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TEST REPORT

Number
Composition of document

RADIO

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33 pages

Standards

FCC Part 15 of September 9, 2009
RSS-102 of November 2005
RSS-210 of June 2007

Issued to

SORIN CRM
Parc d'affaires NOVEOS
4, Avenue Réaumur
92140 CLAMART Cedex

Mme de JESO

Apparatus under test

Trade mark
Manufacturer
Type
Serial number
FCC ID

SMARTVIEW MONITOR
SORIN GROUP
SELCO EOLANE COMBREE
SMARTVIEW MONITOR KA 961 (US version with GPRS)
HB1107001S
YSGKA961

Test date

May 2nd to June 14th, 2011

Tests performed by

Stéphane PHOUDIAH

Test site

LCIE Fontenay aux Roses (92)

Initial date of issue

December 7th, 2011

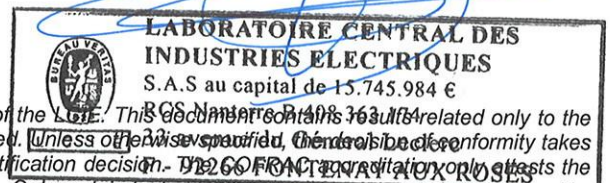
Date of correction

January 10th, 2012

Date of issue

January 10th, 2012

Approved by :
Philippe SISSOKO



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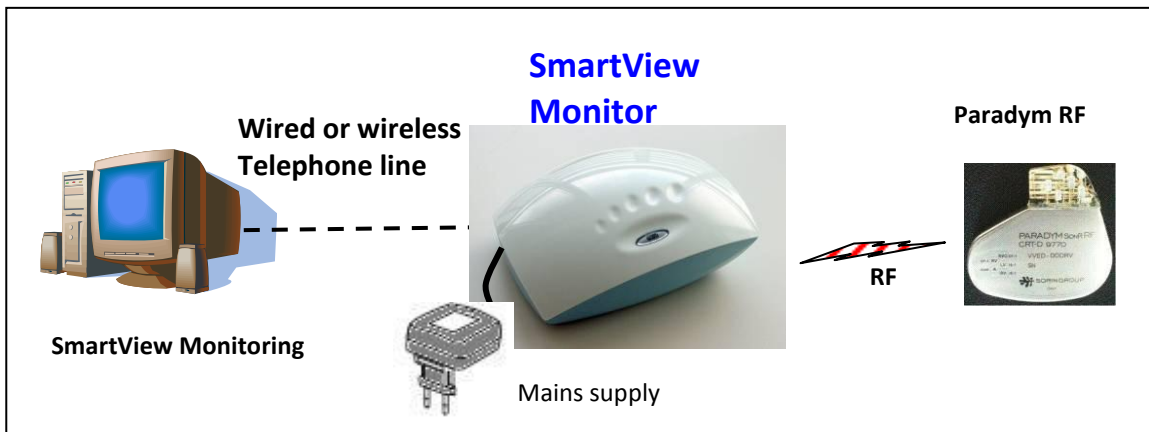


1. REFERENCE DOCUMENTS

- **47 CFR Part 15 of September 9, 2009:** Code of federal regulations – Telecommunication –Radiofrequency devices
- **Radio performance tests procedures given in part 15:**
 - Paragraph 33: frequency range of radiated measurements
 - Paragraph 35: measurement detector functions and bandwidths
 - Paragraph 203: antenna requirement
 - Paragraph 205: restricted bands of operation
 - Paragraph 207: conducted limits
 - Paragraph 209: radiated emission limits; general requirements
 - Paragraph 247: operation within the bands 2400-2483.5 MHz
- **RSS-Gen of June 2007:** General Requirements and Information for the Certification of Radiocommunication Equipment
- **RSS-102 of November 2010:** Radio Frequency Exposure Compliance of Radiocommunication Apparatus
- **RSS-210 of June 2007 -** Low-power Licence-exempt Radiocommunication Devices (All Frequency Bands): Category I Equipment
- **ANSI C63.4 of December 11, 2003:** American national standard for methods of measurement of radio noise emissions from low-voltage electrical and electronic equipment in the range of 9 kHz to 40 GHz.

2. EQUIPMENT UNDER TEST DESCRIPTION

The SmartView Monitor (SM) is intended to collect patient's clinical data from an Implantable Medical Device (IMD) and transfer them to data management system (Back Office server).
 The IMD is implanted into the patient's body. The SmartView Monitor is installed at patient Remote and is intended to collect data from the IMD remotely in absence of physician according to scheduled operation. It is not intended to act as emergency response system.
 The connection between the SmartView Monitor and the implant is achieved through Radio-Frequency (RF) telemetry while the connection to the server is performed through the telephone line (fix or mobile net).



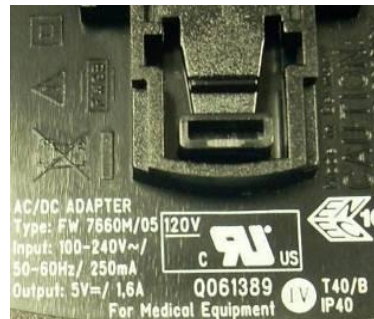
Applicant	SORIN CRM Parc d'affaires NOVEOS 4, Avenue Réaumur 92140 CLAMART Cedex
Manufacturer	SELCO EOLANE COMBREE Le Val d'Ombrée 49520 Combrée France
Dimensions	
Frequencies band	402-405 MHz 2400-2483,5 MHz GSM-GPRS: Allow connection of the SM to mobile telephony. GSM / GPRS SIMCOM SIM340E quad-band module is certified by FCC according following information. <ul style="list-style-type: none"> - FCC IDENTIFIER: UDV-0606020080701. - Name of Grantee: Shanghai Simcom Ltd. - Equipment Class: Part 15 Class B Computing Device Peripheral. - Notes: GSM/GPRS 850/900/1800/1900 Module.
Number of channel	Modular Type: Limited Single Modular. 10 for 402-405 MHz band 15 for 2400-2483.5 band
Channel spacing	-
Modulation	FSK for 402-405 MHz band OOK for 2400-2483.5 band
User power adjustment	No
Is the operation point to point?	Yes
Power supply	Power Supply manufactured by FRIWO, model FW 7660M/05: 100-240V~ 50-60Hz 250mA, Output 5Vdc 1.6A
I/O cables used for testing	USB cable (only for test configuration)

Equipment photograph

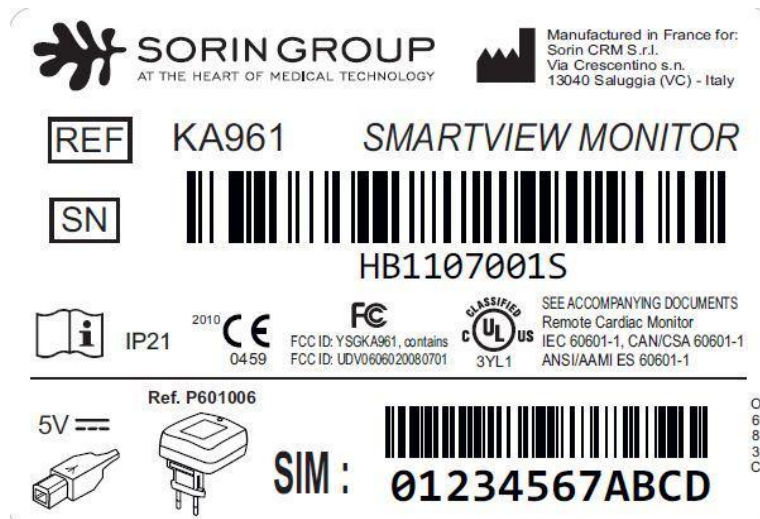


Marking plate

Marking on Power Supply




Marking on SMARTVIEW MONITOR





SORIN GROUP
 AT THE HEART OF MEDICAL TECHNOLOGY

Manufactured in France for:
 Sorin CRM S.r.l.
 Via Crescentino s.n.
 13040 Saluggia (VC) - Italy

REF KA961 SMARTVIEW MONITOR

SN 
 HB1107001S

IP21 2010 CE 0459 FCC ID: YSGKA961, contains FCC ID: UDV0606020080701 FC CLASSIFIED 3YL1 US SEE ACCOMPANYING DOCUMENTS Remote Cardiac Monitor IEC 60601-1, CAN/CSA 60601-1 ANSI/AAMI ES 60601-1

5V   Ref. P601006 SIM:  01234567ABCD

C 0 0 0 0 0



Block part	Description
User interface	<ul style="list-style-type: none">- One pushbutton to allow the user to force a data transmission on demand,- One status LED indicating overall system health,- 5 LEDs showing the data collection and transmission progress
RF	<ul style="list-style-type: none">- Unidirectional link from RM to implant in the ISM band (2.45 GHz) to wake up the implant. Chipcon CC2500 chip,- Bidirectional link between the RM and the implant in the MEDRADIO band (402-405 MHz) for patient data transmission (Zarlink ZL70101 chip)
Power Supply	External 100-240V to 5V AC/DC adapter Power Supply manufactured by FRIWO, model FW 7660M/05: 100-240V~ 50-60Hz 250mA, Output 5Vdc 1.6A
GSM / GPRS	GSM-GPRS: Allow connection of the SM to mobile telephony. GSM / GPRS SIMCOM SIM340E quad-band module is certified by FCC according following information. <ul style="list-style-type: none">- FCC IDENTIFIER: UDV-0606020080701.- Name of Grantee: Shanghai Simcom Ltd.- Equipment Class: Part 15 Class B Computing Device Peripheral.- Notes: GSM/GPRS 850/900/1800/1900 Module. Modular Type: Limited Single Modular.
Ethernet module	To be used in production for RM investigation
Processor	Freescale MCIMX27L chip, ARM9-based 32-bit RISC
Real time clock / Battery	Maxim DS1391 RTC chip with a CR1620 backup lithium cell (60 mAh)
USB cable	Allow connection to the RM via USB
Memory (DRAM, code, data & boot FLASH)	<ul style="list-style-type: none">- DRAM memory: Micron MT46H16M16 chip, 32 MB DDR SDRAM memory- Flash memories: Samsung K9F5608R0D chip, 32 MB NAND flash memory



Antenna Type

SmartView Monitor (Wake-up operating mode – ISM band):

-Monopole antenna (customized by Sorin CRM)

This antenna is internal and can not be removed.

- HP Max gain: -1dBi max

- VP Max gain: +2dBi max

-IFA antenna (customized by Sorin CRM)

This antenna is internal and can not be removed.

- HP Max gain: -6dBi max

- VP Max gain: -8dBi max

SmartView Monitor (Data transmission operating mode – MEDRADIO band)

This antenna is internal and can not be removed.

- HP Max gain: 1,4dBi max

- VP Max gain: 1,4dBi max



3. SMARTVIEW MONITOR FUNCTIONAL DESCRIPTION ET OPERATING MODES

In the following sections the SmartView Monitor is described, highlighting its Features and Operation.

Note: IMD is also described through this section as a slave of the SM.

SmartView Monitor Operation

The summary of mission / operation of the SmartView Monitor is the following:

- SM is a device to be installed in Patient Home.
 - Connection to power line (wall plug adapter)
- SM shall be activated after connecting it to power supply. Executes:
 - bootstrap;
 - self-diagnostic;
 - implant pairing (at first boot)
- SM is paired through an automatic procedure to the Implant present at first boot
- SM shall collect patient's clinical data from Implanted device and transfer them to data management system (Back Office server).
- The Implant data collection shall be performed according to 3 use cases:
 - Scheduled Patient Home Follow-up
 - On Alert event/status evidenced by the Implant diagnostic features
 - On-Demand by Patient (if enabled)
- SM shall give indication to user about its correct operation and the function in progress:
 - SM health is ok (HW and code)
 - Patient should stay close to SM
 - Communication to IMD or BO is in progress
 - Error in IMD or BO communication

SM Operating modes

The SmartView Monitor is installed at patient Home in the context of RMS. The GPRS modem is connected to Back Office through the mobile cellular telephone net.

The SmartView Monitor communicates with the implanted device on two wireless RF bands:

- ISM band (2.45- GHz) for communication initialization (implant wake-up)
- MEDRADIO (402-405 MHz) band for data transfer

IMD Operating modes

The IMD communicates with the SmartView Monitor on two wireless RF bands:

- ISM band (2.45 GHz) for communication initialization (implant wake-up)
- MEDRADIO (402-405 MHz) band for data transfer

IMD Hardware

RF bi-band communication is done using the same ultra low consumption transceiver module connected through a stripe line and a hermetic bipolar feed-thru to a unique RF antenna loop embedded to the external connector of the device. The transceiver is driven by the CPU of the device upon dedicated interrupt request raised by the RF module.



4. TEST PROGRAM

Transmitter & Receiver requirement FCC 15.247 in 2400 – 2483.5 MHz band

Test Description	FCC 15.247	RSS 210	Test requirements	Test results Remarks
Power line conducted emissions	15.207 (a)	RSS-GEN §7.2.2	FCC 15.207 (a) IC: RSS-GEN Table 2	Pass
Channel separation	15.247 (a)(1)	A.8.1 b)	Greater than 2/3 of 20dB bandwidth	Pass
Time of Occupancy	15.247 (a)(1)(ii)	A.8.1 c)	< 0.4s in 6s	Pass
20dB Occupied bandwidth	15.247 (a)(1)	A.8.1 a)	500kHz	Pass
Peak Power Output	15.247 (b)	A.8.4 (2)	1 Watt (30dBm)	Pass
Radiated emissions	15.247 (c)	A.8.5	FCC 15.209 (a) IC: RSS-210 §2.6	Pass

Pass: EUT complies with standard's requirement
 Fail: EUT does not comply with standard's requirement
 N/A: Not Applicable

5. PEAK POWER OUTPUT

5.1. TEST CONDITIONS

Test performed by : Stéphane PHOUDIAH
Date of test : 2011/05/06
Ambient temperature : 21°C
Relative humidity : 37%

5.2. TEST SETUP

Method of measurement

FCC 15.247 (b)

Qualification measurements in the 3 meters full anechoic chamber

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. Continuous linear turntable azimuth search was performed with 360 degrees range. The substitution antenna replaces the equipment under test for Effective Radiated Power (ERP) measurement. Power is measured for the same level of radiated field strength obtained on the measuring antenna.

The EUT was emitting with normal modulation, on lowest, middle and highest channel.

The equivalent isotropic radiated power (eirp in dBm) is defined with the following formula:

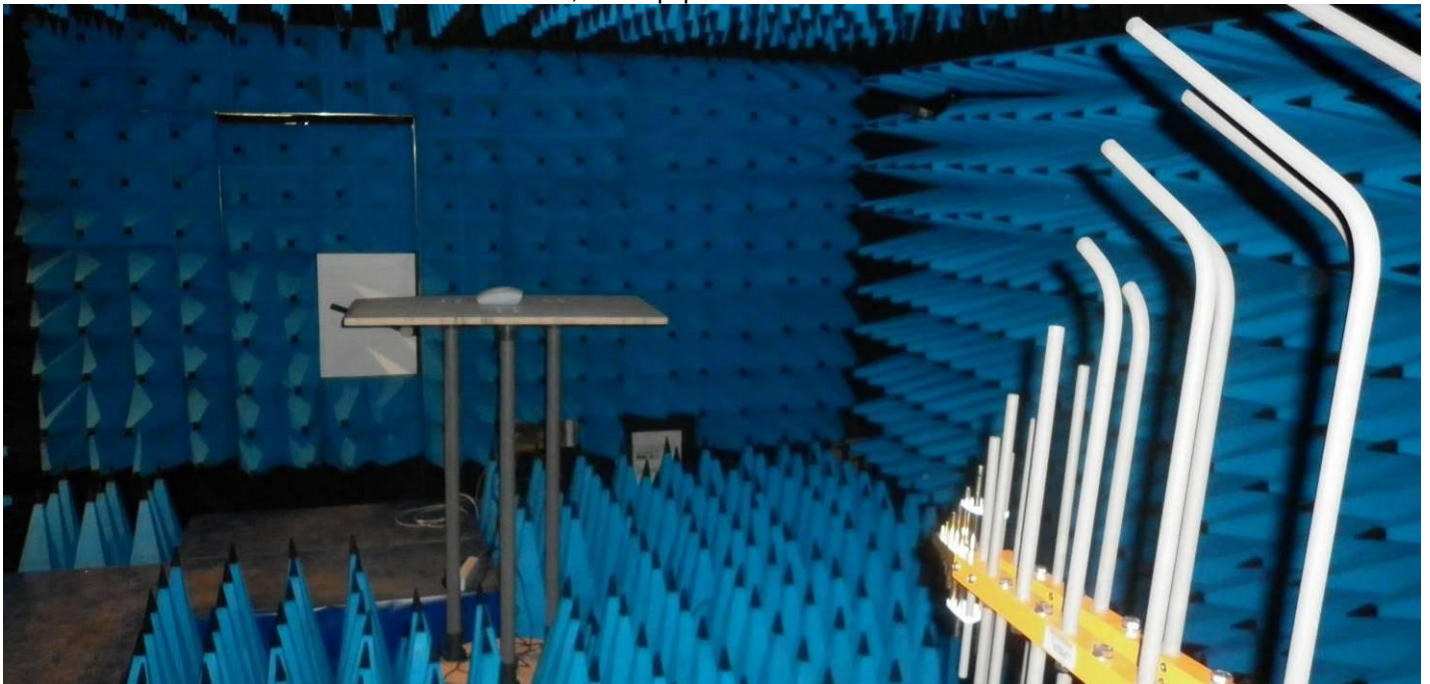
$EIRP = A + G + 10 \text{ Log } (1/x)$ with A (dBm): mean power at the output of the transmitter
G (dBi): product antenna gain
x: duty cycle = $(T_{on})/(T_{on}+T_{off})$

Measurement of the mean power at the output of the transmitter

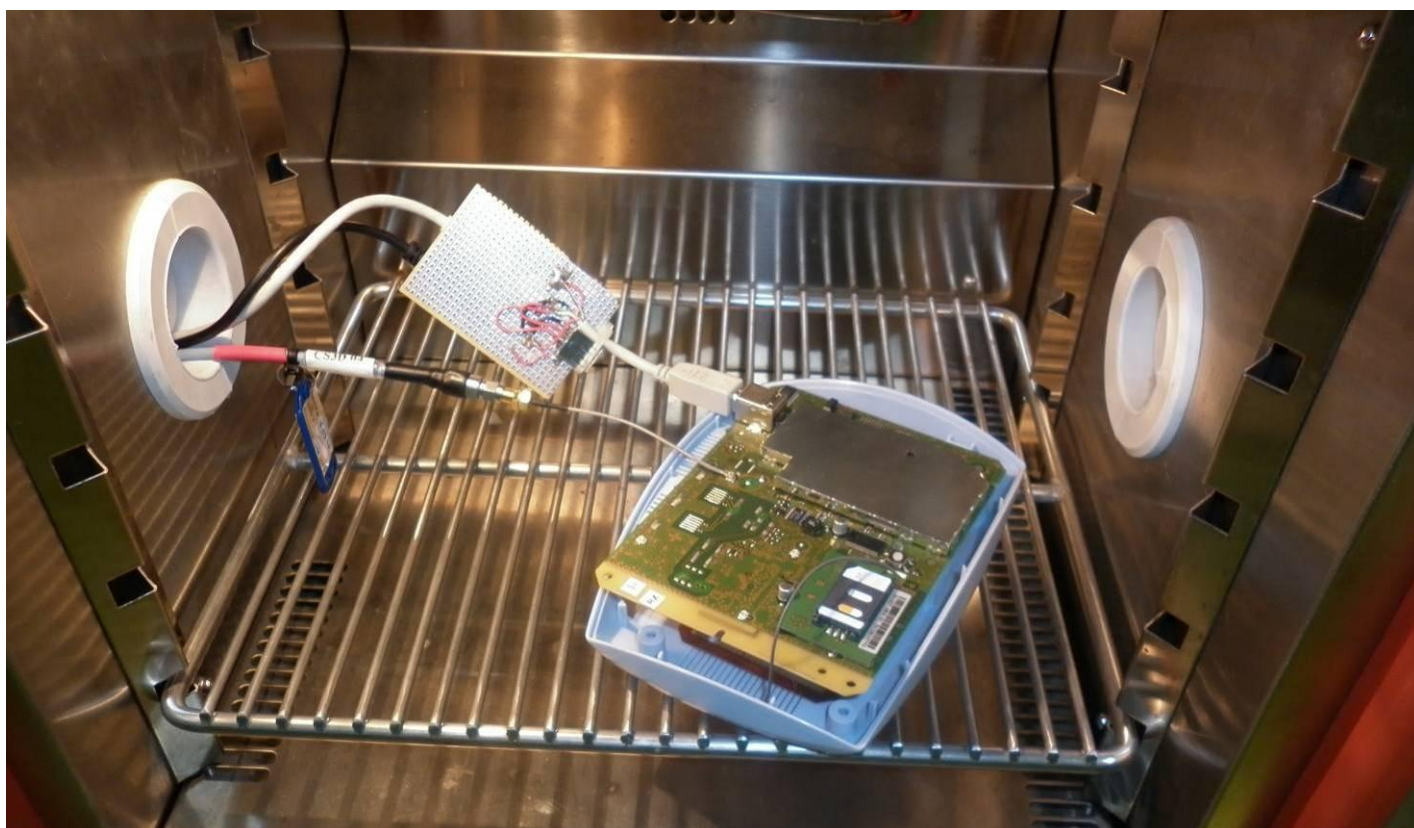
Determination of antenna gain: as declared by the applicant

Measurement of the duty cycle: span 0 with spectrum analyzer

For measurement under extreme test conditions, the Equipment Under Test is installed in the climatic chamber.







5.3. TEST SEQUENCE AND RESULTS

Maximum test result with monopole and IFA antenna:

Temperature	0°C			21°C			+55°C		
Power voltage: 207Vdc	FLow	FMiddle	FHigh	FLow	FMiddle	FHigh	FLow	FMiddle	FHigh
EIRP (dBm)	17,4	17,7	17,3	17,9	17,2	16,7	17,2	17,6	16,7
Power voltage: 230Vdc	FLow	FMiddle	FHigh	FLow	FMiddle	FHigh	FLow	FMiddle	FHigh
EIRP (dBm)	17,2	17,3	17,1	17,6	17,1	16,8	17,5	17,3	17
Power voltage: 253Vdc	FLow	FMiddle	FHigh	FLow	FMiddle	FHigh	FLow	FMiddle	FHigh
EIRP (dBm)	17,5	17,5	17	17,8	17,4	16,5	17,5	17,2	16,9

Maximum peak power output observed is **17,9 dBm** when the temperature is varied from 0°C to +55°C and when the power voltage is varied from 207 Vac to 253 Vac.

Limit: → 30dBm / 1W

Result: PASS

5.4. CONCLUSION

Maximum peak power output test performed on the sample of the product "SMARTVIEW MONITOR KA961", in configuration and description presented in this test report, show levels below the FCC limits.

6. BAND EDGE COMPLIANCE

6.1. TEST CONDITIONS

Test performed by : Stéphane PHOUDIAH
Date of test : 2011/05/10 and 2011/05/11
Ambient temperature : 21°C
Relative humidity : 37%

6.2. TEST SETUP

Method of measurement

FCC 15.247 (c)

The EUT was emitting with normal modulation, on lowest and highest channel.
The Equipment Under Test is installed on a table. A test fixture has been used. Band edge is measured with a spectrum analyzer on the EUT RF conducted access.



**6.3. TEST SEQUENCE AND RESULTS**

The transmitter range of modulation bandwidth is measured at 20dB below the peak power.

Maximum test result with monopole and IFA antenna:

Temperature	+21°C	
Power voltage: 230Vdc	FLow	FHigh
Frequency (MHz)	2419,7	2460,3

See graphic N°1 in annex 2

Maximum Frequency range observed is **2419,7MHz to 2460,3MHz**

Limit:

→ Transmitter range of operating frequencies shall be inside the allocated frequency band 2400 – 2483.5MHz.

F_L shall be > 2.4000GHz

F_H shall be < 2.4835GHz

Result: PASS

6.4. CONCLUSION

Band edge test performed on the sample of the product “SMARTVIEW MONITOR KA961”, in configuration and description presented in this test report, show levels below the FCC limits.

**7. RADIATED EMISSIONS****7.1. TEST CONDITIONS**

Test performed by : Stéphane PHOUDIAH
Date of test : 2011/06/14
Ambient temperature : 20°C
Relative humidity : 40%

7.2. TEST SETUP

The tested equipment is set to transmit operation on low, middle and high channel.

Method of measurement

FCC 15.247 (b)

Characterization in semi-anechoic chamber (30MHz to 25 GHz):

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 100 kHz.

Continuous linear turntable azimuth search was performed with 360 degrees range.

7.3. TEST SEQUENCE AND RESULTS**Characterization in semi anechoic chamber (30MHz to 25GHz):**

Frequency (MHz)	Measure (dBµV/m)	Limit (dBµV/m)
30	28,9	40
34	27,2	40
42,7	29,2	40
43,6	27	40
57,8	27,6	40
91	31,5	43,5
98,5	30,9	43,5
233,8	29,9	46
251	28,7	46
2284	46,7	53,9
2362	49,5	53,9
2596	44,5	53,9
2383	49,2	53,9
2303	40,8	53,9
2536,5	41,1	53,9
4306	39,4	53,9
5537,5	42,1	53,9

See Graphics N°2 to N°4 in annex 2

Result: PASS

7.4. CONCLUSION

Radiated emissions test performed on the sample of the "SMARTVIEW MONITOR KA961" in configuration and description presented in this test report, show levels below the FCC limits.

8. 20 dB OCCUPIED BANDWIDTH

Test performed by : Stéphane PHOUDIAH
Date of test : 2011/05/10
Ambient temperature : 21°C
Relative humidity : 37%

METHOD OF MEASUREMENT

FCC 15.247 (a)(1)

TEST SETUP

The test is performed on EUT in permanent emission with modulation and hopping.
Channel Separation is measured with a spectrum analyzer on the EUT RF conducted access.



MEASUREMENT DATA

Measured 20dB occupied bandwidth: **2.136MHz**

See Graphics N°6 in annex 2

Limit:

The minimum limit of channel separation is **500kHz**

Result: PASS

CONCLUSION

20dB occupied bandwidth test performed on the sample of the "SMARTVIEW MONITOR KA961" in configuration and description presented in this test report, show levels below the FCC limits.

9. CHANNEL SEPARATION

9.1. TEST CONDITIONS

Test performed by : Stéphane PHOUDIAH
Date of test : 2011/05/10 and 2011/05/11
Ambient temperature : 21°C
Relative humidity : 37%

9.2. SET-UP

Method of measurement

FCC 15.247 (a)(1)

Qualification measurements on a table

The test is performed on EUT in permanent emission with modulation and hopping.
Channel Separation is measured with a spectrum analyzer on the EUT RF conducted access.



9.3. RESULT

Measured $2/3 \times (20\text{dB occupied bandwidth})$: **1,424MHz**

Measured channel separation: **2,675 MHz**

See Graphics N°5 and N°6 in annex 2

Limit:

The minimum limit of channel separation is **25kHz or 1,424MHz**

Result: PASS

9.4. CONCLUSION

Channel separation test performed on the sample of the "SMARTVIEW MONITOR KA961" in configuration and description presented in this test report, show levels below the FCC limits.

10. MINIMUM HOPPING CHANNEL

10.1. TEST CONDITIONS

Test performed by : Stéphane PHOUDIAH
Date of test : 2011/05/10 and 2011/05/11
Ambient temperature : 21°C
Relative humidity : 37%

10.2. SET-UP

Method of measurement

FCC 15.247 (a)(1)(iii)

Qualification measurements on a table

The test is performed on EUT in permanent emission with modulation and hopping.
Minimum Hopping channel is measured with a spectrum analyzer on the EUT RF conducted access.



10.3. RESULT

Measured channel number: 15

See Graphic N°7 in annex 2

Limit:

The minimum limit of channel number is 15

Result: PASS

10.4. CONCLUSION

Minimum hopping channel test performed on the sample of the "SMARTVIEW MONITOR KA961" in configuration and description presented in this test report, show levels below the FCC limits.

11. HOPPING SEQUENCE

11.1. TEST CONDITIONS

Test performed by : Stéphane PHOUDIAH
Date of test : 2011/05/10 and 2011/05/11
Ambient temperature : 21°C
Relative humidity : 37%

11.2. SET-UP

Method of measurement

FCC 15.247 (a)(1)(iii)

Qualification measurements on a table

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

Minimum Hopping channel is measured with a spectrum analyzer on the EUT RF conducted access.



11.3. RESULT

Measured dwell time: $0,182s \times 2 = 0,364s$. The system has successively 2 emissions, (IFA antenna and monopole antenna).

Measured period: **5,65s**

See Graphics N°8 and N°9 in annex 2

Limit:

The maximum limit of dwell time is **0,4s**

The maximum period **6s**

Result: PASS

11.4. CONCLUSION

Hopping sequence test performed on the sample of the "SMARTVIEW MONITOR KA961" in configuration and description presented in this test report, show levels below the FCC limits.

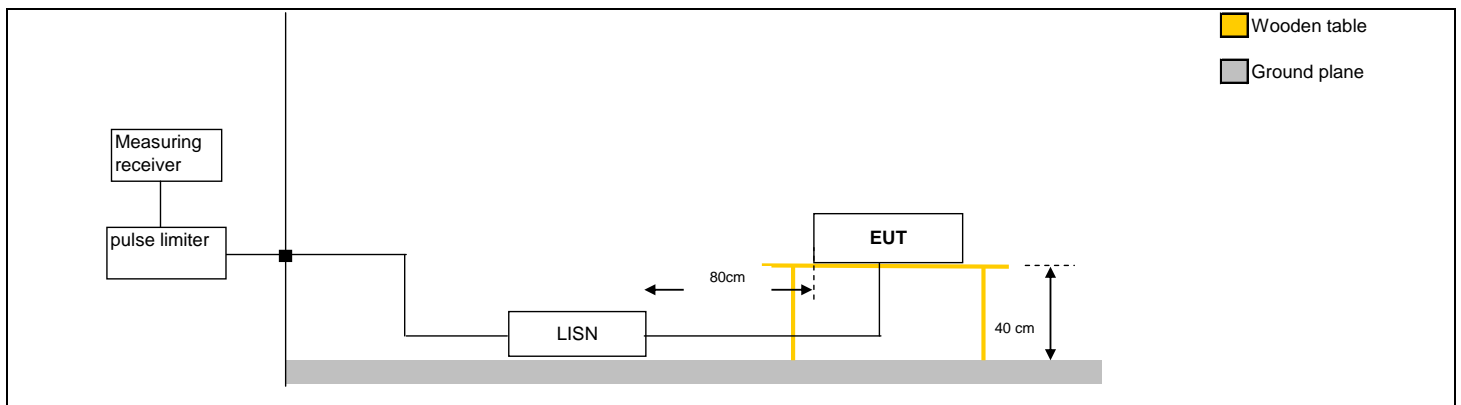
12. MEASUREMENT OF CONDUCTED DISTURBANCE: POWER SUPPLY

Specifications	
Test method according FCC Part 15 (2009)	FCC Part 15.207
Frequency	0.15 – 30 MHz
Limit	See summary table Power supply : Class B
Detector	Peak , Quasi Peak and average RBW 9 kHz

Operating conditions	
Comments	The measurement is performed on power supply with a LISN and telecommunication lines with RSI or current clamp for shielded cables.
Equipment list	See at the end of the paragraph
Deviation method	No
Product installation	The EUT is installed on a wooden table 80 cm above the reference plane, 40 cm from vertical plane, at 80cm of the LISN.
Operating mode	Nominal

Conclusion
The product is compliant with the standard

Measure on main power supply			
Line	Operating mode	Graphics	Comments
Phase	Nominal	N°10	Pass
Neutral	Nominal	N°11	Pass



Test set up of conducted emission on power supply



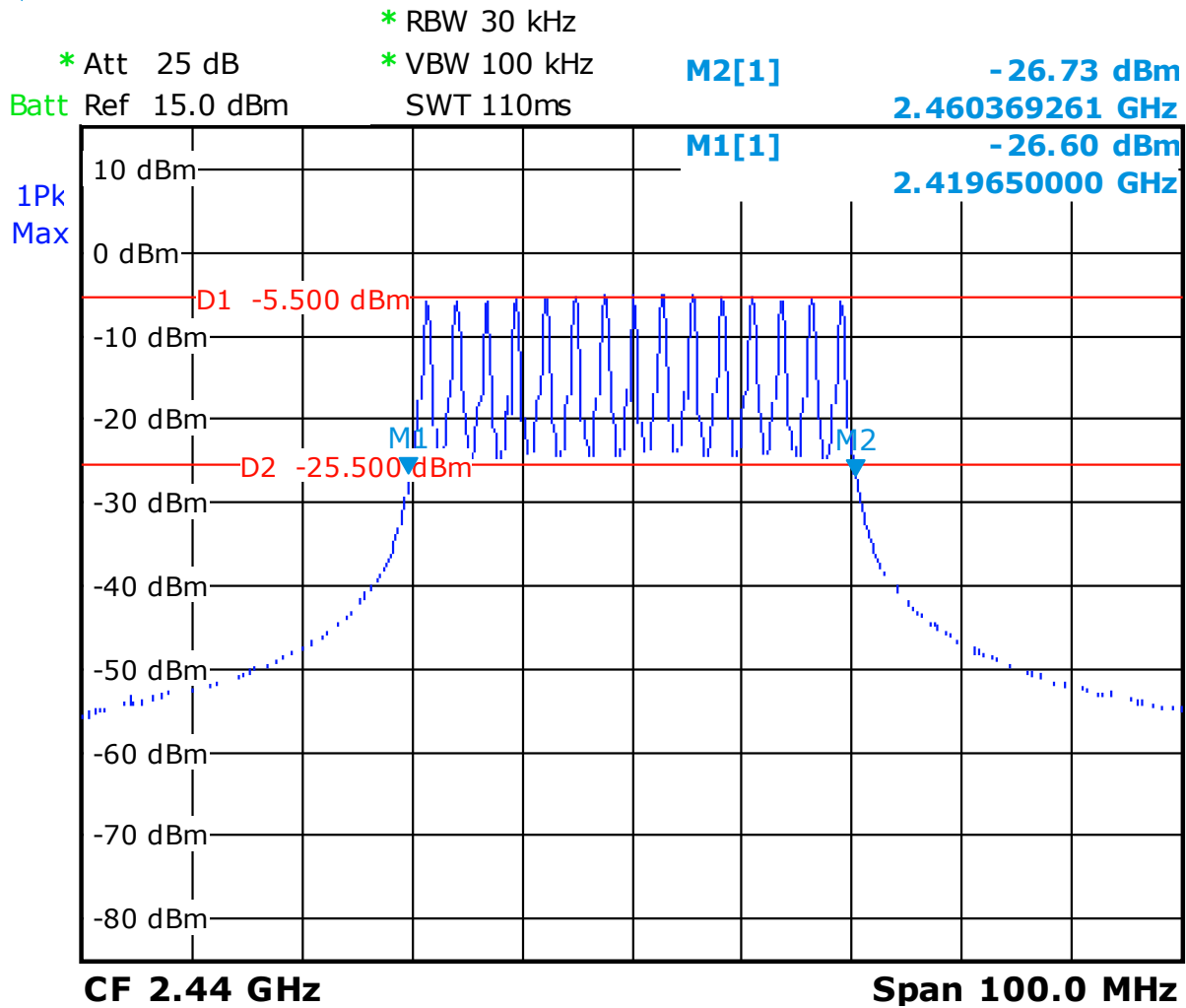
13. ANNEX 1: UNCERTAINTIES CHART

Maximum measurement uncertainties

<i>Kind of test</i>	<i>Wide uncertainty laboratory (k=2) ±x(dB) / (Hz)</i>	<i>uncertainty limit ±y(dB)</i>
TRANSMITTER REQUIREMENTS		
<i>Frequency error</i>	±2.10 ⁻⁸ Hz	±1.10 ⁻⁷ Hz
<i>Effective radiated Power</i> <ul style="list-style-type: none"> • <i>Frequency < 1000 MHz</i> • <i>Frequency > 1000 MHz</i> 	±5.72 dB ±5.69 dB	±6 dB
<i>Range of modulation bandwidth for wide band equipment</i>		
<i>Unwanted Emission</i> <ul style="list-style-type: none"> • <i>Frequency < 1000 MHz</i> • <i>Frequency > 1000 MHz</i> 	±5.72 dB ±5.46 dB	±6 dB

14. ANNEX 2 (GRAPHICS)

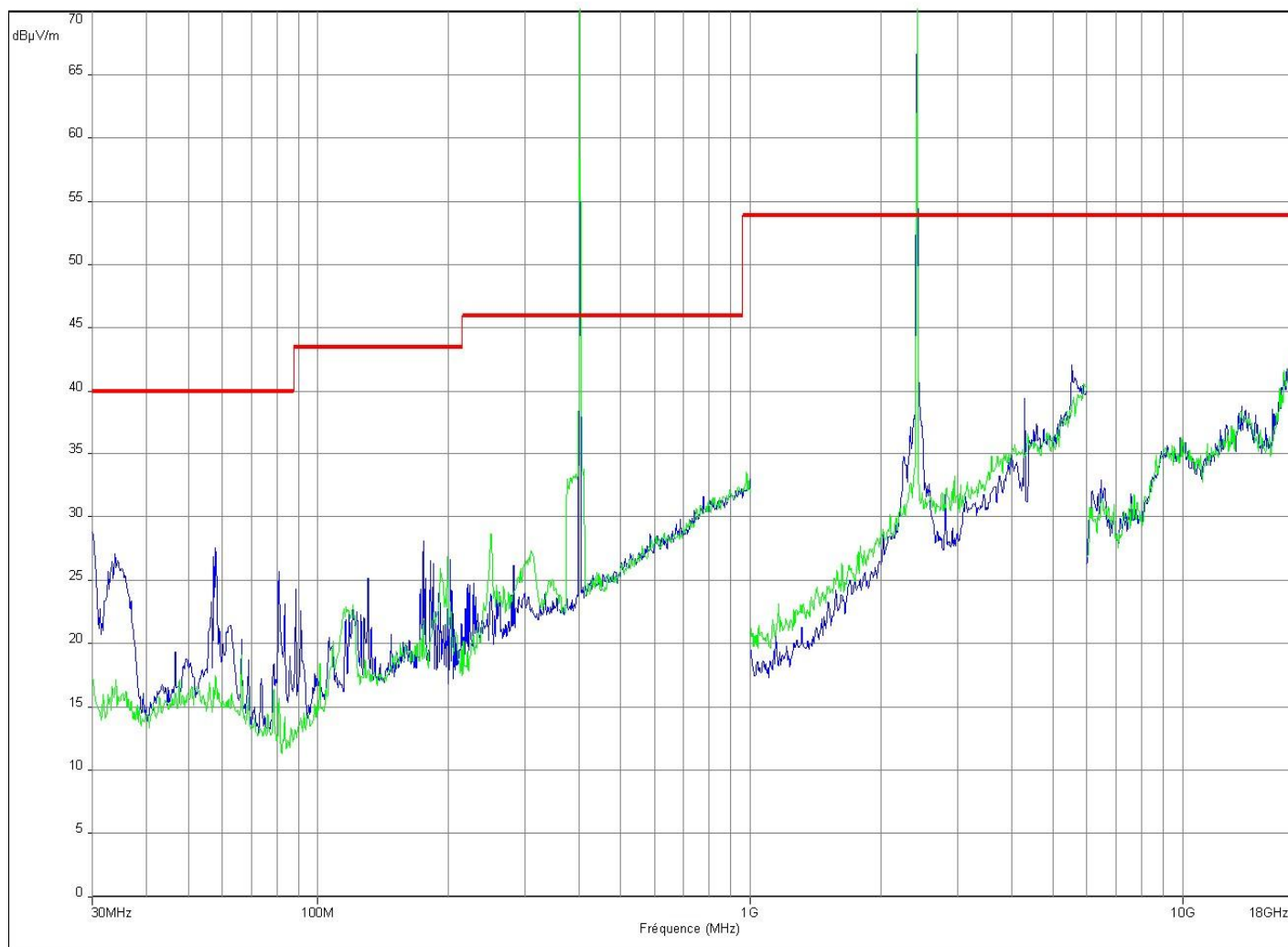
Graphic N°1
 Band Edge
 230Vdc
 21°C



Date: 10.MAY.2011 15:21:46

Graphic N°2
Radiated Emission
Vertical Polarization
230Vdc
21°C

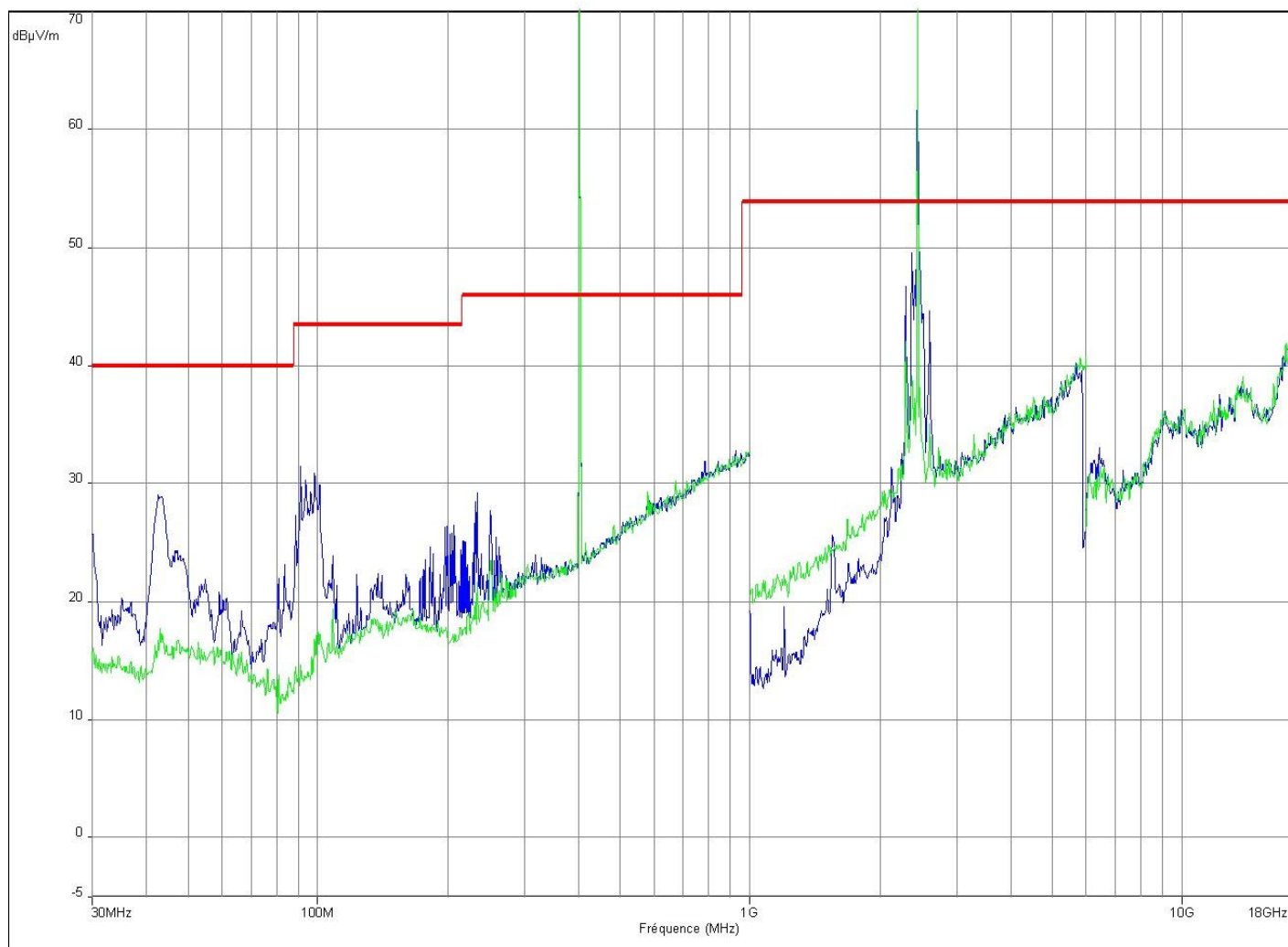
— FCC 15.209 >30M - Classe:1 - QCrête/3.0m/
— Channel Low (Horizontal)
— Channel Low (Vertical)





Graphic N°3
Radiated Emission
Horizontal Polarization
230Vdc
21°C

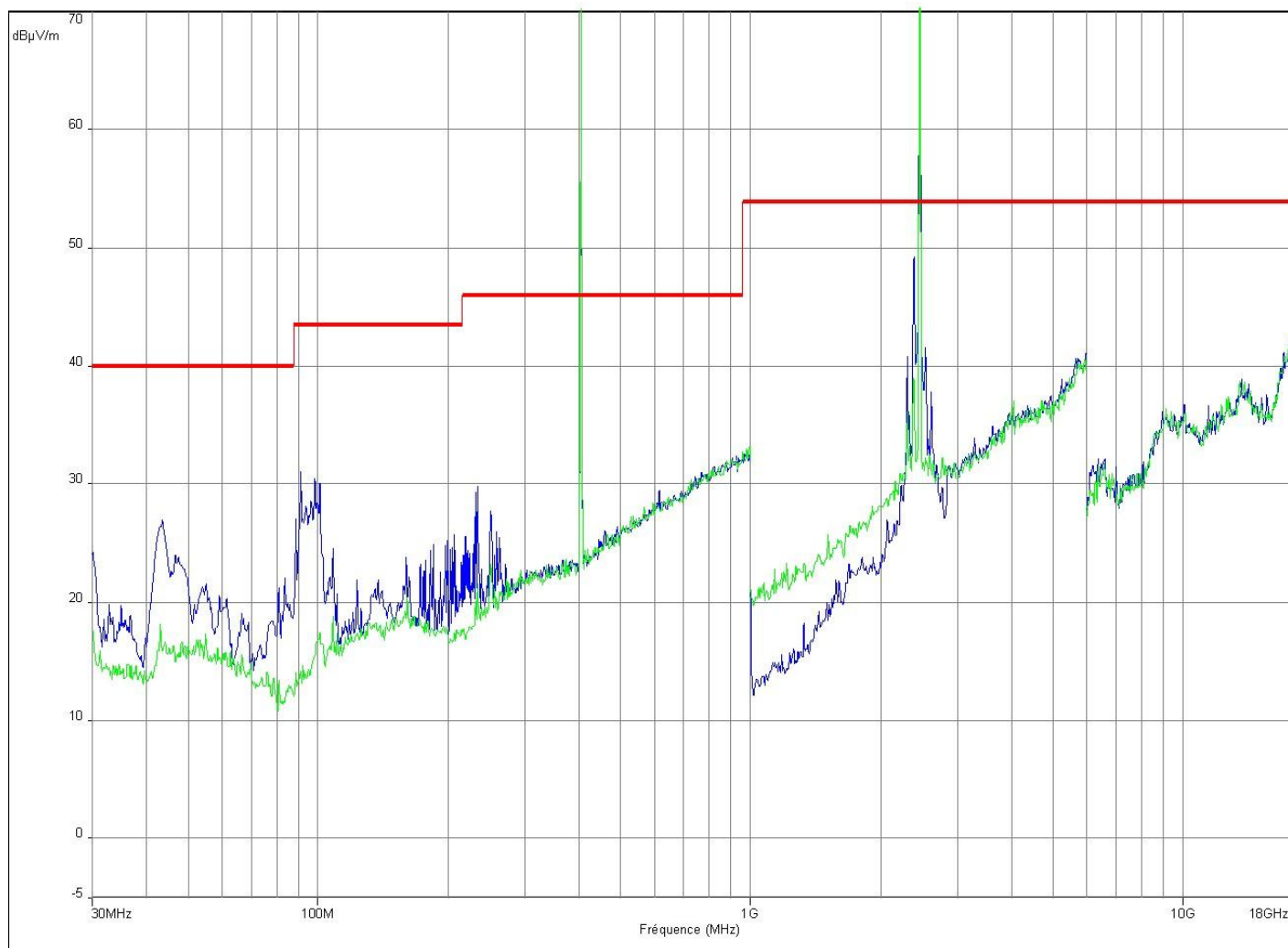
— FCC 15.209 >30M - Classe:1 - QCrête/3.0m/
— Channel Middle (Horizontal)
— Channel Middle (Vertical)





Graphic N°4
Radiated Emission
Horizontal Polarization
230Vdc
21°C

— FCC 15.209 >30M - Classe:1 - QCrête/3.0m/
— Channel High (Horizontal)
— Channel High (Vertical)

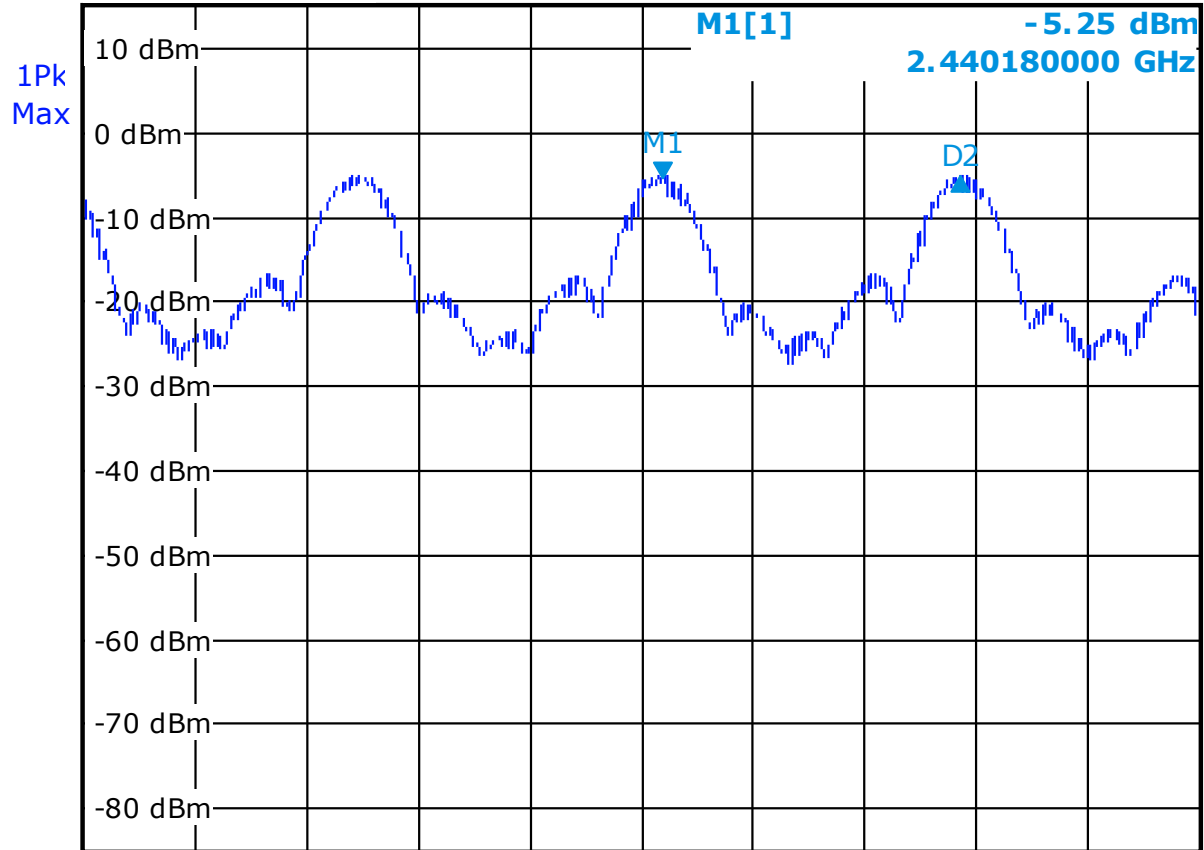




Graphic N°5
Channel Separation
230Vdc
21°C



* Att 25 dB * RBW 30 kHz **D2[1]** **0.27 dB**
Batt Ref 15.0 dBm * VBW 100 kHz **2.67500000 MHz**

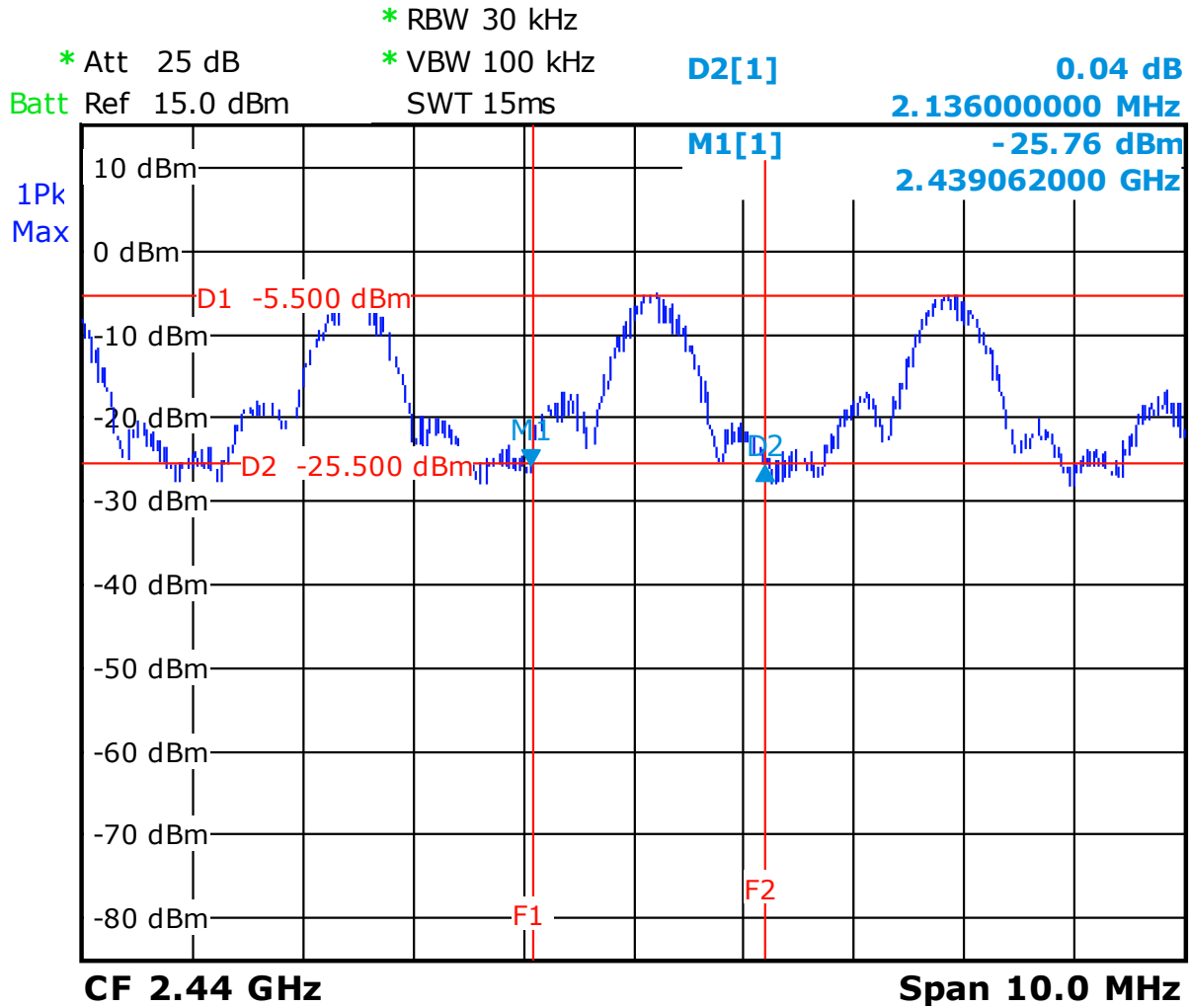


CF 2.44 GHz

Span 10.0 MHz



Graphic N°6
20dB Occupied Bandwidth
230Vdc
21°C

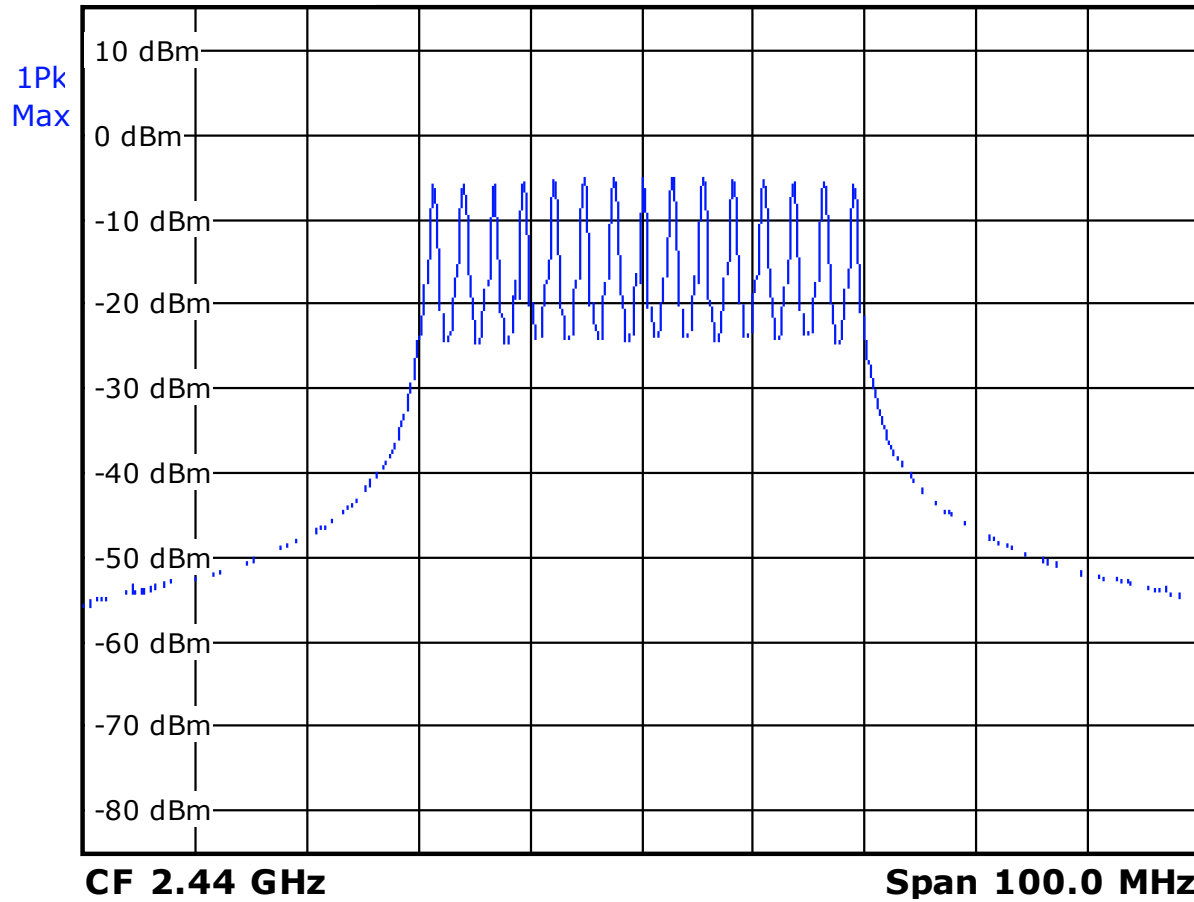




Graphic N°7
Minimum Hopping Channel
230Vdc
21°C

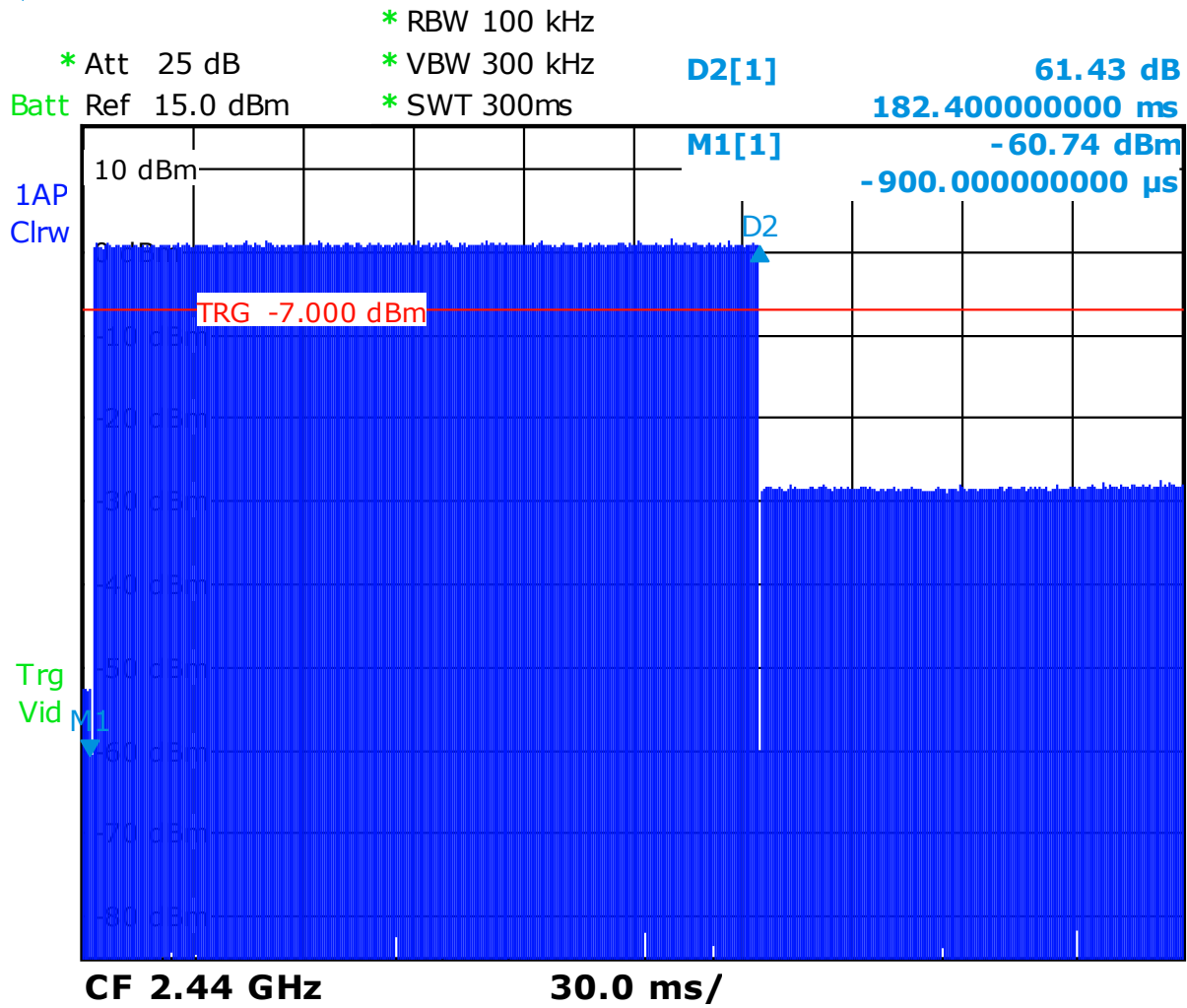


* Att 25 dB
* RBW 30 kHz
* VBW 100 kHz
Batt Ref 15.0 dBm
SWT 110ms

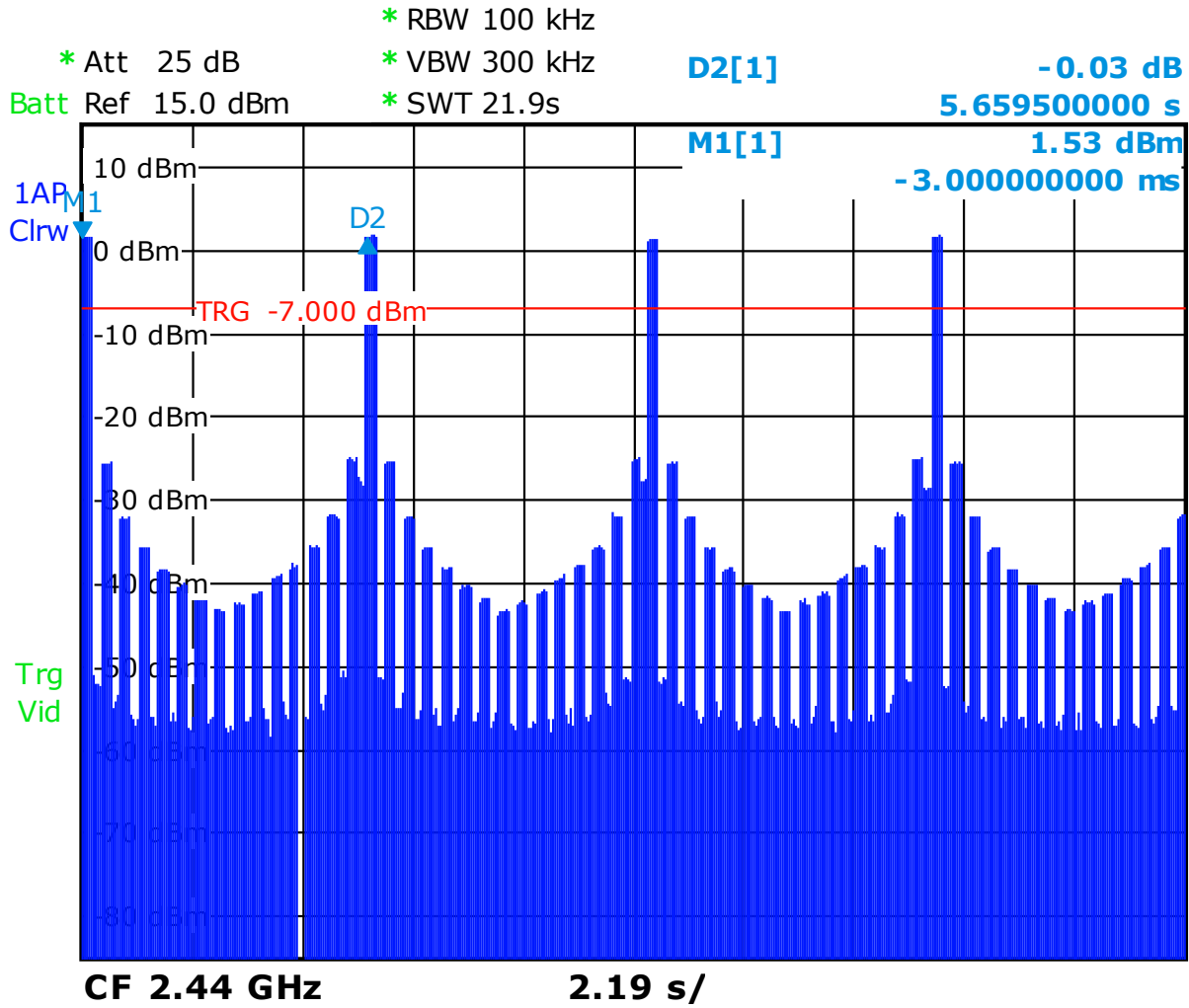




Graphic N°8
Dwell Time
230Vdc
21°C



Graphic N°9
 Number of burst for Time of Occupancy
 230Vdc
 21°C



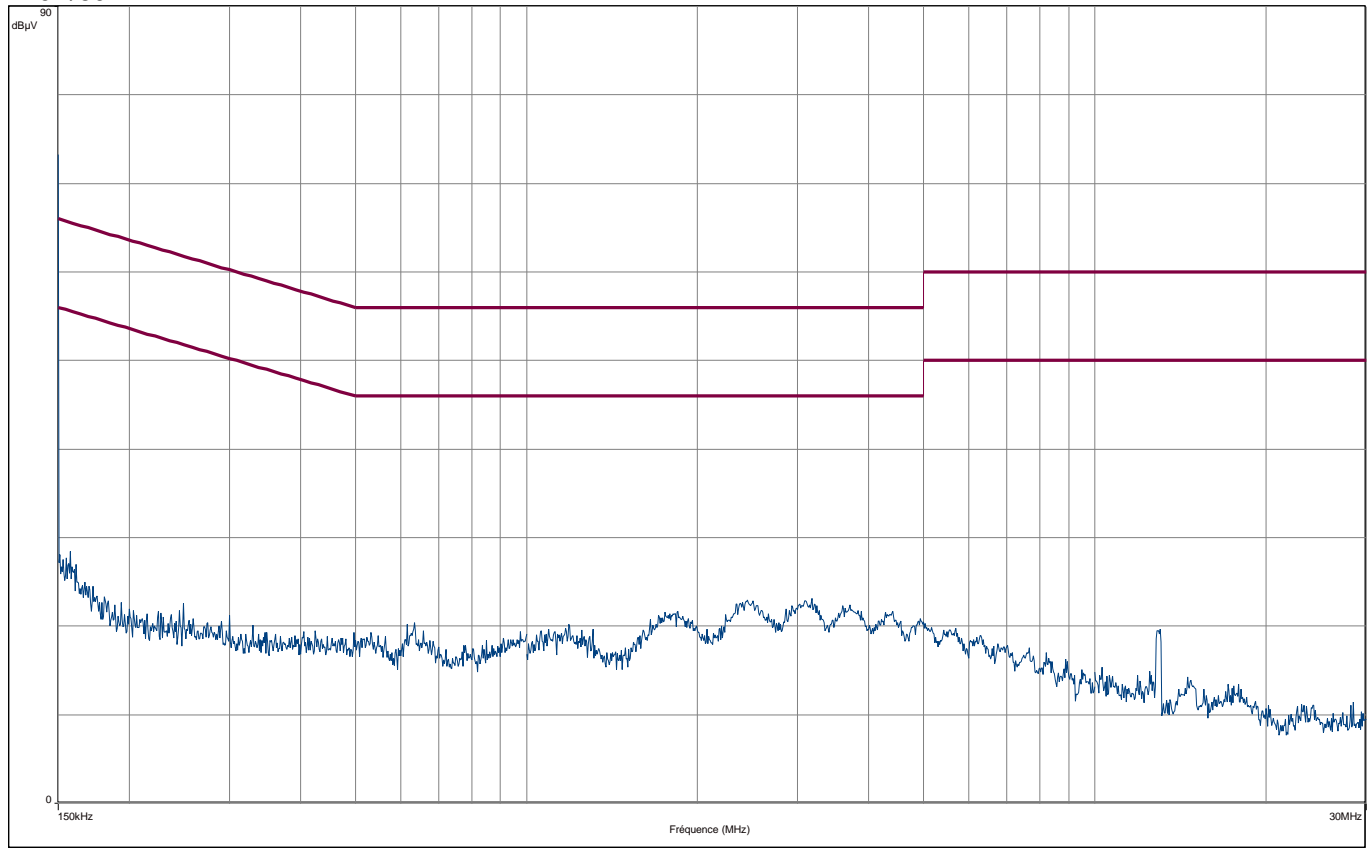


L C I E

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Graphic N°10
Conducted emission
Phase line
110V/60Hz



FCC PART 15 class B

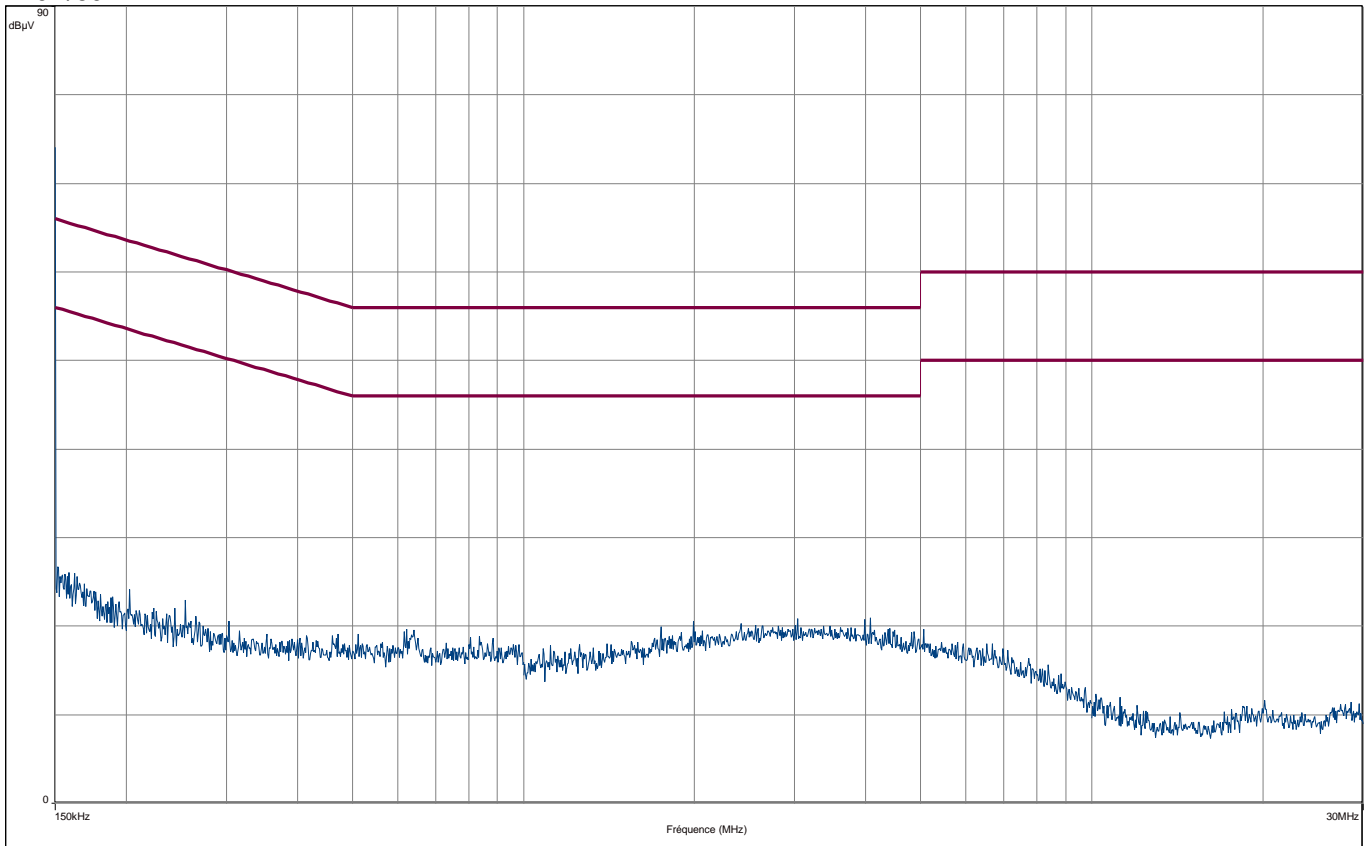


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Graphic N°11
Conducted emission
Neutral line
110V/60Hz



FCC PART 15 class B



15. ANNEX 3 (TEST EQUIPMENT LIST)

Test	Apparatus	Trade Mark	Type	Registration number
X	Full anechoic chamber	SIEPEL	S36	D3044019
X	Bilog Antenna	CHASE	CBL 6111C	C2040124
X	Double Ridge Guide Horn Antenna	AH SYSTEMS	SAS-S71	C2042041
X	Logperiodic antenna	AMPLIFIER RESEARCH	ATR80M6G	C2040149
X	Preamplifier	BONN Elektronik	BLNA 3018-8F30S	A7080053
X	Climatic Chamber	SECASI Technologies	SLT-34	D1024029
X	Horn antenna	EMCO	.3115	C2042016
X	Bilog antenna	CHASE	CBL 6112A	C2040040
X	Semi anechoic chamber	SIEPEL	C01	D3044008
X	Signal Generator	HP	8657B	A5442019
X	Power meter	GIGATRONICS	8542C	A1503009
X	Probe	GIGATRONICS	80401A	A1509027
X	Filter	BL microwave	B2440-120/H-4C1ASJ	A7120006
X	Spectrum analyzer	FSL6	R & S	A4060032
X	EMI Test Receiver	ROHDE & SCHWARZ	ESMI	A2642009
X	Power supply	1501L	CALIFORNIA INSTRUMENT	A7042261

End of this test report