

SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION Co., Ltd.

Declaration of Conformity

Certificate No.:CTE12070117 **R/C**: 62675

Issued Date: Sep 11, 2012

The device, as described herewith, was tested pursuant to applicable test procedure and complies with the requirements of:

IEC 60601-1-2: 2007

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

The test results are traceable to the international or national standards.

Applicant: KIRCHNER & WILHELM GmbH + Co. KG

Eberhardstr. 56 71679 Asperg GERMANY

Manufacturer: KIRCHNER & WILHELM GmbH + Co. KG

Eberhardstr. 56 71679 Asperg GERMANY

EUT Name: Halogen medical practice light

Model number: 10.11000.002

Listed Model(s): 10.11010.002, 10.11011.002, 10.11020.002, 10.11021.002

Laboratory: Shenzhen Huatongwei International Inspection Co., Ltd.

Keji Nan No.12 Road, Hi-tech Park, Shenzhen, China Tel: 86-755-26748078 Fax: 86-755-26748089 Http://www.szhtw.com.cn E-mail: cs@szhtw.com.cn

Note: The certification is only valid for the equipment and configuration described ,in conjunction

with the test data detailed above.

For and on behalf of

Shenzhen Huatongwei International Inspection Co.,Ltd.

Authorized by:





Shenzhen Huatongwei International Inspection Co., Ltd.

Keji Nan No.12 Road, Hi-tech Park, Shenzhen, China

Phone:86-755-26748019 Fax:86-755-26748089 http://www.szhtw.com.cn



TEST REPORT

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests				
Report Reference No::::::::::::::::::::::::::::::::	TRE12070117 R/C: 62675			
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Approved by	Con nend			
(position+printed name+signature):	Manager Tony Jiang			
Date of issue:	Sep 11, 2012			
Testing Laboratory Name	Shenzhen Huatongwei International Inspection Co., Ltd.			
Address	Keji Nan No.12 Road, Hi-tech Park, Shenzhen, China			
Testing location/ procedure:	Full application of Harmonised standards Partial application of Harmonised standards Other standard testing methods			
Applicant's name	KIRCHNER & WILHELM GmbH + Co. KG			
Address	Eberhardstr. 56 71679 Asperg GERMANY			
Test specification: Standard:	IEC 60601-1-2: 2007			
Non-standard test method:				
Test Report Form No				
TRF Originator	Shenzhen Huatongwei International Inspection Co., Ltd.			
TRF Originator	Shenzhen Huatongwei International Inspection Co., Ltd. Dated 2006-06			
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TRF Originator	Shenzhen Huatongwei International Inspection Co., Ltd. Dated 2006-06 Inspection Co., Ltd. All rights reserved. whole or in part for non-commercial purposes as long as the spection Co., Ltd is acknowledged as copyright owner and source of ternational Inspection Co., Ltd takes no responsibility for and will not from the reader's interpretation of the reproduced material due to its Halogen medical practice light / KIRCHNER & WILHELM GmbH + Co. KG 10.11000.002 10.11010.002, 10.11011.002, 10.11020.002, 10.11021.002 220V-240Va.c, 50 Hz, 0.5A; Output 12Va.c., 5.0A Max; Main Device: 12Va.c., 50W MAX.			

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Issued: 2012-09-11 Revised: 2012-12-04

EMC -- TEST REPORT

Test Report No. :	TRE12070117	Sep 11, 2012
rest Report No	IKLIZOTOTIT	Date of issue

Equipment under Test : Halogen medical practice light

Model /Type : 10.11000.002

10.11010.002, 10.11011.002, Listed Models

10.11020.002, 10.11021.002

Applicant : KIRCHNER & WILHELM GmbH + Co. KG

Address : Eberhardstr. 56 71679 Asperg GERMANY

Manufacturer : KIRCHNER & WILHELM GmbH + Co. KG

Address : Eberhardstr. 56 71679 Asperg GERMANY

Test Result according to the standards on page 4:	Positive
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The test report merely corresponds to the test sample.

It is not permitted to copy extracts of these test result without the written permission of the test laboratory.

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1. TEST STANDARDS

<u>IEC 60601-1-2:2007</u> Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Remark: This EUT is ranged to the Group 1 Class B apparatus according to the standard of CISPR 11: 2010 clause 5.2.

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2. SUMMARY

■ - Specified by manufacturer

O - Not specified

2.1. General Remarks:

Date of receipt of test sample : July 30, 2012

Testing commenced on : July 30, 2012

Testing concluded on : September 11, 2012

2.2. Equipment Under Test

Power supply system utilised

Power supply voltage : ■ 230V / 50 Hz o 120V / 60Hz

o 12 V DC o 24 V DC

o Other (specified in blank below)

2.3. Short description of the Equipment under Test (EUT)

The EUT is a Halogen medical practice light.added models: 10.11010.002, 10.11011.002, 10.11020.002, 10.11021.002. They are all the same except for model's name, the data are from the original report.

2.4. EUT operation mode:

The equipment under test was operated during the measurement under the following conditions:

Test program (customer specific)

Emissions tests......: According to IEC 60601-1-2, searching for the highest disturbance.

Immunity tests: According to IEC 60601-1-2, searching for the highest susceptivity.

Harmonics current......: According to IEC 61000-3-2, searching for the highest disturbance.

Voltage fluctuation.....: According to IEC 61000-3-3, searching for the highest disturbance.

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2.5. EUT configuration:

No peripheral devices and interface cables were connected during the measurement.

2.6. Compliance criteria

Under the test conditions specified in 6.2.1.10 of IEC 60601-1-2: 2007, the equipment of system shall be able to provide the essential performance and remain safe. The following degradations associated with essential performance and safety shall not be allowed:

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

For equipment and systems with multiple functions, the criteria apply to each function, parameter and channel.

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

3. TEST ENVIRONMENT

3.1. Address of the test laboratory

Shenzhen Huatongwei International Inspection Co., Ltd Keji Nan No.12 Road, Hi-tech Park, Shenzhen, China Phone: 86-755-26748019 Fax: 86-755-26748089

3.2. Test Facility

The test facility is recognized, certified, or accredited by the following organizations:

CNAS-Lab Code: L1225

Shenzhen Huatongwei International Inspection Co., Ltd has been assessed and proved to be in compliance with CNAS-CL01 Accreditation Criteria for Testing and Calibration Laboratories (identical to ISO/IEC 17025: 2005 General Requirements) for the Competence of Testing and Calibration Laboratories, Date of Registration: March 01, 2012. Valid time is until February 28, 2015.

A2LA-Lab Cert. No. 2243.01

Shenzhen Huatongwei International Inspection Co., Ltd, EMC Laboratory has been accredited by A2LA for technical competence in the field of electrical testing, and proved to be in compliance with ISO/IEC 17025: 2005 General Requirements for the Competence of Testing and Calibration Laboratories and any additional program requirements in the identified field of testing. Valid time is until Sept 30, 2013.

FCC-Registration No.: 662850

Shenzhen Huatongwei International Inspection Co., Ltd, EMC Laboratory has been registered and fully described in a report filed with the FCC (Federal Communications Commission). The acceptance letter from the FCC is maintained in our files. Registration 662850, Renewal date Jul 01, 2009. Valid time is until Jun 01, 2015.

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IC-Registration No.: 5377A

The 3m Alternate Test Site of Shenzhen Huatongwei International Inspection Co., Ltd. has been registered by Certification and Engineering Bureau of Industry CaLuoRin for the performance of radiated measurements with Registration No. 5377A on Jan. 25, 2011, valid time is until Jan. 24, 2014.

ACA

Shenzhen Huatongwei International Inspection Co., Ltd, EMC Laboratory can also perform testing for the Australian C-Tick mark as a result of our A2LA accreditation.

NEMKO-Aut. No.: ELA125

Shenzhen Huatongwei International Inspection Co., Ltd has been assessed the quality assurance system, the testing facilities, qualifications and testing practices of the relevant parts of the organization. The quality assurance system of the Laboratory has been validated against ISO/IEC 17025 or equivalent. The laboratory also fulfils the conditions described in Nemko Document NLA-10, the authorization is valid through Jul 07, 2013

VCCI

The 3m Semi-anechoic chamber (12.2m×7.95m×6.7m) and Shielded Room (8m×4m×3m) of Shenzhen Huatongwei International Inspection Co., Ltd. has been registered in accordance with the Regulations for Voluntary Control Measures with Registration No.: G-292. Date of Registration: Dec. 24, 2010. Valid time is until Dec. 23, 2013.

Main Ports Conducted Interference Measurement of Shenzhen Huatongwei International Inspection Co., Ltd. has been registered in accordance with the Regulations for Voluntary Control Measures with Registration No.: C-2726. Date of Registration: Dec. 20, 2009. Valid time is until Dec. 19, 2012.

Telecommunication Ports Conducted Interference Measurement of Shenzhen Huatongwei International Inspection Co., Ltd. has been registered in accordance with the Regulations for Voluntary Control Measures with Registration No.: T-1837. Date of Registration: May 07, 2010. Valid time is until May 06, 2013.

DNV

Shenzhen Huatongwei International Inspection Co., Ltd. has been found to comply with the requirements of DNV towards subcontractor of EMC and safety testing services in conjunction with the EMC and Low voltage Directives and in the voluntary field. The acceptance is based on a formal quality Audit and follow-ups according to relevant parts of ISO/IEC Guide 17025 (2005), in accordance with the requirements of the DNV Laboratory Quality Manual towards subcontractors. Valid time is until Aug. 24, 2013.

3.3. Environmental conditions

During the measurement the environmental conditions were within the listed ranges:

remperature:	15-35 ° C
Humidity:	25-75 %
Atmospheric pressure:	950-1050mbar

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3.4. Test Description

Emission Measurement		
Radiated Emission	IEC 60601-1-2:2007	PASS
	CISPR 11: 2010	17.00
Conducted Disturbance	IEC 60601-1-2:2007	PASS
(0.15-30MHz)	CISPR 11: 2010	PASS
Harmonic Current	IEC 60601-1-2:2007	PASS
	IEC 61000-3-2: 2009	PASS
Voltage Fluctuation and Flicker	IEC 60601-1-2:2007	PASS
	IEC 61000-3-3: 2008	PASS
Immunity Measurement		
Electrostatic Discharge	IEC 60601-1-2:2007	PASS
	IEC 61000-4-2: 2008	PASS
RF Field Strength Susceptibility	IEC 60601-1-2:2007	PASS
(80~2500MHz)	IEC 61000-4-3: 2010	PASS
Electrical Fast Transient/Burst	IEC 60601-1-2:2007	PASS
Test	IEC 61000-4-4: 2012	FAGG
Surge Test	IEC 60601-1-2:2007	PASS
	IEC 61000-4-5: 2005	FAGG
Conducted Susceptibility Test	IEC 60601-1-2:2007	PASS
	IEC 61000-4-6: 2008	FAGG
Power Frequency Magnetic Field	IEC 60601-1-2:2007	PASS
Susceptibility Test	IEC 61000-4-8: 2009	
Voltage Dips and Interruptions	IEC 60601-1-2:2007	PASS
Test	IEC 61000-4-11: 2004	1 7.00

Note: "N/A" means "not applicable".

The measurement uncertainty is not included in the test result.

IEC 60601-1-2:2007					
Clause	Clause Requirement + Test Result - Remark				
5	IDENTIFICATION, MARKING AND DOCUMENTS		PASS		
5.1	Marking on the outside of ME EQUIPMENT OR M	ME EQUIPMENT parts	N/A		
5.1.1	RF equipment marked with symbol IEC 60417-5140		N/A		
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		N/A		
5.2	ACCOMPANYING DOCUMENTS		PASS		
5.2.1	Instructions for use		PASS		

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5.2.1.1	All equipment and systems:		PASS
a)	A statements that medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information	Please refer to User manual	PASS
b)	A statement that RF communications equipment can effect medical electrical equipment	Please refer to User manual	PASS
5.2.1.2	Equipment for which the connector testing exemption	on 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 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 signal:		PASS
a)	The minimum amplitude or value of signal	Please refer to User manual	PASS
b)	A warning that operation of the equipment below that value may cause incorrect results	Please refer to User manual	PASS
5.2.1.4	Requirements applicable to TYPE A PROFESSIONAL SYSTEMS		N/A
5.2.2	Technical description		PASS
5.2.2.1	All equipment and systems:		PASS
a)	List of cables and accessories		N/A
b)	A warning that other cables and accessories may affect EMC performance	Please refer to User manual	PASS
c)	Table 1, modified as appropriate	Please refer to User manual	PASS
d)	A warning regarding stacking and location close to other equipment	Please refer to User manual	PASS
e)	A justification for each immunity compliance level below 60601 test level		N/A
f)	Table 2, completed as appropriate		N/A
5.2.2.2	Equipment not specified for use only in shielded loc	ation	PASS
	Table 3 and Table 5 shall be used for LIFE- SUPPORTING, Table 4 and Table 6 shall be used are not LIFE-SUPPORTING, selected and completed as appropriate	Please refer to User manual	PASS

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6	ELECTROMAGNETIC COMPATIBILITY	(see appended table)	
5.2.2.10	Requirements applicable to TYPE A PROFESSIONAL SYSTEMS		N/A
5.2.2.9	Requirements applicable to equipment that has no essential performance		N/A
5.2.2.8	Requirements applicable to large permanently installed equipment and systems		N/A
5.2.2.7	Requirements of cables and accessories		N/A
5.2.2.6	Equipment that includes RF transmitters		N/A
5.2.2.5	Equipment that intentionally receive RF energy		N/A
5.2.2.4	Equipment that intentionally apply RF energy		N/A
d)	Table 7 shall be used for LIFE-SUPPORTING, Table 8 shall be used are not LIFE-SUPPORTING		N/A
c)	A specification of allowed emission of other equipment located within the shielded location		N/A
b)	Tables modified if disturbance allowance according in 6.1.1.1 d) is used		N/A
a)	A warning that equipment should be used only in the specified type of shielded location		N/A
5.2.2.3	Equipment specified for use only in shielded location	1	N/A
e)	If,according to 6.2 or the scope of the EMC basic standard not apply to,the corresponding entries shall state "not applicable"	Please refer to User manual	PASS
d)	Table 5 and Table 6,as applicable,shall be completed by calculating the distance corresponding to each entry in columns 2 through 5 in Table 5 or in columns 2 through 4 in Table 6	Please refer to User manual	PASS
c)	The expressions of Table 3 Table 4 and Table 5 Table 6,as applicable, shall be calculated,the results substituted in place of the COMPLIANCE LEVELS for IEC61000-4-6and IEC61000-4-3 test		N/A
b)	Table 3or Table 4,as applicable shall be filled in with the IMMUNITY COMPLIMENT LEVEL in accordance with the requirements of 5.2.2 and 6.2	Please refer to User manual	PASS
a)	ME EQUIPMENT or ME SYSTEM shall be replaced with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT or SYSTEM	Please refer to User manual	PASS

3.5. Statement of the measurement uncertainty

The data and results referenced in this document are true and accurate. The reader is cautioned that there may be errors within the calibration limits of the equipment and facilities. The measurement uncertainty was calculated for all measurements listed in this test report acc. to CISPR 16 - 4 "Specification for radio disturbance and immunity measuring apparatus and methods - Part 4: Uncertainty in EMC Measurements" and is documented in the Shenzhen Huatongwei International Inspection Co., Ltd quality system acc. to DIN EN ISO/IEC 17025. Furthermore, component and process variability of devices similar to that tested may result in additional deviation. The manufacturer has the sole responsibility of continued compliance of the device.

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Hereafter the best measurement capability for Shenzhen Huatongwei laboratory is reported:

Test	Range	Measurement Uncertainty	Notes
Radiated Emission	30~1000MHz	4.65dB	(1)
Conducted Disturbance	0.15~30MHz	3.42dB	(1)

⁽¹⁾ This uncertainty represents an expanded uncertainty expressed at approximately the 95% confidence level using a coverage factor of k=2.

3.6. Equipments Used during the Test

Radia	Radiated Emission					
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.	
1	ULTRA-BROADBAND ANTENNA	ROHDE & SCHWARZ	HL562	100015	2012/06	
2	EMI TEST RECEIVER	ROHDE & SCHWARZ	ESI 26	100009	2012/10	
3	RF TEST PANEL	ROHDE & SCHWARZ	TS / RSP	335015/ 0017	2012/10	
4	TURNTABLE	ETS	2088	2149	2012/10	
5	ANTENNA MAST	ETS	2075	2346	2012/10	
6	EMI TEST SOFTWARE	ROHDE & SCHWARZ	ESK1	N/A	2012/10	

Cond	Conducted Disturbance				
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.
1	EMI Test Receiver	ROHDE & SCHWARZ	ESCS30	100038	2012/10
2	Artificial Mains	ROHDE & SCHWARZ	ESH3-Z5	100049	2012/10
3	Pulse Limiter	ROHDE & SCHWARZ	ESH3-Z2	100044	2012/10
4	EMI TEST SOFTWARE	ROHDE & SCHWARZ	ESK1	N/A	2012/10

Harm	Harmonic Current								
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.				
1	Purified Power Source	CALIFORNIA INSTRUMENTS	HFS500	54513	2012/10				
2	Harmonic And Flicker Analyzer	EM TEST	DPA503S1	0500-10	2012/10				

Voltage Fluctuation and Flicker								
Item	n Test Equipment Manufacturer Model No. Serial No. Last Cal.							
1	Purified Power Source	CALIFORNIA INSTRUMENTS	HFS500	54513	2012/10			
2	Harmonic And Flicker Analyzer	EM TEST	DPA503S1	0500-10	2012/10			

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Electr	Electrostatic Discharge								
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.				
1	ESD Simulator	EM TEST	DITOC0103Z	0301-04	2012/10				

RF Field Strength Susceptibility								
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.			
1	SIGNAL GENERATOR	IFR	2032	203002/100	2012/10			
2	AMPLIFIER	AR	150W1000	301584	2012/10			
3	DUAL DIRECTIONAL COUPLER	AR	DC6080	301508	2012/10			
4	POWER HEAD	AR	PH2000	301193	2012/10			
5	POWER METER	AR	PM2002	302799	2012/10			
6	TRANSMITTING AERIAL	AR	AT1080	28570	2012/10			
7	POWER AMPLIFIER	AR	25S1G4A	0325511	2012/10			
8	DUAL DIRECTIONAL COUPLER	AR	DC7144A	0325100	2012/10			
9	TRANSMITTING AERIAL	AR	AT4002A	0324848	2012/10			

Electr	Electrical Fast Transient/Burst								
Item	Item Test Equipment Manufacturer Model No. Serial No. Last Cal.								
1	Ultra Compact Simulator	EM TEST	UCS500M6	0500-19	2012/10				

Surge								
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.			
1	ULTRA COMPACT SIMULATOR	EM TEST	UCS500M6	0500-19	2012/10			

Cond	Conducted Susceptibility									
Item	Test Equipment Manufacturer Model No. Serial No. La									
1	Signal Generator	IFR	2023A	202304/060	2012/10					
2	Amplifier	AR	75A250	302205	2012/10					
3	Dual Directional Coupler	AR	DC2600	302389	2012/10					
4	6db Attenuator	EMTEST	ATT6/75	0010230A	2012/10					
5	CDN	EMTEST	CDN M3	0802-03	2012/10					
6	EM CLAMP	LÜTHI	EM101	335625	2012/10					

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Power Frequency Magnetic Field Susceptibility									
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.				
1	ULTRA COMPACT SIMULATOR	EM TEST	UCS500M6	202304/060	2012/10				
2	MOTOR DRIVEN VOLTAGE TRANSFORMER	EM TEST	MV2616	302205	2012/10				
3	CURRENT TRANSFORMER	EM TEST	MC2630	302389	2012/10				
4	MAGNETIC COIL	EM TEST	MS100	0010230A	2012/10				

Voltage Dips and Interruptions								
Item	Test Equipment Manufacturer Model No. Serial No. Last Ca							
1	Ultra Compact Simulator	EM TEST	UCS500M6	0500-19	2012/10			
2	Motor Driven Voltage Transformer	EM TEST	MV2616	0301-11	2012/10			

4. TEST CONDITIONS AND RESULTS

4.1. Radiated Emission

For test instruments and accessories used see section 3.6.

4.1.1. Description of the test location

Test location: Shielded room No. 4

4.1.2. Limits of disturbance (Class B)

Frequency (MHz)	Distance (Meters)	Field Strengths Limits (dBμV/m)
30 ~ 230	3	40
230 ~ 1000	3	47

Note: (1) The tighter limit shall apply at the edge between two frequency bands.

(2) Distance refers to the distance in meters between the test instrument antenna and the closest point of any part of the E.U.T.

4.1.3. Description of the test set-up

4.1.3.1. Operating Condition

The EUT is turned on during the test, and the maximum emanating results are recorded.

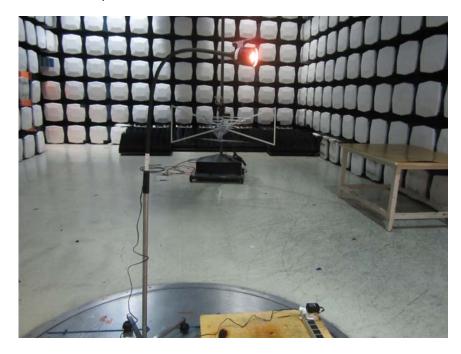
4.1.3.2. Test Configuration and Procedure

EUT is tested in Semi-Anechoic Chamber. EUT is placed on a nonmetal table which is 0.8 meter above a grounded turntable. The turntable can rotate 360 degrees to determine the azimuth of the maximum emission level. EUT is set 3 meters away from the center of receiving antenna. The antenna can move up and down from 1 to 4 meter to find out the maximum emission level. Both horizontal and vertical polarizations of the antenna are set on the test.

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4.1.3.3. Photos of the test set-up



4.1.4. Test result

The requirements are Fulfilled

Band Width: 120kHz

Frequency Range: 30MHz to 1000MHz

Remarks: The limits are kept. For detailed results, please see the following page(s).

Margin=limit-level

Level=read valus+transducer

Transducer=antenna factor+pre-amplifier factor+cable loss

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SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION CO., LTD

RADIATED EMISSION TEST CISPR 11 CLASS B

Halogen medical practice light M/N:10.11000.002

KIRCHNER&WILHELM GmbH+Co.KG Manufacturer:

Operating Condition: ON

3M CHAMBER Test Site:

Operator: JACK

Test Specification: AC 230V/50Hz

Comment:

9/5/2012 / 2:39:42PM Start of Test:

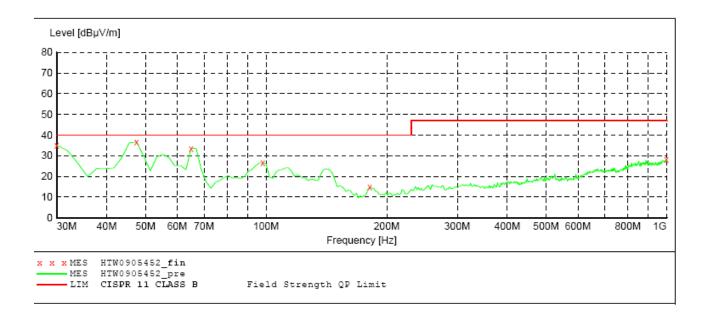
SCAN TABLE: "test Field(30M-1G)QP"

Field Strength(30M-1G) Short Description:

IF Stop Step Start Detector Meas. Transducer

Time Bandw.

Frequency Frequency Width 30.0 MHz 1.0 GHz 60.0 } 120 kHz HL562 60.0 kHz QuasiPeak 1.0 s



MEASUREMENT RESULT: "HTW0905452 fin"

9/5/2012 2:51	.PM							
Frequency MHz	Level dBµV/m	Transd dB	Limit dBµV/m	Margin dB	Det.	Height cm	Azimuth deg	Polarization
30.000000	35.10	-11.1	40.0	4.9	QP	100.0	188.00	VERTICAL
47.490000	36.60	-20.9	40.0	3.4	QP	100.0	25.00	VERTICAL
64.980000	33.60	-23.8	40.0	6.4	QP	100.0	173.00	VERTICAL
98.030000	26.60	-19.9	40.0	13.4	QP	100.0	276.00	VERTICAL
181.620000	14.90	-22.2	40.0	25.1	QP	100.0	247.00	VERTICAL
998.050000	28.30	-5.7	47.0	18.7	OP	100.0	350.00	VERTICAL

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SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION CO., LTD

RADIATED EMISSION TEST CISPR 11 CLASS B

Halogen medical practice light M/N:10.11000.002

KIRCHNER&WILHELM GmbH+Co.KG Manufacturer:

Operating Condition: ON

Test Site: 3M CHAMBER Operator: JACK

Test Specification: AC 230V/50Hz

Comment:

9/5/2012 / 2:51:52PM Start of Test:

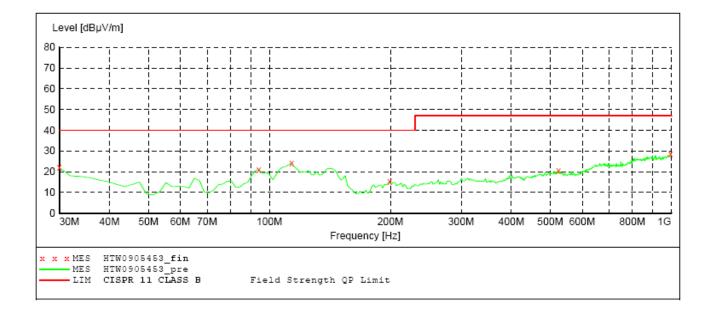
SCAN TABLE: "test Field(30M-1G)QP"

Field Strength (30M-1G) Short Description:

Field Strongen,
Detector Meas. IF
mime Bandw. Start Stop Step Transducer

Frequency Frequency Width

30.0 MHz 1.0 GHz 60.0 kHz QuasiPeak 1.0 s 120 kHz HL562



MEASUREMENT RESULT: "HTW0905453 fin"

9/5/2012 3:03 Frequency MHz	PM Level dBµV/m	Transd dB	Limit dBµV/m	Margin dB	Det.	Height cm	Azimuth deg	Polarization
30.000000	22.00	-11.1	40.0	18.0	QP	100.0	348.00	HORIZONTAL
94.140000	21.00	-20.2	40.0	19.0	QP	300.0	104.00	HORIZONTAL
113.580000	24.30	-19.5	40.0	15.7	QP	300.0	9.00	HORIZONTAL
199.110000	15.20	-21.5	40.0	24.8	QP	100.0	202.00	HORIZONTAL
523.740000	20.40	-13.0	47.0	26.6	QP	300.0	312.00	HORIZONTAL
996.110000	28.70	-5.8	47.0	18.3	QP	300.0	357.00	HORIZONTAL

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4.2. Conducted disturbance

For test instruments and accessories used see section 3.6.

4.2.1. Description of the test location

Test location: Shielded room No. 2

4.2.2. Limits of disturbance

Limit of conducted disturbance at the mains ports(Class B)

Fraguency Banga (MHz)	Limits (dBuV)		
Frequency Range (MHz)	Quasi-Peak	Average	
0.150~0.500	66~56	56~46	
0.5000~5.000	56	46	
5.000~30.000	60	50	

Note: (1) The tighter limit shall apply at the edge between two frequency bands.

4.2.3. Description of the test set-up

4.2.3.1. Operating Condition

The EUT is turned on during the test, and the maximum emanating results are recorded.

4.2.3.2. Test Configuration and Procedure

EUT is placed on a nonmetal table above the grounded reference plane. Connect the power line of the EUT to the LISN which is connected to receiver by coaxial line, then disturbance of the neutral line and live line can be detected by the receiver.

4.2.3.3. Photo of the test set-up



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4.2.4. Test result

The requirements are Fulfilled

Band Width: 9kHz

Frequency Range: 150kHz to 30MHz

Remarks: The limits are kept. For detailed results, please see the following page(s).

Margin=limit-level

Level=read values+transducer

Transducer=insertion loss of LISN+cable loss+insertion loss of pulse limiter

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Shenzhen Huatongwei International Inspection CO., Ltd

Voltage Mains Test CISPR 11 CLASS B

Halogen medical practice light M/N:10.11000.002

Manufacturer: KIRCHNER&WILHELM GmbH+Co.KG

Operating Condition: ON

Test Site: 2# SHIELDED ROOM

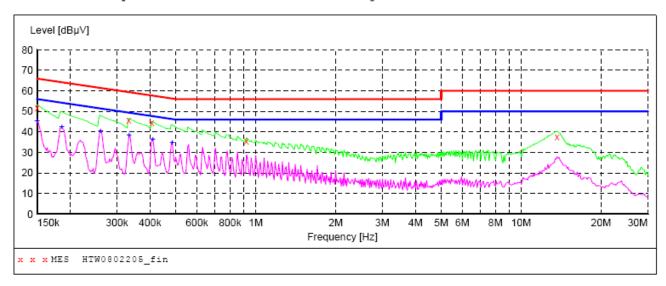
Operator: GENE

Test Specification: AC 230V/50Hz

Comment:

Start of Test: 8/2/2012 / 10:28:51AM

SCAN TABLE: "Voltage (9K-30M)FIN"
Short Description: 150K-30M 150K-30M Voltage



MEASUREMENT RESULT: "HTW0802205 fin"

8/2/2012	10:34AM	1						
Freque	ncy I MHz	dBµV		imit Ma dBµV	argin :	Detector	Line	PE
0.150	000 5	51.70	9.8	66	14.3	QP	N	GND
0.332	761 4	15.80	9.7	59	13.6	QP	N	GND
0.406	113 4	14.30	9.7	58	13.4	QP	N	GND
0.922	764 3	35.60	9.8	56	20.4	QP	N	GND
13.638	050 3	37.40	9.7	60	22.6	QP	N	GND

MEASUREMENT RESULT: "HTW0802205 fin2"

8/	2/2012 10:3 Frequency MHz		Transd dB	Limit dBµV	Margin dB	Detector	Line	PE
	0.150000	45.30	9.8	56	10.7	AV	N	GND
	0.185996	42.50	9.8	54	11.7	AV	N	GND
	0.259933	40.30	9.7	51	11.1	AV	N	GND
	0.332770	38.40	9.7	49	11.0	AV	N	GND
	0.409369	36.40	9.7	48	11.3	AV	N	GND
	0.483931	34.60	9.7	46	11.7	AV	N	GND

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Shenzhen Huatongwei International Inspection CO., Ltd

Voltage Mains Test CISPR 11 CLASS B

Halogen medical practice light M/N:10.11000.002

KIRCHNER&WILHELM GmbH+Co.KG Manufacturer:

Operating Condition: ON

Test Site: 2# SHIELDED ROOM

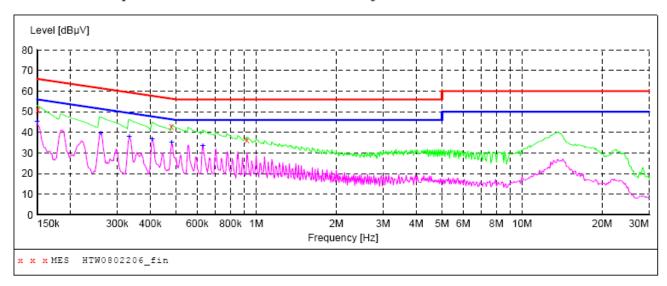
GENE Operator:

Test Specification: AC 230V/50Hz

Comment:

8/2/2012 / 10:35:40AM Start of Test:

SCAN TABLE: "Voltage (9K-30M)FIN"
Short Description: 150K-30M 150K-30M Voltage



MEASUREMENT RESULT: "HTW0802206 fin"

8/2/2012	10:4	0AM						
Freque	ency MHz	Level dBµV		Limit dBµV	Margin dB	Detector	Line	PE
0.151	1200	50.90	9.8	66	15.0	QP	L1	GND
0.480	0090	42.80	9.7	56	13.5	QP	L1	GND
0.922	2764	36.50	9.8	56	19.5	QP	L1	GND

MEASUREMENT RESULT: "HTW0802206 fin2"

8/2/2012	10:40AM						
Freque:	ncy Leve MHz dBp			Margin dB	Detector	Line	PE
0.150	000 45.2	20 9.8	56	10.8	AV	L1	GND
0.2599	933 39.8	30 9.7	51	11.6	AV	L1	GND
0.332	761 38.2	20 9.7	49	11.2	AV	L1	GND
0.406	113 36.6	50 9.7	48	11.1	AV	L1	GND
0.480	090 35.3	30 9.7	46	11.0	AV	L1	GND
0.629	486 33.4	10 9.8	46	12.6	AV	L1	GND

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4.3. Harmonic current

For test instruments and accessories used see section 3.6.

4.3.1. Description of the test location

Test location: Shielded room No. 2

4.3.2. Limits of harmonic current

Test configuration and procedure see clause 7.1 of standard IEC 61000-3-2: 2009.

4.3.3. Description of the test set-up

4.3.3.1. Operating Condition

The EUT is turned on during the test, and the results of the maximum emanation are recorded.

4.3.3.2. Photo of the test set-up



4.3.4. Test result

The requirements are **Fulfilled**

Remarks: The limits are kept. For detailed results, please see the following page(s). Report No.: TRE12070117 Page 22 of 44 Issued: 2012-09-11 Revised: 2012-12-04

Test Report of HTW

Standard used: EN/IEC 61000-3-2 Ed.3 Quasi-stationary

Equipment class A <= 150% of the limit

Observation time: 150s

Windows width: 10 periods - (EN/IEC 61000-4-7 Edition 2002 + A1:2008)

Customer: KIRCHNER & WILHELM GmbH + Co.KG

Mains supply voltage: AC 230V/50Hz

E. U. T.: Halogen medical practice light

M/N:10.11000.002

Date of test: 9:40 2.Aug 2012

Tester: LuoRin

Test Result

E. U. T.: PASS
Power Source: PASS

E. U. T. Result

Check harmonics 2..40 [exception odd 21..39]:

Harmonic(s) > 150%:

Order (n): None

Harmonic(s) with average > 100%:

Order (n): None

Check odd harmonics 21...39:

All Partial Odd Harmonics below partial limits.

Harmonic(s) > 150%:

Order (n): None

Harmonic(s) with average > 150%:

Order (n): None

Power Source Result

First dataset out of limit:

DS (time): None

Harmonic(s) out of limit:

Order (n): None

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Averag	ge harmonic cu	rrent results		
Hn	leff [A]	% of Limit	Limit [A]	Result
1	169.565E-3			
2	183.450E-6	0.017	1.08	PASS
3	13.237E-3	0.576	2.30	PASS
4	151.297E-6	0.035	430.00E-3	PASS
5	5.414E-3	0.475	1.14	PASS
6	168.495E-6	0.056	300.00E-3	PASS
7	10.106E-3	1.312	770.00E-3	PASS
8	156.537E-6	0.068	230.00E-3	PASS
9	5.296E-3	1.324	400.00E-3	PASS
10	137.620E-6	0.075	184.00E-3	PASS
11	4.339E-3	1.315	330.00E-3	PASS
12	145.092E-6	0.095	153.33E-3	PASS
13	2.348E-3	1.118	210.00E-3	PASS
14	213.034E-6	0.162	131.43E-3	PASS
15	1.485E-3	0.990	150.00E-3	PASS
16	148.940E-6	0.130	115.00E-3	PASS
17	1.767E-3	1.335	132.35E-3	PASS
18	154.558E-6	0.151	102.22E-3	PASS
19	2.587E-3	2.185	118.42E-3	PASS
20	175.486E-6	0.191	92.00E-3	PASS
21	2.390E-3	1.487	160.71E-3	PASS
22	157.220E-6	0.188	83.64E-3	PASS
23	1.450E-3	0.988	146.74E-3	PASS
24	151.090E-6	0.197	76.66E-3	PASS
25	750.000E-6	0.556	135.00E-3	PASS
26	148.297E-6	0.210	70.77E-3	PASS
27	1.173E-3	0.939	124.99E-3	PASS
28	144.879E-6	0.220	65.71E-3	PASS
29	1.630E-3	1.401	116.39E-3	PASS
30	143.810E-6	0.234	61.33E-3	PASS
31	1.519E-3	1.395	108.87E-3	PASS
32	142.228E-6	0.247	57.50E-3	PASS
33	1.241E-3	1.214	102.27E-3	PASS
34	164.851E-6	0.305	54.12E-3	PASS
35	604.026E-6	0.626	96.44E-3	PASS
36	141.491E-6	0.277	51.11E-3	PASS
37	628.215E-6	0.689	91.21E-3	PASS
38	144.745E-6	0.299	48.42E-3	PASS
39	910.350E-6	1.052	86.53E-3	PASS
40	161.920E-6	0.352	46.00E-3	PASS

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Maxim	um harmonic d	current results		
Hn	leff [A]	% of Limit	Limit [A]	Result
1	2.043E-3			
2	213.742E-6	0.013	1.62	PASS
3	490.989E-6	0.014	3.45	PASS
4	241.660E-6	0.037	645.00E-3	PASS
5	408.170E-6	0.024	1.71	PASS
6	249.783E-6	0.056	450.00E-3	PASS
7	586.277E-6	0.051	1.15	PASS
8	257.046E-6	0.075	345.00E-3	PASS
9	391.867E-6	0.065	600.00E-3	PASS
10	275.475E-6	0.100	276.00E-3	PASS
11	238.079E-6	0.048	495.00E-3	PASS
12	238.300E-6	0.104	229.99E-3	PASS
13	283.391E-6	0.090	315.00E-3	PASS
14	215.653E-6	0.109	197.15E-3	PASS
15	183.349E-6	0.081	225.00E-3	PASS
16	226.322E-6	0.131	172.50E-3	PASS
17	179.358E-6	0.090	198.52E-3	PASS
18	171.506E-6	0.112	153.33E-3	PASS
19	189.648E-6	0.107	177.63E-3	PASS
20	198.708E-6	0.144	138.00E-3	PASS
21	173.473E-6	0.108	160.71E-3	PASS
22	150.600E-6	0.120	125.46E-3	PASS
23	181.449E-6	0.124	146.74E-3	PASS
24	164.900E-6	0.143	114.99E-3	PASS
25	150.315E-6	0.111	135.00E-3	PASS
26	167.012E-6	0.157	106.16E-3	PASS
27	171.347E-6	0.137	124.99E-3	PASS
28	158.650E-6	0.161	98.57E-3	PASS
29	145.993E-6	0.125	116.39E-3	PASS
30	164.366E-6	0.179	92.00E-3	PASS
31	157.256E-6	0.144	108.87E-3	PASS
32	138.299E-6	0.160	86.25E-3	PASS
33	153.242E-6	0.150	102.27E-3	PASS
34	162.770E-6	0.201	81.18E-3	PASS
35	157.105E-6	0.163	96.44E-3	PASS
36	145.772E-6	0.190	76.66E-3	PASS
37	152.099E-6	0.167	91.21E-3	PASS
38	148.330E-6	0.204	72.63E-3	PASS
39	162.281E-6	0.188	86.53E-3	PASS
40	168.545E-6	0.244	69.00E-3	PASS

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Maxim	um harmonic v	oltage results		
Hn	Ueff [V]	Ueff [%]	Limit [%]	Result
1	230.27	100.118		
2	149.57E-3	0.065	0.2	PASS
3 4	416.80E-3	0.181	0.9	PASS
4	48.53E-3	0.021	0.2	PASS
5	29.45E-3	0.013	0.4	PASS
6	42.50E-3	0.018	0.2	PASS
7	21.41E-3	0.009	0.3	PASS
8	24.22E-3	0.011	0.2	PASS
9	19.21E-3	0.008	0.2	PASS
10	23.44E-3	0.010	0.2	PASS
11	14.20E-3	0.006	0.1	PASS
12	17.02E-3	0.007	0.1	PASS
13	15.49E-3	0.007	0.1	PASS
14	17.37E-3	0.008	0.1	PASS
15	10.05E-3	0.004	0.1	PASS
16	16.04E-3	0.007	0.1	PASS
17	17.02E-3	0.007	0.1	PASS
18	15.39E-3	0.007	0.1	PASS
19	12.46E-3	0.005	0.1	PASS
20	16.98E-3	0.007	0.1	PASS
21	12.35E-3	0.005	0.1	PASS
22	14.84E-3	0.006	0.1	PASS
23	8.39E-3	0.004	0.1	PASS
24	11.44E-3	0.005	0.1	PASS
25	12.97E-3	0.006	0.1	PASS
26	14.98E-3	0.007	0.1	PASS
27	8.95E-3	0.004	0.1	PASS
28	9.44E-3	0.004	0.1	PASS
29	9.52E-3	0.004	0.1	PASS
30	14.93E-3	0.006	0.1	PASS
31	8.07E-3	0.004	0.1	PASS
32	10.24E-3	0.004	0.1	PASS
33	10.75E-3	0.005	0.1	PASS
34	11.35E-3	0.005	0.1	PASS
35	7.93E-3	0.003	0.1	PASS
36	11.59E-3	0.005	0.1	PASS
37	10.19E-3	0.004	0.1	PASS
38	8.31E-3	0.004	0.1	PASS
39	8.20E-3	0.004	0.1	PASS
40	11.11E-3	0.005	0.1	PASS

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4.4. Voltage Fluctuation and Flicker

For test instruments and accessories used see section 3.6.

4.4.1. Description of the test location

Test location: Shielded room No. 2

4.4.2. Limits of voltage fluctuation and flicker

Test configuration and procedure see clause 5 of standard IEC 61000-3-3: 2008.

4.4.3. Description of the test set-up

4.4.3.1. Operating Condition

The EUT is turned on during the test, and the results of the maximum emanation are recorded.

4.4.3.2. Photo of the test set-up



4.4.4. Test result

The requirements are Fulfilled

Remarks: The limits are kept. For detailed results, please see the following page(s).

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Test Report of HTW

Standard used: EN/IEC 61000-3-3 Flicker

Short time (Pst): 10 min

Observation time: 120 min (12 Flicker measurement)

Customer: KIRCHNER & WILHELM GmbH + Co.KG

Flickermeter: AC 230V/50Hz

Ambient Temperature: 23° C Humidity: 51%

Barometric Pressure: 1017mbar

E. U. T.: Halogen medical practice light

M/N: 10.11000.002

Date of test: 9:48 2.Aug 2012

Tester: LuoRin

Test Result	PASS
Test Result	PASS

Maximum Flicker results

	EUT values	Limit	Result
Pst	0.028	1.00	PASS
Plt	0.028	0.65	PASS
dc [%]	0.000	3.30	PASS
dmax [%]	0.092	4.00	PASS
dt [s]	0.000	0.50	PASS

Detail Flicker data

Flicker measurement 1	EUT values	Limit	Result
Pst	0.028	1.00	PASS
dc [%]	0.000	3.30	PASS
dmax [%]	0.092	4.00	PASS
dt [s]	0.000	0.50	PASS

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Flicker measurement 2	EUT values	Limit	Result
Pst	0.028	1.00	PASS
dc [%]	0.000	3.30	PASS
dmax [%]	0.075	4.00	PASS
dt [s]	0.000	0.50	PASS

Flicker measurement 3	EUT values	Limit	Result
Pst	0.028	1.00	PASS
dc [%]	0.000	3.30	PASS
dmax [%]	0.073	4.00	PASS
dt [s]	0.000	0.50	PASS

Flicker measurement 4	EUT values	Limit	Result
Pst	0.028	1.00	PASS
dc [%]	0.000	3.30	PASS
dmax [%]	0.072	4.00	PASS
dt [s]	0.000	0.50	PASS

Flicker measurement 5	EUT values	Limit	Result
Pst	0.028	1.00	PASS
dc [%]	0.000	3.30	PASS
dmax [%]	0.073	4.00	PASS
dt [s]	0.000	0.50	PASS

Flicker measurement 6	EUT values	Limit	Result
Pst	0.028	1.00	PASS
dc [%]	0.000	3.30	PASS
dmax [%]	0.073	4.00	PASS
dt [s]	0.000	0.50	PASS

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Flicker measurement 7	EUT values	Limit	Result
Pst	0.028	1.00	PASS
dc [%]	0.000	3.30	PASS
dmax [%]	0.074	4.00	PASS
dt [s]	0.000	0.50	PASS

Flicker measurement 8	EUT values	Limit	Result
Pst	0.028	1.00	PASS
dc [%]	0.000	3.30	PASS
dmax [%]	0.072	4.00	PASS
dt [s]	0.000	0.50	PASS

Flicker measurement 9	EUT values	Limit	Result
Pst	0.028	1.00	PASS
dc [%]	0.000	3.30	PASS
dmax [%]	0.069	4.00	PASS
dt [s]	0.000	0.50	PASS

Flicker measurement 10	EUT values	Limit	Result
Pst	0.028	1.00	PASS
dc [%]	0.000	3.30	PASS
dmax [%]	0.073	4.00	PASS
dt [s]	0.000	0.50	PASS

Flicker measurement 11	EUT values	Limit	Result
Pst	0.028	1.00	PASS
dc [%]	0.000	3.30	PASS
dmax [%]	0.069	4.00	PASS
dt [s]	0.000	0.50	PASS

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Flicker measurement 12	EUT values	Limit	Result
Pst	0.028	1.00	PASS
dc [%]	0.000	3.30	PASS
dmax [%]	0.065	4.00	PASS
dt [s]	0.000	0.50	PASS

4.5. Electrostatic discharge

For test instruments and accessories used see section 3.6.

4.5.1. Description of the test location and date

Test location: Shielded room No. 1

Date of test: Aug 3, 2012

Operator: LuoRin

4.5.2. Severity levels of electrostatic discharge

Level	Test Voltage	Test Voltage
	Contact Discharge (KV)	Air Discharge (KV)
1	2	2
2	4	4
3	6	8
4	8	15
Х	Special	Special

Note: equipment and systems shall comply with the requirements of 6.2.2 of IEC 60601-1-2: 2007 at immunity test levels of \pm 2KV, \pm 4KV and \pm 8KV for air discharge and \pm 2KV, \pm 4KV and \pm 6KV for contact discharge.

4.5.3. Description of the test set-up

4.5.3.1. Operating Condition

The EUT is turned on during the test, and the results of the maximum susceptive results are recorded.

4.5.3.2. Test Configuration and Procedure:

Air Discharge:

—This test is done on a non-conductive surfaces. The round discharge tip of the Electrostatic Discharge simulator shall be approached as fast as possible then to touch the EUT. After each discharge, the simulator shall be removed from the EUT. The simulator is then re-triggered for a new single discharge and repeated 25 times for each pre-selected test point. This procedure shall be repeated until all the air discharge completed

Contact Discharge:

—All the procedure shall be same as air discharge, except using the acute discharge tip. The top end of the Electrostatic Discharge simulator is touch the EUT all the time when the simulator is re-triggered for a new single discharge and repeated 10 times for each pre-selected test point. Report No.: TRE12070117 Page 31 of 44 Issued: 2012-09-11 Revised: 2012-12-04

Indirect Discharge:

- —The vertical coupling plane(VCP) is placed 0.1m away from EUT. The top end of Electrostatic Discharge simulator should aim at the center of one border of the VCP for at least 10 times discharge.
- —The top end of Electrostatic Discharge simulator should place at the point 0.1m away from EUT on the horizontal coupling plane(HCP). At least 25 times discharge should be done for every pre-selected point around EUT.

Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.

4.5.3.3. Photo of the test set-up



4.5.4. Test specification:

Contact discharge voltage:	■ 2 kV	■ 4 kV	■ 6 kV	
Number of discharges:	1 0	□ 25		
Air discharge voltage:	■ 2 kV	■ 4 kV	■ 8 kV	
Number of discharges:	□ 10	2 5		
Type of discharge:	Direct discharge		Air discharge Contact discharge	
Polarity:	Indirect discharge ■ Positive		Contact dischargeContact dischargeNegative	
Discharge location:	see photo documentation of the test set-up			
	all external	locations acc	essible by hand	
	☐ horizontal o	oupling plane	(HCP)	
	■ vertical cou	pling plane (\	/CP)	

4.5.5. Test result

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4.6. Radiated, radio-frequency, electromagnetic field

For test instruments and accessories used see section 3.6.

4.6.1. Description of the test location and date

Test location: Shielded room No. 4

Date of test: Aug 2, 2012

Operator: LuoRin

4.6.2. Severity levels of radiated, radio-frequency, electromagnetic field

Level	Field Strength (V/m)
1.	1
2.	3
3.	10
Х	Special

Note: equipment and systems shall comply with the requirements of 6.2.3 of IEC 60601-1-2: 2007 at immunity test levels of 3V/m.

4.6.3. Description of the test set-up

4.6.3.1. Operating Condition

The EUT is turned on during the test, and the results of the maximum susceptive results are recorded.

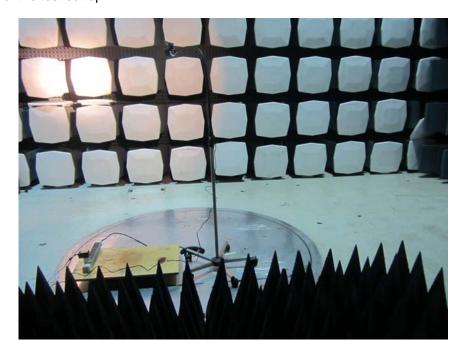
4.6.3.2. Test Procedure

EUT and its auxiliary instrument are placed on a turntable above ground. Transmitting antenna mounted on an antenna mast is set 3 meter away from the EUT. During the test, each of the four sides of EUT will face the transmitting antenna with the turntable cycled. Both horizontal and vertical polarization of the antenna are set on test and measured individually.

In order to judge the performance of the EUT, a set of monitor system is used.

Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.

4.6.3.3. Photo of the test set-up



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4.6.4. Test specification:

Frequency range: ■ 80 MHz to 2500 MHz

<u>Field strength:</u> ■ 3V/m

EUT - antenna separation: ■ 3 m

Modulation: ■ AM: 80 %

■ sinusoidal 1 KHz

Frequency step: ■ 1 % with 3 s dwell time

Antenna polarisation: ■ horizontal ■ vertical

4.6.5. Test result

No degradation of function. Comply with IEC 60601-1-2:2007

4.7. Electrical fast transients / Burst

For test instruments and accessories used see section 3.6.

4.7.1. Description of the test location and date

Test location: Shielded room No. 1

Date of test: Aug 2, 2012

Operator: LuoRin

4.7.2. Severity levels of electrical fast transients / Burst

Open circui	Open circuit output test voltage and repetition rate of the impulses			
Level	On power port, PE			
Level	V peak(KV)	Repetition Frequency (KHz)		
1.	0.5	5 or 100		
2.	1	5 or 100		
3.	2	5 or 100		
4.	4	5 or 100		
X	Special	Special		

Note: equipment and systems shall comply with the requirements of 6.2.4 of IEC 60601-1-2: 2007 at immunity test levels of \pm 2kV for a.c. power lines.

4.7.3. Description of the test set-up

4.7.3.1. Operating Condition

The EUT is turned on during the test, and the results of the maximum susceptive results are recorded.

4.7.3.2. Test Requirements

EUT and its simulators shall be placed above the ground reference plane which is a minimum 1m*1m with minimum 0.65mm thickness. This reference ground plane shall project beyond the EUT by at least 0.1m on all sides and the minimum distance between EUT and all other conductive structure, except the ground plane beneath the EUT, shall be more than 0.5m.

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4.7.3.3. Test Configuration and Procedure

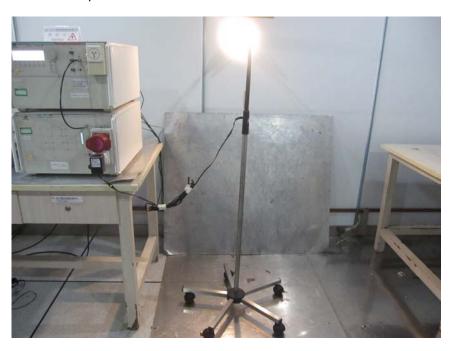
For AC power input ports:

EUT is connected to coupling/decoupling network which couples the EFT signal to power input lines. During the test, both positive and negative polarities of the test voltage should be applied and the duration of the test can't be less than 1mins.

The EUT is unnecessary to test on these signal / control lines.

Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.

4.7.3.4. Photo of the test set-up



4.7.4. Test specification:

Coupling network: ■ 0.5 kV ■ 1 kV ■ 2 kV

Coupling clamp: □ 0.5 kV □ 1 kV

■ 5.0 kHz Burst frequency:

Coupling duration: ■ 60 s

Polarity: positive negative

4.7.5. Coupling points

Cable description: AC power line: L, N, L-N, PE, L-PE, N-PE, L-N-PE

Screening: o screened

o detachable

unscreened ■ undetachable

Signal transmission:

o digital

Length:

Status:

■ 4.1 m

analogue

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4.7.6. Test result

No degradation of function. Comply with IEC 60601-1-2: 2007

4.8. Surge

For test instruments and accessories used see section 3.6.

4.8.1. Description of the test location and date

Test location: Test location No. 1

Date of test: Sep 6, 2012

Operator: LuoRin

4.8.2. Severity levels of surge

Level	Test Voltage (KV)
1	0.5
2	1.0
3	2.0
4	4.0
*	Special

Note: equipment and systems shall comply with the requirements of 6.2.5 of IEC 60601-1-2: 2007 at immunity test levels of \pm 0.5KV, \pm 1KV and \pm 2KV for a.c. power line(s) to earth and \pm 0.5KV and \pm 1KV for a.c. power line(s) to line(s).

4.8.3. Description of the test set-up

4.8.3.1. Operating Condition

The EUT is turned on during the test, and the results of the maximum susceptive results are recorded.

4.8.3.2. Test Configuration and Procedure

In this test, the 1.2/50us& 8/20us surge generator must be used for AC power ports. The voltage for line to earth coupling mode is twice of that for line to line. At least 5 positive and 5 negative (polarity) surge signal with a maximum 1/min repetition rate are injected to AC power lines from 4 different phase angles (0°, 90°, 180°, 270°) during the test.

Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.

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4.8.3.3. Photo of the test set-up



4.8.4. Test specification:

Pulse amplitude-Power line sym.: ■ 0.5 kV ■ 1 kV \square 2 kV □ 4 kV Source impedance: $2 \Omega + 18 \mu F$ Pulse amplitude-Power line unsym: ■ 0.5 kV ■ 1 kV ■ 2 kV □ 4 kV Source impedance: $12 \Omega + 9 \mu F$ ■ 5 Surges/Phase angle Number of surges: ■ 0° ■ 90° Phase angle: ■ 180° ■ 270°

Repetition rate: ■ 60 s

<u>Polarity:</u> ■ positive ■ negative

4.8.5. Coupling points

Cable description: AC power line: L-N, L-PE, N-PE

Screening:o screened■ unscreenedStatus:o detachable■ undetachableSignal transmission:■ analogueo digitalLength:■ 4.1 m

4.8.6. Test result

No degradation of function. Comply with IEC 60601-1-2: 2007

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4.9. Conducted disturbances induced by radio-frequency fields

For test instruments and accessories used see section 3.6.

4.9.1. Description of the test location and date

Test location: Shielded room No. 2

Date of test: Aug 02, 2012

Operator: LuoRin

4.9.2. Severity levels of conducted disturbances induced by radio-frequency fields discharge

Level	Field Strength (V)
1.	1
2.	3
3.	10
Х	Special

Note: equipment and systems shall comply with the requirements of 6.2.6 of IEC 60601-1-2: 2007 at immunity test levels of 3Vrms over the frequency range beginning at the start frequency and extending to 80 MHz.

4.9.3. Description of the test set-up

4.9.3.1. Operating Condition

The EUT is turned on during the test, and the results of the maximum susceptive results are recorded.

4.9.3.2. Test Configuration and Procedure

For AC power input lines:

—EUT is placed on an insulating support above a ground reference plane. It must be 0.3m away the CDN (coupling and decoupling network) of which the bottom is made of metallic material and placed directly on the ground plane. Cables between CDN and EUT are as short as possible, and their height above the ground reference plane shall be between 30 and 50 mm (where possible). The disturbance signal amplified by amplifier is injected to EUT through CDN.

For Signal Line and Control Line:

—EUT is placed on an insulating support above a ground reference plane. The EM clamp is directly placed on the ground reference plane with its metallic bottom contacting the plane. Cables between EUT and auxiliary equipment are put through the EM clamp. The disturbance signal amplified by amplifier is injected to EUT through EM clamp.

Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.

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4.9.3.3. Photo of the test set-up



4.9.4. Test specification:

Frequency range: ■ 0.15 MHz to 80 MHz

<u>Test voltage</u>: ■ 3 V

Modulation: ■ AM: 80 % ■ sinusoidal 1 kHz

Frequency step: ■ 1 % with 3 s dwell time

4.9.5. Coupling points

Cable description : AC power line

Screening:o screened■ unscreenedStatus:o detachable■ undetachableSignal transmission:■ analogueo digital

Length: ■ 4.1 m

4.9.6. Test result

No degradation of function comply with IEC 60601-1-2: 2007.

4.10. Magnetic Field Immunity

For test instruments and accessories used see section 3.6.

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4.10.1. Description of the test location and date

Test location: Shielded room No. 1

Date of test: Aug 02, 2012

Operator: LuoRin

4.10.2. Severity levels of magnetic field immunity

Level	Magnetic Field Strength (A/m)	
1	1	
2	3	
3	10	
4	30	
5	100	
X.	Special	

Note: equipment and systems shall comply with the requirements of 6.2.8 of IEC 60601-1-2: 2007 at immunity test levels of 3A /m.

4.10.3. Description of the test set-up

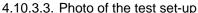
4.10.3.1. Operating Condition

The EUT is turned on during the test, and the results of the maximum susceptive results are recorded.

4.10.3.2. Test Configuration and Procedure:

EUT is placed on an insulating support of 0.1m high above a table of 0.8m high. There is a minimum 1m*1m ground metallic plane put on this table. EUT is put in the center of the magnetic coil then three orientations of the magnetic coil, X, Y and Z, shall be rotated in order to expose the EUT to the difference polarization magnetic field.

Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.





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4.10.4. Test specification:

Test frequency: ■ 50 Hz ■ 60 Hz

Continuous field: ■ 3 A/m

Test duration: ■ 5 minis

Antenna factor: 0.917 A/m

<u>Axis:</u> ■ x-axis ■ y-axis ■ z-axis

4.10.5. Test result

No degradation of function. Comply with IEC 60601-1-2: 2007.

4.11. Voltage Dips and Interruptions

For test instruments and accessories used see section 3.6.

4.11.1. Description of the test location and date

Test location: Test location No. 1

Date of test: Aug 02, 2012

Operator: LuoRin

4.11.2. Severity levels of voltage dips and interruptions

Test Level for Voltage Dips			
Test Level (%Ut)	Voltage Dip And Short Interruptions (%Ut)	Duration (In Period)	
<5	>95	0.5	
40	60	5	
70	30	25	

Test Level for Voltage Interruption			
Test Level (%Ut)	Voltage Dip And Short Interruptions (%Ut)	Duration (In Period)	
<5	>95	250	

4.11.3. Description of the test set-up

4.11.3.1. Operating Condition

The EUT is turned on during the test, and the results of the maximum susceptive results are recorded.

4.11.3.2. Test Configuration and Procedure

EUT is connected to the simulator according to the test photo. When conducting this test ,the power supply shall be set at the minimum and maximum rated input voltages and test voltage changes shall be step changes and start at the phase angle of 0° and 180° .

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4.11.3.3. Photo of the test set-up



4.11.4. Test specification:

Nominal Mains Voltage (V_N): ■ 230 V AC

Number of voltage fluctuations: ■ 3

<u>Level of reduction(dip) / duration:</u> ■ 100 % / 10ms ■ 60 % / 100ms ■ 30 % / 500ms

Nominal Mains Voltage (V_N): ■ 230 V AC

Number of Interruptions: ■ 3

<u>Duration of the Interruption:</u> ■ 5000 ms

4.11.5. Test result

No degradation of function. Comply with IEC 60601-1-2: 2007

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5. External and Internal Photos of the EUT

5.1. External photos of the EUT





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5.2. Internal photos of the EUT



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