EN 60601-1-2:2015 CLASS A

TEST REPORT

For

X Development LLC

10 Mayfield Ave
Mountain View, CA 94043

Model: m20

Report Type: Original Report	**Product Type:** Medical Bio-Amplifier
Prepared By	Xinhao Jiang Test Engineer
Report Number	R1903055-13
Report Date	2019-05-01
Reviewed By	Shoaib Khan EMC Lead
Bay Area Compliance Laboratories Corp. 1274 Anvilwood Ave Sunnyvale, CA 94089, USA Tel: (408) 732-9162, Fax: (408) 732 9164	

CERTIFICATE #3297.02

Note: This test report was prepared for the customer shown above and for the device described herein. It may not be duplicated or used in part without prior written consent from Bay Area Compliance Laboratories Corp. This test report **shall not** be used by the customer to claim product certification, approval, or endorsement by A2LA or any agency of the United States Government or any foreign government.

* This test report may contain data and test methods that are not covered by BACL's scope of accreditation as of the test report date shown above. These items are marked within the test report text with an asterisk "*"

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Attestation of Test Results

EUT Description: Bioamplifier

EUT Serial Number: EUT A: H19021401; EUT B: H19021402

Test Dates: 13 March 2019 to 12 April 2019

Applicable Standards:	
Standard	**Test Result (Pass/Fail)**
EN 60601-1-2:2015 CLASS A	**Pass**

Bay Area Compliance Laboratories Corp. ("BACL") tested the equipment listed above in accordance with the requirements of the standards listed above. The test results documented in the test report bearing the test report number listed above show that the specific EUT tested was in compliance with the requirements of the above standards.

Disclaimer: The results documented in the test report cited above are specific to the sample provided to BACL when tested under the conditions and modes of operation described in the test report. This document may only be altered or revised by the BACL laboratory that issued the test report. All revisions are noted in the revisions section of the test report. Alteration or revision of this document by any party other than the BACL Laboratory that issued the test report will constitute fraud. This report must not be used by the client to claim product endorsement, approval, or certification by A2LA, NIST, or any agency of any government.

Document Revision History

Revision Number	Report Number	Description of Revision	Date of Revision
0	R1903055-13	Original Report	2019-05-01

1 General Description

1.1 General Statements

Bay area Compliance Laboratory Corp. [BACL] hereby makes the following Statements:

- The Unit(s) described in this Test Report were received at BACL's facilities on 13 March 2019. Testing was performed on the Unit(s) described in this Test Report during the period 13 March 2019 through 12 April 2019. The Test Results reported herein apply only to the Unit(s) actually tested, and to substantially identical Units.
- This Test Report must not be used to claim product endorsement by A2LA, or any agency of the U.S. Government, or by any other foreign government.
- This Test Report is the property of BACL, and shall not be reproduced, except in full, without prior written approval of BACL.

1.2 Objective

This report is prepared on behalf of X Development LLC, in accordance with EN 60601-1-2:2015, Medical Electrical Equipment – Part1-2: General Requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

The objective is to determine compliance with EN 60601-1-2:2015.

THE DATA CONTAINED IN THIS TEST REPORT WAS COLLECTED AND COMPILED BY:

Xinhao Jiang
[Test Engineer]

Ashraf Azihan
[Test Engineer]

Jose Huamani
[Test Engineer]

1.3 Agent for the Responsible Party

None

1.4 Responsible Party

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1.5 Product Description of the Equipment under Test (EUT)

The EUT ("Equipment Under Test") was a bio-amplifier system of model name: m20. The EUT was composed of two parts: The bio-amplifier called "TEST1A" (EUT A) and a 5-sensor headset called "TEST1B" (EUT B), which went on top of the bio-amplifier.

1.6 Mechanical Description of the EUT

Dimensions: approximately 19.2 cm(L) x 14.9 cm(W) x 8.8 cm(H)
Weight: approximately 0.8 kg
Serial Number: H19021401 and H19021402
EUT Photos: See Annex C of this Test Report.

1.7 Related Submittal(s)/Grant(s)

No related submittals.

1.8 Test Methodology

All measurements contained in this report were conducted in accordance with EN 60601-1-2:2015, Medical Electrical Equipment

All immunity test measurements were performed at Bay Area Compliance Laboratories Corp.

1.9 Test Facility Registrations

BACLs test facilities that are used to perform Radiated and Conducted Emissions tests are currently recognized by the Federal Communications Commission as Accredited with NIST Designation Number US1129.

BACL's test facilities that are used to perform Radiated and Conducted Emissions tests are currently registered with Industry Canada under Registration Numbers: 3062A-1, 3062A-2, and 3062A-3.

BACL is a Chinese Taipei Bureau of Standards Metrology and Inspection (BSMI) validated Conformity Assessment Body (CAB), under Annex B, Phase I Procedures of the APEC Mutual Recognition Arrangement (MRA). BACL's BSMI Lab Code Number is: SL2-IN-E-1002R

BACL's test facilities that are used to perform AC Line Conducted Emissions, Telecommunications Line Conducted Emissions, Radiated Emissions from 30 MHz to 1 GHz, and Radiated Emissions from 1 GHz to 6 GHz are currently recognized as Accredited in accordance with the Voluntary Control Council for Interference [VCCI] Article 15 procedures under Registration Number A-0027.

1.10 Test Facility Accreditations

Bay Area Compliance Laboratories Corp. (BACL) is:

A- ***An independent, 3rd-Party, Commercial Test Laboratory accredited to ISO/IEC 17025:2005 by A2LA (Test Laboratory Accreditation Certificate Number 3279.02),*** in the fields of: Electromagnetic Compatibility and Telecommunications. Unless noted by an Asterisk (*) in the Compliance Matrix (See Section 3 of this Test Report), BACL's ISO/IEC 17025:2005 Scope of Accreditation includes all of the Test Method Standards and/or the Product Family Standards detailed in this Test Report..

BACL's ISO/IEC 17025:2005 Scope of Accreditation includes a comprehensive suite of EMC Emissions, EMC Immunity, Radio, RF Exposure, Safety and wireline Telecommunications test methods applicable to a wide range of product categories. These product categories include Central Office Telecommunications Equipment [including NEBS - Network Equipment Building Systems], Unlicensed and Licensed Wireless and RF devices, Information Technology Equipment (ITE); Telecommunications Terminal Equipment (TTE); Medical Electrical Equipment; Industrial, Scientific and Medical Test Equipment; Professional Audio and Video Equipment; Industrial and Scientific Instruments and Laboratory Apparatus; Cable Distribution Systems, and Energy Efficient Lighting.

B- ***A Product Certification Body accredited to ISO/IEC 17065:2012 by A2LA (Product Certification Body Accreditation Certificate Number 3279.03)*** to certify

- For the USA (Federal Communications Commission):
  - 1- All Unlicensed radio frequency devices within FCC Scopes A1, A2, A3, and A4;
  - 2- All Licensed radio frequency devices within FCC Scopes B1, B2, B3, and B4;
  - 3- All Telephone Terminal Equipment within FCC Scope C.
- For the Canada (Industry Canada):
  - 1 All Scope 1-Licence-Exempt Radio Frequency Devices;
  - 2 All Scope 2-Licensed Personal Mobile Radio Services;
  - 3 All Scope 3-Licensed General Mobile & Fixed Radio Services;
  - 4 All Scope 4-Licensed Maritime & Aviation Radio Services;
  - 5 All Scope 5-Licensed Fixed Microwave Radio Services
  - 6 All Broadcasting Technical Standards (BETS) in the Category I Equipment Standards List.
- For Singapore (Info-Communications Development Authority (IDA)):
  - 1 All Line Terminal Equipment: All Technical Specifications for Line Terminal Equipment – Table 1 of IDA MRA Recognition Scheme: 2011, Annex 2
  - 2. All Radio-Communication Equipment: All Technical Specifications for Radio-Communication Equipment – Table 2 of IDA MRA Recognition Scheme: 2011, Annex 2
- For the Hong Kong Special Administrative Region:
  - 1 All Radio Equipment, per KHCA 10XX-series Specifications;
  - 2 All GMDSS Marine Radio Equipment, per HKCA 12XX-series Specifications;

3 All Fixed Network Equipment, per HKCA 20XX-series Specifications.

- For Japan:

1 MIC Telecommunication Business Law (Terminal Equipment):
- All Scope A1 - Terminal Equipment for the Purpose of Calls;
- All Scope A2 - Other Terminal Equipment

2 Radio Law (Radio Equipment):
- All Scope B1 - Specified Radio Equipment specified in Article 38-2-2, paragraph 1, item 1 of the Radio Law
- All Scope B2 - Specified Radio Equipment specified in Article 38-2-2, paragraph 1, item 2 of the Radio Law
- All Scope B3 - Specified Radio Equipment specified in Article 38-2-2, paragraph 1, item 3 of the Radio Law

C- ***A Product Certification Body accredited to ISO/IEC 17065:2012 by A2LA (Product Certification Body Accreditation Certificate Number 3279.01)*** to certify Products to USA's Environmental Protection Agency (EPA) ENERGY STAR Product Specifications for:

1 Electronics and Office Equipment:
- for Telephony (ver. 3.0)
- for Audio/Video (ver. 3.0)
- for Battery Charging Systems (ver. 1.1)
- for Set-top Boxes & Cable Boxes (ver. 4.1)
- for Televisions (ver. 6.1)
- for Computers (ver. 6.0)
- for Displays (ver. 6.0)
- for Imaging Equipment (ver. 2.0)
- for Computer Servers (ver. 2.0)

2 Commercial Food Service Equipment
- for Commercial Dishwashers (ver. 2.0)
- for Commercial Ice Machines (ver. 2.0)
- for Commercial Ovens (ver. 2.1)
- for Commercial Refrigerators and Freezers

3 Lighting Products
- For Decorative Light Strings (ver. 1.5)
- For Luminaires (including sub-components) and Lamps (ver. 1.2)
- For Compact Fluorescent Lamps (CFLs) (ver. 4.3)
- For Integral LED Lamps (ver. 1.4)

4 Heating, Ventilation, and AC Products
- for Residential Ceiling Fans (ver. 3.0)
- for Residential Ventilating Fans (ver. 3.2)

5 Other
- For Water Coolers (ver. 3.0)

D- ***A NIST Designated Phase-I and Phase-II Conformity Assessment Body (CAB) for the following economies and regulatory authorities under the terms of the stated MRAs/Treaties:***

- Australia: ACMA (Australian Communication and Media Authority) – APEC Tel MRA -Phase I;
- Canada: (Innovation, Science and Economic development Canada - ISEDC) Foreign Certification Body – FCB – APEC Tel MRA -Phase I & Phase II;
- Chinese Taipei (Republic of China – Taiwan):
  - BSMI (Bureau of Standards, Metrology and Inspection) APEC Tel MRA -Phase I;
  - NCC (National Communications Commission) APEC Tel MRA -Phase I;
- European Union:
  - EMC Directive 2014/30/EU US-EU EMC & Telecom MRA CAB (NB)

  - Radio & Teleterminal Equipment (R&TTE) Directive 1995/5/EC US -EU EMC & Telecom MRA CAB (NB)
  - Radio Equipment (RE) Directive 2014/53/EU US-EU EMC & Telecom MRA CAB (NB)
  - Low Voltage Directive (LVD) 2014/35/EU
- Hong Kong Special Administrative Region: (Office of the Telecommunications Authority – OFTA) APEC Tel MRA -Phase I & Phase II
- Israel – US-Israel MRA Phase I
- Republic of Korea (Ministry of Communications - Radio Research Laboratory) APEC Tel MRA -Phase I
- Singapore: (Infocomm Media Development Authority - IMDA) APEC Tel MRA -Phase I & Phase II;
- Japan: VCCI - Voluntary Control Council for Interference US-Japan Telecom Treaty VCCI Side Letter-
- USA:
  - ENERGY STAR Recognized Test Laboratory – US EPA
  - Telecommunications Certification Body (TCB) – US FCC;
  - Nationally Recognized Test Laboratory (NRTL) – US OSHA
- Vietnam: APEC Tel MRA -Phase I;

1.11 Measurement Uncertainties

All measurements involve uncertainties. In the case of EMC Emissions tests, the influence quantities (factors) that make a significant contribution to the measurement uncertainties for most types of Emissions measurements are detailed in the latest version of CISPR 16-4-2 "Specification for radio disturbance and immunity measuring apparatus and methods – Part 4-2: Uncertainties, statistics and limit modelling – Measurement instrumentation uncertainty" (i.e., in CISPR 16-4-2:2011-06 + C1:2013-04 +A1:2014-02).

Based on the uncertainty models given in the latest version of CISPR16-4-2, and, based on the calibration uncertainties of the specific instruments and facilities used at BACL to perform the measurements documented in this Test Report, the following estimates have been made of BACL's Measurement Uncertainties for the measurements documented in this Test Report.

(Note: the phrase "Typical U_{LAB} values" means that the U_{LAB} values presented are the Expanded Measurement Uncertainty values that resulted from the use of the ordinary test processes that are employed on a daily basis in our Test Laboratory. Note that he smaller the value of Expanded Measurement Uncertainty, the better (i.e., the "less uncertain") the measurement is.

Type of Measurement: **ANSI C63.4-2014 Conducted Emissions (on the BACL Ground Plane Test Site)** **Note: Measurements made using a n R&S ESCI EMI Receiver**	**BACL Typical U_{LAB} Value** **(for a k=2 Coverage Factor, equivalent to ~ 95% level of confidence)**	**U_{CISPR} Value** **worst-allowable values of the latest version of CISPR 16-4-2** **(for a k=2 Coverage Factor, equivalent to ~ 95% level of confidence)**
Conducted Disturbance (Mains Port) 9 kHz to 150 MHz (i.e., AC/DC Line Conducted Emissions measurements made using the Narda PMM L3-100 4-Line LISN)	**3.05 dB**	**3.83 dB**
Conducted Disturbance (Mains Port) 150 kHz to 30 MHz (i.e., AC/DC Line Conducted Emissions measurements made using the Narda PMM L3-100 4-Line LISN)	**3.05 dB**	**3.44 dB**
Conducted Disturbance (Mains Port) 150 kHz to 30 MHz (i.e., AC/DC Line Conducted Emissions measurements made with a Fischer FCC-LISN-50-25-2-10 LISN)	**2.26**	**3.44 dB**
Conducted Disturbance (Mains Port) 9 kHz to 30 MHz (i.e., AC/DC Line Conducted Emissions measurements made with an ETS-Lindgren Model 3701 Line Voltage Probe)	**1.04 dB**	**2.91 dB**

Type of Measurement: **CISPR-type Conducted Emissions (on the BACL Ground Plane Test Site)** **Note: Measurements made using a n R&S ESCI EMI Receiver**	**BACL Typical U_{LAB} Value** **(for a k=2 Coverage Factor, equivalent to ~ 95% level of confidence)**	**U_{CISPR} Value** **worst-allowable values of the latest version of CISPR 16-4-2** **(for a k=2 Coverage Factor, equivalent to ~ 95% level of confidence)**
Conducted Disturbance (Mains Port) 9 kHz to 150 MHz (i.e., AC/DC Line Conducted Emissions measurements made using the Narda PMM L3-100 4-Line LISN)	**3.05 dB**	**3.83 dB**
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Conducted Disturbance (Mains Port) 150 kHz to 30 MHz (i.e., AC/DC Line Conducted Emissions measurements made with a Fischer FCC-LISN-50-25-2-10 LISN)	**2.26**	**3.44 dB**
Conducted Disturbance (Mains Port) 9 kHz to 30 MHz (i.e., AC/DC Line Conducted Emissions measurements made with an ETS-Lindgren Model 3701 Line Voltage Probe)	**1.04 dB**	**2.91 dB**
Conducted Disturbance (Telecommunications I/O Line Port) 150 kHz to 30 MHz (i.e., Telecom Line Conducted Emissions measurements made with a T-ISN (AAN) e.g., the Fischer Model FCC-TLISN-T8-02-09)	**2.38 dB**	**4.20 dB**
Conducted Disturbance (Telecommunications I/O Line Port) 150 kHz to 30 MHz (i.e., Telecom Line Conducted Emissions measurements made with a Capacitive Voltage Probe, e.g., the Fischer Model F-CVP-1 Rev. B)	**0.53 dB**	**3.85 dB**
Conducted Current Disturbance (Telecommunications I/O Line Port) 9 kHz to 30 MHz (i.e., Telecom Line Conducted Emissions measurements made with a Current Probe, e.g., the Fischer Model F-35A Current Probe)	**1.28 dB**	**2.89 dB**

Type of Measurement: **CISPR-type Disturbance Power (in the BACL 10 m – 1 SAC)** **Note: Measurements made using a n R&S ESCI EMI Receiver**	**BACL Typical U_{LAB} Value** **(for a k=2 Coverage Factor, equivalent to ~ 95% level of confidence)**	**U_{CISPR} Value** **worst-allowable values of the latest version of CISPR 16-4-2** **(for a k=2 Coverage Factor, equivalent to ~ 95% level of confidence)**
Disturbance Power (Mains or I/O Ports) 30 MHz to 300 MHz measurements made using the Com-Power CLA-150 CISPR Absorbing Clamp	**3.28 dB**	**4.52 dB**

Type of Measurement: **ANSI C63.4-2014 Radiated Emissions (in the BACL 10 m - 1 SAC)** **Note: Measurements up to 1 GHz made using an R&S ESCI EMI Receiver; Measurements from 1 GHz to 40 GHz made using an R&S ESU40 EMI Receiver**	**BACL Typical U_{LAB} Value** **(for a k=2 Coverage Factor, equivalent to ~ 95% level of confidence)**	**U_{CISPR} Value** **worst-allowable values of the latest version of CISPR 16-4-2 (for a k=2 Coverage Factor, equivalent to ~ 95% level of confidence)**
Radiated Magnetic Field Disturbance – 9 kHz to 30 MHz (i.e., Radiated H-Field levels measured using a Single-axis Active Loop Antenna at a fixed height at either 3 or 10 metres distance)	**1.64 dB**	**U_{CISPR} Value is Not Specified**
Radiated Electric Field Disturbance – Horizontal Polarization, 30 MHz – 200 MHz (i.e., Radiated Emissions measured at 3 metres distance)	**3.25 dB (No Tilting)**	**5.06 dB (No Tilting)**
Radiated Electric Field Disturbance – Vertical Polarization, 30 MHz – 200 MHz (i.e., Radiated Emissions at 3 metres distance)	**3.87 dB (No Tilting)**	**5.17 dB (No Tilting)**
Radiated Electric Field Disturbance – Horizontal Polarization, 30 MHz – 200 MHz (i.e., Radiated Emissions measured at 10 metres distance)	**4.21 dB**	**5.05 dB**
Radiated Electric Field Disturbance – Vertical Polarization, 30 MHz – 200 MHz (i.e., Radiated Emissions measured at 10 metres distance)	**4.07 dB**	**5.03 dB**
Radiated Electric Field Disturbance – Horizontal Polarization, 200 MHz – 1000 MHz (i.e., Radiated Emissions measured at 3 metres distance)	**4.60 dB (No Tilting)**	**5.34 (No Tilting)**
Radiated Electric Field Disturbance – Vertical Polarization, 200 MHz – 1000 MHz (i.e., Radiated Emissions measured at 3 metres distance)	**5.51 dB (No Tilting)**	**6.32 dB (No Tilting)**
Radiated Electric Field Disturbance – Horizontal Polarization, 200 MHz – 1000 MHz (i.e., Radiated Emissions at 10 metres distance)	**4.17 dB**	**5.21 dB**
Radiated Electric Field Disturbance – Vertical Polarization, 200 MHz – 1000 MHz z (i.e., Radiated Emissions measured at 10 metres distance)	**4.46 dB**	**5.22 dB**
Radiated Electric Field Disturbance Horizontal & Vertical Polarizations, 1 GHz – 6 GHz (i.e., Radiated Emissions measured at 3 metres distance)	**4.62 dB (With Boresighting**	**U_{CISPR} Value is Not Specified**
Radiated Electric Field Disturbance Horizontal & Vertical Polarizations, 1 GHz – 6 GHz (i.e., Radiated Emissions measured at 3 metres distance)	**4.67 dB (With Boresighting**	**U_{CISPR} Value is Not Specified**
Radiated Electric Field Disturbance Horizontal & Vertical Polarizations, 18 GHz – 26.5 GHz (i.e., Radiated Emissions measured at 1 metres distance)	**4.81 dB (With Boresighting**	**U_{CISPR} Value is Not Specified**
Radiated Electric Field Disturbance Horizontal & Vertical Polarizations, 26.5 GHz – 40 GHz (i.e., Radiated Emissions at 1 metres distance)	**5.00 dB (With Boresighting**	**U_{CISPR} Value is Not Specified**

Type of Measurement: **CISPR-type Radiated Emissions (in the BACL 10 m - 1 SAC)** **Note: Measurements up to 1 GHz made using an R&S ESCI EMI Receiver; Measurements from 1 GHz to 40 GHz made using an R&S ESU40 EMI Receiver**	**BACL Typical U_{LAB} Value** **(for a k=2 Coverage Factor, equivalent to ~ 95% level of confidence)**	**U_{CISPR} Value** **worst-allowable values of the latest version of CISPR 16-4-2** **(for a k=2 Coverage Factor, equivalent to ~ 95% level of confidence)**
Radiated Magnetic Field Disturbance – 9 kHz to 30 MHz (i.e., Radiated H-Field levels measured using a Single-axis Active Loop Antenna at a fixed height at either 3 or 10 metres distance)	**1.64 dB**	**U_{CISPR} Value is Not Specified**
Radiated Magnetic Disturbance – 9 kHz to 30 MHz (i.e., induced Current levels measured using a 2 m diameter 3-Axis Van Veen Loop Antenna System)	**1.29 dB**	**3.30 dB *** ***Note: proposed value.**
Radiated Electric Field Disturbance – Horizontal Polarization, 30 MHz – 200 MHz (i.e., Radiated Emissions measured at 3 metres distance)	**3.25 dB (No Tilting)**	**5.06 dB (No Tilting)**
Radiated Electric Field Disturbance – Vertical Polarization, 30 MHz – 200 MHz (i.e., Radiated Emissions at 3 metres distance)	**3.87 dB (No Tilting)**	**5.17 dB (No Tilting)**
Radiated Electric Field Disturbance – Horizontal Polarization, 30 MHz – 200 MHz (i.e., Radiated Emissions measured at 10 metres distance)	**4.21 dB**	**5.05 dB**
Radiated Electric Field Disturbance – Vertical Polarization, 30 MHz – 200 MHz (i.e., Radiated Emissions measured at 10 metres distance)	**4.07 dB**	**5.03 dB**
Radiated Electric Field Disturbance – Horizontal Polarization, 200 MHz – 1000 MHz (i.e., Radiated Emissions measured at 3 metres distance)	**4.60 dB (No Tilting)**	**5.34 (No Tilting)**
Radiated Electric Field Disturbance – Vertical Polarization, 200 MHz – 1000 MHz (i.e., Radiated Emissions measured at 3 metres distance)	**5.51 dB (No Tilting)**	**6.32 dB (No Tilting)**
Radiated Electric Field Disturbance – Horizontal Polarization, 200 MHz – 1000 MHz (i.e., Radiated Emissions at 10 metres distance)	**4.17 dB**	**5.21 dB**
Radiated Electric Field Disturbance – Vertical Polarization, 200 MHz – 1000 MHz z (i.e., Radiated Emissions measured at 10 metres distance)	**4.46 dB**	**5.22 dB**
Radiated Electric Field Disturbance Horizontal & Vertical Polarizations, 1 GHz – 6 GHz (i.e., Radiated Emissions measured at 3 metres distance)	**4.94 dB (No Tilting)**	**5.18 dB (No Tilting)**

2 Performance Criteria

The manufacturer has the obligation to express the performance criteria in terms which relate to the performance of his specific product when used as intended.

The following performance criteria are applicable, and shall only be evaluated when the functions referred to are implemented.

2.1 General performance criteria

Examples of functions defined by the manufacturer to be evaluated during testing include, but are not limited to, the following:

- essential operational modes and states;
- tests of all peripheral access (hard disks, floppy disks, printers, keyboard, mouse, etc.);
- quality of software execution;
- quality of data display and transmission;
- quality of speech transmission.

Performance criterion A

The equipment shall continue to operate as intended without operator intervention. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer when the equipment is used as intended. The performance level may be replaced by a permissible loss of performance. If the minimum performance level or the permissible performance loss is not specified by the manufacturer, then either of these may be derived from the product description and documentation, and by what the user may reasonably expect from the equipment if used as intended.

Performance criterion B

After the test, the equipment shall continue to operate as intended without operator intervention. No degradation of performance or loss of function is allowed, after the application of the phenomena below a performance level may be replaced by a permissible loss of performance.

During the test, degradation of performance is allowed. However, no change of operating state or stored data is allowed to persist after the test.

If the minimum performance level (or the permissible performance loss) is not specified by the manufacturer, then either of these may be derived from the product description and documentation, and by what the user may reasonably expect from the equipment if used as intended.

Performance criterion C

Loss of function is allowed, provided the function is self-recoverable, or can be restored by the operation of the controls by the user in accordance with the manufacturer's instructions.

Functions, and/or information stored in non-volatile memory, or protected by a battery backup, shall not be lost.

3 EUT Test Configuration

3.1 Justification

The EUT was configured for testing according to EN 60601-1-2:2015 Standard.

3.2 EUT Exercise Software

The software used to convert digital data stream to waveforms was called “Collect.” The version number of such software was 2.1.3.

3.3 EUT Mode of Operation

Per manufacturer’s instructions, the EUT was powered up through USB, which was connected to a laptop support equipment. In this laptop, a software called “Collect” was executed, which measured, displayed, and recorded data.

3.4 Method of Monitoring

The EUT was monitored visually by observing the laptop screen running the “collect” software and by observing the green LED on top of the bio amplifier.

3.5 Equipment Modifications

None

3.6 Special Equipment

None

3.7 Local Support Equipment

Manufacturer	Description	Model	Serial Number
X Development	Bio-amplifier	TEST1A	B19021401
DELL	Laptop	Precision 5520	C6Z2TQ2

3.8 Remote Support Equipment

None

3.9 EUT Internal Configuration Details

Manufacturers	Descriptions	Models	Rev/Serial Numbers
Texas Instruments	Board	ADS1299	-
NXP	Microcontroller	MKL27Z256VLH4	-

3.10 External I/O Cabling List and Details

Cable Description	Length (M)	From	To
USB	2.5	EUT	Laptop
Sensor Cable	0.3	EUT	Sensor

3.11 EUT External Power Supply List and Details

None

4 Summary of Test Results

4.1 Emissions

Standard	Phenomenon	Test Method	Results
EN 60601-1- 2 Clause 7	Conducted Emissions, AC Mains, 0.15-30 MHz	CISPR 11	Compliant
	Radiated Emissions, 30-1000 MHz	CISPR 11	Compliant
EN 60601-1-2 Clause 7.2.1	Harmonic Distortion	IEC 61000-3-2	Compliant
EN 60601-1-2 Clause 7.2.2	Voltage Fluctuations and Flicker	IEC 61000-3-3	Compliant

4.2 Immunity

Standard	Phenomenon	Test Method	Results
EN 60601-1-2 Clause 8	Electrostatic Discharge	IEC 61000-4-2	Compliant
	Radiated RF Immunity	IEC 61000-4-3	Compliant
	Electrical Fast Transients	IEC 61000-4-4	Compliant
	Surges	IEC 61000-4-5	Compliant
	Conducted RF Immunity	IEC 61000-4-6	Compliant
	Power Frequency Magnetic Fields	IEC 61000-4-8	N/A[1]
	Voltage Dips And Interruptions	IEC 61000-4-11	Compliant

N/A[1]: The EUT did not have any magnetic sensitive devices.

5 EN 60601-1-2:2007 Clause 7 – Conducted Emissions

5.1 Applicable Standard

As per EN 55011 Clause 6: Limits

Class A ISM equipment may be measured either on a test site or *in situ* as preferred by the manufacturer.

NOTE: Due to size, complexity or operating conditions some ISM equipment may have to be measured in situ in order to show compliance with the radiation disturbance limits specified herein.

Frequency Band (MHz)	Class A Equipment Limits (dBµV)					
	Group 1		Group 2		Group 2[a]	
	Quasi-peak	Average	Quasi-peak	Average	Quasi-peak	Average
0.15 – 0.50	79	66	100	90	130	120
0.50 – 5	73	60	86	76	125	115
5 – 30	73	60	90 decreasing linearly with logarithm of frequency to 70	80 decreasing linearly with logarithm of frequency to 60	115	105

NOTE: Care should be taken to comply with leakage current requirements.
([a]) Mains supply currents in excess of 100 A per phase when using the CISPR voltage probe or a suitable V-network (LISN or AMN).

5.2 EUT Setup

The conducted emissions tests were performed in the 5-meter chamber, using the setup in accordance with EN 55011 measurement procedures. The specifications used were in accordance with EN 55011 standard Clause 6, Class A limits.

The spacing between the peripherals was 10 cm.

The external I/O cables were draped along the test table and bundled as required.

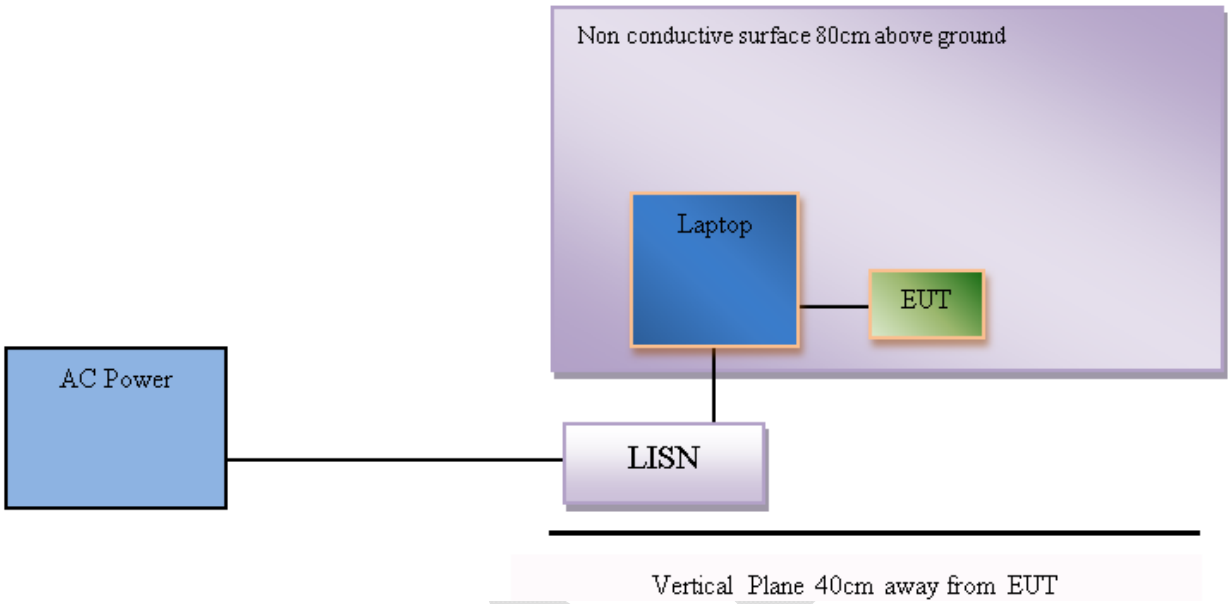
The EUT was connected to AC line power source.

5.3 Test Procedure

During conducted emissions testing, the power cord of the EUT was connected to the main outlet of the LISN-1.

All data was recorded in the peak detection mode, quasi-peak and average. Average readings are labeled “AV,” and Quasi-peak readings are labeled “QP,” in the test data hereinafter.

5.4 Test Setup Block Diagram



5.5 Corrected Amplitude & Margin Calculation

The Corrected Amplitude (CA) is calculated by adding the Cable Loss (CL) plus the High Pass Filter/Attenuator value (HA) and subtracting the Amplifier Gain (Ga) to the indicated Amplitude (Ai) reading. The basic equation is as follows:

CA = Ai + CL + HA – Ga

For example, a corrected amplitude (CA) of 36 dBµV = Indicated Amplitude reading (Ai) of 50.0 dBµV + Cable Loss (CL) 1.0 dB + High Pass Filter/Attenuator (IA) 5 dB - Amplifier Gain (Ga) 20 dB

The "**Margin**" column of the following data tables indicates the degree of compliance within the applicable limit. For example, a margin of -7 dB means the emission is 7 dB below the maximum limit for Class A. The equation for margin calculation is as follows:

Margin (dB) = Corrected Amplitude (dBµV) - Class A Limit (dBµV)

5.6 Test Equipment List and Details

BACL Asset Number	Manufacturer	Descriptions	Models	Serial Numbers	Calibration Date	Calibration Due
00310	Rohde & Schwarz	Receiver, EMI Test	ESCI 1166.5950K 03	100338	2018-07-05	2019-07-05
00679	Rohde & Schwarz	Impulse Limiter	ESH3-Z2	101963	2018-07-19	2019-07-19
00725	Solar Electronics Company	High Pass Filter	Type 7930-100	7930150203	2019-02-25	2020-02-25
00733	FCC	LISN	FCC-LISN-50-25-2-10-CISPR16	160130	2018-04-05	2019-04-05
0885	Wireless Solutions	Conducted Emission Cable	LMR 400	691	2018-09-20	2019-09-20
00348	California Instruments	AC Power Source	5001ix-208	57079	Calibration not Required	Calibration not Required

***Statement of Traceability*:** BACL Corp. attests that all of the calibrations on the equipment items listed above were traceable to NIST or to another internationally recognized National Metrology Institute (NMI), and were compliant with A2LA Policy P102 (dated 9 June 2016) "A2LA Policy on Metrological Traceability".

5.7 Test Environmental Conditions and Test Personnel

Test Date:	2019-3-14
Test Site:	Outside Test Site
Temperature:	24 º C
Relative Humidity:	43 %
Barometric Pressure:	102.1 kPa
Test Personnel:	Xinhao Jiang

5.8 Summary of Test Results

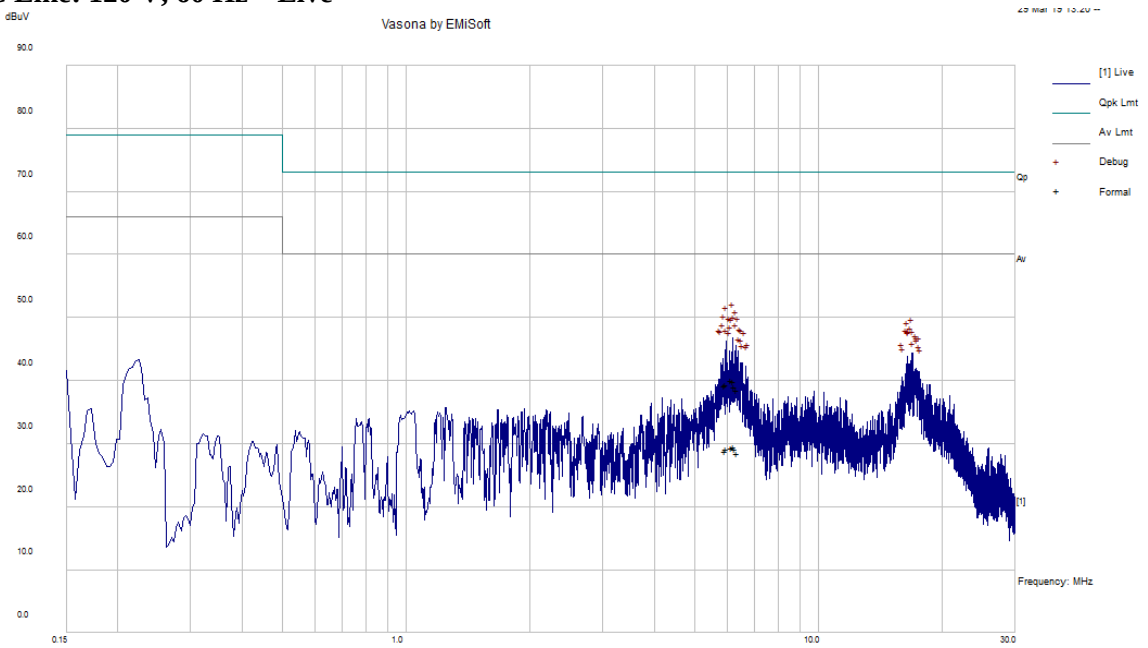
According to the recorded data, the EUT complied with EN 55011 Standard, Clause 6, Class A limits, and had the worst margin reading of:

Connection: 120 V/60 Hz AC			
Margin (dB)	**Frequency (MHz)**	**Conductor Mode (Live/Neutral)**	**Range (MHz)**
-30.41	6.237742	Live	0.15-30

Connection: 230 V/50 Hz AC			
Margin (dB)	**Frequency (MHz)**	**Conductor Mode (Live/Neutral)**	**Range (MHz)**
-11.9	0.156479	Live	0.15-30

5.9 Conducted Emissions Test Plots and Data

AC Line: 120 V, 60 Hz – Live



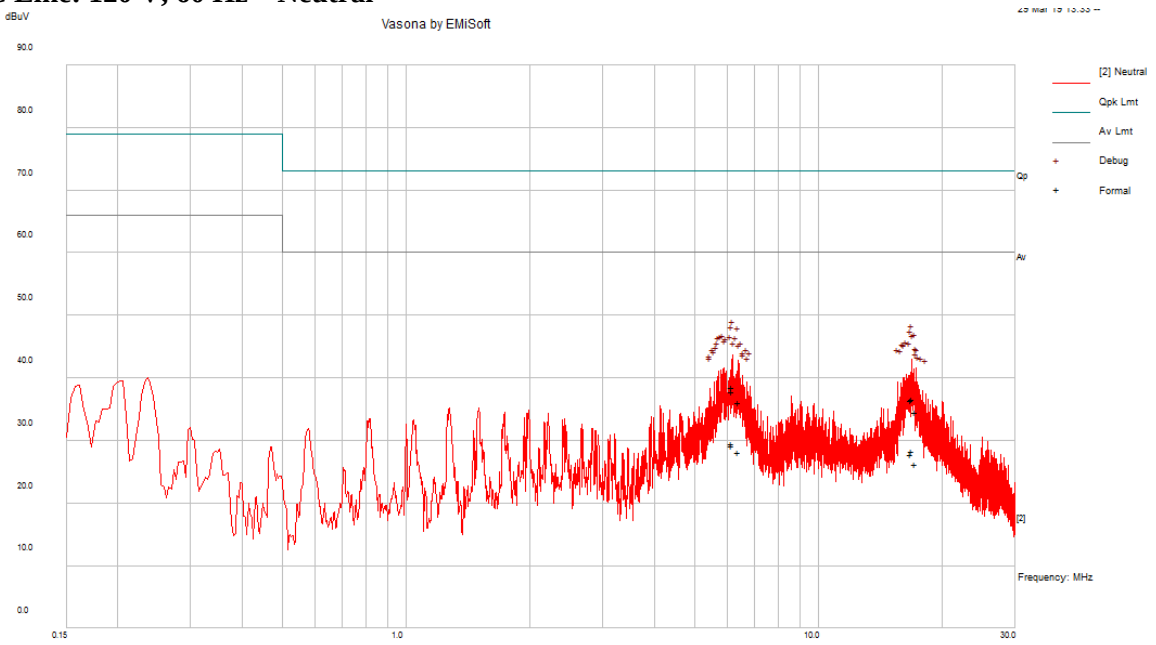
Quasi-Peak Measurements

Frequency (MHz)	Corrected Amplitude (dBµV)	Conductor	Limit (dBµV)	Margin (dB)
6.183786	40.17	Live	73	-32.83
6.237742	39.96	Live	73	-33.04
5.970469	39.35	Live	73	-33.65
5.94069	39.24	Live	73	-33.76
6.285334	39.13	Live	73	-33.87
6.3742	38.47	Live	73	-34.53

Average Measurements

Frequency (MHz)	Corrected Amplitude (dBµV)	Conductor	Limit (dBµV)	Margin (dB)
6.237742	29.59	Live	60	-30.41
6.183786	29.29	Live	60	-30.71
6.285334	29.27	Live	60	-30.73
5.970469	29.11	Live	60	-30.89
5.94069	28.89	Live	60	-31.11
6.3742	28.58	Live	60	-31.42

AC Line: 120 V, 60 Hz – Neutral



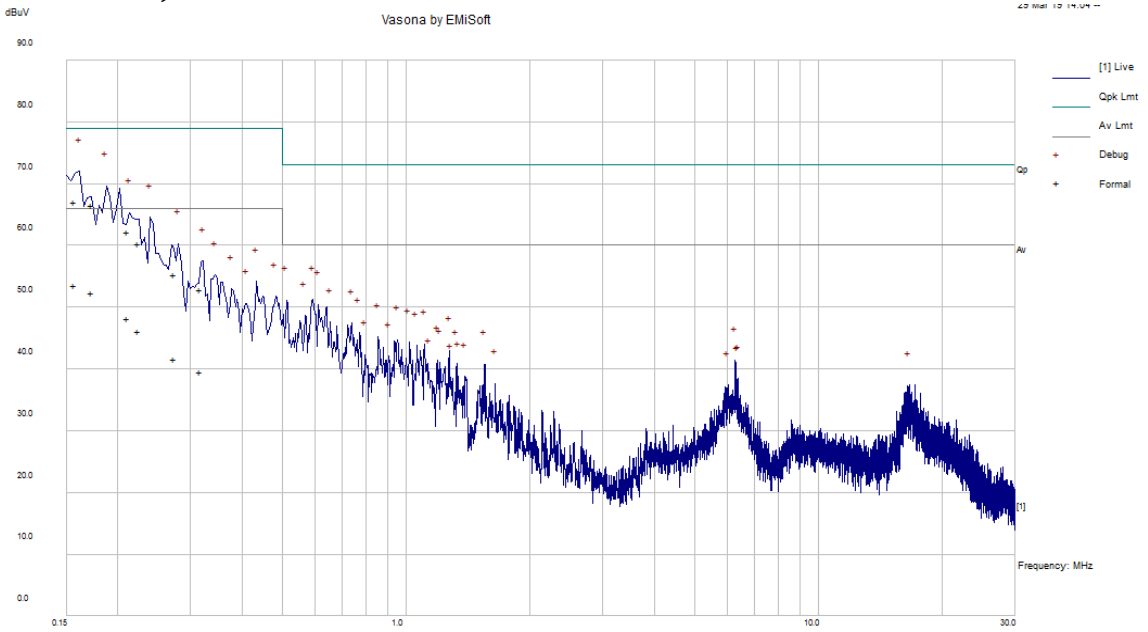
Quasi-Peak Measurements

Frequency (MHz)	Corrected Amplitude (dBµV)	Conductor	Limit (dBµV)	Margin (dB)
6.185046	38.48	Neutral	73	-34.52
6.153791	37.85	Neutral	73	-35.15
16.82849	36.71	Neutral	73	-36.29
16.78773	36.48	Neutral	73	-36.52
6.382055	36.13	Neutral	73	-36.87
17.19533	34.52	Neutral	73	-38.48

Average Measurements

Frequency (MHz)	Corrected Amplitude (dBµV)	Conductor	Limit (dBµV)	Margin (dB)
6.185046	29.53	Neutral	60	-30.47
6.153791	29.17	Neutral	60	-30.83
16.82849	28.27	Neutral	60	-31.73
6.382055	28.19	Neutral	60	-31.81
16.78773	27.86	Neutral	60	-32.14
17.19533	26.24	Neutral	60	-33.76

AC Line: 230 V, 50 H – Live



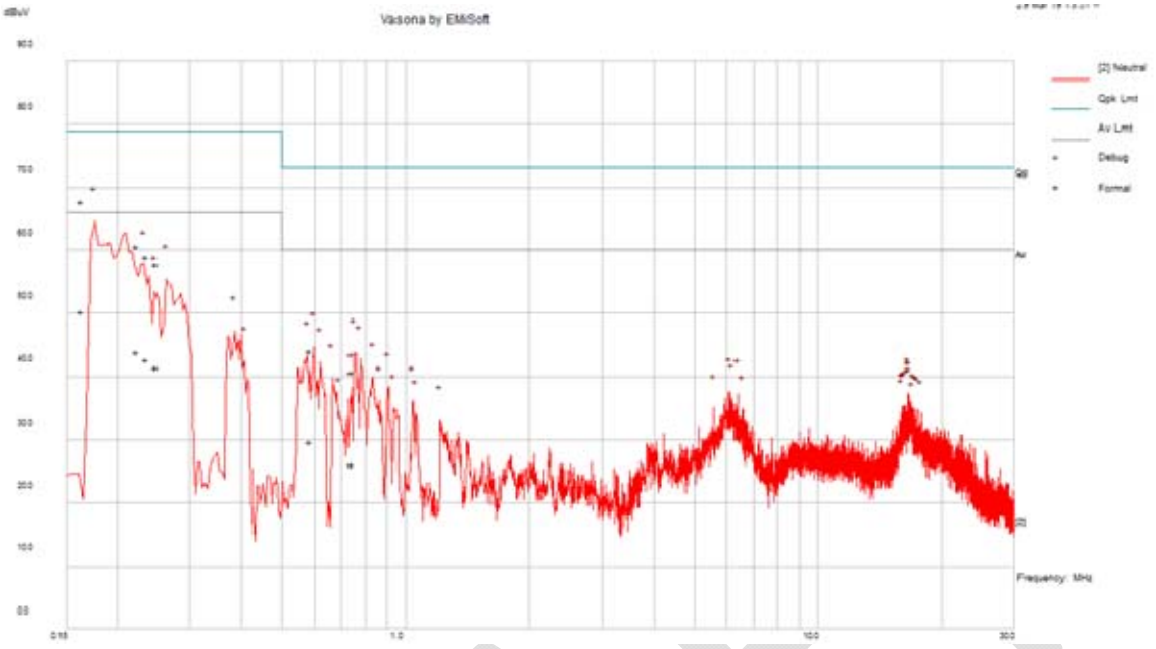
Quasi-Peak Measurements

Frequency (MHz)	Corrected Amplitude (dBµV)	Conductor	Limit (dBµV)	Margin (dB)
0.156479	67.1	Live	79	-11.9
0.173221	66.6	Live	79	-12.4
0.210502	62.16	Live	79	-16.84
0.223662	60.26	Live	79	-18.74
0.274519	55.35	Live	79	-23.65
0.317023	52.96	Live	79	-26.04

Average Measurements

Frequency (MHz)	Corrected Amplitude (dBµV)	Conductor	Limit (dBµV)	Margin (dB)
0.156479	53.53	Live	66	-12.47
0.173221	52.36	Live	66	-13.64
0.210502	48.29	Live	66	-17.71
0.223662	46.14	Live	66	-19.86
0.274519	41.59	Live	66	-24.41
0.317023	39.6	Live	66	-26.4

AC Line: 230 V, 50 H – Neutral



Quasi-Peak Measurements

Frequency (MHz)	Corrected Amplitude (dBµV)	Conductor	Limit (dBµV)	Margin (dB)
0.163269	67.69	Neutral	79	-11.31
0.222823	60.73	Neutral	79	-18.27
0.235823	58.93	Neutral	79	-20.07
0.247851	57.81	Neutral	79	-21.19
0.58401	44.01	Neutral	73	-28.99
0.740866	40.82	Neutral	73	-32.18

Average Measurements

Frequency (MHz)	Corrected Amplitude (dBµV)	Conductor	Limit (dBµV)	Margin (dB)
0.163269	50.34	Neutral	66	-15.66
0.222823	43.84	Neutral	66	-22.16
0.235823	42.64	Neutral	66	-23.36
0.247851	41.49	Neutral	66	-24.51
0.58401	29.66	Neutral	60	-30.34
0.740866	26.04	Neutral	60	-33.96

6 EN 60601-1-2:2007 Clause 7– Radiated Emissions

6.1 Applicable Standard

As per EN 55011 Clause 6: Limits

Class A ISM equipment may be measured either on a test site or *in situ* as preferred by the manufacturer.

NOTE: Due to size, complexity or operating conditions some ISM equipment may have to be measured in situ in order to show compliance with the radiation disturbance limits specified herein.

Frequency Band (MHz)	Measured on a Test Site	Measured *In Situ*
	Group 1, Class A 10 m Measurement Distance (dBµV/m)	Group 1, Class A Measurement Distance* (dBµV/m)
0.15 – 30	Under Consideration	Under Consideration
30 – 230	40	30
230 – 1000	47	37

Note: Limits with measuring distance 30 m from exterior wall outside the building in which the equipment is situated.

6.2 Test Setup

The radiated emissions tests were performed in the 10-meter test chamber, using the setup in accordance with EN 55011 measurement procedures. The specifications used were in accordance with EN 55011 Clause 6 Standard, Class A limits.

The spacing between the peripherals was 10 cm.

The external I/O cables were draped along the test table and bundled as required.

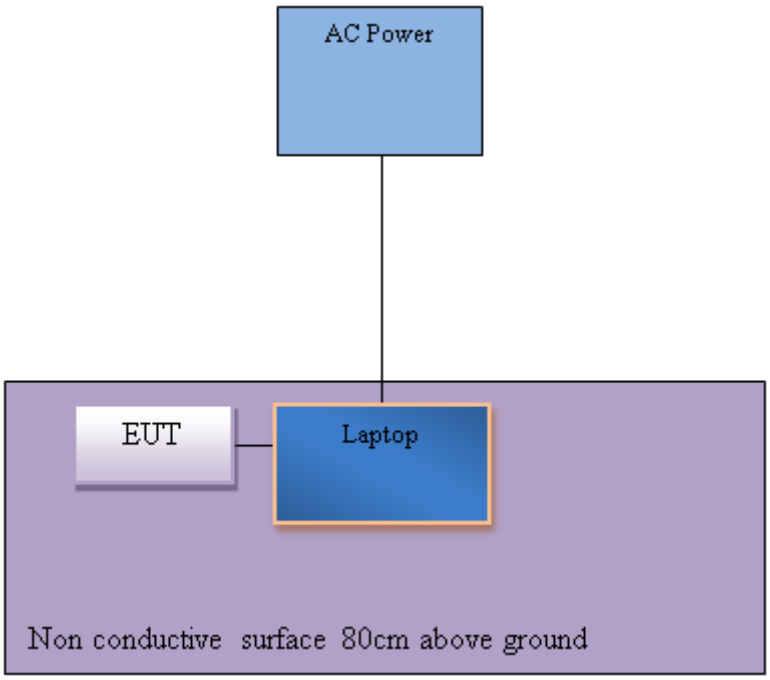
The EUT was connected to a 230 V, 50 Hz AC line power source.

6.3 Test Procedure

Maximizing procedures were performed on the six (6) highest emissions to ensure the EUT is compliant with all installation combinations.

All data was recorded in the peak detection mode. Quasi-peak readings were performed only when an emission was found to be marginal (within -4 dB of specification limits).

6.4 Test Setup Block Diagram



6.5 Corrected Amplitude & Margin Calculation

The Corrected Amplitude (CA) is calculated by adding the Antenna Factor (AF), the Cable Loss (CL), the Attenuator Factor (Atten) and subtracting the Amplifier Gain (Ga) to the indicated Amplitude (Ai) reading. The basic equation is as follows:

CA = Ai + AF + CL + Atten – Ga

For example, the Corrected Amplitude (CA) of 40.3 dBµV/m = indicated Amplitude reading (Ai) 32.5 dBµV + Antenna Factor (AF) 23.5dB + Cable Loss (CL) 3.7 dB + Attenuator (Atten) 10 dB - Amplifier Gain (Ga) 29.4 dB

The "**Margin**" column of the following data tables indicates the degree of compliance within the applicable limit. For example, a margin of -7 dB means the emission is 7 dB below the maximum limit for Class A. The equation for margin calculation is as follows:

Margin (dB) = Corrected Amplitude (dBµV/m) - Class A Limit (dBµV/m)

6.6 Test Equipment List and Details

BACL Asset Number	Manufacturer	Descriptions	Models	Serial Numbers	Calibration Date	Calibration Due
00310	Rohde & Schwarz	Receiver, EMI Test	ESCI 1166.5950.03	100338	2018-07-05	2019-07-05
00311	Sunol Sciences	Controller, System	SC104V	113005-1	Cal. not required	Cal. not required
00445	SONOMA INSTRUMENT	Amplifier	315	303125	2018-07-27	2019-07-27
00714	Keysight Technologies	RF Limiter	11867A	MY42242932	2019-01-18	2020-01-18
00307	Sunol Sciences	Antenna, BiConiLog	JB3	A020106-3	2017-11-02	2019-11-02
00690	Wireless Solutions	N-Type Coax Cable	LMR 400	690	2019-03-12	2020-03-12

***Statement of Traceability*:** BACL Corp. attests that all of the calibrations on the equipment items listed above were traceable to NIST or to another internationally recognized National Metrology Institute (NMI), and were compliant with A2LA Policy P102 (dated 9 June 2016) "A2LA Policy on Metrological Traceability".

6.7 Test Environmental Conditions and Test Personnel

Test Date:	2019-03-13
Test Site:	10M Chamber 1
Temperature:	26 C
Relative Humidity:	41%
Barometric Pressure:	102.1 kPa
Test Personnel:	Xinhao Jiang

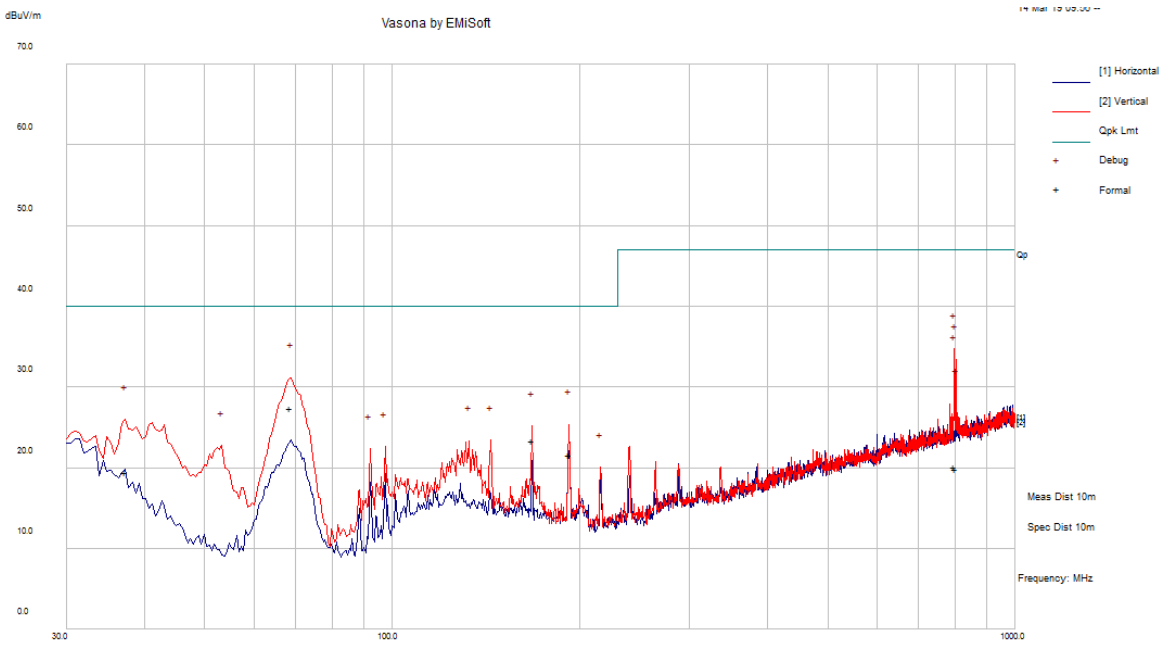
6.8 Summary of Test Results

According to the data in the following table, the EUT complied with EN 55011 Clause 5 Standard, Class A limits, and had the worst margin reading of:

Frequency Range: 30MHz-1GHz			
Margin (dB)	**Frequency (MHz)**	**Polarization (Horizontal/Vertical)**	**Range (MHz)**
-12.56	68.552	Vertical	30-1000

6.9 Radiated Emissions Test Plot and Data

30 to 1000 MHz at 10 Meter Distance



Quasi-Peak Measurements

Frequency (MHz)	Corrected Amplitude (dBµV/m)	Antenna Height (cm)	Polarity (H/V)	Turntable Azimuth (degrees)	Limit (dBµV/m)	Margin (dB)
68.552	27.44	281	V	346	40	-12.56
167.9795	23.44	102	V	131	40	-16.56
192.207	21.61	124	V	51	40	-18.39
37.26075	19.44	209	V	239	40	-20.56
797.389	20.17	301	V	96	47	-26.83
802.5445	19.91	336	V	326	47	-27.09

7 EN 61000-3-2 – Harmonic Current Emissions

7.1 Applicable Standard

As per EN 61000-3-2 Clause 7: Limits (Classes Dependent on Type of Device)

Limits for Class A equipment

For Class A equipment, the harmonics of the input current shall not exceed the values given in Table 1.

Audio amplifiers shall be tested according to Clause C.3. Dimmers for incandescent lamps shall be tested according to Clause C.6.

Table 1 – Limits for Class A

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≤ n ≤ 39	0,15 15/n
Even harmonics	
2	1,08
4	0,43
6	0,30
8≤ n ≤ 40	0,23 8/n

As per EN 61000-3-2 Clause 7: Limits (Classes Dependent on Type of Device)

Limits for Class B equipment

For Class B equipment, the harmonics of the input current shall not exceed the values given in Table 1 multipled by a factor of 1,5

Table 1 – Limits for Class A

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≤ n ≤ 39	0,15 15/n
Even harmonics	
2	1,08
4	0,43
6	0,30
8≤ n ≤ 40	0,23 8/n

As per EN 61000-3-2 Clause 7: Limits (Classes Dependent on Type of Device)

Limits for Class C equipment

a) Active input power >25 W

For lighting equipment having and active input power greater than 25 W, the harmonic currents shall not exceed the relative limits given in Table 2.

However, the limits given in Table 1 apply to incandescent lighting equipment that has bbuilt-in dimmers or dimmers built in an enclosure, the following conditions apply;

- the harmonic current values for the maximum load condition derived from the percentage limits fiven in Table 2 shall not be exceeded
- in any dimming position, the harmonic current shall not exceed the value of current allowed in the maximum laod condition;
- the equipment shall be tested according to the conditions given in C.5

b) Active input power < 25 W

Discharge lighting equipment having an active input power smaller than or equal to 25 W shall comply with one of the following two sets of requirements:

- the harmonic currents shall not exceed the power-related limits of Table 3, column 2, or:
- the third harmonic current, expressed as a percentage of the fundamental current, shall not exceed 86 % and the fifth harmonic current shall not exceed 61 %. Also, the waveform of the input current shall be such that it reaches the 5 % current threshold before or at 60°, has its peak value before or at 65° and does not fall below the 5 % current threshold before 90°, referenced to any zero crossing of the fundamental supply voltage. The current threshold is 5 % of the highest absolute peak value that occurs in the measurement window, and the phase angle measurements are made on the cycle that includes this absolute peak value.

If the discharge lighting equipment has a built-in dimming device, measurement is made only in the full load condition.

Table 2 – Limits for Class c

Harmonic order **n**	**Maximum permissible harmonic current expressed as a percentage of the input current at the fundamental frequency %**
Odd Harmonics	
2	2
3	30 – λ*
5	10
7	7
9	5
$1 \leq n \leq 39$ (odd harmonics only)	3
* λ is the circuit power factor	

As per EN 61000-3-2 Clause 7: Limits (Classes Dependent on Type of Device)

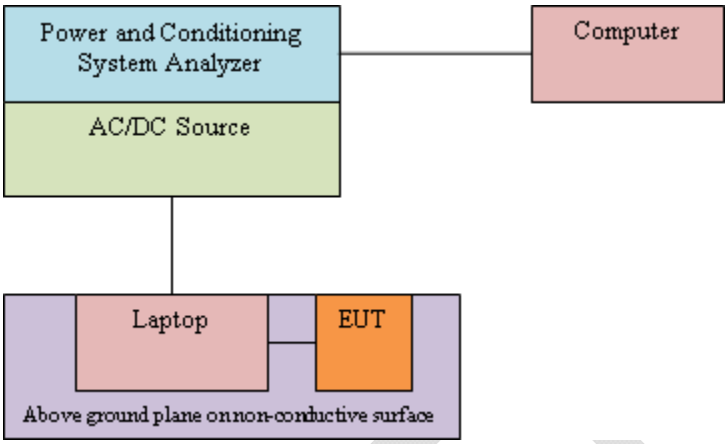
Limits for Class D equipment

For Class D equipment, the harmonic currents and the power shall be measured as defined in 6.2.2. The input currents at harmonic frequencies shall not exceed the values that can be derived from table 3 according to the requirements specified in 6.2.3 and 6.2.4.

Table 3- Limits for Class D equipment

Harmonic order **n**	**Maximum permissible harmonic current per watt** **mA/W**	**Maximum permissible harmonic current** **A**
3	3.4	2.30
5	1.9	1.14
7	1.0	0.77
9	0.5	0.40
11	0.35	0.33
$13 \leq n \leq 39$	3.85/n	See table 1

7.2 Test Setup Block Diagram



7.3 Test Equipment List and Details

BACL Asset Number	Manufacturers	Descriptions	Models	Serial Numbers	Calibration Date	Calibration Due
00349	California Instruments	Analyzer , Power and Conditioning System	PACS-1	72448	2019-03-06	2021-03-05
00485	California Instruments	Source, AC/DC	5001iX	54024	2019-03-06	2021-03-05

***Statement of Traceability*:** BACL Corp. attests that all of the calibrations on the equipment items listed above were traceable to NIST or to another internationally recognized National Metrology Institute (NMI), and were compliant with A2LA Policy P102 (dated 9 June 2016) "A2LA Policy on Metrological Traceability".

7.4 Test Environmental Conditions and Test Personnel

Test Date(s)	2019-04-12
Test Site	Outside Room 2B
Temperature:	23 ºC
Relative Humidity:	36 %
Barometric Pressure:	101.6 kPa
Test Personnel:	Ashraf Azihan

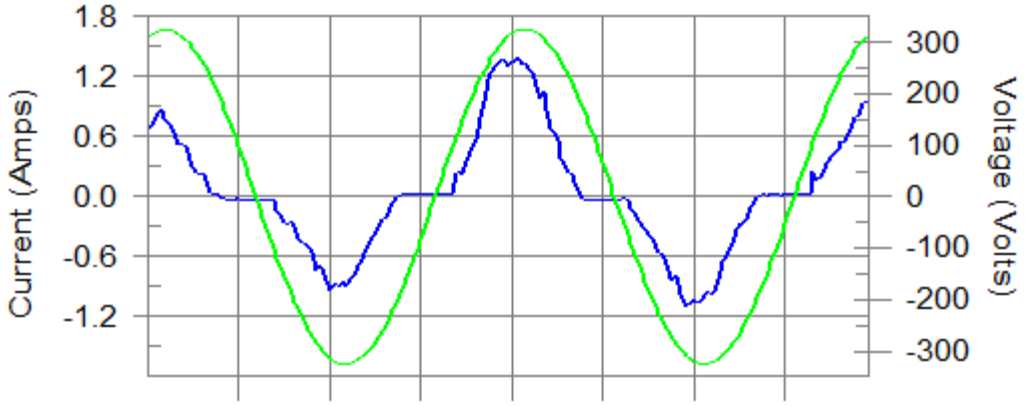
7.5 Harmonic Current Emissions Test

Harmonics – Class-A per Ed. 4.0 (2014)(Run time)

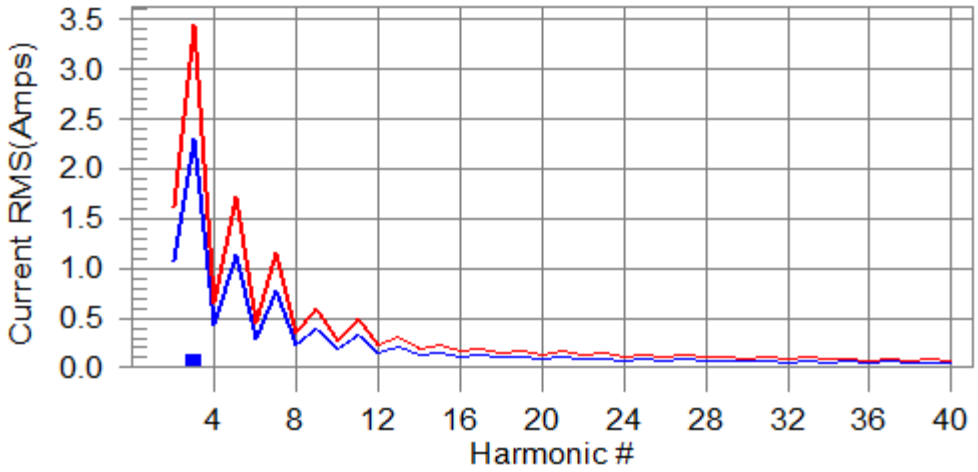
EUT: R1903055 Tested by: Ashraf
Test category: Class-A per Ed. 4.0 (2014) (European limits) Test Margin: 100
Test date: 4/12/2019 Start time: 3:43:01 PM End time: 4:13:13 PM
Test duration (min): 30 Data file name: H-000034.cts_data
Comment: Comments
Customer: X-Development

Test Result: Pass Source qualification: Normal

Current & voltage waveforms



Harmonics and Class A limit line European Limits



Test result: Pass Worst harmonics H17-5.3% of 150% limit, H23-6.2% of 100% limit

Current Test Result Summary (Run time)

EUT: R1903055 Tested by: Ashraf
Test category: Class-A per Ed. 4.0 (2014) (European limits) Test Margin: 100
Test date: 4/12/2019 Start time: 3:43:01 PM End time: 4:13:13 PM
Test duration (min): 30 Data file name: H-000034.cts_data
Comment: Comments
Customer: X-Development

Test Result: Pass Source qualification: Normal
THC(A): 0.128 I-THD(%): 28.9 POHC(A): 0.011 POHC Limit(A): 0.251

Highest parameter values during test:

V_RMS (Volts):	229.97	Frequency(Hz):	50.00
I_Peak (Amps):	1.427	I_RMS (Amps):	0.585
I_Fund (Amps):	0.443	Crest Factor:	3.024
Power (Watts):	99.3	Power Factor:	0.915

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.001	1.080	N/A	0.002	1.620	N/A	Pass
3	0.125	2.300	5.5	0.174	3.450	5.1	Pass
4	0.000	0.430	N/A	0.001	0.645	N/A	Pass
5	0.018	1.140	1.6	0.024	1.710	1.4	Pass
6	0.000	0.300	N/A	0.001	0.450	N/A	Pass
7	0.008	0.770	1.1	0.015	1.155	1.3	Pass
8	0.000	0.230	N/A	0.001	0.345	N/A	Pass
9	0.006	0.400	1.5	0.007	0.600	1.2	Pass
10	0.000	0.184	N/A	0.001	0.276	N/A	Pass
11	0.007	0.330	2.1	0.008	0.495	1.7	Pass
12	0.000	0.153	N/A	0.001	0.230	N/A	Pass
13	0.002	0.210	N/A	0.007	0.315	N/A	Pass
14	0.000	0.131	N/A	0.001	0.197	N/A	Pass
15	0.006	0.150	3.9	0.007	0.225	3.0	Pass
16	0.000	0.115	N/A	0.001	0.173	N/A	Pass
17	0.006	0.132	4.3	0.011	0.198	5.3	Pass
18	0.000	0.102	N/A	0.001	0.153	N/A	Pass
19	0.005	0.118	N/A	0.009	0.178	N/A	Pass
20	0.000	0.092	N/A	0.001	0.138	N/A	Pass
21	0.006	0.107	5.3	0.008	0.161	4.7	Pass
22	0.000	0.084	N/A	0.001	0.125	N/A	Pass
23	0.006	0.098	6.2	0.007	0.147	5.0	Pass
24	0.000	0.077	N/A	0.001	0.115	N/A	Pass
25	0.004	0.090	N/A	0.007	0.135	N/A	Pass
26	0.000	0.071	N/A	0.001	0.107	N/A	Pass
27	0.004	0.083	N/A	0.005	0.125	N/A	Pass
28	0.000	0.066	N/A	0.001	0.099	N/A	Pass
29	0.002	0.078	N/A	0.004	0.116	N/A	Pass
30	0.000	0.061	N/A	0.001	0.092	N/A	Pass
31	0.003	0.073	N/A	0.003	0.109	N/A	Pass
32	0.000	0.058	N/A	0.001	0.086	N/A	Pass
33	0.001	0.068	N/A	0.003	0.102	N/A	Pass
34	0.000	0.054	N/A	0.001	0.081	N/A	Pass
35	0.003	0.064	N/A	0.003	0.096	N/A	Pass
36	0.000	0.051	N/A	0.001	0.077	N/A	Pass
37	0.001	0.061	N/A	0.003	0.091	N/A	Pass
38	0.000	0.048	N/A	0.001	0.073	N/A	Pass
39	0.004	0.058	N/A	0.005	0.087	N/A	Pass
40	0.000	0.046	N/A	0.001	0.069	N/A	Pass

Voltage Source Verification Data (Run time)

EUT: R1903055 Tested by: Ashraf
Test category: Class-A per Ed. 4.0 (2014) (European limits) Test Margin: 100
Test date: 4/12/2019 Start time: 3:43:01 PM End time: 4:13:13 PM
Test duration (min): 30 Data file name: H-000034.cts_data
Comment: Comments
Customer: X-Development

Test Result: Pass Source qualification: Normal

Highest parameter values during test:

Voltage (Vrms):	229.97	Frequency(Hz):	50.00
I_Peak (Amps):	1.427	I_RMS (Amps):	0.585
I_Fund (Amps):	0.443	Crest Factor:	3.024
Power (Watts):	99.3	Power Factor:	0.915

Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.100	0.460	21.80	OK
3	0.374	2.070	18.05	OK
4	0.024	0.460	5.11	OK
5	0.014	0.920	1.55	OK
6	0.029	0.460	6.33	OK
7	0.020	0.690	2.93	OK
8	0.016	0.460	3.58	OK
9	0.014	0.460	3.12	OK
10	0.012	0.460	2.64	OK
11	0.015	0.230	6.65	OK
12	0.018	0.230	7.69	OK
13	0.014	0.230	5.91	OK
14	0.010	0.230	4.20	OK
15	0.006	0.230	2.65	OK
16	0.013	0.230	5.64	OK
17	0.009	0.230	3.99	OK
18	0.013	0.230	5.48	OK
19	0.013	0.230	5.52	OK
20	0.018	0.230	7.82	OK
21	0.013	0.230	5.85	OK
22	0.008	0.230	3.48	OK
23	0.009	0.230	3.79	OK
24	0.005	0.230	2.04	OK
25	0.010	0.230	4.54	OK
26	0.008	0.230	3.47	OK
27	0.010	0.230	4.22	OK
28	0.006	0.230	2.46	OK
29	0.007	0.230	3.20	OK
30	0.007	0.230	3.11	OK
31	0.005	0.230	2.04	OK
32	0.006	0.230	2.60	OK
33	0.004	0.230	1.68	OK
34	0.004	0.230	1.76	OK
35	0.005	0.230	2.18	OK
36	0.005	0.230	2.11	OK
37	0.005	0.230	2.37	OK
38	0.004	0.230	1.86	OK
39	0.010	0.230	4.45	OK
40	0.014	0.230	6.18	OK

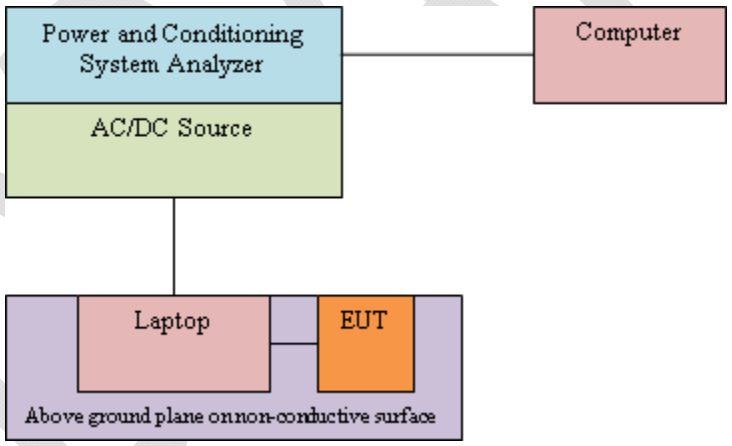
8 EN 61000-3-3 – Voltage Fluctuations and Flicker

8.1 Applicable Standard

As per EN 61000-3-3: 2008 Clause 5: Limits

_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. 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 value of $d(t)$ during a voltage change shall not exceed 3,3 % for more than 500 ms;
— the relative steady-state voltage change, d_c, shall not exceed 3,3 %;
— the maximum relative voltage change, d_{max}, shall not exceed;
a) 4 % without additional conditions;
b) 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.
NOTE The cycling frequency will be further limited by the P_{st} and P_{lt} limit. For example: a d_{max} of 6 % producing a rectangular voltage change characteristic twice per hour will give a P_{lt} of about 0,65.

8.2 Test Setup Block Diagram



8.3 Test Equipment List and Details

BACL Asset Number	Manufacturers	Descriptions	Models	Serial Numbers	Calibration Date	Calibration Due
00349	California Instruments	Analyzer , Power and Conditioning System	PACS-1	72448	2019-03-06	2021-03-05
00485	California Instruments	Source, AC/DC	5001iX	54024	2019-03-06	2021-03-05

***Statement of Traceability*:** BACL Corp. attests that all of the calibrations on the equipment items listed above were traceable to NIST or to another internationally recognized National Metrology Institute (NMI), and were compliant with A2LA Policy P102 (dated 9 June 2016) "A2LA Policy on Metrological Traceability".

8.4 Test Environmental Conditions and Test Personnel

Test Date(s)	2019-04-12
Test Site	Outside Room 2B
Temperature:	23 ºC
Relative Humidity:	36 %
Barometric Pressure:	101.6 kPa
Test Personnel:	Ashraf Azihan

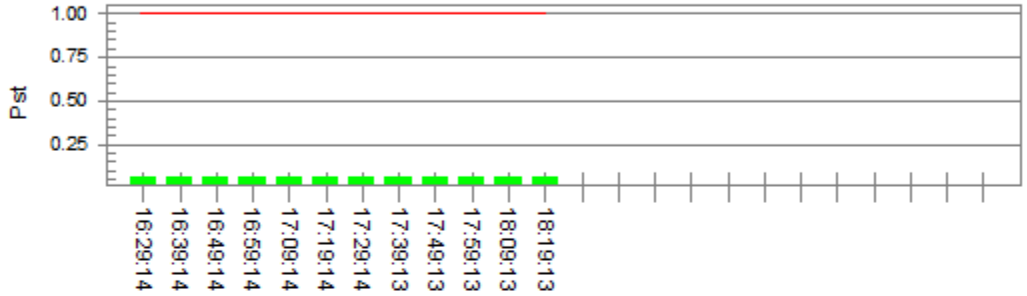
8.5 Voltage Fluctuations and Flicker Test (EN 61000-3-3)

Flicker Test Summary per EN/IEC61000-3-3 Ed. 3.0 (2013) (Run time)

EUT: R1903055 Tested by: Ashraf
Test category: All parameters (European limits) Test Margin: 100
Test date: 4/12/2019 Start time: 4:18:53 PM End time: 6:20:26 PM
Test duration (min): 120 Data file name: F-000035.cts_data
Comment: Comments
Customer: X Development

Test Result: Pass Status: Test Completed

Pst and limit line European Limits



Plt and limit line

Parameter values recorded during the test:

Vrms at the end of test (Volt):	229.86			
Highest dt (%):	0.00	Test limit (%):	N/A	N/A
T-max (mS):	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

9 EN 60601-1-2 Clause 8 – Electrostatic Discharge

9.1 Applicable Standard

As per IEC 61000-4-2, 2009-05: Test Levels

The preferential range of test levels for the ESD test is given in table 1.

Testing shall also be satisfied at the lower levels given in table l.

Details concerning the various parameters which may influence the voltage level to which the human body may be charged are given in clause A.2 of annex A. Clause **A.4** also contains examples of the application of the test levels related to environmental (installation) classes.

Contact discharge is the preferred test method. Air discharges shall be used where contact discharge cannot be applied. Voltages for each test method are given in tables la and 1b.
The voltages shown are different for each method due to the differing methods of test. It is not intended to imply that the test severity is equivalent between test methods.

Further information is given in clauses A.3, A.4 and A.5 of annex A.

Table 1- Test levels

1a-Contact discharge		1b- Air discharge	
Level	**Test voltage (kV)**	**Level**	**Test voltage (kV)**
1	2	1	2
2	4	2	4
3	6	3	8
4	8	4	15
x[1)]	Special	x[1)]	Special
[1)] "x" is an open level. The level has to be specified in the dedicated equipment specification. If higher voltages than those shown are specified, special test equipment may be needed.			

9.2 Electrostatic Discharge Test System

The Schaffner NSG 435 ESD used for testing, is capable of applying Electrostatic Discharges in both contact discharge modes from 2 kV to 4 kV and air discharge modes from 2 kV to 8 kV in both positive and negative polarities, in accordance with IEC 61000-4-2, 2009-05 EMC testing standard and methods.

9.3 Electrostatic Discharge Measurement Uncertainty

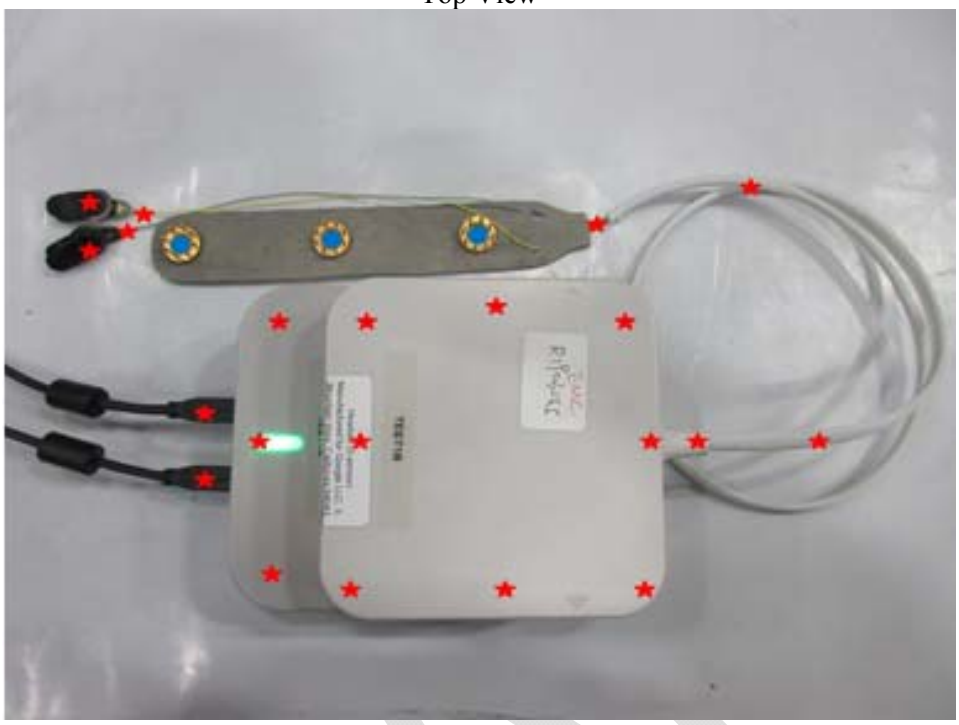
The measurement uncertainty with a 95% confidence factor has determined that the applied voltage has a maximum variance of ± 5% of the stated applied value.

9.4 Application of Electrostatic Discharges

The test was conducted in the following order: Air Discharge, Direct Contact Discharge, Indirect Contact Horizontal Coupling Plane Discharge, and Indirect Contact Vertical Coupling Plane Discharge. The Electrostatic Discharge test levels were set and discharged appropriately. The Electrostatic Discharges are applied to the conductive surface of the EUT, and along all seams and control surfaces on the EUT. When a discharge occurs and an error is caused, the type of error, discharge level and location is recorded.

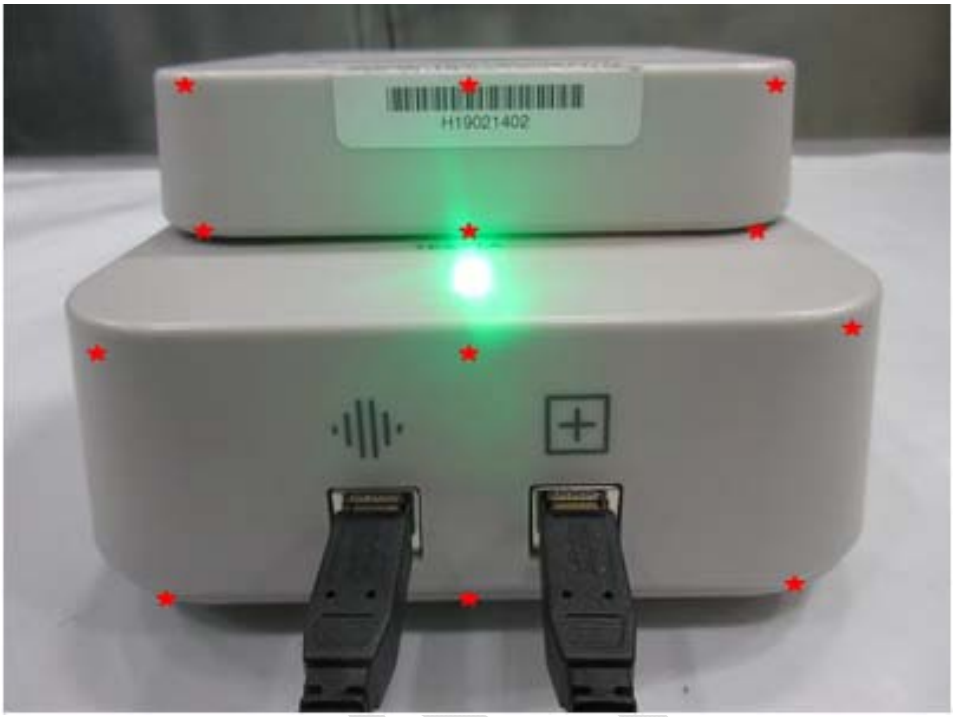
9.5 Electrostatic Discharge Immunity Test Points (Red – Air Discharge and Blue – Direct Contact)

Top View

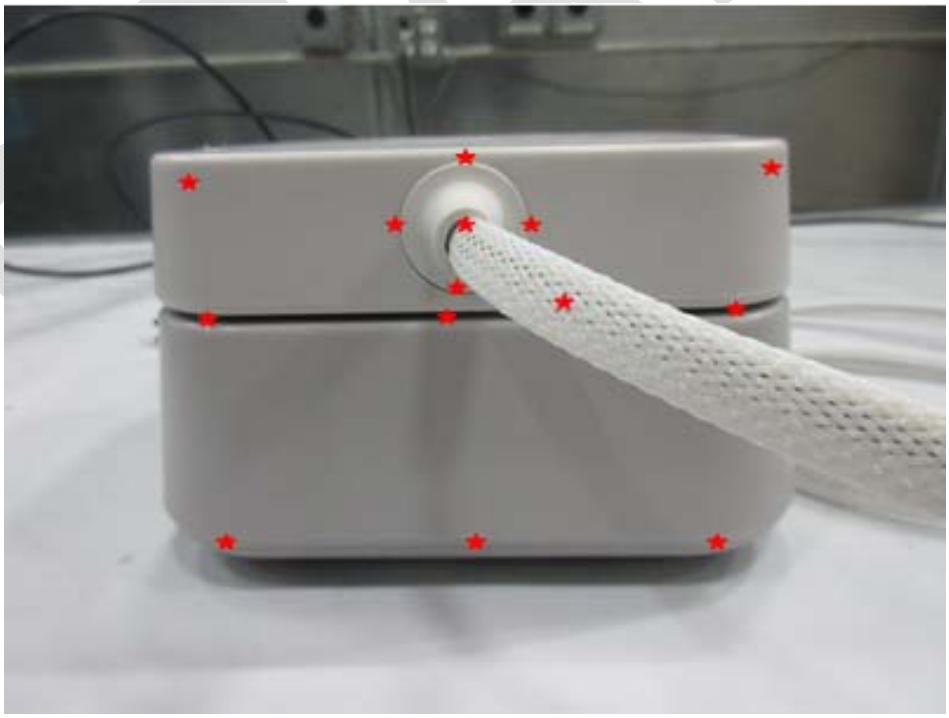


Bottom View

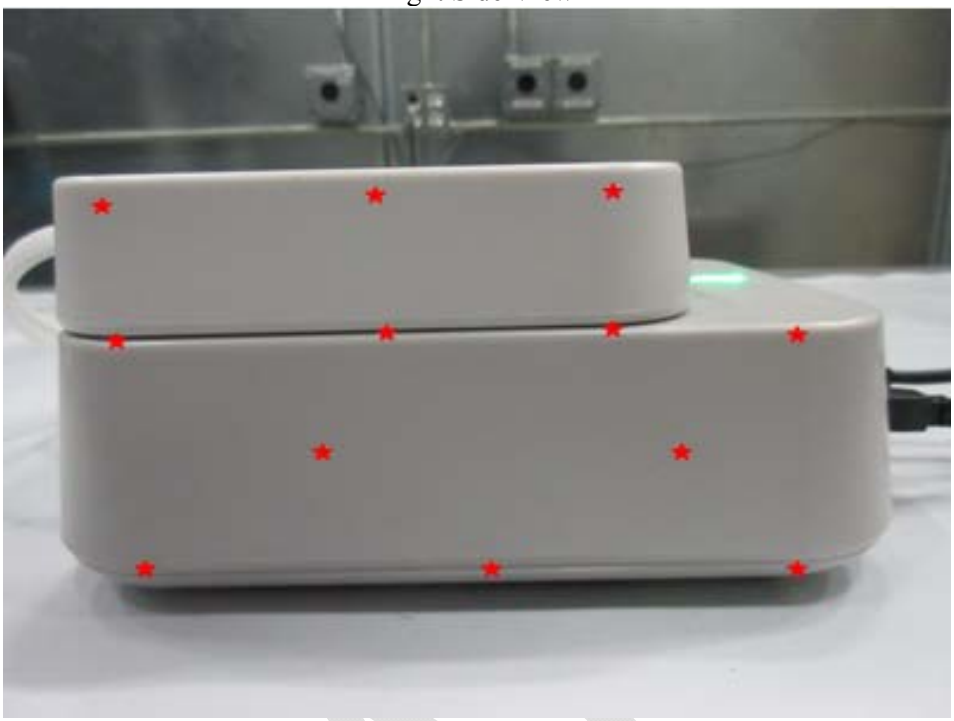
Front Side View



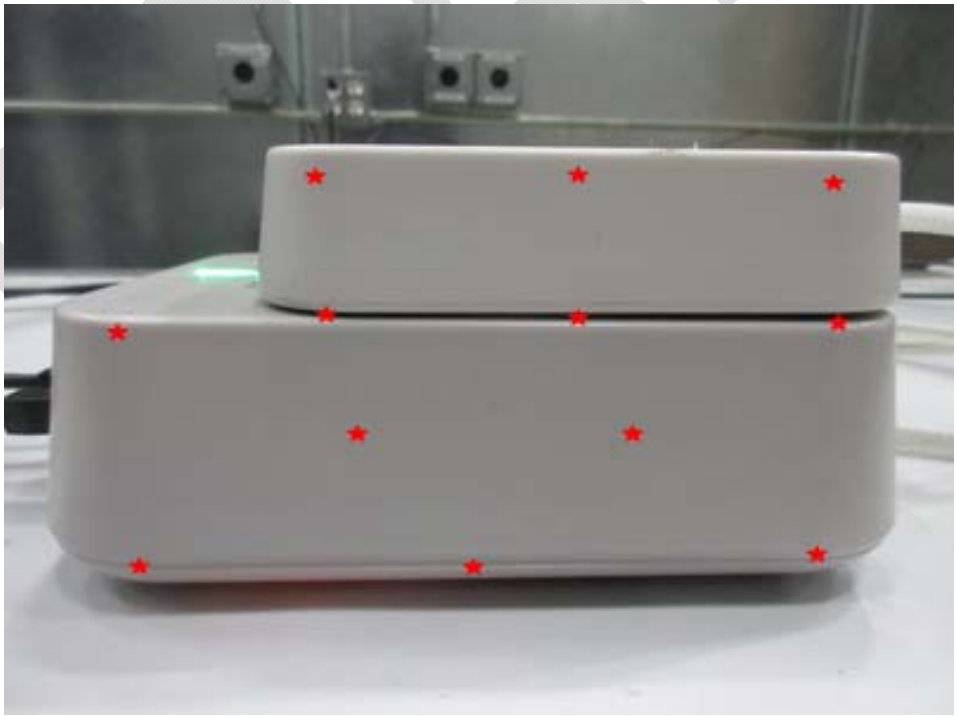
Rear View



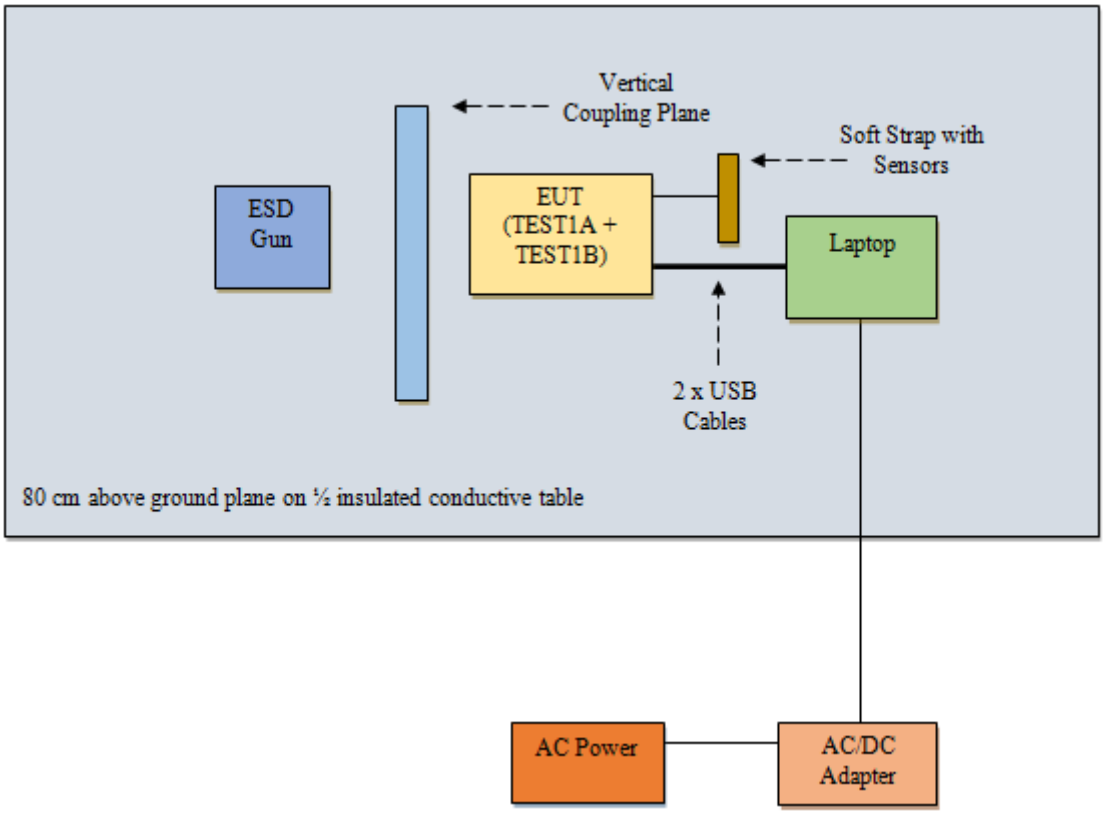
Right Side View



Left Side View



9.6 Test Setup Block Diagram



9.7 Test Equipment List and Details

Manufacturer	Description	Model	Serial Number	Calibration Date	Calibration Due
TESEQ AG	ESD Generator	NSG 438	1282	2019-03-29	2020-03-29

***Statement of Traceability*:** BACL Corp. attests that all calibrations have been performed according to A2LA requirements, traceable to the NIST.

9.8 Environmental Conditions

Testing Date:	03-29-2019
Testing Site:	Immunity Test Area 1A
Temperature:	32 ºC
Relative Humidity:	49 %
ATM Pressure:	102.9 kPa
Testing Personnel:	Jose Huamani

9.9 Electrostatic Discharge Test Data (IEC 61000-4-2)

Table 1: Electrostatic Discharge (Air Discharge)

IEC 61000-4-2 Test Point	Test Level (kV)											
	-2	+2	-4	+4	-6	+6	-8	+8	-15	+15	-20	+20
Top of EUT	A	A	A	A	-	-	A	A	A	A	-	-
Bottom of EUT	A	A	A	A	-	-	A	A	A	A	-	-
Front of EUT	A	A	A	A	-	-	A	A	A	A	-	-
Rear of EUT	A	A	A	A	-	-	A	A	A	A	-	-
Left Side of EUT	A	A	A	A	-	-	A	A	A	A	-	-
Right Side of EUT	A	A	A	A	-	-	A	A	A	A	-	-
Front Cables	A	A	A	A	-	-	A	A	A	A	-	-
Rear Cables	A	A	A	A	-	-	A	A	A	A	-	-

Table 2: Electrostatic Discharge (Direct Contact)

IEC 61000-4-2 Test Point	Test Level (kV)											
	-2	+2	-4	+4	-6	+6	-8	+8	-15	+15	-20	+20
Rear Cables	A	A	A	A	A	A	A	A	-	-	-	-

Table 3: Electrostatic Discharge (Indirect Contact HCP)

IEC 61000-4-2 Test Point	Test Level (kV)											
	-2	+2	-4	+4	-6	+6	-8	+8	-15	+15	-20	+20
Top of EUT	A	A	A	A	A	A	A	A	-	-	-	-
Bottom of EUT	A	A	A	A	A	A	A	A	-	-	-	-
Front of EUT	A	A	A	A	A	A	A	A	-	-	-	-
Rear of EUT	A	A	A	A	A	A	A	A	-	-	-	-
Left Side of EUT	A	A	A	A	A	A	A	A	-	-	-	-
Right Side of EUT	A	A	A	A	A	A	A	A	-	-	-	-

Table 4: Electrostatic Discharge (Indirect Contact VCP)

IEC 61000-4-2 Test Point	Test Level (kV)											
	-2	+2	-4	+4	-6	+6	-8	+8	-15	+15	-20	+20
Top of EUT	A	A	A	A	A	A	A	A	-	-	-	-
Bottom of EUT	A	A	A	A	A	A	A	A	-	-	-	-
Front of EUT	A	A	A	A	A	A	A	A	-	-	-	-
Rear of EUT	A	A	A	A	A	A	A	A	-	-	-	-
Left Side of EUT	A	A	A	A	A	A	A	A	-	-	-	-
Right Side of EUT	A	A	A	A	A	A	A	A	-	-	-	-

Note: A ----- Performance Criteria A
B ----- Performance Criteria B
C ----- Performance Criteria C
- ----- Not Applicable

The EUT was subjected to the electrostatic discharge tests required by EN 60601-1-2 Clause 6.2, and all lower levels specified in EN61000-4-2.

10 EN 60601-1-2 Clause 8 – Radiated RF Fields

10.1 Applicable Standard

As per IEC 61000-4-3: 2006: Test Levels

The preferential range of test levels is given in table 1.

Frequency range: 80 MHz to 1000 MHz.

Table 1- Test levels

Level	Test field strength (V/m)
1	1
2	3
3	10
x	special
NOTE x is an open test level. This level may be given in the product specification.	

Table 1 gives details of the field strength of the unmodulated signal. For testing of equipment, this signal is 80% amplitude modulated with a 1 kHz sinewave to simulate actual threats (see figure 1). Details of how the test is performed are given in clause 8.

NOTE 1 Product committees may decide to choose a lower or higher transition frequency than 80 MHz between IEC 61000-4-3 and IEC 61000-4-6 (see annex H).
NOTE 2 Product committees may select alternative modulation schemes.
NOTE 3 IEC 61000-4-6 also defines test methods for establishing the immunity of electrical and electronic equipment against radiated electromagnetic energy. It covers frequencies below 80 MHz.

10.2 Continuous Radiated Disturbances Test System

HP 8648C signal generator and a CMX5001power amplifier are used to provide a signal at the appropriate power and frequency to a biconilog antenna to obtain the required electromagnetic field at the position of the EUT in accordance with the IEC 61000-4-3, 2006 EMC standard and methods.

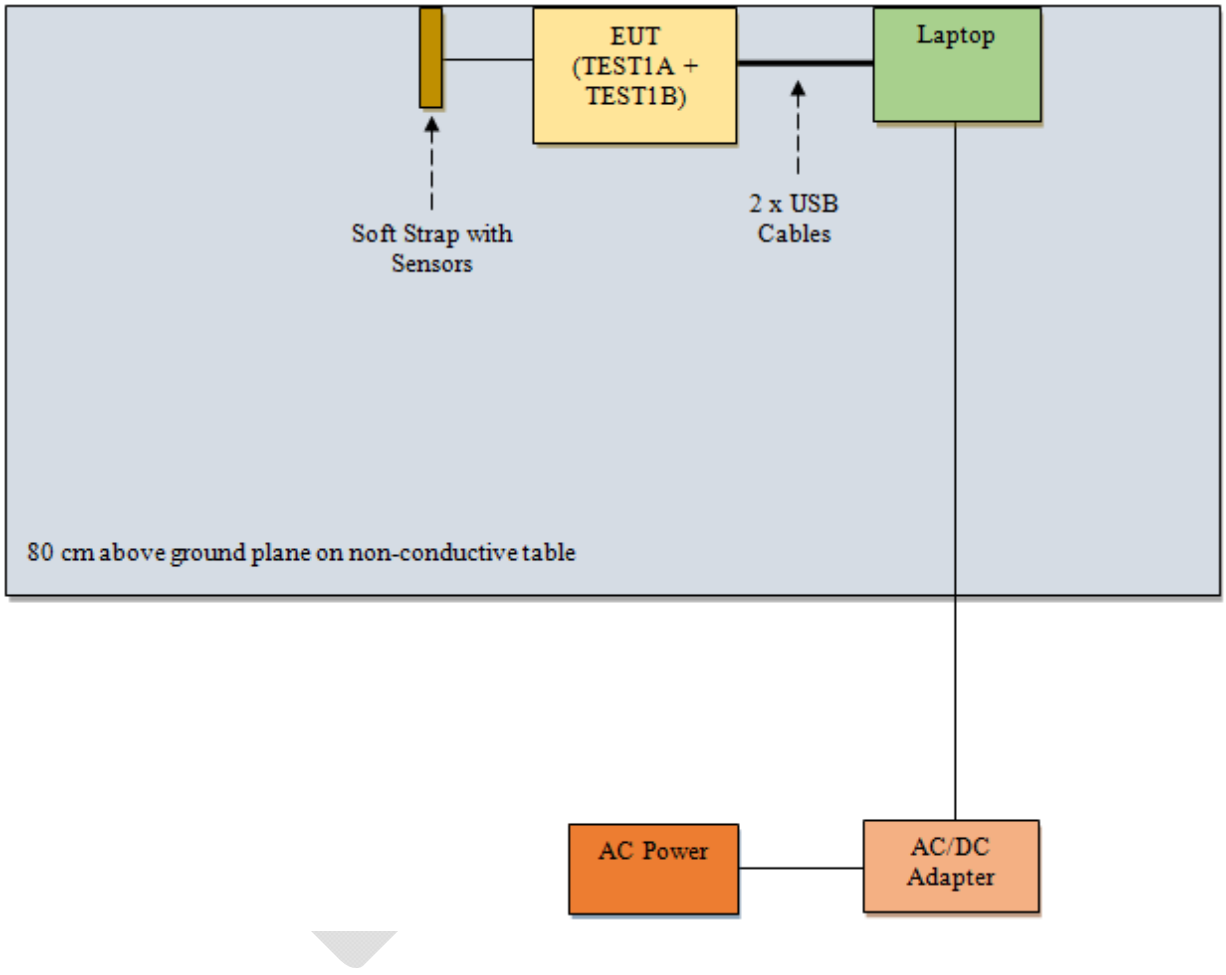
10.3 Continuous Radiated Disturbances Measurement Uncertainty

The measurement uncertainty with a 95 % confidence factor has determined that the applied field has an expanded uncertainty value of 1.97. This yields an uncertainty of 0.15 V (rms) in the applied filed levels.

10.4 Application of Continuous Radiated Disturbances

The electromagnetic field is established at the front edge of the EUT. The frequency range is swept from 80 to 1000 MHz using a power level necessary to obtain a 3 volt/meter, 1 kHz AM sine wave modulated at 80% depth, field directed at the EUT. The test is performed with the most susceptible side of the EUT facing the field-generating antenna. If an error is detected, the field is reduced until the error is not repeatable; the field is then manually increased until the error begins to occur. At this threshold level, the frequency and error created are noted before continuing the scan.

10.5 Test Setup Block Diagram



10.6 Test Equipment List and Details

BACL Asset Number	Manufacturers	Descriptions	Models	Serial Numbers	Calibration Date	Calibration Due
00742	HP	Signal Generator	83620B	3844A00849	2018-11-12	2019-11-12
00862	Ophir RF	700-6000 MHz RF Power Amplifier	5293FE	1057	Calibration not Required	Calibration not Required
00882	Ophir RF	80-1000 MHz RF Power Amplifier	5225FE	1061	Calibration not Required	Calibration not Required
00514	ETS	Antenna, BiConiLog	3140	1019	Calibration not Required	Calibration not Required
00820	Amplifier Research	Stacked Log-Periodic Antenna	ATS700M11G	345747	Calibration not Required	Calibration not Required
00665	Narda Safety Test Solutions	Field Meter	NBM 520	D0887	2018-09-24	2019-09-24
00731	Narda Safety Test Solutions	Field Meter	EF 1891	D-0375	2018-09-24	2019-09-24
00312	Panasonic	Camera System Controller	WV-CU161C	EGR00083	Calibration not Required	Calibration not Required

***Statement of Traceability*:** BACL Corp. attests that all of the calibrations on the equipment items listed above were traceable to NIST or to another internationally recognized National Metrology Institute (NMI), and were compliant with A2LA Policy P102 (dated 9 June 2016) "A2LA Policy on Metrological Traceability".

10.7 Test Environmental Conditions and Test Personnel

Test Date(s)	03-25-2019
Test Site	5M-2
Temperature:	21 ºC
Relative Humidity:	35%
Barometric Pressure:	102.0 kPa
Test Personnel:	Jose Huamani

10.8 Continuous Radiated Disturbances Test Data (IEC 61000-4-3)

Frequency Range (MHz)	V/m	Front Side (3 V/m)		Rear Side (3 V/m)		Left Side (3 V/m)		Right Side (3 V/m)	
		Vertical	Horizontal	Vertical	Horizontal	Vertical	Horizontal	Vertical	Horizontal
80 to2700	10	A	A	A	A	A	A	A	A

Note: A ----- Performance Criteria A
B ----- Performance Criteria B
C ----- Performance Criteria C
- ----- Not Applicable

The EUT was subjected to a 10 volt/meter, 80% Amplitude modulated, 1 kHz sine wave. The EUT was subjected to continuous radiated disturbance required by EN 60601-1-2 and the level specified by EN 61000-4-3. During testing a 2 second dwell time with 1% step from 80 MHz to 2700 MHz was used. The distance from the antenna to the EUT is was1 meter.

Spot Test:

Frequency Range (MHz)	V/m	Front Side		Rear Side		Left Side		Right Side	
		Vertical	Horizontal	Vertical	Horizontal	Vertical	Horizontal	Vertical	Horizontal
385	27	A	A	A	A	A	A	A	A
450	28	A	A	A	A	A	A	A	A
710	9	A	A	A	A	A	A	A	A
745	9	A	A	A	A	A	A	A	A
780	9	A	A	A	A	A	A	A	A
810	28	A	A	A	A	A	A	A	A
870	28	A	A	A	A	A	A	A	A
930	28	A	A	A	A	A	A	A	A
1720	28	A	A	A	A	A	A	A	A
1845	28	A	A	A	A	A	A	A	A
1970	28	A	A	A	A	A	A	A	A
2450	28	A	A	A	A	A	A	A	A
5240	9	A	A	A	A	A	A	A	A
5500	9	A	A	A	A	A	A	A	A
5785	9	A	A	A	A	A	A	A	A

Note: A ----- Performance Criteria A
B ----- Performance Criteria B
C ----- Performance Criteria C
- ----- Not Applicable

11 EN 60601-1-2 Clause 8 – Electrical Fast Transients

11.1 Applicable Standard

As per IEC 61000-4-4, 2007: Test Levels

The preferential range of test levels for the electrical fast transient test, applicable to power, ground**,** signal and control ports of the equipment are given in table 1.

Table 1- Test levels

Open circuit output test voltage and repetition rate of the impulses				
Level	**On power port, PE**		**On I/O (input/output) signals, data and control ports**	
	Voltage peak (kV)	**Repetition rate (kHz)**	**Voltage peak (kV)**	**Repetition rate (kHz)**
1	0.5	5 or 100	0.25	5 or 100
2	1	5 or 100	0.5	5 or 100
3	2	5 or 100	1	5 or 100
4	4	5 or 100	2	5 or 100
X[1)]	Special	Special	Special	Special
NOTE 1 Use of 5 kHz repetition rates is traditional; however, 100 kHz is closer to reality. Product committees should determine which frequencies are relevant for specific products or product types.				
NOTE 2 With some products, there may be no clear distinction between power ports and I/O ports, in which case it is up to product committees to make this determination for test purposes.				
"x" is an open level. The level has to be specified in the dedicated equipment specification.				

These open-circuit output voltages will be displayed on the EFT/B generator. For selection of levels, see Annex B.

11.2 Electrical Fast Transients Test System

An Ecompact4 tester is used for all testing. It is capable of applying fast transients to the AC line at any phase angle with respect to the AC line voltage wave form and to attached cables via a capacitive coupling clamp in accordance with the IEC 61000-4-4, EMC standard and methods.

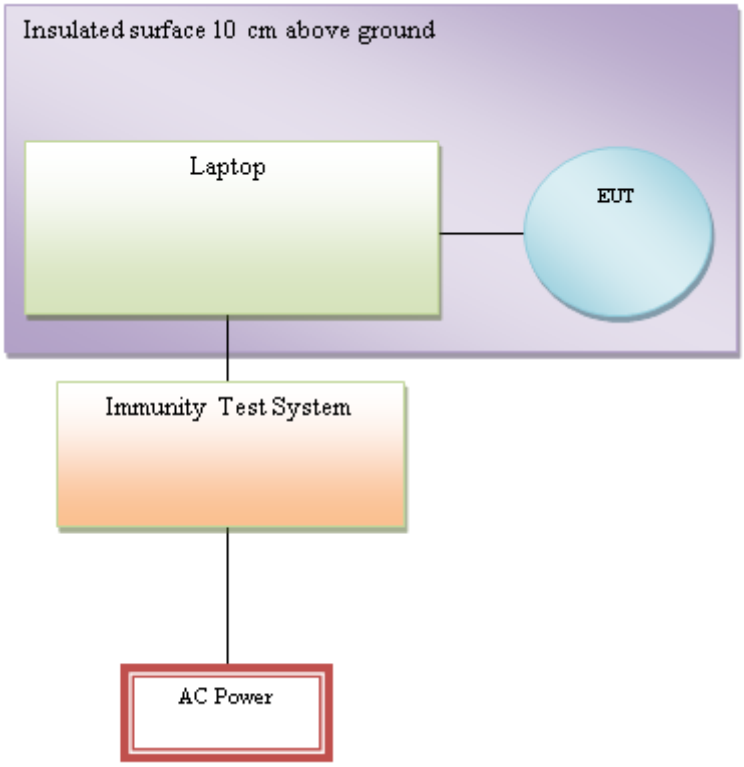
11.3 Electrical Fast Transients Measurement Uncertainty

The measurement uncertainty with a 95% confidence factor has determined that the applied field has an expanded uncertainty value of 1.97.

11.4 Application of Electrical Fast Transients

The EUT was arranged for Power Line Coupling with a coupling/decoupling network and for I/O Line Coupling through a capacitive clamp, where applicable. (Note: The I/O coupling test using a capacitive clamp is performed on the I/O interface cables that are longer in length than 3 meters.) A metal ground plane 2.4 meter by 2.0 meter was placed between the floor and the table and is connected to the earth by a 2.0 meter ground rod. The ground rod is connected to the test facility's electrical earth. The distance between the CDN and any other conductive surface was 50cm.

11.5 Test Setup Block Diagram



11.6 Test Equipment List and Details

BACL Asset Number	Manufacturers	Descriptions	Models	Serial Numbers	Calibration Date	Calibration Due
00801	Haefely	Compact Immunity Test System	AXOS5	182492	2019-02-12	2020-02-12
00802	Haefely	Capacitive Coupling Clamp	IP4B	181974	2019-02-12	2020-02-12
00810	BACL	AXOS5 EUT INPUT POWER FUSE BOX	N/A	N/A	Cal. Not required	Cal. Not required
00147	Agilent	Analyzer, AC Power	6812B	US38390366	Calibration not Required	Calibration not Required

***Statement of Traceability*:** BACL Corp. attests that all of the calibrations on the equipment items listed above were traceable to NIST or to another internationally recognized National Metrology Institute (NMI), and were compliant with A2LA Policy P102 (dated 9 June 2016) "A2LA Policy on Metrological Traceability".

11.7 Test Environmental Conditions and Test Personnel

Test Date(s)	2019-3-14
Test Site	Outside Immunity Room 1B
Temperature:	26 ºC
Relative Humidity:	42 %
Barometric Pressure:	101.2kPa
Test Personnel:	Xinhao Jiang

11.8 Electrical Fast Transient Test Data (IEC 61000-4-4)

EN 61000-4-4 Test Point	Test Level (kV)							
	-0.25	+0.25	-0.5	+0.5	-1.0	+1.0	-2.0	+2.0
L1	-	-	A	A	A	A	A	A
L2	-	-	A	A	A	A	A	A
Earth	-	-	A	A	A	A	A	A
L1+L2	-	-	A	A	A	A	A	A
L1+Earth	-	-	A	A	A	A	A	A
L2+Earth	-	-	A	A	A	A	A	A
L1+L2+Earth	-	-	A	A	A	A	A	A

Note: A ----- Performance Criteria A
B ----- Performance Criteria B
C ----- Performance Criteria C
- ----- Not Applicable

The EUT was subjected to the Electrical Fast Transient tests required by EN 60601-1-2 Clause 6.2, and all lower levels specified in EN 61000-4-4.

12 EN 60601-1-2 Clause 8 - Surges

12.1 Applicable Standard

As per IEC 61000-4-5, 2006: Test Levels

The preferential range of test levels is given in table 1.

Table 1- Test levels

Level	Open-circuit test voltage ±10 % (kV)
1	0.5
2	1.0
3	2.0
4	4.0
x	Special
NOTE x is an open class. This level can be specified in the product specification.	

The test levels shall be selected according to the installation conditions; classes of installation are given in B.3 of annex B.

All voltages of the lower test levels shall be satisfied (see 8.2).

For selection of the test levels for the different interfaces, see annex A.

12.2 Surges Test System

An Ecompact4 Immunity test system is used for all testing. Both positive and negative polarities of voltage up to 2 kV were applied to the AC input lines.

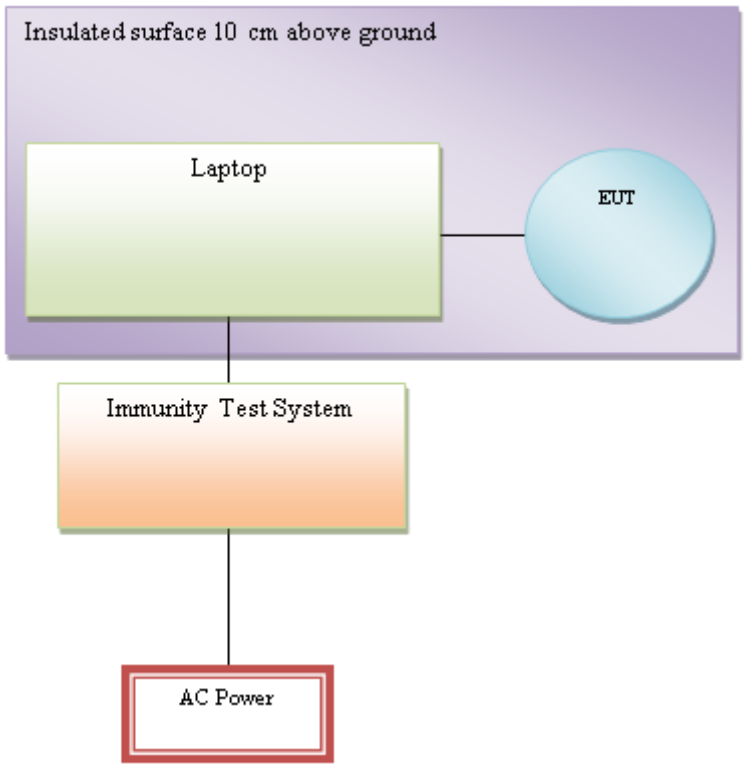
12.3 Surges Measurement Uncertainty

The measurement uncertainty with a 95 % confidence factor has determined that the applied surge is within 5% of the stated value.

12.4 Application of Surges

The EUT was setup in accordance with the setup described in IEC 61000-4-5, 2006 and the test was performed according to the procedures described in the standard.

12.5 Test Setup Block Diagram



12.6 Test Equipment List and Details

BACL Asset Number	Manufacturers	Descriptions	Models	Serial Numbers	Calibration Date	Calibration Due
00801	Haefely	Compact Immunity Test System	AXOS5	182492	2019-02-12	2020-02-12
00810	BACL	AXOS5 EUT INPUT POWER FUSE BOX	N/A	N/A	Cal. Not required	Cal. Not required
00147	Agilent	Analyzer, AC Power	6812B	US38390366	Calibration not Required	Calibration not Required

***Statement of Traceability*:** BACL Corp. attests that all of the calibrations on the equipment items listed above were traceable to NIST or to another internationally recognized National Metrology Institute (NMI), and were compliant with A2LA Policy P102 (dated 9 June 2016) "A2LA Policy on Metrological Traceability".

12.7 Test Environmental Conditions and Test Personnel

Test Date(s)	2019-03-14
Test Site	Outside Immunity Room 1B
Temperature:	26 ºC
Relative Humidity:	42 %
Barometric Pressure:	101.2kPa
Test Personnel:	Xinhao Jiang

12.8 Surges Test Data (IEC 61000-4-5)

Level	Voltage (kV)	Pole	Path	Pass	Fail
1	0.5	±	L-N	A	-
2	1	±	L-N	A	-

Note: A ----- Performance Criteria A
B ----- Performance Criteria B
C ----- Performance Criteria C
- ----- Not Applicable

The EUT was subjected to the Surge Immunity tests required by EN 60601-1-2 and all lower levels specified in EN 61000-4-5.

13 EN 60601-1-2 Clause 8 – Conducted Disturbances, induced by RF Fields

13.1 Applicable Standard

As per IEC 61000-4-6, 2009: Test Levels

No tests are required for induced disturbances caused by electromagnetic fields coming from intentional RF transmitters in the frequency range 9 kHz to 150 kHz.

Table 1- Test levels

Frequency range 150 kHz-80 MHz		
Level	**Voltage level (e.m.f.)**	
	uo **dB(PV)**	***u0*** **v**
1	120	1
2	130	3
3	140	10
X[1)]	Special	
[1)] X is an open level.		

The open-circuit test levels (e.m.f.) of the unmodulated disturbing signal, expressed in r.m.s., are given in Table 1. The test levels are set at the EUT port of the coupling and decoupling devices, see 6.4.1. For testing of equipment, this signal is 80% amplitude modulated with a 1 kHz sine wave to simulate actual threats. The effective amplitude modulation is shown in Figure 4. Guidance for selecting test levels is given in Annex C.

13.2 Continuous Conducted Disturbance Test

An EM Test CWS500C Continuous Wave Simulator was used to perform the test. The EUT was subjected to 3 V rms, AM modulated (1 kHz sinewave at 80% depth), conducted signals from 0.15 MHz to 80 MHz. CDN coupling and de-coupling networks were utilized to inject the signal onto the power line using the 6.2.1 method. The clamp injection method of 6.2.2 was used to inject the signal onto the I/O lines, where applicable.

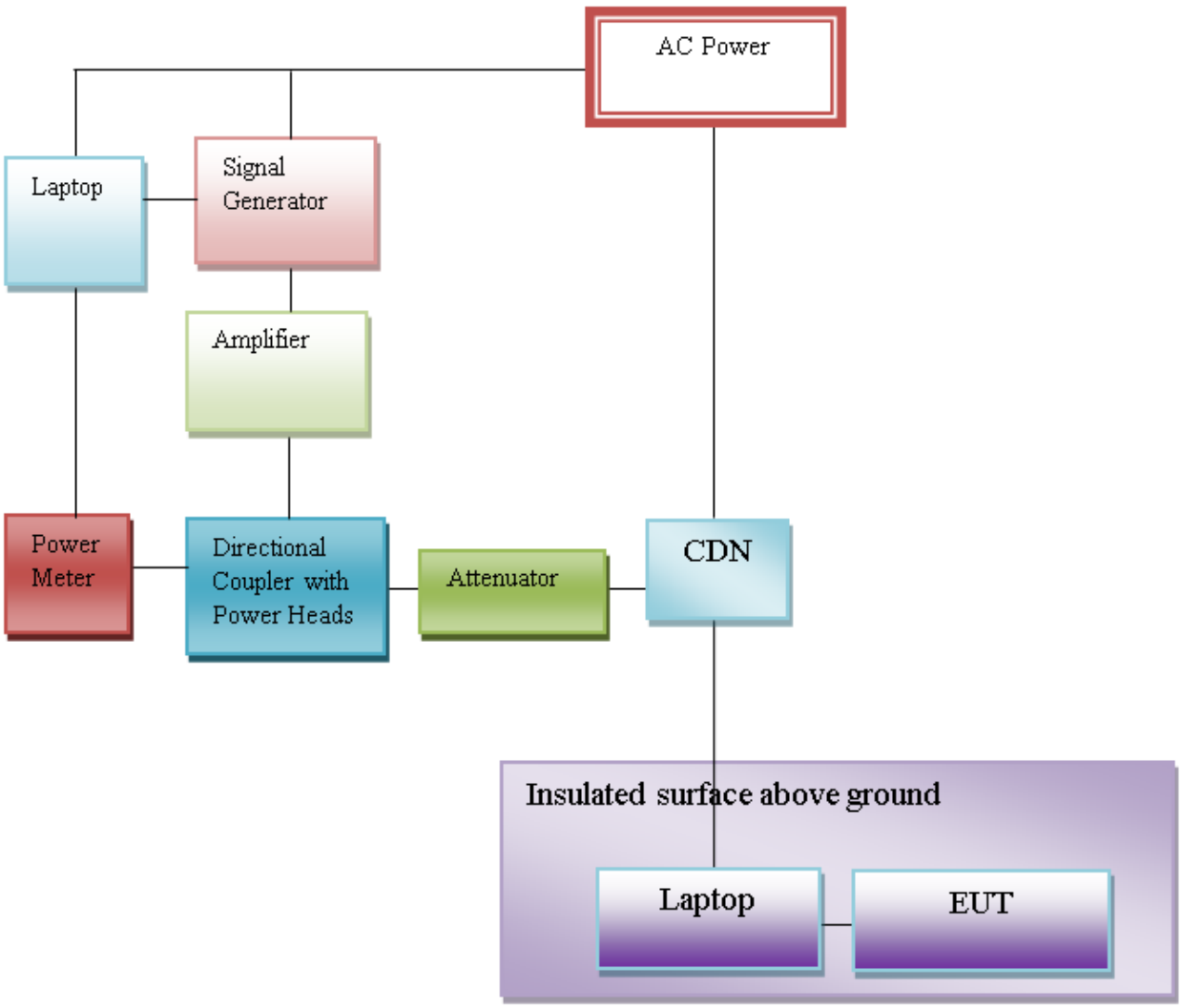
13.3 Continuous Conducted Disturbance Measurement Uncertainty

The measurement uncertainty with a 95 % confidence factor has determined that the applied voltage level is within 0.25 V of stated value.

13.4 Application of Continuous Conducted Disturbance

The EUT was setup according to the IEC 61000-4-6 and the test shall be performed with the test generator connected to each of the coupling and decoupling devices in turn while the other non-excited RF input ports of the coupling devices are terminated by a 50 Ω load resistor. The frequency range is 150 kHz to 80 MHz. When a CDN is not applicable the injection method should be used and a monitor probe is used to monitor the current injected.

13.5 Test Setup Block Diagram



13.6 Test Equipment List and Details

BACL Asset Number	Manufacturers	Descriptions	Models	Serial Numbers	Calibration Date	Calibration Due
00739	R&S	Generator, Signal	SMY02	DE27364	2018-09-04	2019-09-04
00678	RF Power Amplifier	Electronics & Innovation	411LA	183	Cal. not required	Cal. not required
00664	AR	Directional Coupler	DC2600A	0423135	Cal. not required	Cal. not required
00253	Weinshel	Attenuator	58-6-33	ML011	Calibration not Required	Calibration not Required
00797	Fischer Custom Communications, Inc.	Power Line CDN	FCC-801-M3-32A	161355	2019-02-12	2020-02-12
00815	FCC	Bulk Current Injection Probe	F-120-8A	170134	2018-05-31	2019-05-31
00147	Agilent	Analyzer, AC Power	6812B	US38390366	Calibration not Required	Calibration not Required

***Statement of Traceability*:** BACL Corp. attests that all of the calibrations on the equipment items listed above were traceable to NIST or to another internationally recognized National Metrology Institute (NMI), and were compliant with A2LA Policy P102 (dated 9 June 2016) "A2LA Policy on Metrological Traceability".

13.7 Test Environmental Conditions and Test Personnel

Test Date(s)	2019-3-22
Test Site	Immunity Room 1B
Temperature:	26 ºC
Relative Humidity:	42 %
Barometric Pressure:	101.2 kPa
Test Personnel:	Xinhao Jiang

13.8 Continuous Conducted Disturbance Test Data (IEC 61000-4-6)

AC Line
Modulation: Amplitude, 80%, 1 kHz sine wave
Severity Level: 3 Vrms

Frequency (MHz)	Level	Voltage Level (e.m.f.) U_0	Pass	Fail
0.15 to 80	2	3	A	-

Note: A ----- Performance Criteria A
B ----- Performance Criteria B
C ----- Performance Criteria C
- ----- Not Applicable

The EUT was subjected to the Continuous Conducted Disturbance required by EN Basic Environment. The EUT were subjected to a 3 Vrms, 80% Amplitude modulated, 1 kHz sine wave field as required by EN 60601-1-2 and the level specified by EN 61000-4-6. During testing a 3 second dwell time with 1% step from 150 kHz to 80 MHz was used.

14 EN 60601-1-2 Clause 8 - Voltage Dips And Interruptions

14.1 Applicable Standard

As per IEC 61000-4-11, 2004: Test Levels

Class[a]	Test level and durations for voltage dips (t_s) (50Hz/60Hz)				
Class 1	Case-by-case according to the equipment requirements				
Class 2	0 % during ½ cycle	0 % during 1 cycle	70 % during 25/30 cycle[C]		
Class 3	0 % during ½ cycle	0 % during 1 cycle	40 % during 10/12 cycle	70 % during 25/30 cycle	80 % during 250/300 cycle
Class X[b]	X	X	X	X	X

a Classes are per IEC 61000-2-4; SEE Annex B.

b To be defined by product committee. For equipment connected directly or indirectly to the public network, the levels must not be less severe than Class 2.

c "25/30 cycles" means 25 cycles for 50 Hz test" and "30 cycles for 60Hz test"

Class[a]	Test level and durations for short interruptions (t_s) (50Hz/60Hz)
Class 1	Case-by-case according to the equipment requirements
Class 2	0% during 250/300 cycle[C]
Class 3	0% during 250/300 cycles
Class X[b]	X

a Classes are per IEC 61000-2-4; SEE Annex B.

b To be defined by product committee. For equipment connected directly or indirectly to the public network, the levels must not be less severe than Class 2.

c "25/30 cycles" means 25 cycles for 50 Hz test" and "30 cycles for 60Hz test"

14.2 Voltage Dips and Interruptions Test System

An Ecompact4 system is used for all testing.

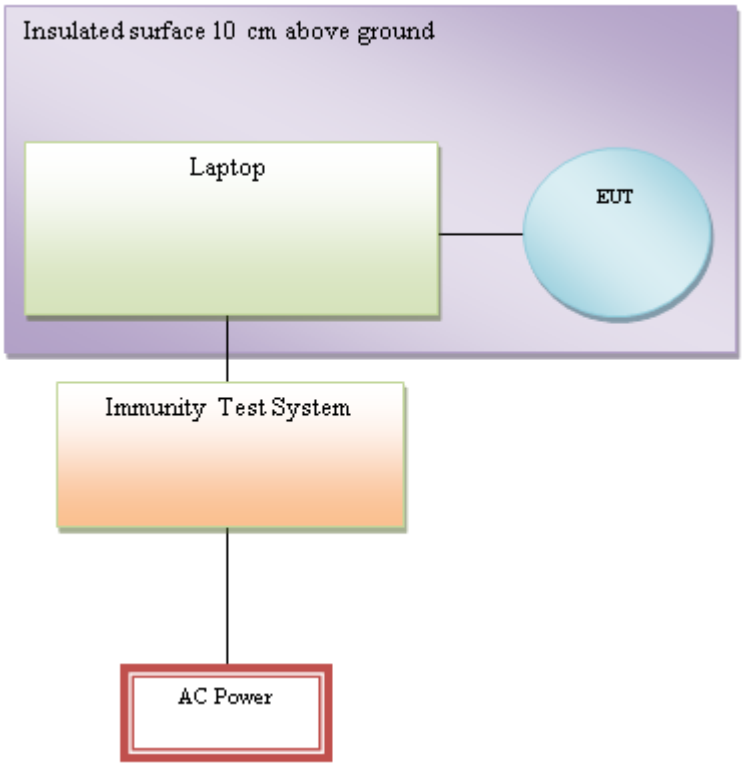
14.3 Voltage Dips and Interruptions Measurement Uncertainty

The measurement uncertainty with a 95 % confidence factor has determined that the applied voltage level is within 0.25 V of the stated value.

14.4 Application of Voltage Dips and Interruptions

The EUT was setup in accordance with the setup described in IEC 61000-4-11 and the test was performed according to procedures described in the standard.

14.5 Test Setup Block Diagram



14.6 Test Equipment List and Details

BACL Asset Number	Manufacturers	Descriptions	Models	Serial Numbers	Calibration Date	Calibration Due
00810	BACL	AXOS5 EUT INPUT POWER FUSE BOX	N/A	N/A	Cal. Not Required	Cal. Not Required
00803	Haefely	Tapped Dips Transformer for AXOS 5	DIP 116	182339	2019-02-12	2020-02-12
00801	Haefely	Compact Immunity Test System	AXOS5	182492	2019-02-12	2020-02-12
00147	Agilent	Analyzer, AC Power	6812B	US38390366	Calibration not Required	Calibration not Required

***Statement of Traceability*:** BACL Corp. attests that all of the calibrations on the equipment items listed above were traceable to NIST or to another internationally recognized National Metrology Institute (NMI), and were compliant with A2LA Policy P102 (dated 9 June 2016) "A2LA Policy on Metrological Traceability".

14.7 Test Environmental Conditions and Test Personnel

Test Date(s)	2018-04-5
Test Site	Outside Immunity Room 1B
Temperature:	26 ºC
Relative Humidity:	42 %
Barometric Pressure:	101.2kPa
Test Personnel:	Xinhao Jiang

14.8 Voltage Dips and Interruptions Test Data (IEC 61000-4-11)

AC Power Line

Phenomenon	% Residual	Cycles	Phase Angle	Pass
Voltage Dip	0	1/2	0, 90, 180, 270	A
Voltage Dip	0	1/2	0, 90, 180, 270	A
Voltage Dip	70	25	0, 90, 180, 270	A
Short Interrupt	0	250	0, 90, 180, 270	A

Note: A ----- Performance Criteria A
B ----- Performance Criteria B
C ----- Performance Criteria C
- ----- Not Applicable

The EUT was subjected to the Electrical Fast Transient tests required by EN 60601-1-2 and all lower levels specified in EN 61000-4-11.

15 Annex A (Normative) - CE Product Labeling Requirements

15.1 Label Information

1. The CE conformity marking must consist of the initials 'CE' taking the form below. If the CE marking is reduced or enlarged the proportions must be respected.

2. The CE marking must have a height of at least 5 mm except where this is not possible on account of the nature of the apparatus.

   The EMC Directive recognizes that there are circumstances where it is "not possible or warranted on account of the nature of the product" to have the marking affixed to the apparatus or to its data plate. In such cases it is allowed to have the CE marking' affixed on the packaging, refer to the Blue Guide when such exemptions are allowed.

3. The CE marking must be affixed to the product or to its data plate. Additionally it must be affixed to the packaging, if any, and to the accompanying documents, where the directive concerned provides for such documents.

4. The CE marking must be affixed visibly, legibly, and indelibly.

5. Other labeling requirements maybe required if the product(s) is/are subject to several directives.

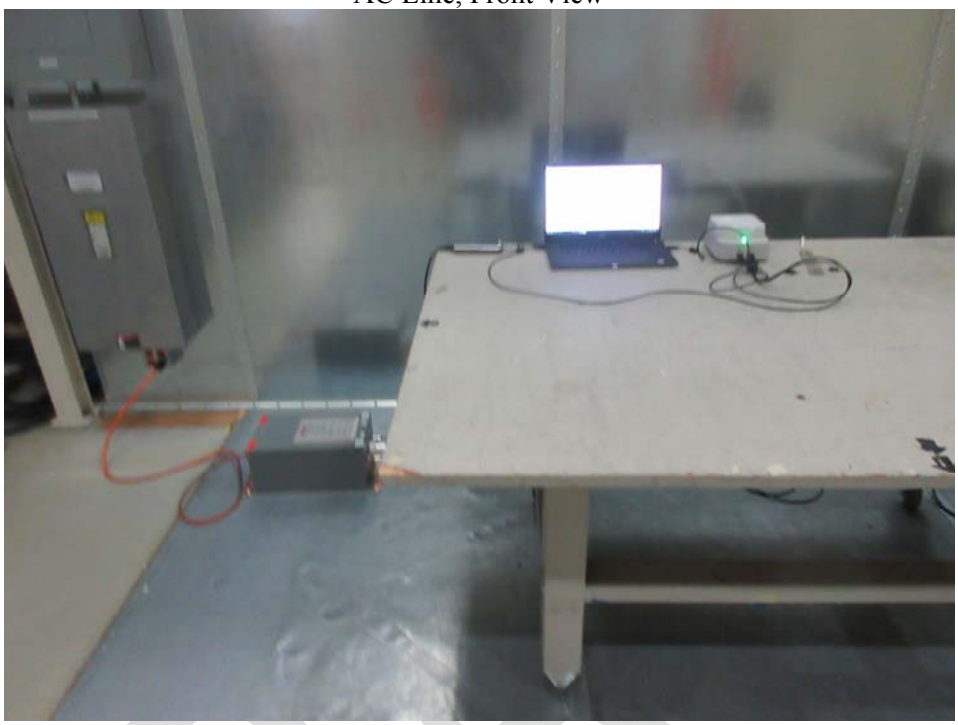
Specifications: Labels are printed in indelible ink on permanent adhesive backing or silk-screened and shall be affixed at a conspicuous location on the EUT. The label can not be positioned on a removable portion of the EUT (e.g. battery cover).

15.2 Label Location on EUT

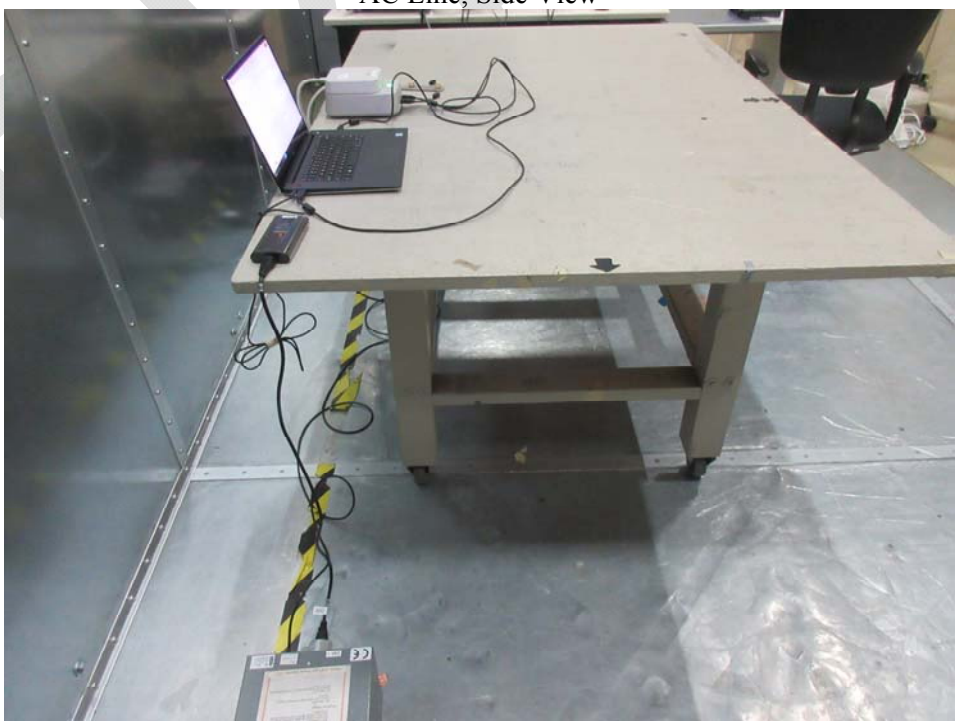
16 Annex B (Normative) – Test Setup Photographs

16.1 Conducted Emissions

AC Line, Front View



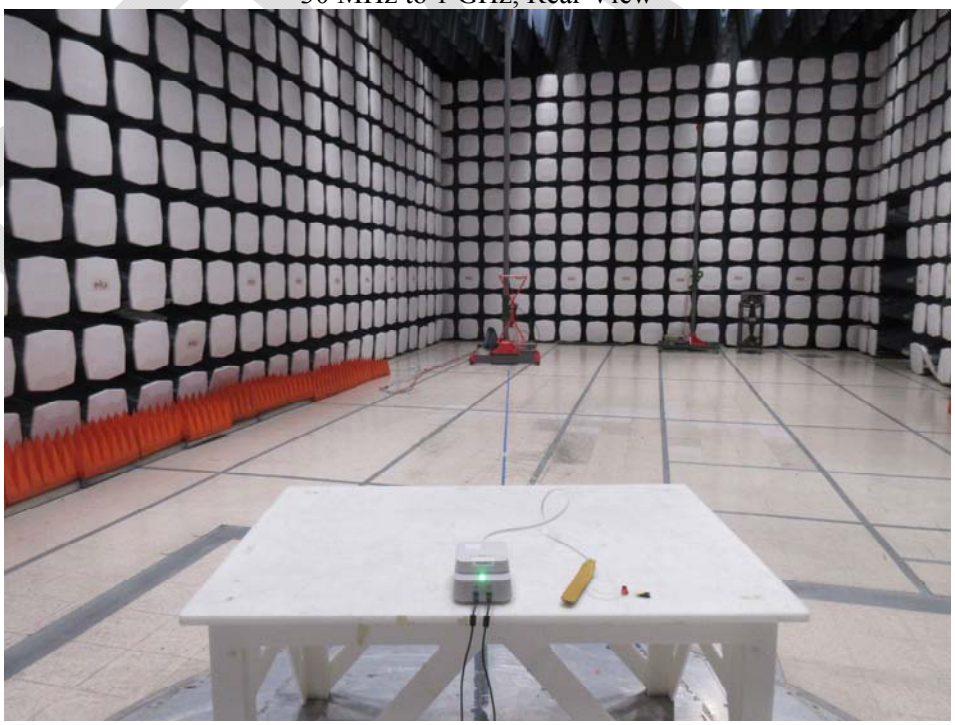
AC Line, Side View



16.2 Radiated Emissions

30 MHz to 1 GHz, Front View

30 MHz to 1 GHz, Rear View



16.3 Harmonic Current Emission (EN 61000-3-2)

Front View

Side View

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

Front View

Rear View

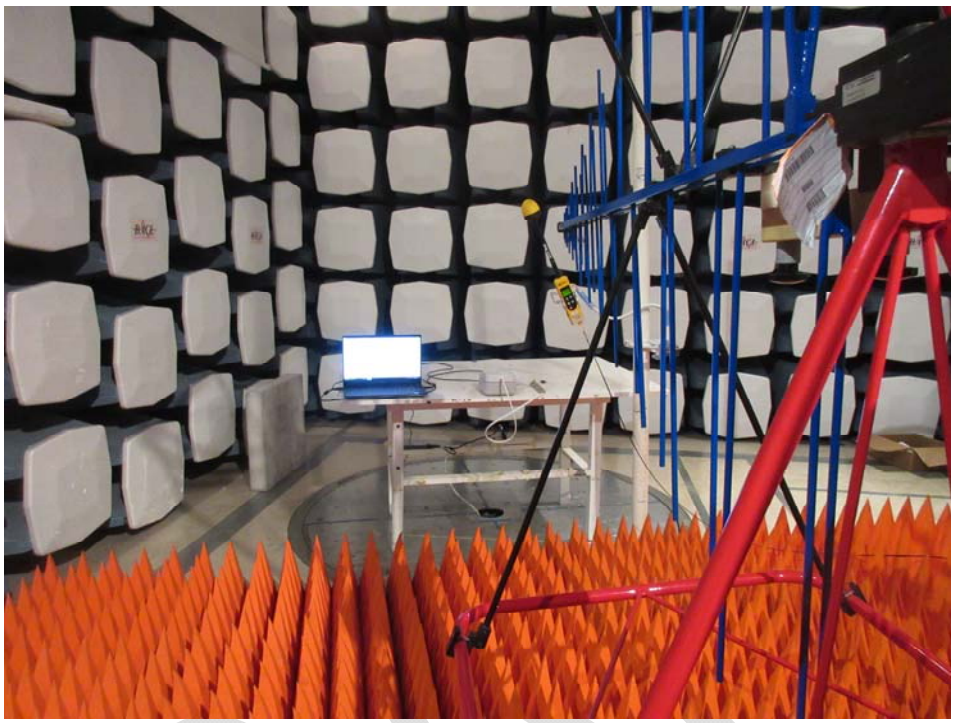
16.5 Electrostatic Discharge (EN 61000-4-2)

Front View

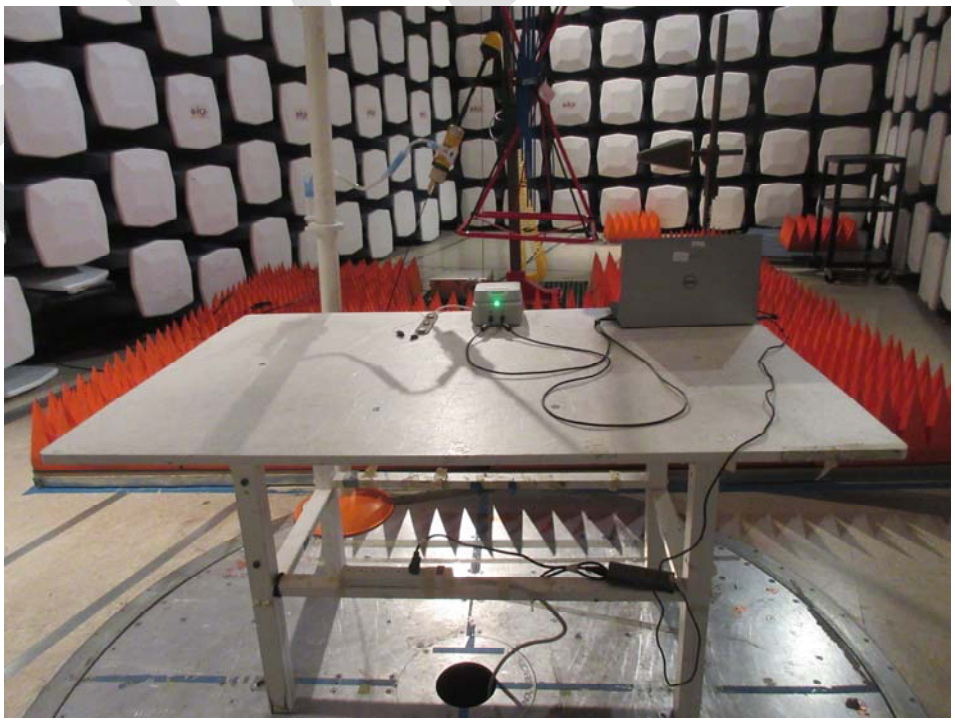
Side View

16.6 Continuous Radiated Disturbances (EN 61000-4-3)

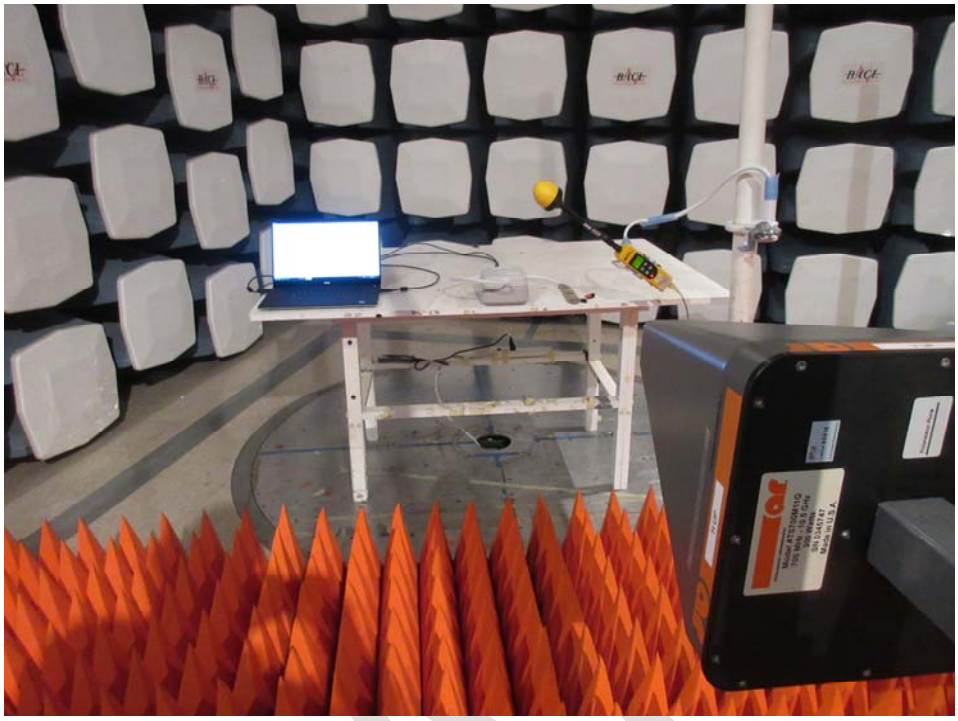
80 MHz to 1000 MHz, Front View



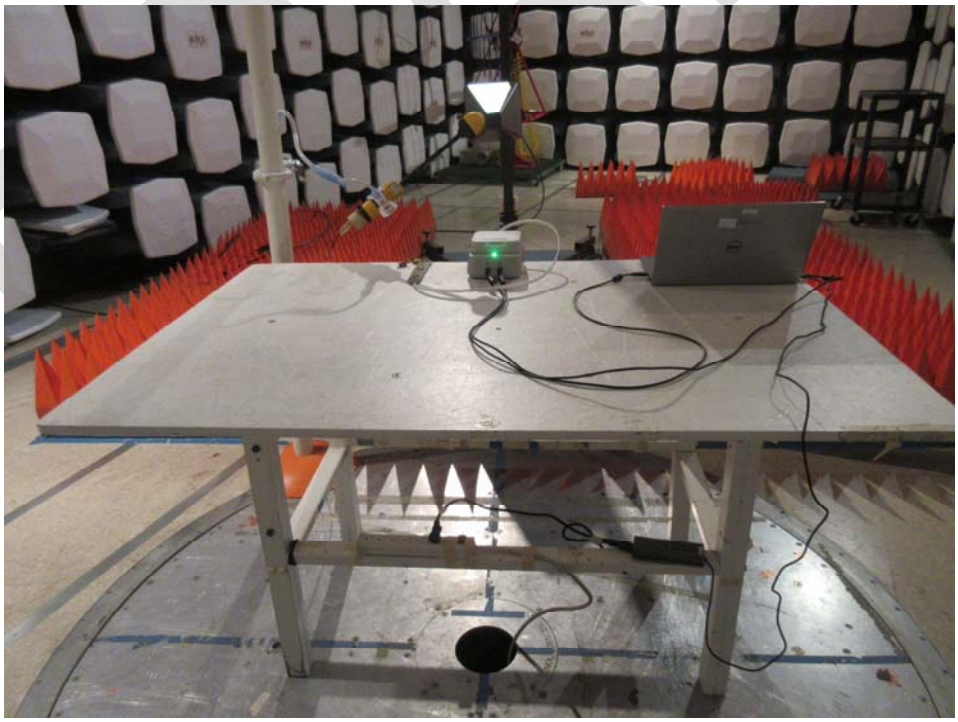
80 MHz to 1000 MHz, Rear View



Above 1 GHz, Front View

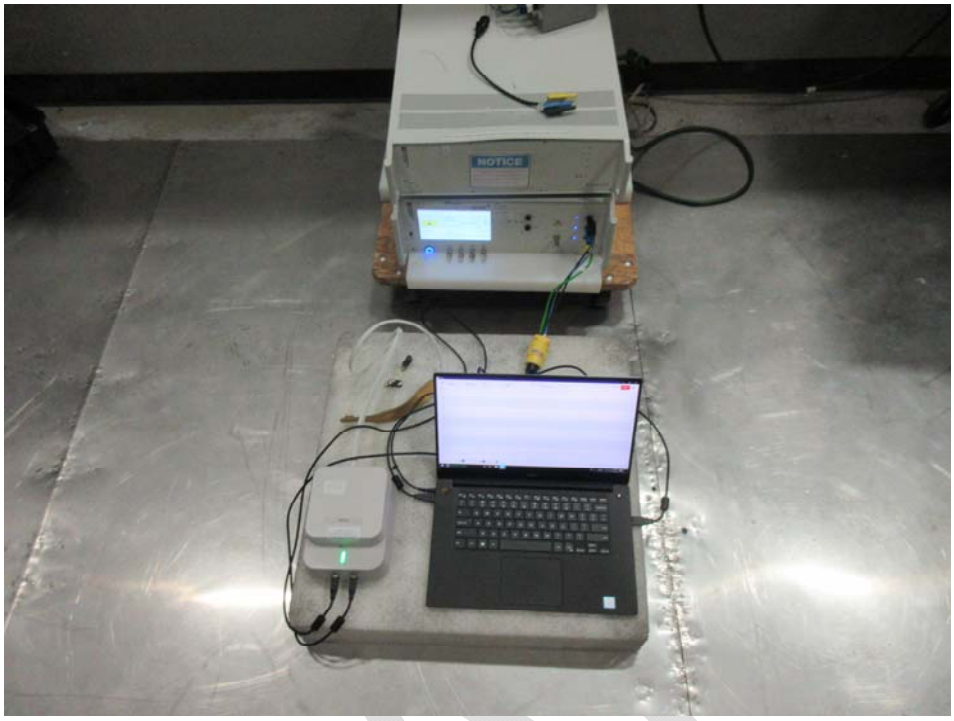


Above 1 GHz, Rear View



16.7 Electrical Fast Transient (EN 61000-4-4)

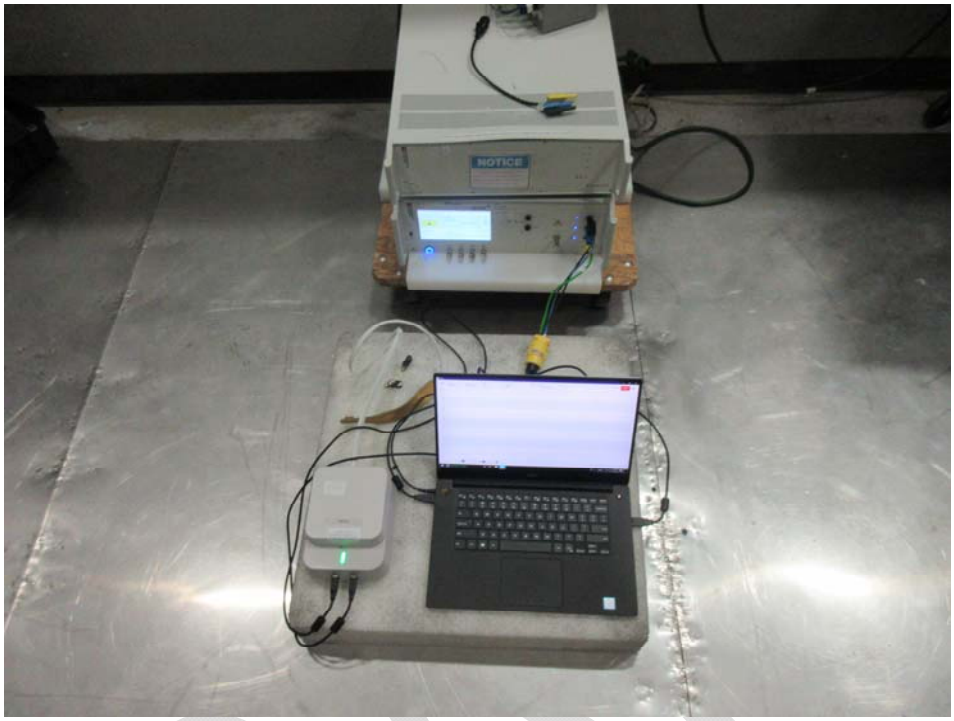
Front View



Side View

16.8 Surge Immunity (EN 61000-4-5)

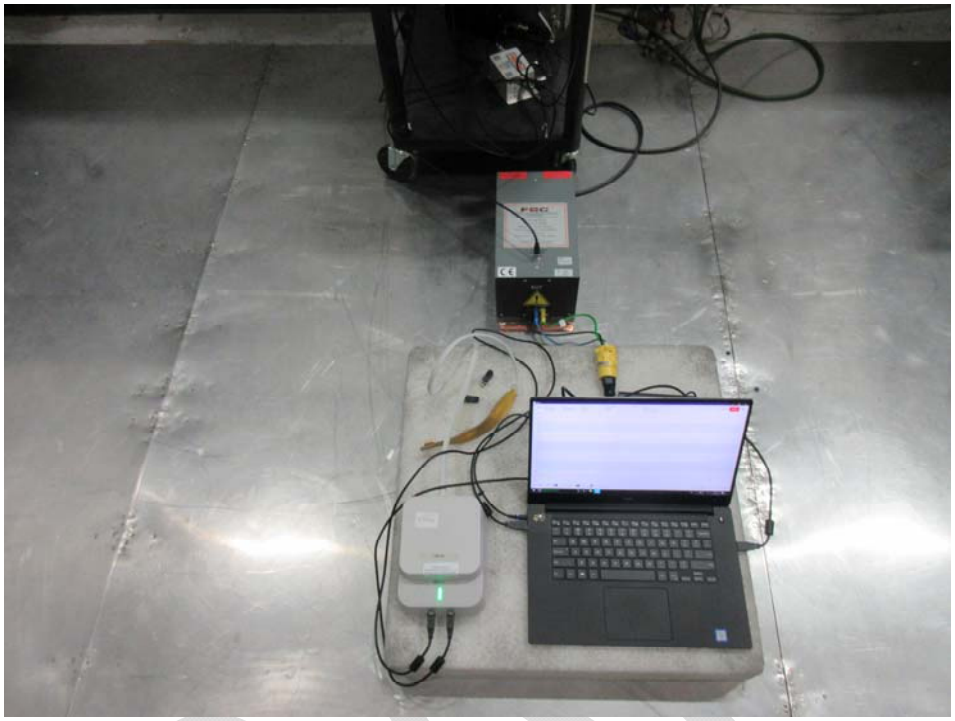
Front View



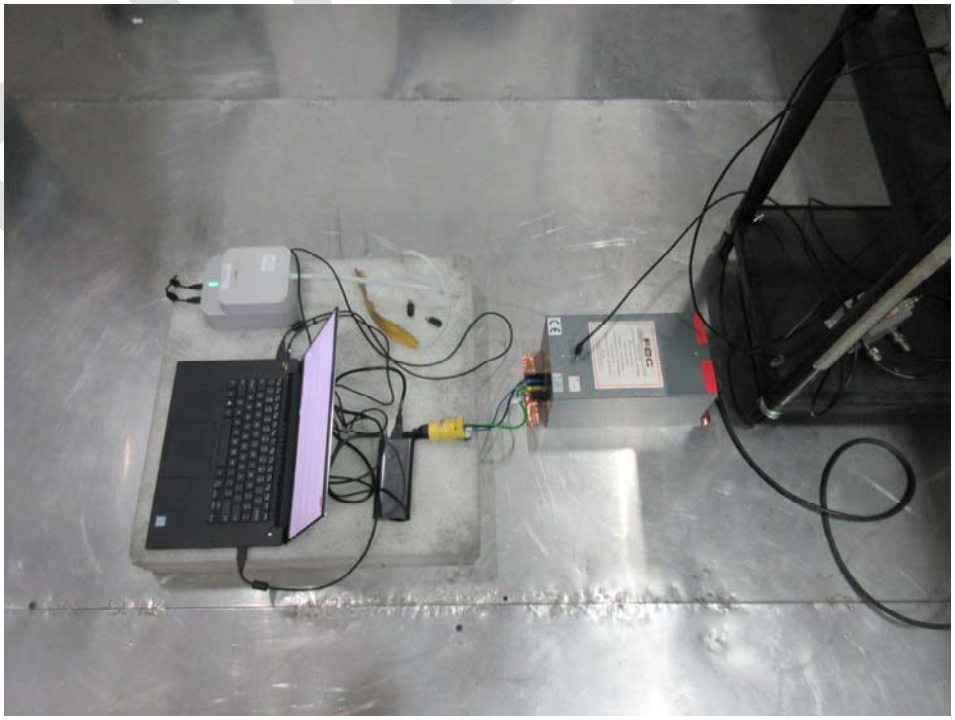
Rear View

16.9 RF Continuous Conducted Disturbances (EN 61000-4-6)

Front View

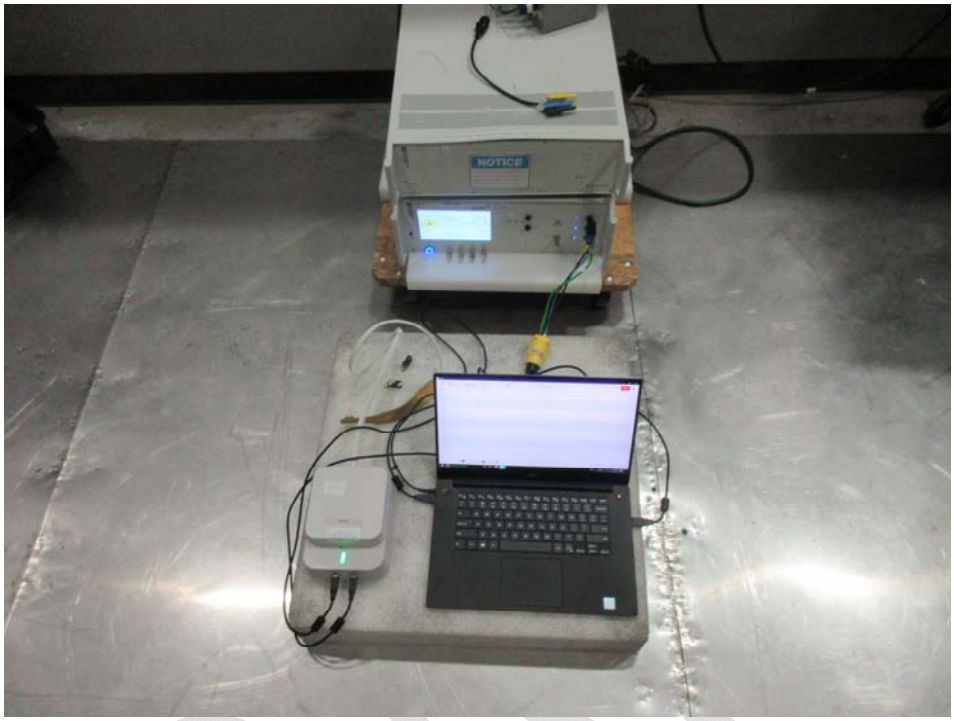


Side View



16.10 Voltage Dips and Short Interruptions (EN 61000-4-11)

Front View



Side View

17 Annex C (Normative) – EUT Photographs

17.1 EUT A Top View

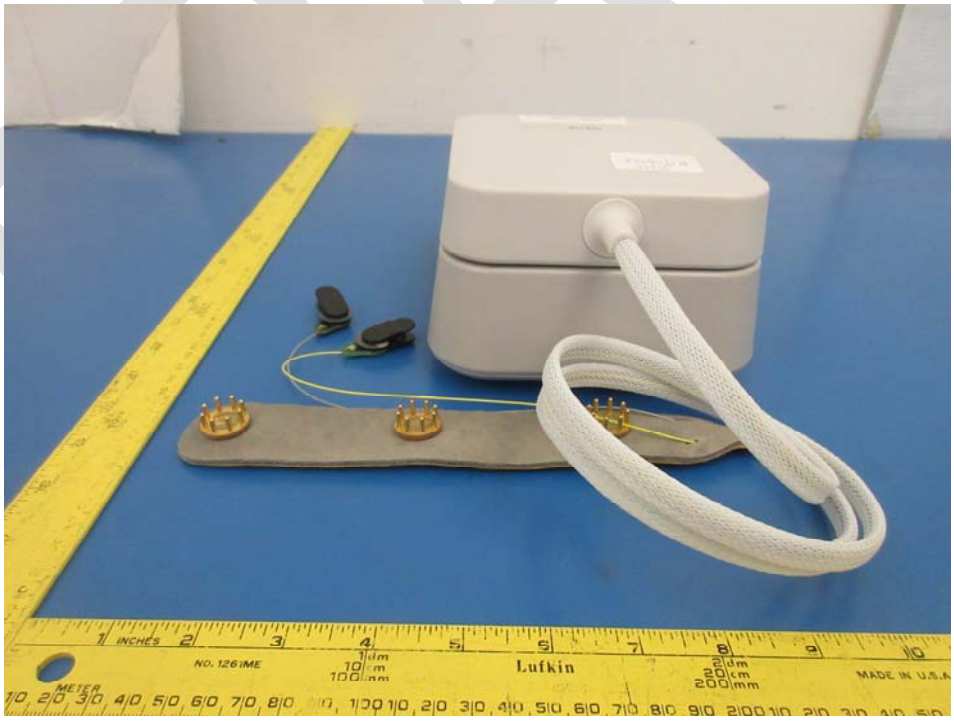
17.2 EUT A Bottom View

17.3 EUT A Left Side View

17.4 EUT A Right Side View

17.5 EUT A Front Side View

17.6 EUT A Rear Side View



17.7 EUT A Top View

17.8 EUT A Bottom View

17.9 EUT A Left View

17.10 EUT A Right View

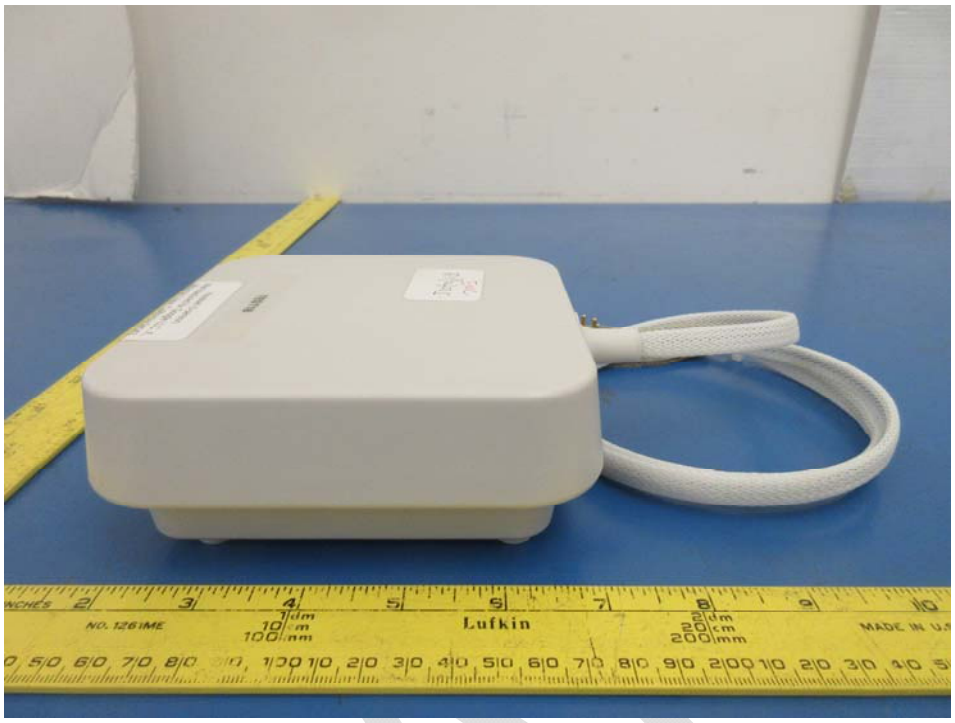
17.11 EUT A Front View

17.12 EUT A Rear View

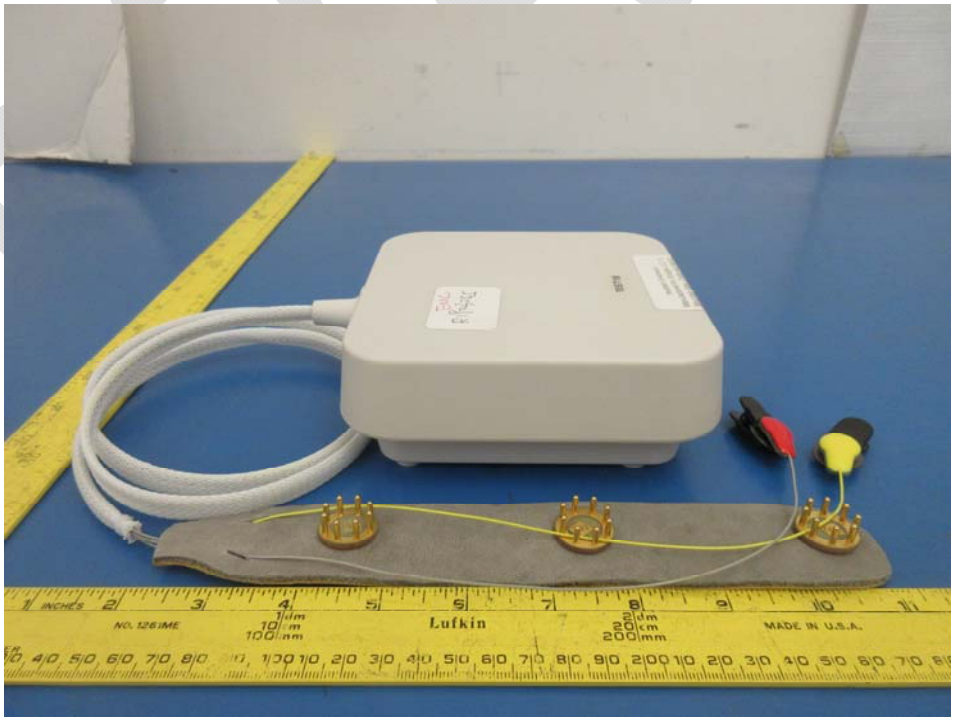
17.13 EUT B Top View

17.14 EUT B Bottom View

17.15 EUT B Left Side View



17.16 EUT B Right Side View



17.17 EUT B Front View

17.18 EUT B Rear View

18 Annex E (Normative) - A2LA Electrical Testing Certificate

Accredited Laboratory

A2LA has accredited

BAY AREA COMPLIANCE LABORATORIES CORP.

Sunnyvale, CA

for technical competence in the field of

Electrical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*. This laboratory also meets A2LA R222 - *Specific Requirements EPA ENERGY STAR Accreditation Program*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (*refer to joint ISO-ILAC-IAF Communiqué dated April 2017*).

Presented this 2nd day of October 2018.

President and CEO
For the Accreditation Council
Certificate Number 3297.02
Valid to September 30, 2020

For the tests to which this accreditation applies, please refer to the laboratory's Electrical Scope of Accreditation.

Please follow the web link below for a full ISO 17025 scope
https://www.a2la.org/scopepdf/3297-02.pdf

---END OF REPORT ---