Certification Test Report

For an

RFID Device

Manufacturer:

Clearcount Medical Solutions, Inc.
101 Bellevue Road
Pittsburgh, Pennsylvania 15229
United States of America

Testing Laboratory:

F-Squared Laboratories
16740 Peters Road
Middlefield, Ohio 44062
United States of America

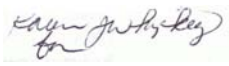
The **RFID Device, model DTX,** was tested and was found to comply with the requirements of the Federal Communications Commission outlined in the Federal Register CFR 47, Part 15.225.

The product was received on Dec. 11, 2009 and the testing was completed on Dec. 11, 2009.

Evaluation Conducted By:

Russell Beattie
EMC Technical Manager

Report Reviewed By:



Wendy Fuster
President

F-Squared Laboratories
16740 Peters Road
Middlefield, Ohio 44062
(440) 632-5541
Fax: (440) 632-5542

Table of Contents

1. ENGINEERING STATEMENT

This report has been prepared on behalf of Clearcount Medical Solutions, Inc. to provide documentation for the testing described herein. This equipment has been tested and found to comply with Part 15.225 of the FCC Rules using ANSI C63.4 2003 standards. The test results found in this test report relate only to the items tested.

1.1. Equipment Under Test:
RFID Device
FCC ID: WWQCCMS002

1.2. Trade Name:
Clearcount Medical Solutions, Inc.

1.3. Model:
DTX

1.4. Power Supply:
Input: 100-240V~, 50-60 Hz, 1.3A. Output: SL Power Electronics Corp. MINT 1065A2475C01

1.5. Applicable Rules:
CFR 47, Part 15.225, (a)-(e)

Reference FCC ID PJMLRM2000. Test results for Part 15.225(e) may be found on page 33 of 58 of CETECOM ICT Services GmbH Test Report 2-4112-01-02/05, under separate cover.

1.6. Equipment Category:
Low Power Communication Device Transmitter
Frequency: 13.56 MHz

1.7. Antenna:
Handheld Wand

1.8. Measurement Location:
F-Squared Laboratories in Middlefield, Ohio. Site description and attenuation data are on file with the FCC's Sampling and Measurement Branch at the FCC Laboratory in Columbia, MD**.**

1.9. Measurement Procedure:

All measurements were performed according to the 2003 version of ANSI C63.4 and recommended FCC parts 15.31, 15.33 and 15.35. A list of the measurement equipment can be found in Section 2.

1.10. Uncertainty Budget:

Conducted Emissions – Combined uncertainly $\pm$1.13 dB, expanded $\pm$2.26 dB
Radiated Emissions – Combined Uncertainty $\pm$2.24 dB; Expanded Uncertainty $\pm$4.48 dB

2. LIST OF MEASUREMENT INFORMATION

Equipment Type	Asset Number	Manufacturer	Model	Serial Number	Calibration Due Date
Shield Room	CL014	Shielding Resources	3 Meter	001	Aug. 14, 2010
Temp/Hum. Recorder	CL118	Extech	RH520	H005870	Dec. 11, 2010
Spectrum Analyzer	CL129	Hewlett Packard	8591E	3246A00780	Oct. 7, 2010
Receiver	0145	Rohde & Schwarz	Display, EASI-0-804-8932-52; RF Unit, ESMI-RF 1032-5640-53	84982/015; 849152/005	Apr. 23, 2010
Antenna 1-Chamber	0142	ETS/EMCO	3142B	9811-1330	Aug. 31, 2010
Antenna 2-OATS	0105	Sunol Sciences	JB1	A101101	July 22, 2011
Pre-Amplifier	CL045	Hewlett-Packard	8447D	2944A08445	Oct. 20, 2010
OATS	CL017	Compliance Labs	N/A	001	Jan. 13, 2010
Transient Limiter	CL102	Hewlett Packard	11947A	3107A03325	Dec. 31, 2009
LISN 1	0149	Solar	8028-50-TS-24-BNC	1130	Oct. 20, 2010
LISN 3	0148	Solar	8028-50-TS-24-BNC	1129	Oct. 20, 2010

3. EQUIPMENT UNDER TEST (EUT) INFORMATION AND DATA

3.1 Test Item Condition:

The equipment to be tested was received in good condition.

3.2 Testing Algorithm:

The EUT was configured into the wand sweep mode which continuously operated the Tx/Rx.

3.3 Radiated Emission Testing on Open Area Test Site (OATS):

The DTX was initially characterized in a semi-anechoic chamber over a frequency range of 0.009 to 1000 MHz. Magnetic field emissions were measured below 30 MHz and electric field emissions were examined above 30 MHz.

The final radiated emissions measurements were performed on an Open Air Test Site (OATS). The DTX was tested at a tested at a distance of 3.0 meters at frequencies below 30 MHz and 3.0 meters above 30 MHz. At frequencies below 30 MHz, the emissions were maximized by rotating the Transmitter and the loop antenna on their axes. Additionally, the Transmitter was examined in three orthogonal positions to ensure maximization of emissions. At frequencies above 30 MHz, the emissions were maximized by rotating the Transmitter while raising/lowering the bilog antenna mounted on a 4.0 meter mast. Again, three orthogonal Transmitter positions were examined to ensure maximization of the emissions. Both horizontal and vertical field components were measured above 30 MHz. A resolution bandwidth of 200 Hz was used between 0.009 to 0.15 MHz, 9 kHz was used between 0.15 to 30 MHz, and 120 kHz was used between 30 to 1000 MHz. The detector function was set to quasi-peak mode for all measurements. The raw measurements were correlated to allow for antenna factor and cable loss.

3.4 Conducted Emissions Measurements

The equipment was installed on a 0.8-meter high table, as described CISPR 11:2007. Power was provided to the Equipment under Test (EUT) through a Line Impedance Stabilization Network (LISN). An EMI receiver was also connected to the LISN to measure the RF emissions on the power lines of the EUT. The EUT was fully exercised with all cabling attached. The setup conforms to CISPR 11:2007.

During the test, each conductor of the power mains was tested and emissions were measured over the frequency range of 0.15 MHz to 30 MHz. The highest levels were recorded and plots were taken showing the emissions on each conductor. These levels were compared to the Class A limits specified in CISPR 11:2007.

4. EUT CONFIGURATION AND CABLES

4.1. Equipment Under Test (EUT):

Device	Manufacturer	Model Number	Serial Number
RFID Device	Clearcount Medical Solutions, Inc.	DTX	1085

4.2. Accessories (Support Equipment): None

4.3. Cables:

Cable Function	Length	Shielded (Yes/No)
AC Mains	N/A	No

5. PRODUCT DESCRPTION

The SmartWand-DTX™ System is used in an operating room to detect and identify tagged surgical items for the purpose of preventing a retained foreign body. The system employs radio-frequency identification (RFID) technology to detect ClearCount SmartSponge® surgical sponges and towels. The system combines detection with the benefit of identification of surgical items (sponges, gauze, and towels) so detected items can be quickly identified. The system consists of a patient scanning wand and a wand box with a user-friendly display that provides detailed information about detected items. When an item is detected, the type and quantity will appear on-screen along with an audible notification. The SmartWand-DTX allows for a quick and easy scan of the patient to identify retained surgical items.

6. FCC PART 15.225(a)-(d) – RADIATED EMISSIONS

6.1. Requirements:

The field strength of emissions of the Transmitter operating to FCC Part 15.225 shall not exceed:

(a) In the band 13.553-13.567 MHz, 15848µV/m (84 dBµV/m) at 30m
(b) In the bands 13.410-13.553 and 13.567-13.710 MHz, 334 µV/m (50.5 dBµV/m) at 30m
(c) In the bands 13.110-13.410 MHz and 13.710-14.010 MHz, 106 µV/m (40.5 dBµV/m) at 30m
(d) Any emissions outside the 13.110-14.010 MHz band shall not exceed the FCC 15.209(a) limits.

The radiated emissions measurements were initially performed in a semi-anechoic chamber to profile the emissions characteristics of the Clearcount DTX. These measurements were performed at a 3 meter distance. The test setups used in the chamber are shown in Pictorial 1.

The final compliance measurements were performed on the OATs at a 3 meter distance for frequencies below 30 MHz and at 3 meters above 30 MHz. The test setup used on the OATS are showed in Pictorials 2-3.

6.2. Results:

The Spectral Plots of the characterization measurements performed in the semi-anechoic chamber are organized as follows:

Figures 1-5	13.5 MHz to 13.6 MHz	H-Field Loop Antenna, Band Edge Emissions
Figures 6-7	30 MHz to 1000 MHz	E-Field Vertical Bilog Antenna, Radiated Emissions
Figures 8-9	30 MHZ to 1000 MHz	E-Field Horizontal Bilog Antenna, Radiated Emissions
Figures 10-13	0.009 MHz to 30MHz	H-Field Loop Antenna, Radiated Emissions

The compliance measurements performed on the OATs are organized as follows, and are found on pages 10-11 of this Test Report:

Table 1	DTX Emissions below 30 MHz
Table 2	DTX Emissions 30 MHz to 1000 MHz
Table 3	DTX Band Edge Emissions

The band-edge analysis performed on the OATS (3m distance) used the EUT orthogonal position, turntable and antenna placement that maximizes the field strength of the fundamental (13.56 MHz). With the Transmitter operating the resultant spectrum was recorded over the 13.061-14.061 MHz range.

The band-edge characteristic Spectral Plot is shown in Figures 1-5. Reviewing the plots, note that the field strength of the fundamental emission at 13.56 MHz is below both the FCC Part 15.225 and 15.209(a) limits. The only emissions detected near the limits are ambient shortwave broadcast stations.

Reviewing the OATS data, it is evident that the Clearcount DTX meets FCC Part 15.225(a)-(d) requirements for radiated emissions.

Table 1

Frequency (MHz)	Antenna Polarization	Reading (dBµV)	Cable Loss & Antenna Factor (dB)	Emission (dBµV/m)	Limit (dBµV/m)	Margin (dB)
0.01217	V	-38.15	68.1	29.94	125.571	-95.6
0.02592	V	-40.84	60.8	19.91	124.577	-104.7
0.03931	V	-41.82	57.1	15.24	123.608	-108.4
0.05306	V	-41.58	54.2	12.63	122.614	-110.0
0.49125	V	-17.62	34.7	17.07	72.870	-55.8
0.4965	V	-24.91	34.7	9.78	72.781	-63.0
0.5675	V	-20.07	34.5	14.43	72.15	-57.7
0.82625	V	-15.03	30.5	15.47	69.75	-54.3
1.09	V	-20.14	28.7	8.56	68.324	-59.8
1.22	V	-20.40	28.7	8.30	68.45	-60.2
1.29	V	-19.80	28.7	8.90	68.45	-59.6
1.38	V	-20.57	28.7	8.13	68.45	-60.3
1.44	H	-18.49	26.7	8.21	68.62	-60.4
9.81	H	1.63	5.6	7.21	68.62	-61.4
24.0	H	6.37	0.8	7.18	68.62	-61.4

Table 2

Frequency (MHz)	Antenna Polarization	Reading (dBµV)	Cable Loss & Antenna Factor (dB)	Emission (dBµV/m)	Limit (dBµV/m)	Margin (dB)
30.660000	H	0.0	22.1	22.1	40.0	-17.9
31.950000	V	11.2	19.7	30.9	40.0	-9.1
40.650000	V	12.6	13.4	26.0	40.0	-14.0
40.670000	H	12.8	14.5	27.3	40.0	-12.7
48.880000	V	9.9	9.0	18.9	40.0	-21.1
63.980000	H	8.7	9.5	18.2	40.0	-21.8
64.810000	V	19.6	9.2	28.8	40.0	-11.2
130.960000	V	3.3	16.0	19.3	43.5	-24.2
131.230000	H	4.1	15.9	20.0	43.5	-23.5
198.250000	H	0.7	15.8	16.5	43.5	-27.0
236.430000	H	4.5	15.0	19.5	46.0	-26.5
851.480000	V	5.4	27.9	33.3	46.0	-12.7
902.270000	V	4.7	28.6	33.3	46.0	-12.7
912.080000	H	4.3	29.1	33.4	46.0	-12.6
934.890000	H	4.1	29.4	33.5	46.0	-12.5
944.190000	V	4.0	29.1	33.1	46.0	-12.9

Table 3 – Band Edge Emissions

Frequency (MHz)	Raw Measurement	Cable Loss & Antenna Factor (dB)	Emission (dBµV/m)	Limit (dBµV/m)	Margin (dB)
13.553	107.37	-23.4	83.99	90.0	-6.0
13.567	109.67	-23.4	86.26	90.0	-3.7
13.568	106.86	-23.4	83.45	90.0	-6.6
13.570	101.01	-23.4	77.59	90.0	-12.4
13.550	98.99	-23.4	75.61	90.0	-14.4
13.560	122.03	-23.4	98.65	123.1	-24.5

7 FIGURES – SPECTRAL DATA PLOTS

Figure 1: Radiated Emissions Characterization Band Edge Ambient
H-Field Loop Antenna, 3m Distance, Peak Reading

13.5 MHz to 14.5 MHz, Ambient

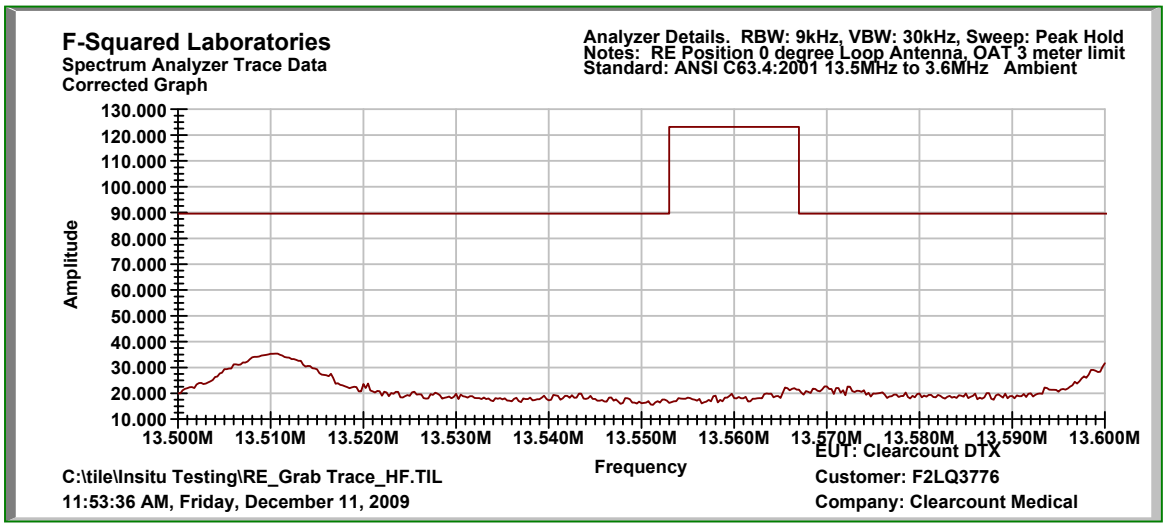


Figure 2: Radiated Emissions Characterization Band Edge
H-Field Loop Antenna, 3m Distance, Peak Reading

13.5 MHz to 14.5 MHz, 0 degrees

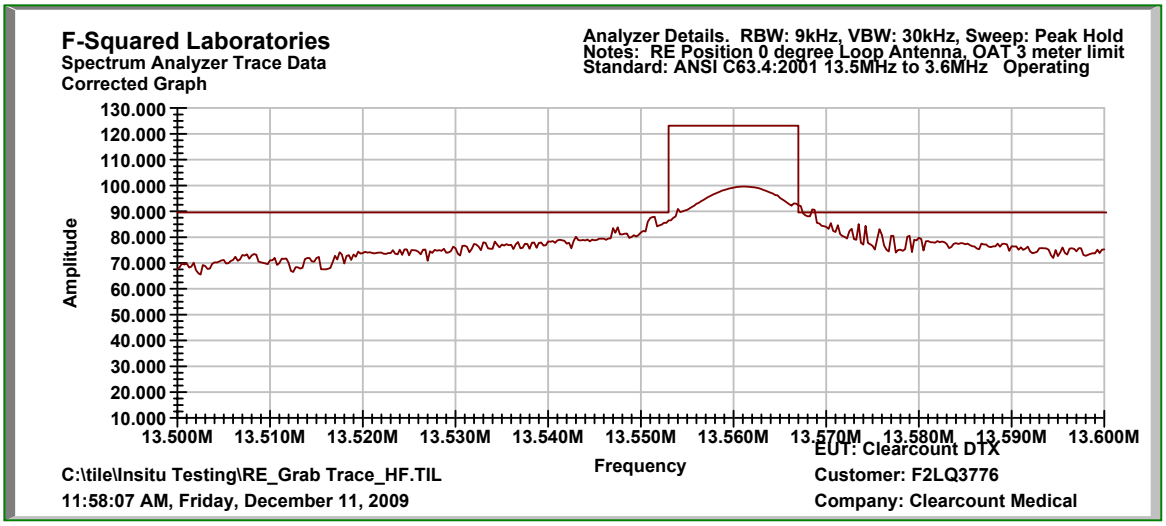


Figure 3: Radiated Emissions Characterization Band Edge

H-Field Loop Antenna, 3m Distance, Peak Reading

13.5 MHz to 14.5 MHz, 90 degrees

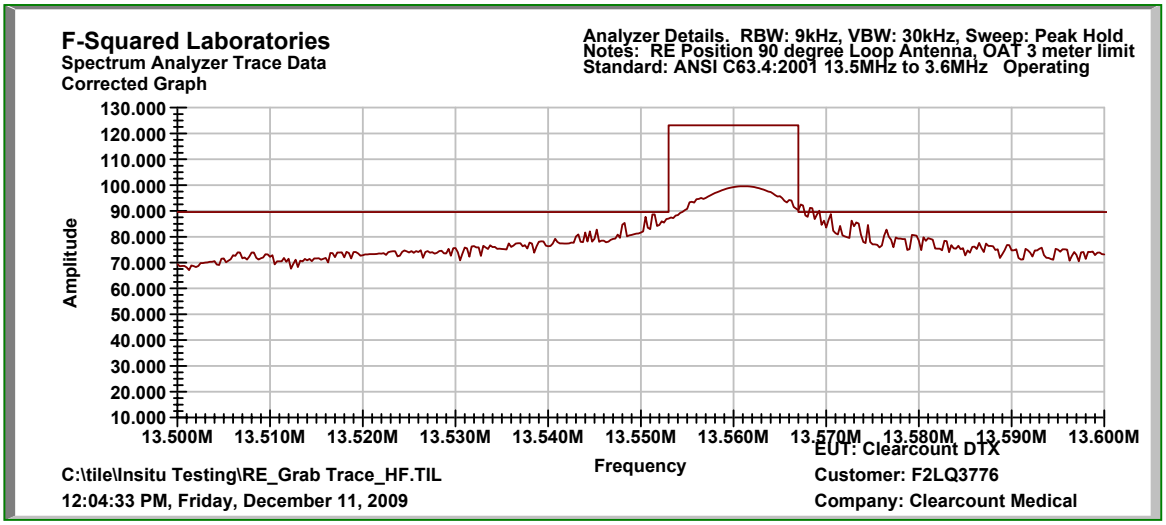


Figure 4: Radiated Emissions Characterization Band Edge
H-Field Loop Antenna, 3m Distance, Peak Reading

13.5 MHz to 14.5 MHz, 180 degrees

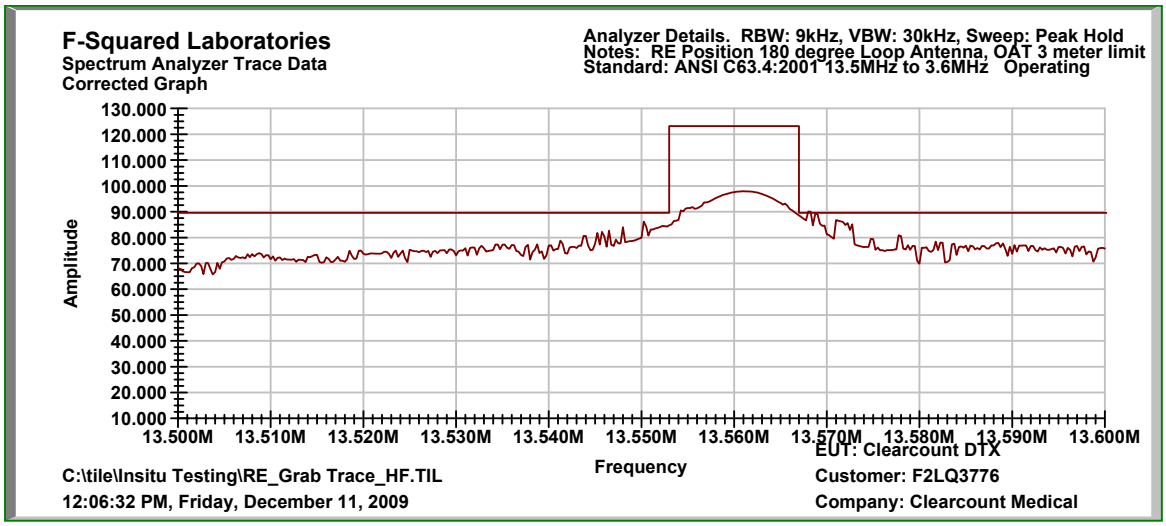


Figure 5: Radiated Emissions Characterization Band Edge
H-Field Loop Antenna, 3m Distance, Peak Reading

13.5 MHz to 14.5 MHz, 270 degrees

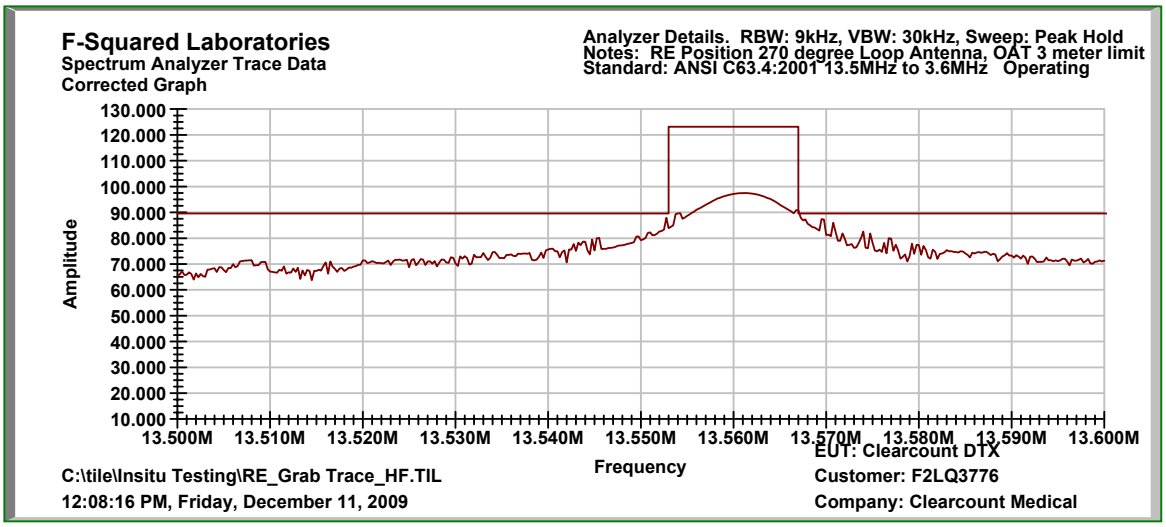


Figure 6: Radiated Emissions Characterization – 30 MHz to 300 MHz
E-Field Vertical Bilog Antenna, 3.0m Distance, Peak Reading

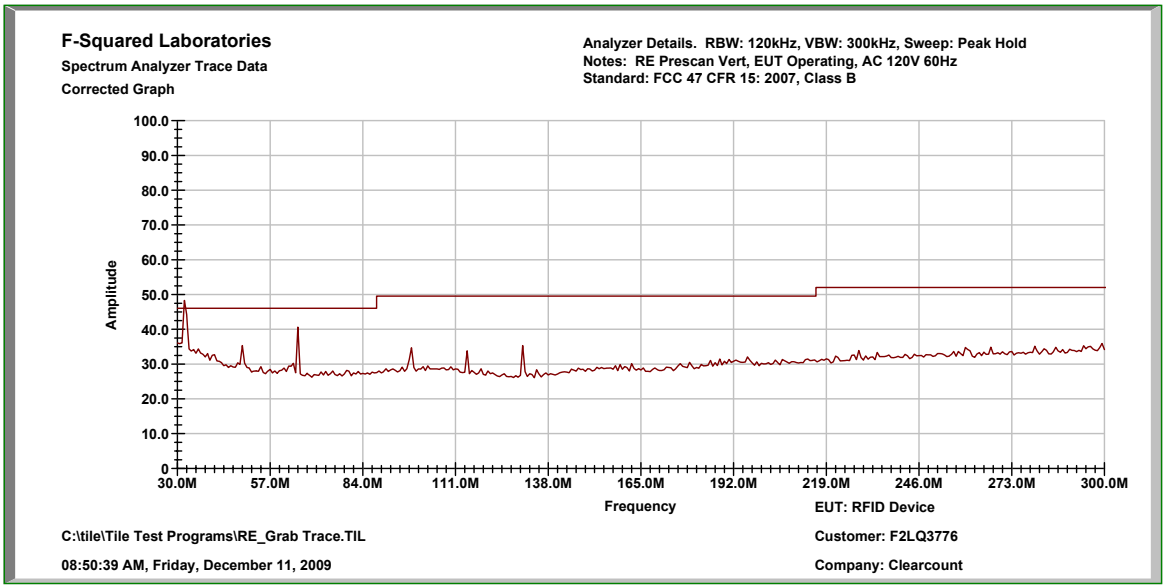


Figure 7: Radiated Emissions Characterization – 300 MHz to 1000 MHz
E-Field Vertical Bilog Antenna, 3.0m Distance, Peak Reading

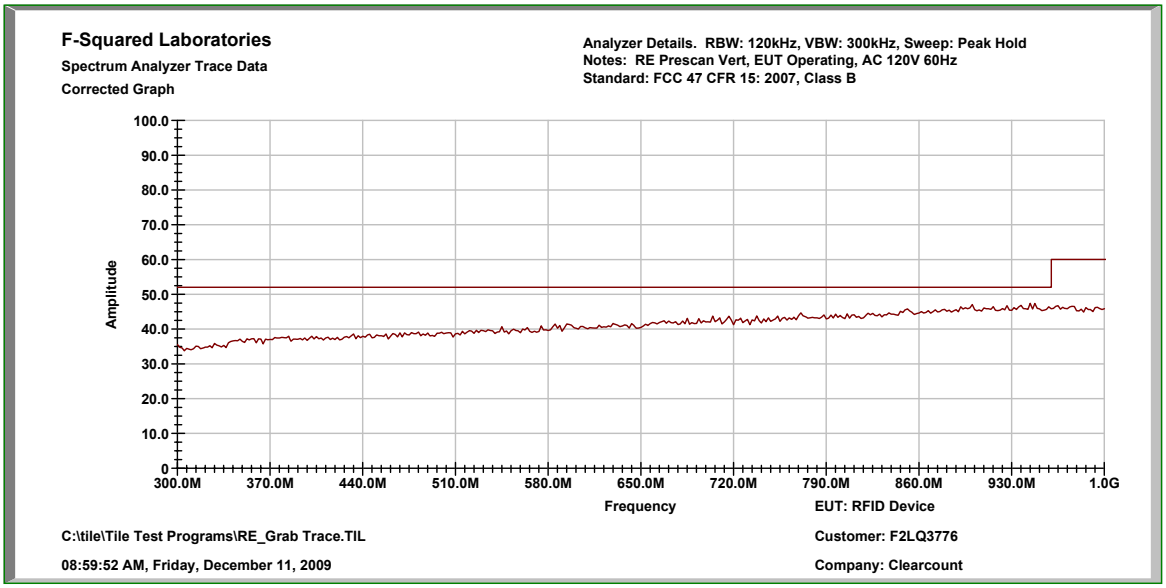


Figure 8: Radiated Emissions Characterization – 30 MHz to 300 MHz
E-Field Horizontal Bilog Antenna, 3.0m Distance, Peak Reading

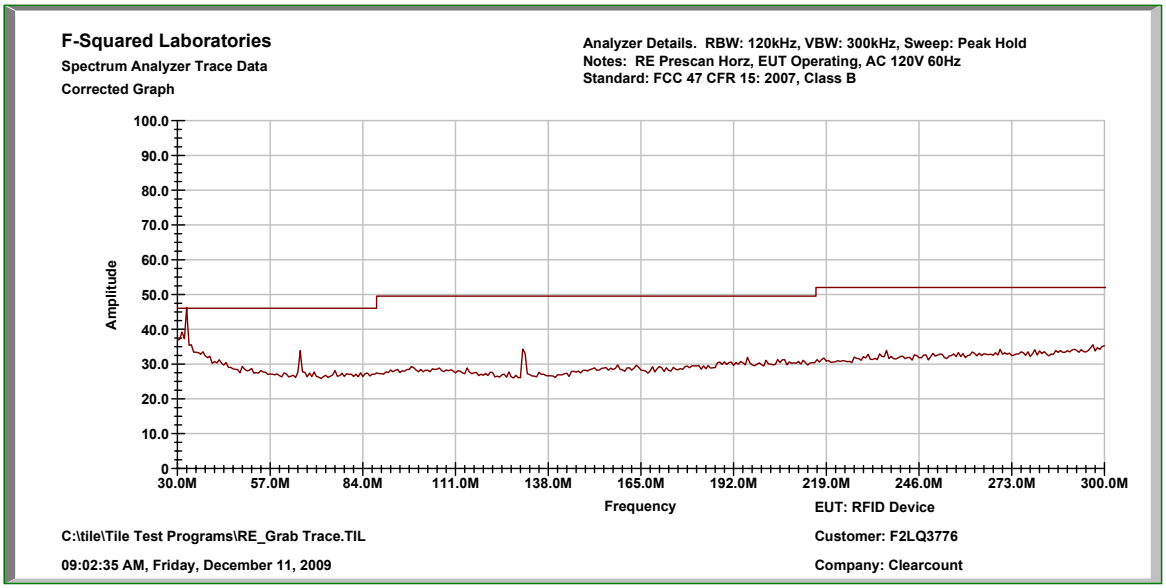


Figure 9: Radiated Emissions Characterization – 300 MHz to 1000 MHz
E-Field Horizontal Bilog Antenna, 3.0m Distance, Peak Reading

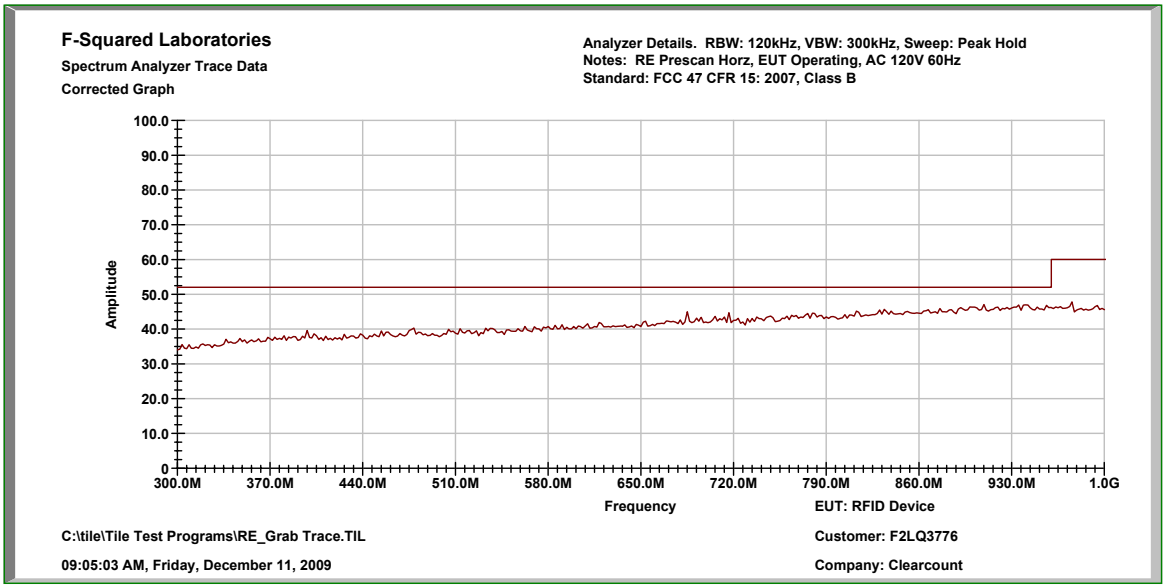


Figure 10: Radiated Emissions Characterization
3m OATS at Maximum Field Strength Orientation

Characterization Scan: 0.09 MHz to 0.15 MHz, 1 kHz Bandwidth

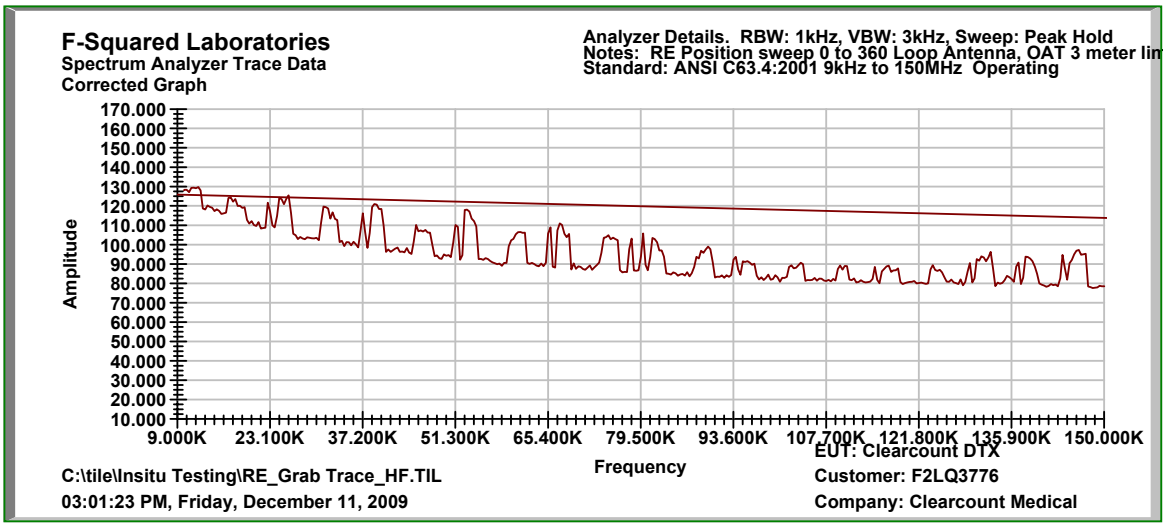


Figure 11: Radiated Emissions Characterization
3m OATS at Maximum Field Strength Orientation

Characterization Scan: 0.15 MHz to 0.5 MHz, 9 kHz Bandwidth

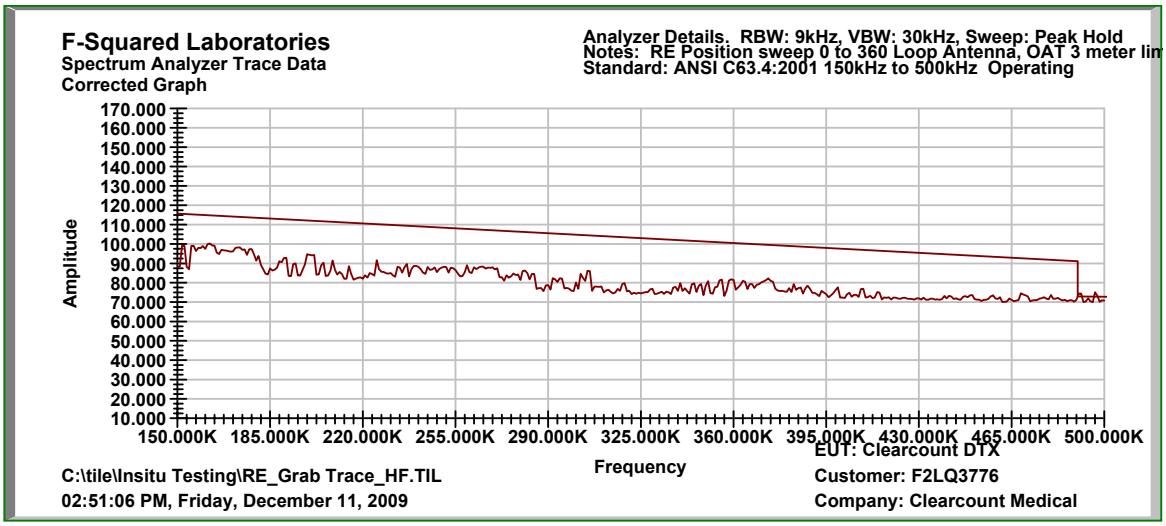


Figure 12: Radiated Emissions Characterization
3m OATS at Maximum Field Strength Orientation

Characterization Scan: 0.5 MHz to 5.0 MHz, 9 kHz Bandwidth

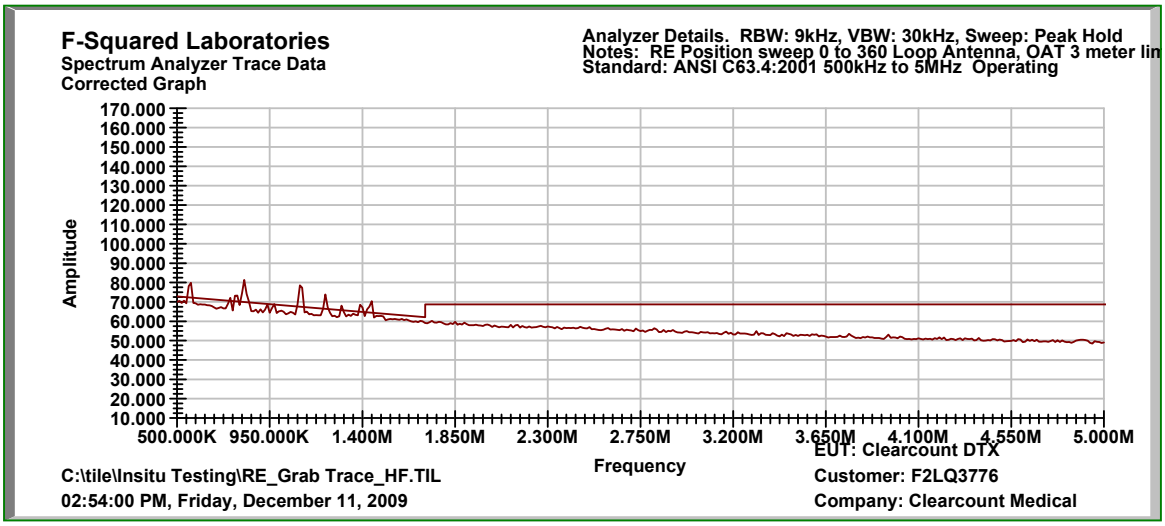


Figure 13: Radiated Emissions Characterization
3m OATS at Maximum Field Strength Orientation

Characterization Scan: 5.0 MHz to 30 MHz, 9 kHz Bandwidth

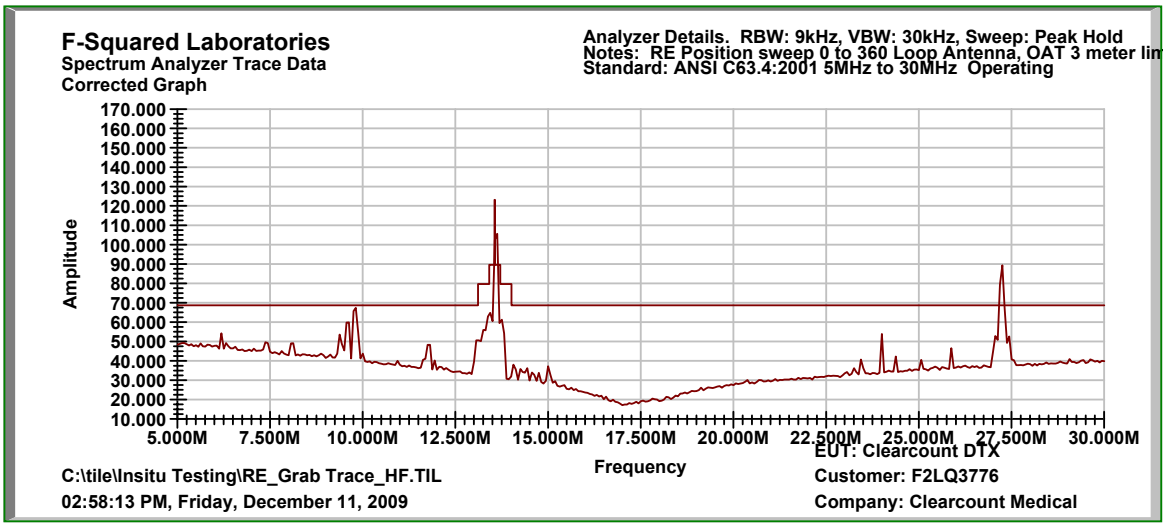


Figure 14: Conducted Test – Line 1: 0.15 MHz to 0.5 MHz

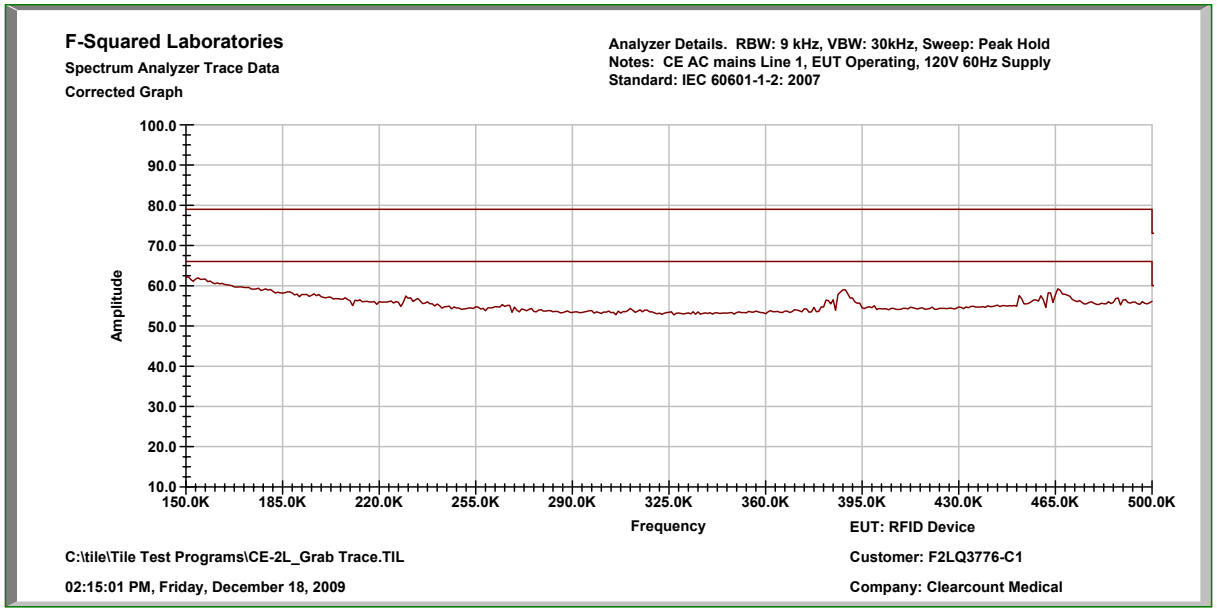


Figure 15: Conducted Test – Line 1: 0.5 MHz to 5.0 MHz

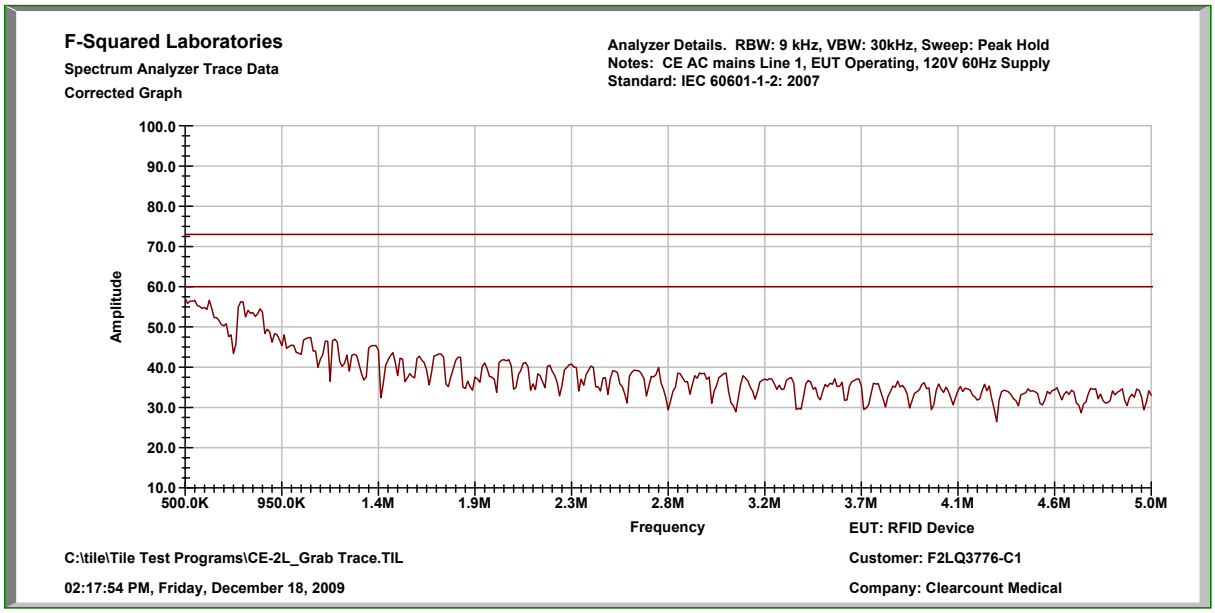


Figure 16: Conducted Test – Line 1: 5.0 MHz to 30.0 MHz (with antenna)

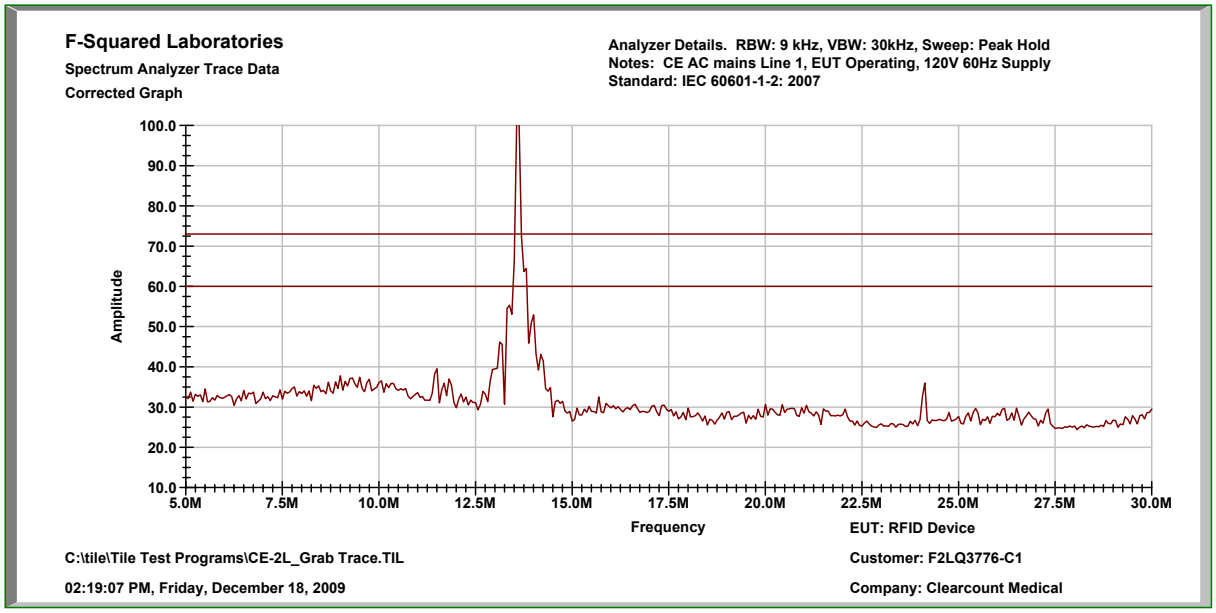


Figure 17: Conducted Test – Line 1: 5.0 MHz to 30.0 MHz (with dummy load)

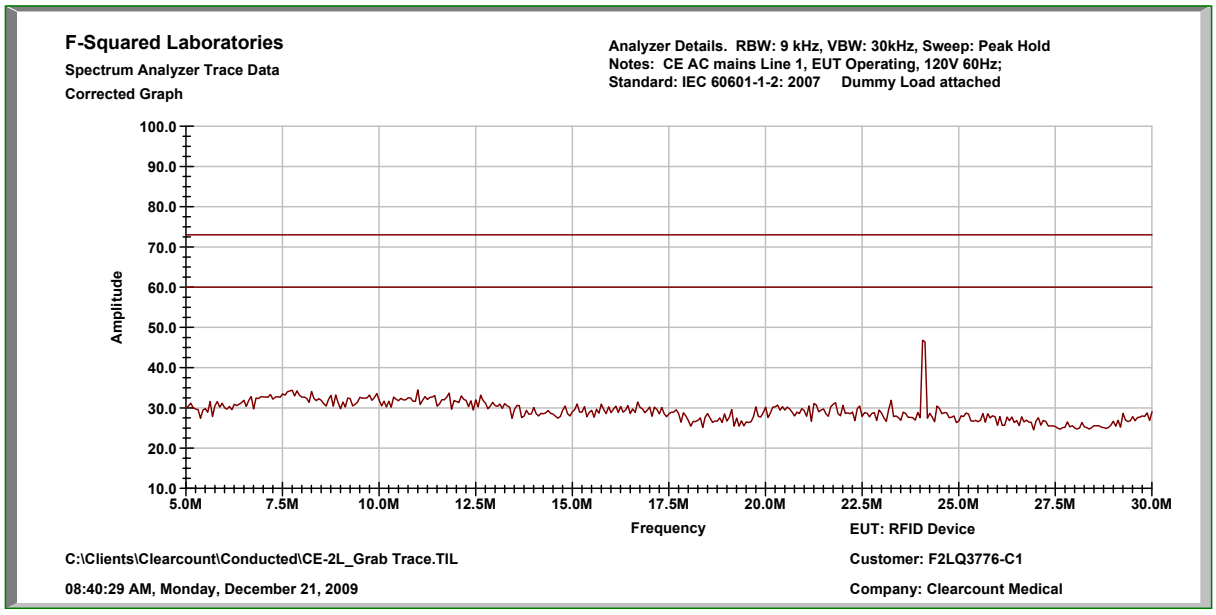


Figure 18: Conducted Test – Line 2: 0.15 MHz to 0.5 MHz

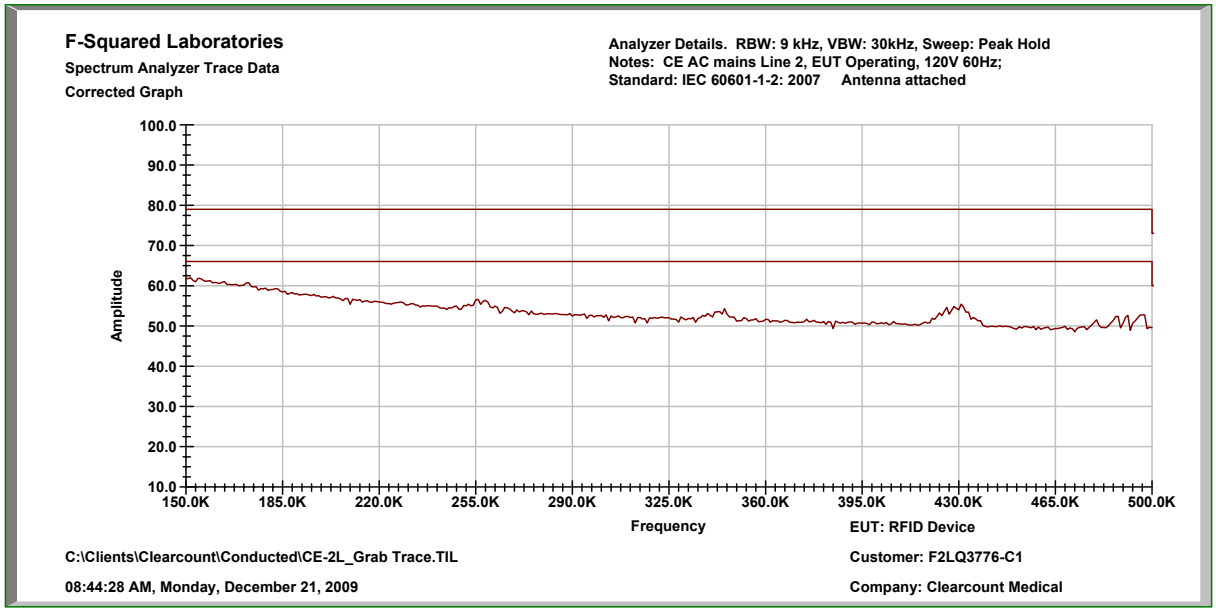


Figure 19: Conducted Test – Line 2: 0.5 MHz to 5.0 MHz

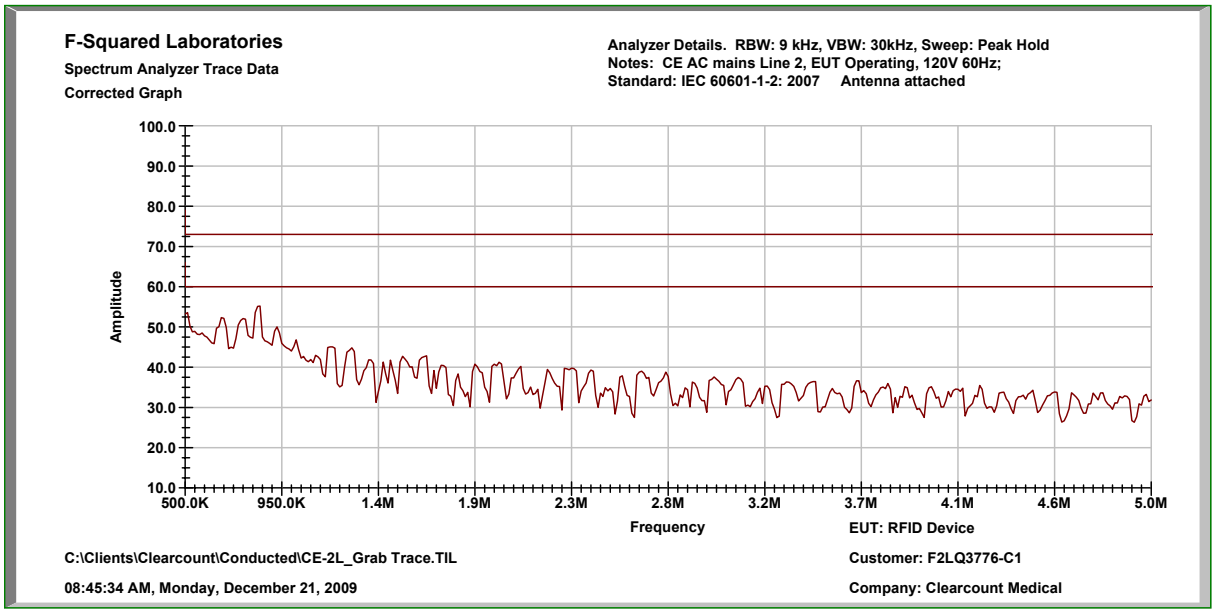


Figure 20: Conducted Test – Line 2: 5.0 MHz to 30.0 MHz (with antenna)

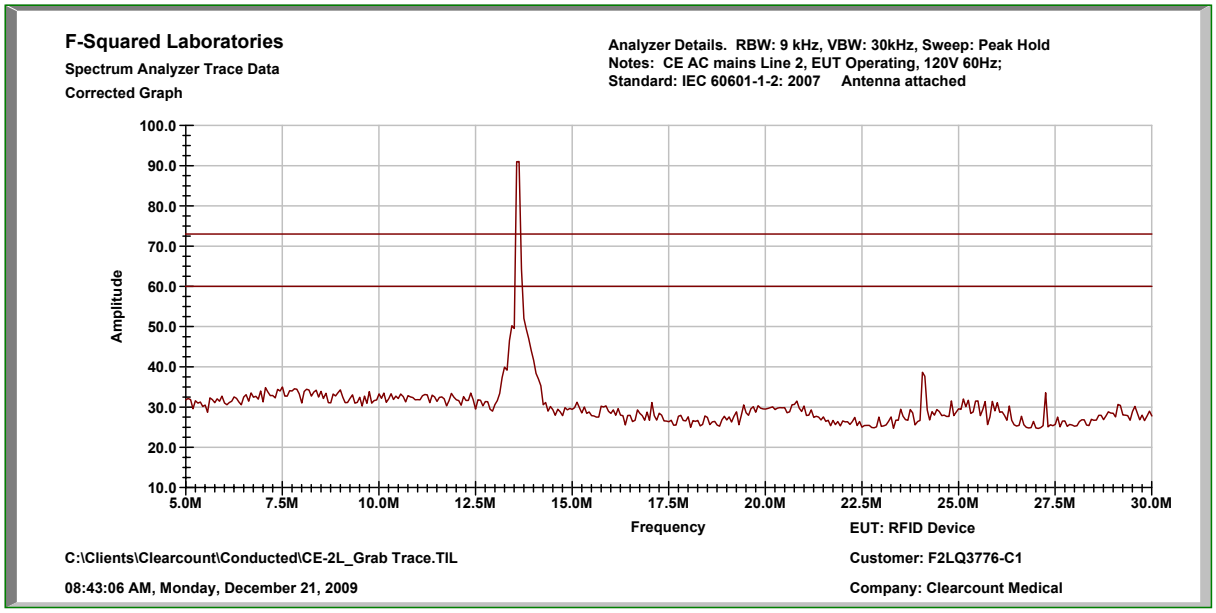
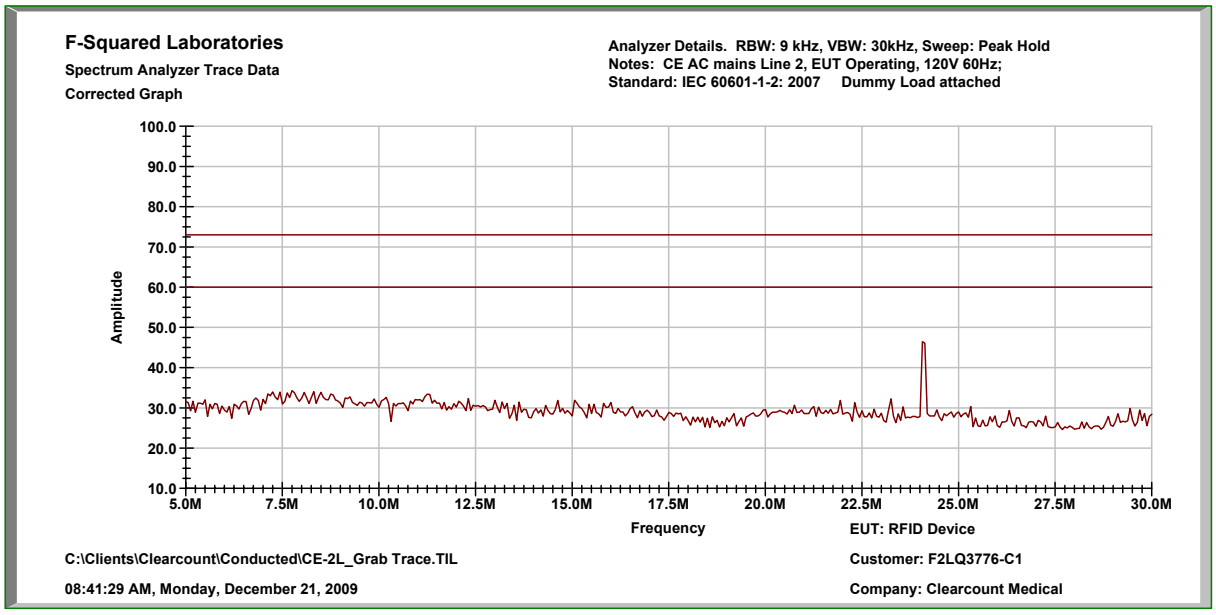
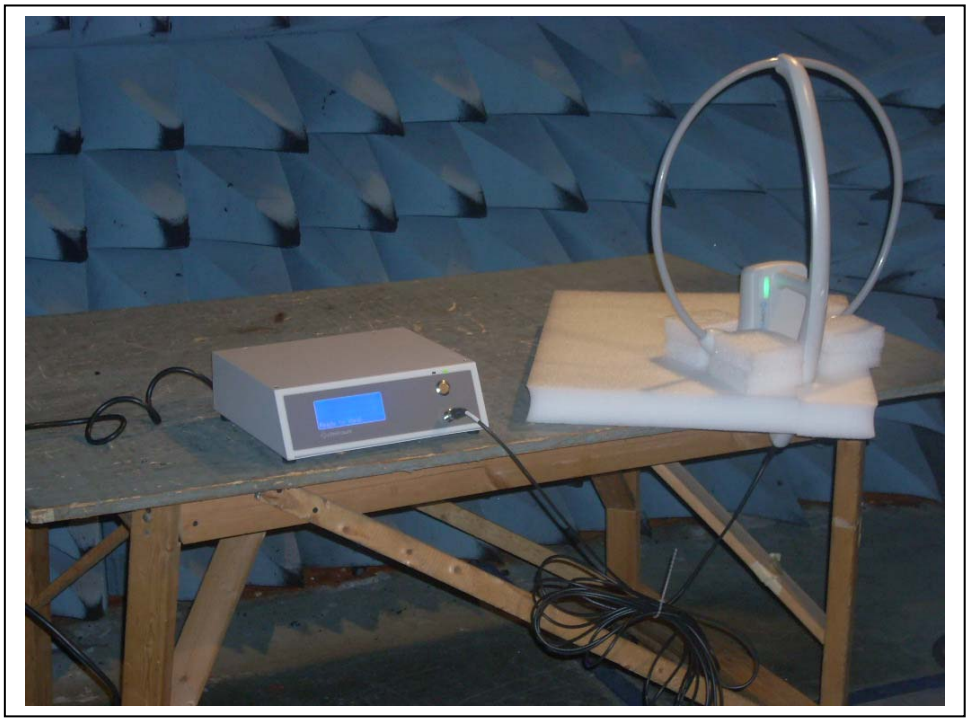


Figure 21: Conducted Test – Line 2: 5.0 MHz to 30.0 MHz (with dummy load)



8 PICTORIALS – TEST SETUP

Pictorial 1: RADIATED TEST – *Prescan*



Pictorial 2: RADIATED TEST – *OATS*

Pictorial 3: RADIATED TEST – *Lower Frequency Range*

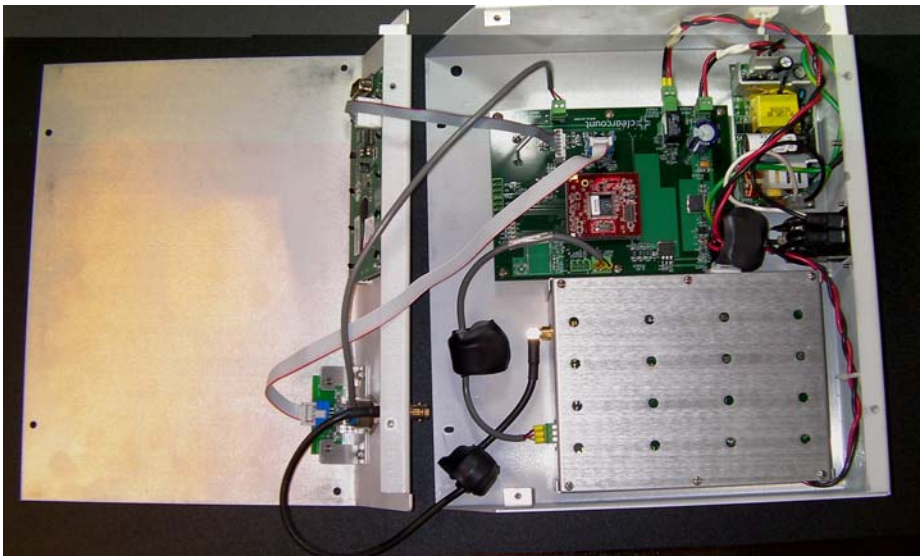
Pictorial 4: Conducted Emissions - Antenna Setup

Pictorial 5: Conducted Emissions - Dummy Load Setup

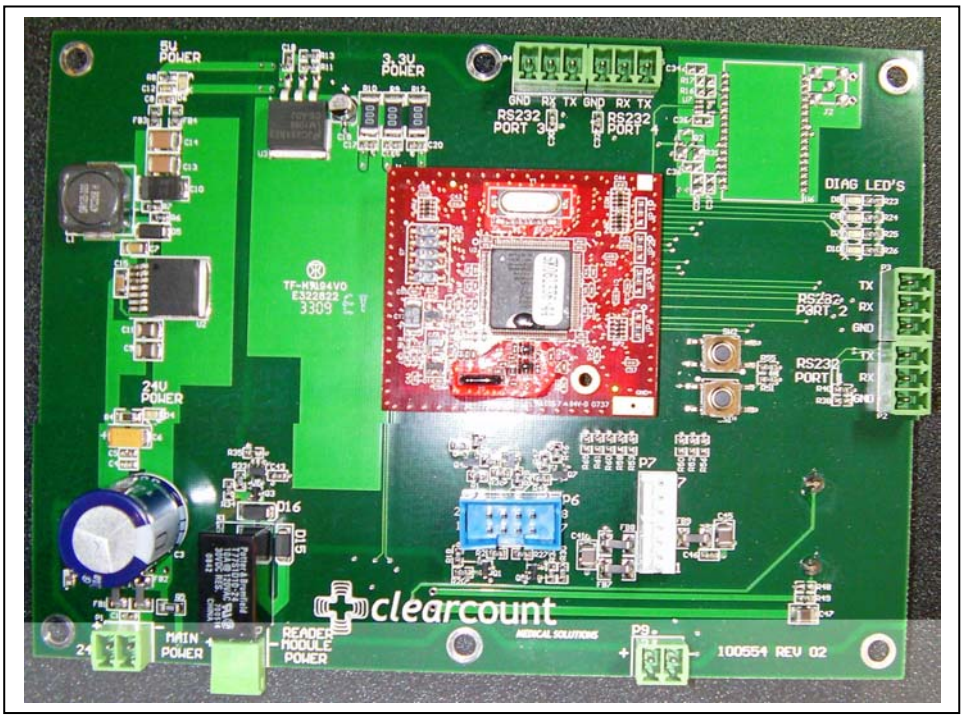
9 PICTORIALS – EUT

External View

DTX Internal View



MCU Front



MCU Rear