

TEST REPORT

Number Composition of document

Standards

RADIO

SORIN CRM

Mme DE JESO

SORIN Group

148YYW053

Parc d'affaires NOVEOS 4. Avenue Réaumur

SORIN BIOMEDICA CRM

PARADYM RF — VR model 9250

92140 Clamart Cedex , FRANCE

112624-622708-P-Cr2012-10-22 45 pages

ETSI EN 301 839-1 V1.2.1 ETSI EN 301 839-2 V1.3.1 FCC RULES PART 95I 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

Apparatus under test Trade mark Manufacturer Type Serial number

Test date

Syndeli RF implantable cardioverter defibrillator

Tests performed by

Test site

File issued on File corrected on File initialy issued on 2012/03/22 and 2012/03/26 to 2012/03/30

Stéphane PHOUDIAH & Laurent DENEUX

Fontenay Aux Roses & Ecuelles

2012/10/22 2012/10/22 2012/04/18

Written by : Stéphane PHOUDIAH & Laurent DENEUX Tests operator

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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 (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** EN § 8.1 - Frequency error PASS 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 **Certification Ordinance**) – Tolerance of frequency EN § 8.3 - Effective radiated power of the fundamental emission PASS 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 Certification Ordinance) – Antenna power EN § 8.2 - Emission bandwidth PASS 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 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 PASS 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 Equipment information p.5) FCC § 2.1057 – Frequency spectrum to be investigated PASS (see §2.1 Equipment information p.5)



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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 |
| Specified low-power radio equipment (Item 8 of Article 2 Paragraph 1 of Certification | |
| Ordinance) – Limit of secondary radiated emission | 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

<u>**Remark**</u>: 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 V -Lead DF-1 SVC -Lead DF-1 RV

Equipment information:

| - External antenna connector: N | No |
|--|--|
| - Frequency band allocated: 40 | 2MHz to 405MHz |
| - Frequency used for test: | -Fmin: 402,15MHz |
| | -Fnom: 403,65MHz |
| | -Fmax: 404,85MHz |
| - Modulation: 2 FSK | |
| - Data rate: 200kb/s | |
| - Number of channel: 10 | |
| Antenna type: Integral | |
| - Equipment intended for use a | s a mobile station |
| - Equipment designed for conti | nuous operation |
| - Stand By mode: No | |
| - Extreme temperature range: | -Tmin: 25°C |
| | -Tnom: 37°C |
| | -Tmax: 45°C |
| - Source voltage: | -Vnom: BOL: 3.25 V. ERI: 2.66 V. EOL: 2.5 V (Internal Battery) |

- Source voltage:
- vnom: BOL: 3.25 V. ERI: 2.66 V. EOL: 2.5 V (Internal Battery)



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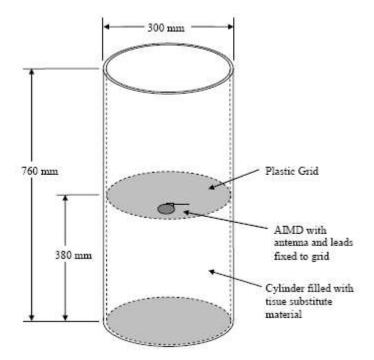
2.2. RUNNING MODE

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).



2.4. EQUIPEMENT LABELLING



2.5. EQUIPMENT MODIFICATIONS

No equipment modification has been necessary during testing.



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) | 402,149 | 402,1494 | 402,1498 |
| Frequency Drift (ppm) | -2,48 | -1,49 | -0,49 |

Frequency: Fnom

| Temperature | Tmin | Tnom | Tmax |
|-----------------------|---------|----------|---------|
| Power voltage: Vnom | | | |
| Frequency (MHz) | 403,652 | 403,6534 | 403,652 |
| Frequency Drift (ppm) | 4,95 | 8,42 | 4,95 |

Frequency: Fmax

| Temperature | Tmin | Tnom | Tmax |
|-----------------------|---------|----------|----------|
| Power voltage: Vnom | | | |
| Frequency (MHz) | 404,852 | 404,8532 | 404,8518 |
| Frequency Drift (ppm) | 4,94 | 7,90 | 4,44 |

See graphics in annex 1

Result: PASS Limit: $\rightarrow \pm 100 \text{ ppm}$



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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 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

| Frequency (MHz) | Generator (dBm) | Cables loss (dB) | Antenna Gain (dBi) | EIRP (dBm) | EIRP (µW) | ERP (dBm) | ERP (µW) |
|--------------------|--------------------|---------------------|-----------------------|---------------|--------------|--------------|-------------|
| Fmin | -36 | 1,6 | 6,6 | -41 | 0,079 | -43,14 | 0,048 |
| Fnom | -37,2 | 1,7 | 6,6 | -42,1 | 0,062 | -44,24 | 0,037 |
| Fmax | -37,6 | 1,8 | 6,6 | -42,4 | 0,057 | -44,54 | 0,035 |

Result: PASS Limit: → 25µW or -16dBm



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 | 205,33 |
| Fnom | 208,6 | 205,33 |
| Fmax | 206,9 | 213,41 |

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 25MHz to 200MHz.

Test is performed in horizontal (H) and vertical (V) polarization with a bilog antenna. 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.



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6.3. RESULTS

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

Vertical antenna

| Operating | | |
|--------------------|------------------------|----------------|
| Frequency (MHz) | Measure E.R.P (dBm) | Limit (dBm) |
| 31.9 | -64 | -36 |
| 33.6 | -62 | -36 |
| 36 | -63 | -36 |
| 37.8 | -66 | -36 |
| 39 | -67 | -36 |
| 40.1 | -66 | -36 |
| 44.3 | -68 | -36 |
| 48 | -69 | -54 |
| 49.9 | -70 | -54 |
| 51.9 | -70 | -54 |
| 56 | -66 | -54 |
| 60 | -71 | -54 |
| 64 | -67 | -54 |
| 72 | -62 | -54 |
| 115.6 | -66 | -54 |
| 120 | -66 | -36 |
| 134.4 | -66 | -36 |
| 156.4 | -68 | -36 |
| 199.9 | -66 | -54 |

Horizontal antenna

| Operating | | |
|--------------------|------------------------|----------------|
| Frequency (MHz) | Measure E.R.P (dBm) | Limit (dBm) |
| 144.4 | -72 | -36 |
| 166.5 | -63 | -36 |
| 192.6 | -73 | -54 |
| 199.9 | -63 | -54 |



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

| Operating | | |
|--------------------|------------------------|--------------------------|
| Frequency (MHz) | Measure E.R.P (dBm) | Measure E.I.R.P (dBm) |
| 785,5 | -73,44 | -71,3 |
| 3962,6 | -49,64 | -47,5 |

Result: PASS

ETSI EN 301 839-1 §8.2

Limit: → 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



7. UNWANTED RADIATION

7.1. TEST CONDITIONS

| Test performed by | : Laurent DENEUX |
|---------------------|------------------|
| Date of test | : 2012/03/22 |
| Ambient temperature | : 23°C |
| Relative humidity | : 42% |

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

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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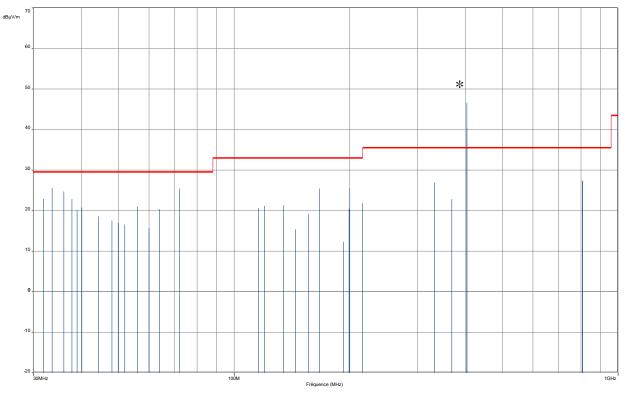
7.3. RESULTS

Out-Of-Band Emissions

Fcc Part.15 CLASS B

SORIN IMPLANT MODEL : PARADYM RF VR 9250 400 Tx

Quasi peak measurement



Limit level

* 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: 29.5BµV/m or 100µV/m 88MHz to 216MHz: 33dBµV/m or 150µV/m 216MHz to 960MHz: 35.5dBµV/m or 200µV/m Above 960MHz: 43.5dBµV/m or 500µV/m



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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 | 105,1 | 150 |
| Fmax | 103,5 | 150 |

Result: PASS

Limit: \rightarrow 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 | 402,048 | Above 401,75 |
| Fmax | 404,955 | Below 405,25 |

Result: PASS

Limit: \rightarrow 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.



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8.3. RESULTS

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

Vertical antenna

| Receiver Mode | | |
|--------------------|------------------|----------------|
| Frequency (MHz) | Measure (dBm) | Limit (dBm) |
| 31.9 | -64 | -57 |
| 33.6 | -65 | -57 |
| 36 | -66 | -57 |
| 37.8 | -66 | -57 |
| 39 | -67 | -57 |
| 40.1 | -66 | -57 |
| 44.3 | -68 | -57 |
| 48 | -69 | -57 |
| 49.9 | -70 | -57 |
| 51.9 | -70 | -57 |
| 56 | -66 | -57 |
| 60 | -67 | -57 |
| 64 | -67 | -57 |
| 72 | -65 | -57 |
| 115.6 | -66 | -57 |
| 120 | -66 | -57 |
| 134.4 | -66 | -57 |
| 156.4 | -68 | -57 |
| 199.9 | -66 | -57 |

Horizontal antenna

| Receiver Mode | | |
|--------------------|------------------|----------------|
| Frequency (MHz) | Measure (dBm) | Limit (dBm) |
| 144.4 | -72 | -57 |
| 166.5 | -67 | -57 |
| 192.6 | -68 | -57 |
| 199.9 | -68 | -57 |



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

| Frequency (MHz) | Measure E.R.P (dBm) | Measure E.I.R.P (dBm) |
|--------------------|------------------------|--------------------------|
| 981,7 | -69,04 | -66,9 |
| 3955,8 | -59,84 | -57,7 |

ETSI EN 301 839-1 §9.1

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



9. RADIATION EMISSIONS

9.1. TEST CONDITIONS

| Test performed by | : Laurent DENEUX |
|---------------------|------------------|
| Date of test | : 2012/03/22 |
| Ambient temperature | : 23°C |
| Relative humidity | : 42% |

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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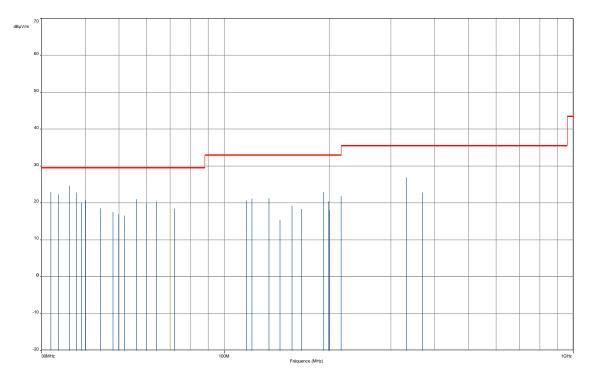
9.3. RESULTS

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

Fcc Part.15 CLASS B

SORIN IMPLANT MODEL : PARADYM RF VR 9250 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: 29.5BµV/m or 100µV/m 88MHz to 216MHz: 33dBµV/m or 150µV/m 216MHz to 960MHz: 35.5dBµV/m or 200µV/m Above 960MHz: 43.5dBµV/m or 500µV/m



Page 22

10. TEST EQUIPMENT LIST

| Test | Apparatus | Trade Mark | Туре | Registration number | |
|--------|--|---|----------------------------|----------------------|--|
| 1001 | Effective Radiated Power Of The Fundamenta | | | | |
| X | Full anechoic chamber | SIEPEL | S36 | D3044019 | |
| X | Logperiodic antenna | AMPLIFIER RESEARCH | ATR80M6G | C2040149 | |
| X | EMI Test Receiver | ROHDE & SCHWARZ | ESMI | A2642009 | |
| X | Signal Generator | ROHDE & SCHWARZ | SMIQ03b | A5442039 | |
| X | Logperiodic antenna | AMPLIFIER RESEARCH | AT1000 | C2040002 | |
| X | Substitution Cable | - | CNJ01 | A5329393 | |
| X | Substitution Cable | | CNS1E 04 | A5329434 | |
| X | Horn Antenna | A.H. SYSTEMS | SAS-571 | C2042041 | |
| X | Horn Antenna | EMCO | 3117 | C2042041 | |
| X | Dipole Antenna | SCHWARZBECK | VHAP | C2042031 C2040020 | |
| X | Dipole Antenna | SCHWARZBECK | UHAP | C2040020 | |
| ~ | Emission Bandwidth, Occupied Band | | | 02040022 | |
| X | Antenna | KATHREIN | | | |
| X | Climatic Chamber | SECASI Technologies | SLT-34 | D1024029 | |
| X | Spectrum Analyser | ROHDE & SCHWARZ | FSL | A4060032 | |
| ^ | | | FSL | A4060032 | |
| x | Spectrum Analyser | rror & Frequency stability ROHDE & SCHWARZ | FSL | A4060032 | |
| X | Antenna | KOHDE & SCHWARZ | F5L | A4000032 | |
| X | Climatic Chamber | SECASI Technologies | | D1024029 | |
| ^ | | | | D1024029 | |
| x | Full anechoic chamber | Emissions & Unwanted Emissic SIEPEL | S36 | D3044019 | |
| X | EMI Test Receiver | ROHDE & SCHWARZ | ESMI | A2642009 | |
| X | | | | | |
| X | Preamplier Horn Antenna | BONN Elektronik A.H. SYSTEMS | BLNA 3018-8F30S SAS-571 | A7080053 C2042041 | |
| X | | | ATR80M6G | | |
| X | Logperiodic antenna | AMPLIFIER RESEARCH | SMR | C2040149 | |
| | Signal Generator | ROHDE & SCHWARZ | | A5444002 | |
| X X | Signal Generator | ROHDE & SCHWARZ SCHWARZBECK | SMIQ03b VHAP | A5442039 | |
| X | Dipole Antenna | | | C2040020 | |
| | Dipole Antenna | SCHWARZBECK | UHAP | C2040022 | |
| X | Open test site | | - | 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 | | .3115 | C2042016 | |
| X X | Signal Generator | ROHDE & SCHWARZ | SMP02 | B2163019 | |
| X | Signal Generator | ROHDE & SCHWARZ | SMY02 | A5442014 | |
| × I | | Emissions & Radiated Emissions | | D2044040 | |
| X | Full anechoic chamber | | 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 | |
| Х | Logperiodic antenna | ROHDE & SCHWARZ | HL 023 A2 | C2040001 | |



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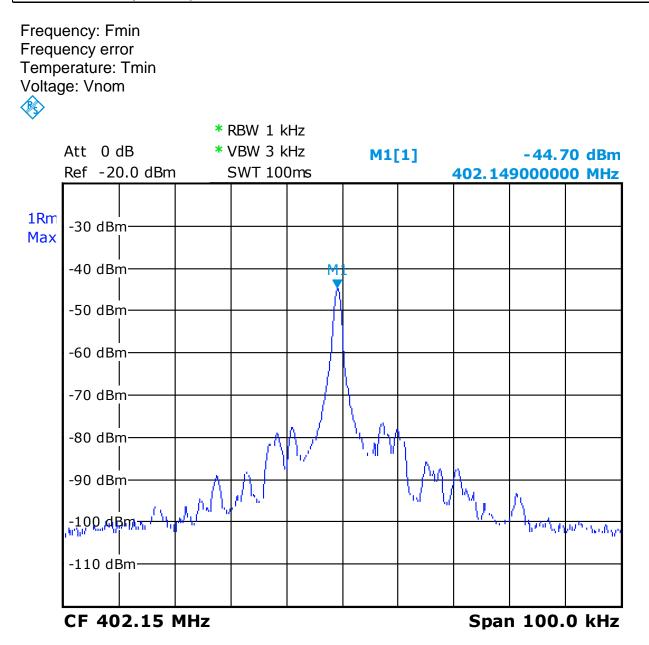
| | | 3115 | C2040023 |
|--------------------|-----------------|---------|----------|
| X Horn antenna | AH SYSTEMS | SAS-572 | C2042026 |
| X Horn antenna | EMCO | .3115 | C2042016 |
| X Signal Generator | ROHDE & SCHWARZ | SMP02 | B2163019 |

11. UNCERTAINTIES CHART

| ETSI EN 300 220 | Measurement uncertainties (k=2) ±x(dB) / (Hz) | Limit for uncertainties ±y(dB) | |
|---|---|--------------------------------------|--|
| TRANSMITTER REQUIREMENTS | | | |
| Frequency Error | ±2.10 ⁻⁸ Hz | ±1.10 ⁻⁷ Hz | |
| Modulation Bandwidth | ± 100 kHz | - | |
| Effective Radiated Power | ±3.9 dB | ±6 dB | |
| Adjacent Channel Power | ±1.6 dB | ±3 dB | |
| Spurious emissions | | | |
| Frequency < 1000 MHz | ±3.9 dB | ±6 dB | |
| Frequency > 1000 MHz | ±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 | | | |
| Frequency < 1000 MHz | ±3.9 dB | ±6 dB | |
| Frequency > 1000 MHz | ±3.1 dB | | |
| Spurious emissions in conduction | ±0.6 dB | ±3 dB | |



12. ANNEX 1 (GRAPHS)



Date: 30.MAR.2012 10:08:14



Frequency: Fmin Frequency error Temperature: Tnom Voltage: Vnom × * RBW 1 kHz Att 0 dB * VBW 3 kHz M1[1] -45.86 dBm Ref -20.0 dBm SWT 100ms 402.149400000 MHz 1Rm -30 dBm-Max -40 dBm-M1 -50 dBm--60 dBm--70 dBm-М IΜ -80 dBm--90 dBmthrow have the state of the L_M -100 dBm h ___ / M_h _/ h __ / h __ / h __ / h __ / -110 dBm-Span 100.0 kHz CF 402.15 MHz

Date: 30.MAR.2012 15:35:24



Frequency: Fmin Frequency error Temperature: Tmax Voltage: Vnom * RBW 1 kHz Att 0 dB * VBW 3 kHz M1[1] -48.39 dBm Ref -20.0 dBm SWT 100ms 402.149800000 MHz 1Rm -30 dBm-Max -40 dBm-**M**1 -50 dBm--60 dBm--70 dBm--80 dBm -90 dBmhulle Δ -100 dBm-And the Stand Suchast and the A. we have the full of which -110 dBm-Span 100.0 kHz CF 402.15 MHz

Date: 30.MAR.2012 16:23:33



Frequency: Fnom Frequency error Temperature: Tmin Voltage: Vnom × * RBW 1 kHz Att 0 dB * VBW 3 kHz M1[1] -44.53 dBm Ref -20.0 dBm SWT 100ms 403.65200000 MHz 1Rm -30 dBm-Max -40 dBm--50 dBm--60 dBm--70 dBm--80 dBm--90 dBmb М South Mar $\mathcal{L}^{(n,n)}$ ØA. used in the formation of the -100 dBm م الکنیک л., М -110 dBm-Span 100.0 kHz CF 403.65 MHz

Date: 30.MAR.2012 10:09:54



Frequency: Fnom Frequency error Temperature: Tnom Voltage: Vnom × * RBW 1 kHz Att 0 dB * VBW 3 kHz M1[1] -47.07 dBm Ref -20.0 dBm SWT 100ms 403.653390000 MHz 1Rm -30 dBm-Max -40 dBm-M1 X -50 dBm--60 dBm--70 dBm-[*μ*, -80 dBm--90 dBm-١٨, -100 dBm-Par Var Var նվյլ we we we want the second of -110 dBm-Span 100.0 kHz CF 403.65 MHz

Date: 30.MAR.2012 15:33:15



Frequency: Fnom Frequency error Temperature: Tmax Voltage: Vnom ¢\$ * RBW 1 kHz Att 0 dB * VBW 3 kHz M1[1] -47.47 dBm Ref -20.0 dBm SWT 100ms 403.65200000 MHz 1Rm -30 dBm-Max -40 dBm-Μ1 $\mathbf{\nabla}$ -50 dBm--60 dBm--70 dBm--80 dBm -90 dBmell'h -100 dBmh_ant'n t -110 dBm-CF 403.65 MHz Span 100.0 kHz

Date: 30.MAR.2012 16:25:41



Frequency: Fmax Frequency error Temperature: Tmin Voltage: Vnom ¢\$ * RBW 1 kHz Att 0 dB * VBW 3 kHz M1[1] -44.79 dBm Ref -20.0 dBm SWT 100ms 404.85200000 MHz 1Rm -30 dBm-Max -40 dBm--50 dBm--60 dBm-W -70 dBm--80 dBm 4.1 Νı h. -90 dBm -100 dBm--110 dBm-Span 100.0 kHz CF 404.85 MHz

Date: 30.MAR.2012 10:11:36



Frequency: Fmax Frequency error Temperature: Tnom Voltage: Vnom ¢\$ * RBW 1 kHz Att 0 dB * VBW 3 kHz M1[1] -47.61 dBm Ref -20.0 dBm SWT 100ms 404.853190000 MHz 1Rm -30 dBm-Max -40 dBm-M1 -50 dBm--60 dBm--70 dBm--80 dBm -90 dBm ^lliΩ0∖dBm -110 dBm-Span 100.0 kHz CF 404.85 MHz

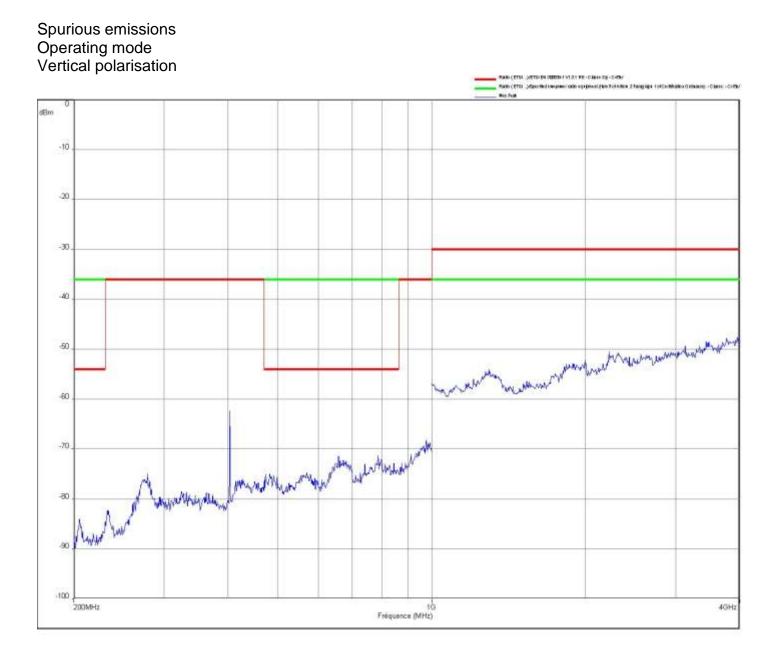
Date: 30.MAR.2012 15:31:30



Frequency: Fmax Frequency error Temperature: Tmax Voltage: Vnom ¢\$ * RBW 1 kHz Att 0 dB * VBW 3 kHz M1[1] -49.40 dBm Ref -20.0 dBm SWT 100ms 404.851800000 MHz 1Rm -30 dBm-Max -40 dBm-Μ1 -50 dBm--60 dBm--70 dBm--80 dBm -90 dBm-100 dBm-Male Lake h. -110 dBm-Span 100.0 kHz CF 404.85 MHz

Date: 30.MAR.2012 16:27:49

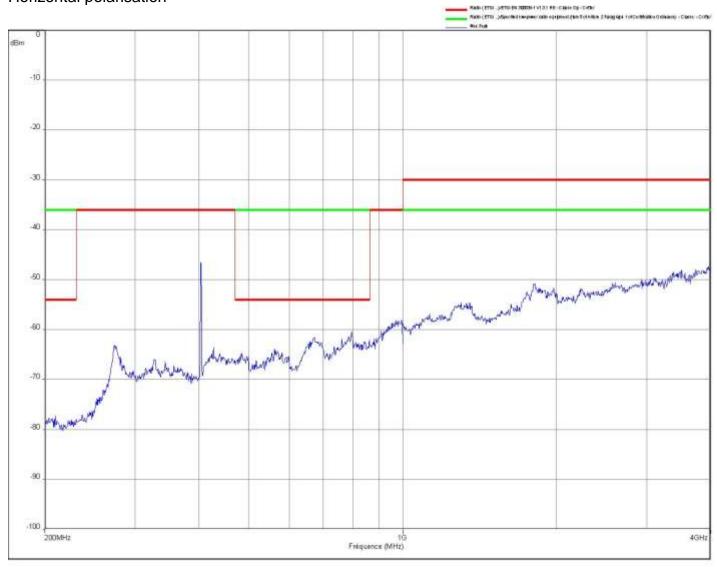






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Spurious emissions Operating mode Horizontal polarisation





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Spurious emissions Receiver mode Vertical polarisation





Page 36

Spurious emissions Receiver mode Horizontal polarisation

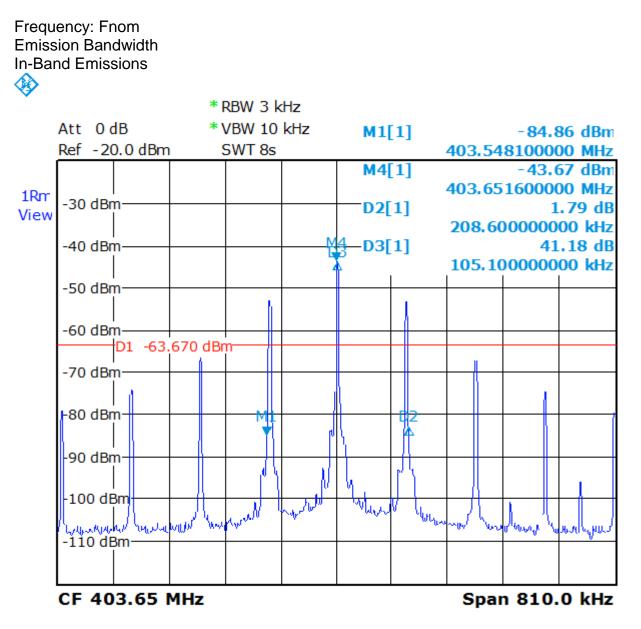




Frequency: Fmin **Emission Bandwidth** Band-Edge Emissions In-Band Emissions ٨ * RBW 3 kHz Att 0dB *VBW 10 kHz M4[1] -41.28 dBm Ref - 20.0 dBm SWT 8s 402.151600000 MHz M1[1] -77.51 dBm 402.048100000 MHz 1Rm -30 dBm D2[1] 0.99 dB View 206.90000000 kHz M4 -40 dBm-D3[1] 36.24 dB 103.50000000 kHz -50 dBm -60 dBn_{D1} -61.280 dBm--70 dBm-Μ 12 -80 dBm -90 **d**Bm Մ(-100 dBm hall Խաս wwwwwww _Գլիպյու և և ويوسلونها. -110 dBm Span 810.0 kHz CF 402.15 MHz

Date: 29.MAR.2012 15:12:01





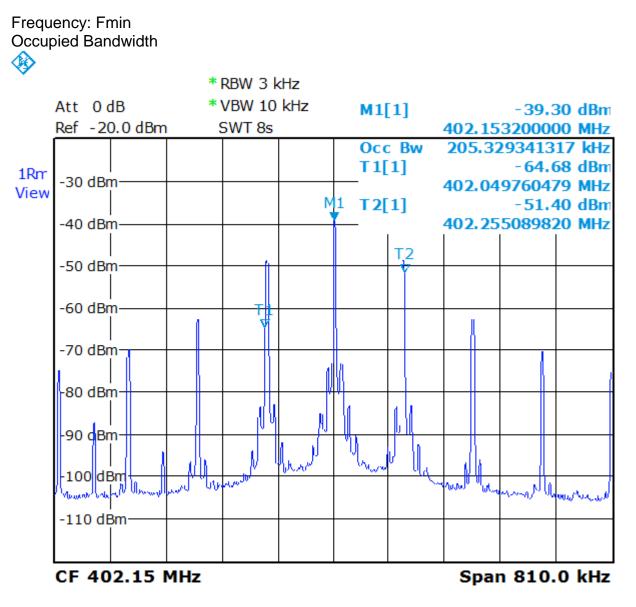
Date: 29.MAR.2012 15:06:44



Frequency: Fmax **Emission Bandwidth** Band-Edge Emissions In-Band Emission ٨ * RBW 3 kHz *VBW 10 kHz Att 0dB -41.18 dBm M4[1] Ref - 20.0 dBm SWT 8s 404.85160000 MHz M1[1] -67.82 dBm 404.955100000 MHz 1Rm -30 dBm-D2[1] -8.18 dB View -206.90000000 kHz M4 -40 dBm D3[1] 26.64 dB -103.50000000 kHz -50 dBm -60 dBn_{D1} -61.180 dBm-M1 -70 dBm--80 dBm -90 dBm 4 100 dBn ,Մ wywwydr -110 dBm Span 810.0 kHz CF 404.85 MHz

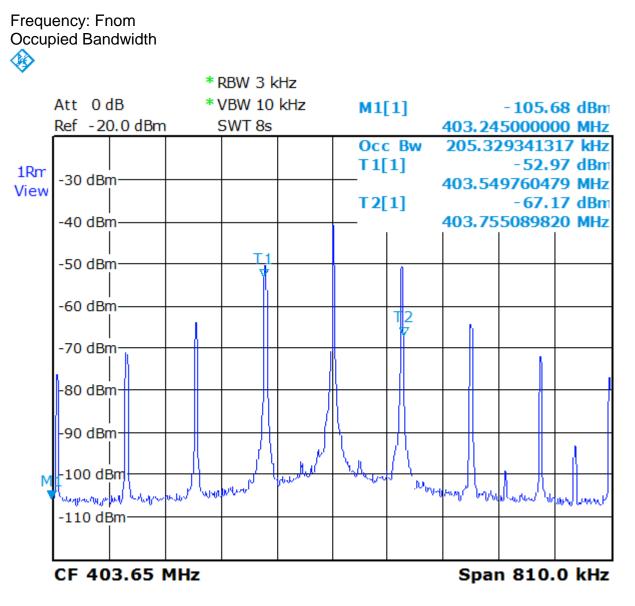
Date: 30.MAR.2012 09:36:56





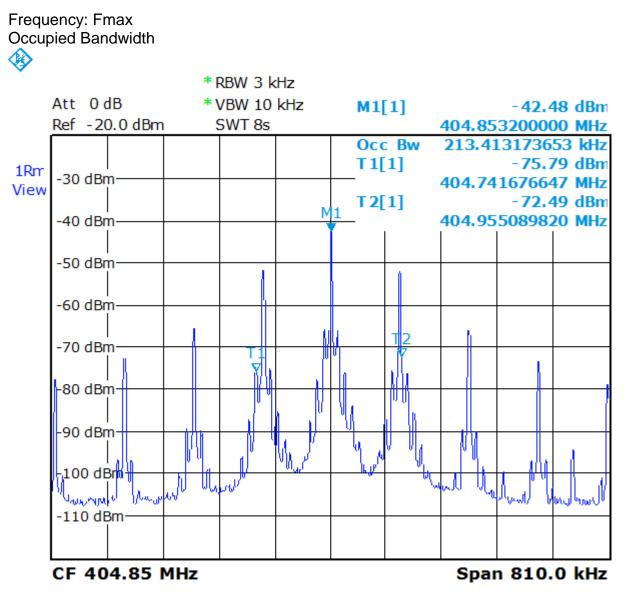
Date: 30.MAR.2012 09:57:00





Date: 30.MAR.2012 09:55:22





Date: 30.MAR.2012 09:49:40



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13. ANNEX 2 (FLUID DATA SHEET MSL 450)

Schmid & Partner Engineering AG S D C A G

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

Material Safety Data Sheet

1 Identification of the substance and of the manufacturer / origin

| Item | Brain Tissue Simulation Liquids B900 |
|-----------------------|--|
| | Head Tissue Simulation Liquids HSL 175, HSL300, HSL450, HSL750, HSL900 |
| | Muscle Tissue Simulation Liquids MSL450, MSL 750, MSL900 |
| Type No | SL 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 ₂ O | Water, 35 – 58% |
| Sucrose | Sugar, white, refined, 40 - 60% |
| NaCl | Sodium Chioride, 0 – 6% |
| Hydroxyethyl-cellulose | Medium Viscosity (CA8# 9004-62-0), <0.3% |
| Preventol-D7 | Preservative: aqueous preparation, (CAS# 55965-84-9), containing |
| | 5-chloro-2-methyl-3(2H)-isothiazolone and 2-methyyl-3(2H)-isothiazolone, |
| | 0.1 - 0.7% |
| | Relevant for safety; Refer to the respective Safety Data Sheet". |

3 Hazards identification

| Symbol | х | Irritant |
|------------|-------|---|
| R-phrases: | 36/38 | irritating to eyes and skin |
| | 43 | May cause sensitization by skin contact |

4 First aid measures

| After skin contact: | Wash off with plenty of water and soap |
|---------------------|---|
| After eye contact: | Rinse out with plenty of water with the eyelid held open, call an ophthalmologist |
| 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: gopgles 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: | odouriess |
| pH-Value: | neutral, with tendency to lower pH values. |
| Boiling point: | 100°C |
| Density: | 1.2 - 1.4 g/cm^3 |
| | |

10 Stability and reactivity

No hazardous decomposition products expected.

11 Toxicological information

initation 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 compliance with the respective national regulations. Packing: Product packing must be disposed of in compliance 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

Labeling according to EC Directives

| Symbol | 20 | Inttant |
|------------|-------|---|
| 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

speag

Zeugheusstrasse 43, 8004 Zurich, Switzerland Phone +41 44 245 9700, Fax +41 44 245 9779 info@speag.com, http://www.speag.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/cm³ TSL Heat-capacity 3.001 kJ/(kg*K)

Results

| i 1 | Measured | | Target | | Diff.to Target [%] | | |
|------------|----------|-------|--------|------|--------------------|-------|---------|
| f [MHz] | HP-e | HP-e" | sigma | eps | sigma | ∆-eps | ∆-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 | 0.95 | -0.5 | -2.9 |
| 375 | 57.1 | 43.81 | 0.91 | 57,5 | 0.83 | -0.8 | -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 |
| 436 | 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 | 6.5 |
| 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.t | 9.7 |
| 538 | 54.5 | 35.07 | 1.05 | 58.4 | 0.95 | -3.3 | 10.6 |
| 550 | 54.3 | 34.58 | 1.06 | 58.3 | D.95 | -3.6 | 11.6 |
| 563 | 54.1 | 34.20 | 1.07 | 56.3 | 0.95 | -3.8 | 12,7 |
| 675 | 54.0 | 33.82 | 1.08 | 58.2 | 0.95 | -4.0 | 13.8 |
| 600 | 53.6 | 33.05 | 1.10 | 56.1 | 0.95 | -4,4 | 15.9 |

