TEST REPORT

Report Number: 101277992MIN-005C
Project Number: G101277992

Testing performed on the
Model 4500, Clinician Programmer

to
ETSI EN 301 839-1 v1.3.1 (2009-10)
ETSI EN 301 839-2 v1.3.1 (2009-10)
ETSI EN 301 489-27 v1.1.1 (2004-06)

Minnetronix

Test Performed by:
Intertek Testing Services NA, Inc.
7250 Hudson Blvd., Suite 100
Oakdale, MN 55128 USA

Test Authorized by:
Minnetronix
1635 Energy Park Drive
St. Paul, MN 55108 USA

Prepared by: _____ Date: November 18, 2013
Uri Spector

Reviewed by: _____ Date: November 18, 2013
Simon Khazon

This report is for the exclusive use of Intertek's Client and is provided pursuant to the agreement between Intertek and its Client. Intertek's responsibility and liability are limited to the terms and conditions of the agreement. Intertek assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this report. Only the Client is authorized to permit copying or distribution of this report and then only in its entirety. Any use of the Intertek name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by Intertek. The observations and test results in this report are relevant only to the sample tested. This report by itself does not imply that the material, product, or service is or has ever been under an Intertek certification program.

TABLE OF CONTENTS

1.0 GENERAL DESCRIPTION

Model:	4500
Type of EUT:	Clinician Programmer, MICS Radio
Serial Number:	DBR 1552
Company:	Minnetronix
Customer:	Sue Sibilski
Address:	1635 Energy Park Drive St. Paul, MN 55108
Phone:	(651) 917-4060
Fax:	(651) 917-4066
e-mail:	ssibilski@minnetronix.com
Test Standards:	☒ EN 301 839-1 v1.3.1 (2009-10) ☒ EN 301 839-2 v1.3.1 (2009-10) ☐ EN 300 330-2 V1.3.1 (2006-04) ☐ EN 300 440-2 V1.3.1 (2009-03) ☐ EN 301 489-1 V1.8.1 (2008-04) ☐ EN 301 489-3 V1.4.1 (2002-08) ☒ EN 301 489-27 V1.1.1 (2006-04) ☐
Operating Frequency Range(s):	Range: from 402-405 MHz
Power Level Setting:	15
Modulation:	☐ FHSS ☒ Digital ☐ Other
Type of radio:	☒ Stand -alone ☐ Module ☐ Hybrid
Date Sample Submitted:	August 16, 2013
Test Work Started:	September 12, 2013
Test Work Completed:	November 18, 2013
Test Sample Conditions:	☐ Damaged ☐Poor (Usable) ☒ Good

2.0 TEST SUMMARY

Referring to the performance criteria and the operating mode during the tests specified in this report, the equipment complies with the requirements according to the following standards.

TEST SPECIFICATION	TEST PARAMETERS	RESULT
8.3	Effective Radiated Power at Fundamental	Pass
8.2	Bandwidth of the emission	Pass
8.4	Radiated Spurious Emissions	Pass
9.1	Receiver Spurious Emissions	Pass
8.1	Frequency Error	Pass
10	The MICS Communication Sessions (Threshold Power Levels, Monitoring System Bandwidth, Scan Cycle Time, Minimum Channel Monitoring Period, Channel Access, Discontinuation of a MICS Session, and Use of Pre-Scanned Alternate Channel)	Pass
8.2	Radiated Emissions of enclosure of ancillary equipment	Pass
8.3	Conducted Emissions, DC ports	N/A
8.4	Conducted Emissions, AC mains	Pass
8.5	Harmonic Current Emissions	Pass
8.6	Voltage Fluctuations	Pass
8.7	Conducted Emissions, telecommunication ports	N/A
9.2	RF Electromagnetic Field	Pass
9.3	Electrostatic Discharge	Pass
9.4	Fast Transients	Pass
9.5	RF common mode	Pass
9.6	Transients and surges in vehicular environment	Pass
9.7	Voltage Dips and Voltage Interruptions	Pass
9.8	Surges	Pass

2.1 Statement of the measurement uncertainty

Note 1: The measured result in this report is within the specification limits by more than the measurement uncertainty; the measured result indicates that the product tested complies with the specification limit.

The expanded uncertainty (k = 2) for radiated emissions from 30 to 1000 MHz has been determined to be: ±4 dB at 10m and ±5.4 dB at 3m

The expanded uncertainty (k = 2) for conducted emissions from 150 kHz to 30 MHz has been determined to be:
±2.6 dB

3.0 EQUIPMENT UNDER TEST

3.1 Power configuration

Rated voltage:	☒ 100-240VAC ☐ 230VAC ☐ 400VAC ☐ VDC ☐ Other:
Rated current:	Amp.
Rated frequency:	☒ 50-60Hz ☐ 60Hz
Power source:	☐ Internal battery ☒ External power source
Battery:	☐ Nickel Cadmium ☐ Alkaline ☐ Nickel-Metal Hydride ☐ Lithium-Ion

3.2 Antenna configuration

Antenna type:	☒ PCB loop antenna (trace) ☐ External
Antenna gain:	-9.1dBi

3.3 EUT Configuration

The equipment under test was operated during the measurement under the following conditions:

☒ - Standby
☒ - Continuous
☒ - Continuous un-modulated
☐ - Test program (customer specific)
☐ -

Operating modes of the EUT:

No.	Description
1	The EUT was powered 230VAC and was activated to transmit continuously modulated carrier except frequency error testing were a CW signal was transmitted. Channel 5 (403.65MHz) was utilized for testing. During Immunity testing the EUT MICS RF communication was established with the remote Implant Emulation (Avid) board.

Cables:

No.	Type	Length	Designation	Note
1	Not shielded USB Power cable	2m	Power Cable	
2	Shielded USB cable	2m	Communication Cable	
3	Shielded HDMI cable	2m	HDMI Cable	

Support equipment/Services:

No.	Item	Description
1	Avid Board	Implant Emulation board used during MICS Communication Sessions testing.

General notes: None

3.4 Environmental conditions

During the measurement the environmental conditions were within the listed ranges:

☐ **Normal**

Temperature: 15-35 ° C

Humidity: 30-60 %

Atmospheric pressure: 86-106 kPa

☒ **Extreme**

☐ **Temperature:**	+25 to +45 ° C
☒ **Temperature:**	-20 to +55 ° C
☒ **AC power:**	± 10%
☐ **Battery:**	As declared by the manufacturer

4.0 TEST CONDITIONS AND RESULTS

4.1 Effective Radiated Power at Fundamental

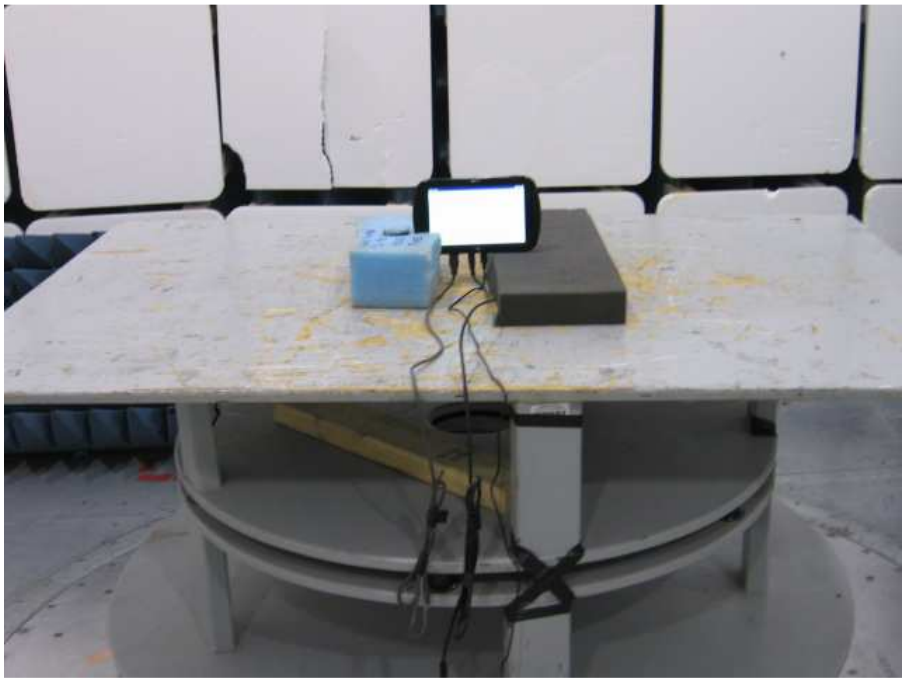
Test location: ☐ OATS ☒ Anechoic Chamber ☐ Other

Test distance: ☐ 10 meters ☒ 3 meters

Test result: **Pass**

Max. Emissions margin at fundamental: 0.8dB below the limits

Notes: Table 1 shows ERP Power at Fundamentals (substitution measurements).



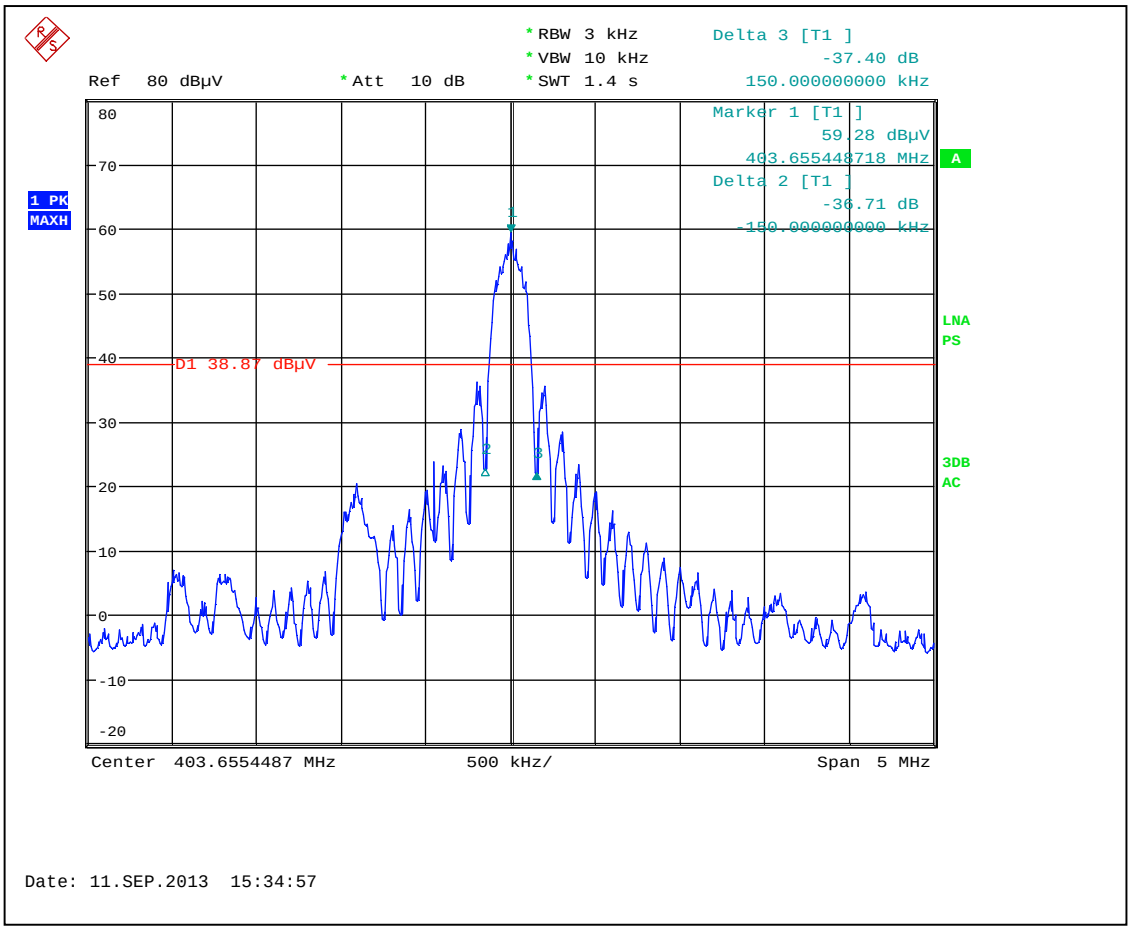
Test Setup Photos

Date:	September 18, 2013	**Result:** **Pass**
Standard:	EN ETSI 301 839-1	
Tested by:	Uri Spector	
Test Point:	Enclosure	
Operation mode:	See Page 7	
Note:	None	

Table 1

Frequency MHz	Antenna Polarity	Measured Emissions dBµV	Substitution Antenna Power dBm	Substitution Antenna Gain dBi	Cable Loss dB	ERP Spur. Emissions dBm	Limit dBm	Margin dB
403.66	V	56.1	-23.4	0.0	0.5	-23.9	-16.0	-7.9
403.66	H	63.5	-16.3	0.0	0.5	-16.8	-16.0	-0.8

Graph 4.1.1


RBW 3 kHz
VBW 10 kHz
SWT 1.4 s
Ref 80 dBµV
Att 10 dB
Delta 3 [T1]
-37.40 dB
150.000000000 kHz
Marker 1 [T1]
59.28 dBµV
403.655448718 MHz
Delta 2 [T1]
-36.71 dB
-150.000000000 kHz
1 PK
MAXH
A
LNA
PS
3DB
AC
D1 38.87 dBµV
80
70
60
50
40
30
20
10
0
-10
-20
Center 403.6554487 MHz
500 kHz/
Span 5 MHz
Date: 11.SEP.2013 15:34:57

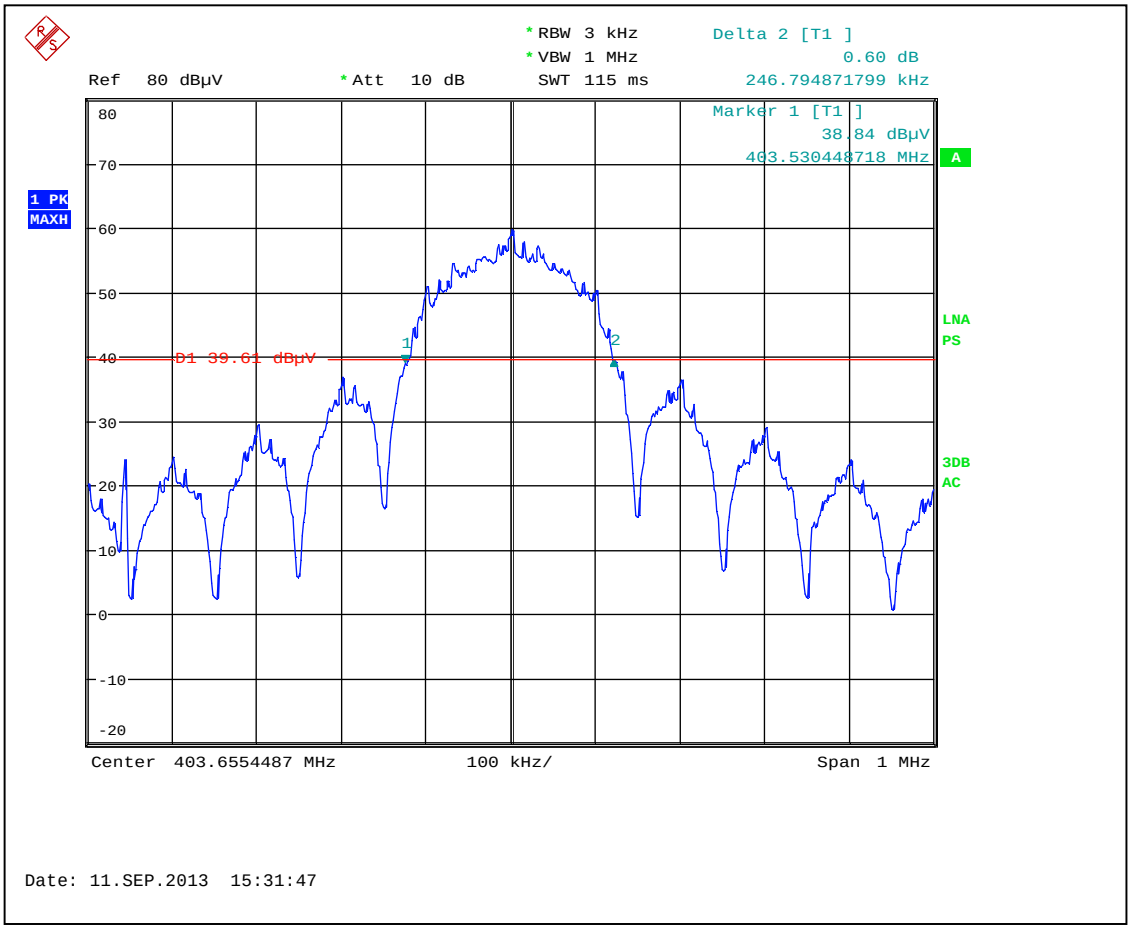
4.2 Bandwidth of Emissions

Center Frequency of operation MHz	Measured 20dB bandwidth kHz	Maximum bandwidth allowed kHz
403.65	246.8	300

Graph 4.2.1 shows bandwidth of emissions

Notes: None

Graph 4.2.1


*RBW 3 kHz
*VBW 1 MHz
Ref 80 dBµV
*Att 10 dB
SWT 115 ms
Delta 2 [T1]
0.60 dB
246.794871799 kHz
Marker 1 [T1]
38.84 dBµV
403.530448718 MHz
1 PK
MAXH
A
LNA
PS
3DB
AC
D1 39.61 dBµV
80
70
60
50
40
30
20
10
0
-10
-20
Center 403.6554487 MHz
100 kHz/
Span 1 MHz
Date: 11.SEP.2013 15:31:47

4.3 Radiated Spurious Emissions

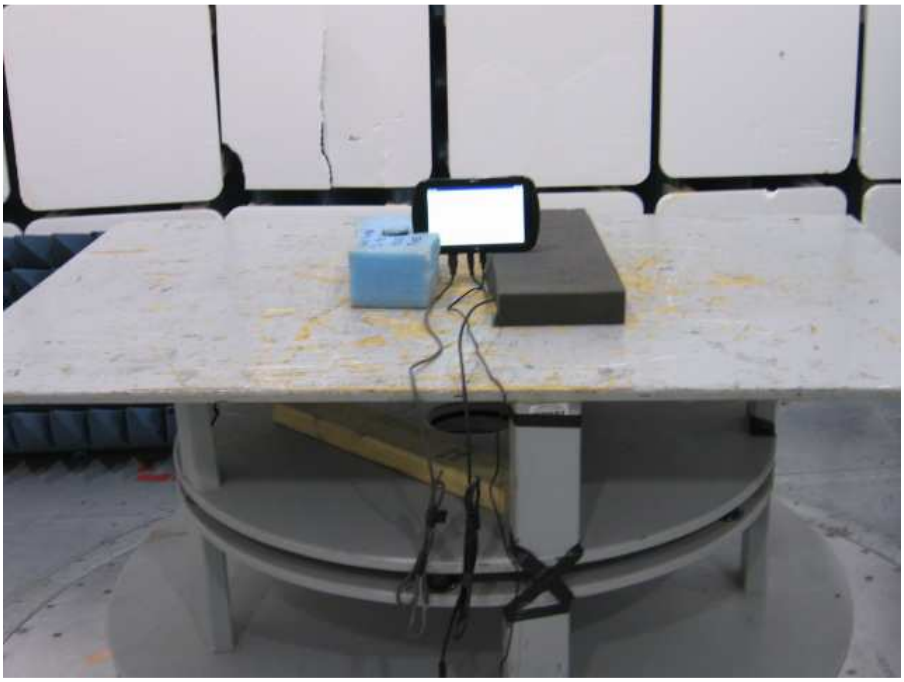
Test location: ☐ OATS ☒ Anechoic Chamber

Test distance: ☐ 10 meters ☒ 3 meters

Test result: **Pass**

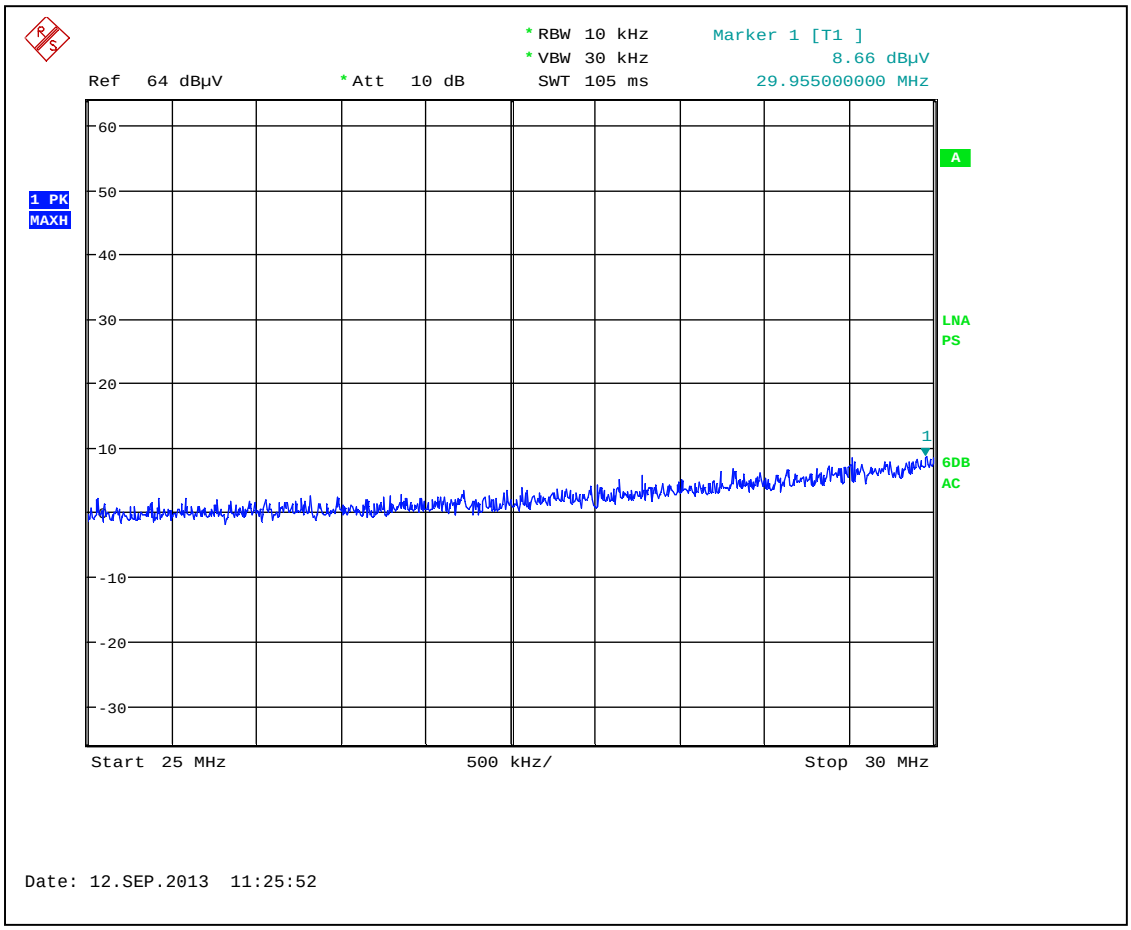
Frequency range: 25MHz-4GHz

Notes: Graphs 4.3.1- 4.3.4 show pre-scan radiated emissions
Emissions at fundamentals and below CISPR 22 Class B limits were excluded from substitution measurements.

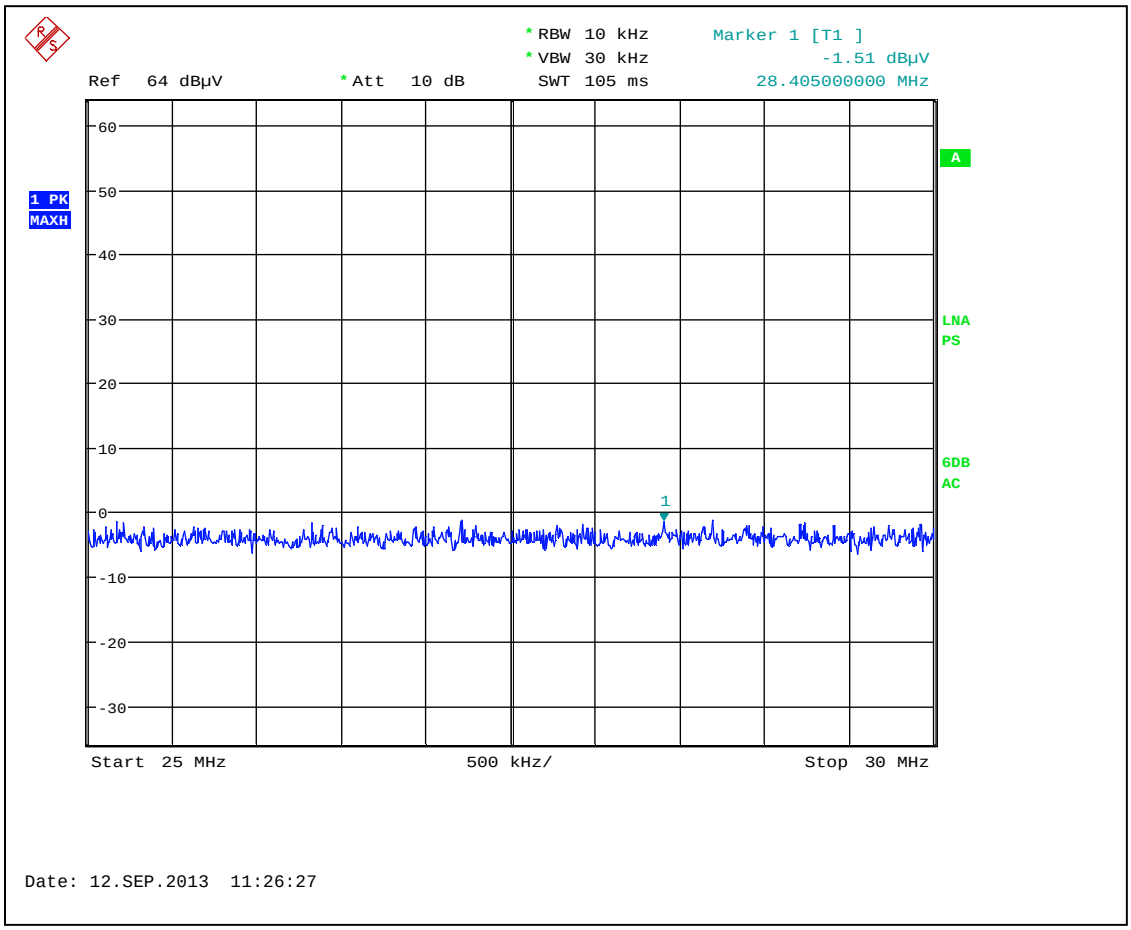


Test Setup Photos

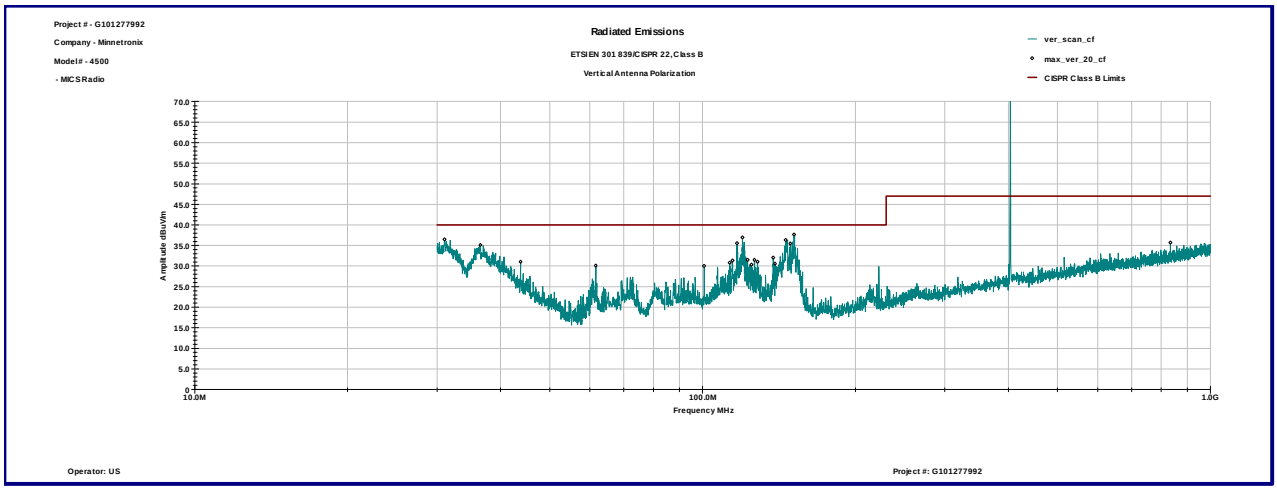
Graph 4.3.1
Vertical Antenna Polarity

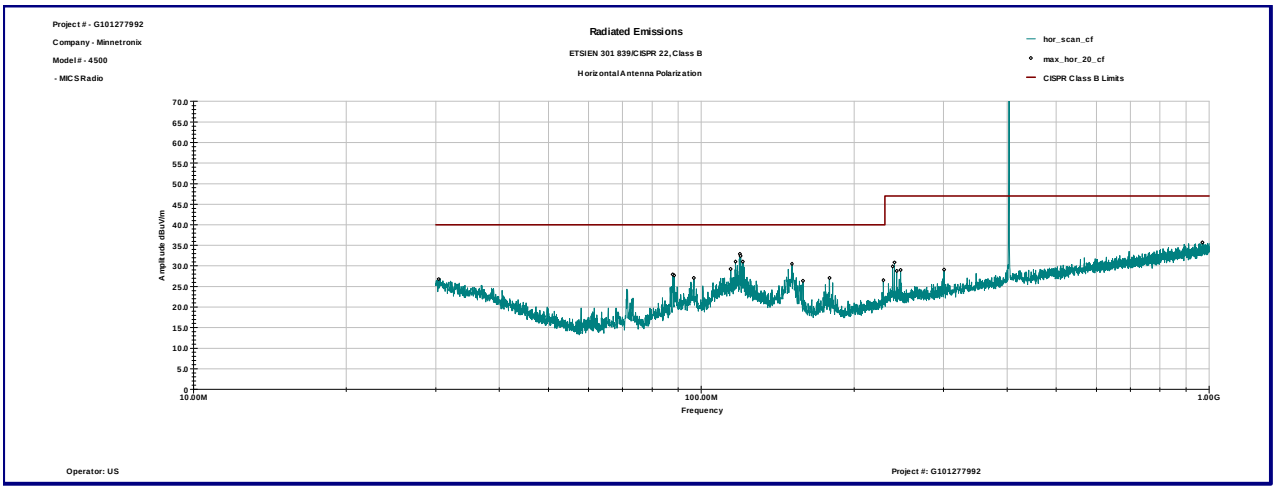


Graph 4.3.2
Horizontal Antenna Polarity

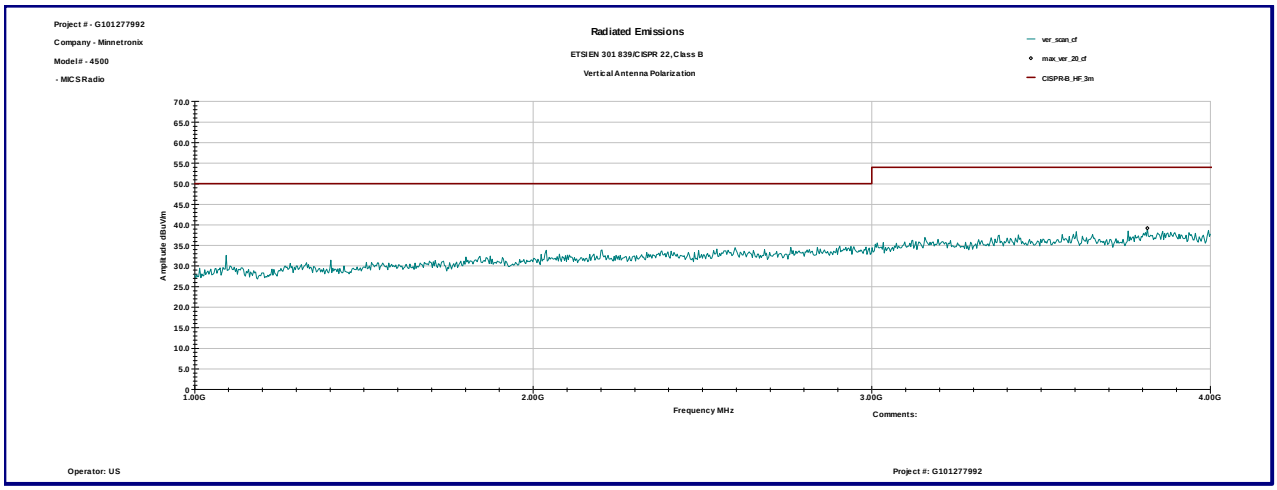


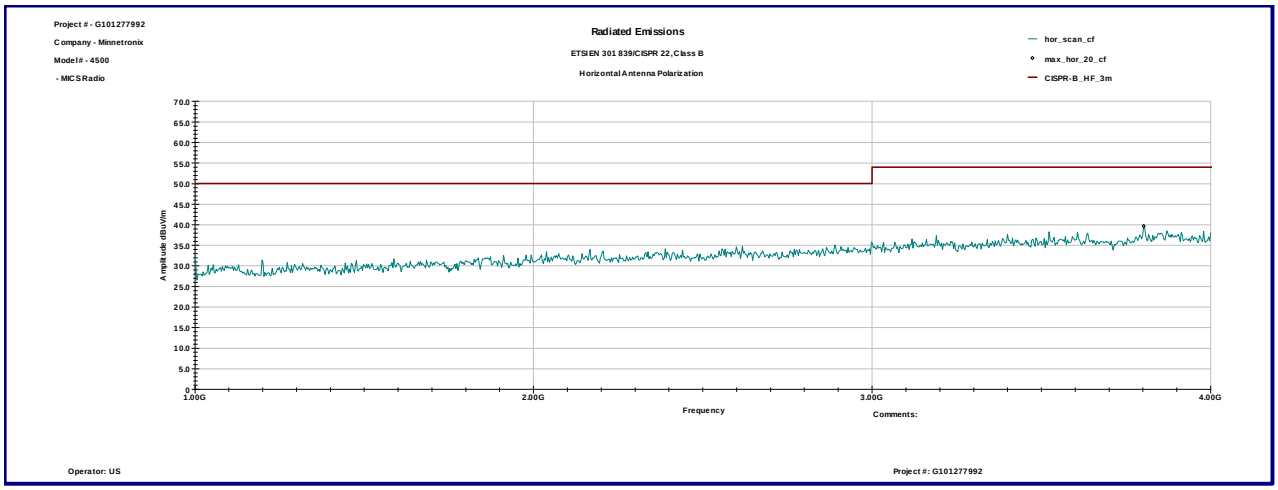
Graph 4.3.3


Project # - G101277992
Company - Minnetronix
Model # - 4500
- MICS Radio
Radiated Emissions
ETSI EN 301 839/CISPR 22, Class B
Vertical Antenna Polarization
ver_scan_cf
max_ver_20_cf
CISPR Class B Limits
Amplitude dBuV/m
70.0
65.0
60.0
55.0
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0
10.0M
100.0M
1.0G
Frequency MHz
Operator: US
Project #: G101277992


Project # - G101277992
Company - Minnetronix
Model # - 4500
- MICS Radio
Radiated Emissions
ETSI EN 301 839/CISPR 22, Class B
Horizontal Antenna Polarization
hor_scan_cf
max_hor_20_cf
CISPR Class B Limits
Amplitude dBuV/m
70.0
65.0
60.0
55.0
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0
10.00M
100.00M
1.00G
Frequency
Operator: US
Project #: G101277992

Graph 4.3.4


Project # - G101277992
Company - Minnetronix
Model# - 4500
- MICS Radio
Radiated Emissions
ETSI EN 301 839/CISPR 22, Class B
Vertical Antenna Polarization
ver_scan_cf
max_ver_20_cf
CISPR-B_HF_3m
Amplitude dBuV/m
70.0
65.0
60.0
55.0
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0
1.00G
2.00G
3.00G
4.00G
Frequency MHz
Comments:
Operator: US
Project #: G101277992


Project # - G101277992
Company - Minnetronix
Model# - 4500
- MICS Radio
Radiated Emissions
ETSI EN 301 839/CISPR 22, Class B
Horizontal Antenna Polarization
hor_scan_cf
max_hor_20_cf
CISPR-B_HF_3m
Amplitude dBuV/m
70.0
65.0
60.0
55.0
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0
1.00G
2.00G
3.00G
4.00G
Frequency
Comments:
Operator: US
Project #: G101277992

4.4 Frequency Error

Table 4.4.1

Temperature Degree C	Output Frequency MHz	Frequency Deviation kHz	Frequency Stability ppm	Frequency error limit ppm	Test Result
-20	403.6442	5.1	12.6	±100	Pass
0	403.6451	4.2	10.4	±100	Pass
15	403.6457	3.6	8.9	±100	Pass
25	403.6493	0.0	0.0	±100	Pass
35	403.6529	3.6	8.9	±100	Pass
55	403.6534	4.1	10.2	±100	Pass

Table 4.4.2

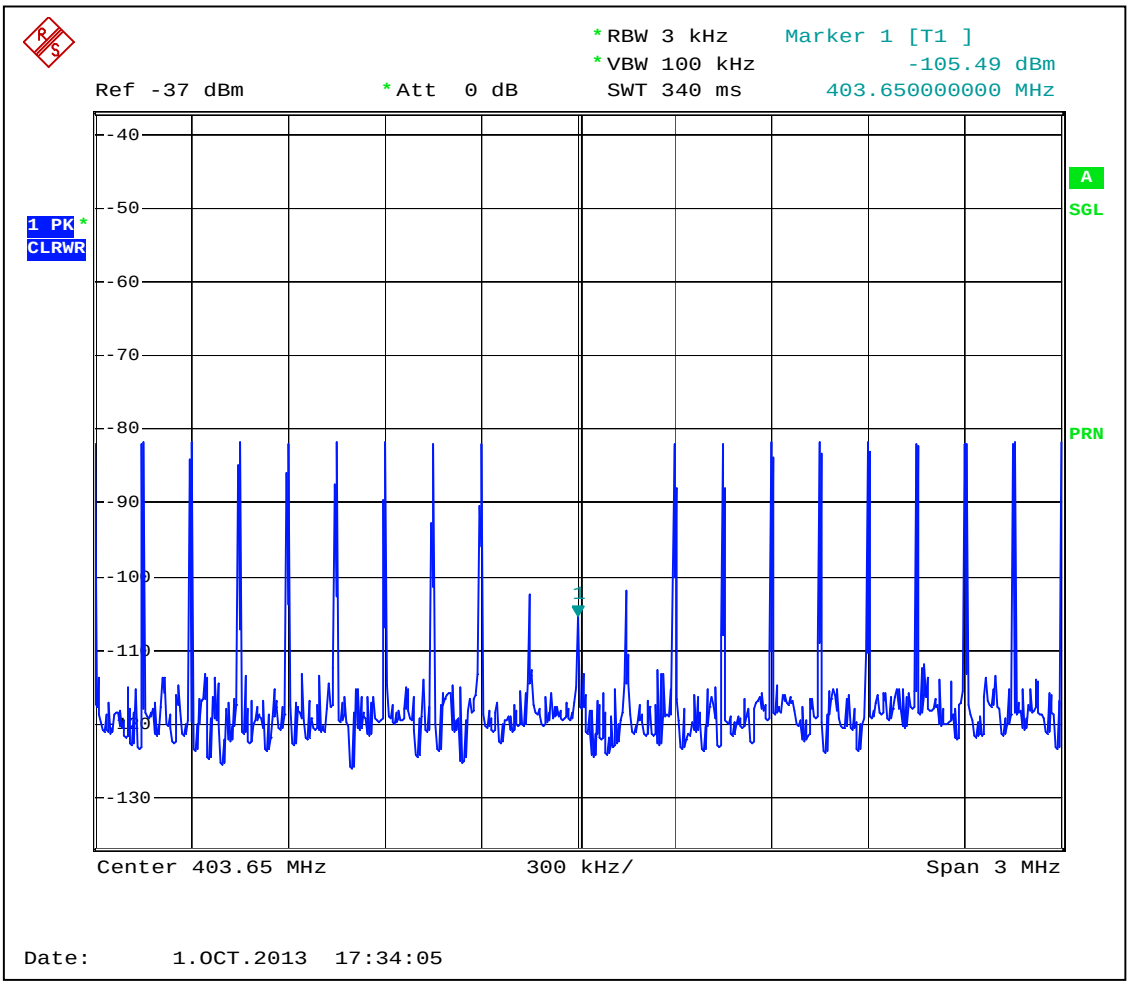
Input Voltage V	Input Voltage Description	Output Frequency MHz	Frequency Band MHz	Test Result
230	Nominal	403.6493	402-405	Pass
253	Upper Extreme	403.6493	402-405	Pass
207	Lower Extreme	403.6493	402-405	Pass

4.5 MICS Operation

The MICS communication sessions must meet operating requirements for Threshold Power Levels, Monitoring System Bandwidth, Scan Cycle Time, Minimum Channel Monitoring Period, Channel Access, Discontinuation of a MICS Session, and Use of Pre-Scanned Alternate Channel.

For these tests, a blocking band was created using the vector signal generator. A notch was created in the blocking band by removing some of the tones, or by lowering the output power of some of the tones in relation to the other. A second signal generator was used to generate a tone on specific channel. Below is an example plot of the blocking band at the EUT, including a single notch in the center.

Graph 4.5.1



System Threshold Power Levels

The monitoring threshold power level shall not be greater the calculated level given by the equation, 10logB(Hz)-150(dBm/Hz)+G(dBi), where B is the emissions bandwidth of the MICS communication session transmitter having the widest emissions bandwidth and G is the antenna gain of the medical implant programmer transmitter monitoring system.

Calculated Threshold Power: 10 log(255.4kHz) -150+(-9.1)= -105.2dBm

The blocking band was set to -102.2dBm (3dB above the calculated threshold level), with a notch left open at 403.65MHz. A tone was introduces at the center of the notch at -111.2dBm, and was stepped up to the threshold level, -105.2dBm. At each step, MICS communications session was initiated and the selected channel was observed.

Measured Threshold Power: -109.2dBm

Monitoring System Bandwidth

The monitoring system bandwidth measured at its 20dB down points shall be equal to, or greater than the emissions bandwidth of the intended transmission.

The blocking band was set to -102.2dBm (3dB above the calculated threshold level), with a notch left open at 403.65MHz. A tone was introduced at the frequencies corresponding to the 20dB down points of the fundamental emission, and was increased until the EUT no longer transmitted on the central frequency. At each step, a MICS communication session was initiated and the selected channel was observed. The difference between the values at which the EUT detects the center channel emission and the channel edge emissions should be less than 20dB in order for the order for the monitoring system bandwidth to be wider than the emission bandwidth.

F_{low} = 403.526MHz
F_{high} = 403.773MHz

Pa= -105.2dBm
Pb= -97.2dBm
Pc= -97.2dBm

D1= Pa-Pb= -105.2-(-97.2)= -8.0dB
D2= Pa-Pc= -105.2-(-97.2)= -8.0dB

D1 and D2 are both less than 20dB

Test result: Pass

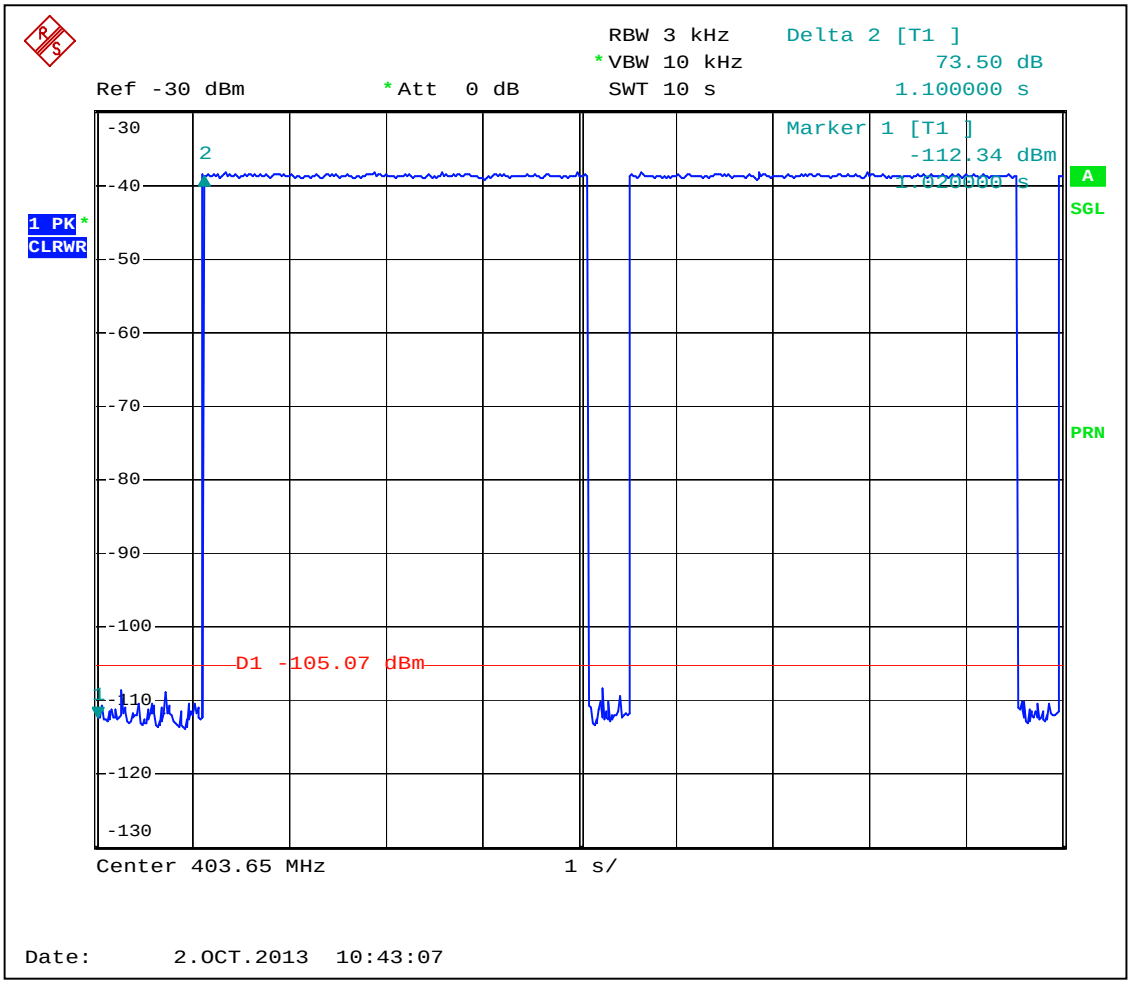
Scan Cycle Time

Within 5 seconds prior to initiating a communications session, circuitry associated with a medical implant programmer transmitter shall monitor all the channels in the 402-405MHz frequency band.

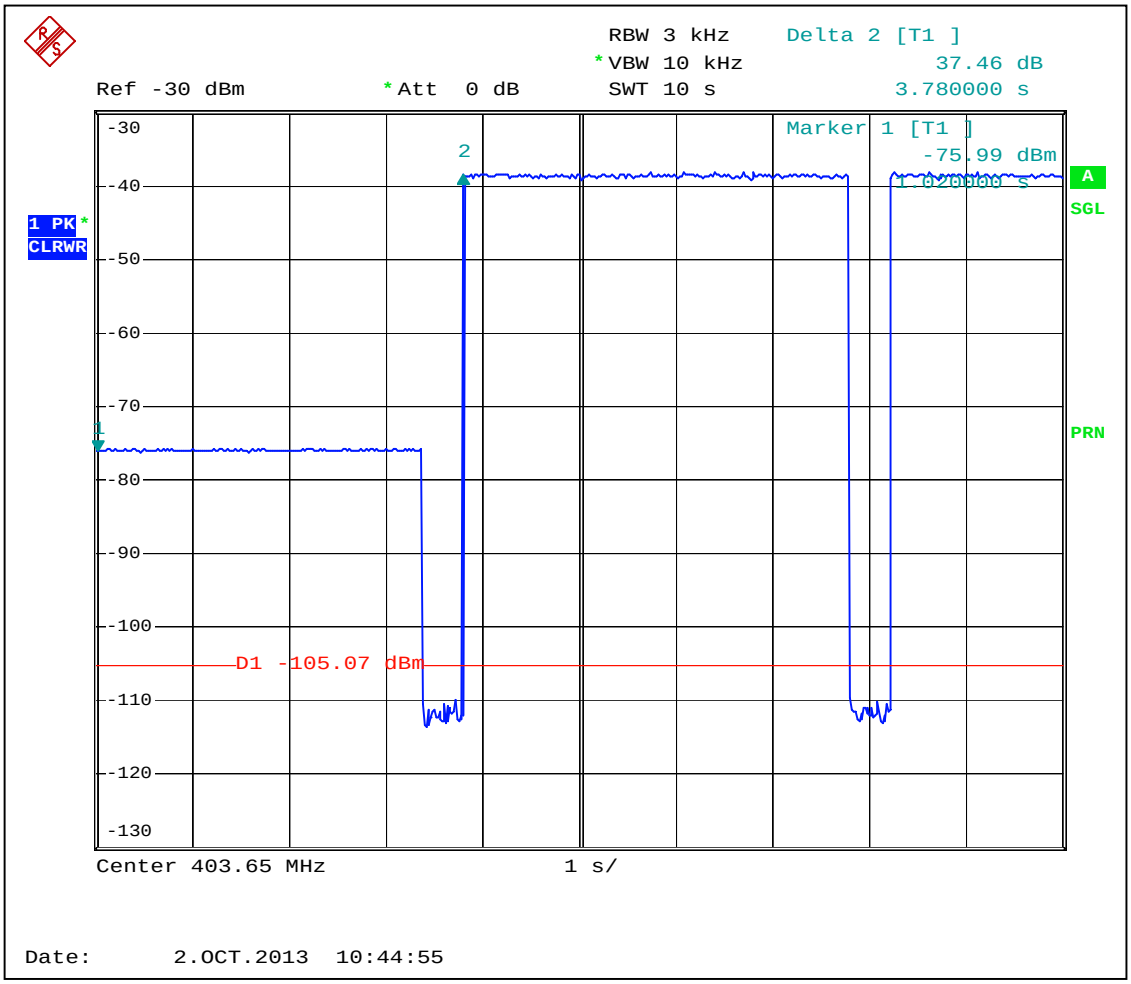
The blocking band was set to -102.2dBm (3dB above the calculated threshold level), with a notch left open at 403.65MHz. A tone was introduced at the center of the notch at -99.2dBm. The tone was removed and a MICS communications session was initiated. The time elapsed between removal of the CW tone and the start of the MICS session was recorded. The highest value was: **3.78sec**

Test result: Pass

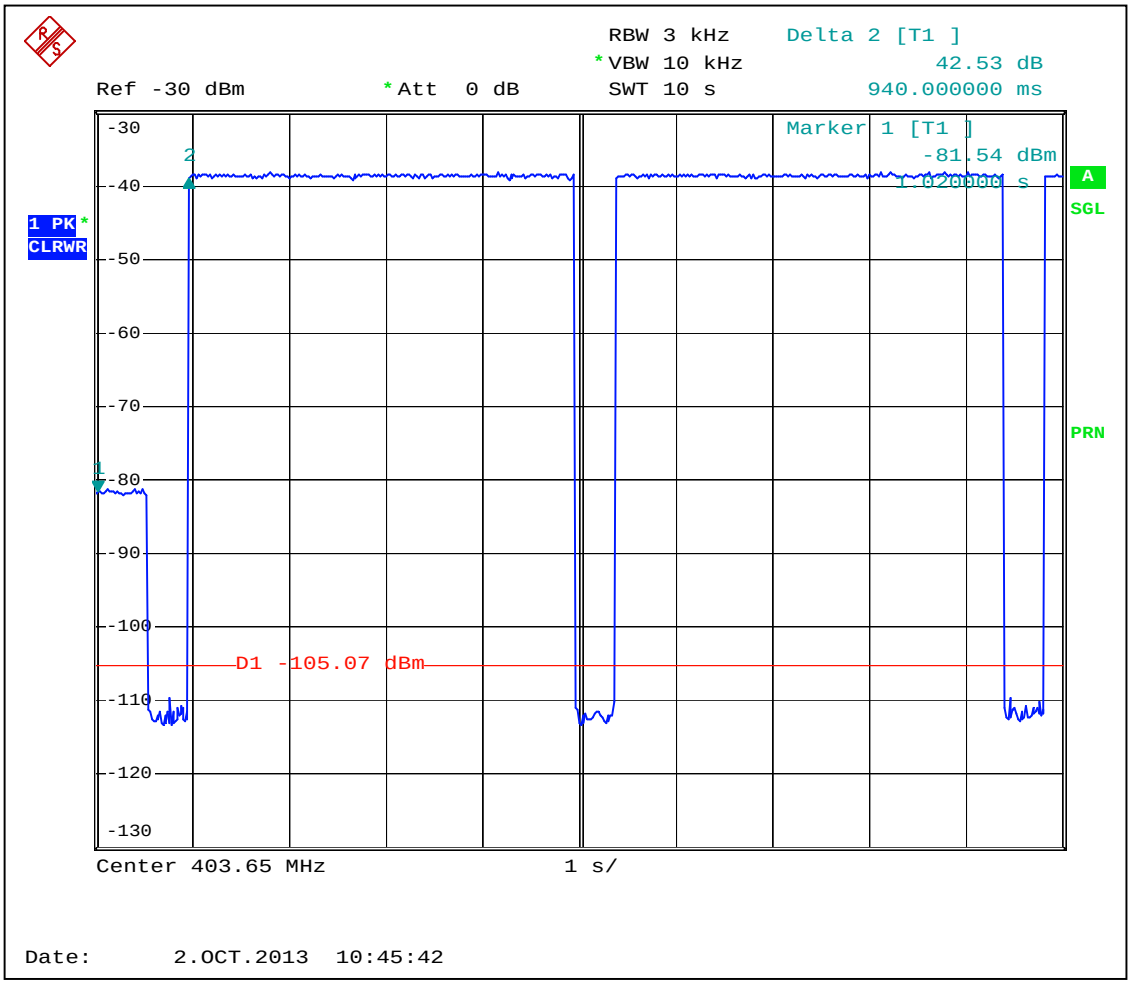
Graph 4.5.2 Scan Cycle Time 1 (1.1sec)



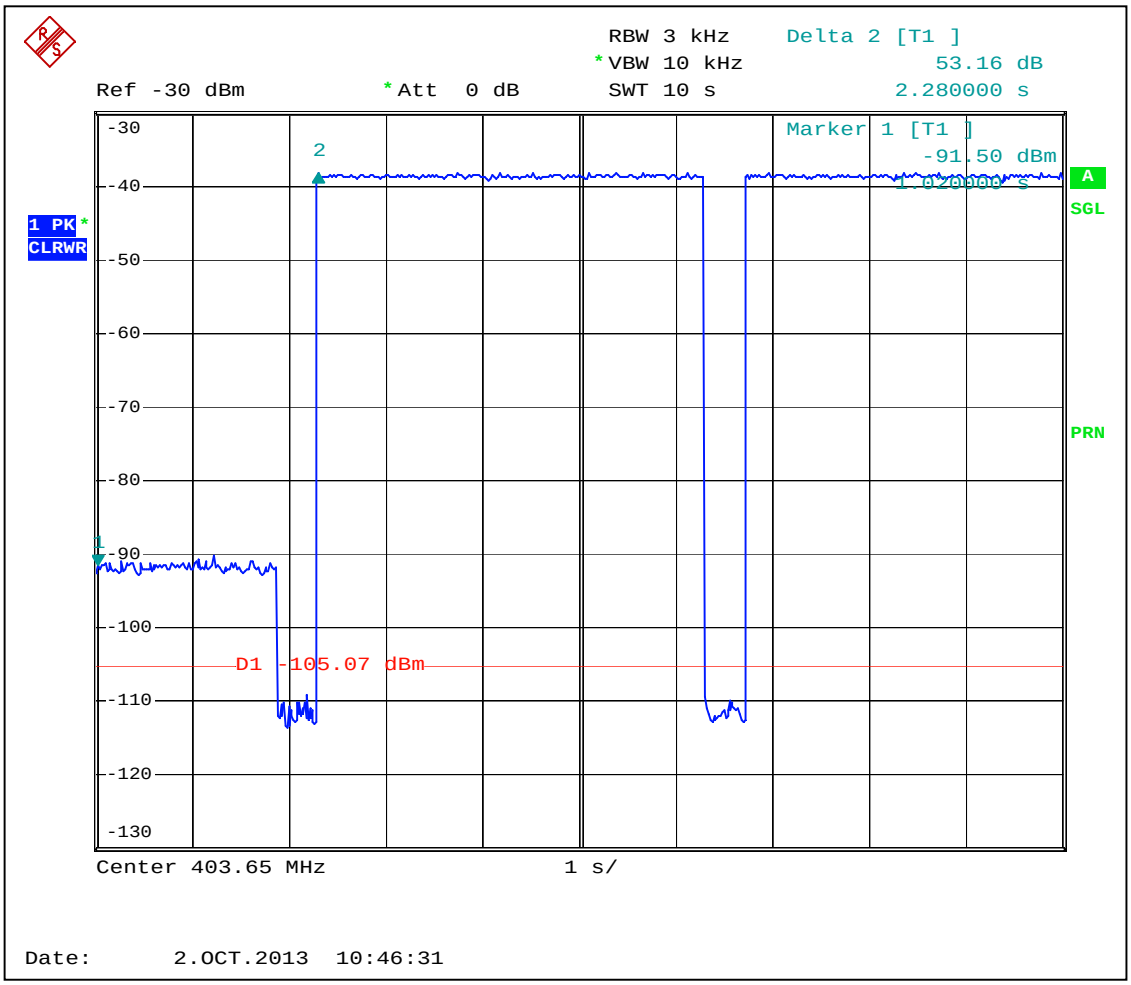
Graph 4.5.3 Scan Cycle Time 2 (3.78sec)



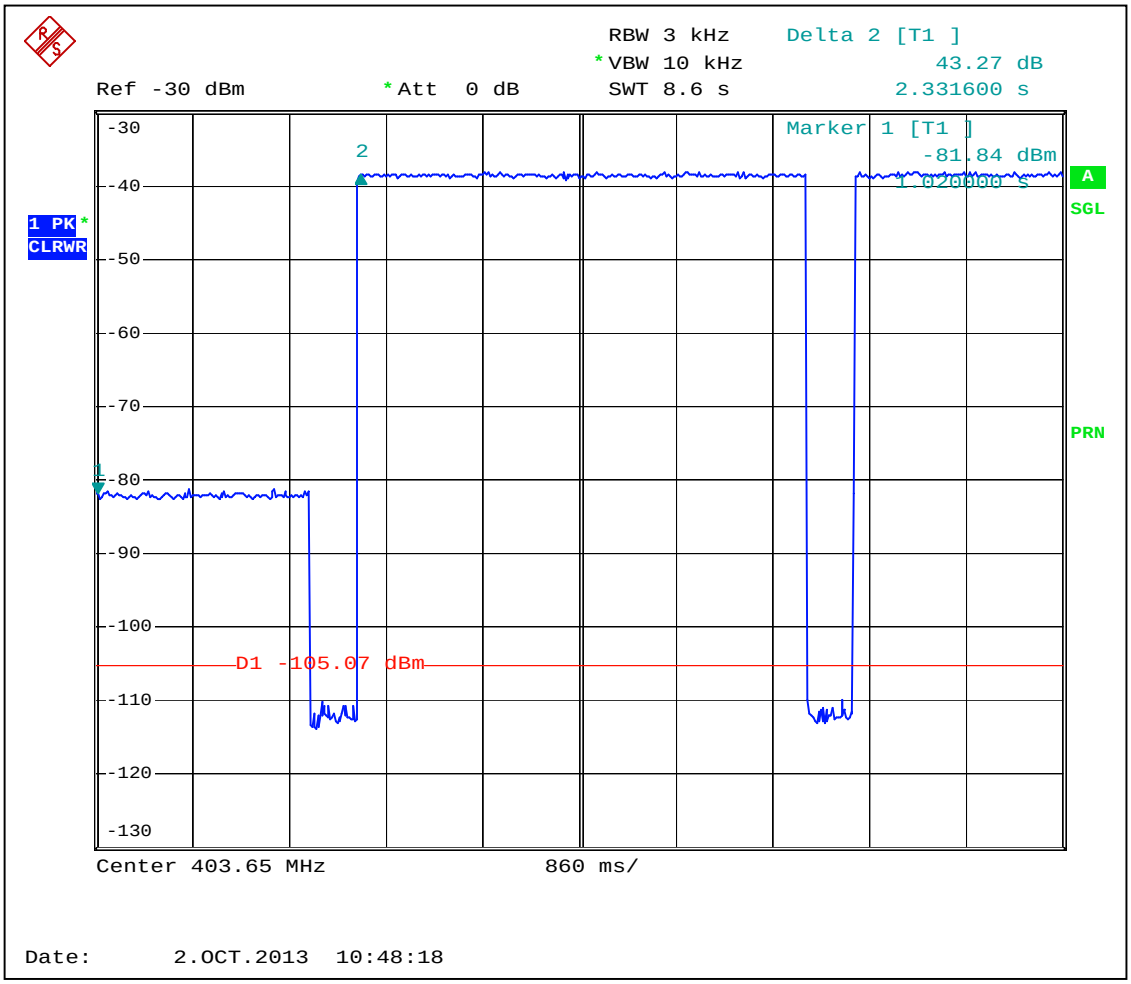
Graph 4.5.4 Scan Cycle Time 3 (940msec)



Graph 4.5.5 Scan Cycle Time 4 (2.28sec)



Graph 4.5.6 Scan Cycle Time 5 (2.33sec)



Minimum Channel Monitoring Period

Each MICS channel shall be monitored for a minimum of 10 milliseconds during each scan cycle of 5 seconds or less.

The level of the out-of-operating-region disturbance was increased sufficiently high to prevent operation under any circumstances on a channel other than fc as specified by the manufacturer. It was verified that the EUT transmits on fc. The CW signal at frequency fc was introduced at a level equal to the out-of operating-region disturbance level. Then the out-of-operating-region disturbance was temporarily removed and the process was initiated and it was verified that the communications do not occur on fc. The out-of-operating-region disturbance was reinserted at a level 3 dB above the level used before. It was verified that the EUT never communicates outside the EUT operating region at fc after reinitiating communication.

The out of operating region disturbance signal was modulated with 0.1 ms pulse whose repetition frequency was adjusted to 100Hz corresponding to a silent period between pulses of 9.9 ms. This condition was monitored for several times, at least 10 attempts, and it was verified that the EUT did not select a channel in the blocking band over several attempts.

Test result: Pass

Channel Access

Immediate access is permitted on any channel having an ambient power level that is below the maximum threshold. If no channel having an ambient power below the maximum threshold is available, the equipment under test shall access and transmit on the least interfered channel.

The blocking band was set to -95.2dBm (10dB above the calculated threshold level), with a notch left open at 403.65MHz. A second notch was created at out-of operating-region by lowering the blocking tones by 7dB. A CW tone was introduced at the center of the channel at -108.2dB (3dB below the calculated threshold). A MICS communication session was then initiated and it was verified that the EUT transmitted only on the center frequency through several attempts. The CW tone at center frequency was then increased by 9dB to -99.2dBm, and it was verified that the EUT transmitted on the center frequency of the LIC channel over 10+ attempts.

Test result: Pass

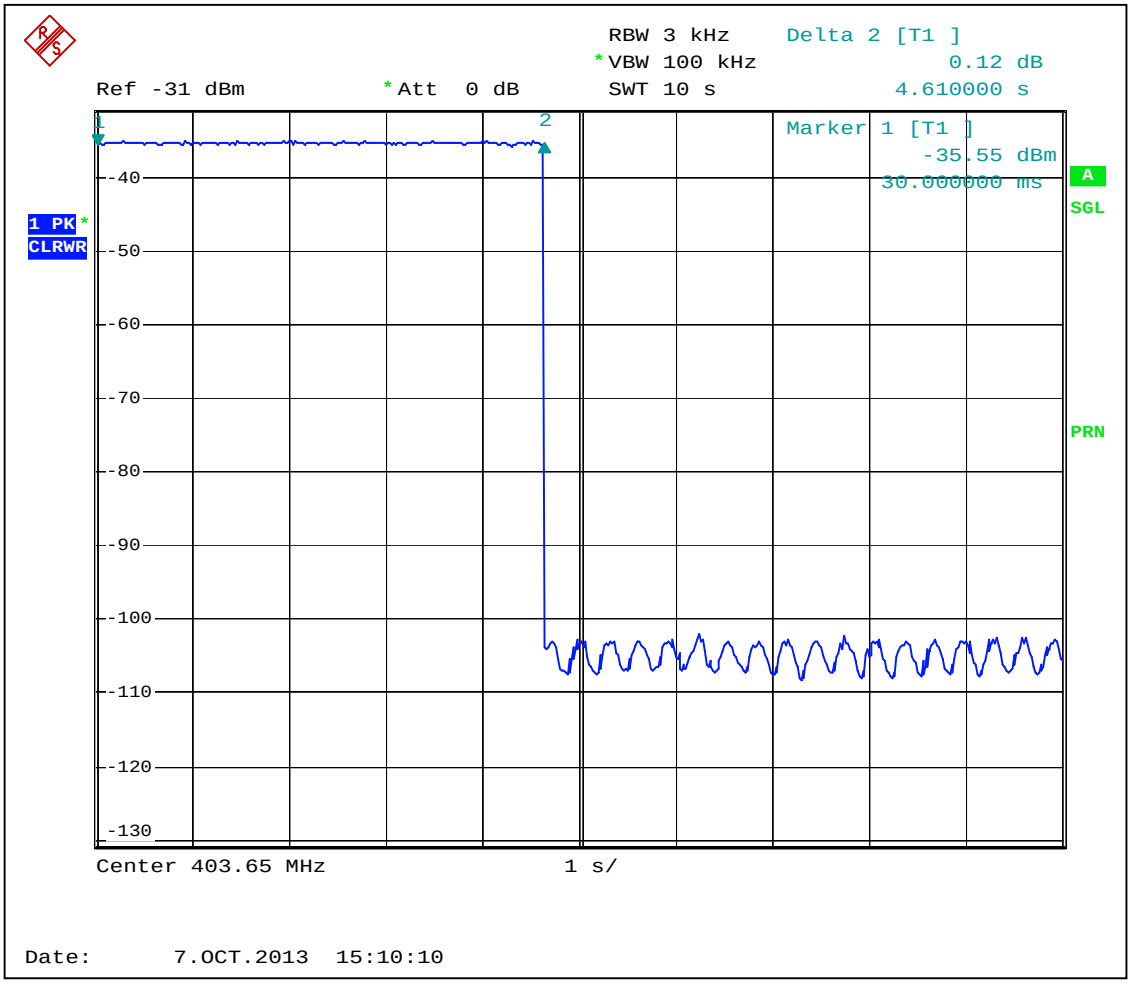
Discontinuation of a MICS session

MICS shall cease transmission in the event the communication session is interrupted for a period of 5 seconds or more.

A MICS communication session was initiated, and the MICS implant was caused to cease transmission during the session. The time from when the implant ceased transmission until the programmer ceased communication was 4.61 seconds, as shown in the plot below. Communication was set on channel 5 (403.65MHz). Power was turned off block the implant transmission.

Test result: Pass

Graph 4.5.7



Use of the Pre-scanned Alternate Channel

Pre-scanned alternate channel operation is not implemented

4.6 Receiver spurious emissions

4.6.1 Enclosure radiated spurious emissions

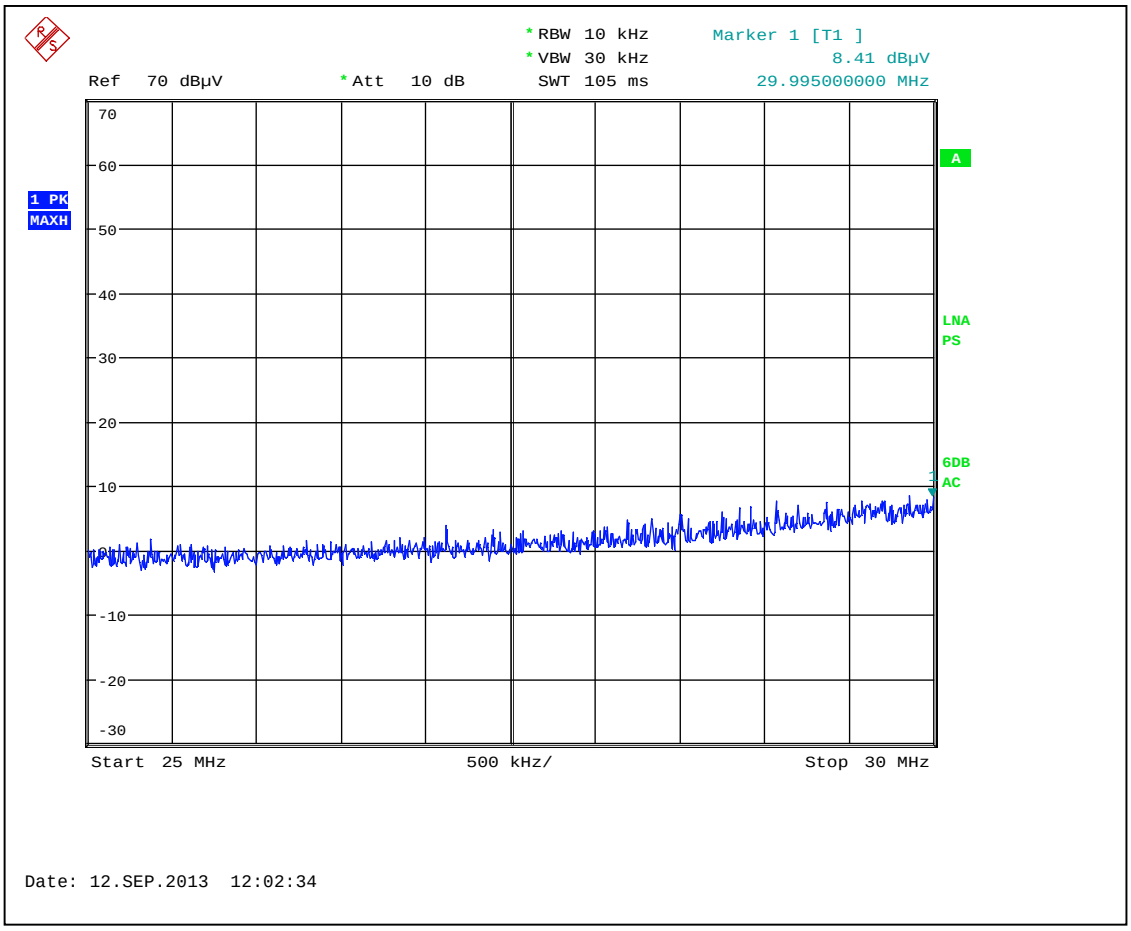
Test location: ☐ OATS ☒ Anechoic Chamber ☐ Other

Test result: **Pass**

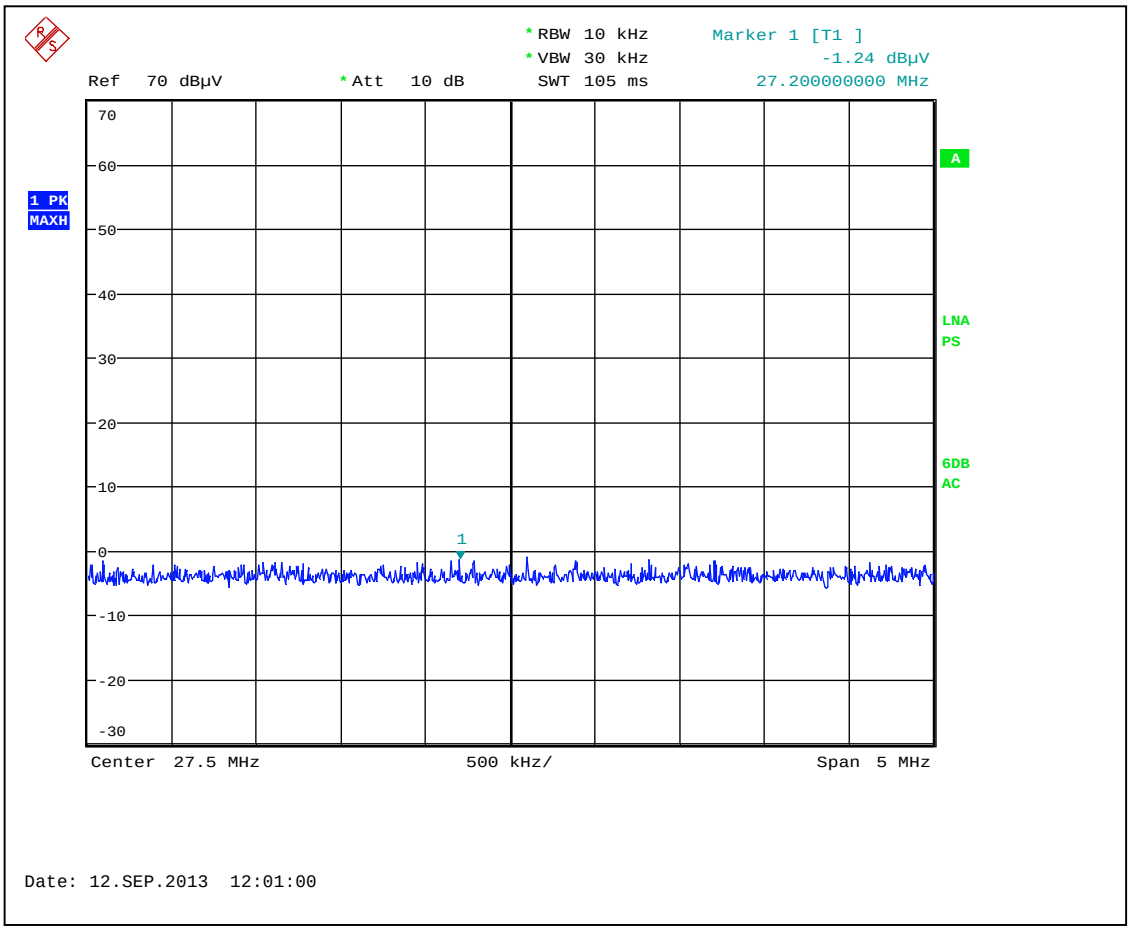
Frequency range: 25MHz-4GHz

Notes: Graphs 4.6.1- 4.6.4 show pre-scan radiated emissions
Spurious emissions below CISPR 22 Class B limits were excluded from substitution measurements.

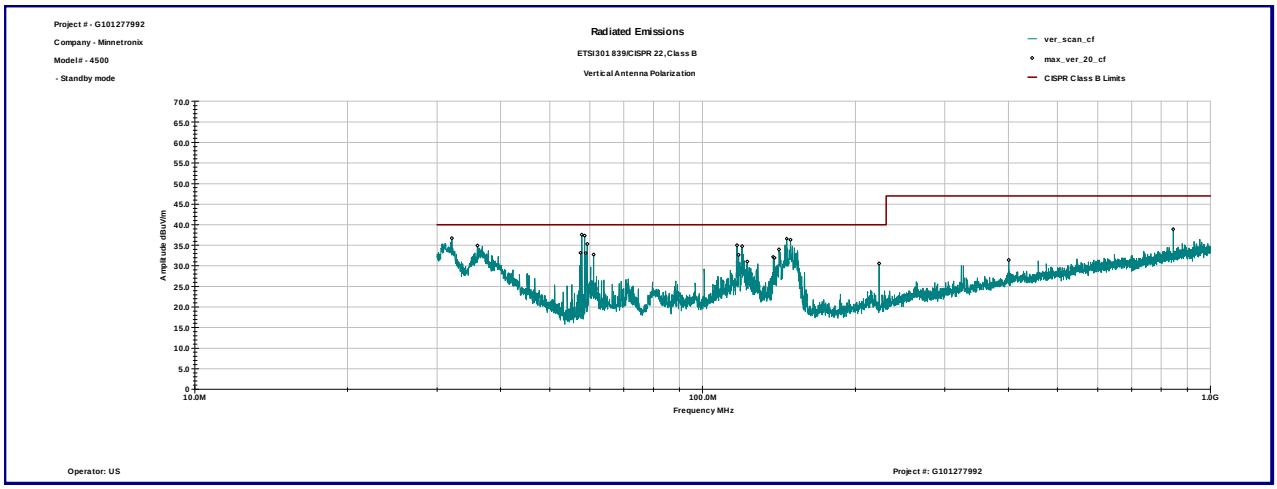
Graph 4.6.1
Vertical Antenna Polarity

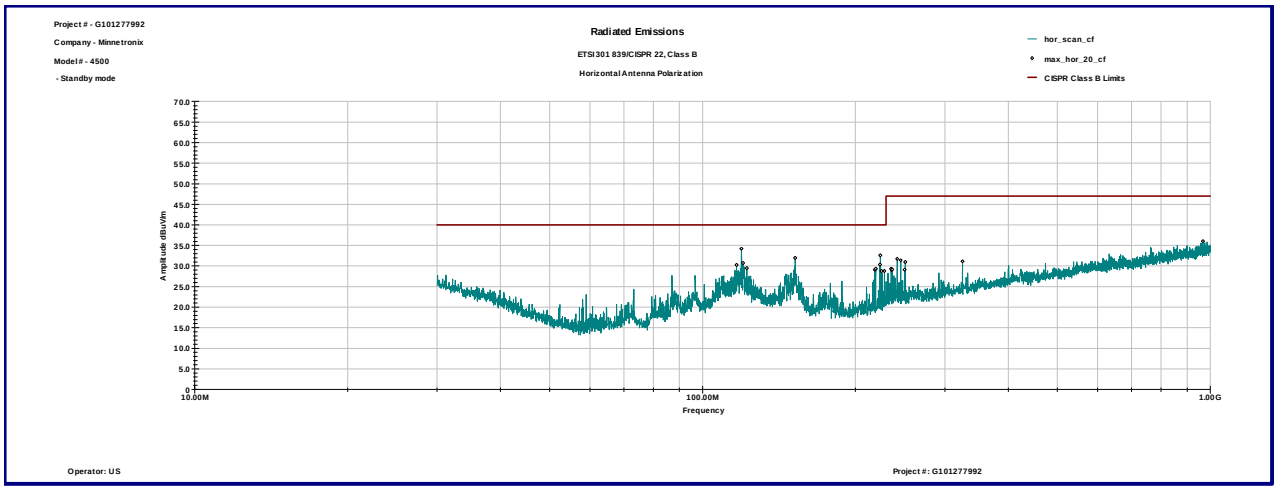


Graph 4.6.2
Horizontal Antenna Polarity

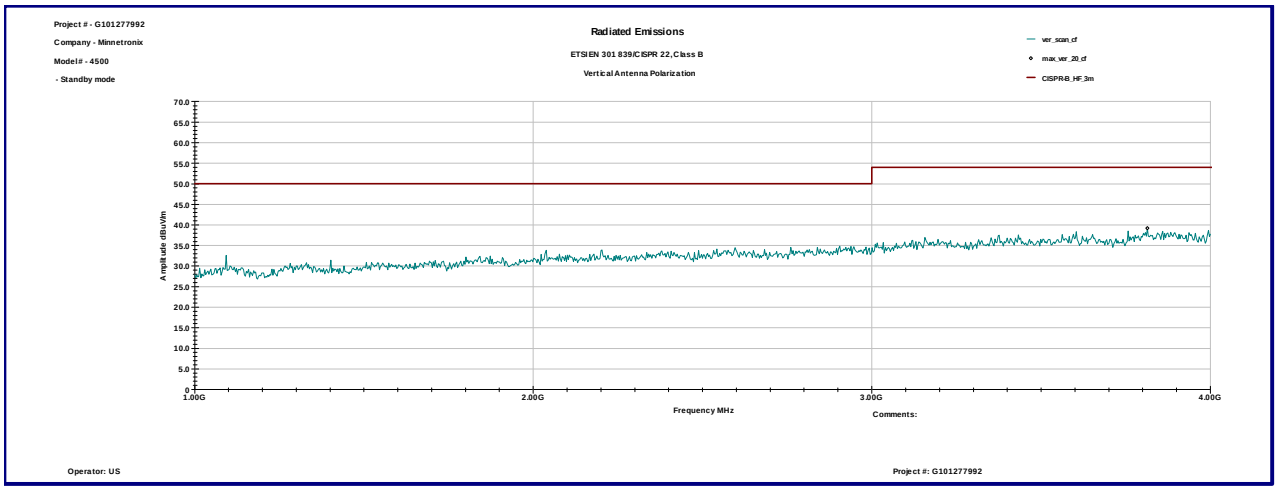


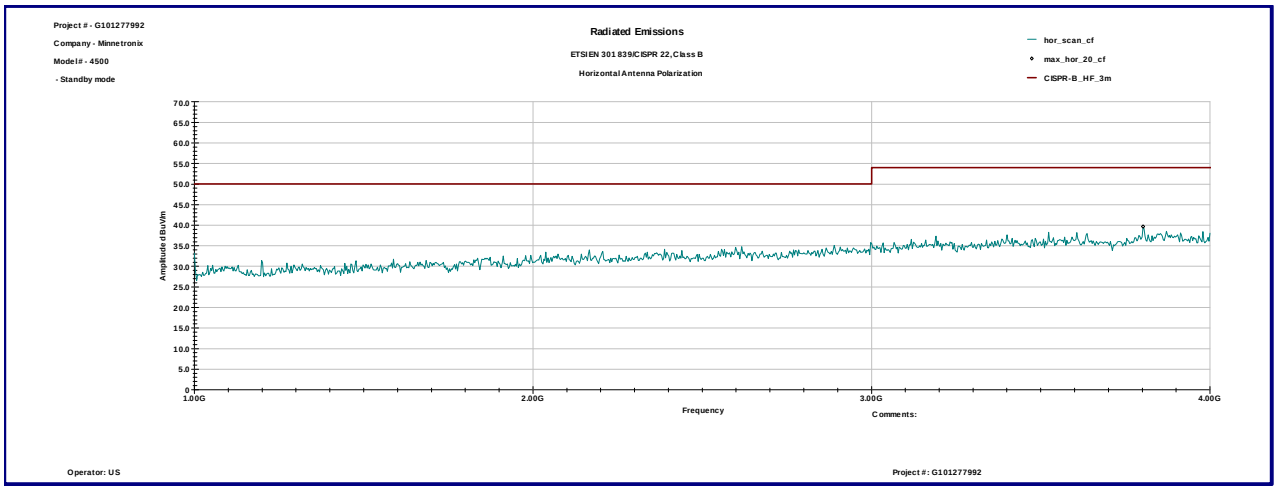
Graph 4.6.3


Project # - G101277992
Company - Minnetronix
Model# - 4500
- Standby mode
Radiated Emissions
ETSI301 839/CISPR 22, Class B
Vertical Antenna Polarization
ver_scan_cf
max_ver_20_cf
CISPR Class B Limits
Amplitude dBuV/m
70.0
65.0
60.0
55.0
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0
10.0M
100.0M
1.0G
Frequency MHz
Operator: US
Project #: G101277992


Project # - G101277992
Company - Minnetronix
Model# - 4500
- Standby mode
Radiated Emissions
ETSI301 839/CISPR 22, Class B
Horizontal Antenna Polarization
hor_scan_cf
max_hor_20_cf
CISPR Class B Limits
Amplitude dBuV/m
70.0
65.0
60.0
55.0
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0
10.00M
100.00M
1.00G
Frequency
Operator: US
Project #: G101277992

Graph 4.6.4


Project # - G101277992
Company - Minnetronix
Model# - 4500
- Standby mode
Radiated Emissions
ETSI EN 301 839/CISPR 22, Class B
Vertical Antenna Polarization
ver_scan_cf
max_ver_20_cf
CISPR-B_HF_3m
Amplitude dBuV/m
Frequency MHz
Comments:
Operator: US
Project #: G101277992

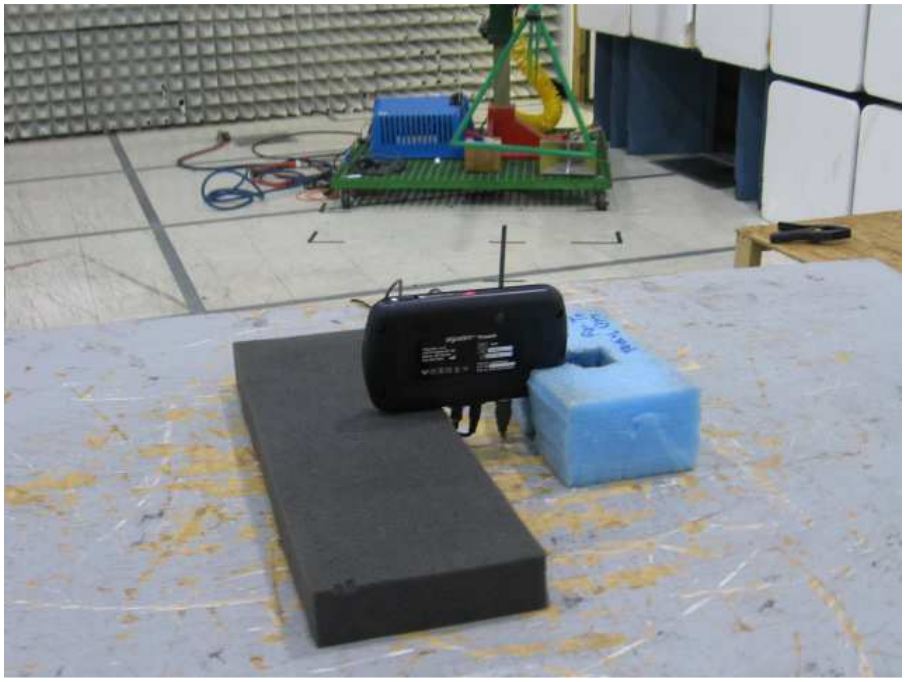

Project # - G101277992
Company - Minnetronix
Model# - 4500
- Standby mode
Radiated Emissions
ETSI EN 301 839/CISPR 22, Class B
Horizontal Antenna Polarization
hor_scan_cf
max_hor_20_cf
CISPR-B_HF_3m
Amplitude dBuV/m
Frequency
Comments:
Operator: US
Project #: G101277992

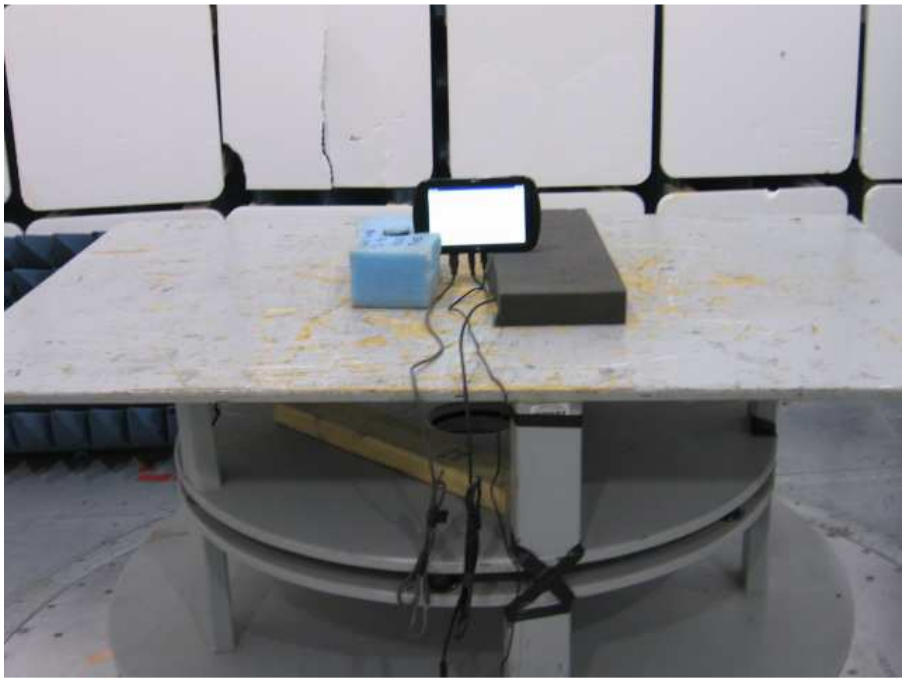
4.7 Radiated Emissions of ancillary equipment enclosure

Description of the test location

Test location:	☐ OATS	☒ Anechoic Chamber
Test distance:	☐ 10 meters	☒ 3 meters
Test result:	**Pass**	
Frequency range:	30MHz-1000MHz	
Max. Emissions margin:	2.4dB below the limits	

Notes: The Radiated Emissions pre-scan was performed in the Anechoic chamber at 3m measurement distance (see Graph 4.7.1 and Table 4.7.1).





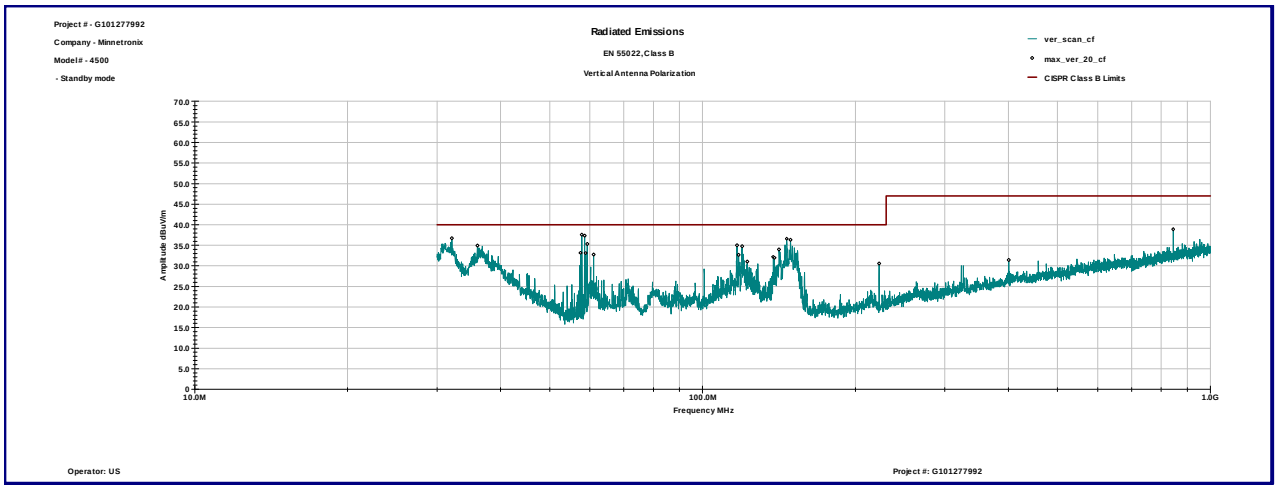
Test Setup Photos

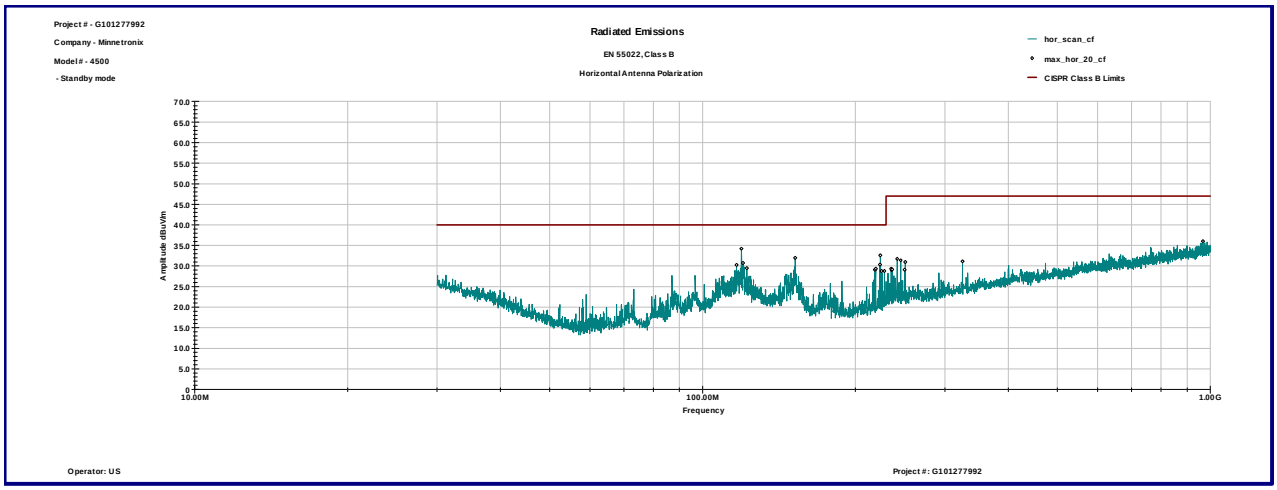
Date:	September 27, 2013	**Result:** **Pass**
Standard:	EN 55022, Class B	
Tested by:	Uri Spector	
Test Point:	Enclosure	
Operation mode:	See Page 7	
Note:	None	

Table 4.7.1

Frequency	Ant. Polarity	Peak Reading dBµV	Total C.F. dB1/m	Total at 3m dBµV/m	Limit dBµV/m	Margin dB
32.113 MHz	V	17.8	18.9	36.7	40.0	-3.3
36.026 MHz	V	18.2	16.8	35.0	40.0	-5.0
57.845 MHz	V	30.1	7.5	37.6	40.0	-2.4
58.607 MHz	V	30.0	7.3	37.4	40.0	-2.6
119.62 MHz	V	20.9	13.9	34.8	40.0	-5.2
141.5 MHz	V	20.8	13.2	34.0	40.0	-6.0
146.48 MHz	V	23.8	12.8	36.6	40.0	-3.4
149.05 MHz	V	23.7	12.7	36.4	40.0	-3.7
400.78 MHz	V	12.5	18.9	31.4	47.0	-15.6
844.74 MHz	V	14.2	24.8	38.9	47.0	-8.1
119.25 MHz	H	20.3	13.9	34.2	40.0	-5.8
152.27 MHz	H	19.5	12.5	32.0	40.0	-8.0
223.96 MHz	H	20.2	12.4	32.6	40.0	-7.4
241.65 MHz	H	17.7	14.0	31.7	47.0	-15.3
245.5 MHz	H	17.0	14.3	31.4	47.0	-15.6
324.94 MHz	H	14.5	16.6	31.2	47.0	-15.9

Graph 4.7.1


Project # - G101277992
Company - Minnetronix
Model# - 4500
- Standby mode
Radiated Emissions
EN 55022,Class B
Vertical Antenna Polarization
ver_scan_cf
max_ver_20_cf
CISPR Class B Limits
Amplitude dBuV/m
70.0
65.0
60.0
55.0
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0
10.0M
100.0M
1.0G
Frequency MHz
Operator: US
Project #: G101277992


Project # - G101277992
Company - Minnetronix
Model# - 4500
- Standby mode
Radiated Emissions
EN 55022,Class B
Horizontal Antenna Polarization
hor_scan_cf
max_hor_20_cf
CISPR Class B Limits
Amplitude dBuV/m
70.0
65.0
60.0
55.0
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0
10.00M
100.00M
1.00G
Frequency
Operator: US
Project #: G101277992

4.8 Conducted Emissions at AC port, DC port, and Telecommunication port

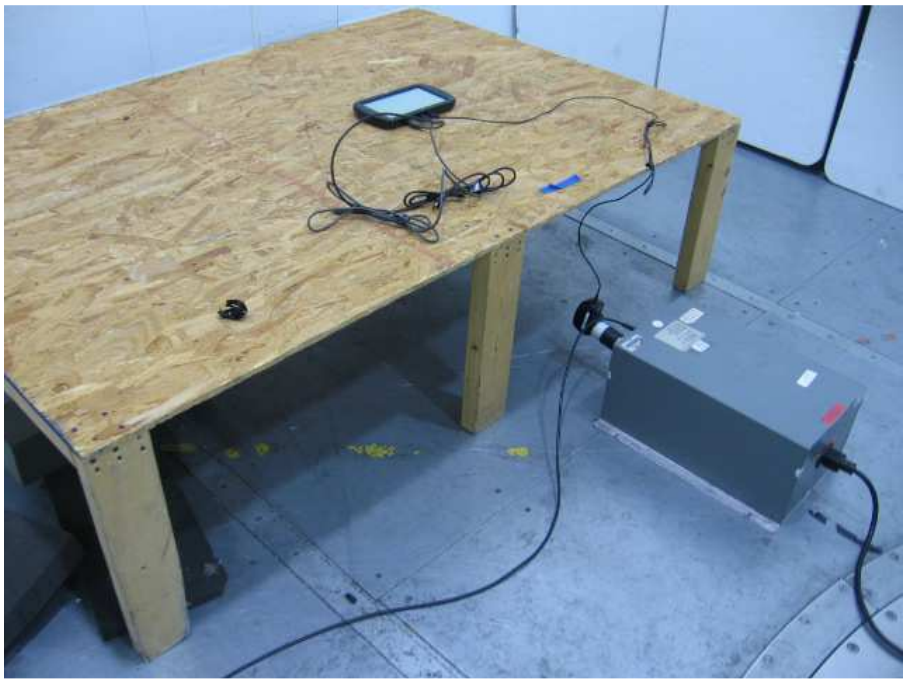
Test location: ☐ OATS ☐ Anechoic Chamber ☐ Other

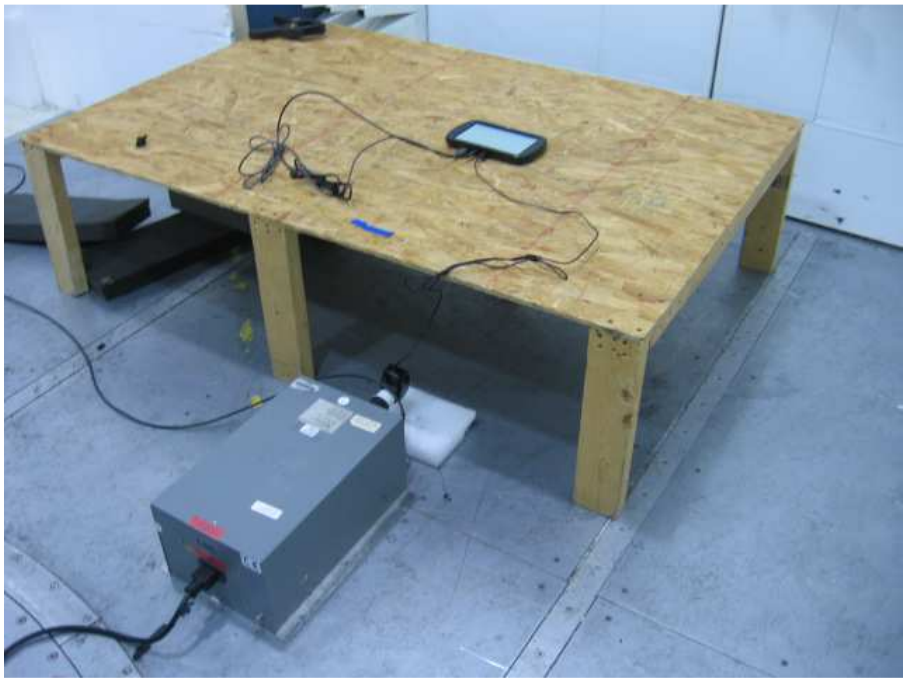
Test result: **Pass**

Frequency range: 0.15MHz-30MHz

Max. Emissions margin: 20.4dB below the limits

Notes: The EUT does not have Telecommunication port.





Test Setup Photos

Date:	September 16, 2013	**Result:**	**Pass**
Standard:	EN 55022, Class B		
Tested by:	Uri Spector		
Test Point:	AC Port		
Operation mode:	See Page 7		
Note:	None		

Table 4.8.1

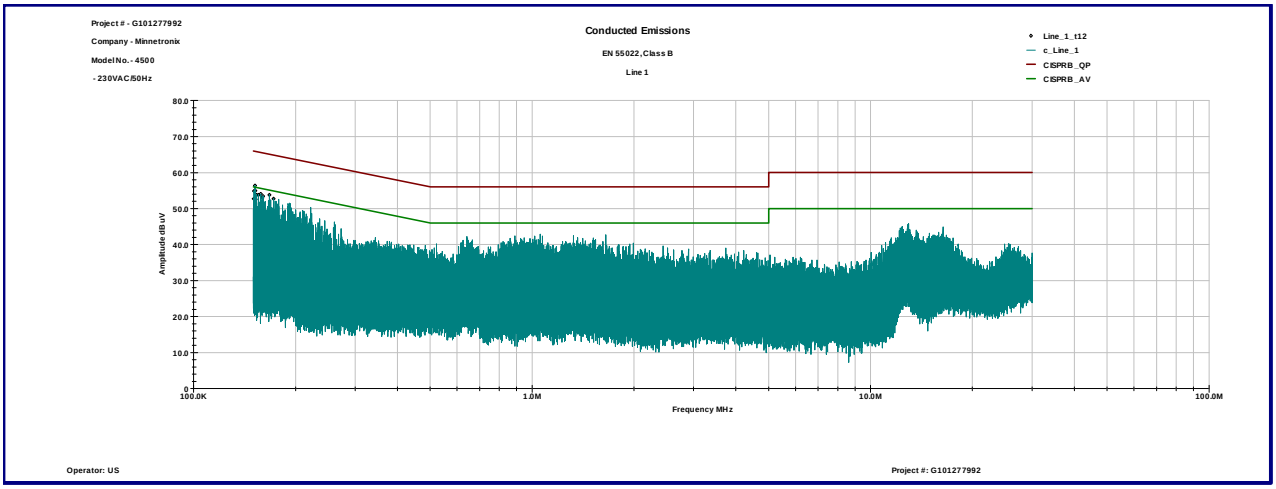
Line 1

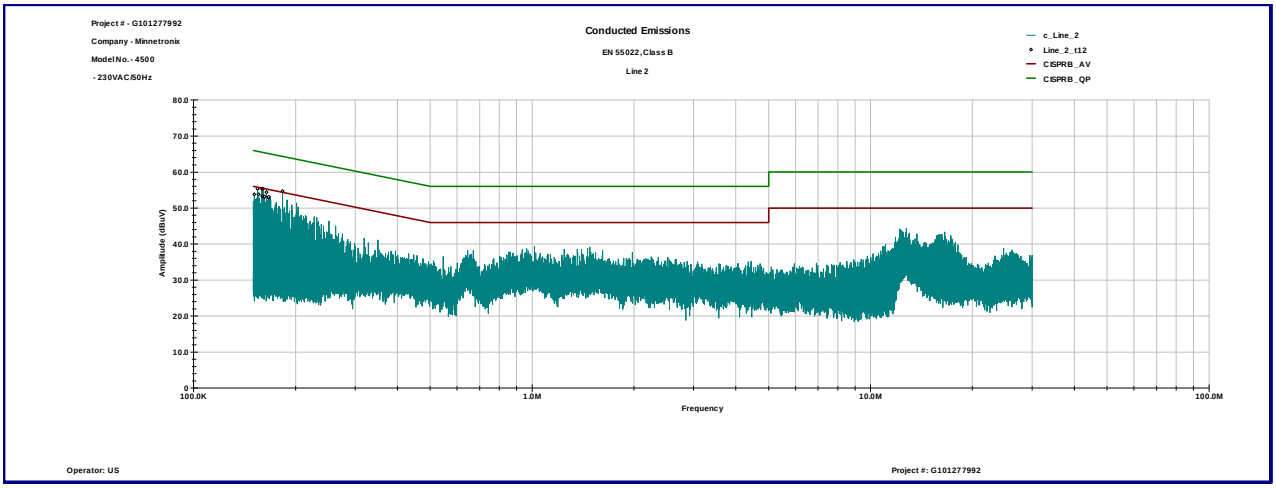
Frequency MHz	QP dBµV	AVG dBµV	Cable Loss dB	QP Lim dBµV	AVG Lim dBµV	QP Margin dB	AVG Margin dB
0.151	44.5	19.4	0.1	65.9	55.9	-21.4	-36.5
0.158	43.5	18.9	0.1	65.6	55.6	-22.0	-36.6
0.167	42.3	18.5	0.1	65.1	55.1	-22.7	-36.5
0.192	39.2	17.4	0.1	63.9	53.9	-24.7	-36.5
1.055	34.9	16.4	0.2	56.0	46.0	-20.9	-29.4
12.948	38.7	24.3	0.9	60.0	50.0	-20.4	-24.8

Line 2

Frequency MHz	QP dBµV	AVG dBµV	Cable Loss dB	QP Lim dBµV	AVG Lim dBµV	QP Margin dB	AVG Margin dB
0.154	43.7	22.5	0.1	65.8	55.8	-22.0	-33.2
0.164	42.9	22.6	0.1	65.3	55.3	-22.3	-32.6
0.183	40.1	22.0	0.1	64.3	54.3	-24.2	-32.3
0.645	31.2	23.7	0.2	56.0	46.0	-24.6	-22.1
12.760	35.5	27.1	0.9	60.0	50.0	-23.6	-22.0
16.557	35.5	21.8	1.0	60.0	50.0	-23.5	-27.2

Graph 4.8.1


Project # - G101277992
Company - Minnetronix
Model No. - 4500
- 230VAC/50Hz
Conducted Emissions
EN 55022,Class B
Line 1
Line_1_t12
c_Line_1
CISPRB_QP
CISPRB_AV
Amplitude dBuV
Frequency MHz
100.0K
1.0M
10.0M
100.0M
Operator: US
Project #: G101277992


Project # - G101277992
Company - Minnetronix
Model No. - 4500
- 230VAC/50Hz
Conducted Emissions
EN 55022,Class B
Line 2
c_Line_2
Line_2_t12
CISPRB_AV
CISPRB_QP
Amplitude (dBuV)
Frequency
100.0K
1.0M
10.0M
100.0M
Operator: US
Project #: G101277992

4.9 Harmonic Current Emissions

Date:	October 10, 2013	**Result:** **Pass**
Standard:	EN 61000-3-2	
Tested by:	Richard Blonigen	
Test Point:	AC Input	
Operation mode:	See Page 7	
Note:	None	

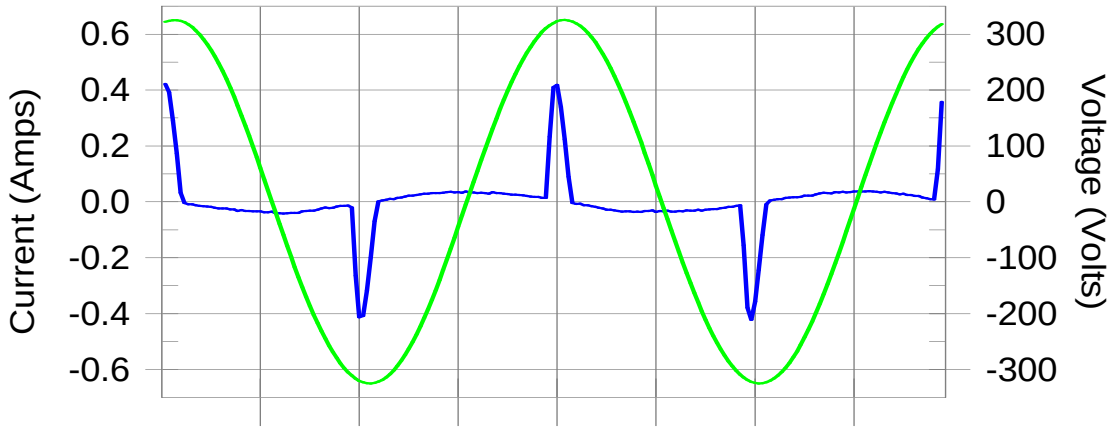
Test Parameters

Frequency Range:	50Hz – 2000Hz
Observation Period:	Tobs = 10 min
Classification:	☒ Class A ☐ Class B ☐ Class C ☐ Class D

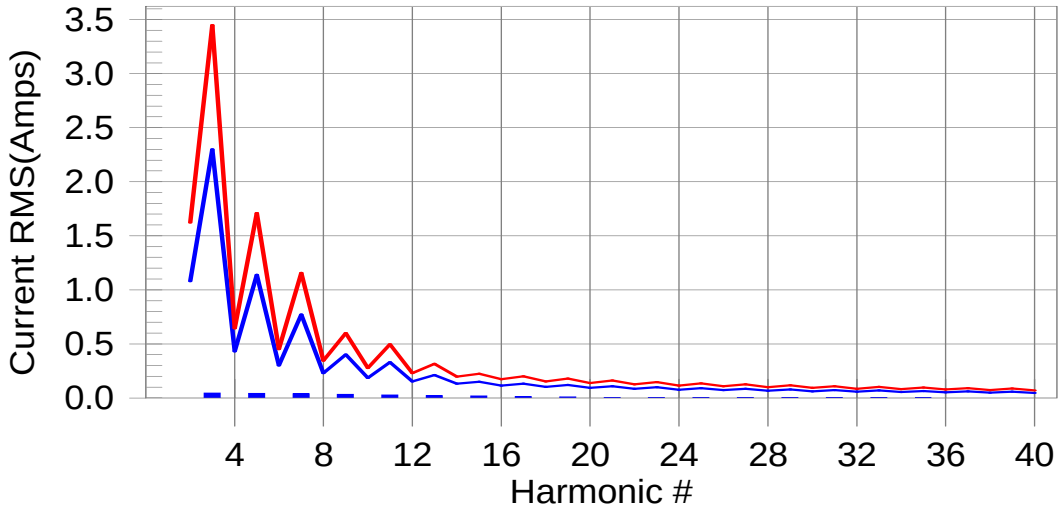
Notes: None

Test Result: Pass **Source qualification: Normal**

Current & voltage waveforms



Harmonics and Class A limit line **European Limits**



Test result: Pass **Worst harmonic was #15 with 11.94% of the limit.**

Current Test Result Summary (Run time)

Test Result: Pass **Source qualification: Normal**
THC(A): 0.09 **I-THD(%): 164.16** **POHC(A): 0.006** **POHC Limit(A): 0.309**
Highest parameter values during test:

V_RMS (Volts):	**229.90**	**Frequency(Hz):**	**50.00**
I_Peak (Amps):	**0.451**	**I_RMS (Amps):**	**0.108**
I_Fund (Amps):	**0.056**	**Crest Factor:**	**4.186**
Power (Watts):	**10.7**	**Power Factor:**	**0.433**

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.000	1.080	0.0	0.000	1.620	0.01	Pass
3	0.045	2.300	2.0	0.045	3.450	1.31	Pass
4	0.000	0.430	0.0	0.000	0.645	0.04	Pass
5	0.042	1.140	3.7	0.042	1.710	2.47	Pass
6	0.000	0.300	0.0	0.001	0.450	0.13	Pass
7	0.038	0.770	5.0	0.039	1.155	3.34	Pass
8	0.000	0.230	0.0	0.000	0.345	0.11	Pass
9	0.034	0.400	8.4	0.034	0.600	5.65	Pass
10	0.000	0.184	0.0	0.000	0.276	0.14	Pass
11	0.029	0.330	8.7	0.029	0.495	5.81	Pass
12	0.000	0.153	0.0	0.000	0.230	0.20	Pass
13	0.023	0.210	11.0	0.023	0.315	7.41	Pass
14	0.000	0.131	0.0	0.000	0.197	0.16	Pass
15	0.018	0.150	11.9	0.018	0.225	8.03	Pass
16	0.000	0.115	0.0	0.000	0.173	0.15	Pass
17	0.013	0.132	9.9	0.013	0.199	6.62	Pass
18	0.000	0.102	0.0	0.000	0.153	0.23	Pass
19	0.009	0.118	7.5	0.009	0.178	5.09	Pass
20	0.000	0.092	0.0	0.000	0.138	0.13	Pass
21	0.006	0.107	5.4	0.006	0.161	3.69	Pass
22	0.000	0.084	0.0	0.000	0.125	0.12	Pass
23	0.004	0.098	0.0	0.004	0.147	2.93	Pass
24	0.000	0.077	0.0	0.000	0.115	0.20	Pass
25	0.004	0.090	0.0	0.004	0.135	3.04	Pass
26	0.000	0.071	0.0	0.000	0.106	0.16	Pass
27	0.004	0.083	0.0	0.004	0.125	3.46	Pass
28	0.000	0.066	0.0	0.000	0.099	0.20	Pass
29	0.004	0.078	0.0	0.004	0.116	3.77	Pass
30	0.000	0.061	0.0	0.000	0.092	0.26	Pass
31	0.004	0.073	0.0	0.004	0.109	3.70	Pass
32	0.000	0.058	0.0	0.000	0.086	0.20	Pass
33	0.003	0.068	0.0	0.003	0.102	3.34	Pass
34	0.000	0.054	0.0	0.000	0.081	0.19	Pass
35	0.003	0.064	0.0	0.003	0.096	2.71	Pass
36	0.000	0.051	0.0	0.000	0.077	0.16	Pass
37	0.002	0.061	0.0	0.002	0.091	1.94	Pass
38	0.000	0.048	0.0	0.000	0.073	0.21	Pass
39	0.001	0.058	0.0	0.001	0.087	1.37	Pass
40	0.000	0.046	0.0	0.000	0.069	0.31	Pass

4.10 Voltage Fluctuations and Flicker

Date:	October 10, 2013	**Result:** **Pass**
Standard:	EN 61000-3-3	
Tested by:	Richard Blonigen	
Test Point:	AC Input	
Operation mode:	See Page 7	
Note:	None	

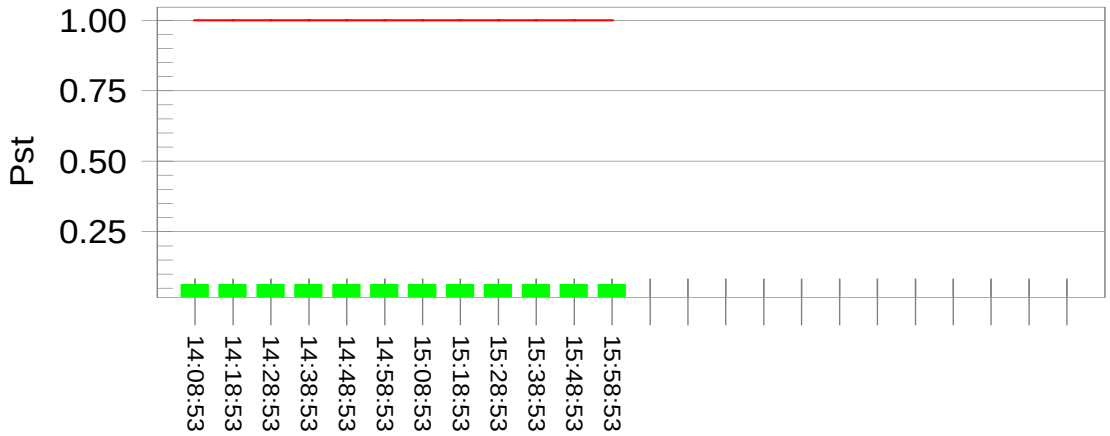
Test Parameters

Flicker Value:	☒ P_{st} ☒ P_{lt}
Observation Period:	T_{obs} = 120 min
Relative Voltage Change:	☒ d_c ☒ d_{max} ☒ d(t)

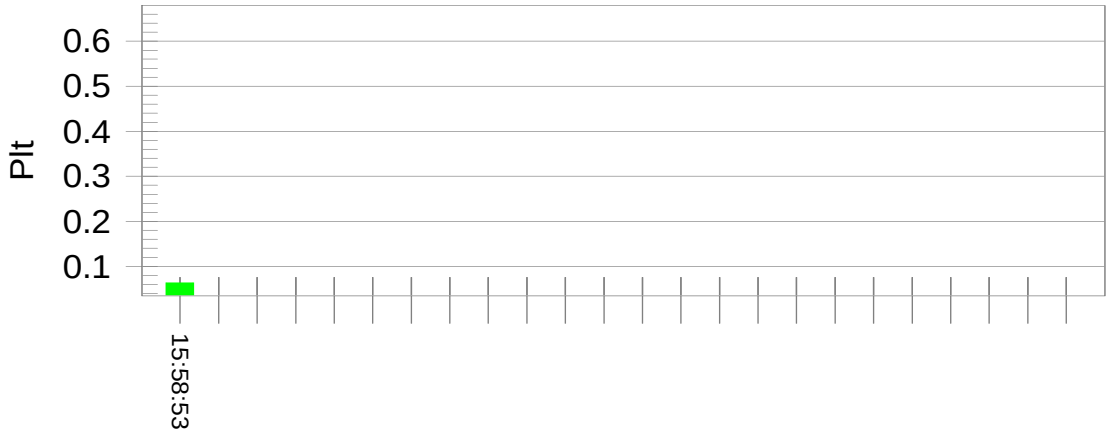
Notes: N/A

Test Result: Pass **Status: Test Completed**

Pst_i and limit line **European Limits**



Plt and limit line



Parameter values recorded during the test:

Vrms at the end of test (Volt):	**229.96**			
Highest dt (%):	**0.00**	**Test limit (%):**	**3.30**	**Pass**
Time(mS) > dt:	**0.0**	**Test limit (mS):**	**500.0**	**Pass**
Highest dc (%):	**0.00**	**Test limit (%):**	**3.30**	**Pass**
Highest dmax (%):	**0.00**	**Test limit (%):**	**4.00**	**Pass**
Highest Pst (10 min. period):	**0.064**	**Test limit:**	**1.000**	**Pass**
Highest Plt (2 hr. period):	**0.064**	**Test limit:**	**0.650**	**Pass**

4.11 Radiated, Radio-frequency, Electromagnetic Field

Description of the test location

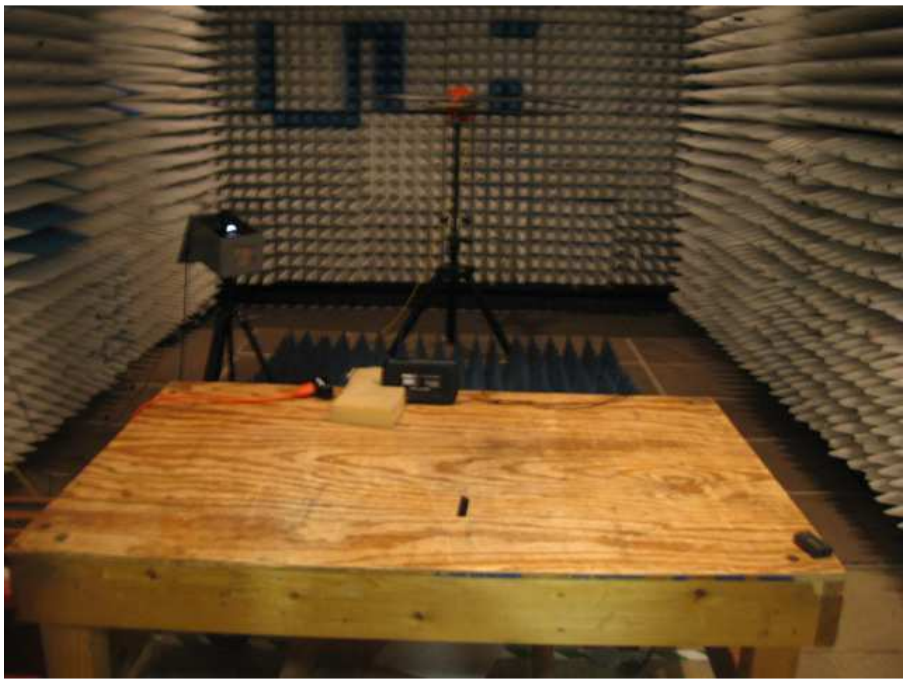
Test location: ☒ Immunity Anechoic Chamber ☐ 3 meters Anechoic Chamber

Date:	November 15, 2013	**Result:** **Pass**
Standard:	EN 61000-4-3	
Tested by:	Ivaylo Nadarliyski	
Test Point:	Four sides of EUT	
Operation mode:	See Page 7	
Note:	None	

Test specification

Frequency range:	☒ 80 MHz to 1000 MHz ☒ 1.4 GHz to 2.7 GHz
Field strength:	☒ 3 V/m ☐ 10 V/m
EUT - antenna separation:	☒ 2.5 m
Modulation:	☒ AM: 80 % ☒ sinusoidal 1000Hz ☐ PM duty cycle 50% 100Hz ☐ 900 MHz Pulse Modulation
Frequency step:	☒ 1 % with 9 sec dwell time
Antenna polarisation:	☒ horizontal ☒ vertical

Notes: The EUT lost MICS communication near 400MHz and did not re-establish communication until the application was restarted manually. Per manufacturer, the Essential Performance of the Clinician Programmer is that it cannot cause the IPG or EPG to exceed pre-set clinician output stimulation limits. Therefore the freeze requiring a power reset to restore normal operation during Electrostatic Discharge, loss of communication with the PFT during radiated RF immunity, or damage to power adaptor during surge does not compromise patient safety or Essential Performance of the device.



Test Setup Photo

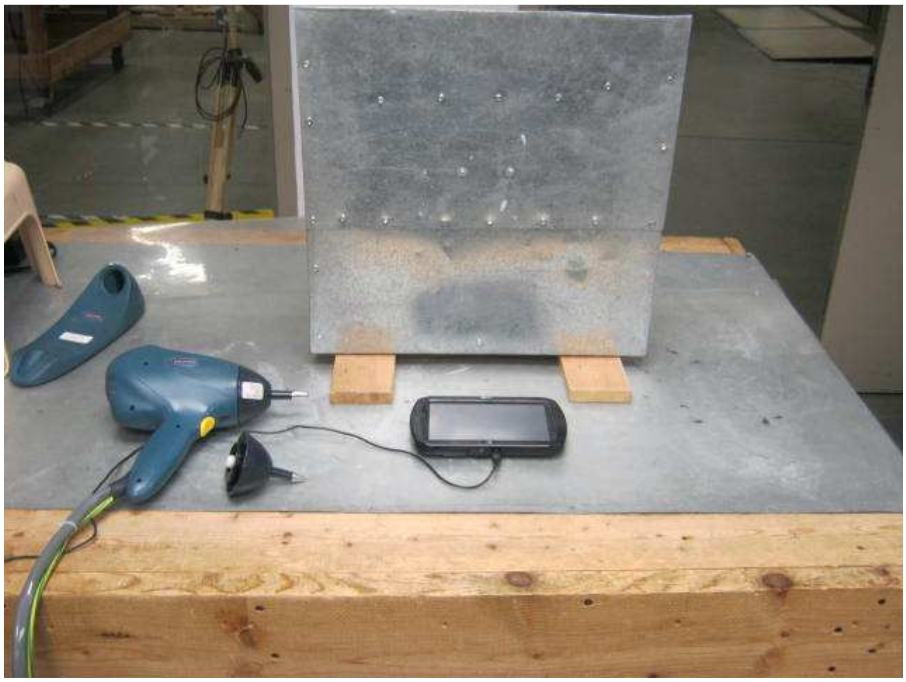
4.12 Electrostatic Discharge

Date:	November 18, 2013	**Result:** **Pass**
Standard:	EN 61000-4-2	
Tested by:	Richard Blonigen	
Test Point:	Enclosure	
Operation mode:	See Page 7	
Note:	None	

Test specification

Contact discharge voltage:	☒ 2 kV ☒ 4 kV ☐ 6 kV
Air discharge voltage:	☒ 2 kV ☒ 4 kV ☒ 6 kV ☒ 8 kV
Discharge impedance:	☒ 330 Ω / 150 pF ☐ Other:
Discharge factor:	☒ ≥ 1 sec.
Number of discharges:	☒ ≥ 10 per each test level and polarity
Type of discharge:	Direct Discharge ☒ Air Discharge ☒ Contact Discharge Indirect Discharge ☒ Contact Discharge
Polarity:	☒ Positive ☒ Negative
Test Setup:	☒ see photo of the test set-up
Discharge location:	☒ all external locations accessible by hand ☒ horizontal plate (HCP) ☒ vertical coupling plate (VCP)

Notes: During the test no deviation was detected to the selected operation mode(s).



Test Setup Photo

4.13 Electrical Fast Transients / Burst

Description of the test location

Test location: ☐ Shielded Room ☐ 3 meters Anechoic Chamber

Date:	October 11, 2013	**Result:** **Pass**
Standard:	EN 61000-4-4	
Tested by:	Richard Blonigen	
Test Point:	☒ L1 ☒ L2 ☐ L3 ☒ N ☒ G ☐ I/O	
Operation mode:	See Page 7	
Note:	None	

Test specification

Coupling network:	☒ 0.5 kV ☒ 1 kV ☐ 2 kV
Coupling clamp:	☐ 0.5 kV ☐ 1 kV
Burst frequency:	☒ 5.0 kHz
Coupling duration:	☒ ≥ 60 s
Polarity:	☒ positive ☒ negative

Coupling points

Cable description:	**AC Port**	
Screening:	☐ screened	☒ unscreened
Status:	☐ passive	☒ active
Signal transmission:	☐ analogue	☒ digital
Length:	☒ 0.5m	
Cable description:		
Screening:	☐ screened	☐ unscreened
Status:	☐ passive	☐ active
Signal transmission:	☐ analogue	☐ digital
Length:	☐	
Cable description:		
Screening:	☐ screened	☐ unscreened
Status:	☐ passive	☐ active
Signal transmission:	☐ analogue	☐ digital
Length:	☐	

Notes: During the test no deviation was detected to the selected operation mode(s).

Test Setup Photo

4.14 RF common mode (Conducted Disturbances)

Description of the test location

Test location: ☐ Shielded Room ☐ 3 meters Anechoic Chamber

Date:	November 14, 2013	**Result:** **Pass**
Standard:	EN 61000-4-6	
Tested by:	Ivaylo Nadarliyski	
Test Point:	☒ AC ☐ I/O	
Operation mode:	See Page 7	
Note:	None	

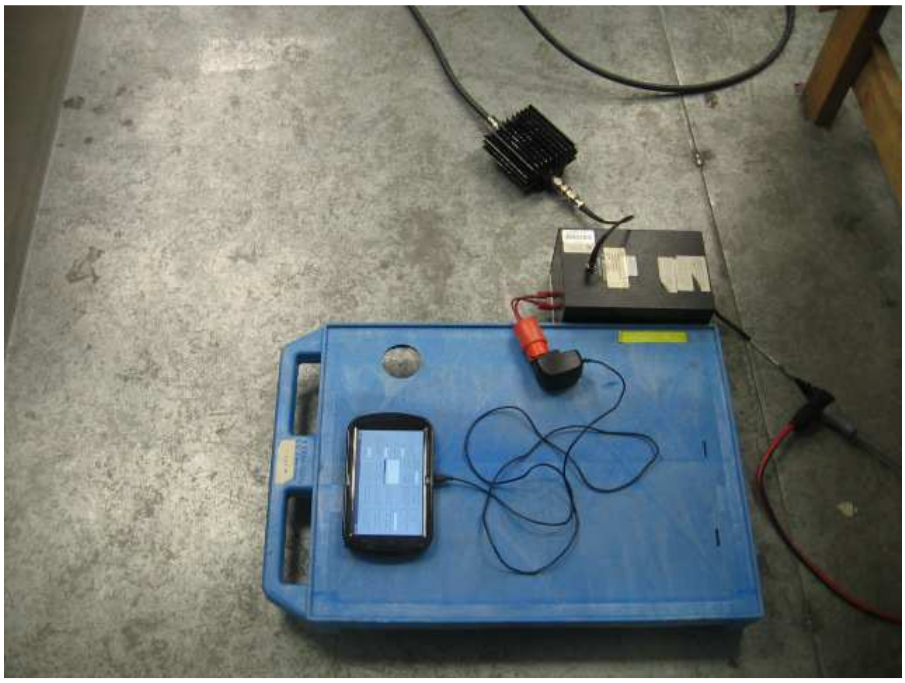
Test specification

Frequency range:	☒ 0.15 MHz to 80 MHz
Test voltage:	☒ 3 V ☐ 10 V RMS
Modulation:	☒ AM: 80 % ☒ sinusoidal 1KHz
Frequency step:	☒ 1 % with 2 sec dwell time

Coupling points

Cable description :	**AC Port**	
Screening:	☐ screened	☒ unscreened
Status:	☐ passive	☒ active
Signal transmission:	☐ analogue	☒ digital
Length:	☒ 0.3m	
Cable description:		
Screening:	☐ screened	☐ unscreened
Status:	☐ passive	☐ active
Signal transmission:	☐ analogue	☐ digital
Length:	☐	
Cable description :		
Screening:	☐ screened	☐ unscreened
Status:	☐ passive	☐ active
Signal transmission:	☐ analogue	☐ digital
Length:	☐	
Cable description:		
Screening:	☐ screened	☐ unscreened
Status:	☐ passive	☐ active
Signal transmission:	☐ analogue	☐ digital
Length:	☐	

Notes: During the test no deviation was detected to the selected operation mode(s).



Test Setup Photo

4.15 Voltage Dips and Voltage Interruptions

Date:	October 11, 2013	**Result:** **Pass**
Standard:	EN 61000-4-11	
Tested by:	Richard Blonigen	
Test Point:	AC Input	
Operation mode:	See Page 7	
Note:	None	

Test specification

Nominal Mains Voltage (V_N):	☒ 230 V AC ☐ 120 V AC
Level of reduction (dip):	☒ 100%
Number of periods:	☒ 0.5
Phase angle:	☒ 0 ° ☒ 90 ° ☒ 180 ° ☒ 270 °
Number of Interruptions:	☒ 3
Repetition:	☒ 15 sec
Level of reduction (dip):	☒ 100%
Number of periods:	☒ 1.0
Phase angle:	☒ 0 ° ☒ 90 ° ☒ 180 ° ☒ 270 °
Number of Interruptions:	☒ 3
Repetition:	☒ 15 sec
Level of reduction (dip):	☒ 60%
Duration:	☒ 200mS
Phase angle:	☒ 0 ° ☒ 90 ° ☒ 180 ° ☒ 270 °
Number of Interruptions:	☒ 3
Repetition:	☒ 15 sec
Level of reduction (dip):	☒ 30%
Duration:	☒ 500mS
Phase angle:	☒ 0 ° ☒ 90 ° ☒ 180 ° ☒ 270 °
Number of Interruptions:	☒ 3
Repetition:	☒ 15 sec
Level of reduction (dip):	☒ 100%
Interruption duration:	☒ 5 sec
Phase angle:	☒ 0 ° ☒ 90 ° ☒ 180 ° ☒ 270 °
Number of Interruptions:	☒ 3
Repetition:	☒ 15 sec

Notes: During the test no deviation was detected to the selected operation mode(s). During 5 sec interruption the EUT was powered from the internal battery and resumes operation from AC port.

4.16 Surges Immunity

Date:	October 29, 2013	**Result:** **Pass**
Standard:	EN 61000-4-5	
Tested by:	Ivaylo Nadarliyski	
Test Point:	☒ L1 ☐ L2 ☐ L3 ☒ N ☐ G ☐ I/O	
Operation mode:	See Page 7	
Note:	None	

Test specification

Source impedance: 12 Ω + 9µF	☐ 0.5 kV ☐ 1 kV ☐ 2 kV ☐ 4 kV ☐ Other
Source impedance: 2 Ω + 18µF	☒ 0.5 kV ☒ 1 kV ☐ 2 kV ☐ 4 kV ☐ Other
Polarity:	☒ positive ☐ negative
Phase angle:	☒ 0° ☒ 90° ☒ 180° ☒ 270°
Line-to-ground surges for I/O lines:	☐ 0.5 kV ☐ 1 kV
Repetition rate:	☒ 60 s
Number of surges:	☒ 5 surges at each position

Coupling points

Cable description:	**AC Port**
Screening:	☐ screened ☒ unscreened
Status:	☐ passive ☒ active
Signal transmission:	☐ analogue ☒ digital
Length:	☒ 2m
Cable description:	
Screening:	☐ screened ☐ unscreened
Status:	☐ passive ☐ active
Signal transmission:	☐ analogue ☐ digital
Length:	☐
Cable description:	
Screening:	☐ screened ☐ unscreened
Status:	☐ passive ☐ active
Signal transmission:	☐ analogue ☐ digital
Length:	☐

Notes: During the surge test, the EUT stopped charging due to the damage to the AC adapter. Per manufacturer, the Essential Performance of the Clinician Programmer is that it cannot cause the IPG or EPG to exceed pre-set clinician output stimulation limits. Therefore the freeze requiring a power reset to restore normal operation during Electrostatic Discharge, loss of communication with the PFT during radiated RF immunity, or damage to power adaptor during surge does not compromise patient safety or Essential Performance of the device.

Test Setup Photo

5.0 TEST EQUIPMENT

DESCRIPTION	MANUFACTURER	MODEL	SERIAL NO.	INTERTEK ID	CAL DUE	USED
Spectrum Analyzer	R & S	ESU	100398	25283	12/19/2013	☒
Spectrum Analyzer	R & S	FSP 40	100024	12559	11/29/2013	☒
Bicono-Log Antenna	Schaffner-Teseq	CBL6112B	2468	9734	11/30/2013	☒
Horn Antenna	EMCO	3115	6579	15580	07/18/2014	☒
LISN	Fischer Custom Communications	FCC-LISN-50-25-2	2014	9665	04/23/2014	☒
System	Quantum Change	TILE! Instrument Control	Ver. 3.4.K.29	15259	VBU	☒
Pre-Amplifier	MITEQ	AMF-5D-00501800-28-13P	1122951	13475	11/01/2013	☒
Environmental Chamber	ESPEC	ESX-4CA	0111386	24300	04/11/2014	☒
Power Amplifier	IFI	SMX150	N987-0809	26024	VBU	☒
Power Amplifier	Milmega	ASO104-30/30BB	980047	12665	VBU	☒
Signal Generator	R & S	SMT 03	DE12157	9950	11/30/2013	☒
Radiant Arrow Antenna	Amplifier Research	AT5080	304256	12723	VBU	☒
ESD Simulator	Schaffner	NSG 438	311	17071	04/11/2014	☒
Power Meter	HP	HP 437B	3215U11273	15237	05/20/2014	☒
Power Sensor	HP	8482A	3318A26196	172159	07/16/2014	☒
Power Source/Analyzer	California Instruments System	5001ix	55864, 55863, 55862, 72277	17668-17673	05/10/2014	☒
Harmonic/Flicker Software	California Instruments	CTS 3.0	Ver. 3.2.0.30	12723	05/10/2014	☒
EMC test set	Schaffner	Modula6100	34384	15546	08/30/2014	☒
CDN	Fischer Custom Communications	FCC-801-AF2	55	9972	03/28/2014	☒
Surge Generator	Schaffner	NSG 2050	200717-600LU	19991	04/01/2014	☒
Impulse Network Plugin	Schaffner	PNW 2050	200711-601LU	19993	04/01/2014	☒