Accreditation
N° 1-0312
Scope
available on
www.cofrac.fr

TEST REPORT

RADIO

Number N° 106440-611204-G-Cr-2012-01-10
Composition of document 27 pages

Standards

FCC Part 15 (2009)
FCC Part 22
FCC Part 24
FCC Part 2 (2005)

Issued to

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

Mme de JESO

Apparatus under test	SMARTVIEW MONITOR
Trade mark	SORIN GROUP
Manufacturer	SELCO EOLANE COMBREE
Type	SMARTVIEW MONITOR KA 961 (US version with GPRS)
Serial number	HB1107001S
FCC ID	YSGKA961
Test date	August 29th and 30th , 2011
Tests performed by	Stéphane PHOUDIAH
Test site	LCIE Fontenay aux Roses (92)
Initial date of issue	August 31th, 2011
Date of correction	January 10th , 2012
Date of issue	January 10th , 2012

Approved by :
Philippe SISSOKO
Technical manager

LABORATOIRE CENTRAL DES INDUSTRIES ELECTRIQUES
S.A.S au capital de 15.745.984 €
RCS Nanterre B 408 363 174
33 avenue du Général Leclerc
F - 92266 FONTENAY AUX ROSES

SUMMARY

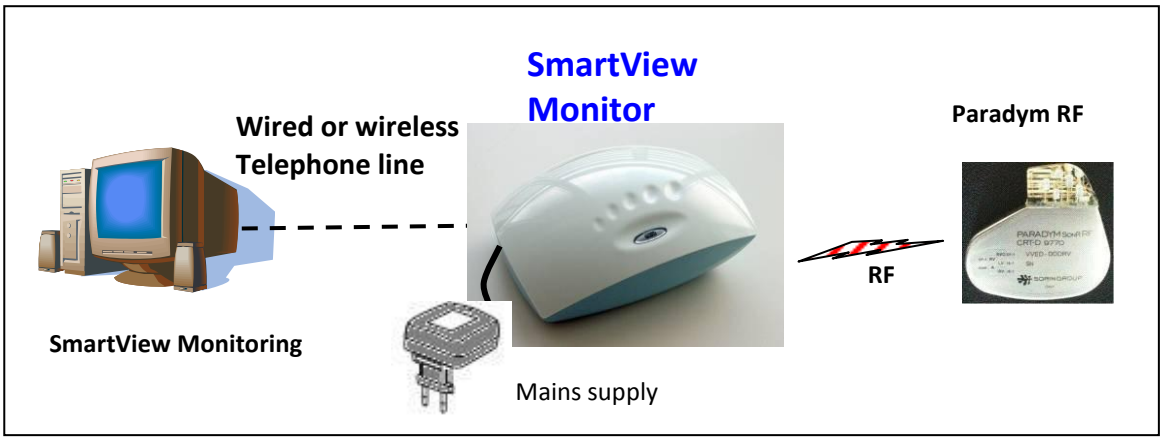
1. REFERENCE DOCUMENTS 3
2. EQUIPMENT UNDER TEST DESCRIPTION 4
3. SMARTVIEW MONITOR FUNCTIONAL DESCRIPTION ET OPERATING MODES 8
4. TEST PROGRAM 9
5. RF OUTPUT POWER 10
6. RADIATED EMISSIONS & RADIATED SPURIOUS EMISSION 12
7. MEASUREMENT OF CONDUCTED DISTURBANCE: POWER SUPPLY 15
8. ANNEX 1: UNCERTAINTIES CHART 16
9. ANNEX 2 (GRAPHICS) 17
10. ANNEX 3 (TEST EQUIPMENT LIST) 27

1. REFERENCE DOCUMENTS

- **47 CFR Part 15:** Code of federal regulations – Telecommunication –Radiofrequency devices
- **Radio performance tests procedures given in part 15:**
    - Paragraph 207: conducted limits
    - Paragraph 209: radiated emission limits; general requirements
- **47 CFR Part 22:** Code of federal regulations – Telecommunication –Public mobile services
- **47 CFR Part 24:** Code of federal regulations – Telecommunication –Personal communications services
- **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.
- **47 CFR Part 2:** Frequency allocations and radio treaty matters; General rules ans regulations

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).

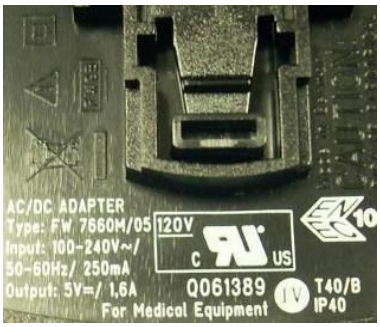


Applicant	**SORIN CRM** Parc d'affaires NOVEOS 4, Avenue Réaumur 92140 CLAMART Cedex
Manufacturer	**SELCO EOLANE COMBREE** Le Val d'Ombrée 49520 Combrée France
Dimensions	
Frequencies band	402-405 MHz 2400-2483,5 MHz GSM-GPRS: Allow connection of the RM to mobile telephony. SIMCOM SIM340E quad-band module previously validated according R&TTE Directive 1999/05/EC and integrated without modification
Number of channel	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)

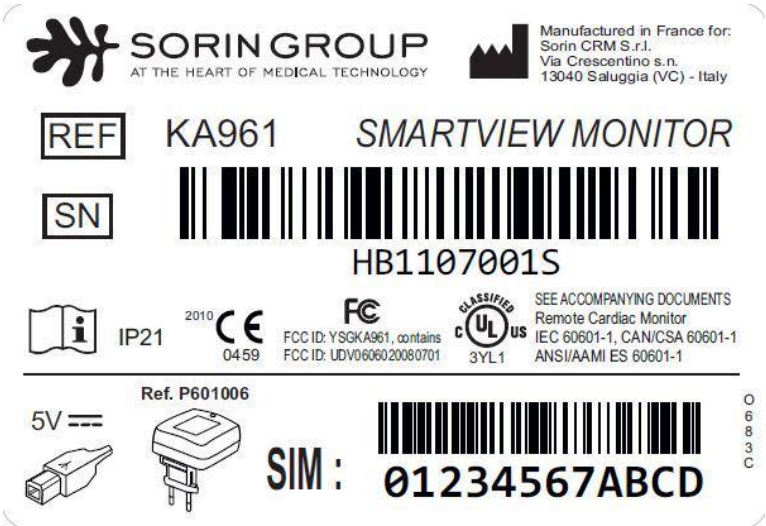
Equipment photograph

Marking plate

Marking on Power Supply



Marking on SMARTVIEW MONITOR



Block part	Description
User interface	- 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	- 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. - 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)	- 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

Test Description	FCC	Test results Remarks
Power line conducted emissions	15.207 (a)	Pass
Radiated emissions	15.247 (c)	Pass
RF output power	22.913 & 24.232	Pass
Occupied bandwidth	2.1049 & 24.238 (b)	N/P (GSM / GPRS SIMCOM SIM340E quad-band module is already certified by FCC))
Spurious emissions at antenna terminal	22.917 & 24.238	N/P (GSM / GPRS SIMCOM SIM340E quad-band module is already certified by FCC)
Emissions at band edges	22.917 & 24.238	N/P (GSM / GPRS SIMCOM SIM340E quad-band module is already certified by FCC)
Radiated spurious emissions	22.917 & 24.238	Pass
Frequency stability	22.355 & 24.235	N/P (GSM / GPRS SIMCOM SIM340E quad-band module is already certified by FCC)

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

5. RF OUTPUT POWER

5.1. TEST CONDITIONS

Test performed by : Stéphane PHOUDIAH
Date of test : 2011/08/29
Ambient temperature : 26°C
Relative humidity : 32%

5.2. TEST SETUP

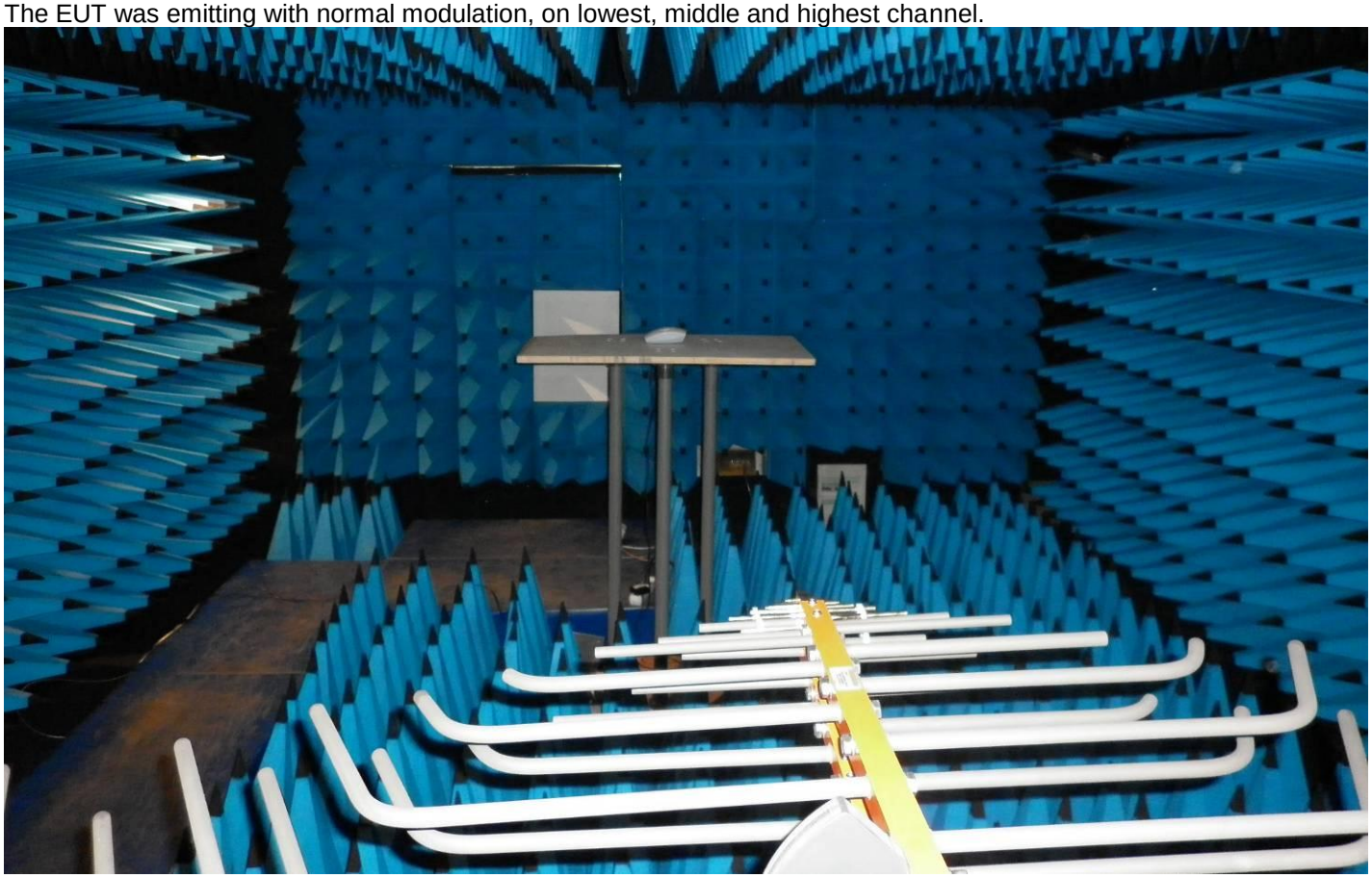
Method of measurement

☒ FCC 22.913 & 24.232

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 Isotropic Radiated Power (EIRP) 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.



5.3. TEST SEQUENCE AND RESULTS

Maximum test result:

Temperature	**21°C**		
GSM850	C128	C190	C251
EIRP (dBm)	19.6	22.4	24.7

Maximum peak power output observed is **24.7dBm**.

Limit: → 38,45dBm / 7W

Temperature	**21°C**		
PCS1900	C512	C661	C810
EIRP (dBm)	27.4	27.8	21.8

Maximum peak power output observed is **27.8dBm**.

Limit: → 33dBm / 2W

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. RADIATED EMISSIONS & RADIATED SPURIOUS EMISSION

6.1. TEST CONDITIONS

Test performed by : Stéphane PHOUDIAH
Date of test : 2011/08/29 and 2011/08/30
Ambient temperature : 25°C
Relative humidity : 40%

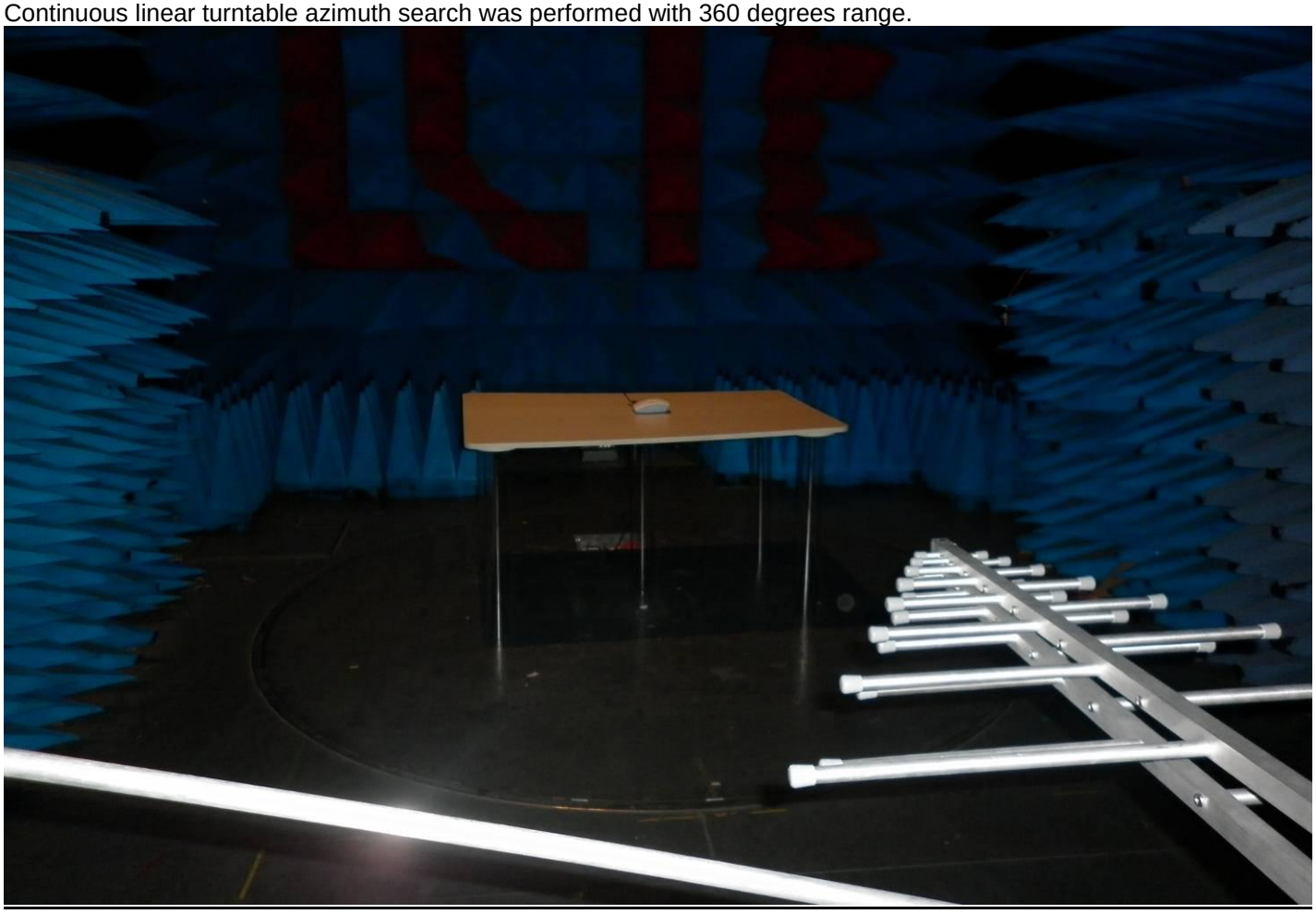
6.2. TEST SETUP

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

Method of measurement

☒ FCC 15.247 (b)
☒ FCC 22.917 & 24.238

Characterization in semi-anechoic chamber (30MHz to 25 GHz):
The setup is 0,8m 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.



6.3. TEST SEQUENCE AND RESULTS

Characterization in semi anechoic chamber (30MHz to 9GHz):

GSM850 C128-C190-C251

Frequency (MHz)	Measure (dBµV/m)	Limit (dBµV/m)	Radiated Spurious Emission Limit(dBµV/m)*
30	27,5	40	84,4
42,9	28,6	40	84,4
87,8	24,6	40	84,4
88,6	27,6	43,5	84,4
96	34,7	43,5	84,4
108,2	25,2	43,5	84,4
204,2	25,6	43,5	84,4
233,7	23,2	46	84,4
805,9	34,6	46	84,4
893,8	33,6	46	84,4
1648	50.8	53,5	84,4
1673	51.6	53,5	84,4
1698	49.4	53,5	84,4
2473	47.8	53,5	84,4
2546	51.6	53,5	84,4
2510	51.8	53,5	84,4

***Limit (dBm)= -13 => Limit (dBµV/m)= 84,4**

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

PCS1900 C512-C661-C810

Frequency (MHz)	Measure (dBµV/m)	Radiated Emission Limit(dBµV/m)	Radiated Spurious Emission Limit(dBµV/m)*
30	25,2	40	84,4
43,9	27	40	84,4
88,5	27,2	43,5	84,4
96	33,8	40	84,4
108,2	25,6	43,5	84,4
204,2	25,7	43,5	84,4
251,1	26,3	46	84,4
869,5	40	46	84,4
1930	44,8	53,5	84,4
1948	44,4	53,5	84,4
3760	52,7	53,5	84,4
3700	46,7	53,5	84,4
3820	48,1	53,5	84,4
7520	34,2	53,5	84,4
5640	42,2	53,5	84,4

*** Limit (dBm)= -13 => Limit (dBµV/m)= 84,4**

See Graphics N°1 to N°8 in annex 2

Result: PASS

6.4. CONCLUSION

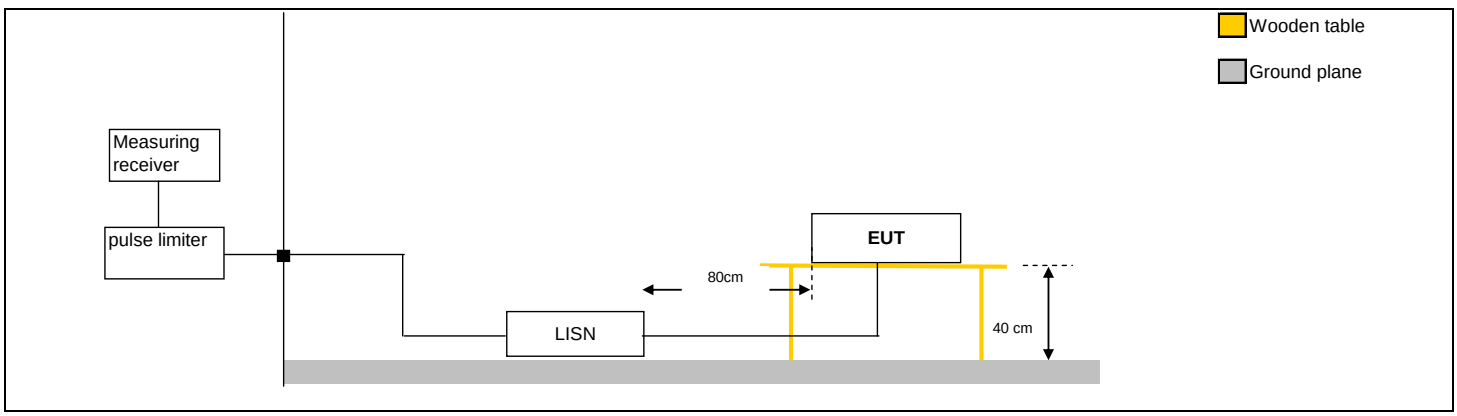
Radiated emissions test performed on the sample of the "SMARTVIEW MONITOR KA961" in configuration and description presented in this test report, show levels below the FCC limits.

7. 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°9	Pass
Neutral	Nominal	N°10	Pass



Test set up of conducted emission on power supply

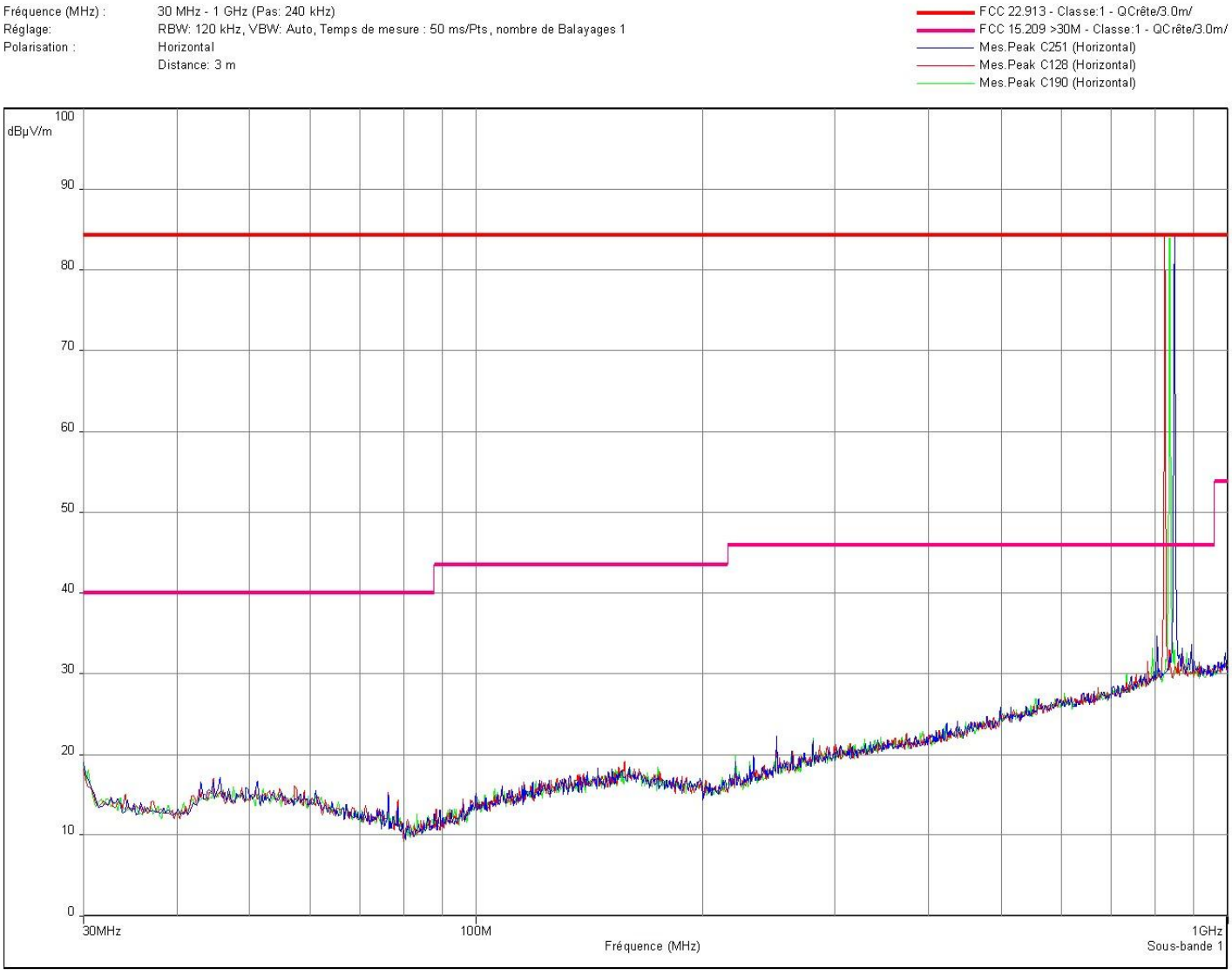
8. ANNEX 1: UNCERTAINTIES CHART

Maximum measurement uncertainties

Kind of test	***Wide uncertainty laboratory* (k=2) ±x(dB) / (Hz)**	***uncertainty limit* ±y(dB)**
TRANSMITTER REQUIREMENTS		
Effective radiated Power • *Frequency < 1000 MHz* • *Frequency > 1000 MHz*	 ±5.72 dB ±5.69 dB	±6 dB
Range of modulation bandwidth for wide band equipment		
Unwanted Emission • *Frequency < 1000 MHz* • *Frequency > 1000 MHz*	 ±5.72 dB ±5.46 dB	±6 dB

9. ANNEX 2 (GRAPHICS)

Graphic N°1
Radiated Emission & Radiated Spurious Emission
Horizontal Polarization
GSM850 Channel 128, 190 and 251
230Vdc



Graphic N°2
Radiated Emission & Radiated Spurious Emission
Horizontal Polarization
GSM850 Channel 128, 190 and 251
230Vdc

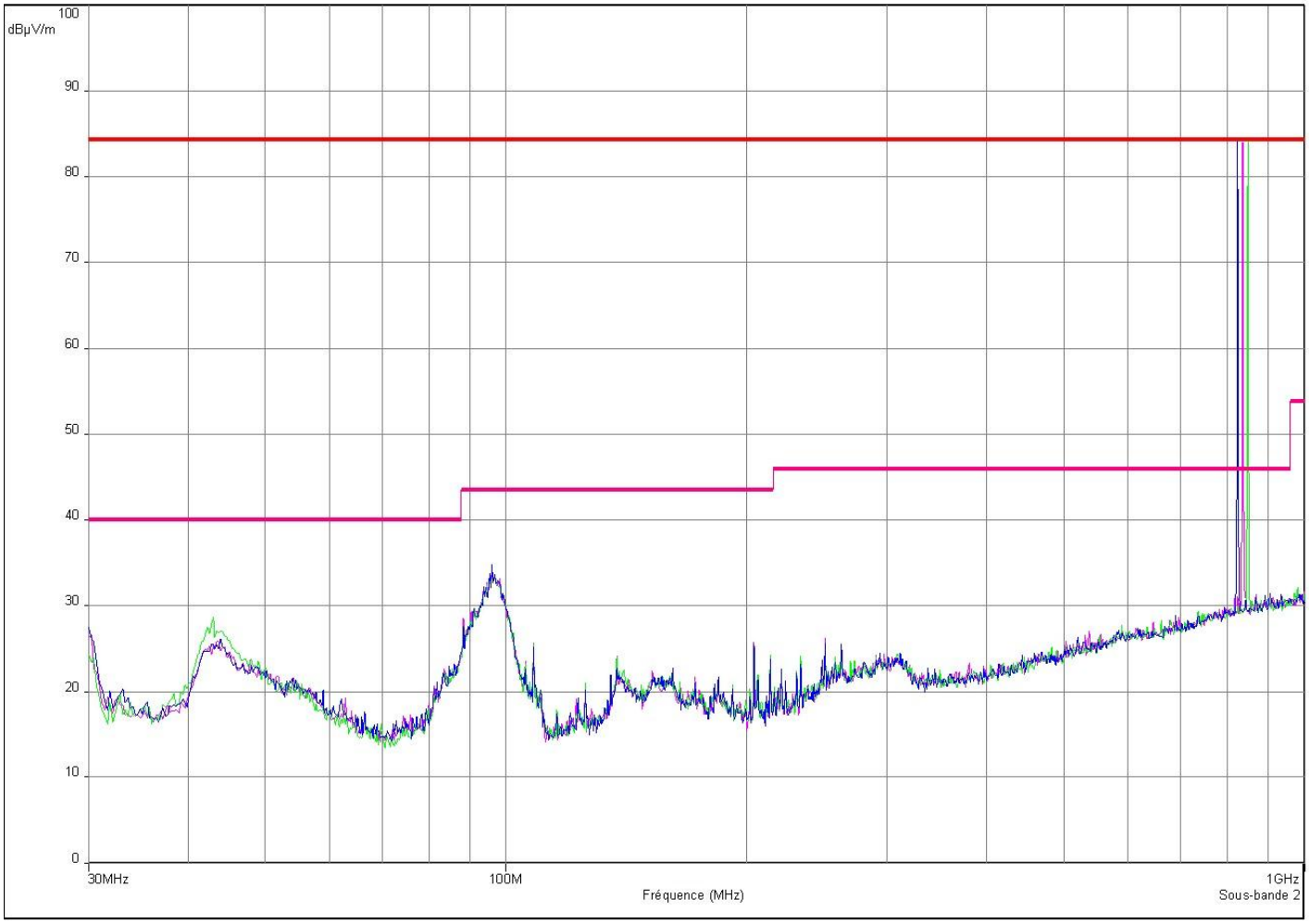
Fréquence (MHz) : 1 GHz - 9 GHz (Pas: 1 MHz)
Réglage: RBW: 1 MHz, VBW: Auto, Temps de mesure : 20 ms/Pts, nombre de Balayages 1
Polarisation : Horizontal
Distance: 3 m

FCC 15.109 - Classe: - QCrête/3.0m/
FCC 22.913 - Classe: - QCrête/3.0m/
Mes.Peak C251 (Horizontal)
Mes.Peak C190 (Horizontal)
Mes.Peak C128 (Horizontal)

Graphic N°3
Radiated Emission & Radiated Spurious Emission
Vertical Polarization
GSM850 Channel 128,190 and 251
230Vdc

Fréquence (MHz) : 30 MHz - 1 GHz (Pas: 240 kHz)
Réglage: RBW: 120 kHz, VBW: Auto, Temps de mesure : 50 ms/Pts, nombre de Balayages 1
Polarisation : Vertical
Distance: 3 m

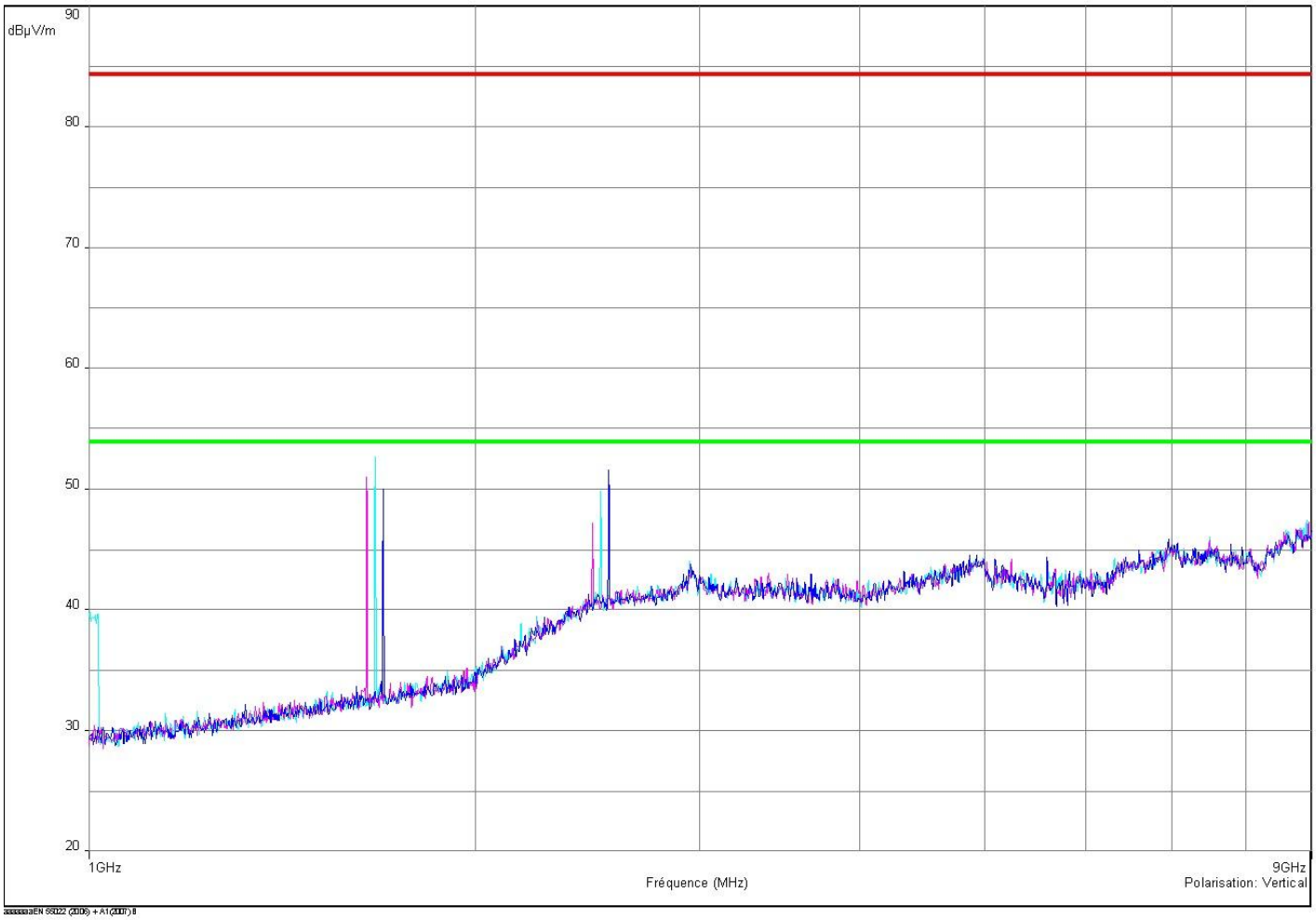
FCC 22.913 - Classe:1 - QCrête/3.0m/
FCC 15.209 >30M - Classe:1 - QCrête/3.0m/
Mes.Peak C128 V (Vertical)
Mes.Peak C251 V (Vertical)
Mes.Peak C190 V (Vertical)



Graphic N°4
Radiated Emission & Radiated Spurious Emission
Vertical Polarization
GSM850 Channel 128,190 and 251
230Vdc

Fréquence (MHz) : 1 GHz - 9 GHz (Pas: 1 MHz)
Réglage: RBW: 1 MHz, VBW: Auto, Temps de mesure : 20 ms/Pts, nombre de Balayages 1
Polarisation : Vertical
Distance: 3 m

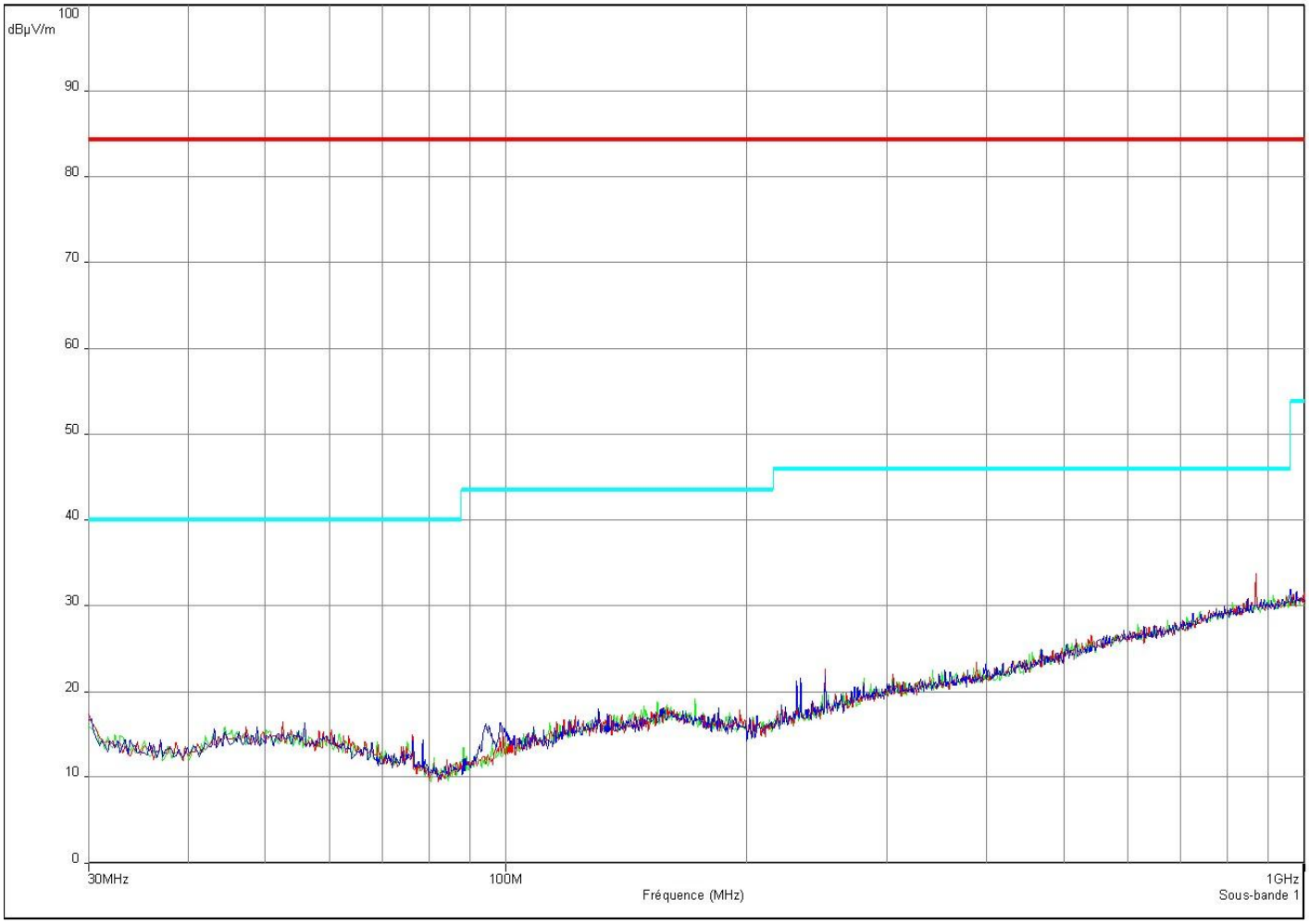
FCC 15.109 - Classe: - QCrête/3.0m/
FCC 22.913 - Classe: - QCrête/3.0m/
Mes.Peak C251V (Vertical)
Mes.Peak C128 V (Vertical)
Mes.Peak C190V (Vertical)



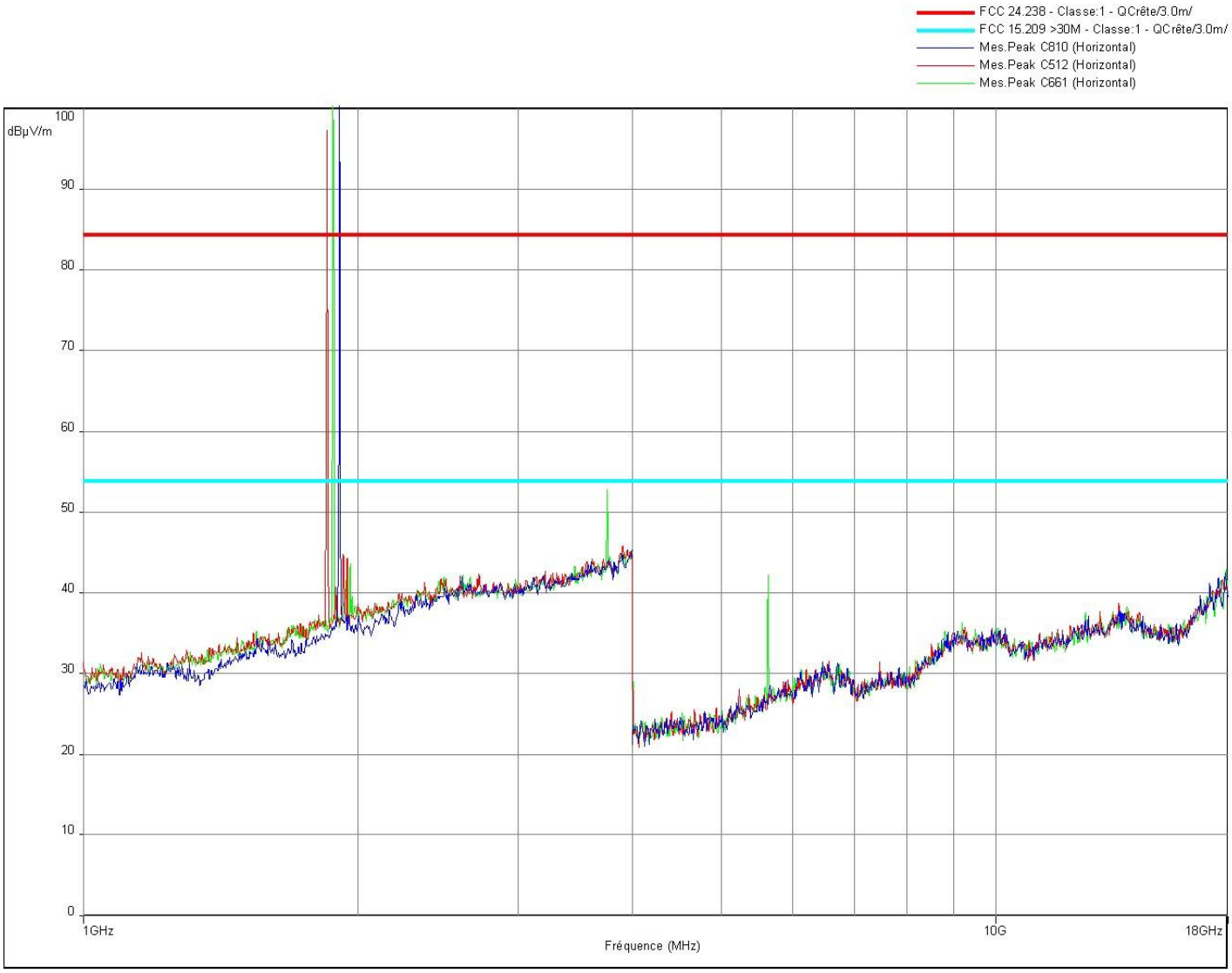
Graphic N°5
Radiated Emission & Radiated Spurious Emission
Horizontal Polarization
PCS1900 Channel 512, 661 and 810
230Vdc

Fréquence (MHz) : 30 MHz - 1 GHz (Pas: 240 kHz)
Réglage: RBW: 120 kHz, VBW: Auto, Temps de mesure : 50 ms/Pts, nombre de Balayages 1
Polarisation : Horizontal
Distance: 3 m

FCC 24.238 - Classe:1 - QCrête/3.0m/
FCC 15.209 >30M - Classe:1 - QCrête/3.0m/
Mes.Peak C512 (Horizontal)
Mes.Peak C810 (Horizontal)
Mes.Peak C661 (Horizontal)



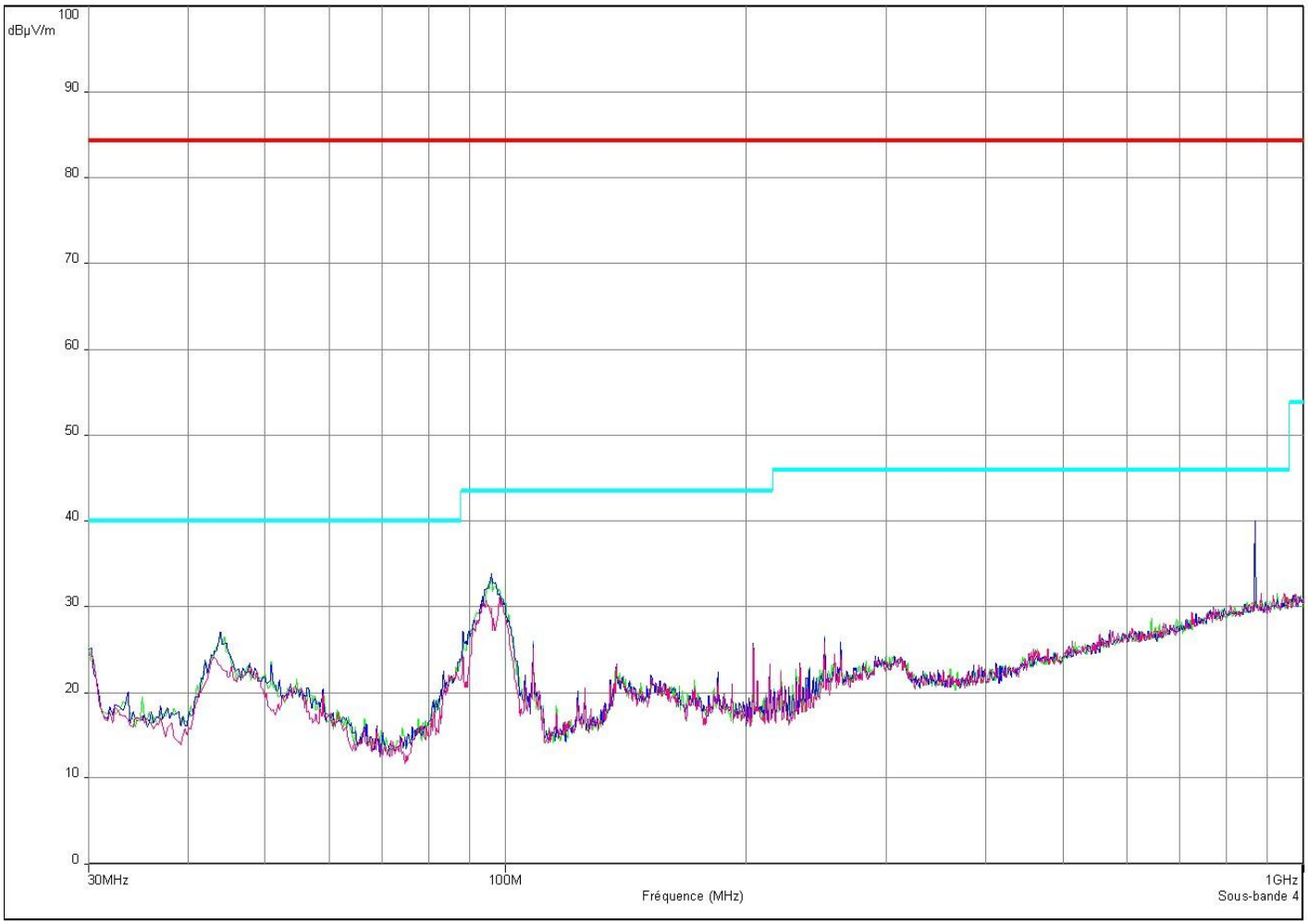
Graphic N°6
Radiated Emission & Radiated Spurious Emission
Horizontal Polarization
PCS1900 Channel 512, 661 and 810
230Vdc



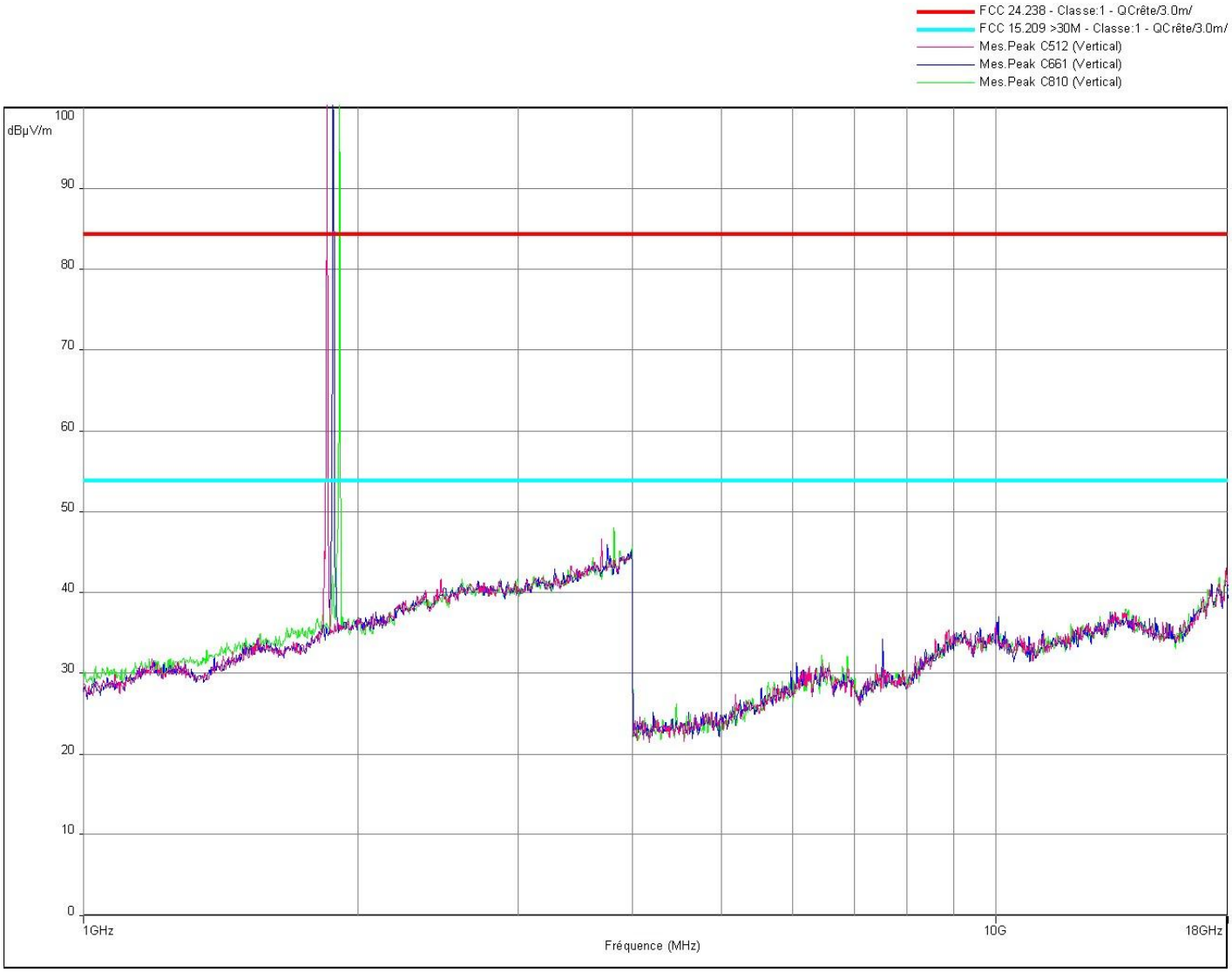
Graphic N°7
Radiated Emission & Radiated Spurious Emission
Vertical Polarization
PCS1900 Channel 512, 661 and 810
230Vdc
20°C

Fréquence (MHz) : 30 MHz - 1 GHz (Pas: 240 kHz)
Réglage: RBW: 120 kHz, VBW: Auto, Temps de mesure : 50 ms/Pts, nombre de Balayages 1
Polarisation : Vertical
Distance: 3 m

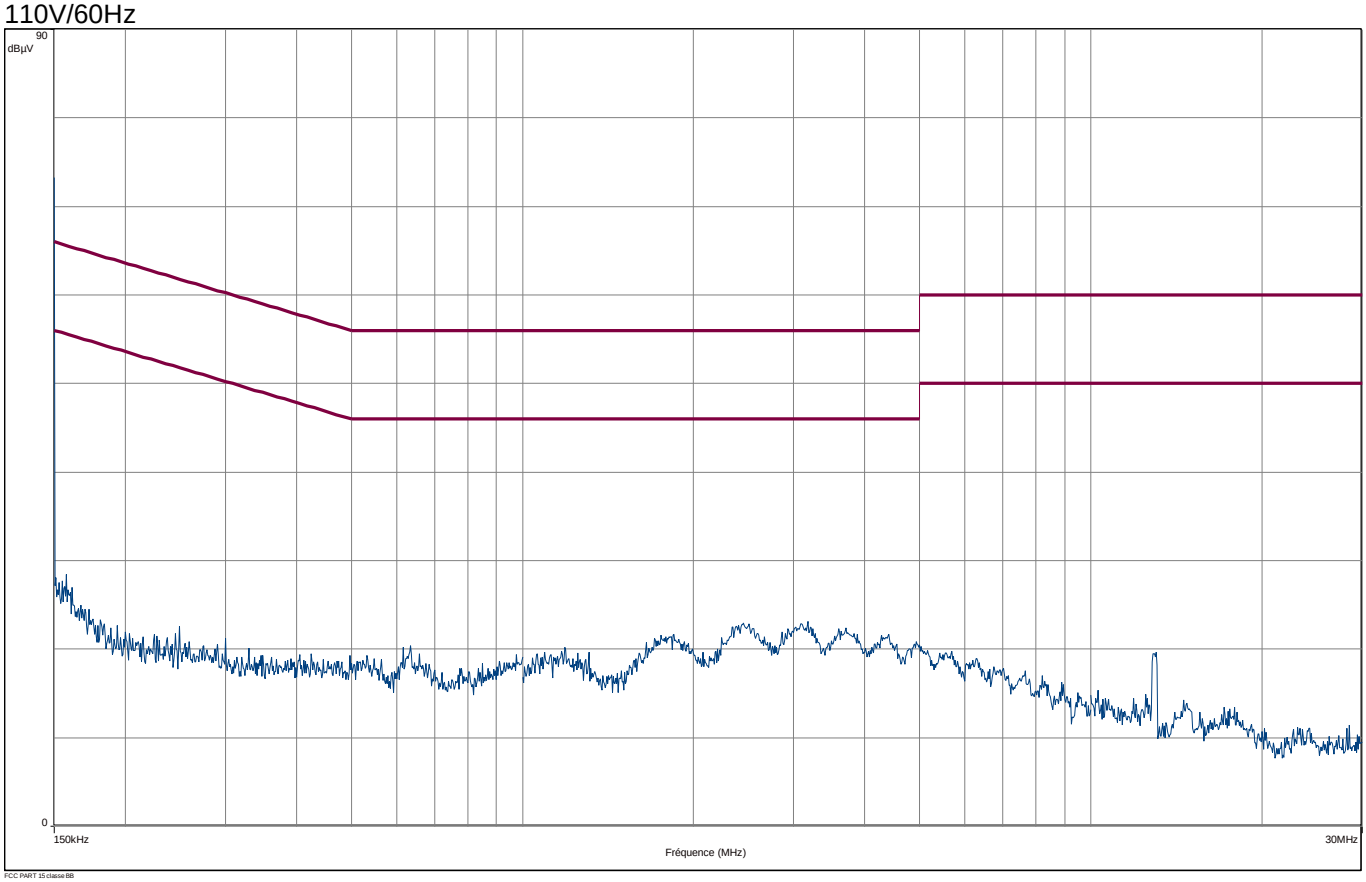
FCC 24.238 - Classe:1 - QCrête/3.0m/
FCC 15.209 >30M - Classe:1 - QCrête/3.0m/
Mes.Peak C810 (Vertical)
Mes.Peak C512 (Vertical)
Mes.Peak C661 (Vertical)



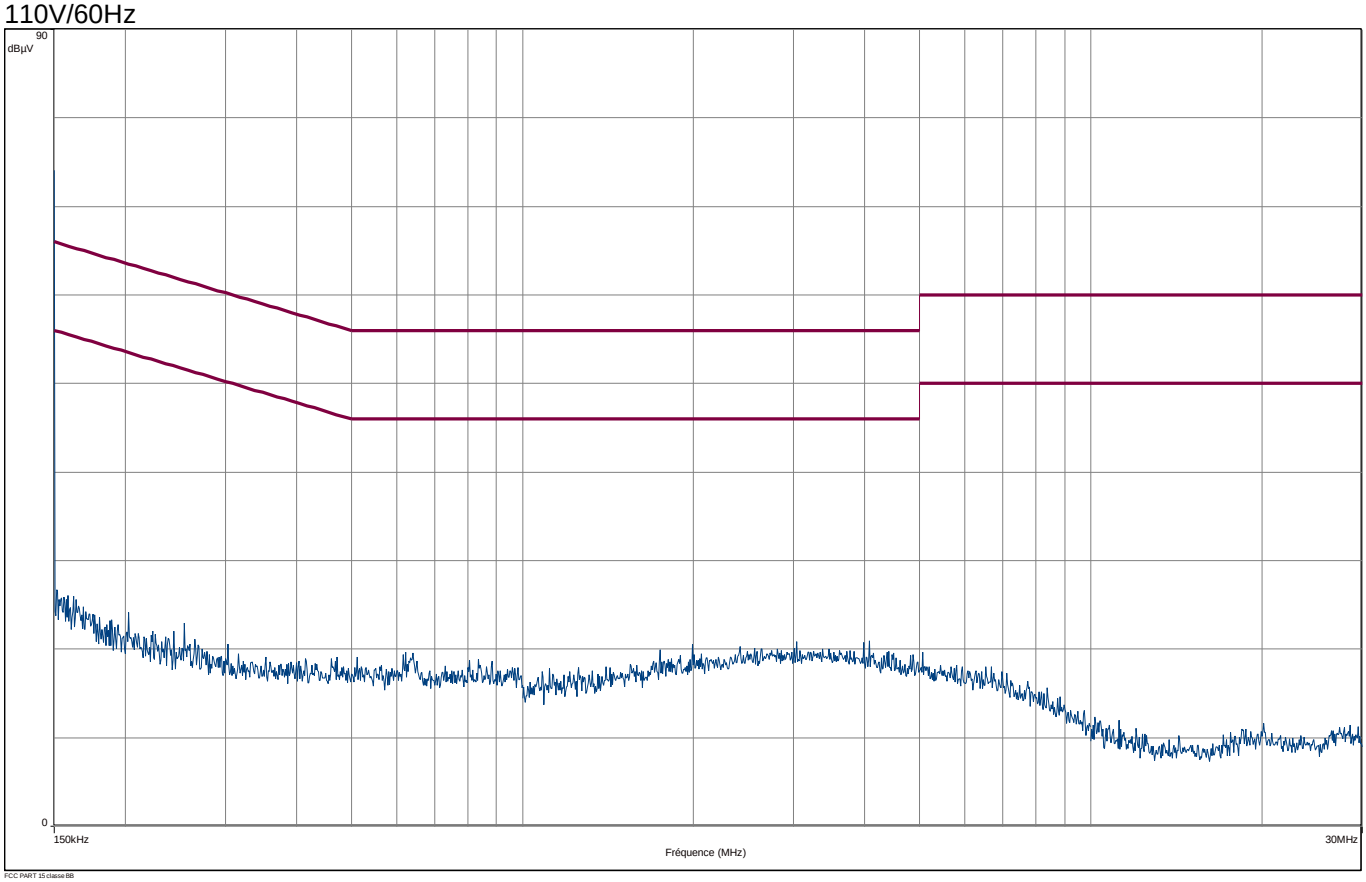
Graphic N°8
Radiated Emission & Radiated Spurious Emission
Vertical Polarization
PCS1900 Channel 512, 661 and 810
230Vdc
20°C



Graphic N°9
Conducted emission
Phase line
110V/60Hz



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



10. ANNEX 3 (TEST EQUIPMENT LIST)

Test	Apparatus	Trade Mark	Type	Registration number
X	Full anechoic chamber	SIEPEL	S36	D3044019
X	Logperiodic antenna	AMPLIFIER RESEARCH	ATR80M6G	C2040149
X	EMI Test Receiver	ROHDE & SCHWARZ	ESMI	A2642009
X	Receiver	ROHDE & SCHWARZ	ESI40	A2642010
X	Preamplier	BONN Elektronik	BLNA 3018-8F30S	A7080053
X	Horn antenna	EMCO	.3115	C2042016
X	Bilog antenna	SHWARZBECK	VULB9160	C2040150
X	Semi anechoic chamber	SIEPEL	C01	D3044008