



**Shenzhen Huatongwei International Inspection Co., Ltd.**

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

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## TEST REPORT

**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**

**Report Reference No.**..... : **TRE12070117 R/C62675**

Compiled by

( position+printed name+signature)..: File administrators Vivi Zhou

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Approved by

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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.**.....: HTWEMCCE\_1A

TRF Originator .....: Shenzhen Huatongwei International Inspection Co., Ltd.

Master TRF.....: Dated 2006-06

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**Test item description** .....: Halogen medical practice light

Trade Mark .....: /

Manufacturer .....: KIRCHNER & WILHELM GmbH + Co. KG

Model/Type reference.....: 10.11000.002

Listed models .....: -

Ratings .....: 220V-240Va.c, 50 Hz, 0.5A ; Output 12Va.c., 5.0A Max;  
Main Device: 12Va.c., 50W MAX.

Result.....: **Positive**

**EMC -- TEST REPORT**

<b>Test Report No. :</b>	<b>TRE12070117</b>	Sep 11, 2012
		Date of issue

Equipment under Test : Halogen medical practice light

Model /Type : 10.11000.002

Listed Models : -

**Applicant** : KIRCHNER & WILHELM GmbH + Co. KG

Address : Eberhardstr. 56 71679 Asperg

**Manufacturer** : KIRCHNER & WILHELM GmbH + Co. KG

Address : Eberhardstr. 56 71679 Asperg

<b>Test Result</b> according to the standards on page 4:	<b>Positive</b>
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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**

[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

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.

### 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 susceptibility.
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.

## 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.

**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:

Temperature:	<u>15-35 ° C</u>
Humidity:	<u>25-75 %</u>
Atmospheric pressure:	<u>950-1050mbar</u>

### 3.4. Test Description

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

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

The measurement uncertainty is not included in the test result.

IEC 60601-1-2:2007			
Clause	Requirement + Test	Result - Remark	Verdict
<b>5</b>	<b>IDENTIFICATION, MARKING AND DOCUMENTS</b>		PASS
<b>5.1</b>	<b>Marking on the outside of ME EQUIPMENT OR ME EQUIPMENT parts</b>		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
<b>5.2</b>	<b>ACCOMPANYING DOCUMENTS</b>		PASS
5.2.1	Instructions for use		PASS
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 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 location		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

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
b)	Table 3 or 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
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 IEC61000-4-6 and IEC61000-4-3 test		N/A
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
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
5.2.2.3	Equipment specified for use only in shielded location		N/A
a)	A warning that equipment should be used only in the specified type of shielded location		N/A
b)	Tables modified if disturbance allowance according in 6.1.1.1 d) is used		N/A
c)	A specification of allowed emission of other equipment located within the shielded location		N/A
d)	Table 7 shall be used for LIFE-SUPPORTING, Table 8 shall be used are not LIFE-SUPPORTING		N/A
5.2.2.4	Equipment that intentionally apply RF energy		N/A
5.2.2.5	Equipment that intentionally receive RF energy		N/A
5.2.2.6	Equipment that includes RF transmitters		N/A
5.2.2.7	Requirements of cables and accessories		N/A
5.2.2.8	Requirements applicable to large permanently installed equipment and systems		N/A
5.2.2.9	Requirements applicable to equipment that has no essential performance		N/A
5.2.2.10	Requirements applicable to TYPE A PROFESSIONAL SYSTEMS		N/A
6	<b>ELECTROMAGNETIC COMPATIBILITY</b>	(see appended table)	

### 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.

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

Radiated Emission					
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.
1	ULTRA-BROADBAND ANTENNA	ROHDE & SCHWARZ	HL562	100015	2011/06
2	EMI TEST RECEIVER	ROHDE & SCHWARZ	ESI 26	100009	2011/10
3	RF TEST PANEL	ROHDE & SCHWARZ	TS / RSP	335015/ 0017	2011/10
4	TURNTABLE	ETS	2088	2149	2011/10
5	ANTENNA MAST	ETS	2075	2346	2011/10
6	EMI TEST SOFTWARE	ROHDE & SCHWARZ	ESK1	N/A	2011/10

Conducted Disturbance					
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.
1	EMI Test Receiver	ROHDE & SCHWARZ	ESCS30	100038	2011/10
2	Artificial Mains	ROHDE & SCHWARZ	ESH3-Z5	100049	2011/10
3	Pulse Limiter	ROHDE & SCHWARZ	ESH3-Z2	100044	2011/10
4	EMI TEST SOFTWARE	ROHDE & SCHWARZ	ESK1	N/A	2011/10

Harmonic Current					
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.
1	Purified Power Source	CALIFORNIA INSTRUMENTS	HFS500	54513	2011/10
2	Harmonic And Flicker Analyzer	EM TEST	DPA503S1	0500-10	2011/10

Voltage Fluctuation and Flicker					
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.
1	Purified Power Source	CALIFORNIA INSTRUMENTS	HFS500	54513	2011/10
2	Harmonic And Flicker Analyzer	EM TEST	DPA503S1	0500-10	2011/10

## Electrostatic Discharge

Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.
1	ESD Simulator	EM TEST	DITOC0103Z	0301-04	2011/10

## RF Field Strength Susceptibility

Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.
1	SIGNAL GENERATOR	IFR	2032	203002/100	2011/10
2	AMPLIFIER	AR	150W1000	301584	2011/10
3	DUAL DIRECTIONAL COUPLER	AR	DC6080	301508	2011/10
4	POWER HEAD	AR	PH2000	301193	2011/10
5	POWER METER	AR	PM2002	302799	2011/10
6	TRANSMITTING AERIAL	AR	AT1080	28570	2011/10
7	POWER AMPLIFIER	AR	25S1G4A	0325511	2011/10
8	DUAL DIRECTIONAL COUPLER	AR	DC7144A	0325100	2011/10
9	TRANSMITTING AERIAL	AR	AT4002A	0324848	2011/10

## Electrical Fast Transient/Burst

Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.
1	Ultra Compact Simulator	EM TEST	UCS500M6	0500-19	2011/10

## Surge

Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.
1	ULTRA COMPACT SIMULATOR	EM TEST	UCS500M6	0500-19	2011/10

## Conducted Susceptibility

Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.
1	Signal Generator	IFR	2023A	202304/060	2011/10
2	Amplifier	AR	75A250	302205	2011/10
3	Dual Directional Coupler	AR	DC2600	302389	2011/10
4	6db Attenuator	EMTEST	ATT6/75	0010230A	2011/10
5	CDN	EMTEST	CDN M3	0802-03	2011/10
6	EM CLAMP	LÜTHI	EM101	335625	2011/10

Power Frequency Magnetic Field Susceptibility					
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.
1	ULTRA COMPACT SIMULATOR	EM TEST	UCS500M6	202304/060	2011/10
2	MOTOR DRIVEN VOLTAGE TRANSFORMER	EM TEST	MV2616	302205	2011/10
3	CURRENT TRANSFORMER	EM TEST	MC2630	302389	2011/10
4	MAGNETIC COIL	EM TEST	MS100	0010230A	2011/10

Voltage Dips and Interruptions					
Item	Test Equipment	Manufacturer	Model No.	Serial No.	Last Cal.
1	Ultra Compact Simulator	EM TEST	UCS500M6	0500-19	2011/10
2	Motor Driven Voltage Transformer	EM TEST	MV2616	0301-11	2011/10

## **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 (dB $\mu$ V/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**

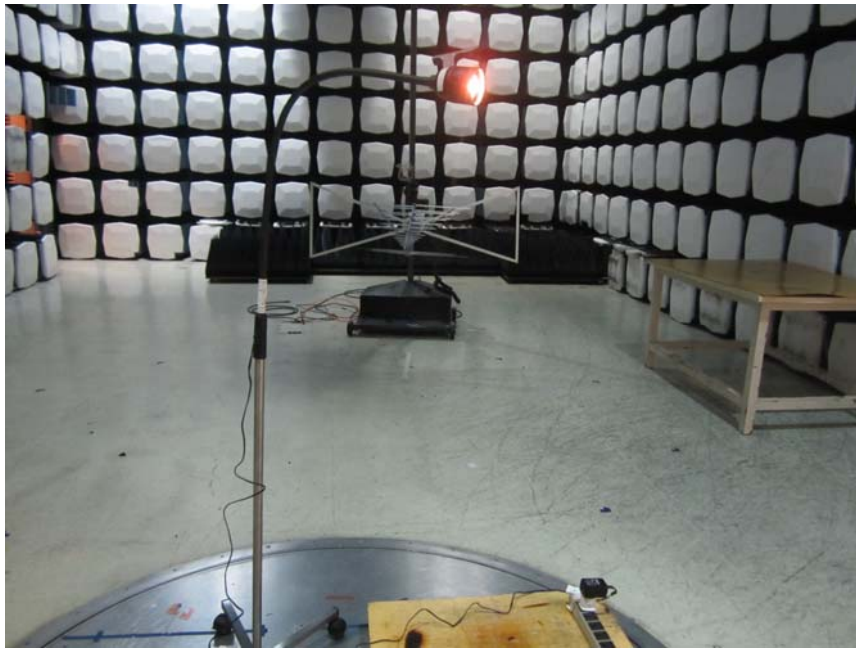
##### **4.1.3.1. Operating Condition**

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.

## 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 value+transducer

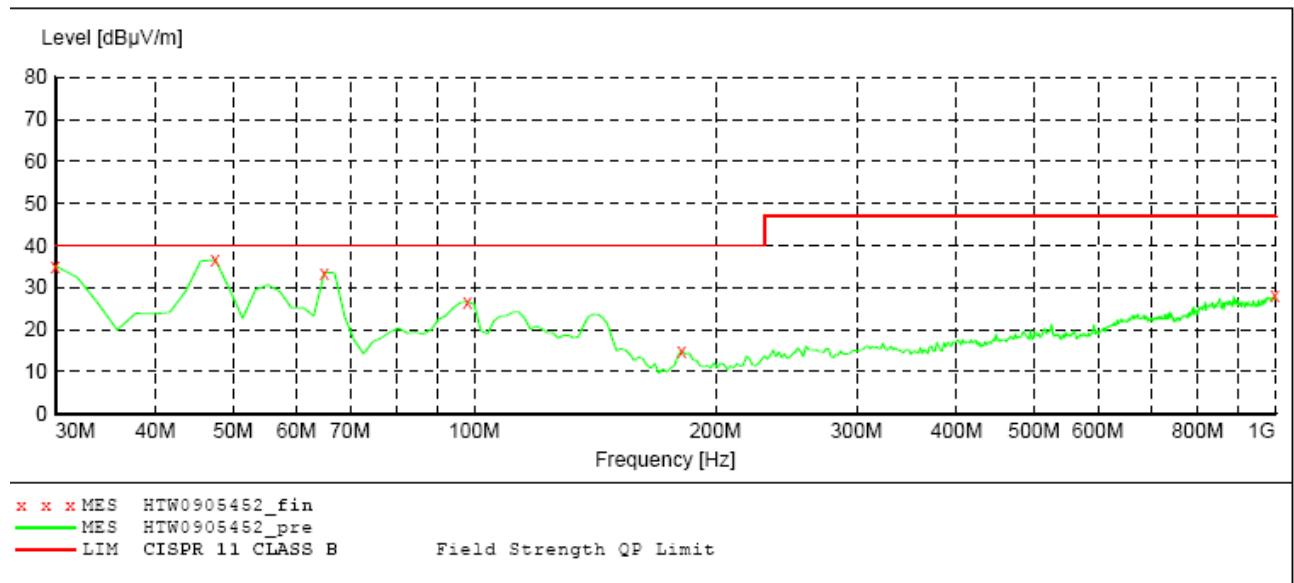
Transducer=antenna factor+pre-amplifier factor+cable loss

**SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION CO.,LTD****RADIATED EMISSION TEST CISPR 11 CLASS B**

EUT: Halogen medical practice light M/N:10.11000.002  
 Manufacturer: KIRCHNER&WILHELM GmbH+Co.KG  
 Operating Condition: ON  
 Test Site: 3M CHAMBER  
 Operator: JACK  
 Test Specification: AC 230V/50Hz  
 Comment:  
 Start of Test: 9/5/2012 / 2:39:42PM

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

Short Description: Field Strength(30M-1G)  
 Start Stop Step Detector Meas. IF Transducer  
 Frequency Frequency Width Time Bandw.  
 30.0 MHz 1.0 GHz 60.0 kHz QuasiPeak 1.0 s 120 kHz HL562

**MEASUREMENT RESULT: "HTW0905452\_fin"**

9/5/2012 2:51PM

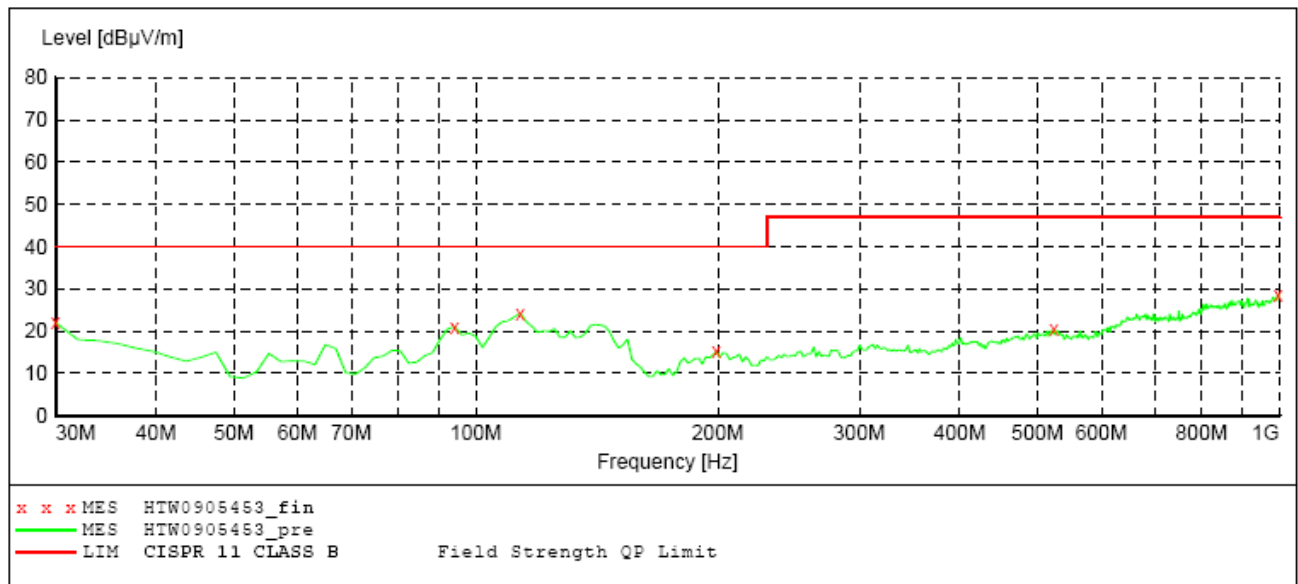
Frequency MHz	Level dBμV/m	Transd dB	Limit dBμV/m	Margin dB	Det.	Height cm	Azimuth deg	Polarization
30.000000	35.10	-11.1	40.0	4.9	QP	100.0	188.00	VERTICAL
47.490000	36.60	-20.9	40.0	3.4	QP	100.0	25.00	VERTICAL
64.980000	33.60	-23.8	40.0	6.4	QP	100.0	173.00	VERTICAL
98.030000	26.60	-19.9	40.0	13.4	QP	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	QP	100.0	350.00	VERTICAL

**SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION CO.,LTD****RADIATED EMISSION TEST CISPR 11 CLASS B**

EUT: Halogen medical practice light M/N:10.11000.002  
 Manufacturer: KIRCHNER&WILHELM GmbH+Co.KG  
 Operating Condition: ON  
 Test Site: 3M CHAMBER  
 Operator: JACK  
 Test Specification: AC 230V/50Hz  
 Comment:  
 Start of Test: 9/5/2012 / 2:51:52PM

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

Short Description: Field Strength(30M-1G)  
 Start Stop Step Detector Meas. IF Transducer  
 Frequency Frequency Width Time Bandw.  
 30.0 MHz 1.0 GHz 60.0 kHz QuasiPeak 1.0 s 120 kHz HL562

**MEASUREMENT RESULT: "HTW0905453\_fin"**

9/5/2012 3:03PM

Frequency MHz	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



## 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)

Frequency Range (MHz)	Limits (dBuV)	
	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



**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

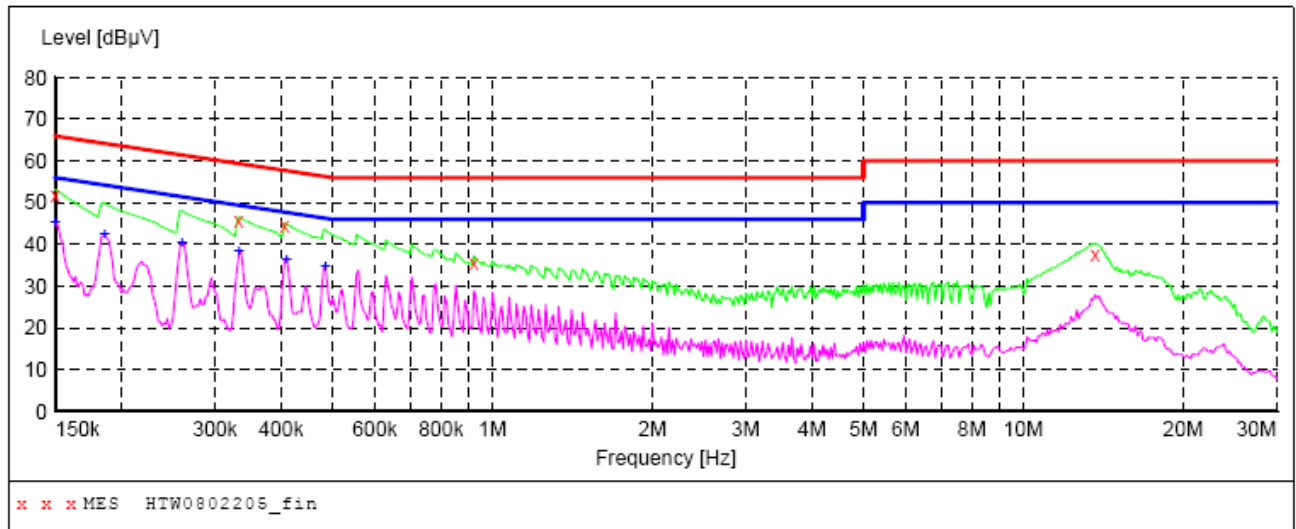
Transducer=insertion loss of LISN+cable loss+insertion loss of pulse limiter

**Shenzhen Huatongwei International Inspection CO.,Ltd****Voltage Mains Test CISPR 11 CLASS B**

EUT: 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 Voltage

**MEASUREMENT RESULT: "HTW0802205\_fin"**

8/2/2012 10:34AM

Frequency MHz	Level dBμV	Transd dB	Limit dBμV	Margin dB	Detector	Line	PE
0.150000	51.70	9.8	66	14.3	QP	N	GND
0.332761	45.80	9.7	59	13.6	QP	N	GND
0.406113	44.30	9.7	58	13.4	QP	N	GND
0.922764	35.60	9.8	56	20.4	QP	N	GND
13.638050	37.40	9.7	60	22.6	QP	N	GND

**MEASUREMENT RESULT: "HTW0802205\_fin2"**

8/2/2012 10:34AM

Frequency MHz	Level dBμV	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

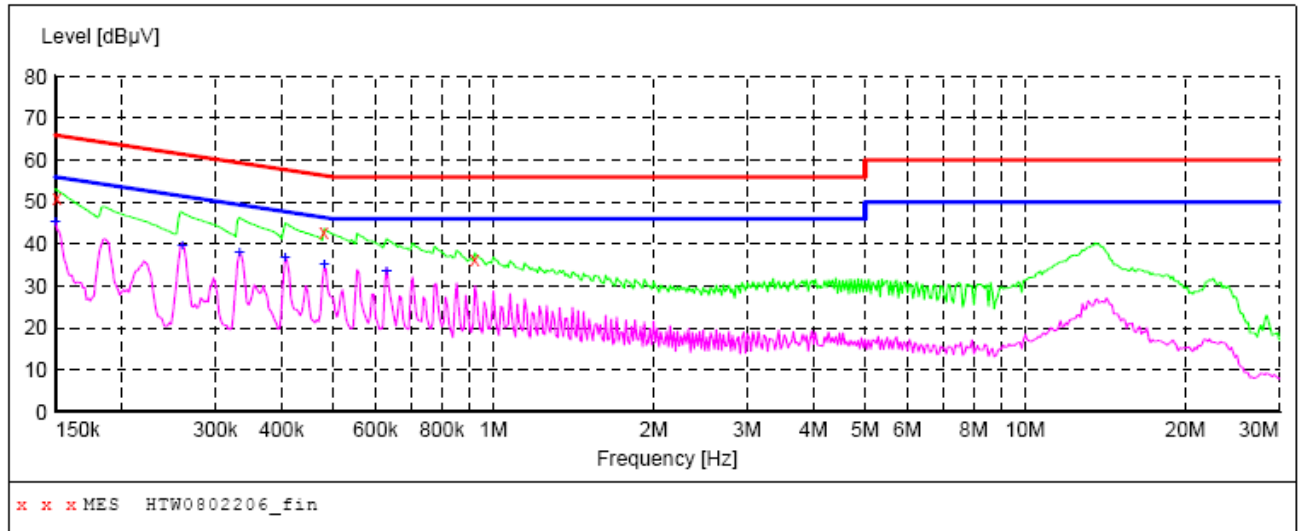
Shenzhen Huatongwei International Inspection CO.,Ltd

**Voltage Mains Test CISPR 11 CLASS B**

EUT: 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 / 10:35:40AM

**SCAN TABLE: "Voltage (9K-30M)FIN"**

Short Description: 150K-30M Voltage

**MEASUREMENT RESULT: "HTW0802206\_fin"**

8/2/2012 10:40AM

Frequency MHz	Level dBµV	Transd dB	Limit dBµV	Margin dB	Detector	Line	PE
0.151200	50.90	9.8	66	15.0	QP	L1	GND
0.480090	42.80	9.7	56	13.5	QP	L1	GND
0.922764	36.50	9.8	56	19.5	QP	L1	GND

**MEASUREMENT RESULT: "HTW0802206\_fin2"**

8/2/2012 10:40AM

Frequency MHz	Level dBµV	Transd dB	Limit dBµV	Margin dB	Detector	Line	PE
0.150000	45.20	9.8	56	10.8	AV	L1	GND
0.259933	39.80	9.7	51	11.6	AV	L1	GND
0.332761	38.20	9.7	49	11.2	AV	L1	GND
0.406113	36.60	9.7	48	11.1	AV	L1	GND
0.480090	35.30	9.7	46	11.0	AV	L1	GND
0.629486	33.40	9.8	46	12.6	AV	L1	GND

### 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).

## Test Report of HTW

Standard used:	EN/IEC 61000-3-2 Ed.3 Quasi-stationary Equipment class A $\leq$ 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]:***

<b>Harmonic(s) &gt; 150%:</b>	
Order (n):	None
<b>Harmonic(s) with average &gt; 100%:</b>	
Order (n):	None

### ***Check odd harmonics 21..39:***

<b>All Partial Odd Harmonics below partial limits.</b>	
<b>Harmonic(s) &gt; 150%:</b>	
Order (n):	None
<b>Harmonic(s) with average &gt; 150%:</b>	
Order (n):	None

## Power Source Result

<b>First dataset out of limit:</b>	
DS (time):	None
<b>Harmonic(s) out of limit:</b>	
Order (n):	None

**Average harmonic current results**

Hn	I <sub>eff</sub> [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

**Maximum harmonic current results**

Hn	I <sub>eff</sub> [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



**Maximum harmonic voltage results**

Hn	Ueff [V]	Ueff [%]	Limit [%]	Result
1	230.27	100.118		
2	149.57E-3	0.065	0.2	PASS
3	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

#### 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).

## 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
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## 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

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

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

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 Contact Discharge (KV)	Test Voltage Air Discharge (KV)
1	2	2
2	4	4
3	6	8
4	8	15
X	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  $\pm 2\text{KV}$ ,  $\pm 4\text{KV}$  and  $\pm 8\text{KV}$  for air discharge and  $\pm 2\text{KV}$ ,  $\pm 4\text{KV}$  and  $\pm 6\text{KV}$  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 susceptible 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.

**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:**

<u>Contact discharge voltage:</u>	<input checked="" type="checkbox"/> 2 kV	<input checked="" type="checkbox"/> 4 kV	<input checked="" type="checkbox"/> 6 kV
<u>Number of discharges:</u>	<input checked="" type="checkbox"/> 10	<input type="checkbox"/> 25	
<u>Air discharge voltage:</u>	<input checked="" type="checkbox"/> 2 kV	<input checked="" type="checkbox"/> 4 kV	<input checked="" type="checkbox"/> 8 kV
<u>Number of discharges:</u>	<input type="checkbox"/> 10	<input checked="" type="checkbox"/> 25	
<u>Type of discharge:</u>	Direct discharge	<input checked="" type="checkbox"/> Air discharge <input checked="" type="checkbox"/> Contact discharge	
	Indirect discharge	<input checked="" type="checkbox"/> Contact discharge <input checked="" type="checkbox"/> Negative	
<u>Polarity:</u>	<input checked="" type="checkbox"/> Positive		
<u>Discharge location:</u>	<input checked="" type="checkbox"/> see photo documentation of the test set-up <input checked="" type="checkbox"/> all external locations accessible by hand <input type="checkbox"/> horizontal coupling plane (HCP) <input checked="" type="checkbox"/> vertical coupling plane (VCP)		

**4.5.5. Test result**

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

## 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
X	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 susceptible results are recorded.

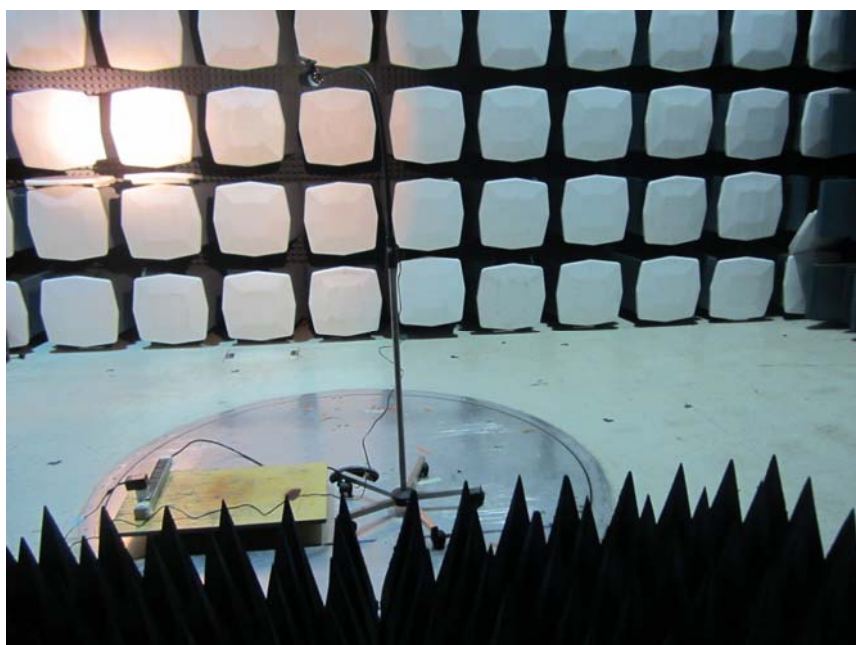
#### 4.6.3.2. Test Procedure

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





**4.6.4. Test specification:**

<u>Frequency range:</u>	■ 80 MHz to 2500 MHz
<u>Field strength:</u>	■ 3V/m
<u>EUT - antenna separation:</u>	■ 3 m
<u>Modulation:</u>	■ AM: 80 % ■ sinusoidal 1 KHz
<u>Frequency step:</u>	■ 1 % with 3 s dwell time
<u>Antenna polarisation:</u>	■ 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 circuit output test voltage and repetition rate of the impulses		
Level	On power port, PE	
	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  $\pm 2$ kV 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 susceptible 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.

## 4.7.3.3. Test Configuration and Procedure

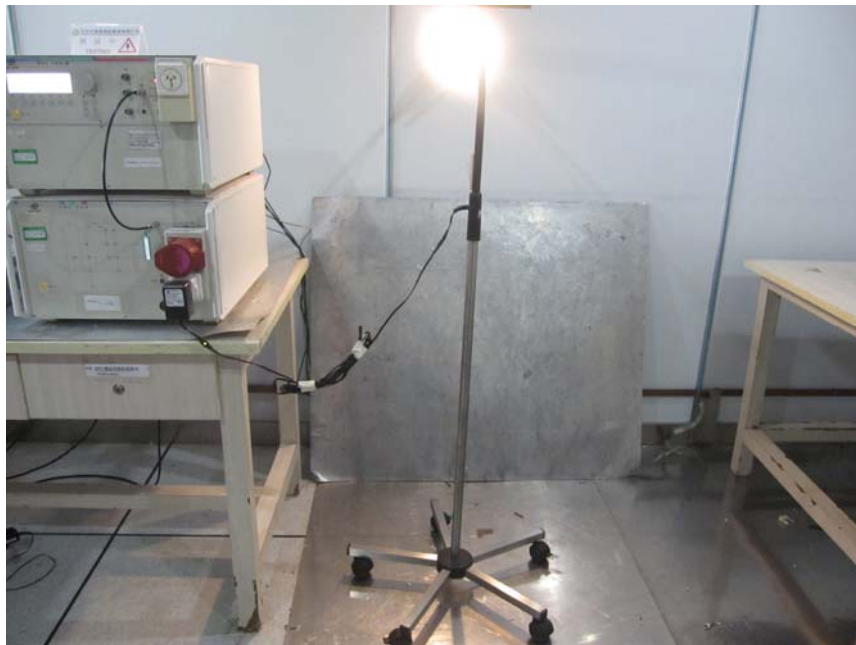
For AC power input ports:

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:

<u>Coupling network:</u>	<input checked="" type="checkbox"/> 0.5 kV	<input checked="" type="checkbox"/> 1 kV	<input checked="" type="checkbox"/> 2 kV
<u>Coupling clamp:</u>	<input type="checkbox"/> 0.5 kV	<input type="checkbox"/> 1 kV	
<u>Burst frequency:</u>	<input checked="" type="checkbox"/> 5.0 kHz		
<u>Coupling duration:</u>	<input checked="" type="checkbox"/> 60 s		
<u>Polarity:</u>	<input checked="" type="checkbox"/> positive	<input checked="" type="checkbox"/> negative	

## 4.7.5. Coupling points

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

Screening:	<input type="checkbox"/> screened	<input checked="" type="checkbox"/> unscreened
Status:	<input type="checkbox"/> detachable	<input checked="" type="checkbox"/> undetachable
Signal transmission:	<input checked="" type="checkbox"/> analogue	<input type="checkbox"/> digital
Length:	<input checked="" type="checkbox"/> 4.1 m	

#### 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  $\pm 0.5\text{KV}$ ,  $\pm 1\text{KV}$  and  $\pm 2\text{KV}$  for a.c. power line(s) to earth and  $\pm 0.5\text{KV}$  and  $\pm 1\text{KV}$  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 susceptible 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 ( $0^\circ$ ,  $90^\circ$ ,  $180^\circ$ ,  $270^\circ$ ) during the test.

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

## 4.8.3.3. Photo of the test set-up



## 4.8.4. Test specification:

Pulse amplitude-Power line sym.:  
Source impedance:  $2\ \Omega + 18\mu\text{F}$

☒ 0.5 kV    ☒ 1 kV    ☐ 2 kV    ☐ 4 kV

Pulse amplitude-Power line unsym.:  
Source impedance:  $12\ \Omega + 9\mu\text{F}$

☒ 0.5 kV    ☒ 1 kV    ☒ 2 kV    ☐ 4 kV

Number of surges:

☒ 5 Surges/Phase angle

Phase angle:

☒  $0^\circ$     ☒  $90^\circ$     ☒  $180^\circ$     ☒  $270^\circ$

Repetition rate:

☒ 60 s

Polarity:

☒ positive    ☒ negative

## 4.8.5. Coupling points

Cable description:

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

Screening:

☐ screened    ☒ unscreened

Status:

☐ detachable    ☒ undetachable

Signal transmission:

☒ analogue    ☐ digital

Length:

☒ 4.1 m

## 4.8.6. Test result

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

#### 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
X	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 susceptible 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.

## 4.9.3.3. Photo of the test set-up



## 4.9.4. Test specification:

<u>Frequency range:</u>	■ 0.15 MHz to 80 MHz
<u>Test voltage :</u>	■ 3 V
<u>Modulation:</u>	■ AM: 80 % ■ sinusoidal 1 kHz
<u>Frequency step:</u>	■ 1 % with 3 s dwell time

## 4.9.5. Coupling points

Cable description :	AC power line	
Screening:	o screened	■ unscreened
Status:	o detachable	■ undetachable
Signal transmission:	■ analogue	o 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.

**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 susceptible 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.

**4.10.3.3. Photo of the test set-up**





## 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

Level of reduction(dip) / duration:

■ 100 % / 10ms

■ 60 % / 100ms

■ 30 % / 500ms

Nominal Mains Voltage ( $V_N$ ):

■ 230 V AC

Number of Interruptions:

■ 3

Duration of the Interruption:

■ 5000 ms

## 4.11.5. Test result

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

## **5. External and Internal Photos of the EUT**

### **5.1. External photos of the EUT**







## 5.2. Internal photos of the EUT



..... End of Report.....

# **Annex of Report**

**Manufacturer's Declaration of the EUT**  
**(altogether 5 pages)**


Guidance and manufacturer's declaration – electromagnetic emission –  
for all EQUIPMENT AND SYSTEMS

1	Guidance and manufacturer's declaration – electromagnetic emission		
2	The 10.11000.002 Halogen medical practice light is intended for use in the electromagnetic environment specified below. The customer or the user of Halogen medical practice light should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group 1	The 10.11000.002 Halogen medical practice light uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.  The 10.11000.002 Halogen medical practice light is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
5	RF emissions CISPR 11	Class B	
6	Harmonic emissions IEC 61000-3-2	Class A	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

**Guidance and manufacturer's declaration – electromagnetic immunity –  
for all EQUIPMENT and SYSTEMS**

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
The 10.11000.002 Halogen medical practice light is intended for use in the electromagnetic environment specified below. The customer or the user of the 10.11000.002 Halogen medical practice light should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD)  IEC 61000-4-2	$\pm 6$ kV contact  $\pm 8$ kV air	$\pm 6$ kV contact  $\pm 8$ kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst  IEC 61000-4-4	$\pm 2$ kV for power supply lines  $\pm 1$ kV for input/output lines	$\pm 2$ kV for power supply lines  $\pm 1$ kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge  IEC 61000-4-5	$\pm 1$ kV differential mode  $\pm 2$ kV common mode	$\pm 1$ kV differential mode  $\pm 2$ kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	$< 5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 0.5 cycle  $40\% U_T$ ( $60\%$ dip in $U_T$ ) for 5 cycles  $70\% U_T$ ( $30\%$ dip in $U_T$ ) for 25 cycles  $< 5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 5 sec	$< 5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 10.11000.002 Halogen medical practice light requires continued operation during power mains interruptions, it is recommended that the 10.11000.002 Halogen medical practice light be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field  IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE $U_T$ is the a. c. mains voltage prior to application of the test level.			

**Guidance and manufacturer's declaration – electromagnetic immunity –  
for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING**

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
The 10.11000.002 Halogen medical practice light is intended for use in the electromagnetic environment specified below. The customer or the user of the 10.11000.002 Halogen medical practice light should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the 10.11000.002 Halogen medical practice light, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where <math>p</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).<sup>b</sup></p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.</p>			
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 10.11000.002 Halogen medical practice light is used exceeds the applicable RF compliance level above, the 10.11000.002 Halogen medical practice light should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 10.11000.002 Halogen medical practice light .</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.</p>			



**Recommended separation distances between portable and mobile  
RF communications equipment and the EQUIPMENT or SYSTEM -  
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

<b>Recommended separation distances between portable and mobile RF communications equipment and the BP3NL1-H Digital Blood Pressure Monitor</b>			
The 10.11000.002 Halogen medical practice light is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 10.11000.002 Halogen medical practice light can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 10.11000.002 Halogen medical practice light as recommended below, according to the maximum output power of the communications equipment			
Rated maximum output of transmitter  W	<b>Separation distance according to frequency of transmitter m</b>		
	150 kHz to 80 MHz  $d = [\frac{3.5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz  $d = [\frac{3.5}{E_1}] \sqrt{P}$	800 MHz to 2.5 GHz  $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			