

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 Reference No.....:	GZME140800065601
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CB Testing Laboratory.....:	SGS CSTC Standards Technical Services Co. Ltd - E&E Lab Guangzhou
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Applicant's name.....:	Guangdong Biolight Meditech Co., Ltd
Address	No.2 Innovation First Road, Technical Innovation Coast, Hi-tech Zone, Zhuhai, P.R. China
Test specification:	
Standard	IEC 60601-1-2: 2007, IEC 60601-1-11: 2010 Clause 12
Test procedure	SGS-CSTC
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC60601_1_2CEMC
Test Report Form(s) Originator	UL
Master TRF	Dated 2013-04
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Test item description	Electronic Thermometer
Trade Mark	BLT
Manufacturer.....:	Same as applicant
Factory.....:	Same as applicant
Model/Type reference	WT1, WT2
Ratings	WT1: CR2032, 3V/225mAH button battery, IPX7 WT2: CR2025, 3V/170mAH button battery, IP22

1.0 Testing Program Details

Testing procedure and testing location:	
<input checked="" type="checkbox"/> CB Testing Laboratory:	SGS CSTC Standards Technical Services Co. Ltd - E&E Lab Guangzhou
Testing location/ address	198 Kezhu Road, Sciencetech Park Guangzhou Economic & Technology Development District, 510663 Guangzhou, Guangdong, P.R China
<input type="checkbox"/> Associated CB Test Laboratory:	N/A
Testing location/ address	
Tested by (name + signature)	Fvan Tu 
Approved by (name + signature) :	Fly Lu 
<input type="checkbox"/> Testing procedure: TMP	N/A
Tested by (name + signature)	
Approved by (name + signature) :	
Testing location/ address	
<input type="checkbox"/> Testing procedure: WMT	N/A
Tested by (name + signature)	
Witnessed by (name + signature)	
Approved by (name + signature) :	
Testing location/ address	
<input type="checkbox"/> Testing procedure: SMT	N/A
Tested by (name + signature)	
Approved by (name + signature) :	
Supervised by (name+ signature)	
Testing location/ address	



List of Attachments (including a total number of pages in each attachment): 1) EUT Construction photos Page 45 to Page 47.		
Summary of testing:		
Tests performed (name of test and test clause):		Testing location: SGS CSTC Standards Technical Services Co. Ltd - E&E Lab Guangzhou
Test	Test Clause	
Electromagnetic Interference (EMI)		
Radiated Emission (30 MHz to 1 GHz)	Clause 6.1.1	
Electromagnetic Susceptibility(EMS)		
Electrostatic Discharge	Clause 6.2.2	
Radiated Immunity (80 MHz to 2500 MHz)	Clause 6.2.3	
Power-frequency magnetic field immunity	Clause 6.2.8.1	
Summary of compliance with National Differences List of countries addressed: N/A <input checked="" type="checkbox"/> The product fulfils the requirements of <u>IEC 60601-1-2: 2007, IEC 60601-1-11: 2010 Clause 12</u>		
Copy of marking plate The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks. Refer to the report GZME140800065501 (relevant safety report IEC 60601-1) .		

Test item description:	Electronic Thermometer
Trade Mark:	BLT
Manufacturer:	Same as applicant
Factory:	Same as applicant
Model/Type reference:	WT1, WT2
Ratings	WT1: CR2032, 3V/225mAH button battery, IPX7 WT2: CR2025, 3V/170mAH button battery, IP22
Possible test case verdicts:	
- test case does not apply to test object...: N/A	
- test object does meet requirement.....: P (Pass)	
- test object does not meet requirement...: F (Fail)	
Testing	
Date of receipt of test item	2014-08-28
Date(s) of performance of tests:	2014-09-05 to 2014-09-12
General remarks:	
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.	
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.	
"(see Enclosure #)" refers to additional information appended to the report.	
"(see appended table)" refers to a table appended to the report.	
Throughout this report <input checked="" type="checkbox"/> point <input type="checkbox"/> comma is used as decimal separator.	
General product information:	
The device is intended to be used for measuring and monitoring human temperature continuously via wireless signal transmission of the measuring result.	

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1.1 Equipment Description

Electronic Thermometer

1.1.1 Equipment Marking Plate

Refer to the report GZME140800065501 (relevant safety report IEC 60601-1) .

1.1.2 Supporting Equipment Used During Test:

Use*	Product Type	Manufacturer	Model	Comments
EUT	Electronic Thermometer	Guangdong Biolight Meditech Co., Ltd	WT1, WT2	None

Note: * Use one of the following:
EUT - Equipment Under Test
AE - Auxiliary/Associated Equipment
SIM - Simulator (Not Subjected to Test) *Note: Use abbreviations:

1.1.3 Input/Output Ports:

Port No.	Name	Type*	Cable Max. >3m	Cable Shielded	Comments
0	Enclosure	N/E	—	—	None
<p>*Note: AC = AC Power Port DC = DC Power Port N/E = Non-Electrical BO = Battery operate I/O = Signal Input or Output Port (Not Involved in Process Control) TP = Telecommunication Ports</p>					

1.1.4 EUT Internal Operating Frequencies:

Frequency (MHz)	Description	Frequency (MHz)	Description
32MHz	Internal working frequency (model: WT2)	32MHz	Internal working frequency (model: WT1)
2.4-2.4835GHz	Operating frequency for Bluetooth module		

1.1.5 Power Interface

Mode No.	Voltage (V)	Current (A)	Power (W)	Frequency (DC/AC-Hz)	Phases (No.)	Comments
1	3.0V	—	—	DC	—	None

1.2 EUT Operation Modes:

Mode #	Description
1	Test the EUT in measuring mode
2	Test the EUT in idle mode

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.

1.4 Immunity Performance Criteria

Medical Equipment Performance Criteria - unacceptable operating conditions / responses are:

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

Medical Specific Compliance Criteria for the Voltage Dips and Interruptions Test:

Clause 6.2.7.1 b) - the equipment is allowed a deviation from the requirements of 6.2.1.10 at the immunity levels specified in Table 11 (<5% / >95% / 5s), provided the equipment remains safe, experiences no component failures and is restorable to the pre-test state with operator intervention.

1.5 Compliance Summary

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict
5	Identification, Marking And Documents		—
5.1	Marking on the outside		P
5.1.1	RF equipment marked with symbol IEC 60417-5140 for non-ionizing radiation.		P
5.1.2	Equipment for which the connector testing exemption is used marked with symbol IEC 60417-5134		N/A
5.1.3	Equipment specified for use only in shielded location has appropriate marking/warning labels		N/A
5.2	Accompanying documents		P
5.2.1	Instructions for use		P
5.2.1.1	All equipment and systems:		P
a)	A statements that medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information		P
b)	A statement that mobile RF communications equipment can effect medical electrical equipment		P
5.2.1.2	Equipment for which the connector testing exemption is used		N/A
a)	A reproduction of the ESD warning symbol (IEC 60417-5134)		N/A
b)	A warning that pins of connectors marked with the warning symbol shall not be touched and connections shall not be made without special precautions		N/A
c)	A specification of ESD precautionary procedures		N/A
d)	A recommendation that all staff receive explanation and training in ESD procedures		N/A
e)	A specification of the minimum contents of ESD precautions procedure training		N/A
5.2.1.3	For equipment and systems without a manual sensitivity adjustment and for which the manufacturer specifies a minimum amplitude or value:		N/A
a)	The minimum amplitude or value of signal		N/A
b)	A warning that operation of the equipment below that value may cause inaccurate results		N/A
5.2.1.4	For Type A Professional ME Equipment intended for use in domestic establishment instructions for use includes a warning: This ME Equipment is intended for use by professional healthcare personnel only.		N/A
5.2.2	Technical description		P
5.2.2.1	Requirement for all ME Equipment and Systems (replace by IEC 60601-1-11, please refer the IEC 60601-1-11 report for detail)		—
a)	List of cables and accessories		—

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict
b)	A warning that other cables and accessories may negatively affect EMC performance		–
c)	Table 1, modified as appropriate using Fig. 1 and 2		–
d)	A warning regarding stacking and location close to other equipment		–
e)	A justification for each immunity compliance level below 60601 test level		–
f)	Table 2, completed as appropriate using Figure 3		–
g)	The essential performance of ME Equipment		–
5.2.2.2	ME Equipment not specified for use in shielded location (replace by IEC 60601-1-11, please refer the IEC 60601-1-11 report for detail)		–
	Tables 3 and 5 (life-supporting) using Figure 4, Tables 4 and 6 (non-life-supporting) using Figure 5 selected and completed as appropriate following a)-e)		–
5.2.2.3	ME Equipment specified for use only in shielded location (replace by IEC 60601-1-11, please refer the IEC 60601-1-11 report for detail)		–
a)	A warning that equipment should be used only in the specified type of shielded location		–
b)	Tables modified if disturbance allowance according to 6.1.1.1 d) is used		–
c)	A specification of allowed emission of other equipment located within the shielded location		–
d)	Table 7 (life-supporting) or 8 (non-life-supporting) as appropriate		–
5.2.2.4	ME Equipment that intentionally apply RF energy – documents shall include guidelines for avoiding or identifying and resolving adverse electromagnetic effects on other equipment		P
5.2.2.5	ME Equipment that intentionally receive RF energy		P
a)	Each (preferred if applicable) frequency or frequency band of reception, and the bandwidth of the receiving section of the ME Equipment in those bands		P
b)	A warning that the ME Equipment may be interfered with by other equipment		P
5.2.2.6	ME Equipment that includes RF transmitters – documentation shall include each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and ERD		P
5.2.2.7	Requirements of cables, transducers and accessories		N/A
a)	Documentation shall include list of ME Equipment		N/A
b)	A warning that use of other accessories results in non-compliance		N/A
5.2.2.8	Requirements applicable to large permanently installed ME Equipment and Systems		N/A
a)	A statement that an exemption has been used and that the ME Equipment has not been tested for radiated RF immunity over the entire frequency range 80 MHz to 2,5 GHz		N/A

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict
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 transmitters or equipment used as RF test sources and the frequency and modulation characteristics of each source.		N/A
5.2.2.9	Requirements applicable to ME Equipment that has no essential performance		N/A
a)	Statement that the ME Equipment was not tested for immunity to electromagnetic disturbances		N/A
b)	Document shall include information applicable to the ME Equipment		N/A
5.2.2.10	Requirements applicable to ME Equipment that is Type A Professional only		N/A
	Document include a justification for not complying with the CISPR 11 group 2 Class B electromagnetic radiation disturbance limit		N/A

1.6 Result Summary

Clause	Requirement – Test	Result/Comments	Verdict P / F / N/A
6.1	Emissions		
6.1.1.1	Classification		—
	Class B		—
	Group 1		—
	CISPR 11		—
6.1.1.2	Limits of mains terminal disturbance voltage		N/A
	Limits for radiated disturbance		P
6.1.3.1	Harmonic Current Emissions per IEC61000-3-2		N/A
6.1.3.2	Voltage Fluctuations and Flicker per IEC61000-3-3.....		N/A
6.2	Immunity		
6.2.2	Electrostatic Discharges (ESD)		P
6.2.3	Radiated RF electromagnetic Fields		P
6.2.4	Electrical Fast Transients and bursts		N/A
6.2.5	Surges		N/A
6.2.6	Conducted Disturbances, induced by RF fields		N/A
6.2.7	Voltage Dips, Interruptions, and variations.....		N/A
6.2.8	Power-frequency Magnetic Field		P

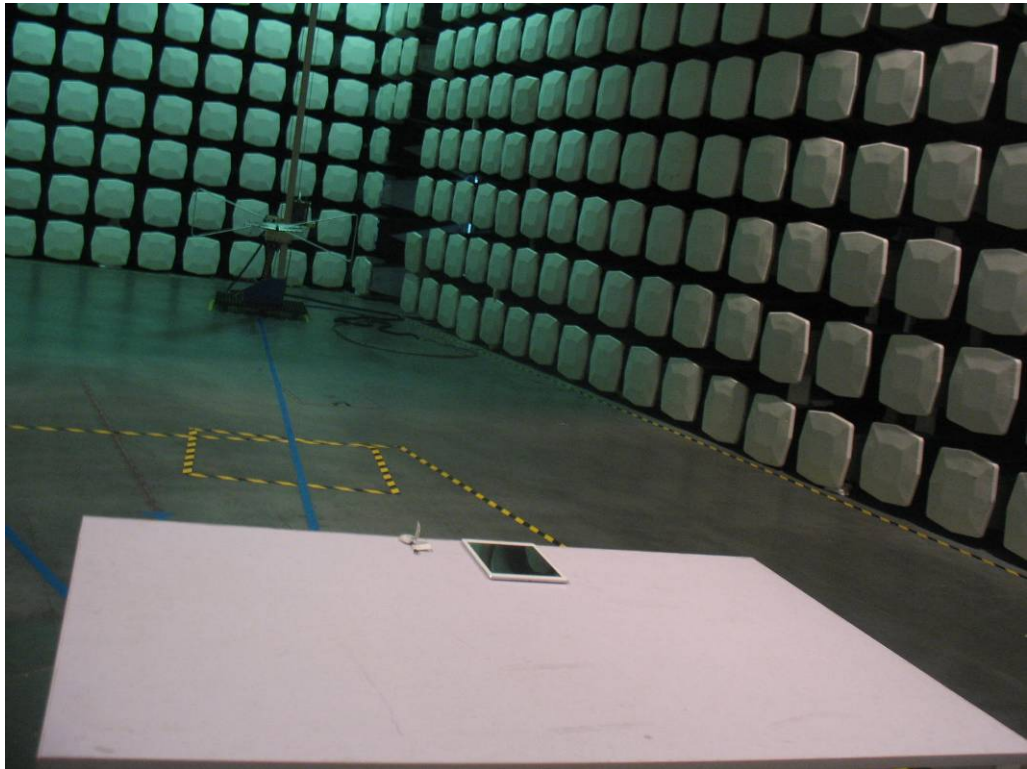
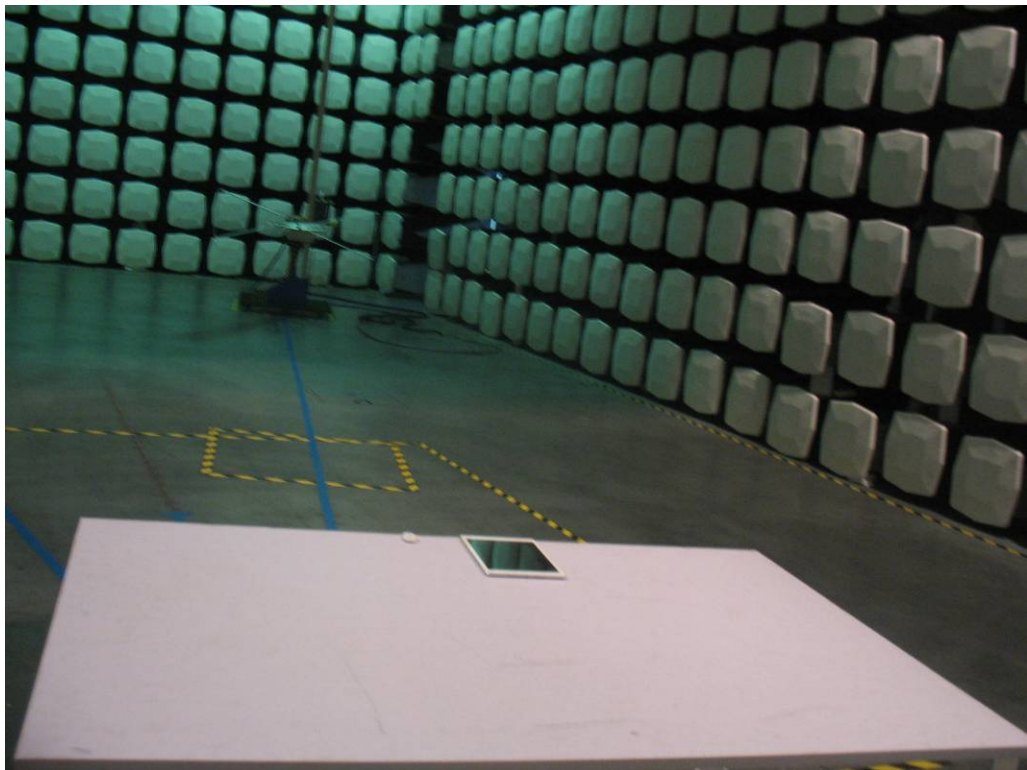
1.7 Test Conditions and Results – Conducted Emissions

CISPR 11	TEST: Limits of mains terminal disturbance voltage			Verdict	
<p><u>Method:</u> 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.</p>				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	
Equipment mode		Power interface mode			
		EUT configurations mode			
		Operation mode			
Limits - Group 1 - Class B					
Frequency (MHz)		Limit dB (µV)			
		Quasi-Peak	Result*	Average	Result*
0.15 to 0.50		66 to 56		56 to 46	
0.50 to 5		56		46	
5 to 30		60		50	
Supplementary information: * - The result in tables may be a minimum margin to the limit.					

1.8 Test Conditions and Results – Radiated Emissions

CISPR 11	TEST: Limits for radiated disturbance 30 MHz –1 GHz		Verdict
<p>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 10 meter. 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>			P
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	10 to 40 °C	23 °C	
Relative Humidity	10 to 90 %	52 %	
Fully configured sample scanned over the following frequency range	Frequency range on each side of line	Measurement Point	
	30MHz – 1GHz	10 m measurement distance	
Equipment mode	Power interface mode	Mode1	
	EUT configurations mode	Mode 1	
	Operation mode	Pre-test in mode 1 to mode 2, compliance test in mode 1 as the worst case was found	
Limits – Group 1 Class B (for model: WT2)			
Frequency (MHz)	Limit dB (µV/m)		
	Quasi-Peak	Results *	
30 to 230	30	13.88	
230 to 1000	37	15.44	
Limits – Group 1 Class B (for model: WT1)			
Frequency (MHz)	Limit dB (µV/m)		
	Quasi-Peak	Results *	
30 to 230	30	10.98	
230 to 1000	37	13.70	
<p>Supplementary information: * -The result in this table may be a minimum margin to the limit.</p>			

Test Equipment Used						
RE in Chamber						
No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date	Cal. Due date
					(YYYY-MM-DD)	(YYYY-MM-DD)
EMC0525	Compact Semi-Anechoic Chamber	ChangZhou ZhongYu	N/A	N/A	2013-12-5	2014-12-5
EMC0522	EMI Test Receiver	Rohde & Schwarz	ESIB26	100283	2014-04-19	2015-04-19
EMC0056	EMI Test Receiver	Rohde & Schwarz	ESCI	100236	2014-03-03	2015-03-03
EMC0528	RI High frequency Cable	SGS	20 m	N/A	2014-05-09	2015-05-09
EMC2025	Trilog Broadband Antenna 30-1000MHz	SCHWARZBECK MESS-ELEKTRONIK	VULB 9160	9160-3372	2014-07-14	2017-07-14
EMC0524	Bi-log Type Antenna	Schaffner -Chase	CBL6112B	2966	2013-08-31	2016-08-31
EMC0519	Bilog Type Antenna	Schaffner -Chase	CBL6143	5070	2014-05-04	2017-05-04
EMC2026	Horn Antenna 1-18GHz	SCHWARZBECK MESS-ELEKTRONIK	BBHA 9120D	9120D-841	2013-08-31	2016-08-31
EMC0518	Horn Antenna	Rohde & Schwarz	HF906	100096	2012-07-01	2015-07-01
EMC0521	1-26.5 GHz Pre-Amplifier	Agilent	8449B	3008A01649	2014-03-03	2015-03-03
EMC2065	Amplifier	HP	8447F	N/A	2014-08-25	2015-08-25
EMC0075	310N Amplifier	Sonoma	310N	272683	2014-03-03	2015-03-03
EMC0523	Active Loop Antenna	EMCO	6502	42963	2014-03-03	2016-03-03
EMC2041	Broad-Band Horn Antenna (14)15-26.5(40)GHz	SCHWARZBECK MESS-ELEKTRONIK	BBHA 9170	9170-375	2014-05-26	2017-05-26
EMC2069	2.4GHz filter	Micro-Tronics	BRM 50702	149	2014-04-19	2015-04-19
EMC0530	10m Semi-Anechoic Chamber	ETS	N/A	N/A	2014-05-03	2016-05-03

Photo of test setup for Radiated Disturbance**For model: WT2****For model: WT1**

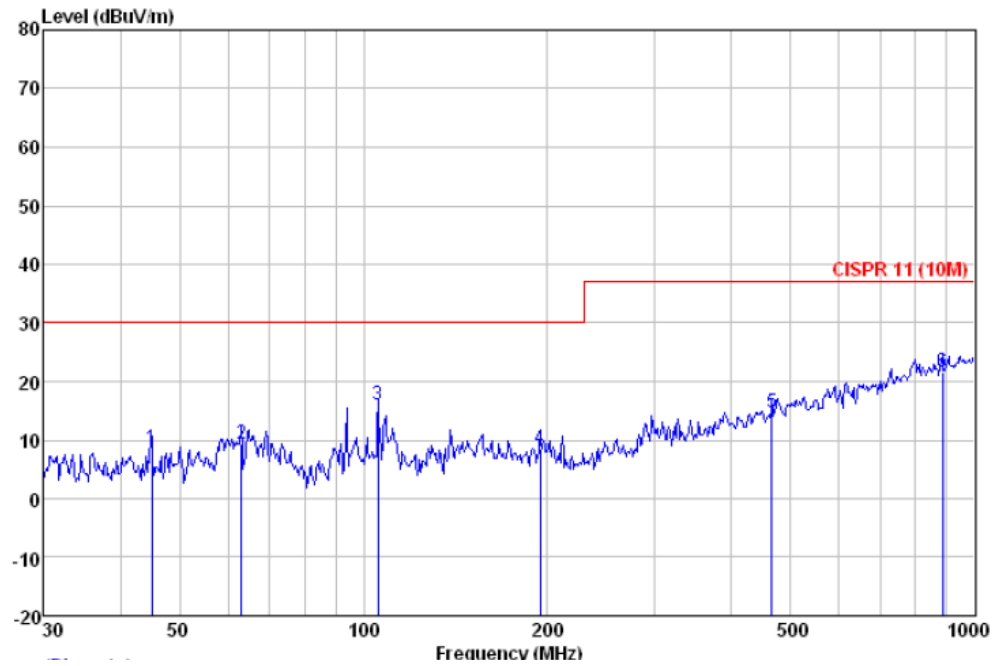
Tabulated Results for Radiated Disturbance (For model: WT2)									
Polarity (Vertical)									
	Freq	ReadAntenna Level	Antenna Factor	Cable Loss	Preamp Factor	Level	Limit Line	Over Limit	Remark
	MHz	dBuV	dB/m	dB	dB	dBuV/m	dBuV/m	dB	
1	45.058	26.50	12.02	1.05	31.00	8.57	30.00	-21.43	QP
2	63.092	27.49	11.73	1.13	31.00	9.35	30.00	-20.65	QP
3	105.642	35.68	10.03	1.41	31.00	16.12	30.00	-13.88	QP
4	194.453	27.67	10.19	1.89	31.10	8.65	30.00	-21.35	QP
5	465.599	25.88	16.81	3.03	30.97	14.75	37.00	-22.25	QP
6	884.503	25.59	22.89	3.98	30.90	21.56	37.00	-15.44	QP
Polarity (Horizontal)									
	Freq	ReadAntenna 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	27.85	12.02	1.05	31.00	9.92	30.00	-20.08	QP
2	64.887	29.36	11.61	1.15	31.00	11.12	30.00	-18.88	QP
3	105.272	32.40	9.98	1.41	31.00	12.79	30.00	-17.21	QP
4	150.011	26.63	13.17	1.65	31.06	10.39	30.00	-19.61	QP
5	383.932	24.75	15.05	2.77	30.91	11.66	37.00	-25.34	QP
6	603.539	26.50	19.57	3.20	30.90	18.37	37.00	-18.63	QP

Tabulated Results for Radiated Disturbance (For model: WT1)									
Polarity (Vertical)									
	Freq	ReadAntenna 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	39.162	34.02	11.91	0.98	31.01	15.90	30.00	-14.10	QP
2	60.492	25.17	11.92	1.10	31.00	7.19	30.00	-22.81	QP
3	165.487	33.32	12.83	1.78	31.08	16.85	30.00	-13.15	QP
4	302.481	28.08	13.13	2.41	31.00	12.62	37.00	-24.38	QP
5	531.964	29.40	17.89	3.12	30.97	19.44	37.00	-17.56	QP
6	815.968	27.38	22.41	3.82	30.90	22.71	37.00	-14.29	QP

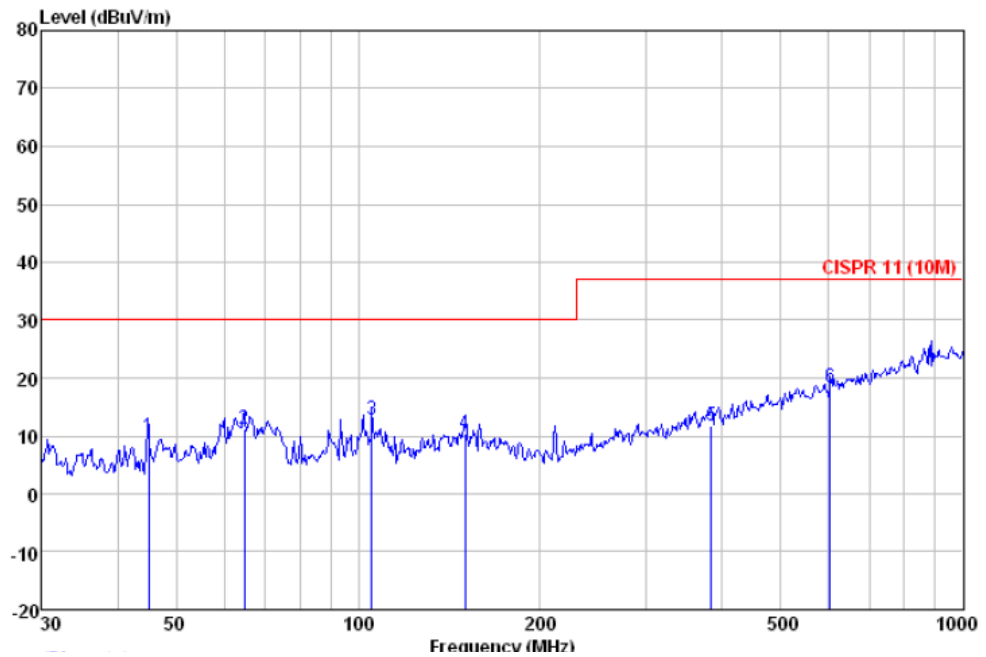
Polarity (Horizontal)									
	Freq	ReadAntenna Level	Antenna Factor	Cable Loss	Preamp Factor	Level	Limit Line	Over Limit	Remark
	MHz	dBuV	dB/m	dB	dB	dBuV/m	dBuV/m	dB	
1	30.853	29.07	11.50	0.82	31.02	10.37	30.00	-19.63	QP
2	60.069	27.72	11.95	1.10	31.00	9.77	30.00	-20.23	QP
3	165.487	33.32	12.83	1.78	31.08	16.85	30.00	-13.15	QP
4	201.393	38.40	9.82	1.90	31.10	19.02	30.00	-10.98	QP
5	449.556	28.16	16.54	2.95	30.96	16.69	37.00	-20.31	QP
6	574.626	32.21	18.83	3.18	30.92	23.30	37.00	-13.70	QP

Graphical representation of Radiated Disturbance Measurement (for model: WT2)

Vertical:

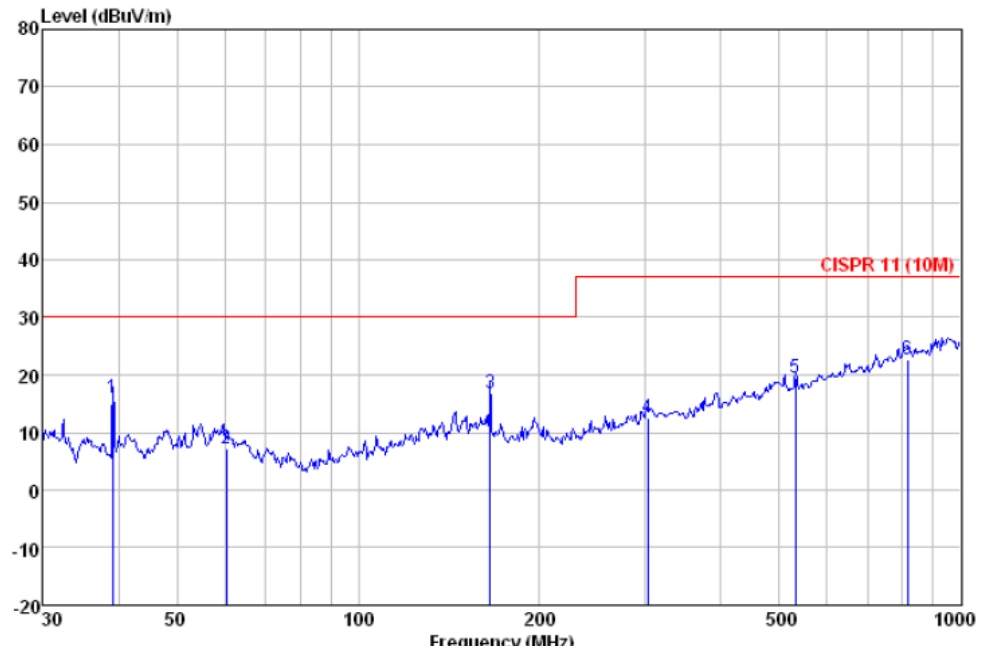


Horizontal:

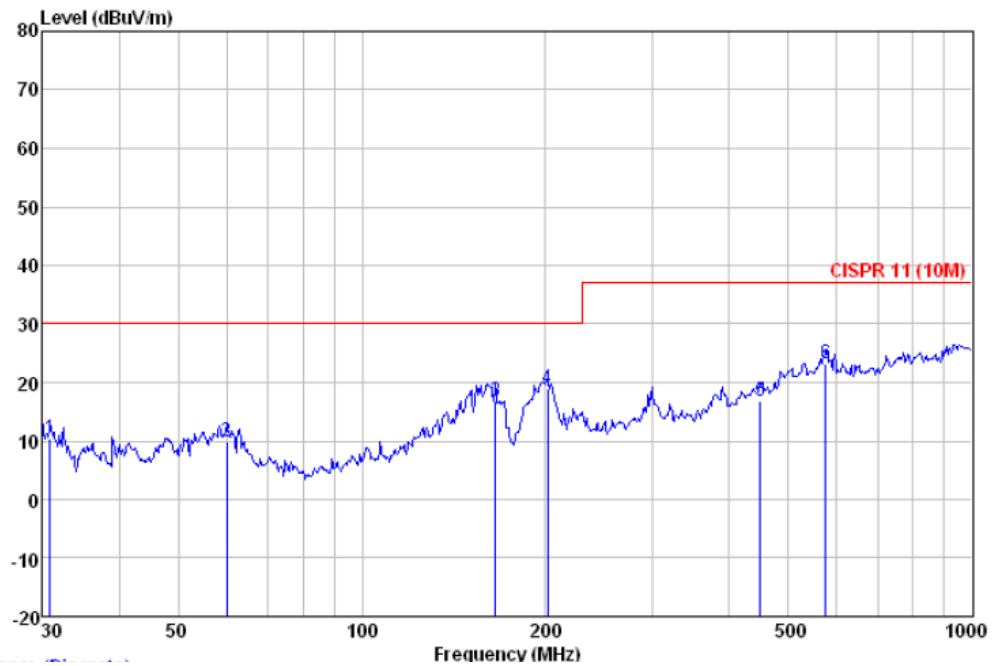


Graphical representation of Radiated Disturbance Measurement (for model: WT1)

Vertical:



Horizontal:



1.9 Test Conditions and Results – Limits for Harmonic Current Emissions

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 %	
Equipment mode	Power interface mode	
	EUT configurations mode	
	Operation mode	
Classification of Equipment..... :		
Supplementary information:		

Test Equipment Used						
Harmonics / Flicker test						
No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date	Cal.Due date
					(YYYY-MM-DD)	(YYYY-MM-DD)
EMC0608	AC Power Source	California	50001iX	56627	2014-04-19	2015-04-19
EMC0607	Power Analyzer	California	PACS	72400	2014-04-19	2015-04-19

Photo of test setup for Harmonic Current Emissions

Tabulated Results for Harmonic Current Emissions

Tabulated Results for Harmonic Current Emissions

1.10 Test Conditions and Results – Limitation of Voltage Fluctuations and Flicker

61000-3-3	TEST: Limitation of Voltage Fluctuations And Flicker (IEC 61000-3-3:2008)		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 %		
Equipment mode	Power interface mode		
	EUT configurations mode		
	Operation mode		
Control Method of Equipment (see below).....:			
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:			

Test Equipment Used						
Harmonics / Flicker test						
No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date	Cal.Due date
					(YYYY-MM-DD)	(YYYY-MM-DD)
EMC0608	AC Power Source	California	50001iX	56627	2014-04-19	2015-04-19
EMC0607	Power Analyzer	California	PACS	72400	2014-04-19	2015-04-19

Photo of test setup for Voltage Fluctuations And Flicker

Tabulated Results for Voltage Fluctuations And Flicker

1.11 Test Conditions and Results – Immunity to Electrostatic Discharges

61000-4-2	TEST: Electrostatic discharges (IEC 61000-4-2:2008)		Verdict
<p>Method: The test is intended to demonstrate the immunity of equipment subjected to static electricity discharges from operators directly and to adjacent objects. The tabletop 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>			P
Laboratory Parameters:		Required prior to the test	During the test
Ambient Temperature		15 to 35 °C	23 °C
Relative Humidity		30 to 60 %	52 %
Atmospheric pressure:		860 to 1060 mbar (86 to 106 kPa)	1003 mbar
Equipment mode		Power interface mode	Mode 1
		EUT configurations mode	Mode 1
		Operation mode	Mode 1-2
Test Levels			
Discharge type	Discharge Level (kV)		Number of discharges per location (each polarity)
	Positive	Negative	
Air – Direct	2, 4, 8	2, 4, 8	10
Contact – Direct	2, 4, 6	2, 4, 6	10
Contact – Indirect	2, 4, 6	2, 4, 6	10
Discharge location	<p>See photo documentation of the test set-up All external locations accessible by hand, Horizontal plate (HCP) Vertical coupling plate (VCP)</p>		
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	Cal. Due date
					(YYYY-MM-DD)	(YYYY-MM-DD)
EMC2071	ESD Simulator	TESEQ AG	NSG 435	6739	2014-05-05	2015-05-05
EMC0804	ESD Ground Plane	SGS	3m x 3m	N/A	N/A	N/A
EMC0078	Temperature, & Humidity	Shanghai Meteorological Instrument factory Co., Ltd.	ZJ1-2B	709131	2014-09-16	2015-09-16

Photo of test setup for Immunity to Electrostatic Discharges

For model: WT2



For model: WT1



Tabulated Results for Electrostatic Discharges (for all models)			
Nominal Voltage (V)			DC 3V
Nominal Frequency (Hz)			N/A
Direct discharges: Air and Contact			
Discharge location	Air discharge voltage (kV)	Polarity	Remark
All insulated enclosure & seams	2	Positive	1
	2	Negative	1
	4	Positive	1
	4	Negative	1
	8	Positive	1
	8	Negative	1
Discharge location	Contact discharge voltage (kV)	Polarity	Remark
All accessible metal parts of the enclosure with discharge resistor used	2	Positive	1
	2	Negative	1
	4	Positive	1
	4	Negative	1
	6	Positive	1
	6	Negative	1

Indirect discharges			
Discharge location	Contact discharge voltage (kV)	Polarity	Remark
HCP - Front	2 & 4 & 6	Positive	2
HCP - Left	2 & 4 & 6	Negative	2
HCP - Right	2 & 4 & 6	Positive	2
HCP - Rear	2 & 4 & 6	Negative	2
VCP - Front	2 & 4 & 6	Positive	2
VCP - Left	2 & 4 & 6	Negative	2
VCP - Right	2 & 4 & 6	Positive	2
VCP - Rear	2 & 4 & 6	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.			

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

61000-4-3		TEST: RF electromagnetic fields (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 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.					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 %	
Equipment mode		Power interface mode		Mode 1	
		EUT configurations mode		Mode 1	
		Operation mode		Mode 1-2	
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 bandwidth		80 MHz to 2500 MHz			
Level	Non-Life Supporting Equipment	3 V/m			
		Amplitude modulation	80 % / 1 kHz sine wave		
	Controls, monitors or measures a physiological parameter, (80 % / 2 Hz)				
	Life Supporting Equipment	10 V/m			
Amplitude modulation		80 % / 1 kHz sine wave			
	Controls, monitors or measures a physiological parameter, (80 % / 2 Hz)				
Frequency step		1%			
Dwell time		2 Hz Modulation	3 sec minimum*		
		1 kHz Modulation	1 sec minimum*		
Supplementary information:					
EUT powered at one of the Nominal input voltages and frequencies.					
Note * - The actual dwell time shall be provided in the Tabulated Results table.					

Test Equipment Used						
Radiated Immunity						
No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date	Cal. Due date
					(YYYY-MM-DD)	(YYYY-MM-DD)
EMC0525	Compact 3m Semi-Anechoic Chamber	Changzhou zhongyu	N/A	N/A	2013-12-5	2014-12-5
EMC0516	Signal Generator	Rohde & Schwarz	SMR20	100416	2014-04-19	2015-04-19
EMC0519	Bilog Type Antenna	Schaffner -Chase	CBL6143	5070	2014-05-04	2017-05-04
EMC0915	Amplifier	EMPOWER	BBS2E4ALP	1007	2014-03-03	2015-03-03
EMC0914	Amplifier	EMPOWER	BBS3Q5KIN	1006	2014-03-03	2015-03-03
EMC0904	Power Meter	Rohde & Schwarz	NRVS	825770/074	2014-03-03	2015-03-03
EMC0071	URV5-Z2 Insert. Unit	R&S	URV5-Z2	100309	2014-03-03	2015-03-03
EMC0917	Dual Directional Coupler	EMCA	715-10-1.400	70031	2014-08-30	2015-08-30
EMC0907	Electric Field Probe	Wandel & Goltermann	EMC-20	M-0063	2014-04-28	2015-04-28
EMC2055	Oscilloscope	Tektronix	TDS3052C	C011815	2014-03-03	2015-03-03
EMC0909	Monitor System	Mitsubish Corp.	M-0552AB	91510185	N/A	N/A

Photo of test setup for Radio Frequency Electromagnetic Fields

For model: WT2

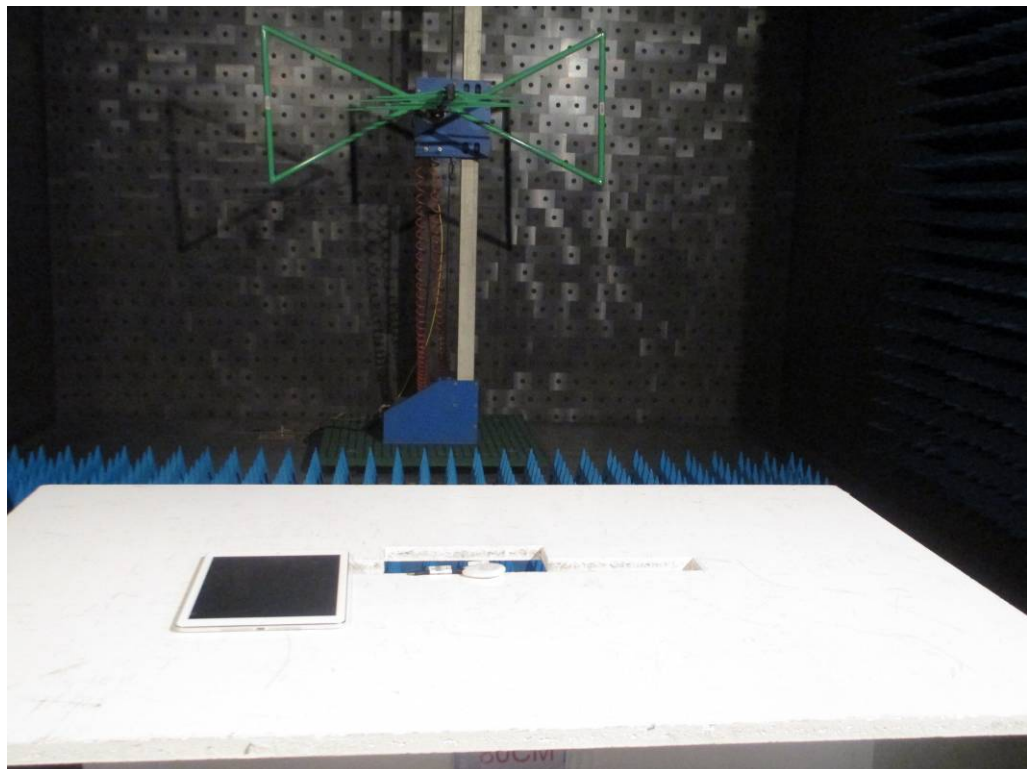
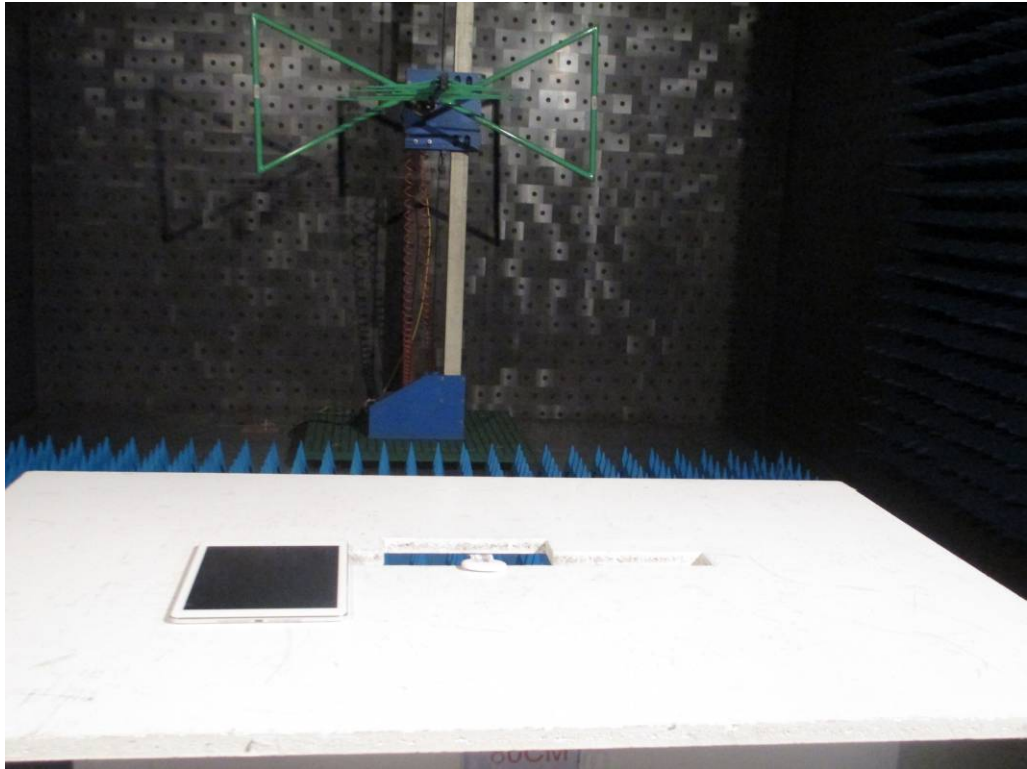


Photo of test setup for Radio Frequency Electromagnetic Fields

For model: WT1



Tabulated Results for RF Electromagnetic Field (for all models) 80 MHz to 2500 MHz 3 V/m 80 % / 2 Hz sine wave				
Nominal Voltage (V)				DC 3V
Nominal Frequency (Hz).....				N/A
Side of the equipment under test	Frequency (MHz)	Antenna polarization (V/H)	Dwell Time (second)	Remark
Front	80 MHz to2500 MHz	V	3S	1
		H	3S	1
Back	80 MHz to2500 MHz	V	3S	1
		H	3S	1
Left	80 MHz to2500 MHz	V	3S	1
		H	3S	1
Right	80 MHz to2500 MHz	V	3S	1
		H	3S	1
Results Descriptions: X - Not performed nor required. 1 – Compliant - No observed response from EUT.				

1.13 Test Conditions and Results – Electrical Fast Transients

61000-4-4	TEST: Fast Transients – (IEC 61000-4-4:2012)		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 Ports longer than 3 meters		
Equipment mode	Power interface mode		
	EUT configurations mode		
	Operation mode		
Applied Level			
Application Point	(kV)	Repetition Frequency (kHz)	
Input a.c. Power Ports	±2	5	
Input d.c. Power Ports	±2	5	
Signal Ports	±1	5	
Supplementary information:			
Test is performed at the minimum and maximum RATED input voltages at any nominal frequency			

Test Equipment Used						
EFT, Surge, Voltage dips and Interruption						
No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date	Cal.Due date
					(YYYY-MM-DD)	(YYYY-MM-DD)
EMC2059	Modular Impulse Surge Generator	EMC PARTNER	MIG0603EN	259	2014-03-03	2015-03-03
EMC2060	High speed signal Surge CDN	EMC PARTNER	CDN-UTP	CDN-UTP0089	2014-03-03	2015-03-03
EMC2072	EMC Immunity Test System	TESEQ AG	NSG 3060 CDN3061 INA 6502 CIB CND3425	1580 1466 222	2014-04-19	2015-04-19
EMC2012	Oscilloscope	Tektronix	TDS 744A	N/A	2014-05-13	2015-05-13

Photo of test setup for Electrical Fast Transients

Tabulated Results for Minimum Input Voltage	
Minimum Rated Voltage (V).....:	
Nominal Rated Frequency (Hz) :	
Point of application	Comments/Results
USB cable	
I/O Line 1 -	
I/O Line 2 -	

Tabulated Results for Maximum Input Voltage	
Maximum Rated Voltage (V) ... :	
Nominal Rated Frequency (Hz) :	
Point of application	Comments/Results
USB cable	
I/O Line 1 -	
I/O Line 2 -	

X - Not performed
1 – Compliant - No observed response from EUT.
2 –
Note: Description of the response should detail observations during testing.

1.14 Test Conditions and Results – Surge Immunity

61000-4-5	TEST: Surge Immunity Test – (IEC 61000-4-5:2005)		Verdict
<p><u>Method:</u> 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).</p>			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	
Equipment mode		Power interface mode	
		EUT configurations mode	
		Operation mode	
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)	
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: Test is performed at the minimum and maximum RATED input voltages and at any nominal frequency.			

Test Equipment Used						
EFT, Surge, Voltage dips and Interruption						
No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date	Cal.Due date
					(YYYY-MM-DD)	(YYYY-MM-DD)
EMC2059	Modular Impulse Surge Generator	EMC PARTNER	MIG0603EN	259	2014-03-03	2015-03-03
EMC2060	High speed signal Surge CDN	EMC PARTNER	CDN-UTP	CDN-UTP0089	2014-03-03	2015-03-03
EMC2072	EMC Immunity Test System	TESEQ AG	NSG 3060 CDN3061 INA 6502 CIB CND3425	1580 1466 222	2014-04-19	2015-04-19
EMC2012	Oscilloscope	Tektronix	TDS 744A	N/A	2014-05-13	2015-05-13

Photo of test setup for Surge Immunity

Tabulated Results for Surges for Minimum Input Voltage			
Minimum Rated Voltage (V).....			
Nominal Rated Frequency (Hz)			
Mode of Application – Mains	Level	Polarity	Comments/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	

X – Not performed
1 – Compliant – No observed response from EUT.
2 –
Note: Description should detail the observation during testing.

Tabulated Results for Surges for Maximum Input Voltage			
Maximum Rated Voltage (V) ...			
Nominal Rated Frequency (Hz)			
Mode of Application - Mains	Level	Polarity	Comments
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	

X - Not performed
1 – Compliant – No observed response from EUT.
2 –
Note: Description should detail the observation during testing.

1.15 Test Conditions and Results – Conducted Disturbances Immunity

61000-4-6	TEST: RF Continuous Conducted – (IEC 61000-4-6:2008)		Verdict
Method: 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.			N/A
Laboratory Parameters:		Required prior to the test	During the test
Ambient Temperature		10 to 40 °C	
Relative Humidity		10 to 90 %	
Equipment mode		Power interface mode	
		EUT configurations mode	
		Operation mode	
Test Specifications:		Frequency range	Measurement Point
Fully configured sample scanned over the following frequency range		150kHz* to 80MHz	Input a.c. Power Ports Input d.c. Power Ports Signal Ports
		Note* Verify against Clause 6.2.6.1 f)	
Level	Non Life Supporting Equipment	3 V RMS	
		Amplitude modulation	80 % / 1 kHz sine
			Controls, monitors or measures a physiological parameter 80 % / 2 Hz
	Life Supporting Equipment	3 V RMS outside the ISM band, 10 V RMS in the ISM band	
		Amplitude modulation	80 % / 1 kHz sine
			Controls, monitors or measures a physiological parameter 80 % / 2 Hz
Frequency step		1%	
Dwell time		2 Hz Modulation	3 sec minimum*
		1 kHz Modulation	1 sec minimum*
Supplementary information: EUT powered at one of the Nominal input voltages and frequencies. Note * - The actual dwell time shall be provided in the Tabulated Results table.			

Test Equipment Used						
Conducted Immunity						
No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date	Cal. Due date
					(YYYY-MM-DD)	(YYYY-MM-DD)
EMC1101	Signal Generator	Rohde & Schwarz	SMY01	825675/016	2014-08-25	2015-08-25
EMC1102	Amplifier 0.15-230MHz	Ophirrf	GRF5048	1003	2014-08-25	2015-08-25
EMC1103	Power Meter	Rohde & Schwarz	NRVS	825770/079	2014-03-03	2015-03-03
EMC0071	URV5-Z2 Insert. Unit	R&S	URV5-Z2	100309	2014-03-03	2015-03-03
EMC1105	Dual Directional coupler	Werlatone Inc.	C1795	6635	2014-08-30	2015-08-30
EMC2012	Oscilloscope	Tektronix	TDS 744A	N/A	2014-05-13	2015-05-13
EMC2048	CDN	Elektronik- Feinmechanik	L-801:M2/M3	2738	2011-11-11	2014-11-11
EMC1107	CDN M2	Schaffner Chase	CDN-M2-16	9863	2011-11-11	2014-11-11
EMC1116	Current Probe	Schaffner Chase	CIP9136	1155	2011-11-11	2014-11-11
EMC1117	Current Probe	Schaffner Chase	CSP8445	18	2011-11-11	2014-11-11

Photo of test setup for Conducted Disturbances

Tabulated Results for Conducted Disturbances 150kHz to 80MHz 3 V/m 80 % / 1 KHz sine wave		
Nominal Rated Voltage (V)		
Nominal Rated Frequency (Hz)		
Point of Application	Comments/Results	Dwell Time (second)
USB cable	1	
electrode cables	1	
I/O Line 1 -	X	
I/O Line 2 -	X	
X - Not performed		
1 – Compliant - No observed/perceived response from EUT.		
2 -		
Note: Description of response should detail the observation during testing.		

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

61000-4-11	TEST: Voltage Dips and Interruptions – (IEC 61000-4-11:2004)	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	
Equipment mode	Power interface mode	
	EUT configurations mode	
	Operation mode	
Applied Levels		
Voltage Dips % U_T	Period (Cycles)	Sync Angle [degrees]
30	25	0
60	5	0
>95	0.5	0
Voltage Interruption % U_T	Seconds	Sync Angle [degrees]
>95	5	0
0 degrees is the crossover point of the voltage waveform.		
Test is performed at the minimum and maximum RATED input voltages and at the <u>minimum</u> rated frequency.		
Supplementary information: none		

Test Equipment Used						
EFT, Surge, Voltage dips and Interruption						
No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date	Cal. Due date
					(YYYY-MM-DD)	(YYYY-MM-DD)
EMC2059	Modular Impulse Surge Generator	EMC PARTNER	MIG0603EN	259	2014-03-03	2015-03-03
EMC2060	High speed signal Surge CDN	EMC PARTNER	CDN-UTP	CDN-UTP0089	2014-03-03	2015-03-03
EMC2072	EMC Immunity Test System	TESEQ AG	NSG 3060 CDN3061 INA 6502 CIB CND3425	1580 1466 222	2014-04-19	2015-04-19
EMC2012	Oscilloscope	Tektronix	TDS 744A	N/A	2014-05-13	2015-05-13

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

Tabulated Results for Voltage Dips and Interruptions			
Minimum Rated Voltage (V)....			
Minimum Rated Frequency (Hz)			
Point of application	Voltage reduction	Period (Cycles)	Comments/Results
Mains	30	25	
Mains	60	5	
Mains	>95	0.5	
Point of application	Voltage reduction	Seconds	Comments/Results
Mains	>95	5	

Supplementary information: None.

Tabulated Results for Voltage Dips and Interruptions			
Maximum Rated Voltage (V)....			
Minimum Rated Frequency (Hz)			
Point of application	Voltage reduction	Period (Cycles)	Comments/Results
Mains	30	25	
Mains	60	5	
Mains	>95	0.5	
Point of application	Voltage reduction	Seconds	Comments/Results
Mains	>95	5	

Supplementary information: None.

X - Not performed
1 – Compliant - No observed/perceived 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 response should detail the observation during testing.

1.17 Test Conditions and Results – Power- Frequency Magnetic Fields

61000-4-8	TEST: Power-frequency magnetic field – (IEC 61000-4-8:2009)		Verdict
Method: Measurements were made on a ground plane that extends 1-meter minimum beyond sides of the system under test. Tabletop 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 %	52 %
Equipment mode		Power interface mode	Mode 1
		EUT configurations mode	Mode 1
		Operation mode	Mode 1-2
Fully configured sample tested at the power line frequency (See Note 1)		Frequency	Application Point
		50Hz and 60 Hz ¹	Enclosure
Frequency (Hz)		Test Level (A/m)	
50		3	
60		3	
Tested at 50Hz and 60Hz powered at any one of its NOMINAL RATED input voltages.			
Supplementary information: The test is performed at both 50 Hz and 60 Hz, with the exception that ME Equipment rated for use only at one of these frequencies need only be tested at that frequency.			

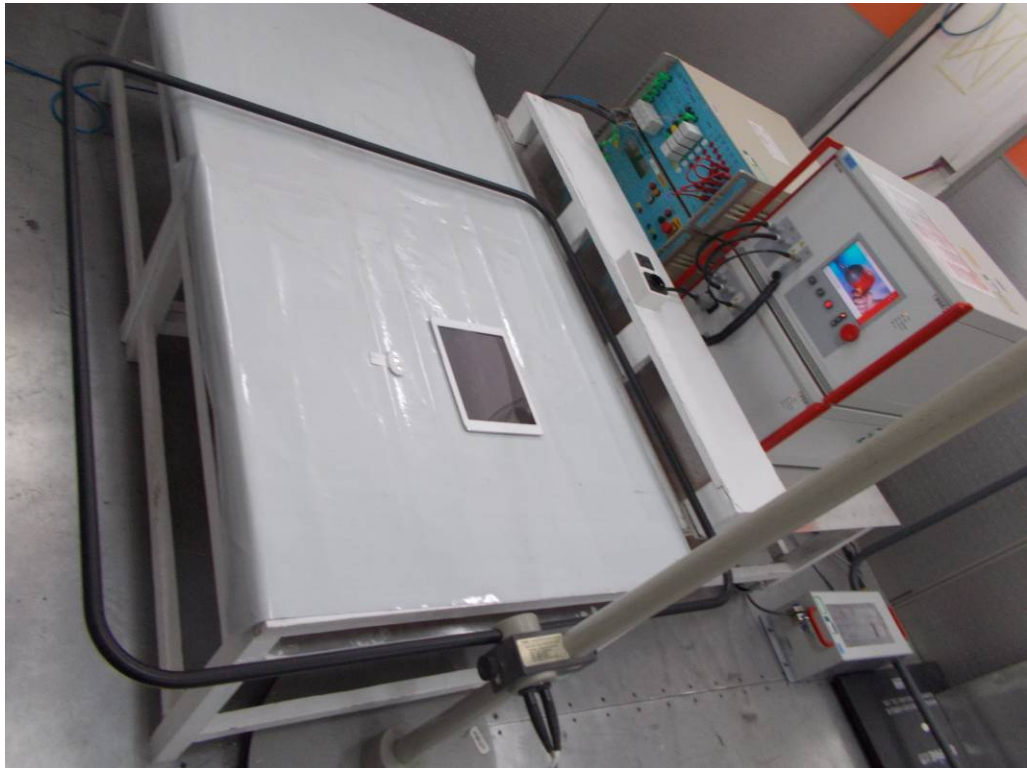
Test Equipment Used						
Power Frequency Magnetic Field Immunity						
No.	Test Equipment	Manufacturer	Model No.	Serial No.	Cal. date	Cal.Due date
					(YYYY-MM-DD)	(YYYY-MM-DD)
EMC1010	EMC Immunity Test System	Thermo KeyTek	Pro-Plus	501276	2014-04-19	2015-04-19
EMC2061	Power Frequency Magnetic Field Immunity Test System	EVERFINE CO.LTD.	EMS61000-8K	YY100376N11100003	2014-09-14	2016-09-14
EMC0704	Magnetic Field Immunity Loop	Fischer Custom Communications Inc.	F-1000-4-8-9/10-L-1M	N/A	2014-04-19	2017-04-19

Photo of test setup for Power- Frequency Magnetic Fields

For model: WT2



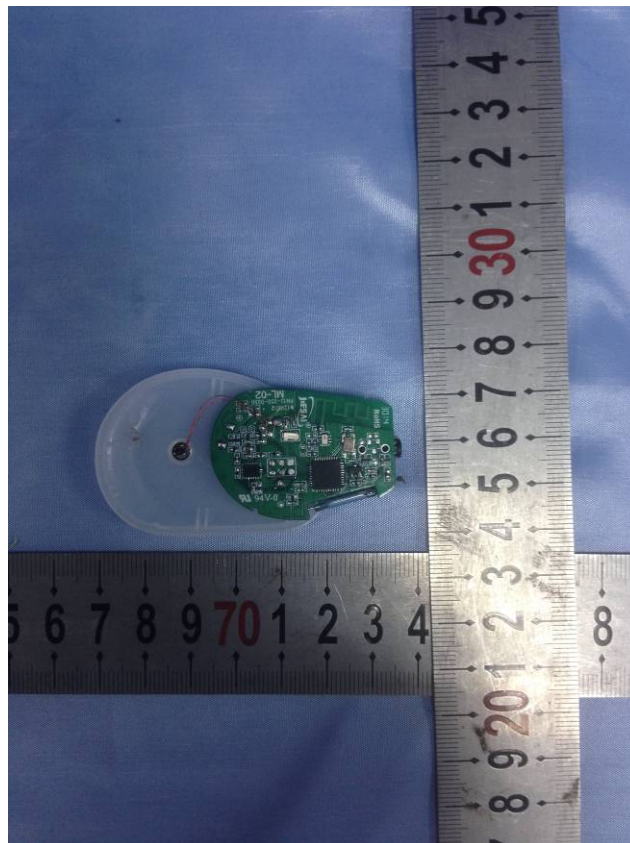
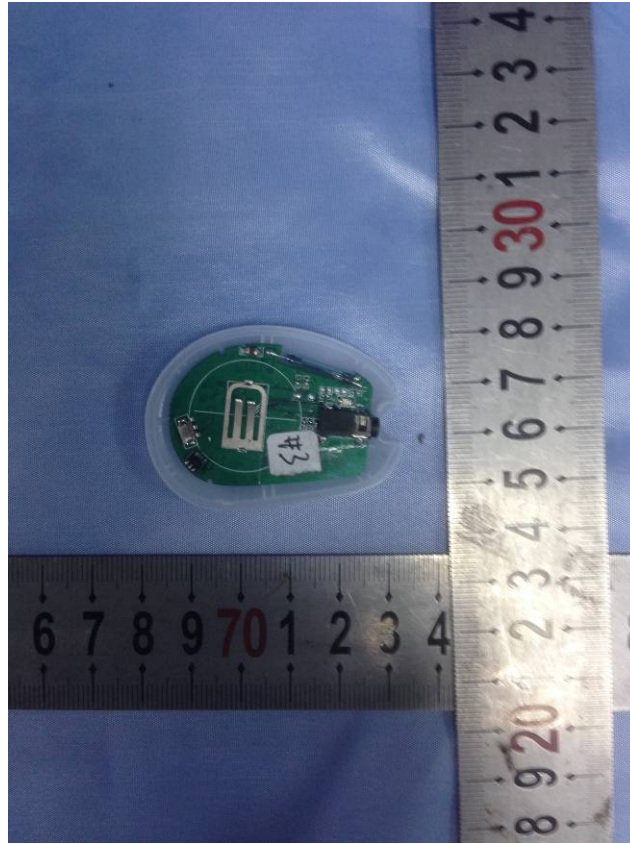
For model: WT1



Tabulated Results for Power Frequency Magnetic Field (for all models)		
Nominal Rated Voltage (V)		DC 3V
Point of application	Results	
	50 Hz	60 Hz
X-Axis	1	1
Y-Axis	1	1
Z-Axis	1	1
Supplementary information:		
X-AXIS: EUT as refer to Power Frequency Magnetic Field Immunity test setup photo.		
Y-AXIS: As X, but rotate EUT by 90° clockwise.		
Z-AXIS: As Y, but rotate EUT by 90° vertically.		
X - Not performed or not required.		
1 – Compliant - No observed response from EUT.		

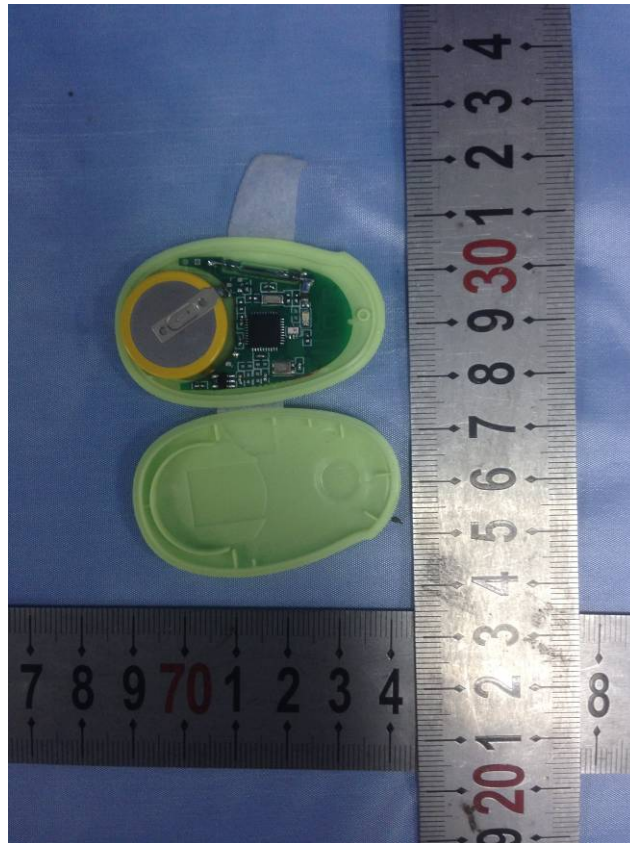
Annex EUT Constructional Details

Model: WT2





Model: WT1





--End of Report--