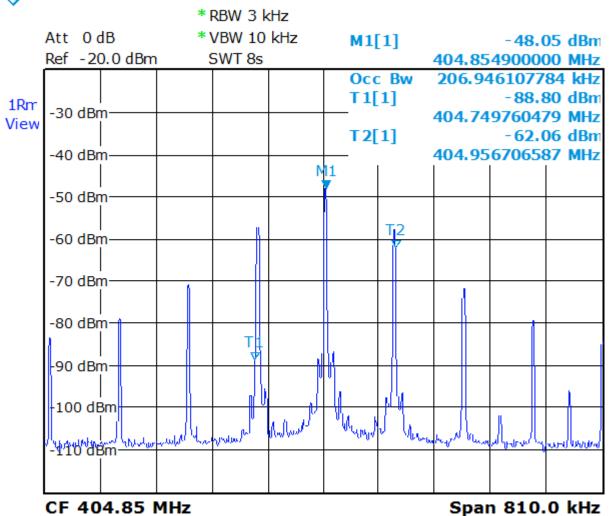


Date: 29.MAR.2012 11:22:51



## Frequency: Fmax Occupied Bandwidth





Date: 29.MAR.2012 11:20:42

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#### 13. ANNEX 2 (FLUID DATA SHEET MSL 450)

Schmid & Partner Engineering AG peag

Zeughausstrasse 43, 8004 Zurich, Switzerland Phone +41 44 245 9700, Fax +41 44 245 9779 info@speag.com, http://www.speag.com

#### Material Safety Data Sheet

#### 1 Identification of the substance and of the manufacturer / origin

Item	Brain Tissue Simulation Liquids B900			
l	Head Tissue Simulation Liquids HSL 175, HSL300, HSL450, HSL750,			
l	H8L900			
	Muscle Tissue Simulation Liquids M3L450, M3L 750, M3L900			
Type No	8L AAB 090			
	SL AAH 017, SL AAH 030, SL AAH 045, SL AAH 075, SL AAH 090			
	SL AAM 045, SL AAM 075, SL AAM 090			
Series No	N/A			
Manufacturer / Origin	Schmid & Partner Engineering AG			
	Zeughausstrasse 43			
	8004 Zürich			
	Switzerland			
	Phone +41 44 245 9700, Fax +41 44 245 9779, support@speag.com			

#### Use of the substance:

Liquid simulating physical parameters of Brain, Head or Muscle Tissue in the RF range below 2GHz.

## 2 Composition / Information on ingredients

The Item is composed of the following ingredients:  $H_2O$  Water, 35 – 58%

Sucrose Sugar, white, refined, 40 - 60%

NaCl Sodium Chloride, 0 - 6%

Hydroxyethyl-cellulose Medium Viscosity (CAS# 9004-62-0), <0.3%

Preventol-D7 Preservative: aqueous preparation, (CAS# 55965-84-9), containing 5-chloro-2-methyl-3(2H)-isothlazolone and 2-methyyl-3(2H)-isothlazolone,

0.1 - 0.7%

Relevant for safety; Refer to the respective Safety Data Sheet".

#### 3 Hazards identification

Symbol XI Irritant

R-phrases: 36/38 irritating to eyes and skin

> May cause sensitization by skin contact 43

#### 4 First aid measures

After skin contact: Wash off with plenty of water and soap

Rinse out with plenty of water with the eyelid held open, call an ophthalmologist After eye contact: After swallowing: Make victim drink plenty of water, the mouth should be rinsed out several times.

Do not Induce vomiting.

## 5 Fire-fighting measures

Not required

#### 6 Accidental release measures

Do not allow to enter sewerage system in large quantities, clean up affected area, forward for disposal. The preservative can be destroyed with sodiumhydrogensuifite. Add plenty of water if spilled.

#### 7 Handling and storage

Handling: Keep in open container only for minimum required time in order to avoid water evaporation. Storage: No special measures against fire or explosion required.

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#### 8 Exposure controls / personal protection

Eye protection: goggles

Hand protection: e.g. rubber or plastic gloves

Avoid contact with skin and eyes. Wash hands after working with sustance.

#### 9 Physical and chemical properties

Form: liquid

Colour: yellowish to light brown, transparent

Odour: odourless

pH-Value: neutral, with fendency to lower pH values.

Balling point: 100°C

Density: 1.2 - 1.4 g/cm^3

## 10 Stability and reactivity

No hazardous decomposition products expected.

#### 11 Toxicological information

irritation to skin and eyes: tendency to corrosive reaction.

In susceptible people, sensitization is possible.

#### 12 Ecological information

Do not allow to enter waters, waste water, or soil.

In order to avoid adverse effects on the degradation activity of a sewage plant due to the preservative contained, the preservative concentration must not exceed 3mg/l, which up to 1000 times lower than the amount contained. Considerable amounts of water must therefore be added to amounts spilled into sewers or waste water.

#### 13 Disposal considerations

Product: Chemicals must be disposed of in compilance with the respective national regulations. Packing: Product packing must be disposed of in compilance with respect national regulations.

#### 14 Transport information

Not subject to transport regulations.

No UN number is applicable

Avoid temperatures below 0°C. Keep separated from foodstuffs.

#### 15 Regulatory information

Labelling according to EC Directives

Symbol XI Initiant

R-phrases: 36/38 Irritating to eyes and skin.

43 May cause sensitization by skin contact

MAK value for the preservative is 0.05mg/m\*3, corresponding to a concentration of <25mg/m\*3 of the final product.

#### 16 Other information

\* Safety relevant information bases on:

[1] MSDS for Preventol D7 (Art.Nr.: 329049/08 by Bayer AG, Leverkusen, Germany )

Release date: 11.09.2009 Responsible: FB

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Schmid & Partner Engineering AG

s p e a g

Zeugheusstrasse 43, 8004 Zurich, Switzerland Phone +41 44 245 9700, Fax +41 44 245 9779 info@speeg.com, http://www.speeg.com

#### Measurement Certificate / Material Test

Item Name Body Tissue Simulating Liquid (MSL 450)
Product No. SL AAM 045 BC-A (Charge: 120206-1)

Manufacturer SPEAG

Measurement Method

TSL dielectric parameters measured using calibrated OCP probe (type DAK).

**Target Parameters** 

Target parameters as defined in the IEEE 1528 and IEC 62209 compliance standards.

**Test Condition** 

Ambient Condition 22°C; 30% humidity

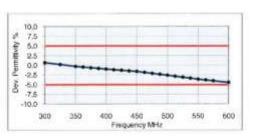
TSL Temperature 22°C Test Date 8-Feb-12

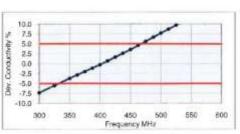
Additional Information

TSL Density 1.226 g/cm<sup>3</sup> TSL Heat-capacity 3.001 kJ/(kg\*K)

Results

Measured		Target		Diff.to Target [%]			
f [MHz]	HP-e	HP-e"	sigma	aps	sigma	A-eps	A-sigma
300	58.6	51.08	0.85	58.2	0.92	0.7	-7.3
325	58.1	48,44	0.87	58.0	0.92	0.2	-5.5
360	57.5	45,81	0.89	57.7	0.93	+0.3	-3.8
363	57.3	44.81	0.90	57.6	0.93	-0.5	-2.9
375	57.1	43.81	0.91	57.5	0.83	-0.6	-2.0
386	56.9	42.81	0.92	57.3	0.93	-0.0	+1.2
400	56.6	41.82	0.93	57.2	0.93	-1.0	-0.3
413	56,4	41.08	0.94	57.1	0.93	-1.1	0.7
425	56.2	40.34	0.95	57.0	0.94	-1.3	1,6
438	56.0	39.60	0.96	56.8	0.94	-1.5	2.6
450	55.8	38.86	0.97	56.7	0.94	-1.6	2.5
463	55.6	38.28	0.98	56.7	0.94	1.8	4,5
475	55.4	37,70	0.99	56,6	0.94	-2.1	5.6
466	55,2	37.11	1.01	56.6	0.94	-2.3	6.6
500	55.0	36.53	1.02	58.5	0.84	-2.6	7,7
513	54.9	36,04	1.03	58.5	0.94	-2.8	8.7
525	54.7	35.56	1.04	55.4	0.95	+3.1	9.7
536	54.5	35.07	1.05	56.4	0.95	-3.3	10.6
550	54.3	34.58	1.06	56.3	0.95	-3.6	11.6
583	54.1	34.20	1.07	56.3	0.95	-3.8	12.7
575	54.0	33.82	1.08	56.2	0.95	-4.0	13.8
600	53.6	33.05	1.10	55.1	0.95	4.4	15.9





TSL Dielectric Parameters Page 1 of 1