Cover Sheet for ESU-110 60601-1-2 EMC Compliance (Updated) Report

APPROVALS

	Name	Signature	Date
Prepared by:	Jeremy Freed		06/28/2021
Reviewed by:	Ricky Dixon		06/28/2021

1.0 PURPOSE

The purpose of this document is to control the ESU-110 60601-1-2 EMC Compliance (Updated) report.

2.0 SCOPE

See purpose above.

3.0 CONTENT

This cover sheet is appended to the report.

DOCUMENT HISTORY

Date	Revision	CN #	Description of Change	Author
06/28/2021	A	0358	New Document created from REP-020 revision A. ~~Moved to current company drawing template~~. Updated to current company document numbering protocol.	JF

Cover Sheet for VPI Test Report V048806_02

1.0 PURPOSE

The purpose of this document is to control the external document VO48806_02 from VPI Laboratories.

2.0 SCOPE

This document is the final test report for the ISO 60601-1-2 testing for the ESU-110 for emissions and immunity.

3.0 REPORT SUMMARY

The controlled document is appended to this cover sheet.

The ESU-110 was tested against the requirements of IEC 60601-1-2:2014 and EN 60601-1-2:2015 by VPI Laboratories on August 12th and 20th of 2019. VPI Laboratories is an NVLAP accredited testing lab (NVLAP Code 100272-0).

The results of the test verify that the ESU-110 complies with the requirements for both emissions and immunity for a professional healthcare environment.

DOCUMENT HISTORY

Date	Revision	CN #	Description of Change	Author
08/26/2019	A	0257	New Document	MC

313 West 12800 South, Suite 311
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Test Report

Declaration of Conformity

Equipment Under Test	ESU-110
Test Report Serial No	V048806_02
Date of Test	August 12, 2019 (Emissions) August 20, 2019 (Immunity)
Report Issue Date	August 15, 2019

Test Specifications:	**Applicant:**
IEC 60601-1-2:2014 EN 60601-1-2:2015	Liger Medical, LLC dba Cure Medical, LLC 3300 N. Running Creek Way, Bld G, Basement Lehi, UT 84043 U.S.A.

NVLAP Testing
NVLAP Lab Code 100272-0

Certification of Engineering Report

This report has been prepared by VPI Laboratories, Inc. to document compliance of the device described below with the emissions requirements of IEC 60601-1-2:2014. This report may be reproduced in full. Partial reproduction of this report may only be made with the written consent of the laboratory. The results in this report apply only to the sample tested.

Applicant	Liger Medical, LLC dba Cure Medical LLC
Manufacturer	Liger Medical
Brand Name	Cure Medical
Model Number	ESU-110

On this 26th day of August 2019, I, individually and for VPI Laboratories, Inc., certify that the statements made in this engineering report are true, complete, and correct to the best of my knowledge, and are made in good faith.

Although NVLAP has accredited the VPI Laboratories, Inc. EMC testing facilities, this report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government.

VPI Laboratories, Inc.

Emissions Tested by: Norman P. Hansen

Immunity Tested by: Benjamin N. Antczak

Reviewed by: Jason Stewart

Revision History		
Revision	**Description**	**Date**
01	Original Report Release	August 15, 2019
02	Immunity Tests Performed and Reported	August 26, 2019

Table of Contents

1 Client Information

1.1 Applicant

Company Name	Liger Medical, LLC dba Cure Medical LLC 3300 N. Running Creek Way, Bld G, Basement Lehi, UT 84043 U.S.A.
Contact Name	Dean Wallace
Title	President

1.2 Manufacturer

Company Name	Liger Medical, LLC dba Cure Medical LLC 3300 N. Running Creek Way, Bld G, Basement Lehi, UT 84043 U.S.A.
Contact Name	Dean Wallace
Title	President

1.3 Party Responsible for Declaration of Conformity

Company Name	Liger Medical, LLC dba Cure Medical LLC 3300 N. Running Creek Way, Bld G, Basement Lehi, UT 84043 U.S.A.
Contact Name	Dean Wallace
Title	President

2 Equipment Under Test (EUT)

2.1 Identification of EUT

Brand Name	Cure Medical
Model Number	ESU-110
Serial Number	004
Dimensions (cm)	20 x 8 x 11

2.2 Description of EUT

The ESU-110 is an electrosurgical generator specifically designed for larger loop excision of the transformation zone procedures. The ESU-110 is single-purpose, battery-operated and has no user adjustable parameters. The simplicity of the design allows for lower cost, portability and surgical potential in geographic areas with limited or unreliable access to power mains. A Kobalt 24V 2Ah rechargeable battery provides power to the ESU-110.

2.3 EUT and Support Equipment

The EUT and support equipment used during the test are listed below.

Brand Name **Model Number** **Serial Number**	**Description**	**Name of Interface Ports / Interface Cables**
BN: Cure Medical MN: ESU-110 (Note 1) SN: 004	Electrosurgical generator	See Section 2.4
BN: Conmed MN: 131327A SN: None	Disposable hand switch	Hand Piece/3 conductor cable with banana type connectors (Note 2)
BN: Cure Medical MN: Load SN: None	Load simulator	Pad/2 conductor cable (Note 2)

Notes: (1) EUT

(2) Interface port connected to EUT (See Section 2.4)

The support equipment listed above was not modified in order to achieve compliance with this standard.

2.4 Interface Ports on EUT

Name of Ports	No. of Ports Fitted to EUT	Cable Description/Length
Hand piece	1	3 conductor cable with banana type connectors/7 meters
Pad	1	2 conductor cable with Molex type connector/7 meters

2.5 Modification Incorporated/Special Accessories on EUT

There were no modifications or special accessories required to comply with the specification.

2.6 Deviation from Test Standard

There were no deviations from the test specification.

3 Test Specification, Methods and Procedures

3.1 Test Specification

Title	IEC 60601-1-2:2014 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility Requirements and tests
Purpose of Test	The tests were performed to demonstrate initial compliance.

3.1.1 IEC 60601-1-2:2014 Refers to the following Basic Standards

Basic Standard	Date	Title
CISPR 11: 2009 + A1: 2010 (EN 55011: 2010)	2010 2009	Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement

3.2 Methods & Procedures

The equipment under test was tested using the procedure and limits of the standards listed in section 3.1.1 of this report.

3.2.1 Limits for Conducted Emissions at Mains Terminals

The equipment under test (EUT) shall meet the limits either:

a) both the average limit specified for measurements with an average detector and the quasi-peak limit specified for measurements with a quasi-peak detector; or

b) the average limit when using a quasi-peak detector.

The EUT is deemed compliant when the average limit is met when using peak detection.

Frequency range (MHz)	Rated input power of ≤20 kVA		Rated input power of ≥20 kVA[a]	
	Quasi-peak dB(µV)	Average dB(µV)	Quasi-peak dB(µV)	Average dB(µV)
0.15 – 0.50	79	66	100	90
0.50 – 5	73	60	86	76
5 – 30	73	60	90 Decreasing linearly with logarithm of frequency to 73	80 60
At the transition frequency, the more stringent limit shall apply. NOTE 1 Limits only apply to low voltage a.c. mains input ports. NOTE 2 For class A equipment intended to be connected solely to isolated neutral or high impedance earthed (IT) industrial power distribution networks (see IEC 60364-1), the limits defined for group 2 equipment with a rated input power >75 kVA in Table 6 can be applied.				

[a] These limits apply to equipment with a rated input power > 20 kVA and intended to be powered by a dedicated power transformer or generator, and which is not connected to Low Voltage (LV) overhead power lines. For equipment not intended to be powered by a user specific power transformer, the limits for ≤ 20 kVA apply. The manufacturer and/or supplier shall provide information on installation measures that can be used to reduce emissions from the installed equipment. In particular, it shall be indicated that this equipment is intended to be powered by a dedicated power transformer or generator and not by LV overhead power lines.

Table 1: CISPR 11 Table 2 Mains terminal emissions voltage limits for Class A Group 1 equipment measured on a test site

Frequency range (MHz)	Groups 1 and 2	
	Quasi-peak	Average
0.15 to 0.50	66 Decreasing linearly with logarithm of frequency to 56	56 Decreasing linearly with logarithm of frequency to 46
0.50 to 5	56	46
5 to 30	60	50
At the transition frequency, the more stringent limit shall apply.		

Table 2: CISPR Table 3 Mains terminal disturbance voltage limits for Class B equipment on a test site.

3.2.2 Limits for Radiated Disturbance

The equipment under test shall meet the quasi-peak limits when using a quasi-peak detector.

Frequency Range (MHz)	10 m measuring distance rated input power		3 m measuring distance[b] rated input power of	
	≤20 kVA	≥20 kVA[a]	≤20 kVA	≥20 kVA[a]
	Quasi-Peak dB(µV/m)	Quasi-Peak dB(µV/m)	Quasi-Peak dB(µV/m)	Quasi-Peak dB(µV/m)
30 – 230	40	50	50	60
230 – 1000	47	50	57	60
On a test site, class A equipment can be measured at a nominal distance of 3 m, 10 m or 30 m. A measuring distance less than 10 m is allowed only for equipment which complies with the definition given in 3.10. In case of measurements at a separation distance of 30 m, an inverse proportionality factor of 20 dB per decade shall be used to normalize the measured data to the specified distance for determining compliance. At the transition frequency, the more stringent limit shall apply.				
[a] These limits apply to equipment with a rated input power of > 20 kVA and intended to be used at locations where there is a distance greater than 30 m between the equipment and third party sensitive radio communications. The manufacturer shall indicate in the technical documentation that this equipment is intended to be used at locations where the separation distance to third party sensitive radio services is > 30 m. If these conditions are not met, then the limits for ≤ 20 kVA apply.				

[b] The limits specified for the 3 m separation distance apply only to small equipment meeting the size criterion defined in 3.10.

Table 3: CISPR 11 Table 4 Electromagnetic radiation disturbance limits for Class A group 1 equipment measured on a test site.

Frequency Range (MHz)	10 m measuring distance	3 m measuring distance[a]
	Quasi-peak dB(µV/m)	Quasi-peak dB(µV/m)
30 – 230	30	40
230 – 1000	37	47
On a test site, class B equipment can be measured at a nominal distance of 3 m or 10 m. A measuring distance less than 10 m is allowed only for equipment which complies with the definition given in 3.10. At the transition frequency, the more stringent limit shall apply.		
[a] The limits specified for the 3 m separation distance apply only to small equipment meeting the size criterion defined in 3.10.		

Table 4: CISPR Table 5 Electromagnetic radiation emissions limits for Class B Group 1 equipment measured on a test site.

3.2.3 Harmonic Emissions (EN 61000-3-2)

If the EUT is rated at 220V or above the following limits apply.

Harmonic Order N	Maximum permissible harmonic current A
Odd harmonics	
3	2.30
5	1.14
7	0.77
9	0.40
11	0.33
13	0.21
$15 \le n \le 39$	$0.15 \frac{15}{n}$
Even harmonics	
2	1.08
4	0.43
6	0.30
$8 \le n \le 40$	$0.23 \frac{8}{n}$

Table 5: Harmonic Emission Limit

3.2.4 Voltage Fluctuations and Flicker (EN 61000-3-3)

If the EUT is rated at 220V or above the following limits apply.

The limits shall be applicable to voltage fluctuations and flicker at the supply terminals of the equipment under test, measured or calculated according to clause 4 under test conditions described in clause 6 and

annex A of EN 61000-3-3. Tests made to prove the compliance with the limits are considered to be type tests.

The following limits apply:

- The value of P_{st} shall not be greater than 1.0
- The value of P_{lt} shall not be greater than 0.65
- The relative steady-state voltage change, d_c, shall not exceed 3.3%
- The value of d(t) during a voltage change shall not exceed 3.3% for more than 500 ms.
- The maximum relative voltage change, d_{max}, shall not exceed
    - 4% without additional conditions
    - 6% for equipment which is
        - switched manually, or
        - switched automatically more frequently than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds), or manual restart, after a power supply interruption.
    - 7% for equipment which is
        - attended whilst in use (for example: hair dryers, vacuum cleaners, kitchen equipment such as mixers, garden equipment such as lawn mowers, portable tools such as electric drills), or
        - switched on automatically, or is intended to be switched on manually, no more than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds) or manual restart, after a power supply interruption.

In the case of equipment having several separately controlled circuits in accordance with 6.6, limits b and c shall apply only if there is delayed or manual restart after a power supply interruption; for all equipment with automatic switching which is energized immediately on restoration of supply after a power supply interruption, limits a shall apply; for all equipment with manual switching, limits b or c shall apply depending on the rate of switching.

3.3 Test Procedure

The conducted emissions at mains ports and radiated emissions testing was performed according to the procedures in CISPR 11 as specified in EN 60601-1-2. Testing was performed at the VPI Laboratories, Inc. Wanship Open Area Test Site #2, located at 29145 Old Lincoln Highway, Wanship, UT.

Immunity testing to EN 60601-1-2 was performed at VPI Laboratories, Inc., located at 313 West 12800 South, Suite 311, Draper, UT.

VPI Laboratories, Inc. is accredited by National Voluntary Laboratory Accreditation Program (NVLAP); NVLAP Lab Code: 100272-0, which is effective until September 30, 2019.

4 Operation of EUT During Testing

4.1 Operating Environment

Power Supply	240 VAC
AC Mains Frequency	50 Hz

4.2 Operating Modes

The EUT was tested with the unit ready to initiate a surgical procedure.

4.3 EUT Exercise Software

Internal firmware was used to exercise the EUT.

4.4 Block Diagram of Test Configuration

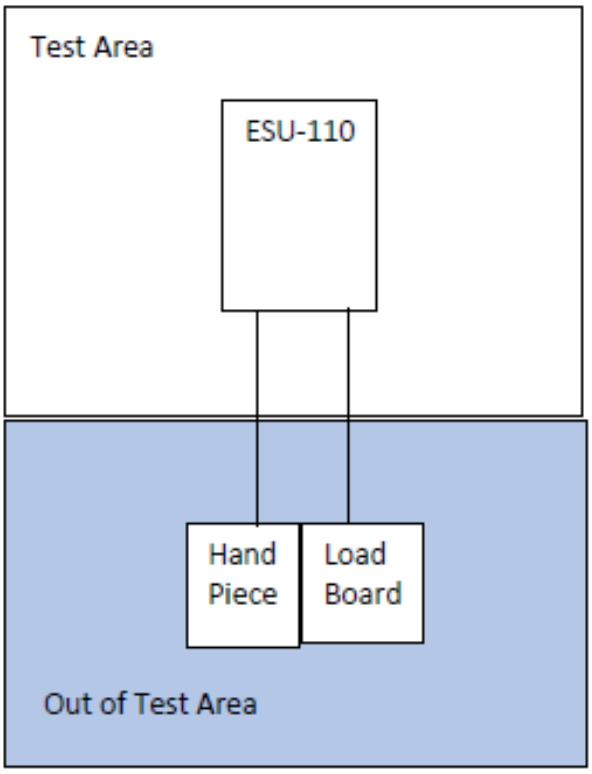


Diagram 1: Test Configuration Block Diagram

4.5 Pass/Fail Criteria

For this EUT, the client has stated that the pass/fail criteria defined in EN 60601-1-2 should be applied as follows: The EUT shall continue to operate as intended, with no degradation of performance allowed.

The following degradations, if associated with basic safety and essential performance, shall not be allowed:

- component failures;

- changes in programmable parameters;
- reset to factory defaults (manufacturer's presets);
- change of operating mode;
- false alarms;
- cessation or interruption of any intended operation, even if accompanied by an alarm;
- initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm;
- error of a displayed numerical value sufficiently large to affect diagnosis or treatment;
- noise on a waveform in which the noise would interfere with diagnosis, treatment or monitoring;
- artefact or distortion in an image in which the artefact would interfere with diagnosis, treatment or monitoring;
- failure of automatic diagnosis or treatment ME EQUIPMENT and ME SYSTEMS to diagnose or treat, even if accompanied by an alarm.

For ME EQUIPMENT and ME SYSTEMS with multiple functions, the criteria apply to each function, parameter and channel.

The ME EQUIPMENT or ME SYSTEM may exhibit degradation of performance (e.g. deviation from manufacturer's specifications) that does not affect basic safety or essential performance.

4.6 Monitoring of the EUT

The ESU-110 was monitored using an oscilloscope that displayed the waveform at the conductor on the disposable hand piece while the conductor simulated cutting skin and coagulating skin by touching a resistive network on the Load Board that simulates the resistance of skin.

5 Summary of Test Results

5.1 Summary of Emission Tests

Port	Test Description	Frequency Range (MHz)	Result
AC Power	Conducted Emissions (Hot Lead to Ground)	0.15 to 30	Not Applicable (Note 1)
AC Power	Conducted Emissions (Neutral Lead to Ground)	0.15 to 30	Not Applicable (Note 1)
Enclosure	Radiated Emissions (Vertical Polarity)	30 to 1000	Complied
Enclosure	Radiated Emissions (Horizontal Polarity)	30 to 1000	Complied
Note 1: The EUT is battery powered and has no provisions for connecting to a device that maybe connected to the AC mains.			

5.2 Summary of Immunity Tests

Enclosure Port		
Basic Standard	**Environmental Phenomena**	**Result**
EN 61000-4-2	Electrostatic Discharge	Complied
EN 61000-4-3	Radio Frequency Electromagnetic Field	Complied
EN 61000-4-3	Proximity fields from RF wireless communication equipment	Complied
EN 61000-4-8	Power-frequency magnetic field	Note 1
Note 1: The EUT does not contain any elements that are susceptible to magnetic fields, therefore; testing to this standard is not applicable.		

AC Power Ports		
Basic Standard	**Environmental Phenomena**	**Result**
EN 61000-4-4	Electrical fast transient/burst	Note 1
EN 61000-4-5	Lightning Surge	Note 1
EN 61000-4-6	Radio-frequency continuous conducted	Note 1
EN 61000-4-11	Voltage Dips and Interruptions	Note 1
Note 1: The EUT is not equipped with an AC power port, therefore; testing to this port is not applicable.		

5.3 Summary of Tests (EN 61000-3-2 and EN 61000-3-3)

AC Power Port		
Basic Standard	**Environmental Phenomena**	**Result**
EN 61000-3-2	Harmonic Current Measurement.	Note 1
EN 61000-3-3	Voltage Flicker Measurement.	Note 1
Note 1: The EUT is not equipped with an AC power port, therefore; testing to this port is not applicable.		

6 Measurements, Examinations and Derived Results

6.1 General Comments

This section contains the test results only. Details of the test methods used and a list of the test equipment used during the measurements can be found in Section 7 of this report.

6.2 Test Results (Emissions)

6.2.1 Radiated Emissions Data (Vertical Polarity)

Frequency (MHz)	Detector	Receiver Reading (dBµV)	Correction Factor (dB/m)	Field Strength (dBµV/m)	Class B 3 m Limit (dBµV/m)	Margin (dB)
41.2	Quasi-Peak (Note 1)	19.1	17.6	36.7	40.0	-3.3
50.1	Quasi-Peak (Note 1)	24.6	14.7	39.3	40.0	-0.7
53.8	Quasi-Peak (Note 1)	21.3	14.6	35.9	40.0	-4.1
68.6	Peak (Note 1)	18.5	14.8	33.3	40.0	-6.7
196.8	Peak (Note 1)	10.4	18.7	29.1	40.0	-10.9
216.0	Peak (Note 1)	10.7	19.7	30.4	40.0	-9.6

Note 1: The reference detector used for the measurements was peak or quasi-peak and the data was compared to the quasi-peak limit.
Note 2: The reference detector used for the measurements was quasi-peak and average and the data was compared to the respective limits.

Result

The EUT complied with the specification limit by a margin of 0.7 dB.

6.2.2 Radiated Emissions Data (Horizontal Polarity)

Frequency (MHz)	Detector	Receiver Reading (dBµV)	Correction Factor (dB/m)	Field Strength (dBµV/m)	Class B 3 m Limit (dBµV/m)	Margin (dB)
49.7	Peak (Note 1)	9.6	14.8	24.4	40.0	-15.6
173.0	Peak (Note 1)	7.9	18.2	26.1	40.0	-13.9
196.9	Peak (Note 1)	7.5	18.8	26.3	40.0	-13.7
216.0	Peak (Note 1)	9.5	19.7	29.2	40.0	-10.8
234.4	Peak (Note 1)	11.0	20.8	31.8	47.0	-15.2
531.2	Peak (Note 1)	2.0	31.1	33.1	47.0	-13.9

Note 1: The reference detector used for the measurements was peak or quasi-peak and the data was compared to the quasi-peak limit.
Note 2: The reference detector used for the measurements was quasi-peak and average and the data was compared to the respective limits.

Result

The EUT complied with the specification limit by a margin of 10.8 dB.

6.3 Sample Field Strength Calculation

The field strength is calculated by adding the *Correction Factor* (*Antenna Factor* + *Cable Factor*), to the measured level from the receiver. The receiver amplitude reading is compensated for any amplifier gain. The basic equation with a sample calculation is shown below:

$$Receiver\ Amplitude\ Reading = Receiver\ Reading - Amplifier\ Gain$$

$$Correction\ Factor = Antenna\ Factor + Cable\ Factor$$

$$Field\ Strength = Receiver\ Amplitude\ Reading + Correction\ Factor$$

Example

Assuming a *Receiver Reading* of 42.5 dBµV is obtained from the receiver, the *Amplifier Gain* is 26.5 dB the *Antenna Factor* is 4.5 dB, and the *Cable Factor* is 4.0 dB. The *Field Strength* is calculated by subtracting the *Amplifier Gain* and adding the *Correction Factor*, giving a *Field Strength* of 24.5 dBµV/m.

$$Receiver\ Amplitude\ Reading\ =\ 42.5 - 26.5\ =\ 16.0\ \mathrm{dB\mu V/m}$$

$$Correction\ Factor\ =\ 4.5 + 4.0\ =\ 8.5\ \mathrm{dB}$$

$$Field\ Strength\ =\ 16.0 + 8.5\ =\ 24.5\ \mathrm{dB\mu V/m}$$

6.4 Test Results (Immunity)

6.4.1 Electrostatic Discharge

Port	Enclosure
Basic Standard	EN 61000-4-2
Limit	8 kV (Contact discharge) 2, 4, 8, 15 kV (Air discharge)
Temperature during testing	23°C
Relative Humidity during testing	31%
Atmospheric Pressure during testing	1001 mbar

Discharge Point	Discharge Voltage (kV)	Discharge Type	Comment	Result
Horizontal Coupling Plane	8	Contact	Note 1	Complied
Vertical Coupling Plane	8	Contact	Note 1	Complied
1-2	8	Contact	Note 1	Complied
2-9	2, 4, 8, 15	Air	Note 1	Complied
Note 1: There was no observable degradation in the performance of the EUT.				

Discharge Points		Description	Reference to Photograph No.
Contact	1	Conductive pad on bottom	8
Air	2 - 19	Enclosure faces, power button, battery's power button, front ports, battery release buttons	9 - 11

Result

In the configuration tested, the EUT complied with the specification.

6.4.2 Radio-Frequency Electromagnetic Field

Port	Enclosure
Basic Standard	EN 61000-4-3
Limit	10 V/m and the levels specified in Table 9 of this standard.
Dwell Time	1 s
Modulation	1 kHz 80% Amplitude Modulated, and 50% Pulse Modulated according to Table 9 of this standard.
Temperature during testing	23°C
Relative Humidity during testing	35%

Frequency (MHz)	Level (V/m)	Exposed Area	Antenna Polarity	Comment	Result
80 – 2700	10	Front, Right, Left and Rear	Horizontal & Vertical	Note 1	Complied
385	27	Front, Right, Left and Rear	Horizontal & Vertical	Note 1	Complied
450	28	Front, Right, Left and Rear	Horizontal & Vertical	Note 1	Complied
710 745 780	9	Front, Right, Left and Rear	Horizontal & Vertical	Note 1	Complied
810 870 930	28	Front, Right, Left and Rear	Horizontal & Vertical	Note 1	Complied
1720 1845 1970 2450	28	Front, Right, Left and Rear	Horizontal & Vertical	Note 1	Complied
5240 5500 5785	9	Front, Right, Left and Rear	Horizontal & Vertical	Note 1	Complied
Note 1: There was no observable degradation in the performance of the EUT.					

Result

In the configuration tested, the EUT complied with the specification.

7 Test Equipment

7.1 Radiated Emissions

The radiated emissions from the EUT were measured using a spectrum analyzer with a quasi-peak adapter for peak and quasi-peak readings.

A preamplifier with a fixed gain of 51 dB was used to increase the sensitivity of the measuring instrumentation. The quasi-peak adapter uses a bandwidth of 120 kHz, with the spectrum analyzer's resolution bandwidth set at 1 MHz, for readings in the 30 to 1000 MHz frequency ranges.

A biconilog antenna was used to measure the frequency range of 30 to 1000 MHz, at a distance of 3 meters from the EUT. The readings obtained by these antennas are correlated to the levels obtained with a tuned dipole antenna by adding antenna factors.

The configuration of the EUT was varied to find the maximum radiated emission. The EUT was connected to the peripherals listed in Section 2.3 via the interconnecting cables listed in Section 2.4. A technician manually manipulated these interconnecting cables to obtain worst-case radiated emissions. The EUT was rotated 360 degrees, and the antenna height was varied from 1 to 4 meters to find the maximum radiated emission. Where there were multiple interface ports all of the same type, cables are either placed on all of the ports or cables added to these ports until the emissions do not increase by more than 2 dB.

Desktop EUT are measured on a non-conducting table 0.8 meters above the ground plane. The table is placed on a turntable, which is level with the ground plane. For equipment normally placed on floors, the equipment shall be placed directly on the turntable.

For radiated emissions testing that is performed at distances closer than the specified distance; an inverse proportionality factor of 20 dB per decade is used to normalize the measured data for determining compliance.

Type of Equipment	Manufacturer	Model Number	Asset Number	Date of Last Calibration	Due Date of Calibration
Spectrum Analyzer	Hewlett Packard	8566B	V048078	05/26/2019	05/26/2020
Quasi-Peak Detector	Hewlett Packard	85650A	V039474	05/02/2018	05/02/2020
Biconilog Antenna	EMCO	3142E-PA	V035736	07/05/2018	07/05/2020
6’ High Frequency Cable	Microcoax	UFB197C-0-0720-000000	V033638	01/08/2019	01/08/2020
3 Meter Radiated Emissions Cable Wanship Site #2	Microcoax	UFB205A-0-4700-000000	V033639	01/08/2019	01/08/2020
Test Software (CE)	VPI Labs	Revision 01	V035672	N/A	N/A

Table 6: List of equipment used for radiated emissions testing.

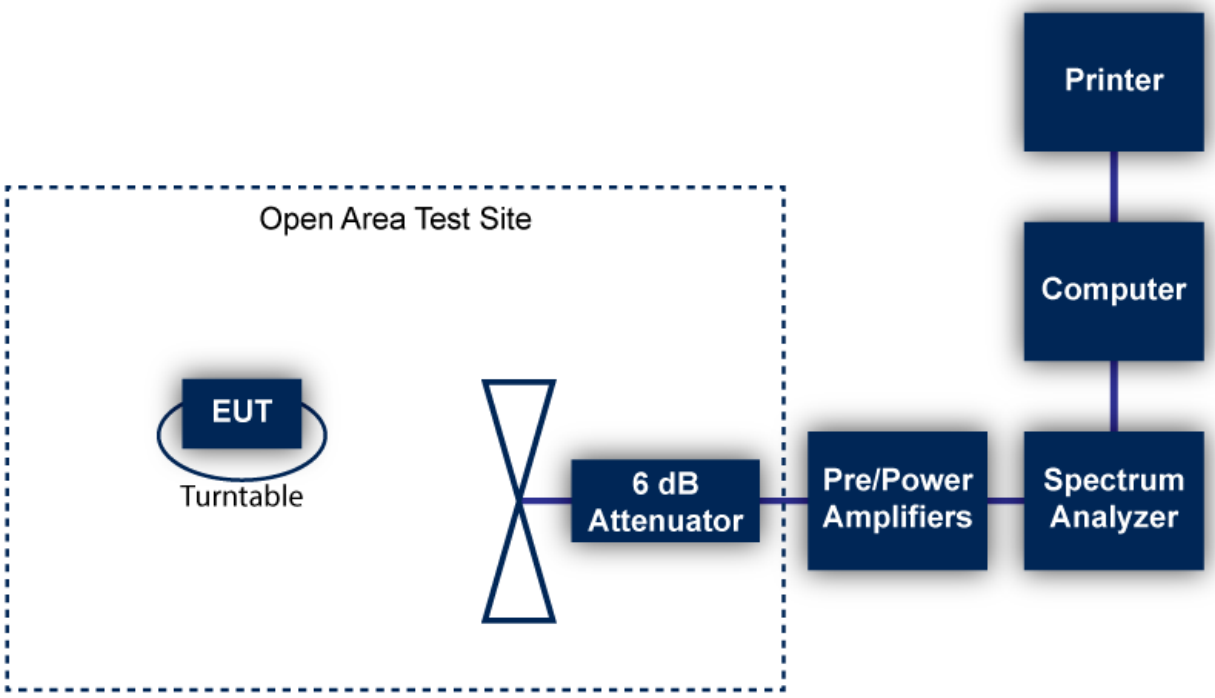


Figure 1: Radiated Emissions Test

7.2 Electrostatic Discharge

The EUT is tested to the test procedures outlined in EN 61000-4-2 Section 8 and is configured for normal operation as described in Sections 4.2 and 4.3 of this report.

The tests are performed atop a non-conductive table, 0.8 m high, over a ground reference plane (GRP). The room is large enough to provide sufficient distance between the equipment under test (EUT)/Horizontal Coupling Plane (HCP) and the walls of the room or other metallic objects. A HCP, 1.6 m x 0.8 meters is placed on the top of the table and connected to the GRP via a cable with a 470 KΩ resistor located at each end. The EUT is isolated from the HCP by an insulating support 0.5 mm thick. A vertical coupling plane (VCP), 0.5 m x 0.5 m, is placed vertical 0.1 m from the EUT and connected to the GRP via a cable with a 470 KΩ resistor located at each end. The HCP and VCP are used to simulate discharges to objects placed or installed near the EUT.

The test voltage is increased from the minimum severity level to the selected test severity level, in order to determine any encountered threshold of failure. Ten single discharges are applied on pre-selected points in both the vertical and horizontal polarities. The time interval between successive single discharges was sufficiently long enough in order to in order to determine whether a system failure had occurred. The ESD generator is held perpendicular to the surface to which the discharge is applied.

For contact discharges, the tip of the discharge electrode touches the EUT before the discharge switch is operated. In the case of painted surfaces covering a conducting substrate, the pointed tip of the ESD generator shall penetrate the coating so as to make contact with the conducting surface. If the coating is declared as “insulating” by the manufacturer, the EUT shall only be submitted to air discharges.

For air discharges, the EUT is approached as fast as possible (without causing mechanical damage) with the round discharge tip of the discharge electrode. After each discharge, the ESD generator (discharge electrode) is removed from the EUT and the generator is then re-triggered for a new single discharge.

In order to simulate discharges to objects placed or installed near the EUT discharges of the ESD generator to a coupling plane is applied in the contact discharge mode.

For the HCP 10 single discharges (in the most sensitive polarity) are applied at the front edge of each HCP opposite the center point of each unit (if applicable) of the EUT and at least 0.1 m from the front of the EUT. The long axis of the discharge electrode was in the plane of the HCP and perpendicular to the front edge during the discharge.

For the VCP ten single discharges (in the most sensitive polarity) are applied to the center of a vertical edge of the coupling plane. The coupling plane is placed parallel to and positioned at a distance of 0.1 m from the EUT. Discharges are applied to the coupling plane, with this plane in a sufficient number of different positions that the four faces of the EUT were completely illuminated.

Type of Equipment	Manufacturer	Model Number	Asset Number
ESD Simulation System	Teseq	NSG 438A	V033288

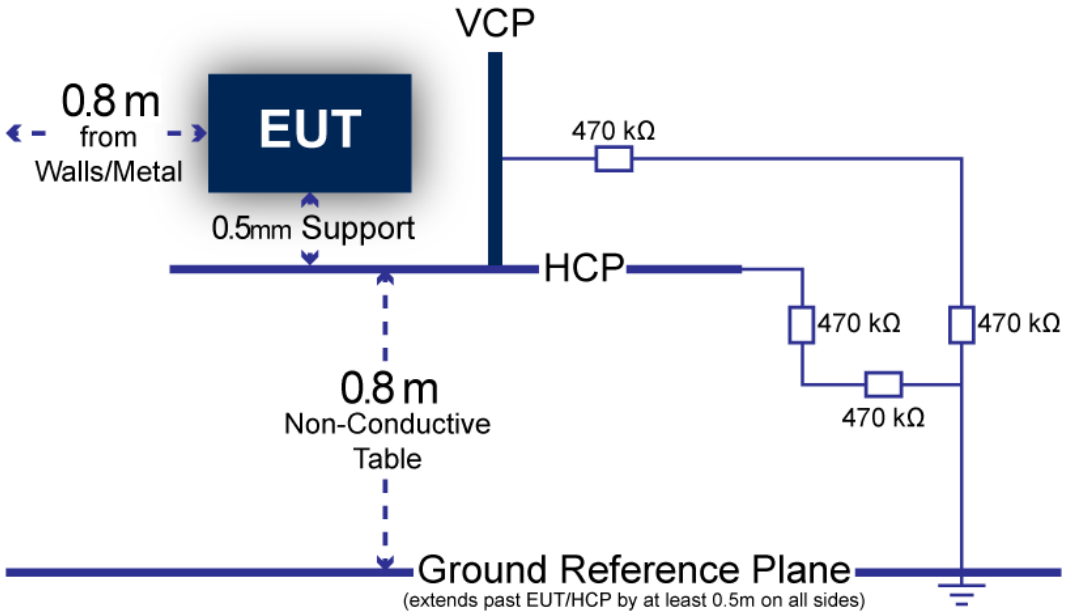


Diagram 2: Electrostatic Discharge Test

7.3 Radio-Frequency Electromagnetic Field

The EUT is tested to the test procedures outlined in EN 61000-4-3 Section 8 and is configured for normal operation as described in Sections 4.2 and 4.3 of this report.

The measurements are performed in a semi anechoic chamber with internal dimensions 2.8 m x 6.1 m (absorber-to-absorber). The radiating antenna is placed 3 m from the EUT.

The chamber is calibrated for field uniformity every twelve months using the constant field strength calibration method (EN 61000-4-3, Section 6.2.1). Additionally, when changes have been made in the enclosure configuration the full field calibration is repeated. Before each batch of testing (see Clause 8), the validity of the calibration is verified. A vertical plane that is 1.5 m by 1.5 m defines the uniform field area. The bottom of this vertical plane is 0.8 m above the floor of the chamber. Sixteen points are defined in this vertical plane located 0.5 m apart arranged in a grid pattern in the plane. The uniformity of the chamber is met if 12 of the 16 points are within -0 to +6 dB of the nominal field level. The point with the

maximum forward power measured is used for the calibration power when determining the field level at that frequency.

The uniformity of the chamber is determined by placing an isotropic field strength probe 3 m from the transmitting antenna at a height of 0.8 m from the floor of the chamber in the corner of the vertical field (position 1). The frequency range is swept incrementally (1% of fundamental) from 80 MHz to 6000 MHz. The forward power from the amplifier required to produce the desired field strength is measured and recorded. After the entire frequency range has been swept the probe is moved to the next position and the process is repeated until all 16 positions have been measured and recorded.

The radiating antenna was placed 3 m from the front of the EUT, in the position used during calibration.

The EUT is placed on a non-conducting foam table that is 0.8 m from the floor of the chamber, at the distance specified above. The frequency range is swept incrementally from 80 MHz to 6000 MHz using the previously recorded power levels to re-establish the field. The EUT is rotated in 90° increments to ensure that all four sides are exposed to the radiating field.

The dwell time at each frequency is not less than the time necessary for the EUT to be exercised and respond to stimulus. The EUT's sensitive frequencies, clock frequencies and harmonics, or frequencies of dominant interest are analyzed separately when necessary.

Type of Equipment	Manufacturer	Model Number	Asset Number
Semi-Anechoic Chamber	Rohde & Schwarz	XL-CDC	V033181
Signal Generator	Rohde & Schwarz	SMB100A	V033229
RF Power Meter	Rohde & Schwarz	NRP2	V033230
Amplifier, 0.8-3GHz, 2.5-6GHz	Rohde & Schwarz	BBA150	V033232
Antenna, Biconi-Log, 30 MHz to 1 GHz	Rohde & Schwarz	TS-PANT	V033236
Antenna, Double Log-Periodic, 0.7-9 GHz	Schwarzbeck	STLP9149	V033237

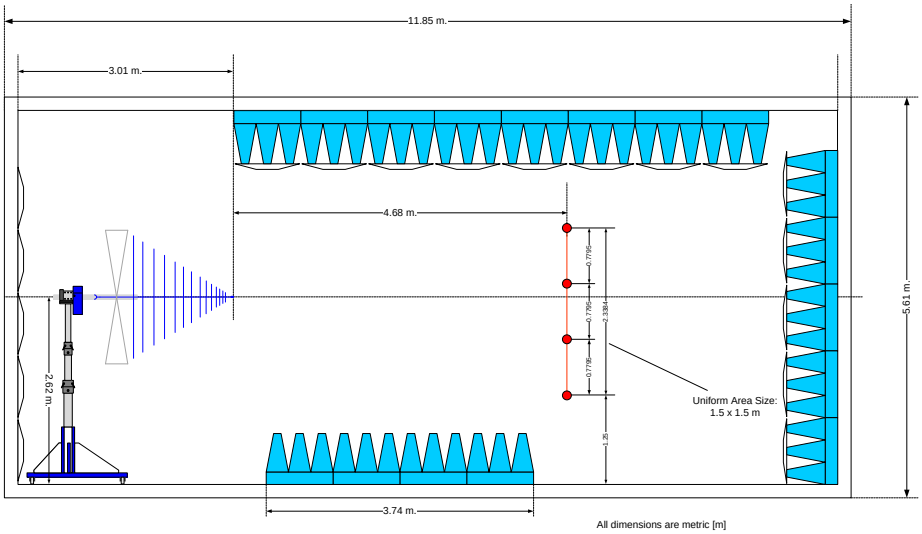


Diagram 3: Radiated Electromagnetic Field Test

7.4 Equipment Calibration

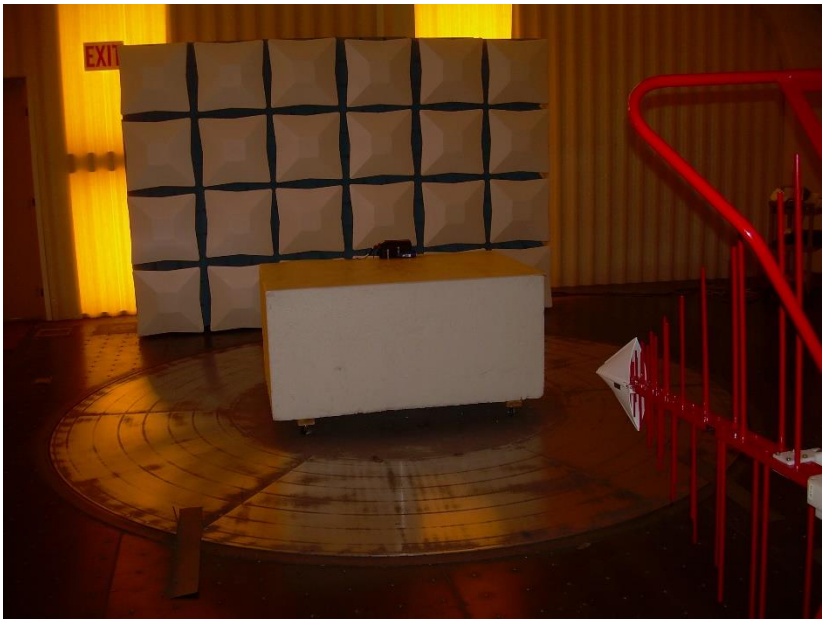
All applicable equipment listed above is calibrated using either an independent calibration laboratory or VPI Laboratories, Inc. personnel following outlined calibration procedures. All measurement instrumentation is traceable to the National Institute of Standards and Technology (NIST). Supporting documentation relative to tractability is on file and is available for examination upon request.

7.5 Measurement Uncertainty

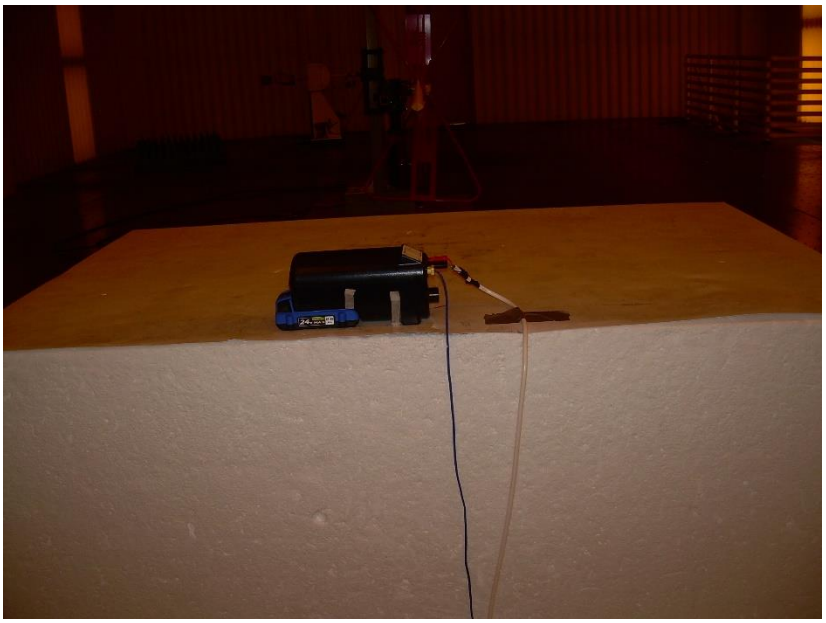
Test	Uncertainty (±dB)	Confidence (%)
Conducted Emissions	2.8	95
Radiated Emissions (30 MHz to 1 GHz)	3.4	95

The test equipment used for all tests meets or exceeds the specifications of this standard, showing precise and reproducible results. Measurement uncertainty has been calculated and is found in VPI document *Laboratory Measurement Uncertainty* (V034583).

8 Photographs



Photograph 1: Front View Radiated Emissions Worst Case Configuration



Photograph 2: Back View Radiated Emissions Worst Case Configuration

Photograph 3 – Top View of the ESU-110

Photograph 4 – Side View of the EUT Showing Ports for Connection of the Hand Piece and Pad

Photograph 5 – Side View of the ESU-110

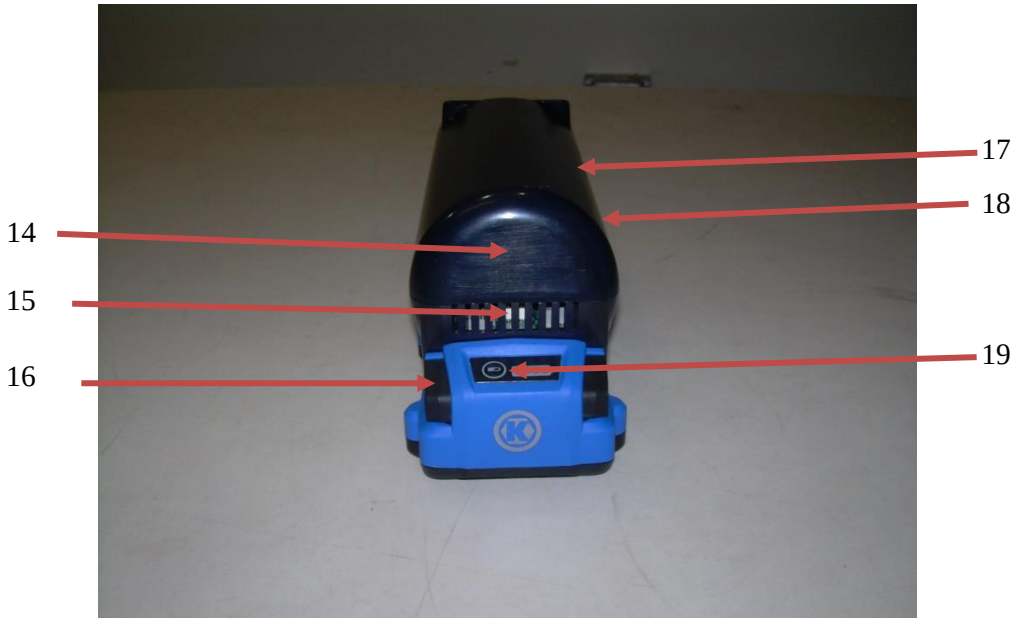
Photograph 6 – View of the Battery End of the ESU-110

Photograph 7 – View of the Battery and Battery Port on the ESU-110

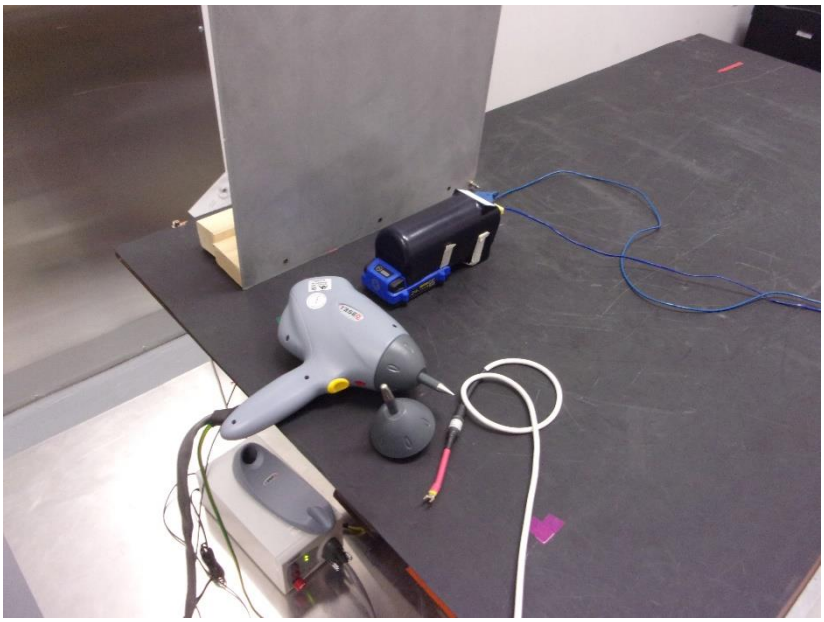
Photograph 8: ESD Test Point Photos 1.

Photograph 9: ESD Test Point Photos 2.

Photograph 10: ESD Test Point Photos 3.

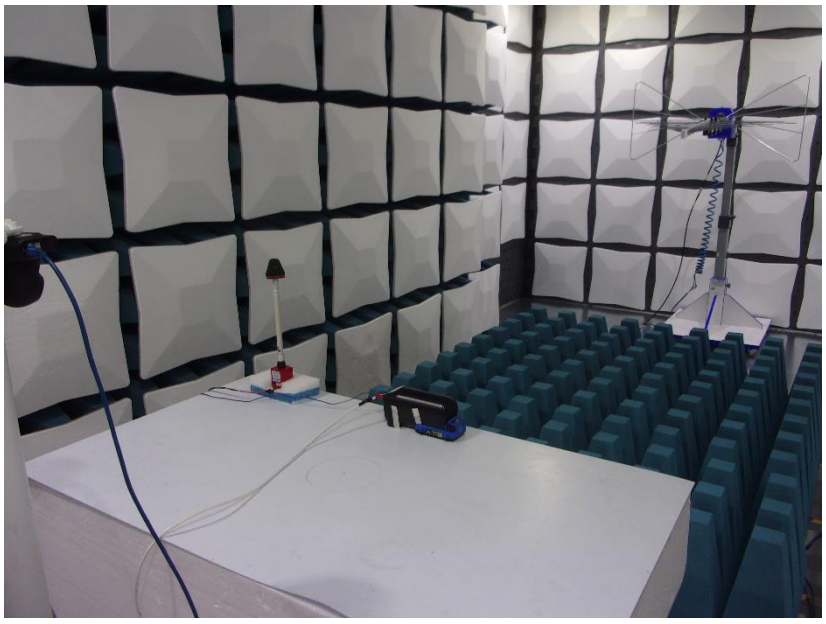


Photograph 11: ESD Test Point Photos 4.



Photograph 12 – ESD Test Setup

Photograph 13 – RF Immunity Test Setup Front



Photograph 14 – RF Immunity Test Setup Back

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