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EST REPORT

Number
Composition of document

RADIO

112624-622708-Q-Cr2012-05-16
19 pages

Standards

ETSI EN 300328 V1.7.1
FCC RULES PART 15
IC RADIO STANDARDS RSS-210
ARIB STD-T66 V2.1

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 — VR model 9250
148YYW053

Test date

2012/03/22 & 2012/03/26 to 2012/03/30

Tests performed by

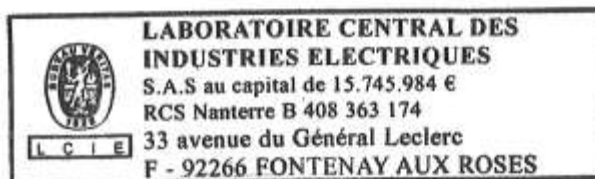
Stéphane PHOUDIAH & Laurent DENEUX

Test site

Fontenay Aux Roses & Ecuelles

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2012/05/16
2012/05/16
2012/04/18



Written by :
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Tests operator

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1. TEST PROGRAM

• **References**

Standards: ETSI EN 300328 V1.7.1
 ERC Recommendation 70-03
 ARIB STD-T66 V2.1
 FCC RULES PART 15
 IC RADIO STANDARDS RSS-210

• **Transmitter requirement:**

Clause (ETSI EN 300 328) Test Description	TEST RESULT - Comments
4.2.1 – FHSS modulation	N/A (Receiver Equipment)
5.7.2 – Equivalent Isotropic Radiated Power	N/A (Receiver Equipment)
5.7.3 – Maximum EIRP spectral density	N/A (Receiver Equipment)
5.7.4 – Frequency Range	N/A (Receiver Equipment)
5.7.5 – Transmitter Spurious Emissions	N/A (Receiver Equipment)

Clause (ARIB STD-T66) Test Description	TEST RESULT - Comments
3.1 (1) – Communication method	PASS
3.1 (2) – Contents of communication	PASS
3.1 (3) – Frequency band	PASS
3.1 (4) – Environmental operating conditions	PASS
3.2 (1) – Modulation system	N/A (Receiver Equipment)
3.2 (2) – Antenna power	N/A (Receiver Equipment)
3.2 (4) – Frequency tolerance	N/A (Receiver Equipment)
3.2 (6) – Spurious emissions intensity	N/A (Receiver Equipment)
3.2 (7) – Occupied bandwidth	N/A (Receiver Equipment)
3.2 (8) – Spread bandwidth	N/A (Receiver Equipment)
3.2 (9) – Process gain	N/A (Receiver Equipment)
3.2 (10) – Number of carrier within 1MHz bandwidth in OFDM	N/A (Receiver Equipment)
3.2 (11) – Dwell time	N/A (Receiver Equipment)
3.6 (2) – Antenna Characteristics	N/A (Receiver Equipment)

Clause (FCC PART 15) Test Description	TEST RESULT - Comments
Power line conducted emissions	N/A (Receiver Equipment)
Channel separation	N/A (Receiver Equipment)
Time of Occupancy	N/A (Receiver Equipment)
20dB Occupied bandwidth	N/A (Receiver Equipment)
Peak Power Output	N/A (Receiver Equipment)
Radiated emissions	N/A (Receiver Equipment)



Clause (RSS 210) Test Description	TEST RESULT - Comments
Power line conducted emissions	N/A (Receiver Equipment)
Channel separation	N/A (Receiver Equipment)
Time of Occupancy	N/A (Receiver Equipment)
20dB Occupied bandwidth	N/A (Receiver Equipment)
Peak Power Output	N/A (Receiver Equipment)
Radiated emissions	N/A (Receiver Equipment)

• **Receiver requirement:**

Clause (ETSI EN 300 328) Test Description	TEST RESULT - Comments
8.6 –Receiver Spurious Emissions	PASS

Clause (ARIB STD-T66) Test Description	TEST RESULT - Comments
3.3 (1) – Receiver spurious radiation	PASS

Clause (FCC 15.247) Test Description	TEST RESULT - Comments
Radiated emissions	PASS

Clause (RSS 210) Test Description	TEST RESULT - Comments
Radiated emissions	PASS

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

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.

- **Input/output:**

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

- **Equipment information:**

- Modulation technology: FHSS modulation
- Modulation type: OOK
- Operating frequency range: 2400MHz to 2483,5MHz
- Type of the equipment: stand-alone equipment
- Antenna 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
- Source voltage:
 - Vnom: BOL: 3.25 V. ERI: 2.66 V. EOL: 2.5 V (Internal Battery)

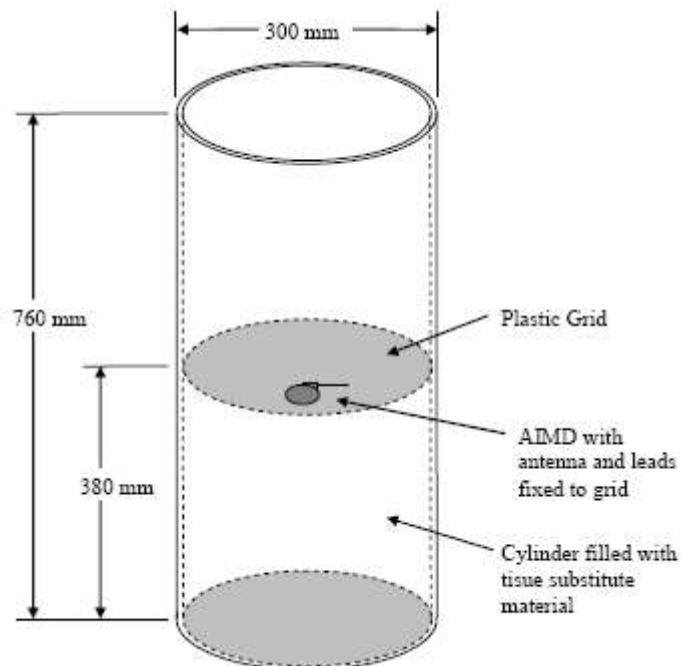
2.2. RUNNING MODE

Permanent reception

2.1. 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.

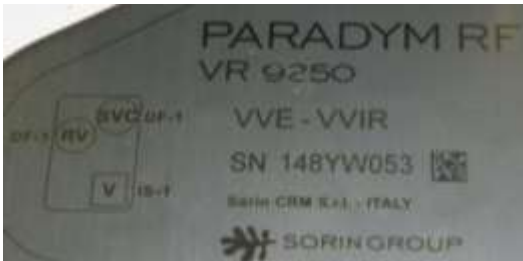


For the testing, the equipment under test (EUT) was suspended in a Plexiglas torso simulator as specified above. The simulator used was constructed in accordance with FCC 95.639(a)(2)(i), EN 301 839-1 (A.113) and EN 301 489-27 annex B.

During the test, the EUT was centred vertically in Plexiglas cylinder. The torso simulator was filled with a fluid formulated 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).



2.2. EQUIPEMENT LABELLING



2.3. EQUIPMENT MODIFICATIONS

No equipment modification has been necessary during testing.



3. RECEIVER SPURIOUS EMISSIONS

3.1. TEST CONDITIONS

Test performed by : Stéphane PHOUDIAH
Date of test : 2012/03/26
Ambient temperature : 23°C
Relative humidity : 30%

3.2. TEST SETUP

ETSI EN 300 328 §8.6
ARIB STD-T66 §3.3 (1)

- **Method of measurement**

- Effective Radiated Power, cabinet radiation
- Effective Radiated Power, cabinet and antenna radiation

- **Qualification measurements on an open test site (30MHz 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. 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 12.75GHz):**

The setup is 1.5m above the ground reference plane.

Distance between measuring antenna and the EUT is 3meters for frequency 200MHz to 12,75GHz.

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.

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

**3.3. RESULTS**

- Characterization on open test site chamber (30MHz 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



- **Characterization in a full anechoic chamber (200MHz to 12,75GHz):**

Frequency (MHz)	Measure E.I.R.P (dBm)
968,4	-69,1
4972,9	-53,5
5979,8	-52,6

ETSI EN 300 328 §8.6

Limit: → 30MHz to 1GHz: -57dBm
1GHz to 12,75GHz: -47dBm

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

Limit: → 30MHz to 1GHz: -54dBm
1GHz to 12,75GHz: -47dBm

Result: **PASS**

See annex 1 for graphics



4. RADIATION EMISSIONS

4.1. TEST CONDITIONS

Test performed by : Laurent DENEUX
Date of test : 2012/03/22
Ambient temperature : 23°C
Relative humidity : 45%

4.2. TEST SETUP

FCC 15.109 (a)
RSS 210 §2.6

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 2 horns 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.



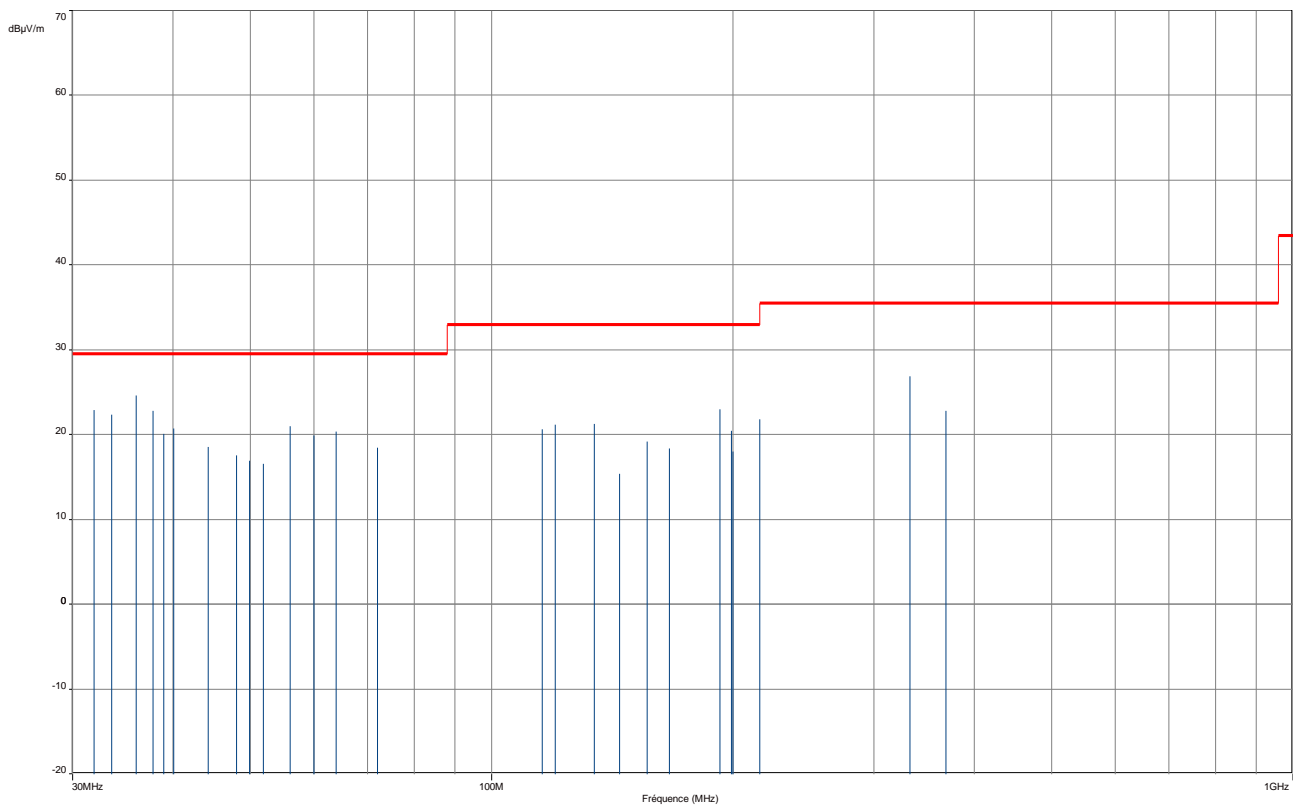
4.3. RESULTS

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

Fcc Part.15 CLASS B

SORIN
IMPLANT
MODEL : PARADYM RF VR 9250
400 Rx and 2.4 Rx mode

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: 29.5dBµV/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



5. TEST EQUIPMENT LIST

Test	Apparatus	Trade Mark	Type	Registration number
	Receiver Spurious Emissions			
X	Full anechoic chamber	SIEPEL	S36	D3044019
X	EMI Test Receiver	ROHDE & SCHWARZ	ESMI	A2642009
X	EMI Test Receiver	ROHDE & SCHWARZ	ESIB26	A2642021
X	Preamplifier	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	Bilog Antenna	CHASE	CBL 6111C	C2040124
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	AnSpectrum analyseur	HEWLETT PACKARD	8566B	A4060004
X	Preselector	HEWLETT PACKARD	85685A	A4069001
X	Quas-Peak adaptator	HEWLETT PACKARD	85650A	A4069003
X	Preamplifier	HEWLETT PACKARD	8449B	A4069002
X	Bilog antenna	CHASE	CBL 6112A	C2040040
X	Bilog antenna	AH SYSTEM	SAS-2001251	C2040025
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 ,C2042025
X	Horn antenna	EMCO	.3115	C2042016
X	Signal Generator	ROHDE & SCHWARZ	SMP02	B2163019
X	Signal Generator	ROHDE & SCHWARZ	SMY02	A5442014

**6. UNCERTAINTIES CHART**

ETSI EN 300 328 Kind of test	Measurement uncertainties (k=2) ±x(dB) / (Hz)	Limit for uncertainties ±y(dB)
Temperature	±0.5°C	±1°C
Humidity	±2.5 %	±5 %
RECEIVER REQUIREMENTS		
Spurious emissions <ul style="list-style-type: none">• Frequency < 1000 MHz• Frequency > 1000 MHz	±3.9 dB ±3.1 dB	±6 dB



7. ANNEX 1 (GRAPHICS)

Receiver Spurious Emission
Horizontal polarisation





Receiver Spurious Emission Vertical polarisation



**8. ANNEX 2 (FLUID DATA SHEET MSL 450)**

Schmid & Partner Engineering AG

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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 Head Tissue Simulation Liquids HSL 175, HSL300, HSL450, HSL750, HSL900 Muscle Tissue Simulation Liquids MBL450, MBL 750, MBL900
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 Zurich 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 – 55%
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)-isothiazolone and 2-methyl-3(2H)-isothiazolone, 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
	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 sodiumhydrogensulfite. 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.



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 substance.

9 Physical and chemical properties

Form: liquid
Colour: yellowish to light brown, transparent
Odour: odourless
pH-Value: neutral, with tendency to lower pH values.
Boiling point: 100°C
Density: 1.2 - 1.4 g/cm³

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 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	X1	Irritant
R-phrases:	36/38 43	Irritating to eyes and skin May cause sensitization by skin contact

MAK value for the preservative is 0.05mg/m³, corresponding to a concentration of <25mg/m³ 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



Schmid & Partner Engineering AG

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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

f [MHz]	Measured			Target		Diff. to Target [%]	
	HP-e'	HP-e''	sigma	eps	sigma	Δ-eps	Δ-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
350	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	0.93	-0.6	-2.0
386	56.9	42.81	0.92	57.3	0.93	-0.6	-1.2
400	56.5	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	0.95	56.8	0.94	-1.5	2.6
450	55.8	38.86	0.97	56.7	0.94	-1.6	3.5
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
488	55.2	37.11	1.01	56.6	0.94	-2.3	6.6
500	55.0	36.53	1.02	56.5	0.94	-2.6	7.7
513	54.9	36.04	1.03	56.5	0.94	-2.8	8.7
525	54.7	35.56	1.04	56.4	0.95	-3.1	9.7
538	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
563	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	56.1	0.95	-4.4	15.9

