

Test Report # 318353 D

Equipment Under Test: Revolve Control Module with EX Holster

Test Date(s): March 28th – May 17th, 2019

Prepared for: Devicor Medical Products, Inc.
Attn: Kyle Wagner
300 E-Business Way, Fifth Floor
Cincinnati, OH 45241

Report Issued by: Zach Wilson, EMC Engineer

Signature: 

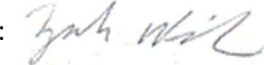
Date:

Report Reviewed by: Adam Alger, Quality Manager

Signature: 

Date:

Report Constructed by: Zach Wilson, EMC Engineer

Signature: 

Date: 5/14/2019

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Laird Technologies Test Services in Review

The Laird Technologies, Inc. laboratory located at W66 N220 Commerce Court Cedarburg, Wisconsin, 53012 USA is recognized through the following organizations:



A2LA – American Association for Laboratory Accreditation

Accreditation based on ISO/IEC 17025:2017 with Electrical (EMC) Scope

A2LA Certificate Number: 1255.01

Scope of accreditation includes all test methods listed herein unless otherwise noted



Federal Communications Commission (FCC) – USA

Accredited Test Firm Registration Number: 953492

Recognition of two 3 meter Semi-Anechoic Chambers



Innovation, Science and Economic Development Canada

Accredited U.S. Identification Number: US0218

Recognition of two 3 meter Semi-Anechoic Chambers

Company: Devicor Medical Prodcuts, Inc.	Page 3 of 23	Name: Revolve Control Module with EX Holster
Report: TR 318353 D		Model: MHEXH1
Job: C-3148		Serial: MHEXH1000001, MHEXH1000002

1 TEST REPORT SUMMARY

During **March 28th – May 17th, 2019** the Equipment Under Test (EUT), **Revolve Control Module with EX Holster**, as provided by **Devicor Medical Products Inc.** was tested to the following requirements of the **Federal Communications Commission** and **Innovation, Science and Economic Development Canada**:

Requirements	Description	Specification	Method	Compliant
FCC: 15.209 (c) IC: RSS-GEN (8.9)	Radiated Emissions 1-13.11 MHz, 14.010 – 1000 MHz	29.5 dBμV/m @ 30m	ANSI C63.10	Yes
FCC: 15.225 (a) IC: RSS-210 (B.6)	Radiated Emissions 13.110-14.010 MHz	84 dBμV/m @ 30m	ANSI C63.10	Yes
FCC: 15.207 (a) IC: RSS-GEN (8.8)	Conducted AC Emissions	See Section 5.2.1	ANSI C63.10	Yes
FCC: 2.1049 IC: RSS-GEN (6.7)	Occupied Bandwidth	Reported	ANSI C63.10	Reported
FCC: 15.225 (e) IC: RSS-210 (B.6)	Carrier Frequency Stability	±0.01%	ANSI C63.10	Yes

Notice:

The results relate only to the item tested as configured and described in this report. Any additional configurations, modes of operation, or modifications made to the equipment under test after the specified test date(s) are at the decision of the client and may not apply to the data seen in this test report.

The decision rule for Pass / Fail assessment to the specification or standard listed in this test report has been agreed upon by the client and laboratory to be as follows:

Measurement Type	Rule
Emissions – Amplitude	1 dB below specified limit
Emissions – Frequency	1% less than the specification
Immunity	Tested at specified level

2 CLIENT INFORMATION

Company Name	Devicor Medical Products, Inc.
Contact Person	Kyle Wagner
Address	300 E-Business Way, Fifth Floor Cincinnati, OH 45241

2.1 Equipment Under Test (EUT) Information

The following information has been supplied by the client

Product Name	Revolve Control Module with EX Holster
Revolve EX Holster Model Number	MHEXH1
Revolve Control Module Model Number	MSCM1
Revolve EX Holster Serial Number	MHEXH1000001, MHEXH1000002
Revolve Control Module Serial Number	MSCM1001769, MSCM1001770
Revolve EX Holster Radio FCC ID	2ATMT-MHEXH101
Revolve EX Holster Radio IC ID	25143-MHEXH101

2.2 Product Description

The Mammotome® Revolve system is a state-of-the-art next generation dual vacuum-assisted biopsy platform. The procedure performed with the Mammotome® system is a minimally invasive breast biopsy procedure using a single insertion vacuum assisted device that provides multiple samples for percutaneous removal of (breast) tissue for histological diagnosis. The user can provide inputs to the Mammotome® system at the control module and/or at buttons on the holster, keypad or footswitch to activate clinical functions for the biopsy procedure such as Biopsy, Vacuum, and Open/Close Aperture.

The holster contains a TRF7970A Texas Instruments 13.56 MHz RFID Transceiver. The RFID was active with a passive tag, GammaTag, inserted in the holster during testing. The manufacturer declared temperature range of the radio is -40°C to 110°C. The input voltage of the radio is 2.7

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VDC to 5.5 VDC. The antenna is a loop antenna etched into the PCB. Due to the nature of loop antennas, the conservative estimate of the antenna gain is 0 dBi. The radio uses ASK modulation. Per customer, unit tested at 100VAC/60Hz and 240VAC/50Hz.

2.3 Modifications Incorporated for Compliance

Conducted AC Emissions required the antenna to be disconnected to enable the frequencies near the transmit fundamental to be measured. A dummy load was placed at the output of the radio consisting of a 1.8Ω resistor and 910nH inductor in series. This is allowed per FCC/KDB-174176. The antenna was connected for all other testing.

2.4 Deviations and Exclusions from Test Specifications

None noted at time of test

2.5 Mode of Operation – Active Biopsy

EUT tested with an EX holster attached with a footswitch being used to trigger a biopsy. The EUT was placed in “normal mode” with the biopsy button held down, so the system would continuously cycle through biopsies endlessly.

2.6 Radio Programming Information

The radio begins transmitting and receiving when the holster is powered up by the console. No programming needed.

2.7 Software Versions

Revolve Control Module Software Version - 3.1.0.1721.315

Revolve EX Holster Software Version - 3.3.1676.315

Company: Devicor Medical Prodcuts, Inc.	Page 6 of 23	Name: Revolve Control Module with EX Holster
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3 REFERENCES

Publication	Edition	Date	AMD 1
ANSI C63.10	-	2013	-
CFR Title 47	-	2019	-
RSS-GEN	5	2018	2019
RSS-210	9	2016	2017
FCC/KDB-174176 D01	v01r01	2015	-

4 UNCERTAINTY SUMMARY

Using the guidance of the following publications the calculated measurement uncertainty represents an expanded uncertainty expressed at approximately the 95 % confidence level, using a coverage factor of $k = 2$.

References	Version / Date
CISPR 16-4-1	Ed. 2 (2009-02)
CISPR 16-4-2	Ed. 2 (2011-06)
CISPR 32	Ed. 1 (2012-01)
ANSI C63.23	2012
A2LA P103	February 4, 2016
A2LA P103c	August 10, 2015
ETSI TR 100-028	V1.3.1 (2001-03)

Measurement Type	Configuration	Uncertainty $\pm$
Radiated Emissions	Biconical Antenna	5.0 dB
Radiated Emissions	Log Periodic Antenna	5.3 dB
Radiated Emissions	Horn Antenna	4.7 dB
AC Line Conducted Emissions	Artificial Mains Network	3.4 dB
Telecom Conducted Emissions	Asymmetric Artificial Network	4.9 dB
Disturbance Power Emissions	Absorbing Clamp	4.1 dB
Radiated Immunity	3 Volts/meter	2.2 dB
Conducted Immunity	CDN/EM/BCI	2.4/3.5/3.4 dB
EFT Burst/Surge	Peak pulse voltage	164 volts
ESD Immunity	15 kV level	1377 Volts

Parameter	ETSI U.C. $\pm$	U.C. $\pm$
Radio Frequency, from F0	1×10^{-7}	0.55×10^{-7}
Occupied Channel Bandwidth	5 %	2 %
RF conducted Power (Power Meter)	1.5 dB	1.2 dB
RF conducted emissions (Spectrum Analyzer)	3.0 dB	1.7 dB
All emissions, radiated	6.0 dB	5.3 dB
Temperature	1° C	0.65° C
Humidity	5 %	2.9 %
Supply voltages	3 %	1 %

5 TEST DATA

5.1 Radiated Emissions

Description of Measurement	The frequency spectrum is investigated for intentional and / or unintentional signals emanating from the EUT by use of a standardized test site and measurement antenna. The antenna, cable, pre-amp, and other necessary measurement system correction factors are loaded onto the EMI receiver / spectrum analyzer when the measurements are performed allowing the data to be gathered and reported as corrected values. The maximum emissions from the EUT are determined by turn-table azimuth rotation (360°) and scanning of the measurement antenna. Maximized levels are noted at degree values of azimuth, measurement antenna height, and measurement antenna polarity.
Example Calculations	Measurement (dBμV) + Cable factor (dB) + Other (dB) + Antenna Factor (dB/m) = Corrected Reading (dBμV/m) Margin (dB) = Limit (dBμV/m) - Corrected Reading (dBμV/m) Example at 4000 MHz: Reading = 40 dBμV + 3.4 dB + 0.9 dB + 6.5 dB/m = 50.8 dBμV/m Average Limit = 20 log (500) = 54 dBμV/m Margin = 54 dBμV/m - 50.8 dBμV/m = 3.2 dB

Block Diagram



5.1.1 Radiated Emissions – Spurious and Fundamental

Operator	Jon Dille	QA	Shane Dock
Temperature	23.3°C	R.H. %	32.8%
Test Date	3/28/2019, 4/4/2019	Location	Chamber 3
Requirement	FCC 15.225, FCC 15.209 RSS-210, RSS-GEN	Method	ANSI C63.10

Limits:

Spurious = 29.5 dBμV/m @ 30m

Fundamental = 84 dBμV/m @ 30m

Test Parameters

Frequency	1-1000 MHz	Distance	3m
Detector(s)	Max peak hold with peak detector for plots. Quasi peak detector for final measurements.	Table height	80cm
RBW	1-30 MHz: 9 kHz 30-1000 MHz: 120 kHz	VBW	1-30 MHz: 90 kHz 30-1000 MHz: 1.2 MHz
Notes (below 30 MHz)	Parallel Antenna data shown as worst case with respect to the limit. Parallel, skew, and horizontal antenna configurations tested. Emission measurements extrapolated to 30m. Fundamental meets the spurious limit and no emission was higher than the fundamental.		
Example Calculations	Adjusting a 30m limit to a 3m limit = (30m limit) + 40*LOG(dnear/3) + 20*LOG(30/dnear)		

EUT Parameters

Input Power	100VAC/60Hz, 240VAC/50Hz	Mode	Active Biopsy
EUT Radio	RFID Transmit and Receive with GammaTag		

Instrumentation



Date: 27-Mar-2019

Test: Radiated Emissions

Job: C-3148

PE: Zach Wilson

Customer: Leica Biosystems

Quote: 318353

No.	Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due Date	Equipment Status
1	EE 960085	Analyzer - EMI Receiver	Agilent	N9038A	MY51210148	4/24/2019	4/24/2020	Active Calibration
2	AA 960128	Antenna - Biconical	ETS Lindgren	3110B	00062899	5/16/2018	5/16/2019	Active Calibration
3	AA 960163	Antenna - Log Periodic	A.H. Systems, Inc	SAS-512-2	500	1/30/2018	1/30/2020	Active Calibration
4	AA 960158	Antenna - Double Ridge Horn	ETS Lindgren	3117	109300	3/26/2018	3/26/2020	Active Calibration
5	EE 960159	Antenna - Low Noise Amplifier	Mini-Circuits	ZVA-213X-S+	691801732	3/26/2018	3/26/2020	Active Calibration
6	LSC-300	Cable	Chamber 3 Emiss -		-	7/27/2018	7/27/2019	Active Verification
7	LSC-500	Cable	Chamber 5 Emiss -		-	3/1/2018	3/1/2020	Active Verification

Tables

1-30 MHz Data

Frequency (MHz)	dnear field	Limit Distance (m)	Antenna Polarity	Antenna Height (m)	Azimuth (degree)	Field Strength @ 3 m (dBμV/m)	FS Limit @ limit distance (dBμV/m)	Limit (dBμV/m)	Margin (dB)
4.9888	9.6	30	Parallel	1.00	0	28.8	-1.3	29.5	30.8
5.0743	9.4	30	Skew	1.00	0	28.8	-1.1	29.5	30.7
5.1824	9.2	30	Perpendicular	1.00	0	28.9	-0.9	29.5	30.4
13.5577	3.5	30	Parallel	1.00	183	45.9	24.5	29.5	5.0
13.5604	3.5	30	Perpendicular	1.00	74	39.9	18.5	29.5	11.0
13.5623	3.5	30	Skew	1.00	302	37.0	15.6	29.5	14.0

30 -1000 MHz Data

Frequency (MHz)	Antenna Polarity	Height (cm)	Azimuth (degree)	Quasi-Peak Reading (dBμV/m)	Quasi-Peak Limit (dBμV/m)	Quasi-Peak Margin (dB)	EUT Power
200.0	Horizontal	100	265	33.6	43.5	9.9	240VAC 50Hz
200.0	Vertical	100	90	37.3	43.5	6.2	240VAC 50Hz
70.2	Vertical	100	50	32.3	40.0	7.7	240VAC 50Hz
800.0	Horizontal	166	40	36.6	46.0	9.4	240VAC 50Hz
300.0	Horizontal	140	330	39.9	46.0	6.1	240VAC 50Hz
300.0	Vertical	140	185	42.8	46.0	3.2	240VAC 50Hz
320.0	Horizontal	100	52	38.5	46.0	7.5	100VAC 60Hz
300.0	Vertical	140	191	44.0	46.0	2.0	100VAC 60Hz
70.5	Vertical	100	45	31.0	40.0	9.0	100VAC 60Hz
160.2	Vertical	100	0	31.3	43.5	12.2	100VAC 60Hz
160.2	Horizontal	120	0	30.5	43.5	13.0	100VAC 60Hz
200.0	Vertical	100	140	35.3	43.5	8.2	100VAC 60Hz

Company: Devicor Medical Prodcuts, Inc.

Report: TR 318353 D

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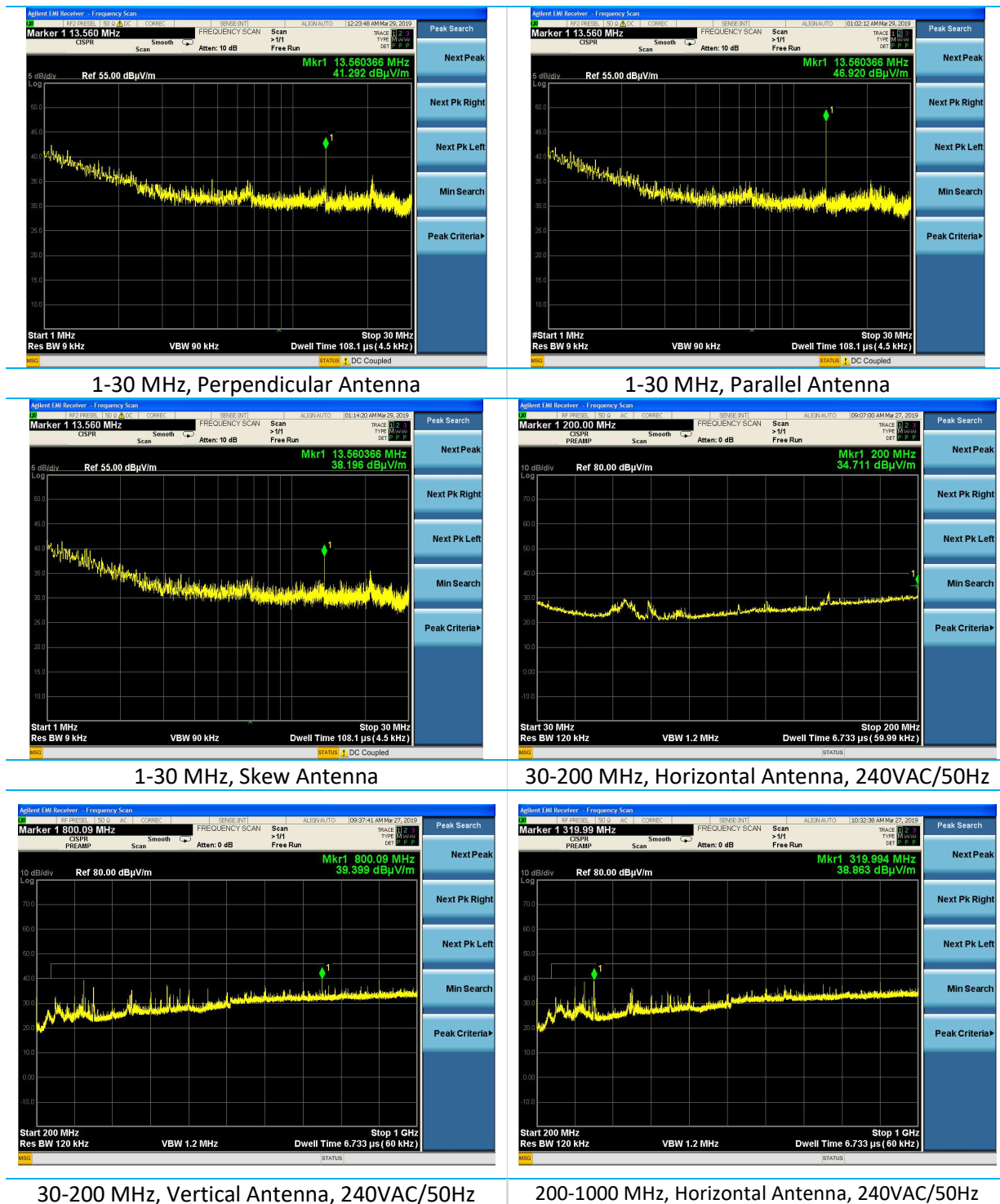
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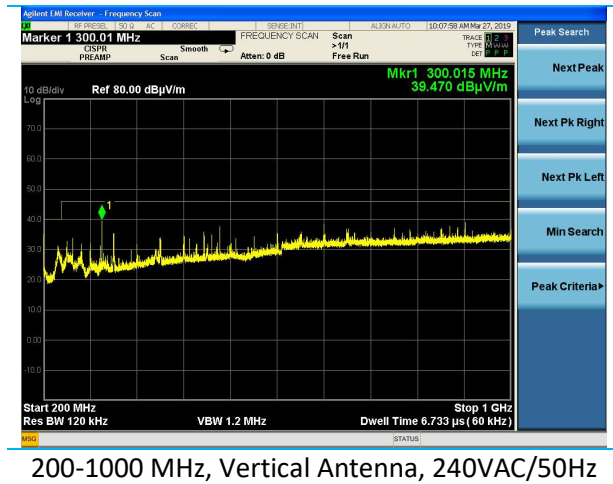
Name: Revolve Control Module with EX Holster

Model: MHEXH1

Serial: MHEXH1000001, MHEXH1000002

Plots





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5.1.2 Radiated Emissions – 99% Occupied Bandwidth

Operator	Zach Wilson	QA	Anthony Smith
Temperature	23.3°C	R.H. %	32.8%
Test Date	5/15/2019	Location	Environmental Chamber
Requirement	FCC 15.225, RSS-GEN	Method	ANSI C63.10

Test Parameters

Frequency	13.56 MHz	Span	5 kHz
Detector(s)	Peak detector with Max Hold	Sweep	Auto
RBW	300 Hz	VBW	1 kHz

EUT Parameters

Input Power	100VAC/60Hz	Mode	Active Biopsy
EUT Radio	RFID Transmit and Receive with GammaTag		

Instrumentation



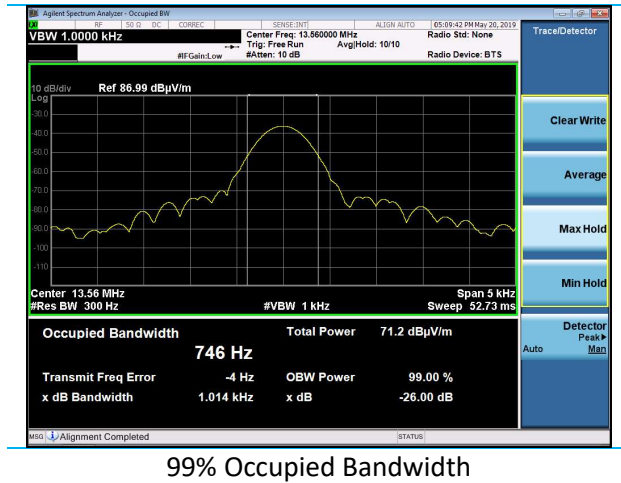
Date: 16-May-2019 Test: OBW, Freq. Stab. Job: C-3148
 PE: Zach Wilson Customer: Leica Biosystems Quote: 318353

No.	Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due Date	Equipment Status
1	CC 000210C	Chamber - Environmental	Thermotron	S-8C	28133	10/26/2018	10/26/2019	Active Verification
2	EE 960087	Analyzer - Spectrum	Agilent	N9010A	MY53400296	4/24/2019	4/24/2020	Active Calibration
3	AA 960006	Antenna - Active Loop	EMCO	6502	9205-2753	8/28/2017	8/28/2019	Active Calibration
4	AA 960172	Cable	A.H. Systems, Inc.	SAC-26G-1	387	6/4/2018	6/4/2019	Active Verification

Table

99% Occupied Bandwidth (Hz)
746.0

Plots



5.1.3 Radiated Emissions – Frequency Stability

Operator	Zach Wilson	QA	Anthony Smith
Temperature	23.3°C	R.H. %	32.8%
Test Date	5/15/2019	Location	Environmental Chamber
Requirement	FCC 15.225, RSS-210	Method	ANSI C63.10

Test Parameters

Frequency	13.56 MHz	Temp Range	-20°C to 50°C
Detector(s)	Peak detector with Max Hold	Limit	±0.01% of Operating Frequency
RBW	30 Hz	VBW	100 Hz
Notes	Voltage variation not possible as unit is powered off a data/power cable connected to console. Device will not function if this cable is changed.		

EUT Parameters

Input Power	100VAC/60Hz	Mode	Active Biopsy
EUT Radio	RFID Transmit and Receive with GammaTag		

Instrumentation



Date: 16-May-2019 Test: OBW, Freq. Stab. Job: C-3148
 PE: Zach Wilson Customer: Leica Biosystems Quote: 318353

No.	Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due Date	Equipment Status
1	CC 000210C	Chamber - Environmental	Thermotron	S-8C	28133	10/26/2018	10/26/2019	Active Verification
2	EE 960087	Analyzer - Spectrum	Agilent	N9010A	MY53400296	4/24/2019	4/24/2020	Active Calibration
3	AA 960006	Antenna - Active Loop	EMCO	6502	9205-2753	8/28/2017	8/28/2019	Active Calibration
4	AA 960172	Cable	A.H. Systems, Inc	SAC-26G-1	387	6/4/2018	6/4/2019	Active Verification

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Table

Temperature (°C)	Center Frequency (Hz)	Limit (±Hz)	Difference from Nominal (Hz)	Margin (Hz)
-20.0	13560030.0	1356.0	32.4	1323.6
20.0	13559997.6	N/A	N/A	N/A
50.0	13559994.5	1356.0	3.1	1352.9

Plots



5.2 AC Mains Conducted Emissions

A line impedance stabilization network (LISN) or artificial mains network (AMN) allows the emissions of the power supply conductors to be measured while isolating the EUT from the supply mains.

Description of Measurement

The AMN, cable, and other necessary measurement system correction factors are loaded onto the EMI receiver when the measurements are performed. The data is gathered and reported as the corrected values.

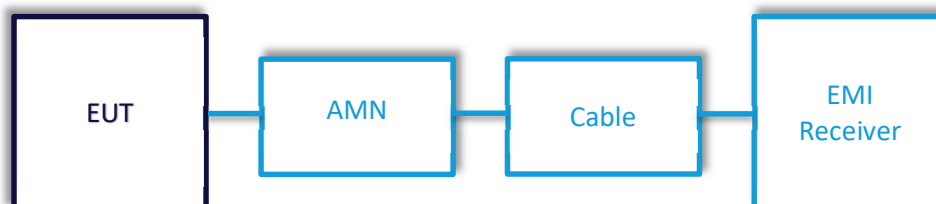
Maximum emissions are determined with a peak max hold trace then measurements at a selection of the highest points are made with quasi-peak and average detectors. Results are recorded and compared to limit for each line. (e.g. line and neutral)

Example Calculations

Measurement (dBμV) + Cable factor (dB) + Other (dB) = Corrected Reading (dBμV)

Margin (dB) = Limit (dBμV) - Corrected Reading (dBμV)

Block Diagram



5.2.1 AC Mains Conducted Emissions

Operator	Braden Smith, Anthony Smith	QA	Zach Wilson
Temperature	21.1°C, 22.7°C	R.H. %	44.4%, 44.1%
Test Date	5/9/2019, 5/17/2019	Location	Conducted Emissions GRP
Requirement	FCC 15.207, RSS-GEN	Method	ANSI C63.10, KDB-174176

Limits: FCC/ISED

Frequency (MHz)	Quasi-peak Limit (dBμV)	Average Limit (dBμV)
0.15-0.5	66 to 56*	56 to 46*
0.5-5	56	46
5-30	60	50

* Limit decreases with the logarithm of the frequency.

Test Parameters

Frequency	0.15-30 MHz	Distance	40cm from VGP
Detector(s)	Max peak hold with peak detector for plots. Quasi-peak and average detectors for final measurements.	Table height	80cm
RBW	9 kHz	VBW	90 kHz
Notes	Emissions tested with both antenna connected and disconnected. Antenna was disconnected to look at emissions near fundamental. Disconnection of antenna and replacement with a dummy load allowed per FCC/KDB-174176. Dummy load consists of a 1.8Ω resistor and 910nH inductor in series.		

Instrumentation



Date: 7-May-2019

Test: Conducted Emissions

Job: C-3148

PE: Zach Wilson

Customer: Leica Biosystems

Quote: 318353

No.	Asset	Description	Manufacturer	Model	Serial	Cal Date	Cal Due Date	Equipment Status
1	EE 960089	LISN	COM-POWER	LI-215A	191943	4/22/2019	4/22/2020	Active Calibration
2	EE 960088	Analyzer - EMI Receiver	Agilent	N9038A	MY51210138	4/23/2019	4/23/2020	Active Calibration
3	LSC-206	Cable	Micro-Coax	UFB311A-0-0840-70U	64639 224068-002	11/14/2018	11/14/2019	Active Verification

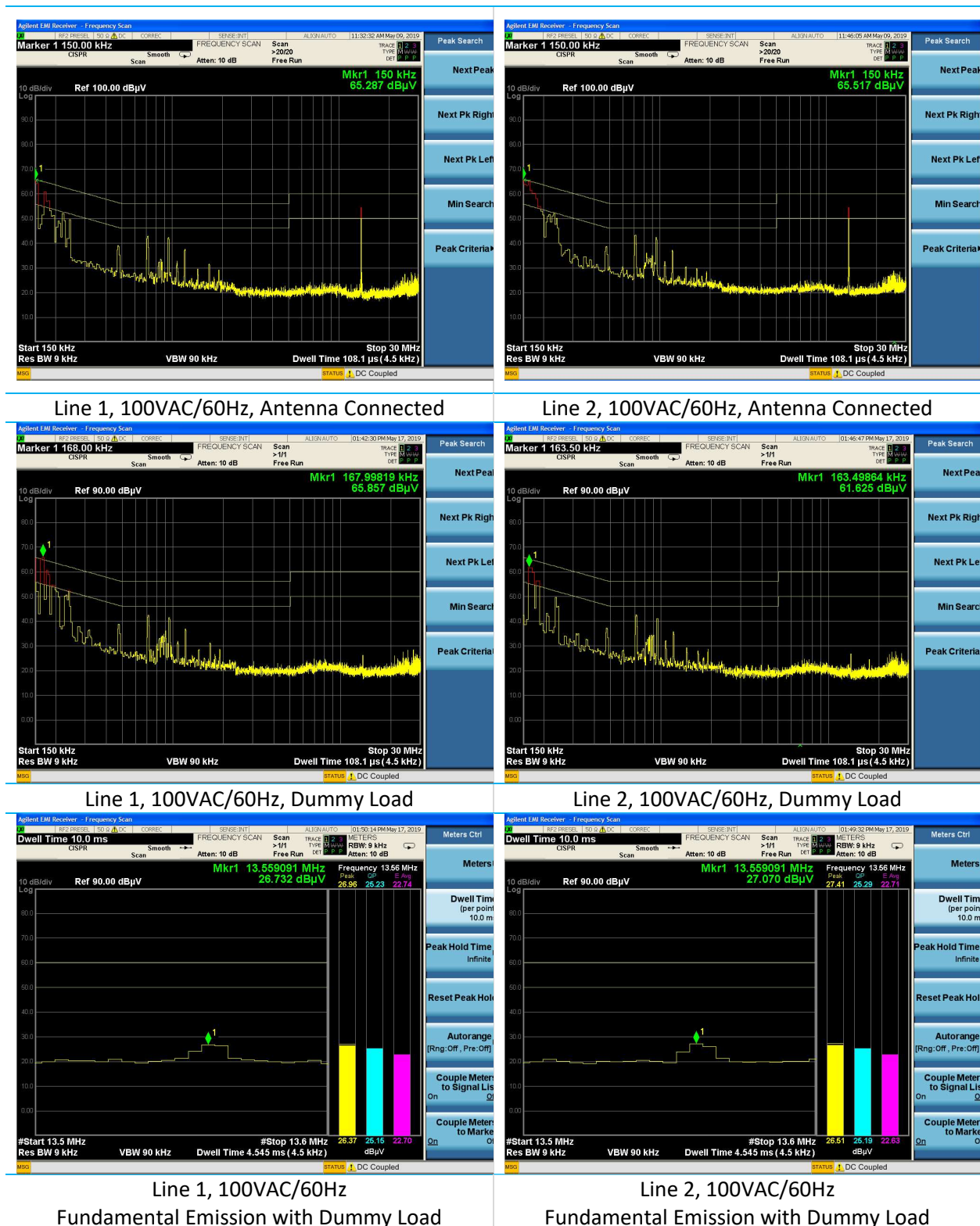
EUT Parameters

Input Power	100VAC/60Hz, 240VAC/50Hz	Mode	Active Biopsy
EUT Radio	RFID Transmit and Receive with GammaTag		

Table

Line	Frequency (MHz)	Peak Reading (dBμV)	Quasi-Peak Reading (dBμV)	Quasi-Peak Limit (dBμV)	Quasi-Peak Margin (dB)	Average Reading (dBμV)	Average Limit (dBμV)	Average Margin (dB)	Input Power
1	0.168	65.9	56.5	65.1	8.6	29.2	55.1	25.9	100VAC/60Hz
1	0.240	52.4	43.6	62.1	18.5	33.9	52.1	18.2	100VAC/60Hz
1	0.712	42.8	41.5	56.0	14.5	38.2	46.0	7.8	100VAC/60Hz
1	13.559	27.0	25.2	60.0	34.8	22.7	50.0	27.3	100VAC/60Hz
2	0.164	64.7	55.6	65.3	9.7	29.2	55.3	26.1	100VAC/60Hz
2	0.222	52.8	42.8	62.7	19.9	24.0	52.7	28.7	100VAC/60Hz
2	0.712	43.4	42.0	56.0	14.0	38.8	46.0	7.2	100VAC/60Hz
2	13.559	27.4	25.3	60.0	34.7	22.7	50.0	27.3	100VAC/60Hz
1	0.150	55.1	49.1	66.0	16.9	33.3	56.0	22.7	240VAC/50Hz
1	0.717	42.2	40.6	56.0	15.4	35.6	46.0	10.4	240VAC/50Hz
1	0.951	41.2	39.3	56.0	16.7	34.1	46.0	11.9	240VAC/50Hz
1	13.559	27.4	25.3	60.0	34.7	22.9	50.0	27.1	240VAC/50Hz
2	0.155	54.4	47.1	65.8	18.7	34.0	55.8	21.8	240VAC/50Hz
2	0.717	42.8	41.3	56.0	14.7	36.2	46.0	9.8	240VAC/50Hz
2	0.951	41.6	39.3	56.0	16.7	33.9	46.0	12.1	240VAC/50Hz
2	13.559	27.7	25.2	60.0	34.8	22.7	50.0	27.3	240VAC/50Hz

Plots



Company: Devicor Medical Prodcuts, Inc.

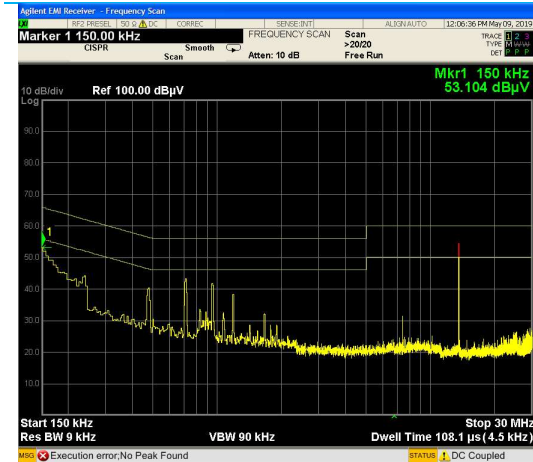
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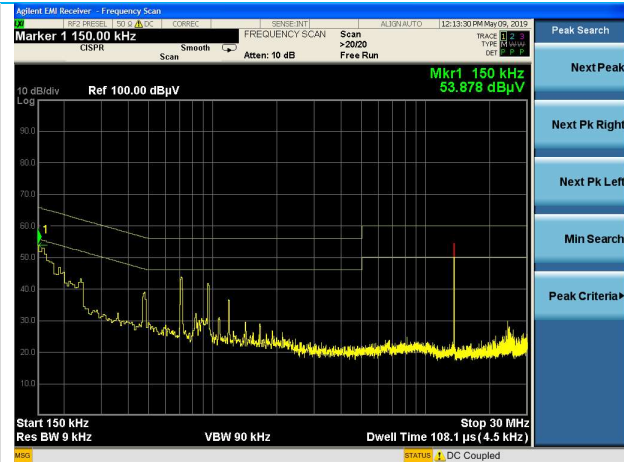
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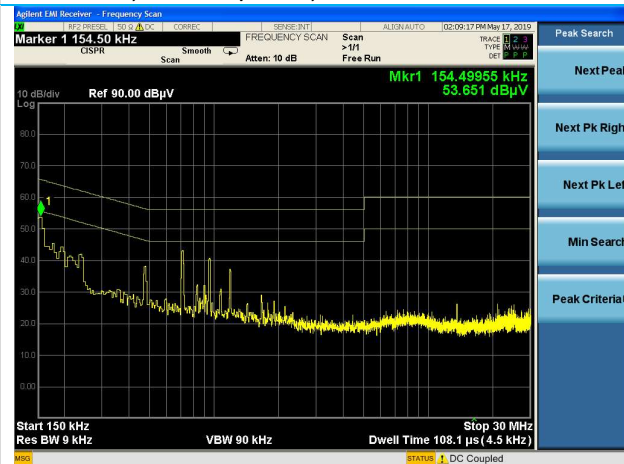
Line 1, 240VAC/50Hz, Antenna Connected



Line 2, 240VAC/50Hz, Antenna Connected



Line 1, 240VAC/50Hz, Dummy Load



Line 2, 240VAC/50Hz, Dummy Load



Line 1, 240VAC/50Hz
Fundamental Emission with Dummy Load



Line 2, 240VAC/50Hz
Fundamental Emission with Dummy Load

6 REVISION HISTORY

Version	Date	Notes	Person
v0.0	5-28-2019	Initial Draft	Zach Wilson
v0.1	5-28-219	Added information about the antenna.	Zach Wilson
v1.0	5-30-2019	Revised after internal review	Zach Wilson
v2.0	3-5-2020	Revised per TCB comments	Zach Wilson

END OF REPORT