Test Report issued under the responsibility of:

TEST REPORT
IEC 60601-1-2
Medical Electrical Equipment
PART 1-2: General Requirements for Basic Safety
and Essential Performance
Collateral Standard: Electromagnetic Compatibility

Report Number. ..... :	GZES190701970201
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CB Testing Laboratory ..... :	SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch
Address ..... :	198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China
Applicant's name ..... :	Contec Medical Systems Co., Ltd
Address ..... :	No.112 Qinhuang West Street, Economic &Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
Test specification:	
Standard ..... :	IEC 60601-1-2:2014, ISO 80601-2-61:2011 clause 201.17 & 202
Test procedure ..... :	SGS-CSTC
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC60601_1_2DEMC
Test Report Form(s) Originator .... :	UL
Master TRF ..... :	Dated 2014-12

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General disclaimer:

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1.0 Testing Program Details

Test item description ..... :		Pulse Oximeter	
Trade Mark ..... :		CONTEC™	
Manufacturer ..... :		Same as applicant	
Model/Type reference ..... :		CMS50D	
Ratings ..... :		DC 3.0V (2*AAA batteries)	
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
☒	**Testing Laboratory:**	SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch	
Testing location/ address ..... :		198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China	
☐	**Associated CB Testing Laboratory:**	N/A	
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :		Surel Guo	
Approved by (name, function, signature)... :		Fvan Tu	
☐	**Testing procedure: TMP/CTF Stage 1:**	N/A	
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Approved by (name, function, signature)... :			
☐	**Testing procedure: WMT/CTF Stage 2:**	N/A	
Testing location/ address ..... :			
Tested by (name + signature) ..... :			
Witnessed by (name, function, signature) . :			
Approved by (name, function, signature)... :			
☐	**Testing procedure: SMT/CTF Stage 3 or 4:**	N/A	
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Witnessed by (name, function, signature) . :			
Approved by (name, function, signature)... :			
Supervised by (name, function, signature) :			

Summary of testing:	
Tests performed (name of test and test clause): **Electromagnetic Interference (EMI):** **Radiated Emission (30 MHz to 1 GHz)** **Electromagnetic Susceptibility(EMS):** **Electrostatic Discharge** **Radiated Immunity** **(80 MHz to 2700 MHz)** **Radiated Immunity to proximity fields** **Power-frequency magnetic field immunity**	**Testing location:** **SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch**
Summary of compliance with National Differences: **List of countries addressed:** **N/A** ☒ **The product fulfils the requirements of** **IEC 60601-1-2:2014, ISO 80601-2-61:2011 clause 201.17 & 202**	

Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement .....:	P (Pass)
- test object does not meet the requirement .....:	F (Fail)
Testing .....:	
Date of receipt of test item.....:	2019-07-02
Date (s) of performance of tests .....:	2019-07-03 to 2019-07-19

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The test results presented in this report relate only to the object tested.

The results contained in this report reflect the results for this particular model and serial number. It is the responsibility of the manufacturer to ensure that all production models meet the intent of the requirements detailed within this report.

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List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

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Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.
Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Name and address of factory (ies):

Same as applicant.

General product information:

Refer to the relevant safety report.
The Pulse Oximeter is a non-invasive device intended for spot-checking of functional oxygen saturation of arterial haemoglobin(SpO2) and pulse rate.

Intended Use:

Intended use home healthcare environment and professional healthcare facility environment.

Any deviations from the Basic EMC standards or from this collateral standard: none.

Measurement Uncertainty

No.	Item	Measurement Uncertainty
1	Conducted Disturbance Voltage at Mains Terminals	±3.63dB (9kHz to 150kHz)
		±3.22dB (150kHz to 30MHz)
2	Disturbance Power	±3.78dB
3	Radiated Emissions	±5.0dB (30MHz-1GHz)
		±5.0dB (1GHz-6GHz)
4	Radiated Immunity	±2.18dB(80MHz-3GHz)
5	Conducted Immunity	±3.5dB(150kHz-230MHz)
6	Electrostatic Discharge	±6 %
7	EFT (Electrical Fast Transients)	±4 %
8	Surge Immunity	±6%
9	Voltage Dips and Interruptions	±4 %
10	Temperature	±0.4°C
11	Humidity	±1.3%
12	DC power	±0.5 %

Report Index:

1.1 Equipment Description

Pulse Oximeter

1.1.1 Supporting Equipment Used During Test:

Use*	Product Type	Manufacturer	Model	Comments
EUT	Pulse Oximeter	Contec Medical Systems Co., Ltd	CMS50D	None
SIM	Pulse Oximeter Simulator	Fluke	INDEX-2XLFE	None

Note: * Use one of the following:

EUT - Equipment Under Test

AE - Auxiliary/Associated Equipment

SIM - Simulator (Not Subjected to Test) *Note: Use abbreviations:

1.1.2 Input/output Ports:

Port No.	Name	Type*	Cable Max. >3m	Cable Shielded	Comments (Sip/Sop lines must include description of use)
0	Enclosure	N/E	—	—	None

Supplementary information: none.

***Note: AC = AC Power Port DC = DC Power Port N/E = Non-Electrical Batt=Battery**

Sip/Sop = Signal Input/output Port PC = Patient-Coupled Cable

TP = Telecommunication Ports

1.1.3 Power Interface

Mode No.	Voltage (V)	Current (A)	Power (W)	Frequency (DC/AC-Hz)	Phases (No.)	Comments
1	3V	—	—	DC	—	2*AAA batteries

Supplementary information: none.

1.2 EUT Operation Modes:

Mode #	Description
1	Test the EUT in measurement mode.
2	Test the EUT in idle mode.
Supplementary information: none. **Remark:** **During all emission tests, the EUT was configured to measure its highest possible emission level and the worst case's test data was presented in this test report. While during all immunity tests, the EUT was configured to have its highest possible susceptibility against the tested phenomena.**	

1.3 EUT Configuration Modes

Mode #	Description
1	The EUT had been test as full configuration (any one possible configuration). The test conditions were adapted accordingly in reference to the instruction for use.
Supplementary information: none.	

1.4 Immunity Pass/Fail Criteria as determined by the Manufacturer

Immunity Pass/Fail Criteria
The following degradations, if associated with BASIC SAFETY and ESSENTIAL PERFORMANCE or resulted in unacceptable risks, shall not be allowed: - malfunction; - non-operation when operation is required; - unwanted operation when no operation is required; - deviation from normal operation that poses an unacceptable RISK to the PATIENT or OPERATOR; - component failures; - change in programmable parameters; - reset to factory defaults (manufacturer's presets); - change of operating mode; - a FALSE POSITIVE ALARM CONDITION; - a FALSE NEGATIVE ALARM CONDITION (failure to alarm); - cessation or interruption of any intended operation, even if accompanied by an ALRAM SIGNAL; - initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an ALARM SIGNAL; - 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 or ME SYSTEM to diagnose or treat, even if accompanied by an ALARM SIGNAL. For equipment and systems with multiple functions, the criteria apply to each function, parameter and channel. The ME EQUIPMENT or ME SYSTEM may exhibit degradation of charging current that will not result in unacceptable risk as declared by manufacturer. Essential Performance: refer to the relevant safety report IEC 60601-1.

1.5 Compliance Summary

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict
4	**GENERAL REQUIREMENTS**		
4.1	Risk management process for ME equipment and ME systems.		P
5	**IDENTIFICATION, MARKING AND DOCUMENTS**		
5.1	Equipment specified for use only in shielded location has appropriate marking/warning labels		N/A
5.2	Accompanying Documents		
5.2.1	Instructions for use		
5.2.1.1	General		
a)	A statement of the environments the ME equipment will be used. Relevant exclusions, as determined by Risk Analysis, shall also be listed.		P
b)	The essential performance of ME equipment and a description of what the operator can expect if the Essential Performance is lost or degraded due to EM disturbances.		P
c)	A warning regarding stacking and location close to other equipment		P
d)	List of cables, transducers and accessories		P
e)	A warning that other cables and accessories may negatively affect EMC performance		P
f)	A statement that portable RF communications equipment. Including antennas, can effect medical electrical equipment. The warning should include a use distance such as "…be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer"		P
5.2.1.2	Required statement from standard for Class A equipment		N/A
5.2.2	Technical description		
5.2.2.1	All equipment and systems		
	Describe precautions to be taken to prevent adverse events to the Patient and Operator due to electromagnetic disturbances		P
a)	Compliance information for each test		P
b)	Statement of any deviations from standards used		N/A
c)	Statements to maintain basic safety and essential performance in regards to EMC		P

5.2.2.2	ME Equipment specified for use only in shielded location		
a)	A warning that equipment should be used only in the specified type of shielded location		N/A
b)	Specifications for shielded location including: – minimum RF shielding effectiveness; – for each cable that enters or exits the shielded location, the minimum RF filter attenuation; and – the frequency range(s) over which the specifications apply		N/A
c)	Test methods for measurement of RF shielding effectiveness and RF filter attenuation		N/A
d)	Required statement(s) from standard and recommended notice for information post at entrance.		N/A
5.2.2.3	ME Equipment that intentionally receive RF energy shall include: frequency and/or band and bandwidth of receiving section		N/A
5.2.2.4	ME Equipment that include transmitters shall include frequency and/or band, modulation, and ERP		N/A
5.2.2.5	Large ME Equipment that are permanently installed		
a)	A statement that an exemption has been used and that the equipment has not been tested for radiated RF immunity over the entire frequency range 80 MHz to 6 GHz		N/A
b)	A warning that the ME equipment has been tested for radiated RF immunity only at selected frequencies		N/A
c)	A list of the frequencies and modulations tested		N/A
5.2.2.6	ME equipment that claim compatibility with HF surgical equipment shall include statement of compatibility and conditions of intended use during HR surgery		N/A

1.6 Result Summary

Requirement – Test	Result/Comments	Verdict
Clause 7 - Emissions		
Classification		—
Class A or B.....:	Class B	—
Group 1 or 2 .....:	Group 1	—
CISPR 11, 14-1, 32 or ISO 7137.....:	CISPR 11	—
Conducted RF Emissions.....:	N/A	N/A
Radiated RF Emissions.....:	Compliant	P
Disturbance Power (if applicable).....:	N/A	N/A
Harmonic Distortion per IEC61000-3-2 (Class A, B, C, D):	N/A	N/A
Voltage Fluctuations and Flicker per IEC61000-3-3 .....:	N/A	N/A
Clause 8 - Immunity		
Electrostatic Discharges.....:	Compliant	P
Radiated RF EM Fields and Proximity Wireless fields.....:	Compliant	P
Electrical Fast Transients and bursts.....:	N/A	N/A
Surges .....:	N/A	N/A
Conducted Disturbances, induced by RF fields .....:	N/A	N/A
Voltage Dips and Interruptions.....:	N/A	N/A
Rated Power-frequency Magnetic Field .....:	Compliant	P

1.7 Test Conditions and Results – Conducted Emissions

CISPR 11	TEST: Limits of mains terminal disturbance voltage		Verdict
Method: The AMN placed 0,8 m from the boundary of the unit under test and bonded to a ground reference plane. This distance was between the closest points of the AMN and the EUT. All other units of the EUT and associated equipment were at least 0,8 m from the AMN. All power was connected to the system through Artificial Mains Network (AMN). Conducted voltage measurements on mains lines were made at the output of the AMN.			N/A
Laboratory Parameters	**Required prior to the test**	**During the test**	
Ambient Temperature	**10 to 40 °C**		
Relative Humidity	**10 to 90 %**		
Fully configured sample scanned over the following frequency range	**Frequency range on each side of line**	**Measurement Point**	
	150kHz to 30MHz	**Mains**	

Test Equipment Used

Conducted Emission

No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date (YYYY-MM-DD)	Cal.Due date (YYYY-MM-DD)
EMC0306	Shielding Room	Zhong Yu	8 x 3 x 3.8 m^3	N/A	2016-12-27	2019-12-26
EMC0118	Two-line v-netwok	R&S	ENV216	100359	2019-01-19	2020-01-18
EMC2135	Two-line v-netwok	R&S	ENV216	102259	2018-09-21	2019-09-20
EMC0203	LISN	AFJ	LS16-OPT001	116019831056	2019-01-08	2020-01-07
EMC0506	EMI Test Receiver	Rohde & Schwarz	ESCS30	100085	2018-11-19	2019-11-18
EMC0107	Coaxial Cable	SGS	2m	N/A	2019-07-22	2021-07-21
EMC0106	Voltage Probe	SGS	N/A	N/A	2018-04-04	2020-04-03
EMC2123	8 Line ISN Cat 6	SCHWARZBECK MESS-ELEKTRONIK	NTFM 8158	NTFM 8158 0151	2019-05-29	2020-05-28
EMC2124	8 Line ISN Cat 5	SCHWARZBECK MESS-ELEKTRONIK	CAT5 8158	CAT5 8158-188	2019-05-29	2020-05-28
EMC2126	8 Line ISN Cat 3	SCHWARZBECK MESS-ELEKTRONIK	CAT3 8158	CAT38158-0081	2019-05-29	2020-05-28
EMC2122	ISN S8	SCHWARZBECK MESS-ELEKTRONIK	ISN S8	57	2019-05-29	2020-05-28
EMC2121	ISN S1	SCHWARZBECK MESS-ELEKTRONIK	ISN S1	10	2019-05-29	2020-05-28
EMC2125	2 wires ISN	SCHWARZBECK MESS-ELEKTRONIK	NTFM 8131	8131-198	2019-05-29	2020-05-28
EMC2047	CDN	Elektronik-Feinmechanik	L-801:AF2	2793	2018-09-29	2020-09-28
EMC2048	CDN	Elektronik-Feinmechanik	L-801:M2/M3	2738	2018-08-13	2020-08-12
EMC2062	6dB Attenuator	HP	8491A	24487	2018-04-04	2020-04-03
EMC0167	Conical metal housing	SGS-EMC	N/A	N/A	2018-04-19	2020-04-18

Photo of test setup for Mains Terminal Disturbance Current

Tabulated Results for Mains Terminal Disturbance Current	
Test voltage:	**Operation mode:**
Line (Live) :	
Line (Neutral) :	

Graphical representation of Mains Terminal Disturbance Current Measurement
Line (Live) :
Line (Neutral) :

1.8 Test Conditions and Results – Radiated Emissions

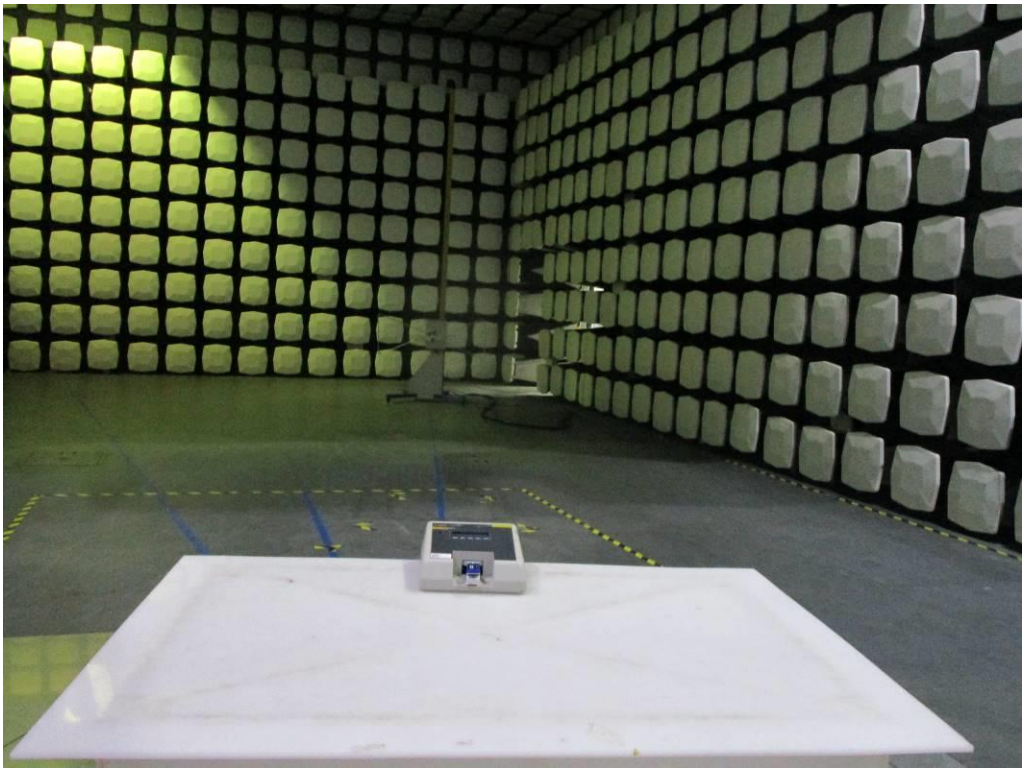
CISPR 11	TEST: Limits for radiated disturbance 30 MHz –1 GHz	Verdict
Method: Measurements were made in a 10-meter semi-anechoic chamber or Open Area Test Site that complies to CISPR 16. Preliminary (peak) measurements were performed at an antenna to EUT separation distance of listed below. The EUT was rotated 360° about its azimuth with the receive antenna located at various heights in horizontal and vertical polarities. Final measurements (quasi-peak) were then performed by rotating the EUT 360° and adjusting the receive antenna height from 1 to 4 m. All frequencies were investigated in both horizontal and vertical antenna polarity, where applicable.		P

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	23 °C
Relative Humidity	10 to 90 %	56 %
Fully configured sample scanned over the following frequency range	Frequency range on each side of line	Measurement Point
	30MHz – 1GHz	10 m measurement distance

Test Equipment Used

RE in Chamber

No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date (YYYY-MM-DD)	Cal.Due date (YYYY-MM-DD)
EMC0530	10m Semi-Anechoic Chamber	ChangZhou ZhongYu	N/A	N/A	2019-06-18	2022-06-17
EMC0522	EMI Test Receiver	Rohde & Schwarz	ESIB26	100283	2019-01-19	2020-01-18
EMC0056	EMI Test Receiver	Rohde & Schwarz	ESCI	100236	2019-01-19	2020-01-18
EMC2025	Trilog Broadband Antenna 30-1000MHz	SCHWARZBECK MESS-ELEKTRONIK	VULB 9160	9160-3372	2016-09-08	2019-09-07
SEM003-18	Trilog Broadband Antenna 25-2000MHz	SCHWARZBECK MESS-ELEKTRONIK	VULB 9168	665	2019-06-29	2022-06-28
EMC0524	Bi-log Type Antenna	Schaffner -Chase	CBL6112B	2966	2016-09-08	2019-09-07
EMC0519	Bilog Type Antenna	Schaffner -Chase	CBL6143	5070	2017-05-04	2020-05-03
EMC2026	Horn Antenna 1-18GHz	SCHWARZBECK MESS-ELEKTRONIK	BBHA 9120D	9120D-841	2016-09-09	2019-09-08
EMC0521	1-26.5 GHz Pre-Amplifier	Agilent	8449B	3008A01649	2019-01-08	2020-01-07
EMC2065	Amplifier	HP	8447F	N/A	2019-06-01	2020-05-31
EMC2086	PRE AMPLIFIER MH648A	ANRITSU CORP	MH648A	N/A	2018-11-19	2019-11-18
EMC0523	Active Loop Antenna	EMCO	6502	42963	2018-03-05	2020-03-04
EMC2041	Broad-Band Horn Antenna (14)15-26.5(40)GHz	SCHWARZBECK MESS-ELEKTRONI	BBHA 9170	9170-375	2017-05-23	2020-05-22
EMC2079	High Pass Filter(915MHz)	FSY MICROWAVE	HM1465-9SS	009	2019-01-19	2020-01-18
EMC2142	966 Anechoic Chamber	C.R.T	9mX6mX6m	NA	2017-12-19	2019-12-18
EMC2139	MXE EMI Receiver	Keysight	N9038A	MY57290121	2018-11-19	2019-11-18
EMC2138	EXA Signal Analyzer	Keysight	N9010A	MY57120105	2018-11-19	2019-11-18
EMC2069	2.4GHz Filter	Micro-Tronics	BRM 50702	149	2019-01-08	2020-01-07

Photo of test setup for Radiated Disturbance


Tabulated Results for Radiated Disturbance

Test voltage: DC 3V **Operation mode: mode 1**

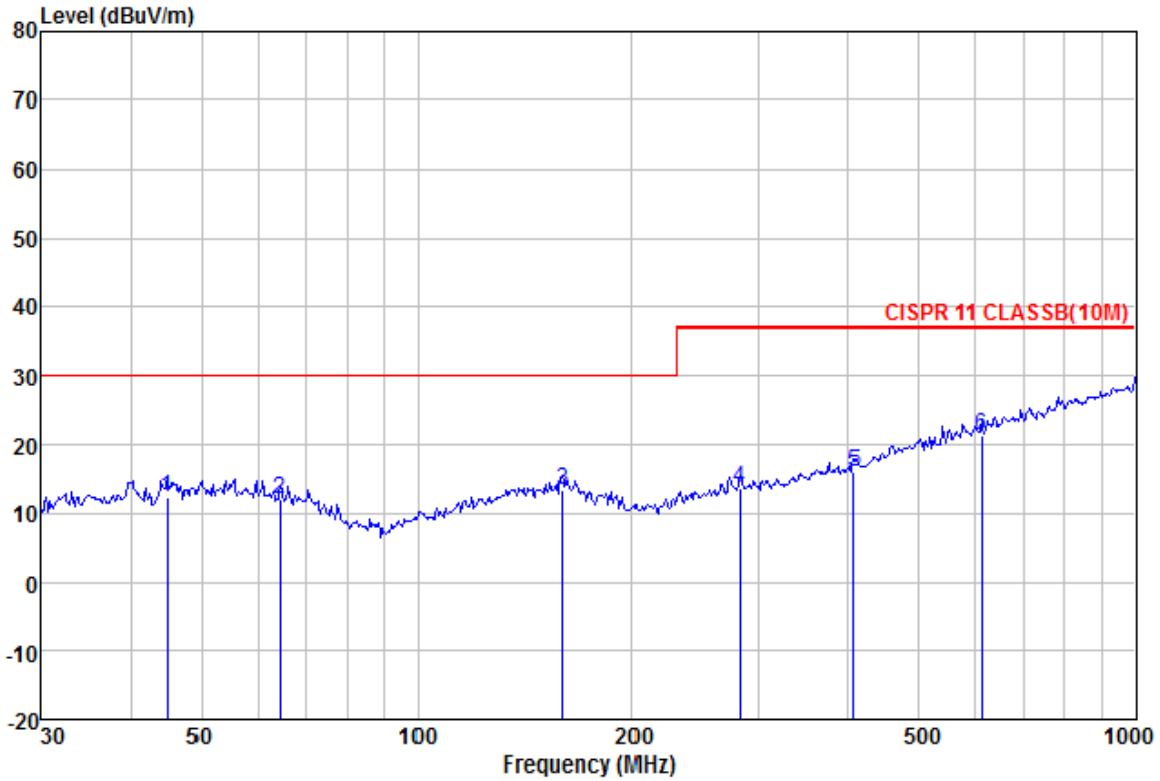
Polarity (Vertical)

	Freq	Read Level	Antenna Factor	Cable Loss	Preamp Factor	Level	Limit Line	Over Limit	Remark
	MHz	dBuV	dB/m	dB	dB	dBuV/m	dBuV/m	dB	
1	45.058	24.47	13.48	0.70	26.51	12.14	30.00	-17.86	QP
2	64.433	24.63	12.97	0.80	26.48	11.92	30.00	-18.08	QP
3	159.784	25.13	13.40	1.33	26.44	13.42	30.00	-16.58	QP
4	281.995	25.49	13.02	1.74	26.68	13.57	37.00	-23.43	QP
5	406.088	25.59	15.48	2.22	27.36	15.93	37.00	-21.07	QP
6	612.064	26.49	19.71	2.65	27.41	21.44	37.00	-15.56	QP

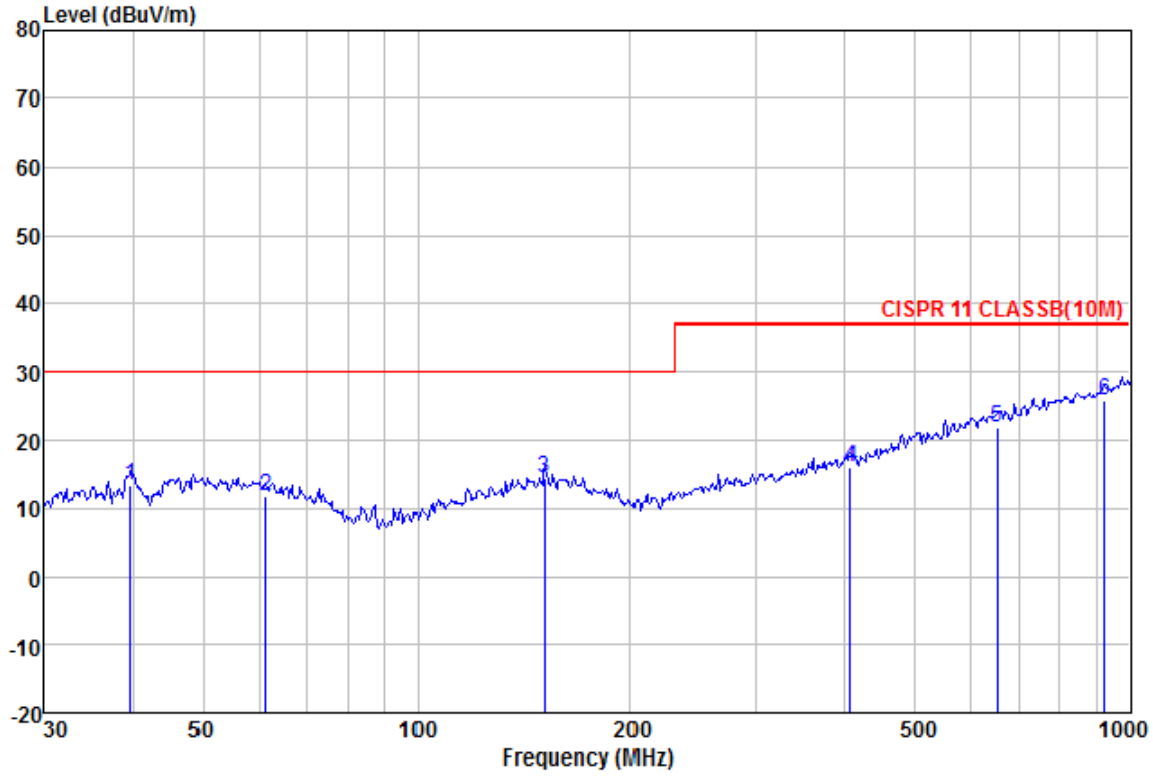
Polarity (Horizontal)

	Freq	Read Level	Antenna Factor	Cable Loss	Preamp Factor	Level	Limit Line	Over Limit	Remark
	MHz	dBuV	dB/m	dB	dB	dBuV/m	dBuV/m	dB	
1	39.715	26.43	12.80	0.65	26.52	13.36	30.00	-16.64	QP
2	61.346	23.87	13.47	0.80	26.48	11.66	30.00	-18.34	QP
3	151.067	26.51	13.14	1.30	26.44	14.51	30.00	-15.49	QP
4	406.088	25.72	15.48	2.22	27.36	16.06	37.00	-20.94	QP
5	651.942	26.19	20.29	2.74	27.35	21.87	37.00	-15.13	QP
6	919.287	26.54	23.16	3.17	26.98	25.89	37.00	-11.11	QP

Graphical representation of Radiated Disturbance Measurement
Vertical:



Horizontal:



1.9 Test Conditions and Results – Disturbance Power Emissions

CISPR 14-1	TEST: Limits of disturbance power	Verdict
Method: Measurements were made on a ground plane that extends 1-meter minimum beyond all sides of the system under test. All power was connected to the system through Line Impedance Stabilization Networks (LISN). The lead to be measured on is stretched in a straight line for a distance sufficient to accommodate the absorbing clamp, and to permit the necessary measuring adjustment of position for tuning. The clamp is placed around the lead so as to measure a quantity proportional to the disturbance on the lead.		N/A

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	°C
Relative Humidity	30 to 60 %	%
Fully configured sample scanned over the following frequency range	Frequency range	Measurement point
	30 MHz to 300 MHz	Mains

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due

Photo of test setup for Disturbance Power Emissions

Graphical representation of Disturbance Power Emissions Measurement

Tabulated Results for disturbance power

1.10 Test Conditions and Results – Harmonic Distortion

61000-3-2	TEST: Limits for Harmonic current emissions (IEC 61000-3-2:2005 A1:2008 A2:2009)	Verdict
Method: This test consists on the measurement of harmonics components of the input current which may be produced by equipment having an input current up to and including 16 A per phase, and intended to be connected to public low-voltage distribution systems. The equipment is tested under specified conditions of operation.		N/A

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	
Relative Humidity	30 to 60 %	
Classification of Equipment.....:		Class A

Supplementary information: None.

Test Equipment Used

Harmonics / Flicker test

No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date (YYYY-MM-DD)	Cal.Due date (YYYY-MM-DD)
EMC0608	AC Power Source	California	50001iX	56627	2019-04-08	2020-04-07
EMC0607	Power Analyzer	California	PACS	72400	2019-04-08	2020-04-07

Photo of test setup for Harmonic Current Emissions

Tabulated Results for Harmonic Current Emissions

1.11 Test Conditions and Results – Voltage Fluctuations and Flicker

61000-3-3	TEST: Limitation of Voltage Fluctuations and Flicker (IEC 61000-3-3:2013)	Verdict
Method: The test circuit consists of a test supply voltage, reference impedance, the equipment under test and a flicker meter compliant with IEC 60868. The equipment shall be tested in the condition in which the manufacturer supplies it.		**N/A**

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	
Relative Humidity	30 to 60 %	
Control Method of Equipment (see below).....:		Method 1

1 - without additional conditions

2 - 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.

3 - attended while 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.

Supplementary Information: None.

Test Equipment Used

Harmonics / Flicker test

No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date (YYYY-MM-DD)	Cal.Due date (YYYY-MM-DD)
EMC0608	AC Power Source	California	50001iX	56627	2019-04-08	2020-04-07
EMC0607	Power Analyzer	California	PACS	72400	2019-04-08	2020-04-07

Photo of test setup for Voltage Fluctuations and Flicker

Tabulated Results for Voltage Fluctuations and Flicker

1.12 Test Conditions and Results – Immunity to Electrostatic Discharges

61000-4-2	TEST: Electrostatic discharges (IEC 61000-4-2:2008)	Verdict
Method: The test is intended to demonstrate the immunity of equipment subjected to static electricity discharges from operators directly and to adjacent objects. The table top equipment under test is placed on a wooden table, 0.8 m high, standing on the ground reference plane. A horizontal coupling plane (HCP), 1.6 x 0.8 m, is placed on the table. The EUT and the cables are isolated from the coupling plane by an insulating support 0.5 mm thick. The floor standing equipment is isolated from the ground reference plane by an insulating support about 0.1 m thick. The vertical coupling plane (VCP) of dimensions 0.5 m x 0.5 m is placed parallel to, and positioned at a distance of 0.1 m from, the EUT.		P

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	23 °C
Relative Humidity	30 to 60 %	54 %

Test Levels

Discharge type	Discharge Level (kV)		Number of discharges per location (each polarity)
	Positive	Negative	
Air – Direct	2,4,8,15	2,4,8,15	10
Contact – Direct	8	8	10
Contact – Indirect	8	8	10
Discharge location	See photo documentation of the test set-up All external locations accessible by hand, Horizontal plate (HCP) Vertical coupling plate (VCP)		

Supplementary information: EUT powered at one of the Nominal input voltages and frequencies

Test Equipment Used

Electrostatic Discharge

No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date (YYYY-MM-DD)	Cal.Due date (YYYY-MM-DD)
EMC2071	ESD Simulator	TESEQ AG	NSG 435	6739	2019-03-06	2020-03-07
EMC0078	Temperature, & Humidity	Shanghai Meteorological Instrument factory Co., Ltd.	ZJ1-2B	709131	2019-07-05	2020-07-04

Photo of test setup for Immunity to Electrostatic Discharges


Tabulated Results for Electrostatic Discharges			
Direct discharges: Air and Contact			
Discharge location	**Air discharge voltage (kV)**	**Polarity**	**Result**
All insulated enclosure & seams	2	Positive	**1**
	2	Negative	**1**
	4	Positive	**1**
	4	Negative	**1**
	8	Positive	**1**
	8	Negative	**1**
	15	Positive	**1**
	15	Negative	**1**
Discharge location	**Contact discharge voltage (kV)**	**Polarity**	**Result**
All accessible metal parts of the enclosure with discharge resistor used	8	Positive	**1**
	8	Negative	**1**
Indirect discharges			
Discharge location	**Contact discharge voltage (kV)**	**Polarity**	**Result**
HCP - Front	8	Positive	**2**
HCP - Left	8	Negative	**2**
HCP - Right	8	Positive	**2**
HCP - Rear	8	Negative	**2**
VCP - Front	8	Positive	**2**
VCP - Left	8	Negative	**2**
VCP - Right	8	Positive	**2**
VCP - Rear	8	Negative	**2**
Results Descriptions: **X - Not Performed nor required.** **1 – Compliant - No perceived discharge, no observed response from EUT.** **2 – Compliant – Discharge observed, no observed response from EUT.**			
Note: Description of the response should detail observations during testing.			

1.13 Test Conditions and Results - Immunity to Radio Frequency Electromagnetic Fields

<table>
<tr><td>61000-4-3</td><td colspan="3">TEST: RF electromagnetic fields (IEC 61000-4-3:2006 A1:2007 A2:2010)</td><td>Verdict</td></tr>
<tr><td colspan="4"><u>Method</u>: The test allows estimating of the radiated immunity of electrical and electronic equipment to electromagnetic disturbances coming from intended radio-frequency (RF) transmitters in the frequency range 80 MHz to 2500 MHz. The interference is applied on the enclosure of the equipment by using transmitting antennas.</td><td>P</td></tr>
<tr><td colspan="2">Laboratory Parameters:</td><td>Required prior to the test</td><td>During the test</td><td></td></tr>
<tr><td colspan="2">Ambient Temperature</td><td>15 to 35 °C</td><td>21 °C</td><td></td></tr>
<tr><td colspan="2">Relative Humidity</td><td>30 to 60 %</td><td>53 %</td><td></td></tr>
<tr><td colspan="5">Test specifications</td></tr>
<tr><td colspan="2" rowspan="2">Calibration Requirements</td><td rowspan="2">Uniform field area (UFA)</td><td colspan="2">1.5 m x 1.5 m, 16 points with a minimum UFA size 0.5 m x 0.5 m</td></tr>
<tr><td colspan="2">75 % of calibration points within specifications if UFA is larger than 0.5 m x 0.5 m. 100 % (all 4 points) in the specifications for 0.5 x 0.5 m UFA</td></tr>
<tr><td colspan="2">Frequency bandwidth</td><td colspan="3">80 MHz to 2700 MHz</td></tr>
<tr><td colspan="2">Modulation</td><td colspan="3">80% AM at 1kHz*</td></tr>
<tr><td rowspan="2">Level</td><td>Professional Healthcare Environment</td><td colspan="3">3 V/m</td></tr>
<tr><td>Home Healthcare Environment</td><td colspan="3">10 V/m</td></tr>
<tr><td colspan="2">Frequency step</td><td colspan="3">1%</td></tr>
<tr><td colspan="5">Supplementary information:
EUT powered at one of the Nominal input voltages and frequencies.
Dwell time minimum 1 s. Actual dwell time noted in results table.
Actual test level noted in results table.
Note * - Testing may be performed at other modulation frequencies identified by the Risk Management Process.</td></tr>
</table>

Test Equipment Used

Radiated Immunity

No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date (YYYY-MM-DD)	Cal.Due date (YYYY-MM-DD)
EMC0525	Compact 3m Semi-Anechoic Chamber	Changzhou zhongyu	N/A	N/A	2016-12-04	2019-12-03
EMC2055	Oscilloscope	Tektronix	TDS3052C	C011815	2019-01-08	2020-01-07
EMC2091	Broadband Amplifier（80M~1GHZ/250W)	R&S	BBA150	102036	2019-01-08	2020-01-07
EMC2092	Broadband Amplifier（800M~3GHZ/110W)	R&S	BBA150	102047	2019-01-08	2020-01-07
EMC2093	Signal Generator	R&S	SMB100A	113083	2019-01-08	2020-01-07
EMC2094	Laser probe	RF Microwave Instrumentation	FL7006	0345061	2019-03-13	2020-03-12
EMC2095	NRP-Z91 Power Sensor 6GHZ	R&S	NPR-Z91	103354	2019-01-08	2020-01-07
EMC2096	NRP-Z91 Power Sensor 6GHZ	R&S	NPR-Z91	103355	2019-01-08	2020-01-07
EMC2097	High-Gain Log-periodic Antenna	R&S	HL046E	100203	2018-02-15	2020-02-14
EMC2098	RI Cable	R&S	7m	N/A	2019-05-23	2020-05-22
SEM003-21	Stacked Logarithmic-Periodic Broadband Antenna (0.7~9GHz)/300W	SCHWARZBECK MESS - ELEKTRONIK	STLP 9149	356	2018-09-18	2021-09-17

Photo of test setup for Radio Frequency Electromagnetic Fields


Tabulated Results for RF Electromagnetic Field 80 MHz to 2700 MHz				
Side of the equipment under test	**Test Level (V/m)**	**Antenna polarization (V/H)**	**Dwell Time (second)**	**Result**
Front	**10**	**H**	**1S**	**1**
	10	**V**	**1S**	**1**
Back	**10**	**H**	**1S**	**1**
	10	**V**	**1S**	**1**
Left	**10**	**H**	**1S**	**1**
	10	**V**	**1S**	**1**
Right	**10**	**H**	**1S**	**1**
	10	**V**	**1S**	**1**
Results Descriptions: **X - Not performed nor required.** **1 – Compliant - No observed response from EUT.**				
Note: Description of the response should detail observations during testing.				

1.14 Test Conditions and Results – Proximity fields from RF wireless communications equipment

61000-4-3	TEST: Proximity fields from RF wireless communications equipment (IEC 61000-4-3:2006 A1:2007 A2:2010)	Verdict
Method: The test allows estimating of the radiated immunity of electrical and electronic equipment to electromagnetic disturbances coming from RF communications equipment. The interference is applied on the enclosure of the equipment by using transmitting antennas.		P

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	21 °C
Relative Humidity	30 to 60 %	53 %
Test specifications		
Calibration Requirements	Uniform field area (UFA)	1.5 m x 1.5 m, 16 points with a minimum UFA size / 0.5 m x 0.5 m
		75 % of calibration points within specifications if UFA is larger than 0.5 m x 0.5 m. 100 % (all 4 points) in the specifications for 0.5 x 0.5 m UFA

Frequency Range and Level: RF wireless communication equipment		
Test Frequency (MHz)	Modulation	Immunity Level (V/m)
385	**Pulse Modulation: 18Hz	27
450	*FM ± 5Hz deviation: 1kHz sine	28
710 745 780	**Pulse Modulation: 217Hz	9
810 870 930	**Pulse Modulation: 18Hz	28
1720 1845 1970	**Pulse Modulation: 217Hz	28
2450	**Pulse Modulation: 217Hz	28
5240 5500 5785	**Pulse Modulation: 217Hz	9

Supplementary information:
EUT powered at one of the Nominal input voltages and frequencies.
Dwell time minimum 1 s. Actual dwell time noted in results table.

Note * - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.
Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.

Test Equipment Used

Radiated Immunity

No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date (YYYY-MM-DD)	Cal.Due date (YYYY-MM-DD)
EMC0525	Compact 3m Semi-Anechoic Chamber	Changzhou zhongyu	N/A	N/A	2016-12-04	2019-12-03
EMC2055	Oscilloscope	Tektronix	TDS3052C	C011815	2019-01-08	2020-01-07
EMC2091	Broadband Amplifier（80M~1GHZ/250W)	R&S	BBA150	102036	2019-01-08	2020-01-07
EMC2092	Broadband Amplifier（800M~3GHZ/110W)	R&S	BBA150	102047	2019-01-08	2020-01-07
EMC2093	Signal Generator	R&S	SMB100A	113083	2019-01-08	2020-01-07
EMC2094	Laser probe	RF Microwave Instrumentation	FL7006	0345061	2019-03-13	2020-03-12
EMC2095	NRP-Z91 Power Sensor 6GHZ	R&S	NPR-Z91	103354	2019-01-08	2020-01-07
EMC2096	NRP-Z91 Power Sensor 6GHZ	R&S	NPR-Z91	103355	2019-01-08	2020-01-07
EMC2097	High-Gain Log-periodic Antenna	R&S	HL046E	100203	2018-02-15	2020-02-14
EMC2098	RI Cable	R&S	7m	N/A	2019-05-24	2020-05-23
EMC2105	Broadband Amplifier（2.5~6GHZ/30W)	R&S	BBA150	102305	2018-10-18	2019-10-17
SEM003-21	Stacked Logarithmic-Periodic Broadband Antenna (0.7~9GHz)/300W	SCHWARZBECK MESS - ELEKTRONIK	STLP 9149	356	2018-09-18	2021-09-17

Photo of test setup for Proximity fields from RF wireless communications equipment


Tabulated Results for Proximity Fields from RF Wireless Communications Equipment				
Side of the equipment under test	**Frequency Band (MHz)**	**Antenna polarization (V/H)**	**Dwell Time (second)**	**Result**
Front	**380 – 390**	**H**	**1S**	**1**
	430 – 470	**H**	**1S**	**1**
	704 – 787	**H**	**1S**	**1**
	800 – 960	**H**	**1S**	**1**
	1700 – 1990	**H**	**1S**	**1**
	2400 – 2570	**H**	**1S**	**1**
	5100 – 5800	**H**	**1S**	**1**
Front	**380 – 390**	**V**	**1S**	**1**
	430 – 470	**V**	**1S**	**1**
	704 – 787	**V**	**1S**	**1**
	800 – 960	**V**	**1S**	**1**
	1700 – 1990	**V**	**1S**	**1**
	2400 – 2570	**V**	**1S**	**1**
	5100 – 5800	**V**	**1S**	**1**
Back	**380 – 390**	**H**	**1S**	**1**
	430 – 470	**H**	**1S**	**1**
	704 – 787	**H**	**1S**	**1**
	800 – 960	**H**	**1S**	**1**
	1700 – 1990	**H**	**1S**	**1**
	2400 – 2570	**H**	**1S**	**1**
	5100 – 5800	**H**	**1S**	**1**
Back	**380 – 390**	**V**	**1S**	**1**
	430 – 470	**V**	**1S**	**1**
	704 – 787	**V**	**1S**	**1**
	800 – 960	**V**	**1S**	**1**
	1700 – 1990	**V**	**1S**	**1**
	2400 – 2570	**V**	**1S**	**1**
	5100 – 5800	**V**	**1S**	**1**
Left	**380 – 390**	**H**	**1S**	**1**
	430 – 470	**H**	**1S**	**1**
	704 – 787	**H**	**1S**	**1**
	800 – 960	**H**	**1S**	**1**
	1700 – 1990	**H**	**1S**	**1**
	2400 – 2570	**H**	**1S**	**1**

Tabulated Results for Proximity Fields from RF Wireless Communications Equipment				
Side of the equipment under test	**Frequency Band (MHz)**	**Antenna polarization (V/H)**	**Dwell Time (second)**	**Result**
	5100 – 5800	**H**	**1S**	**1**
Left	**380 – 390**	**V**	**1S**	**1**
	430 – 470	**V**	**1S**	**1**
	704 – 787	**V**	**1S**	**1**
	800 – 960	**V**	**1S**	**1**
	1700 – 1990	**V**	**1S**	**1**
	2400 – 2570	**V**	**1S**	**1**
	5100 – 5800	**V**	**1S**	**1**
Right	**380 – 390**	**H**	**1S**	**1**
	430 – 470	**H**	**1S**	**1**
	704 – 787	**H**	**1S**	**1**
	800 – 960	**H**	**1S**	**1**
	1700 – 1990	**H**	**1S**	**1**
	2400 – 2570	**H**	**1S**	**1**
	5100 – 5800	**H**	**1S**	**1**
Right	**380 – 390**	**V**	**1S**	**1**
	430 – 470	**V**	**1S**	**1**
	704 – 787	**V**	**1S**	**1**
	800 – 960	**V**	**1S**	**1**
	1700 – 1990	**V**	**1S**	**1**
	2400 – 2570	**V**	**1S**	**1**
	5100 – 5800	**V**	**1S**	**1**
Results Descriptions: **X - Not performed nor required.** **1 – Compliant - No observed response from EUT.**				
Supplementary information: none. Note: Description of the response should detail observations during testing.				

1.15 Test Conditions and Results – Electrical Fast Transients

61000-4-4	TEST: Fast Transients – (IEC61000-4-4:2012)	Verdict
Method: Measurements were made on a ground plane that extends 1-meter minimum beyond all sides of the system under test. Mains power tests were conducted with the product connected to a Coupling/Decoupling Network (CDN). I/O lines were tested in a Capacitive Coupling Clamp. One of each unique interface was tested for a period of one (1) minute per polarity.		**N/A**

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	
Relative Humidity	10 to 90 %	

Fully configured sample subject to the levels shown below.	Measurement Point
	Input a.c. Power Ports Input d.c. Power Ports Signal Input/Output Ports

Applied Level			
Application Point	**(kV)**	**Coupling Method**	**Repetition Frequency (kHz)**
Input a.c. Power Ports	±2	Direct Injection	100
Input d.c. Power Ports	±2	Direct Injection	100
Signal Input/Output Ports*	±1	Capacitive Clamp	100
Input d.c. Power ports (transportation)	See ISO 7637-2		

Supplementary information:

EUT powered at one of the Nominal input voltages and frequencies.

Note* - SIP/SOPS whose maximum cable length is less than 3m are excluded

Test Equipment Used

EFT, Surge, Voltage dips and Interruption

No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date (YYYY-MM-DD)	Cal.Due date (YYYY-MM-DD)
EMC2059	Modular Impulse Surge Generator	EMC PARTNER	MIG0603EN	259	2019-01-08	2020-01-07
EMC2060	High speed signal Surge CDN	EMC PARTNER	CDN-UTP	CDN-UTP0089	2019-01-08	2020-01-07
EMC2072	EMC Immunity Test System	TESEQ AG	NSG 3060&CDN3061&INA 6502 CIB	1580 &1466 &222	2019-01-08	2020-01-07
EMC2055	Oscilloscope 500MHz	Tektronix	TDS3052C	C011815	2019-01-08	2020-01-07

Photo of test setup for Electrical Fast Transients

Tabulated Results for Electrical Fast Transients	
Point of application	**Results**
Mains	
Results Descriptions: **X - Not performed nor required.** **1 – Compliant - No observed response from EUT.**	
Supplementary information: none. Note: Description of the response should detail observations during testing.	

1.16 Test Conditions and Results – Surge Immunity

61000-4-5	TEST: Surge Immunity Test – (IEC61000-4-5:2005)	Verdict
Method: Mains power tests were conducted with the product connected to a Coupling/ Decoupling Network (CDN). The test voltage was increased from the lowest indicated level up to the maximum level. Five (5) positive surges and five (5) negative surges were applied at each of phases of the a.c. waveform: 0°, 90°, 180° and 270°. Each surge was applied 60 seconds after the previous surge. Signal and Telecommunications ports were subject to five (5) positive and five (negative) surges applied through the appropriate Coupling/Decoupling Network (CDN).		N/A

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	
Relative Humidity	10 to 90 %	

Fully configured sample subject to the levels shown below.	Measurement Point
	Input AC and DC Power Ports

Applied Level		
Application Point	**[kV]**	**Required Surge Waveform**
Input Power Ports	0.5 and 1.0 (Line to Line)	Combination Wave (2µs x 50µs Voltage, 8µs x 20µs Current)
	0.5, 1.0 and 2.0 (Line to Earth)	Combination Wave (2µs x 50µs Voltage, 8µs x 20µs Current)
Signal input/output*	2.0 (Line to Earth)	Combination Wave (2µs x 50µs Voltage, 8µs x 20µs Current)

ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at 2 kV line(s) to earth and 1 kV line(s) to line(s).

Supplementary information:

EUT powered at one of the Nominal input voltages and frequencies.
Note* - Applicable to output lines intended to connect directly to outdoor cables

Test Equipment Used

EFT, Surge, Voltage dips and Interruption

No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date (YYYY-MM-DD)	Cal.Due date (YYYY-MM-DD)
EMC2059	Modular Impulse Surge Generator	EMC PARTNER	MIG0603EN	259	2019-01-08	2020-01-07
EMC2060	High speed signal Surge CDN	EMC PARTNER	CDN-UTP	CDN-UTP0089	2019-01-08	2020-01-07
EMC2072	EMC Immunity Test System	TESEQ AG	NSG 3060&CDN3061&INA 6502 CIB	1580 &1466 &222	2019-01-08	2020-01-07
EMC2055	Oscilloscope 500MHz	Tektronix	TDS3052C	C011815	2019-01-08	2020-01-07

Photo of test setup for Surge Immunity

Tabulated Results for Surge - Mains			
Mode of Application	**Level**	**Polarity**	**Results**
Line 1 to Line 2 (Differential mode)	0.5kV	Positive	
		Negative	
	1.0kV	Positive	
		Negative	
Line 1 to Earth (Common mode)	0.5kV	Positive	
		Negative	
	1.0kV	Positive	
		Negative	
	2.0kV	Positive	
		Negative	
Line 2 to Earth (Common mode)	0.5kV	Positive	
		Negative	
	1.0kV	Positive	
		Negative	
	2.0kV	Positive	
		Negative	

Results Descriptions:

X - Not performed nor required.
1 – Compliant - No observed response from EUT.

Supplementary information: none.

Note: Description of the response should detail observations during testing.

Tabulated Results for Surge – Signal Input/output Lines Directly Connected to Outdoor Lines			
Mode of Application	**Level**	**Polarity**	**Results**
Line 1 to Earth (Common mode)	2kV	Positive	
		Negative	
Line 2 to Earth (Common mode)	2kV	Positive	
		Negative	

Results Descriptions:

X - Not performed nor required.
1 – Compliant - No observed response from EUT.

Supplementary information: none.

Note: Description of the response should detail observations during testing.

1.17 Test Conditions and Results – Conducted Disturbances Immunity

<table>
<tr><td>61000-4-6</td><td colspan="3">TEST: RF Continuous Conducted – (IEC61000-4-6:2013)</td><td>Verdict</td></tr>
<tr><td colspan="4"><u>Method</u>: Measurements were made on a ground plane that extends 0.5-meter minimum beyond all sides of the system under test. The EUT was located 10cm above the reference ground plane and any associated I/O cables attached to the EUT were located between 30mm and 50mm above the ground plane. The indicated field was pre-calibrated prior to placement of the system under test.</td><td>N/A</td></tr>
<tr><td colspan="2">Laboratory Parameters:</td><td>Required prior to the test</td><td colspan="2">During the test</td></tr>
<tr><td colspan="2">Ambient Temperature</td><td>10 to 40 °C</td><td colspan="2">°C</td></tr>
<tr><td colspan="2">Relative Humidity</td><td>10 to 90 %</td><td colspan="2">%</td></tr>
<tr><td colspan="2">Test Specifications:</td><td>Frequency range</td><td colspan="2">Measurement Point</td></tr>
<tr><td colspan="2">Fully configured sample scanned over the following frequency range</td><td>150kHz to 80MHz</td><td colspan="2">Input a.c. Power Ports
Input d.c. Power Ports
Signal Input/output Ports
Patient Connected Ports</td></tr>
<tr><td rowspan="2">Level</td><td>Home Healthcare Environment</td><td colspan="3">3 V RMS outside the ISM band, 6 V RMS in the ISM and amateur radio bands</td></tr>
<tr><td>Professional Healthcare Environment</td><td colspan="3">3 V RMS outside the ISM band, 6 V RMS in the ISM band</td></tr>
<tr><td colspan="2">Frequency step</td><td colspan="3">1%</td></tr>
<tr><td colspan="2">Modulation</td><td colspan="3">80% Am at 1kHz*</td></tr>
<tr><td colspan="5">Supplementary information:
EUT powered at one of the Nominal input voltages and frequencies.
Dwell time minimum 1 s.
Note * - Testing may be performed at other modulation frequencies identified by the Risk Management Process.</td></tr>
</table>

Test Equipment Used

Conducted Immunity

No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date (YYYY-MM-DD)	Cal.Due date (YYYY-MM-DD)
EMC2115	TEST SYSTEM OF CI	TESEQ AG	NSG 4070B-80	46144	2019-07-04	2020-07-03
EMC2116	6dB Attenuator	TESEQ AG	ATN 6075	45823	2019-07-23	2020-07-22
EMC2113	CDN S502A	TESEQ	CDN S502A	46206	2017-06-19	2020-06-18
EMC2112	CDN ST08A	TESEQ	CDN ST08A	36631	2017-07-03	2020-07-02
EMC2114	CDN USB3.0	TESEQ	CDN USB3.0	45777	2017-06-19	2020-06-18
EMC1105	Dual Directional coupler	Werlatone Inc.	C1795	6635	2019-06-01	2020-05-31
EMC2055	Oscilloscope 500MHz	Tektronix	TDS3052C	C011815	2019-01-08	2020-01-07
EMC2048	CDN	Elektronik-Feinmechanik	L-801:M2/M3	2738	2018-08-13	2020-08-12
EMC2169	Coupling Decoupling Network	TESEQ	CDN M016	46989	2018--08-10	2021-08-09
EMC1107	CDN M2	Schaffner Chase	CDN-M2-16	9863	2017-10-26	2020-10-25
EMC1116	Current Probe	Schaffner Chase	CIP9136	1155	2017-10-26	2020-10-25
EMC1117	Current Probe	Schaffner Chase	CSP8445	18	2017-10-26	2020-10-25

Photo of test setup for Conducted Disturbances

Tabulated Results for Conducted Disturbances

Point of Application	Results	Dwell Time (second)

Supplementary information: none.

Results Descriptions:

X - Not performed nor required.
1 – Compliant - No observed response from EUT.

Note: Description of the response should detail observations during testing.

Note: Delete rows not used

Note: Describe each port tested

1.18 Test Conditions and Results – Power- Frequency Magnetic Fields

61000-4-8	TEST: Power-frequency magnetic field – (IEC61000-4-8:2009)	Verdict
Method: Measurements were made on a ground plane that extends 1-meter minimum beyond sides of the system under test. Table top EUT is located 80cm above the reference ground plane and floor-standing EUT is located 10cm above the reference ground plane. The indicated field was pre-calibrated prior to placement of the EUT under test.		P

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	22 °C
Relative Humidity	10 to 90 %	55 %
Fully configured sample tested at the power line frequency (See Note 1)	Frequency	Application Point
	50Hz and 60 Hz	Enclosure
Test Level	30 (A/m)	

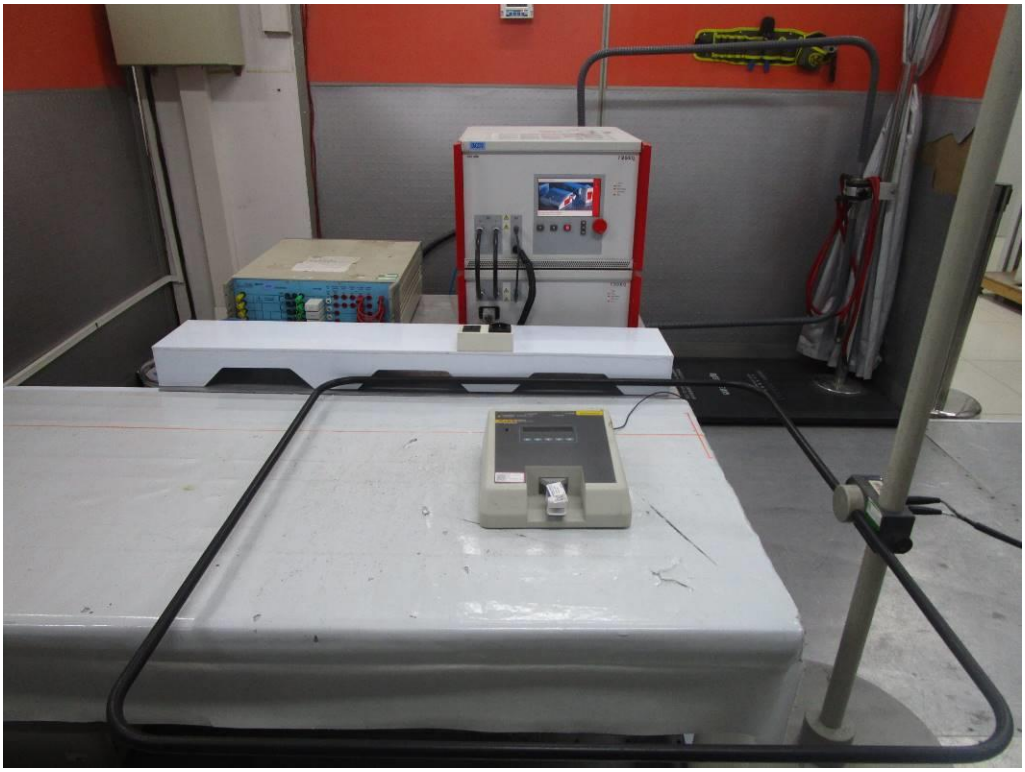
Supplementary information:

EUT powered at one of the Nominal input voltages and frequency of either 50Hz or 60Hz. During the test, the frequency of the field and line frequency of the ME equipment shall be the same.

Test Equipment Used

Power Frequency Magnetic Field Immunity

No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date (YYYY-MM-DD)	Cal.Due date (YYYY-MM-DD)
EMC2072	EMC Immunity Test System	TESEQ AG	NSG 3060&CDN3061&INA 6502 CIB	1580 &1466 &222	2019-01-08	2020-01-07
EMC2061	Power Frequency Magnetic Field Immunity Test System	EVERFINE CO.LTD.	EMS61000-8K	YY100376N11100003	2018-08-20	2020-08-19
EMC2078	Tesla Meter	KANETEC CO., LTD.	TM-701	14444	2017-11-24	2020-11-23
EMC0704	Magnetic Field Immunity Loop	Fischer Custom Communications Inc.	F-1000-4-8-9/10-L-1M	N/A	2019-04-25	2022-04-24

Photo of test setup for Power- Frequency Magnetic Fields


Tabulated Results for Power Frequency Magnetic Field	
Point of application	**Results**
X-Axis	**1**
Y-Axis	**1**
Z-Axis	**1**

Supplementary information: none.

Results Descriptions:

X - Not performed nor required.
1 – Compliant - No observed response from EUT.

Note: Description of the response should detail observations during testing.

1.19 Test Conditions and Results – Voltage Dips, Interruptions, and Variations

61000-4-11	TEST: Voltage Dips and Interruptions – (IEC61000-4-11:2004)	Verdict
Method: The product was subjected to voltage dips and interruptions. Testing was performed with the product connected directly to a generator capable of simulating the voltage drops and interrupts as described.		**N/A**

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	
Relative Humidity	10 to 90 %	

Fully configured subjected to the levels indicated below.	Measurement Point
	Input A.C. Power Ports

Applied Levels		
Voltage Dips % U_T	Cycles	Sync Angle (degrees)
>95	0.5*	0,45,90,135,180,225,270,315
>95	1	0
30	25 (50Hz) 30 (60Hz)	0
Voltage Interruption % U_T	Cycles	Sync Angle [degrees]
>95	250 (50Hz),300 (60Hz)	0

Supplementary information:

If the Rated voltage range <25% of the lowest rated input voltage, one rated input voltage. Otherwise, minimum and maximum rated voltage. EUT powered at one of the Nominal input frequencies.

ME EQUIPMENT and ME SYSTEMS with power input voltage selection by transformer taps shall be tested at only one tap setting.

Note* - Only applicable to ME equipment with single phase a.c. mains

Supply Voltage Range	Difference of Max Voltage – Min Voltage	25% of Lowest Rated Input Voltage	Test at Min/Max Voltages required (Y/N)

Test Equipment Used

EFT, Surge, Voltage dips and Interruption

No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date (YYYY-MM-DD)	Cal.Due date (YYYY-MM-DD)
EMC2059	Modular Impulse Surge Generator	EMC PARTNER	MIG0603EN	259	2019-01-08	2020-01-07
EMC2060	High speed signal Surge CDN	EMC PARTNER	CDN-UTP	CDN-UTP0089	2019-01-08	2020-01-07
EMC2072	EMC Immunity Test System	TESEQ AG	NSG 3060&CDN3061&INA 6502 CIB	1580 &1466 &222	2019-01-08	2020-01-07
EMC2055	Oscilloscope 500MHz	Tektronix	TDS3052C	C011815	2019-01-08	2020-01-07

Photo of test setup for Voltage Dips, Interruptions, and Variations

Tabulated Results for Voltage Dips and Interruptions			
		Minimum Rated Voltage (V).....	
		Frequency (Hz)	
Point of application	**Voltage Dips**	**Period (Cycles)**	**Results**
Mains	>95	0.5	
Mains	>95	1	
Mains	30	25/30 (50/60Hz)	
Point of application	**Voltage Interruptions**	**Period (Cycles)**	**Results**
Mains	>95	250/300 (50/60Hz)	

Supplementary information: none.

Results Descriptions:

X - Not performed nor required.
1 – Compliant - No observed response from EUT.

2 – During test the EUT was power off, after test it can be restorable to the pre-test state with OPERATOR intervention and remains safe, no component failures.

Note: Description of the response should detail observations during testing.

Tabulated Results for Voltage Dips and Interruptions			
		Maximum Rated Voltage (V)....	
		Frequency (Hz)	
Point of application	**Voltage Dips**	**Period (Cycles)**	**Results**
Mains	>95	0.5	
Mains	>95	1	
Mains	30	25/30 (50/60Hz)	
Point of application	**Voltage Interruptions**	**Period (Cycles)**	**Results**
Mains	>95	250/300 (50/60Hz)	

Supplementary information: none.

Results Descriptions:

X - Not performed nor required.
1 – Compliant - No observed response from EUT.

2 – During test the EUT was power off, after test it can be restorable to the pre-test state with OPERATOR intervention and remains safe, no component failures.

Note: Description of the response should detail observations during testing.

1.20 Test Conditions and Results – Electrical transient conduction along supply lines

ISO 7637-2	TEST: Electrical transient conduction along supply lines	Verdict
Method: The DUT shall be placed on a non-conductive low relative permittivity ($\varepsilon_r \leq 1.4$) support with a thickness of (50 ± 5) mm. Grounding of the DUT case to the ground plane shall reflect the vehicle installation. Preferably, the load simulator shall be placed directly on the ground plane. If the load simulator has a metallic case, this case shall be bonded to the ground plane. The peak voltage U_s shall be adjusted to be the required test level with the tolerances of +10 % and 0 %.		N/A

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	°C
Relative Humidity	10 to 90 %	%

Applied Level		
Application Point	**Test pulse and level**	**Coupling Method**
Input d.c. Power ports (transportation)	1 (-150V)	Direct Injection
	2a (+112V)	Direct Injection
	2b (10V for 12V system; 20V for 24V system)	Direct Injection
	3a (-220V for 12V system; -300V for 24Vsystem)	Direct Injection
	3b (+150V for 12V system; +300 for 24V system)	Direct Injection

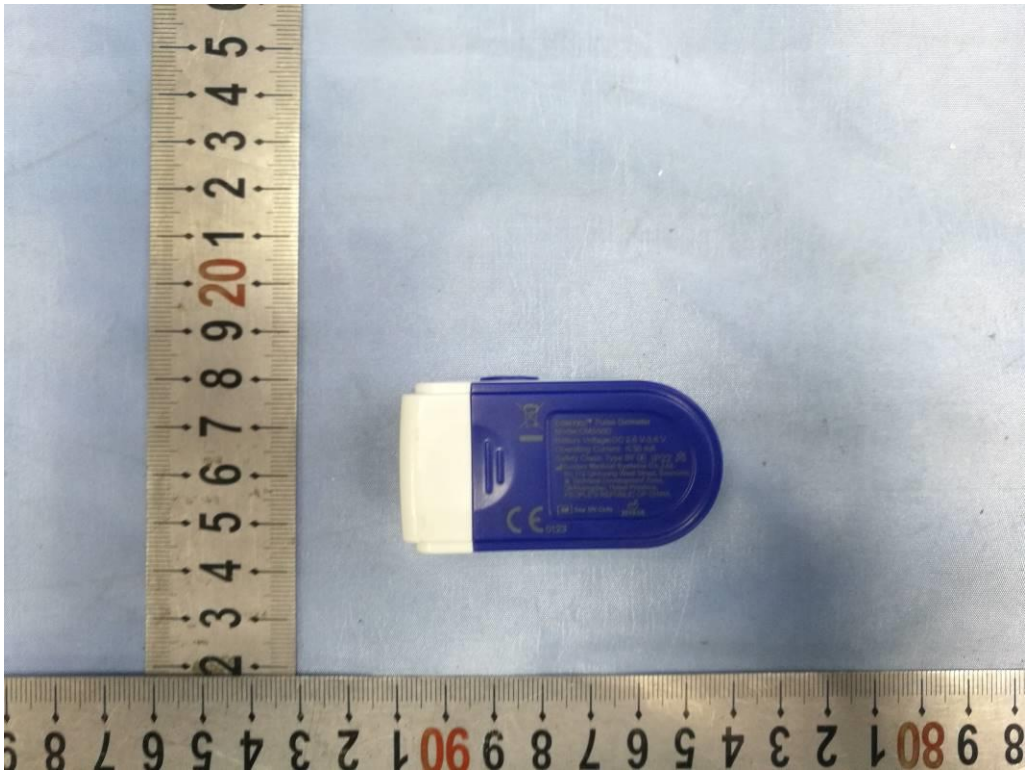
Supplementary information: For ME EQUIPMENT and ME SYSTEMS intended to be installed in passenger cars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems.

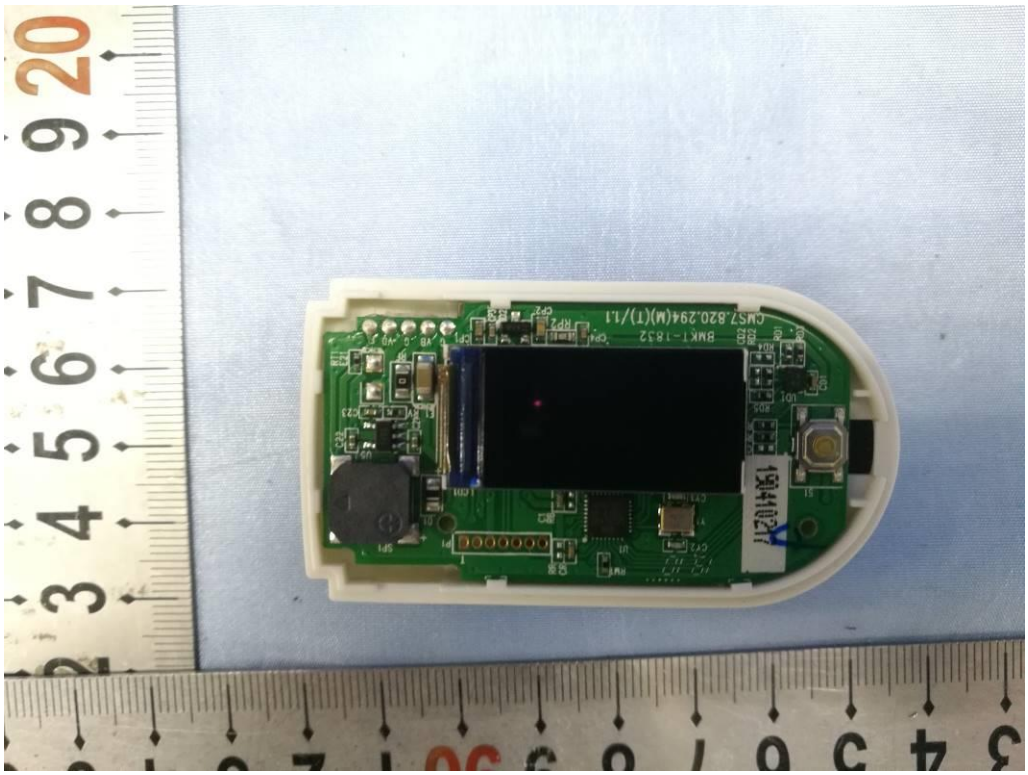
Test Equipment Used					
Description	**Manufacturer**	**Model**	**Identifier**	**Cal. Date**	**Cal. Due**

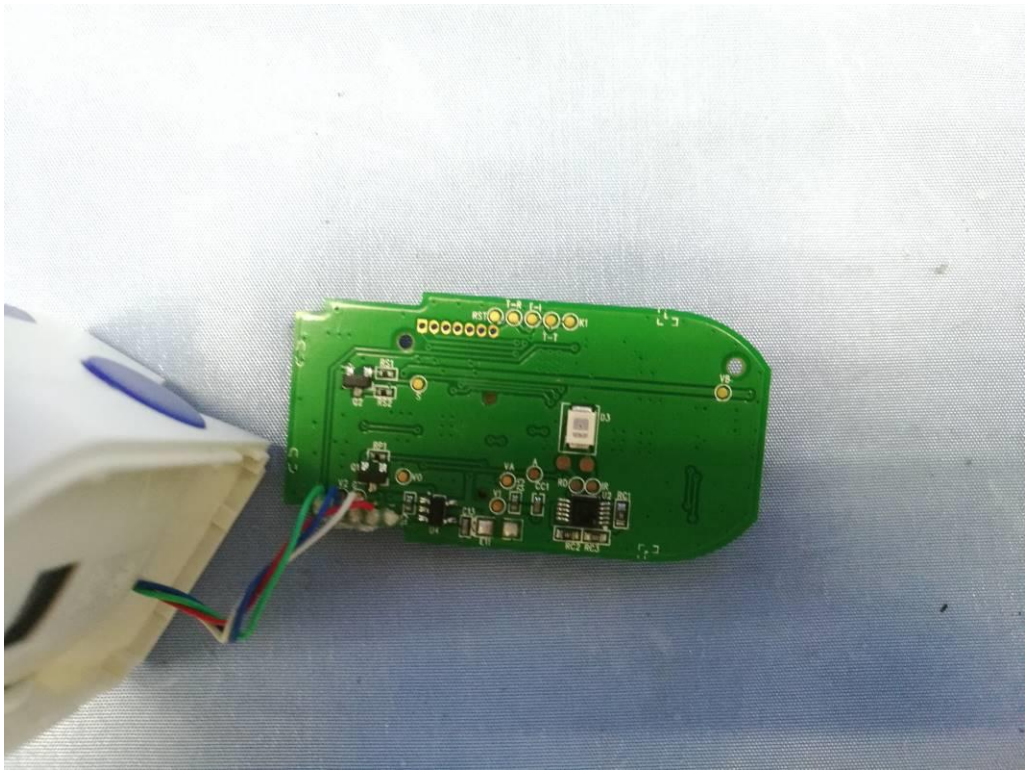
Photo of test setup for Electrical Transient Conduction Along Supply Lines

Tabulated Results for Electrical Transient Conduction Along Supply Lines	
Point of application	**Results**
Mains Pulse 1	
Mains Pulse 2a	
Mains Pulse 2b	
Mains Pulse 3a	
Mains Pulse 3b	
Results Descriptions: **X - Not performed nor required.** **1 – Compliant - No observed response from EUT.**	
Note: Description of the response should detail observations during testing.	

Annex EUT Constructional Details







--End of the Report--