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

Report No. ..... :	BJ990208-6
Date of issue..... :	August 26, 2009
Total number of pages	78
Testing Laboratory..... :	Jiangsu TÜV Product Service Ltd.
Address ..... :	10 Huaxia Road(m), Dongting, Wuxi, Jiangsu, P.R.China PC:21410
Applicant's name..... :	Contec Medical Systems Co., Ltd.
Address ..... :	No.24 Huanghe West Road, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, 066004, People's Republic of China.
Test specification:	
Standard ..... :	IEC 60601-1-2: 2007 (Third Edition)
	IEC 60601-2-25/A1: 1999
Non-standard test method……..…..:	N/A
Test Report Form No..... :	EMC_TEST REPORT_Med2007_e
Master TRF..... :	Dated 2009-09

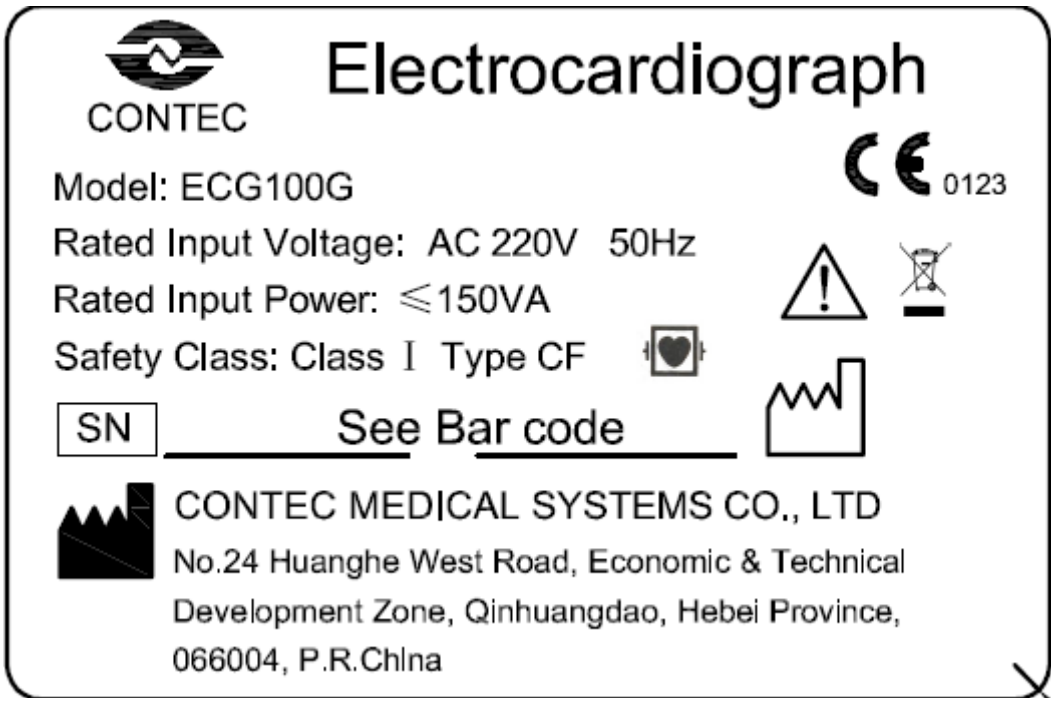
Test item description ..... :	
Trade Mark ..... :	Contec
Manufacturer ..... :	Contec Medical Systems Co., Ltd.
Model/Type reference..... :	ECG100G / ECG
Ratings ..... :	220-240VAC / 50Hz
	Protection Class I

1.0 Testing Program Details

Testing procedure and testing location:	
☒ **Testing Laboratory:**	
Testing location/ address.....:	Jiangsu TÜV Product Service Ltd. 10 Huaxia Road(m), Dongting, Wuxi, Jiangsu, P.R.China PC:21410
☐ **Associated Test Laboratory:**	N/A
Testing location/ address.....:	N/A
Tested by (name + signature).....	Weisheng Jiang
Approved by (name + signature)... :	Jun Bao

Summary of testing:		
Tests performed (name of test and test clause):		**Testing location:**
Conducted Emissions	Clause 6.1.1	Test Area - C
Radiated Emissions	Clause 6.1.1.	Test Area - E
Harmonics Current Emissions	Clause 6.1.3	Test Area - F
Voltage Fluctuations and Flicker	Clause 6.1.3	Test Area - F
Electrostatic Discharge	Clause 6.2.2	Test Area - A
RF electromagnetic fields	Clause 6.2.3	Test Area - E
Electrical Fast Transients	Clause 6.2.4	Test Area - G
Surges	Clause 6.2.5	Test Area - G
Conducted Disturbances	Clause 6.2.6	Test Area - G
Voltage Dips, Interruptions	Clause 6.2.7	Test Area - F
Power Frequency Magnetic	Clause 6.2.8	Test Area - H

Copy of marking plate



Test item description ..... :	
Trade Mark ..... :	Contec
Manufacturer ..... :	Contec Medical Systems Co., Ltd.
Model/Type reference..... :	ECG100G / ECG
Ratings ..... :	220-240VAC / 50Hz
	Protection Class I
Possible test case verdicts:	
- test case does not apply to the test object .. :	N/A
- test object does meet the requirement ..... :	P (Pass)
- test object does not meet the requirement .. :	F (Fail)
Testing ..... :	
Date of receipt of test item ..... :	July 25, 2009
Date (s) of performance of tests ..... :	July 26-31, 2009

General remarks:

N/A

General product information:

N/A

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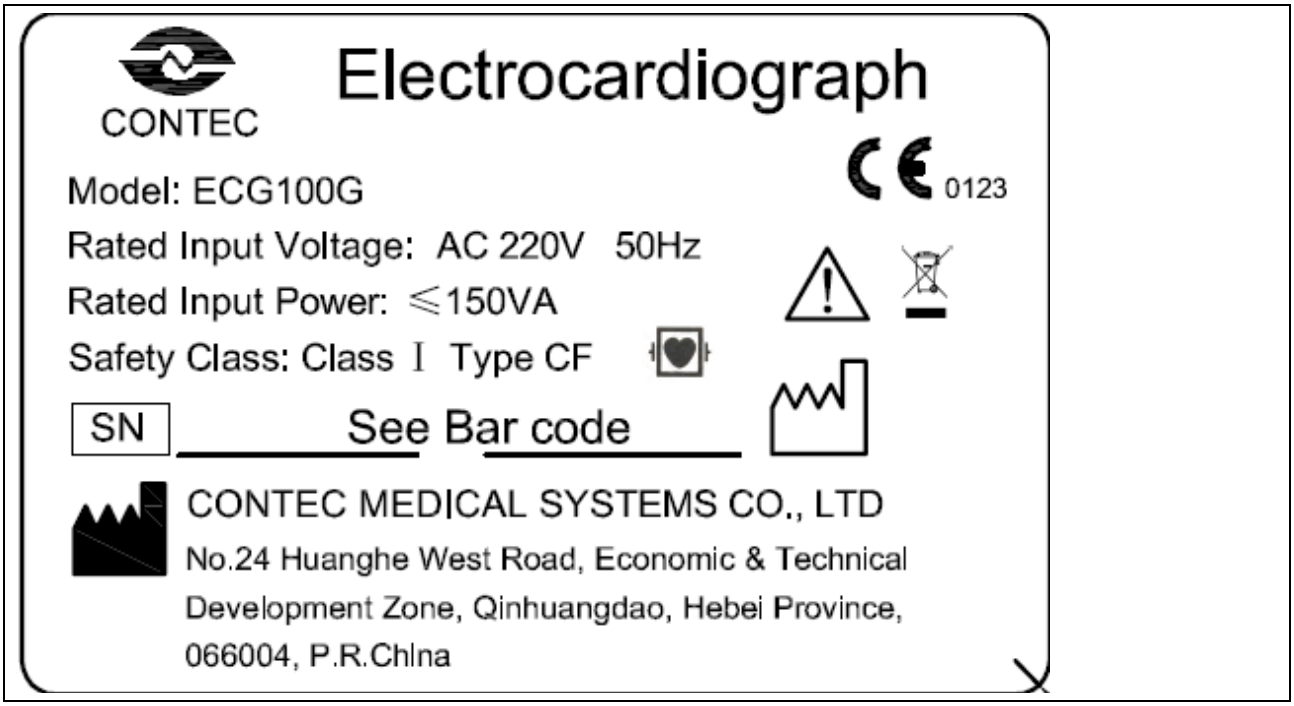
1.1 Equipment Description

The ECG 100G Electrocardiograph is intended to use in hospital and other medical institution. It has built-in Lithium polymer rechargeable battery, and can continuously record single-channel ECG waveform clearly and notes, including lead mark, sensitivity, paper speed, filter status, etc.

1.1.1 Equipment Marking Plate



1.1.2 Supporting Equipment Used During Test:

Use*	Product Type	Manufacturer	Model	Comments
SIM	N/A	N/A	N/A	Use water as simulator

Note: * Use

EUT - Equipment Under Test

AE - Auxiliary/Associated Equipment

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

1.1.3 Input/Output Ports:

Port No.	Name	Type*	Cable Length	Cable Shielded	Comments
0	Enclosure	N/E	—	—	None
1	Input AC Port	AC	1m	None	None
2	ECG line	I/O	>1m	shielded	None

*Note: AC = AC Power Port DC = DC Power Port N/E = Non-Electrical
I/O = Signal Input or Output Port (Not Involved in Process Control)
TP = Telecommunication Ports

1.1.4 EUT Internal Operating Frequencies:

Frequency (MHz)	Description	Frequency (MHz)	Description
12MHz	--	--	--
32.768KHz	--	--	--

1.1.5 Power Interface

Mode No.	Voltage (V)	Current (A)	Power (VA)	Frequency (DC/AC-Hz)	Phases (No.)	Comments
Rated	220~240	--	60	AC 50Hz	1	--
--	--	--	--	--	--	--
--	--	--	--	--	--	--
--	--	--	--	--	--	--
--	--	--	--	--	--	--

1.2 EUT Operation Modes:

Mode #	Description
1	Power on, recording
--	--
--	--

1.3 EUT Configuration Modes

Mode #	Description
1	Normal configuration
--	--
--	--
--	--

1.4 Immunity Performance Criteria

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

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

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

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

1.5 Compliance Summary

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

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict
5.2.2	Technical description		
5.2.2.1	Requirement for all ME equipment and systems:		--
a)	List of cables and accessories		--
b)	A warning that other cables and accessories may negatively affect EMC performance		P
c)	Table 1, modified as appropriate using Figure 1 and 2		P
d)	A warning regarding stacking and location close to other equipment		P
e)	A justification for each immunity compliance level below 60601 test level		N/A
f)	Table 2, completed as appropriate using Figure 3		P
g)	The essential performance of ME equipment		P
5.2.2.2	ME Equipment not specified for use in shielded location		--
	Tables 3 and 5 (life-supporting) using Figure 4, Tables 4 and 6 (non-life-supporting) using Figure 5 selected and completed as appropriate following a)-e)		P
5.2.2.3	ME 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 to 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 (life-supporting) or 8 (non-life-supporting) as appropriate		N/A
5.2.2.4	ME Equipment that intentionally apply RF energy – documents shall include guidelines for avoiding or identifying and resolving adverse electromagnetic effects on other equipment		N/A
5.2.2.5	ME Equipment that intentionally receive RF energy		N/A
a)	Each (preferred if applicable) frequency or frequency band of reception, and the bandwidth of the receiving section of the ME equipment in those bands		N/A
b)	A warning that the ME equipment may be interfered with by other equipment		N/A
5.2.2.6	ME Equipment that includes RF transmitters – documentation shall include each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and ERD		N/A

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict
5.2.2.7	Requirements of cables, transducers and accessories		--
a)	Documentation shall include list of ME Equipment		P
b)	A warning that use of other accessories results in non-compliance		P
5.2.2.8	Requirements applicable to large permanently installed ME equipment and systems		N/A
a)	A statement that an exemption has been used and that the me equipment has not been tested for radiated RF immunity over the entire frequency range 80 MHz to 2,5 GHz		N/A
b)	A warning that the ME equipment has been tested for radiated RF immunity only at selected frequencies		N/A
c)	A list of the transmitters or equipment used as RF test sources and the frequency and modulation characteristics of each source.		N/A
5.2.2.9	Requirements applicable to ME equipment that has no essential performance		N/A
a)	Statement that the ME equipment was not tested for immunity to electromagnetic disturbances		N/A
b)	Document shall include information applicable to the me equipment		N/A
5.2.2.10	Requirements applicable to ME equipment that is Type A Professional only		N/A
	Document include a justification for not complying with the CISPR 11 group 2 Class B electromagnetic radiation disturbance limit		N/A

1.6 Result Summary

Clause	Requirement – Test	Result/Comments	Verdict
6.1	Emissions		
6.1.1.1	Classification		—
	Class A or B..... :	Class A	—
	Group 1 or 2 ..... :	Group 1	—
	CISPR 11, 14-1, or 15 ..... :	CISPR 11	—
6.1.1.2	Limits of mains terminal disturbance voltage ..... :		P
	Limits for radiated disturbance ..... :		P
	Limits for disturbance power (if applicable) ..... :		N/A
6.1.3.1	Harmonic Current Emissions per IEC61000-3-2..:		P
6.1.3.2	Voltage Fluctuations and Flicker per IEC61000-3-3		P
6.2	Immunity		
6.2.2	Electrostatic Discharges (ESD)..... :	IEC 61000-4-2: 1995/A2:2000	P
6.2.3	Radiated RF electromagnetic Fields……..:	IEC 61000-4-3: 2006	P
6.2.4	Electrical Fast Transients and bursts ..... :	IEC 61000-4-4: 2004	P
6.2.5	Surges ..... :	IEC 61000-4-5: 2001	P
6.2.6	Conducted Disturbances, induced by RF fields .. :	IEC 61000-4-6: 2003/A2:2006	P
6.2.7	Voltage Dips, Interruptions, and variations ..... :	IEC 61000-4-11: 2001	P
6.2.8	Power-frequency Magnetic Fields..... :	IEC 61000-4-8: 2001	P

1.7 Test Conditions and Results – Conducted Emissions

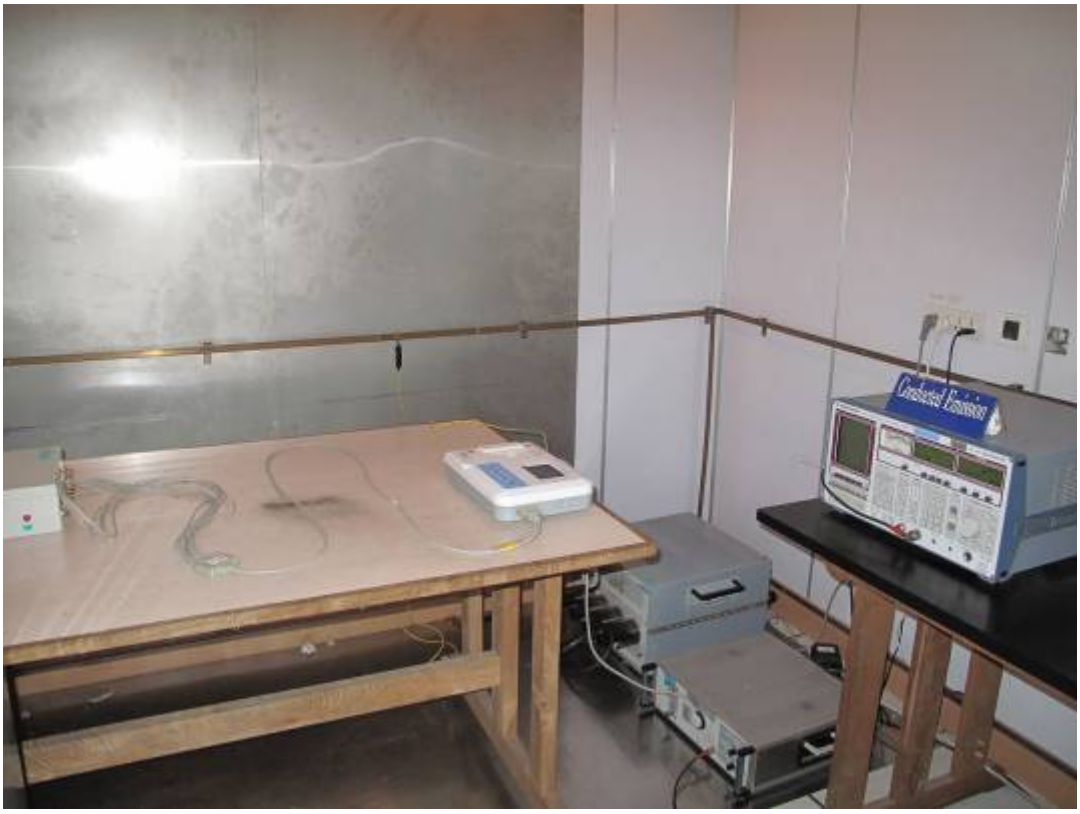
CISPR 11	**TEST:** Limits of mains terminal disturbance voltage				**Verdict**
Method: The AMN placed 0,8 m from the boundary of the unit under test and bonded to a ground reference plane. This distance was between the closest points of the AMN and the EUT. All other units of the EUT and associated equipment were at least 0,8 m from the AMN. All power was connected to the system through Artificial Mains Network (AMN). Conducted voltage measurements on mains lines were made at the output of the AMN.					P
Laboratory Parameters		Required prior to the test		During the test	
Ambient Temperature		10 to 40 °C		21°C	
Relative Humidity		10 to 90 %		58%	
Fully configured sample scanned over the following frequency range		Frequency range on each side of line		Measurement Point	
		150kHz to 30MHz		AC Mains	
Limits – Group 1 - Class A					
Frequency (MHz)	Limit dB (µV)				
	Quasi-Peak	Result	Average	Result	
0.15 to 0.50	79	P	66	P	
0.50 to 30	73	P	60	P	

CISPR 14	**TEST:** Limits of terminal disturbance voltage	**Verdict**
Method: The AMN was placed 0,8 m from the boundary of the unit under test and bonded to a ground reference plane. This distance was between the closest points of the AMN and the EUT. All other units of the EUT and associated equipment was at least 0,8 m from the AMN. All power was connected to the system through Artificial Mains Network (AMN). Conducted voltage measurements on mains lines were made at the output of the AMN.		N/A

CISPR 15	**TEST:** Limits of terminal disturbance voltage	**Verdict**
Methods: 1). The disturbance voltage was measured at the **mains terminals** of the lighting equipment by means of the arrangement described in Figures 5 and 6 for the relevant type of equipment. The output terminals of the artificial mains network (V-network) and terminals a-b was positioned 0,8 m ± 20 % apart and was connected by the two power conductors of a flexible three-core cable of 0,8 m length. 2). A voltage probe was used when measuring on the **load terminals**. It contained a resistor having a resistance value of at least 1500 Ω in series with a capacitor with a reactive value negligible to the resistance (in the range 150 kHz to 30 MHz). 3). Measurement at **control terminals** was carried out by means of an impedance stabilization network as described in CISPR 22. The ISN was bounded to ground (see 8.2). Measurement was carried out in a stable mode of operation, which means with a stable light output.		N/A

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
EMI Test Receiver	Rohde & Schwarz	ESHS30	707/639701	2009.05.30	2010.05.29
LISN	Schwarzbeck	NSLK8127	487/600215	2009.05.30	2010.05.29

Photo of test setup for Mains Terminal Disturbance Voltage



Tabulated Results for Mains Terminal Disturbance Voltage							
Terminal	Test Frequency (MHz)	Meter Reading dB (μV)	Detector (Pk/QP/Av)	Correction Factor (dB)	Level dB (μV)	Limit dB (μV)	Margin (dB)
Phase L	0.15-30	--	QP	--	--	--	> 6
Phase N	0.15-30	--	QP	--	--	--	> 6
Phase L	0.15-30	--	AV	--	--	--	> 6
Phase N	0.15-30	--	AV	--	--	--	> 6
Note: This table is to be used for combined correction factors (Gain/Loss and Transducer) Table above may be deleted. Use column “Terminal” to identify the Line and /or Neutral that was tested. Other table formats are allowed as long as all information is included.							

Graphical representation of Mains Terminal Disturbance Voltage Measurement
N/A

1.8 Test Conditions and Results – Radiated Emissions

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

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	21°C
Relative Humidity	10 to 90 %	58%
Fully configured sample scanned over the following frequency range	Frequency range on each side of line	Measurement Point
	30MHz – 1GHz	10 m measurement distance

Limits – Group 1 Class A

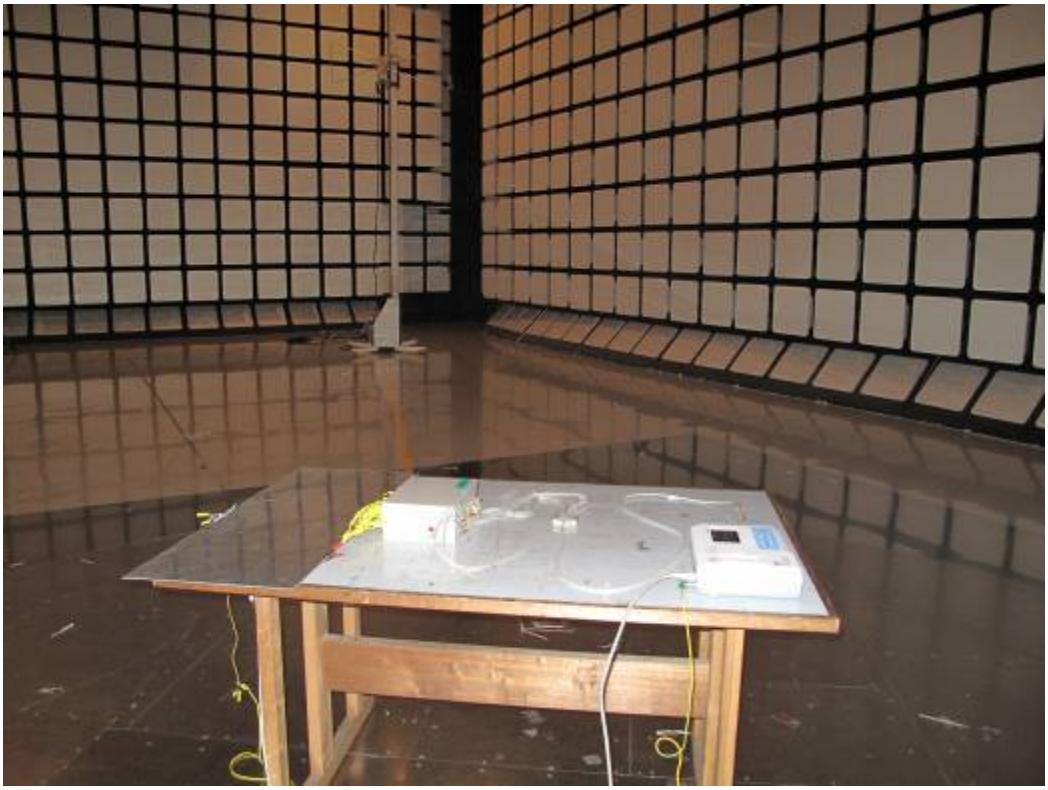
Frequency (MHz)	Limit dB (µV/m)	
	Quasi-Peak	Results
30 to 230	40	P
230 to 1000	47	P

CISPR 14	TEST: Limits for radiated disturbance 30 MHz –1 GHz	Verdict
Radiated disturbance requirements in CISPR 14 standard are restricted to toys		N/A
Supplementary information:		

CISPR 15	Test: Limits for radiated disturbance 9 kHz – 300 MHz	Verdict
Method: Measurements were made in a 10-meter semi-anechoic chamber or Open Area Test Site that complies to CISPR 16. Preliminary (peak) measurements were performed at an antenna to EUT separation distance of 10 meter. The EUT was rotated 360° about its azimuth with the receive antenna located at various heights in horizontal and vertical polarities. Final measurements (quasi-peak) were then performed by rotating the EUT 360° and adjusting the receive antenna height from 1 to 4 m. All frequencies were investigated in both horizontal and vertical antenna polarity, where applicable. The quasi-peak limits of the magnetic component of the radiated disturbance field strength in the frequency range 9 kHz to 30 MHz, measured as a current in 2 m, 3 m or 4 m loop antennas around the lighting equipment.		N/A

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
EMI Receiver	Rohde & Schwarz	ESIB7	487/630408	2009.01.17	2010.01.16
Broadband Antenna	Schwarzbeck	VULB9168	487/620214	2008.12.27	2010.12.26
Anechoic Chamber	TDK	10m	487/770201	N/A	N/A

Photo of test setup for Radiated Disturbance



Tabulated Results for Radiated Disturbance										
Test Frequency (MHz)	Meter Reading dB(μV)	Detector (Pk/QP/Av)	Polarity (V/H)	Azimuth (Degrees)	Antenna Height (cm)	Gain/Loss Factor (dB)	Transducer Factor(dB)	Level dB(μV/m)	Limit dB(μV/m)	Margin (dB)
72.0	--	QP	H	- -	- -	- -	- -	28.55	40	>6
120.0	--	QP	H	- -	- -	- -	- -	29.78	40	>6
72.0	--	QP	V	--	--	--	--	27.44	40	>6
120.0	--	QP	V	--	--	--	--	30.55	40	4.45
Note: Other table formats are allowed as long as all information is included.										

Graphical representation of Radiated Disturbance Measurement
N/A

1.9 Test Conditions and Results – Disturbance Power Emissions

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

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

Photo of test setup for Disturbance Power Emissions
N/A

Tabulated Results for Disturbance Power Emissions							
Test Frequency (MHz)	Meter Reading dB(μV)	Detector (Pk/QP/Av)	Gain/Loss Factor (dB)	Transducer Factor(dB)	Level dB(μV/m)	Limit dB(μV/m)	Margin (dB)
--	--	--	--	--	--	--	--
--	--	--	--	--	--	--	--
--	--	--	--	--	--	--	--
--	--	--	--	--	--	--	--
--	--	--	--	--	--	--	--
--	--	--	--	--	--	--	--
Note: Other table formats are allowed as long as all information is included.							

Graphical representation of Disturbance Power Emissions Measurement
N/A

1.10 Test Conditions And Results – Limits for Harmonic Current Emissions

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

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	21°C
Relative Humidity	30 to 60 %	58%
Equipment mode	Power interface mode	AC
	EUT configurations mode	normal
	Operation mode	Power on
Classification of Equipment.....:		Class A
--		

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
UNIVERSAL POWER ANALYZER	Voltech	PM 6000	487/740741	2008.11.21	2009.11.20
AC Power Supply Testing System	California Instruments	C15003ix-400/3-CTS	487/689910	2008.11.21	2009.11.20

Photo of test setup for Harmonic Current Emissions


Tabulated Results for Harmonic Current Emissions
Note: Enter compilation of results in any format that fulfils requirements of the standard.

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

61000-3-3	**TEST:** Limitation of Voltage Fluctuations And Flicker (IEC 61000-3-3: 1994/A2:2005)	Verdict
Method: The test circuit consists of a test supply voltage, reference impedance, the equipment under test and a flicker meter compliant with IEC 60868. The equipment shall be tested in the condition in which the manufacturer supplies it.		P

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	21°C
Relative Humidity	30 to 60 %	58%
Equipment mode	Power interface mode.....:	AC
	EUT configurations mode .....:	normal
	Operation mode .....:	Power on
Control Method of Equipment (see below)..... :		1

1 - without additional conditions

2 - switched manually, or
switched automatically more frequently than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds), or manual restart, after a power supply interruption.

3 - attended while in use (for example: hair dryers, vacuum cleaners, kitchen equipment such as mixers, garden equipment such as lawn mowers, portable tools such as electric drills), or
switched on automatically, or is intended to be switched on manually, no more than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds) or manual restart, after a power supply interruption.

Supplementary information:

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
UNIVERSAL POWER ANALYZER	Voltech	PM 6000	487/740741	2008.11.21	2009.11.20
Reference Impedance Network	Voltech	IEC Standard 555	707/579501	2009.03.12	2010.03.11
AC Power Supply Testing System	California Instruments	C15003ix-400/3-CTS	487/689910	2008.11.21	2009.11.20

Photo of test setup for Voltage Fluctuations And Flicker


Tabulated Results for Voltage Fluctuations And Flicker
Note: Enter compilation of results in any format that fulfils requirements of the standard.

1.12 Test Conditions and Results – Immunity to Electrostatic Discharges

61000-4-2	**TEST:** Electrostatic discharges (IEC 61000-4-2:1995/A2:2000)	Verdict
Method: The test is intended to demonstrate the immunity of equipment subjected to static electricity discharges from operators directly and to adjacent objects. The tabletop equipment under test is placed on a wooden table, 0.8 m high, standing on the ground reference plane. A horizontal coupling plane (HCP), 1.6 x 0.8 m, is placed on the table. The EUT and the cables are isolated from the coupling plane by an insulating support 0.5 mm thick. The floor standing equipment is isolated from the ground reference plane by an insulating support about 0.1 m thick. The vertical coupling plane (VCP) of dimensions 0.5 m x 0.5 m is placed parallel to, and positioned at a distance of 0.1 m from, the EUT.		P

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	22°C
Relative Humidity	30 to 60 %	57%

Test Levels

Discharge type	Discharge Level (kV)		Number of discharges per location (each polarity)
	Positive	Negative	
Air – Direct	2, 4, 8	2, 4, 8	10
Contact – Direct	2, 4, 6	2, 4, 6	10
Contact – Indirect	2, 4, 6	2, 4, 6	10
Discharge location	See photo documentation of the test set-up All external locations accessible by hand, Horizontal plate (HCP) Vertical coupling plate (VCP)		

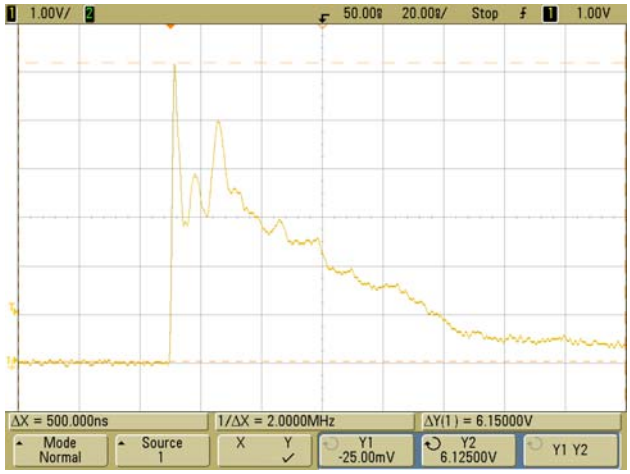
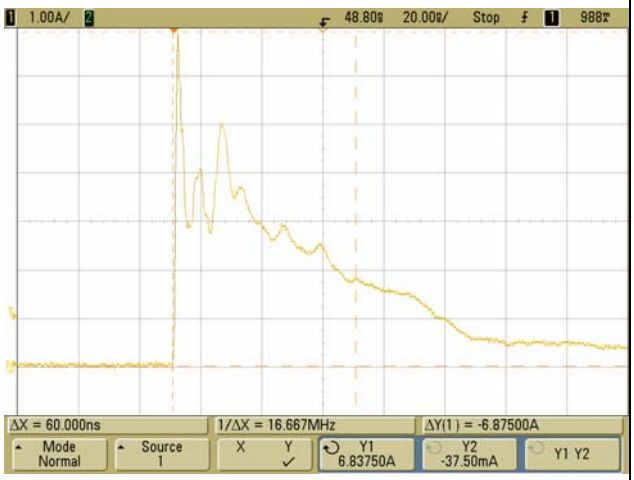
Supplementary information:

During the test, the LCD of ECG powered off, but it can restore to normal mode within 5 seconds, it complies with the product standard IEC 60601-2-25/A1:1999

Test Equipment Used

Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
ESD SIMULATOR SYSTEM	HAEFELY	PESD3010	487/750508	2009.05.30	2010.05.29
Horizontal Coupling Plane	TÜV Product Service (Shanghai).	---	---	N/A	N/A
Vertical Coupling Plane	TÜV Product Service (Shanghai).	---	---	N/A	N/A

Photo of test setup for Immunity to Electrostatic Discharges


ESD Waveform Verification	
Voltage（Set:1000V）	First peak current of discharge±10%：
	
Test value :1011V; Δ=1,1％	Test value : 6,875A; Δ=8,3％

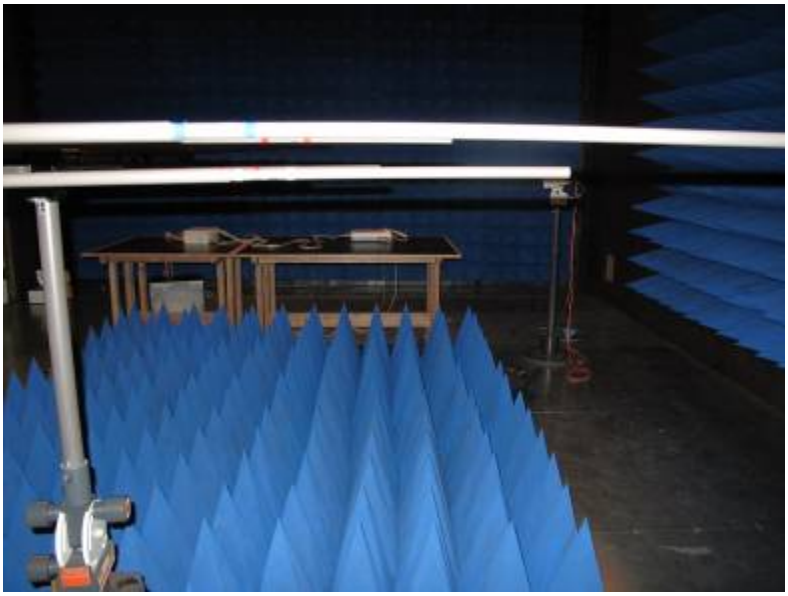
Tabulated Results for Electrostatic Discharges			
Nominal Voltage (V).....:	230VAC		
Nominal Frequency (Hz).....:	50Hz		
Direct discharges: Air and Contact			
Discharge location	**Air discharge voltage (kV)**	**Polarity**	**Remark**
Gaps	2, 4, 8	Positive, Negative	No degradation of function
Buttons	2, 4, 8	Positive, Negative	No degradation of function
Screen	2, 4, 8	Positive, Negative	No degradation of function
Discharge location	**Contact discharge voltage (kV)**	**Polarity**	**Remark**
Foot Switch	2, 4, 6	Positive, Negative	No degradation of function
Plug metal connector	2, 4, 6	Positive, Negative	No degradation of function
Indirect discharges			
Discharge location	**Contact discharge voltage (kV)**	**Polarity**	**Remark**
HCP - Front	2, 4, 6	Positive, Negative	No degradation of function
HCP - Left	2, 4, 6	Positive, Negative	No degradation of function
HCP - Right	2, 4, 6	Positive, Negative	No degradation of function
HCP - Rear	2, 4, 6	Positive, Negative	No degradation of function
VCP - Front	2, 4, 6	Positive, Negative	No degradation of function
VCP - Left	2, 4, 6	Positive, Negative	No degradation of function
VCP - Right	2, 4, 6	Positive, Negative	No degradation of function
VCP - Rear	2, 4, 6	Positive, Negative	No degradation of function

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

61000-4-3	**TEST:** RF electromagnetic fields (IEC 61000-4-3: 2006)			Verdict
Method: The test allows estimating of the radiated immunity of electrical and electronic equipment to electromagnetic disturbances coming from intended radio-frequency (RF) transmitters in the frequency range 30 MHz to 2500 MHz. The interference is applied on the enclosure of the equipment by using transmitting antennas.				P
Laboratory Parameters:		Required prior to the test	During the test	
Ambient Temperature		15 to 35 °C	22°C	
Relative Humidity		30 to 60 %	57%	
Test specifications				
Calibration Requirements		Uniform field area (UFA)	1.5 m x 1.5 m, 16 points with a minimum UFA size 0.5 m x 0.5 m	
			75 % of calibration points within specifications if UFA is larger than 0.5 m x 0.5 m. 100 % (all 4 points) in the specifications for 0.5 x 0.5 m UFA	
Frequency bandwidth		80 MHz to 2500 MHz		
Level	**Non-Life Supporting Equipment**	3 V/ m		
		Amplitude modulation	80 % / 2Hz sine wave	
Frequency step		1% with 3s dwell time		
Supplementary information: EUT powered at one of the Nominal input voltages and frequencies.				

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
SIGNAL GENERATOR	Rohde & Schwarz	SML03	487/390304	2008.11.20	2009.11.20
Power Amplifier	TESEQ	CBA1G-500	487/400908	2009.04.18	2010.04.17
Power Amplifier	TESEQ	CBA3G-100	487/400909	2009.04.18	2010.04.17
Power Meter	Rohde & Schwarz	NRVD	487/740224	2009.07.20	2010.07.19
Log-periodic Antenna	Amplifier Research	AT1080	487/620519	2009.04.19	2010.04.18
Horn Antenna	Amplifier Research	AT4002A	487/620621	2009.04.19	2010.04.18

Photo of test setup for Radio Frequency Electromagnetic Fields



Tabulated Results for RF Electromagnetic Field 80 MHz to 2500 MHz			
		Nominal Voltage (V) .....:	220 ~ 240
		Nominal Frequency (Hz) .....:	50
Side of the equipment under test	**Frequency (MHz)**	**Antenna polarization (V/H)**	**Remark**
Front	Full bandwidth	V	No degradation of function
Front	Full bandwidth	H	No degradation of function
Back	Full bandwidth	V	No degradation of function
Back	Full bandwidth	H	No degradation of function
Left	Full bandwidth	V	No degradation of function
Left	Full bandwidth	H	No degradation of function
Right	Full bandwidth	V	No degradation of function
Right	Full bandwidth	H	No degradation of function

1.14 Test Conditions and Results – Electrical Fast Transients

61000-4-4	**TEST:** Fast Transients – (IEC61000-4-4:2004)	Verdict
Method: Measurements were made on a ground plane that extends 1-meter minimum beyond all sides of the system under test. Mains power tests were conducted with the product connected to a Coupling/Decoupling Network (CDN). I/O lines were tested in a Capacitive Coupling Clamp. One of each unique interface was tested for a period of one (1) minute per polarity.		P

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	21°C
Relative Humidity	10 to 90 %	58%

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

Applied Level		
Application Point	(kV)	Repetition Frequency (kHz)
Input a.c. Power Ports	±0.5, ±1, ±2	5
Input d.c. Power Ports	±0.5, ±1, ±2	5

Supplementary information:

Test is performed at the minimum and maximum RATED input voltages at any nominal frequency

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
EFT/Burst Generator	EM Test	EFT500	707/759601	2009.05.30	2010.05.29

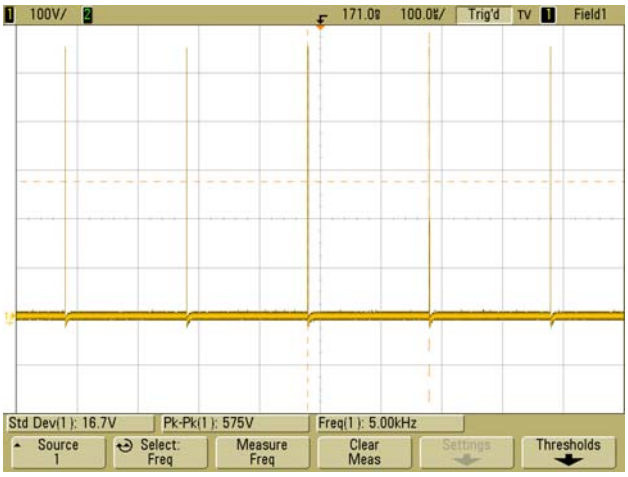
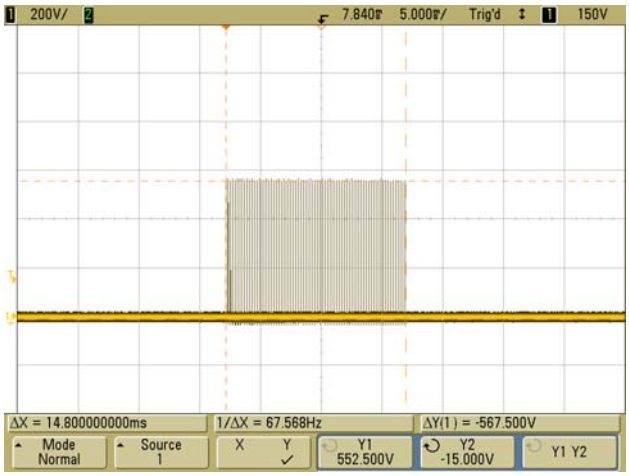
Electrical Fast Transients Waveform Verification	
Pulse Frequency: 5KHz  Test value : 5KHz	Burst duration: 15ms ± 20%  Test value : 14,8ms; Δ=1,3%

Photo of test setup for Electrical Fast Transients


Tabulated Results for Minimum Input Voltage	
Minimum Rated Voltage (V) .....:	220
Nominal Rated Frequency (Hz)..:	50

Point of application	Comments/Results
Mains	1
I/O Line 1 -	X

Tabulated Results for Maximum Input Voltage	
Maximum Rated Voltage (V) ..... :	240
Nominal Rated Frequency (Hz). :	50

Point of application	Comments/Results
Mains	1
I/O Line 1 -	X

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

1.15 Test Conditions and Results – Surge Immunity

61000-4-5	**TEST:** Surge Immunity Test – (IEC61000-4-5: 2001)	Verdict
Method: Mains power tests were conducted with the product connected to a Coupling/ Decoupling Network (CDN). The test voltage was increased from the lowest indicated level up to the maximum level. Five (5) positive surges and five (5) negative surges were applied at each of phases of the a.c. waveform: 0°, 90°, 180° and 270°. Each surge was applied 60 seconds after the previous surge. Signal and Telecommunications ports were subject to five (5) positive and five (negative) surges applied through the appropriate Coupling/Decoupling Network (CDN).		P

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	23°C
Relative Humidity	10 to 90 %	58%

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

Applied Level

Application Point	[kV]	Required Surge Waveform
Input Power Ports	0.5 and 1.0 (Line to Line)	Combination Wave (1.2μS x 50μS Voltage, 8μS x 20μS Current)
	0.5, 1.0 and 2.0 (Line to Earth)	Combination Wave (1.2μS x 50μS Voltage, 8μS x 20μS Current)

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

Supplementary information:
Test is performed at the minimum and maximum RATED input voltages and at any nominal frequency.

Test Equipment Used

Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Surge Generator	EM TEST	VCS 500	707/759603	2009.05.30	2010.05.29

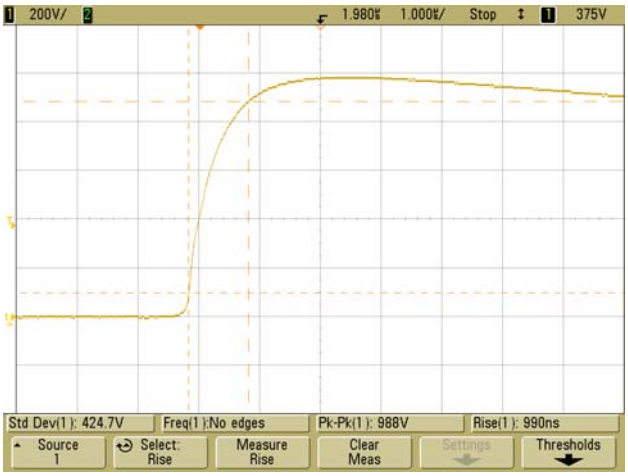
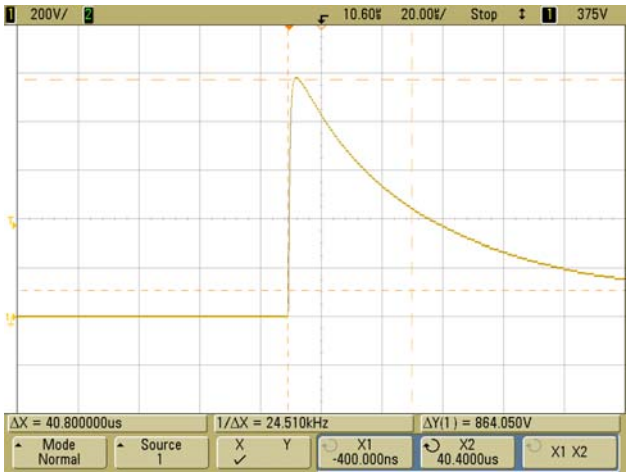
Surge Waveform Verification	
Rise time (10% - 90%): 1μs	Duration time (50% - 50%): 50μs
	
Test value: 0,99μs	Test value: 40,8μs; Δ=18.4％

Photo of test setup for Surge Immunity

Tabulated Results for Surges for Minimum Input Voltage			
	Minimum Rated Voltage (V)		220
	Nominal Rated Frequency (Hz).		50
Mode of Application – Mains	**Level**	**Polarity**	**Comments/Results**
Line 1 to Line 2 (Differential mode)	0.5kV	Positive	1
		Negative	1
	1.0kV	Positive	1
		Negative	1
Line 1 to Earth (Common mode)	0.5kV	Positive	1
		Negative	1
	1.0kV	Positive	1
		Negative	1
	2.0kV	Positive	1
		Negative	1
Line 2 to Earth (Common mode)	0.5kV	Positive	1
		Negative	1
	1.0kV	Positive	1
		Negative	1
	2.0kV	Positive	1
		Negative	1

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

Tabulated Results for Surges for Maximum Input Voltage			
Maximum Rated Voltage (V).....			240
Nominal Rated Frequency (Hz) .			50
Mode of Application - Mains	**Level**	**Polarity**	**Comments**
Line 1 to Line 2 (Differential mode)	0.5kV	Positive	1
		Negative	1
	1.0kV	Positive	1
		Negative	1
Line 1 to Earth (Common mode)	0.5kV	Positive	1
		Negative	1
	1.0kV	Positive	1
		Negative	1
	2.0kV	Positive	1
		Negative	1
Line 2 to Earth (Common mode)	0.5kV	Positive	1
		Negative	1
	1.0kV	Positive	1
		Negative	1
	2.0kV	Positive	1
		Negative	1

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

1.16 Test Conditions and Results – Conducted Disturbances Immunity

61000-4-6	**TEST:** RF Continuous Conducted – (IEC61000-4-6: 2003 /A2:2006)			Verdict
Method: Measurements were made on a ground plane that extends 0.5-meter minimum beyond all sides of the system under test. The EUT was located 10cm above the reference ground plane and any associated I/O cables attached to the EUT were located between 30mm and 50mm above the ground plane. The indicated field was pre-calibrated prior to placement of the system under test.				P
Laboratory Parameters:		Required prior to the test	During the test	
Ambient Temperature		10 to 40 °C	23°C	
Relative Humidity		10 to 90 %	58%	
Test Specifications:		**Frequency range**	**Measurement Point**	
Fully configured sample scanned over the following frequency range		150kHz* to 80MHz	Input a.c. Power Ports ECG Line Ports	
		Note* Verify against Clause 6.2.6.1 f)		
Level	**Non Life Supporting Equipment**	3 V rms		
		Amplitude modulation	80 % / 2 Hz sine min 1 sec dwell	
Frequency step size		1%		
Supplementary information: EUT powered at one of the Nominal input voltages and frequencies.				

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
RF-Generator	EM Test	CWS 500D	487/750812	2009.07.14	2010.07.13
Current Probe	Schaffner	CIP9136	487/430209	2009.05.30	2010.05.29

Photo of test setup for Conducted Disturbances


Tabulated Results for Conducted Disturbances	
Nominal Rated Voltage (V)	220 ~ 240
Nominal Rated Frequency (Hz)..	50

Point of Application	Comments/Results
Mains	1
I/O Line 1 – ECG line	1

X - Not performed
1 – Compliant - No observed/perceived response from EUT.
Note: Add more rows if needed. Description should detail the observation during testing.

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

61000-4-11	**TEST:** Voltage Dips and Interruptions – (IEC61000-4-11: 2001)	Verdict
Method: The product was subjected to voltage dips and interruptions. Testing was performed with the product connected directly to a generator capable of simulating the voltage drops and interrupts as described.		P

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	23°C
Relative Humidity	10 to 90 %	58%

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

Applied Levels		
Voltage Dips % U_T	Period (Cycles)	Sync Angle [degrees]
30	25	0
60	5	0
>95	0.5	0
Voltage Interruption % U_T	Seconds	Sync Angle [degrees]
>95	5	0

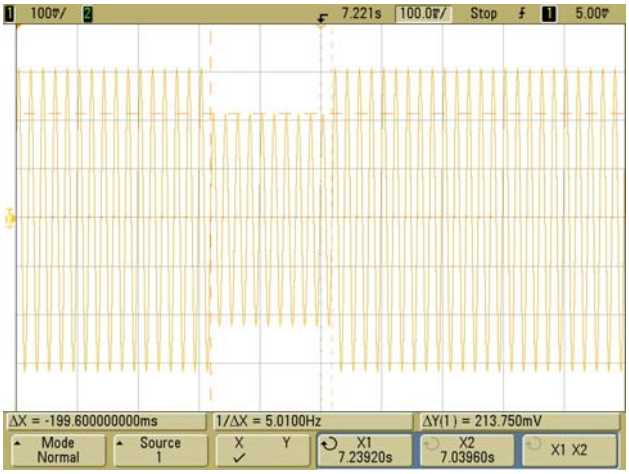
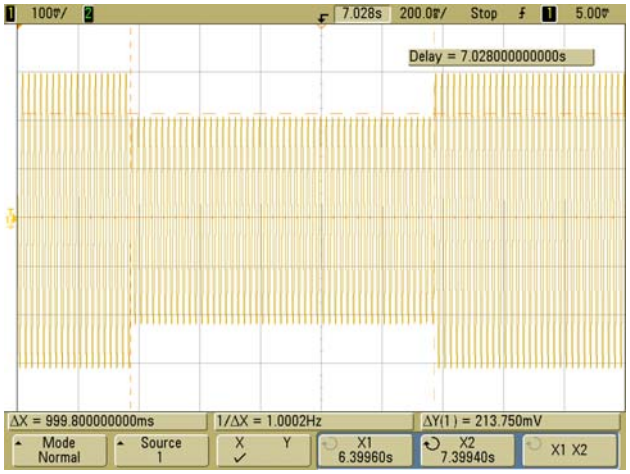
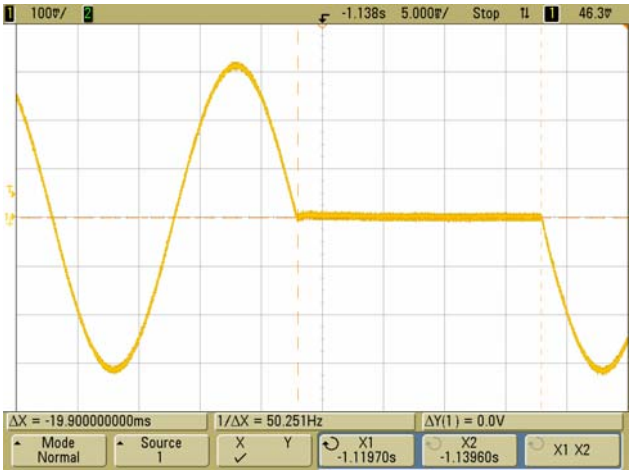
0 degrees is the crossover point of the voltage waveform.

Test is performed at the minimum and maximum RATED input voltages and at the minimum rated frequency.

Supplementary information:

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
AC Power Supply Testing System	California Instruments	C15003ix-400/3-CTS	487/689910	2008.11.21	2009.11.21

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


Voltage Dips and Interruption Verifications	
30% Dip	60% Dip
Duration time: 200ms(10Cycle)  Test value: 199,6ms	Duration time: 1000ms(50Cycle)  Test value: 999,8ms
>95% Interruption	
Duration time: 20ms(1Cycle)  Test value: 19,9ms	Intentionally Left Blank

Tabulated Results for Voltage Dips and Interruptions			
		Minimum Rated Voltage (V)	220
		Maximum Rated Frequency (Hz)	50
Point of application	Voltage reduction	Period (Cycles)	Comments/Results
Mains	30	25	P
Mains	60	5	P
Mains	>95	0.5	P
Point of application	Voltage reduction	Seconds	Comments/Results
Mains	>95	5	P
Supplementary information: The test was performed with battery installed.			

Tabulated Results for Voltage Dips and Interruptions			
		Maximum Rated Voltage (V)	240
		Minimum Rated Frequency (Hz)	50
Point of application	Voltage reduction	Period (Cycles)	Comments/Results
Mains	30	25	P
Mains	60	5	P
Mains	>95	0.5	P
Point of application	Voltage reduction	Seconds	Comments/Results
Mains	>95	5	P
Supplementary information: The test was performed with battery installed.			

X - Not performed
1 – Compliant - No observed/perceived response from EUT.
Note: Add more rows if needed. Description should detail the observation during testing.

1.18 Test Conditions and Results – Power- Frequency Magnetic Fields

61000-4-8	**TEST:** Power-frequency magnetic field – (IEC61000-4-8: 2001)	Verdict
Method: Measurements were made on a ground plane that extends 1-meter minimum beyond sides of the system under test. Tabletop EUT is located 80cm above the reference ground plane and floor-standing EUT is located 10cm above the reference ground plane. The indicated field was pre-calibrated prior to placement of the EUT under test.		P

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	23°C
Relative Humidity	10 to 90 %	58%

Fully configured sample tested at the power line frequency (See Note 1)	**Frequency**	**Application Point**
	50Hz and 60 Hz [1]	Enclosure

Frequency (Hz)	**Test Level (A/m)**
50	3
60	3

Tested at 50Hz and 60Hz powered at any one of its NOMINAL RATED input voltages.

Supplementary information:

Note 1: The test is performed at both 50 Hz and 60 Hz, with the exception that me equipment rated for use only at one of these frequencies need only be tested at that frequency.

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
MAGNETIC FIELD COIL	Schaffner	INA702	487/440201	2009.05.30	2010.05.29
Induction Coil Interface	Schaffner	INA2141	487/440202	2009.05.30	2010.05.29
Power Source	California Instrument	4500L	707/689501	2009.05.30	2010.05.29

Photo of test setup for Power- Frequency Magnetic Fields


Tabulated Results for Power Frequency Magnetic Field		
Nominal Rated Voltage (V).....	220 ~ 240	
Point of application	**Results**	
	50 Hz	**60 Hz**
X-Axis	1	X
Y-Axis	1	X
Z-Axis	1	X
Supplementary information:		

X - Not performed or not required.
1 – Compliant - No observed response from EUT.
2 -
Note: Add more rows if needed. Description should detail the observation during testing.

1.19 Particular test item – Test Conditions and Results – Electrosurgery interference

	TEST: Electrosurgery interference – (IEC 60601-2-25/A1:1999)		Verdict
Method: The HF SURGICAL EQUIPMENT which is used shall comply with IEC 60601-2-2 and shall have a minimum power cut mode capability of 300 W, a minimum coagulation mode of 100 W and working frequency of 400 kHz ±10 %.			P
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	10 to 40 °C	22°C	
Relative Humidity	10 to 90 %	56%	
Fully configured sample tested[1]	**Working Frequency**	**Application Point**	
	400KHz	Patient cable via coupling network	
Mode	**Test Level (W)**		
Cut	300		
Coagulation	100		
Supplementary information: Note 1: using PATIENT CABLES, LEAD WIRES, accessories or settings recommended by the manufacturer.			

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Electrosurgical Units	Changzhou Yanling	POWER-420D	N/A	N/A	N/A

Photo of test setup for Power- Frequency Magnetic Fields


Tabulated Results for Electrosurgery interference		
Nominal Rated Voltage (V).....	220 ~ 240	
Times	**Results**	
	Cut	Coagulation
5	1	1
5	1	1
Supplementary information:		

X - Not performed or not required.
1 – Compliant - Comply with §36.202.101 of IEC 60601-2-25/A1:1999. No observed response from EUT.
2 – Compliant - Comply with §36.202.101 of IEC 60601-2-25/A1:1999. Return to previous operating mode within 10s after exposure to the field produced by the HF SURGICAL EQUIPMENT, without loss of any stored data.

Appendix A

Test data sheets

150kHz-30MHz Conducted Emission Test

ECG100G

EUT: ECG
Manuf: Contec Medical Systems Co.,Ltd.
Op Cond: Power on
Operator: WJiang
Test Spec: CISPR 11 classA
Comment: Phase L

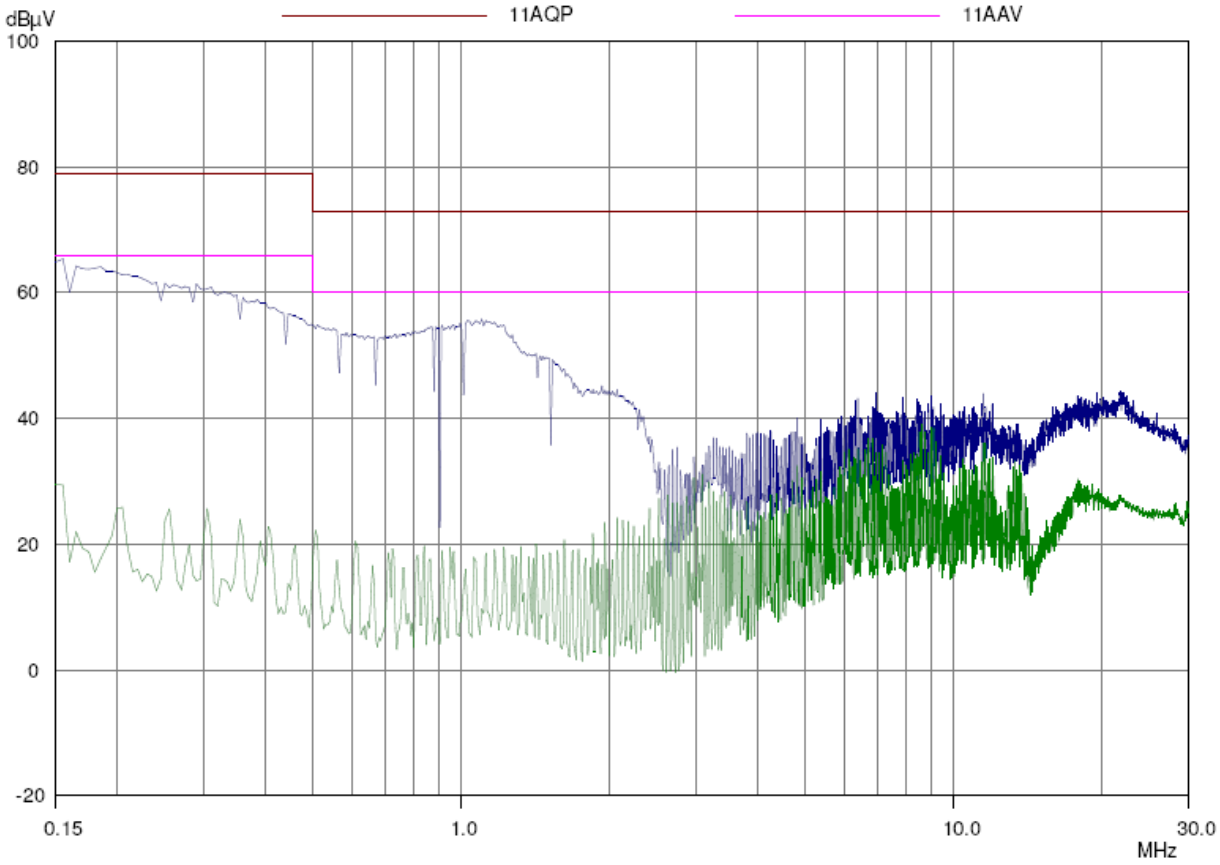
Result File: 100GI.dat : New Measurement

Scan Settings (2 Ranges)

Frequencies			Receiver Settings					
Start	Stop	Step	IF BW	Detector	M-Time	Atten	Preamp	OpRge
150kHz	1000kHz	5kHz	10kHz	PK+AV	20msec	Auto	OFF	60dB
1000kHz	30MHz	10kHz	10kHz	PK+AV	20msec	Auto	OFF	60dB

Transducer	No.	Start	Stop	Name
	1	9kHz	30MHz	NSLK

Prescan Measurement:
Detectors: X PK / + AV
Meas Time: see scan settings
Subranges: 16
Acc Margin: 8 dB



150kHz-30MHz Conducted Emission Test

ECG100G

EUT: ECG
Manuf: Contec Medical Systems Co.,Ltd.
Op Cond: Power on
Operator: WJiang
Test Spec: CISPR 11 classA
Comment: Phase N

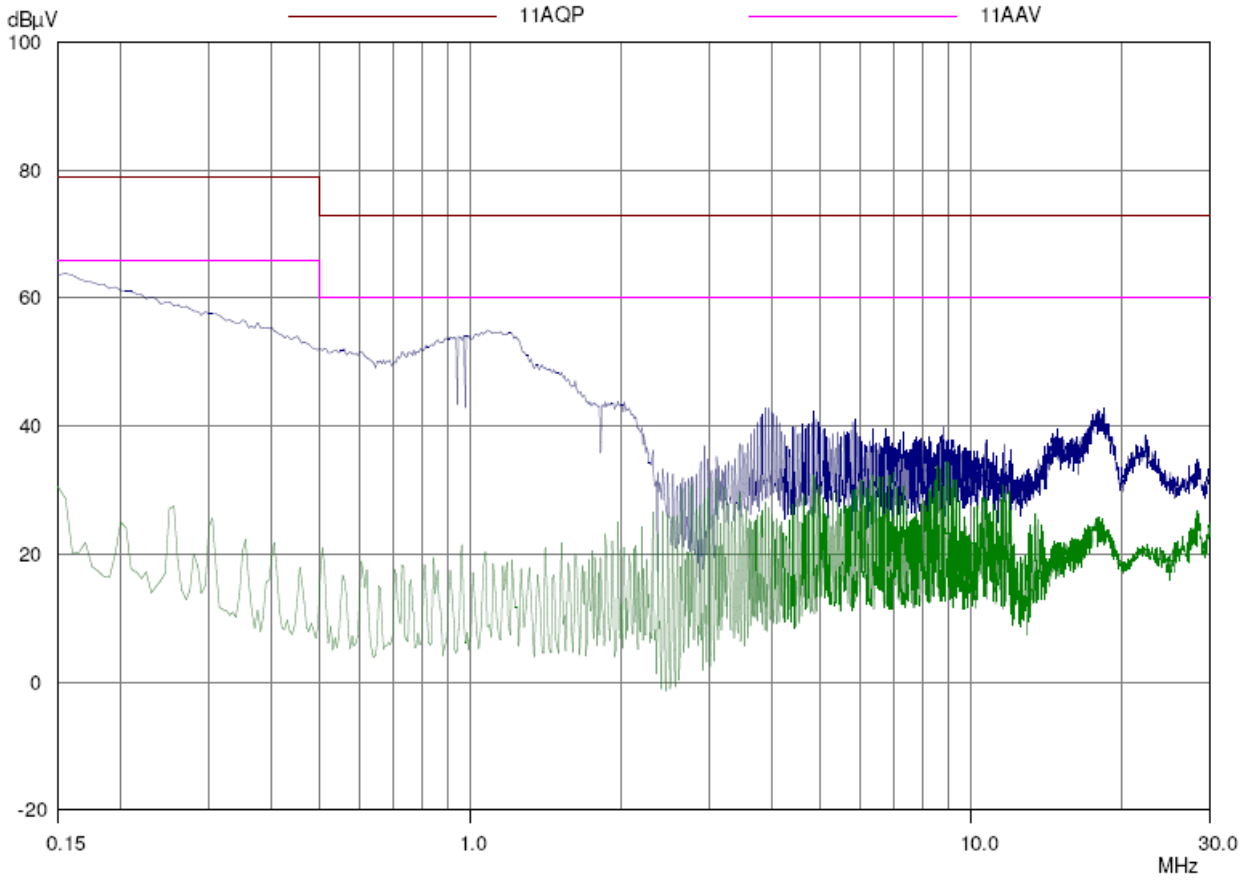
Result File: 100GN.dat : New Measurement

Scan Settings (2 Ranges)

Frequencies			Receiver Settings					
Start	Stop	Step	IF BW	Detector	M-Time	Atten	Preamp	OpRge
150kHz	1000kHz	5kHz	10kHz	PK+AV	20msec	Auto	OFF	60dB
1000kHz	30MHz	10kHz	10kHz	PK+AV	20msec	Auto	OFF	60dB

Transducer	No.	Start	Stop	Name
	1	9kHz	30MHz	NSLK

Prescan Measurement:
Detectors: X PK / + AV
Meas Time: see scan settings
Subranges: 16
Acc Margin: 8 dB



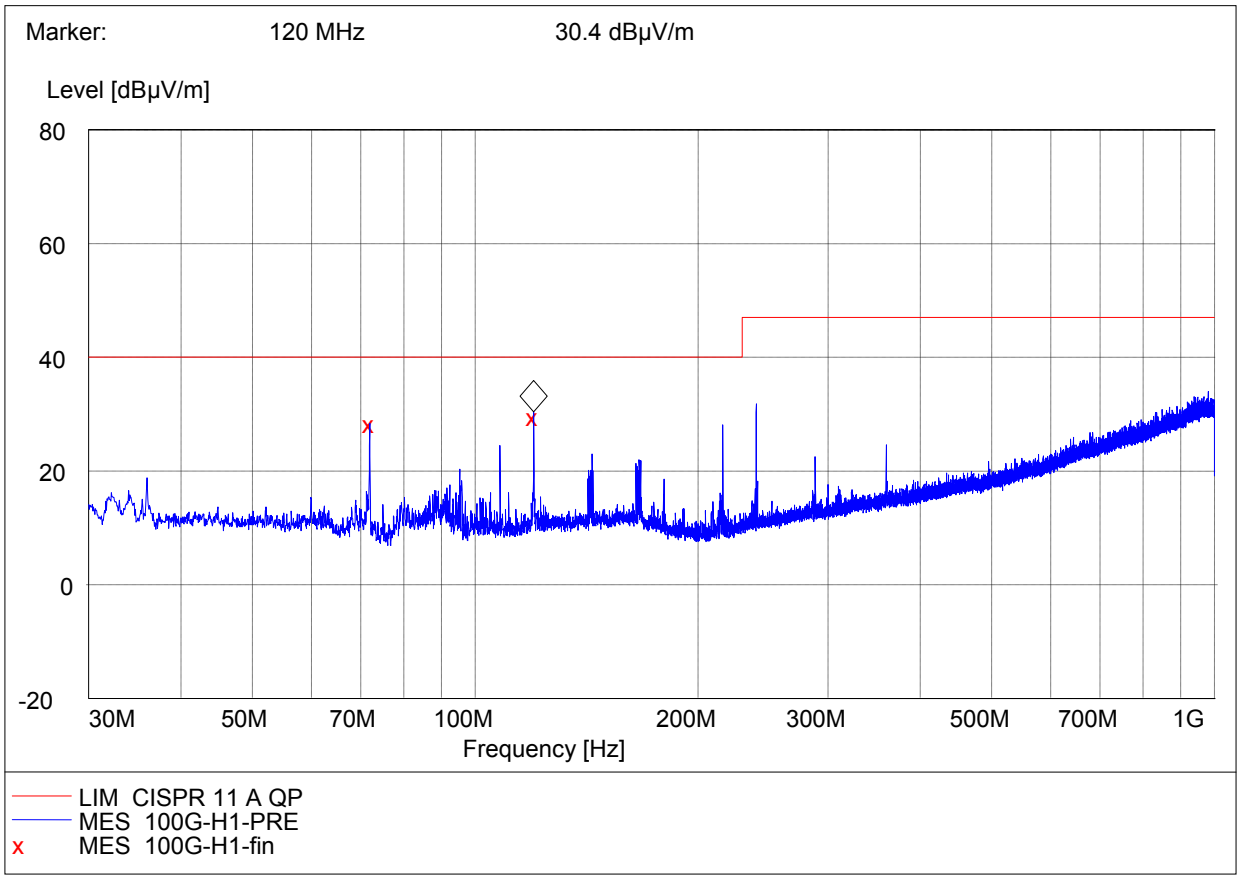
30MHz-1GHz Radiated Emission Test

ECG100G

EUT: ECG
Manufacturer: Contec Medical Systems Co.,Ltd.
Operating Condition: power on
Teat Site: JIANGSU TUV PS 10m CHAMBER
Operator: WJiang
Test Specification: CISPR 11, Group 1, Class A
Comment : Horizontal

SCAN TABLE: "CISPR 11 Field"

Start Frequency	Stop Frequency	Step Width	Detector	Meas. Time	IF Bandw.	Transducer
30.0 MHz	1.0 GHz	60.0 kHz	MaxPeak	1.0 ms	120 kHz	RE_8447F08



MEASUREMENT RESULT: "100G-H1-fin"

Frequency MHz	Level dBµV/m
72.000000	28.55
120.000000	29.78

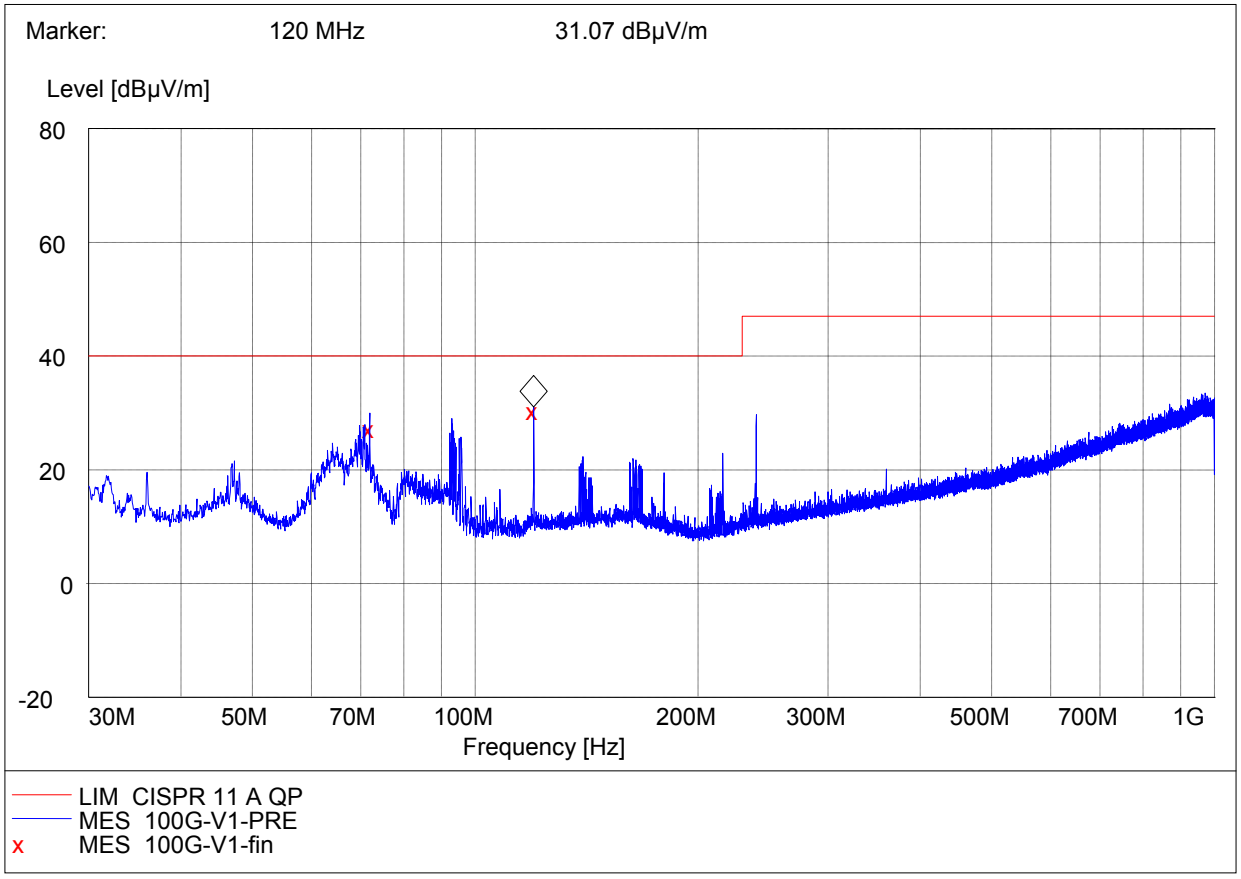
30MHz-1GHz Radiated Emission Test

ECG100G

EUT: ECG
Manufacturer: Contec Medical Systems Co.,Ltd.
Operating Condition: power on
Teat Site: JIANGSU TUV PS 10m CHAMBER
Operator: WJiang
Test Specification: CISPR 11, Group 1, Class A
Comment : Vertical

SCAN TABLE: "CISPR 11 Field"

Start Frequency	Stop Frequency	Step Width	Detector	Meas. Time	IF Bandw.	Transducer
30.0 MHz	1.0 GHz	60.0 kHz	MaxPeak	1.0 ms	120 kHz	RE_8447F08



MEASUREMENT RESULT: "100G-V1-fin"

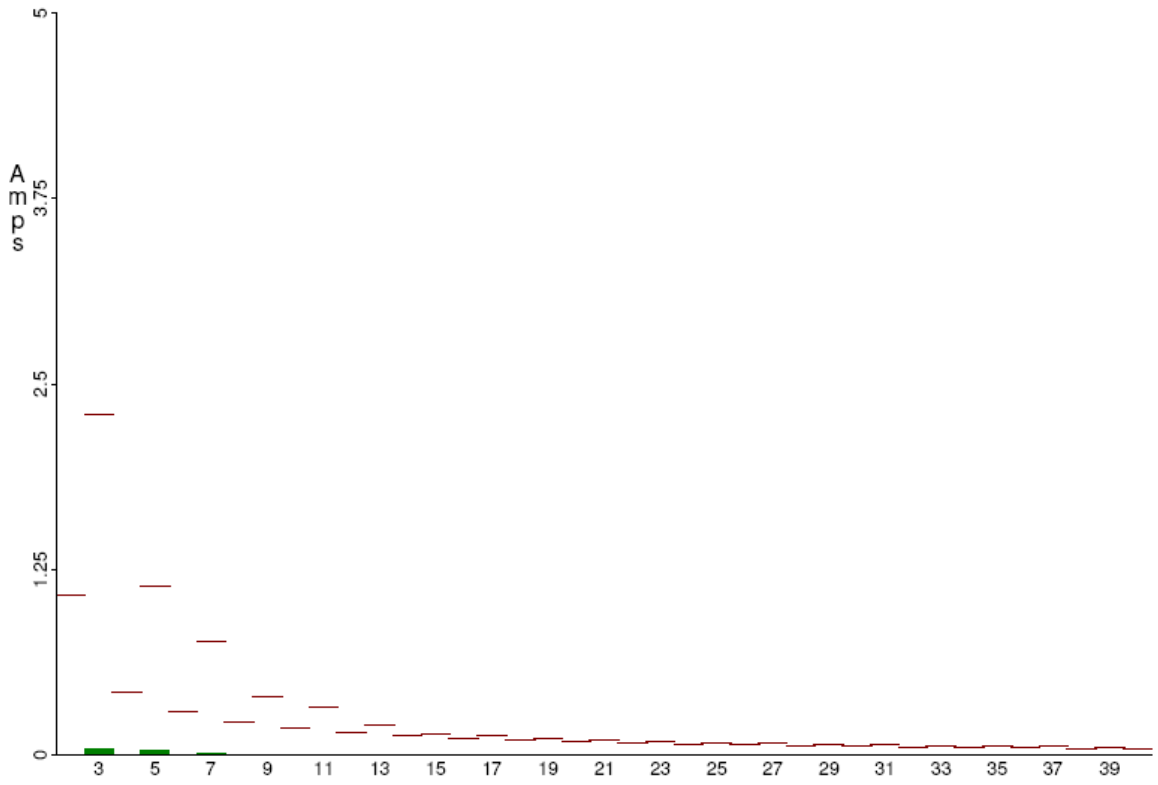
Frequency MHz	Level dBµV/m
72.000000	27.44
120.000000	30.55

Product:	ECG	Jul 29 2009 15:15
Serial no:	ECG100G	Page 1 of 1
Description:	Contec Medical Systems Co.,Ltd. Power on	
Result Name:	100G	
Voltech IEC61000-3 Windows Software 1.13.05RC1		Test Date: Jul 29 2009 15:11
Type of Test:	Fluctuating Harmonics Test - Worst Case Table (2006)	
Power Analyzer:	Voltech PM6000 SN: 100006700199 Firmware version: v1.20.06RC4	
	Channel(s):	
	1. SN: 090015500299, 25 Adjusted Date: 18 NOV 2007. 2. SN:None Adjusted Date:None	
	3. SN:None Adjusted Date:None 4. SN:None Adjusted Date:None	
	5. SN:None Adjusted Date:None 6. SN:None Adjusted Date:None	
	Shunt(s):	
	1. SN: 091024300570, 4 Adjusted Date: 18 NOV 2007. 2. SN:None Adjusted Date:None	
	3. SN:None Adjusted Date:None 4. SN:None Adjusted Date:None	
	5. SN:None Adjusted Date:None 6. SN:None Adjusted Date:None	
AC Source:	Mains / Manual Source	
Overall Result: **N/A**		

Class	Class A
Class Multiplier	1

Harm	Limit 1	Limit 2	Average Reading	<L1 <L2	Max Reading	<L2	Pass FAIL	Harm	Limit 1	Limit 2	Average Reading	<L1 <L2	Max Reading	<L2	Pass FAIL
2	1.0800A	1.6200A	1.287mA	✓ ✓	1.810mA	✓	N/A	3	2.3000A	3.4500A	48.46mA	✓ ✓	48.71mA	✓	N/A
4	430.0mA	645.0mA	0.283mA	✓ ✓	0.399mA	✓	N/A	5	1.1400A	1.7100A	34.39mA	✓ ✓	34.55mA	✓	N/A
6	300.0mA	450.0mA	0.644mA	✓ ✓	1.041mA	✓	N/A	7	770.0mA	1.1550A	18.08mA	✓ ✓	18.15mA	✓	N/A
8	230.0mA	345.0mA	0.374mA	✓ ✓	0.538mA	✓	N/A	9	400.0mA	600.0mA	4.560mA	✓ ✓	4.593mA	✓	N/A
10	184.0mA	276.0mA	0.153mA	✓ ✓	0.316mA	✓	N/A	11	330.0mA	495.0mA	2.884mA	✓ ✓	2.928mA	✓	N/A
12	153.3mA	230.0mA	0.266mA	✓ ✓	0.364mA	✓	N/A	13	210.0mA	315.0mA	4.542mA	✓ ✓	4.578mA	✓	N/A
14	131.4mA	197.1mA	0.126mA	✓ ✓	0.157mA	✓	N/A	15	150.0mA	225.0mA	2.426mA	✓ ✓	2.448mA	✓	N/A
16	115.0mA	172.5mA	0.134mA	✓ ✓	0.179mA	✓	N/A	17	132.3mA	198.5mA	0.323mA	✓ ✓	0.340mA	✓	N/A
18	102.2mA	153.3mA	0.160mA	✓ ✓	0.195mA	✓	N/A	19	118.4mA	177.6mA	1.460mA	✓ ✓	1.487mA	✓	N/A
20	92.00mA	138.0mA	0.138mA	✓ ✓	0.169mA	✓	N/A	21	107.1mA	160.7mA	1.296mA	✓ ✓	1.318mA	✓	N/A
22	83.63mA	125.4mA	0.094mA	✓ ✓	0.110mA	✓	N/A	23	97.82mA	146.7mA	0.460mA	✓ ✓	0.475mA	✓	N/A
24	76.66mA	115.0mA	0.161mA	✓ ✓	0.180mA	✓	N/A	25	90.00mA	135.0mA	0.457mA	✓ ✓	0.475mA	✓	N/A
26	70.76mA	106.1mA	0.129mA	✓ ✓	0.145mA	✓	N/A	27	83.33mA	125.0mA	0.703mA	✓ ✓	0.730mA	✓	N/A
28	65.71mA	98.57mA	0.109mA	✓ ✓	0.120mA	✓	N/A	29	77.58mA	116.3mA	0.387mA	✓ ✓	0.401mA	✓	N/A
30	61.33mA	92.00mA	0.090mA	✓ ✓	0.101mA	✓	N/A	31	72.58mA	108.8mA	0.176mA	✓ ✓	0.194mA	✓	N/A
32	57.50mA	86.25mA	0.094mA	✓ ✓	0.107mA	✓	N/A	33	68.18mA	102.2mA	0.401mA	✓ ✓	0.415mA	✓	N/A
34	54.11mA	81.17mA	0.101mA	✓ ✓	0.117mA	✓	N/A	35	64.28mA	96.42mA	0.306mA	✓ ✓	0.318mA	✓	N/A
36	51.11mA	76.66mA	0.092mA	✓ ✓	0.103mA	✓	N/A	37	60.81mA	91.21mA	0.119mA	✓ ✓	0.131mA	✓	N/A
38	48.42mA	72.63mA	0.087mA	✓ ✓	0.099mA	✓	N/A	39	57.69mA	86.53mA	0.220mA	✓ ✓	0.235mA	✓	N/A
40	46.00mA	69.00mA	0.095mA	✓ ✓	0.110mA	✓	N/A								

Product:	ECG	Jul 29 2009 15:15
Serial no:	ECG100G	Page 1 of 1
Description:	Contec Medical Systems Co.,Ltd. Power on	
Result Name:	100G	
Voltech IEC61000-3 Windows Software 1.13.05RC1		Test Date: Jul 29 2009 15:11
Type of Test:	Fluctuating Harmonics Test - Average Vs Limit1 Bar Chart (2006)	
Power Analyzer:	Voltech PM6000 SN: 100006700199 Firmware version: v1.20.06RC4	
	Channel(s):	
	1. SN: 090015500299, 25 Adjusted Date: 18 NOV 2007. 2. SN:None Adjusted Date:None	
	3. SN:None Adjusted Date:None 4. SN:None Adjusted Date:None	
	5. SN:None Adjusted Date:None 6. SN:None Adjusted Date:None	
	Shunt(s):	
	1. SN: 091024300570, 4 Adjusted Date: 18 NOV 2007. 2. SN:None Adjusted Date:None	
	3. SN:None Adjusted Date:None 4. SN:None Adjusted Date:None	
	5. SN:None Adjusted Date:None 6. SN:None Adjusted Date:None	
AC Source:	Mains / Manual Source	
Overall Result: **N/A**		



Product:	ECG	Jul 29 2009 15:27
Serial no:	ECG100G	Page 1 of 1
Description:	Contec Medical Systems Co.,Ltd. Power on	
Result Name:	100G	
Voltech IEC61000-3 Windows Software 1.13.05RC1		Test Date: Jul 29 2009 15:17
Type of Test:	Flickermeter Test - Table	
Power Analyzer:	Voltech PM6000 SN: 100006700199 Firmware Version: v1.20.06RC4	
	Channel(s):	
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	3. SN:None Adjusted Date:None 4. SN:None Adjusted Date:None	
	5. SN:None Adjusted Date:None 6. SN:None Adjusted Date:None	
	Shunt(s):	
	1. SN: 091024300570, 4 Adjusted Date: 18 NOV 2007. 2. SN:None Adjusted Date:None	
	3. SN:None Adjusted Date:None 4. SN:None Adjusted Date:None	
	5. SN:None Adjusted Date:None 6. SN:None Adjusted Date:None	
AC Source:	Mains / Manual Source	
Overall Result: **PASS**	Notes: Measurement method - Voltage	

	Pst	dc (%)	dmax (%)	d(t) > 3.3%(ms)
Limit	1.000	3.300	4.000	500
Reading 1	0.088	0.006	0.267	0

Appendix B

Guidance and manufacturer's declaration

Guidance and manufacturer's declaration – electromagnetic emissions-
for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission		
The ECG100G ECG is intended for use in the electromagnetic environment specified below. The customer of the user of the *ECG100G ECG* should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The ***ECG100G ECG*** 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.
RF emission CISPR 11	Class A	The ***ECG100G ECG*** is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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

Guidance and manufacture's declaration – electromagnetic immunity			
The *ECG100G ECG* is intended for use in the electromagnetic environment specified below. The customer or the user of *ECG100G ECG* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±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 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *ECG100G ECG* requires continued operation during power mains dip & interruptions, it is recommended that the *ECG100G ECG* be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/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 SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity

The *ECG100G ECG* is intended for use in the electromagnetic environment specified below. The customer or the user of *ECG100G ECG* should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the *ECG100G ECG*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

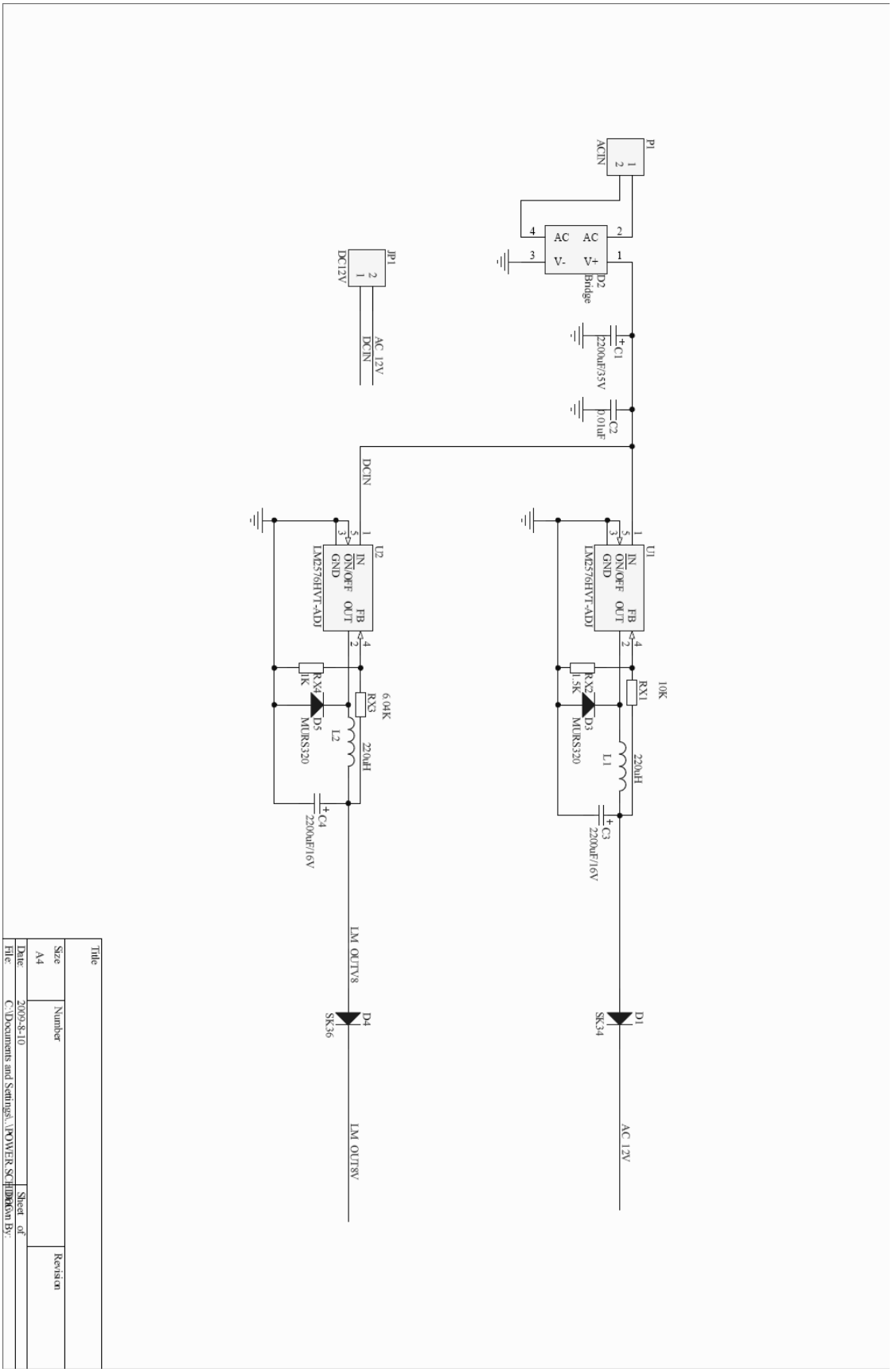
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] 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 *ECG100G ECG* is used exceeds the applicable RF compliance level above, the *ECG100G ECG* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *ECG100G ECG*.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

Recommended separation distances between portable and mobile RF communications equipment and the *ECG100G ECG*			
The *ECG100G ECG* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *ECG100G ECG* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *ECG100G ECG* as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
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.			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AC
AC
V-
V+
D2
Bridge
C1
2200uF/35V
C2
0.01uF
JP1
DC12V
AC 12V
DCIN
U1
U2
LM2576HVT-ADJ
IN
ON/OFF
GND
FB
OUT
RX1
10K
RX2
1.5K
RX4
1K
RX3
6.04K
D3
MURS320
D5
MURS320
L1
220uH
L2
220uH
C3
2200uF/16V
C4
2200uF/16V
D1
SK34
D4
SK36
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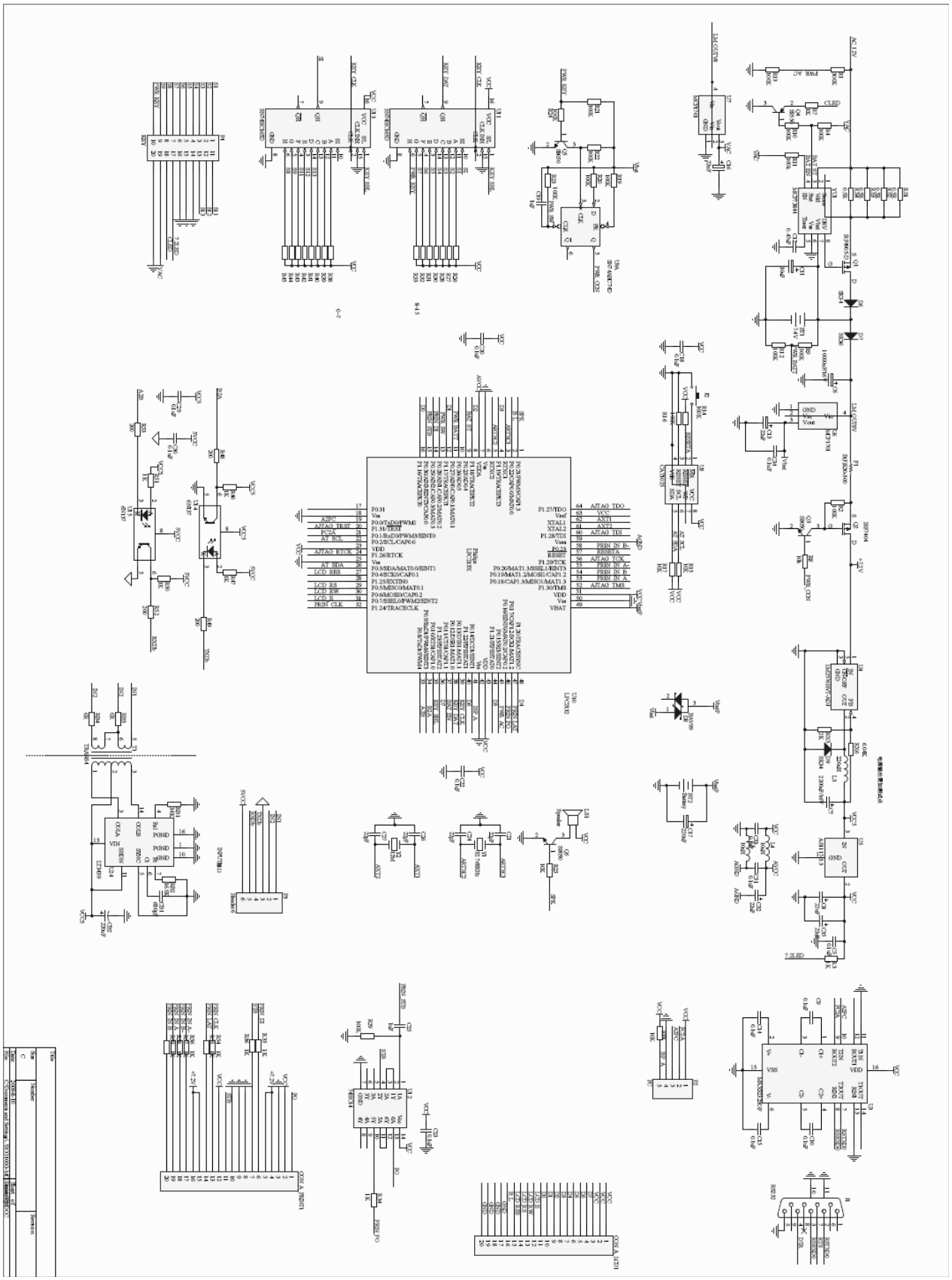

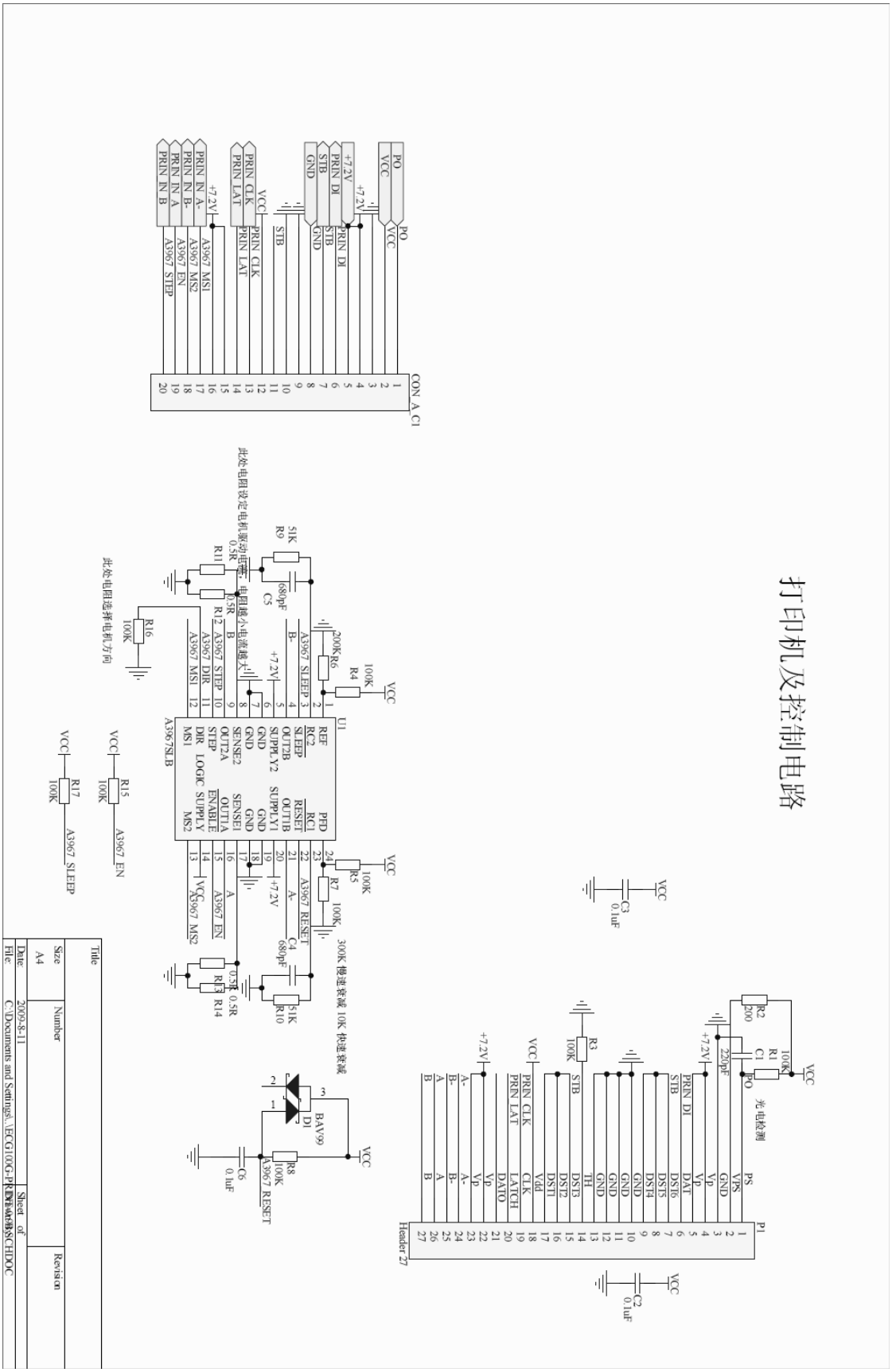
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CON A C1
A3967 MS1
A3967 MS2
A3967 EN
A3967 STEP
PRIN CLK
PRIN LAT
PRIN DI
STB
GND
PRIN IN A
PRIN IN B
PRIN IN A-
PRIN IN B-
+7.2V
VCC
PO
U1
A3967SLB
REF
RC2
SLEEP
OUT2B
SUPPLY2
GND
GND
SENSE2
OUT2A
STEP
DIR
LOGIC SUPPLY
MS1
MS2
PFD
RC1
RESET
OUT1B
SUPPLY1
GND
GND
SENSE1
OUT1A
ENABLE
A3967 SLEEP
A3967 STEP
A3967 DIR
A3967 MS1
A3967 RESET
A3967 EN
此处电阻设定电机驱动电流
此处电阻选择电机方向
电阻越小电流越大
300K 慢速衰减 10K 快速衰减
光电检测
P1
Header 27
BAV99
D1
R1
R2
R3
R4
R5
R6
R7
R8
R9
R10
R11
R12
R13
R14
R15
R16
R17
C1
C2
C3
C4
C5
C6
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220pF
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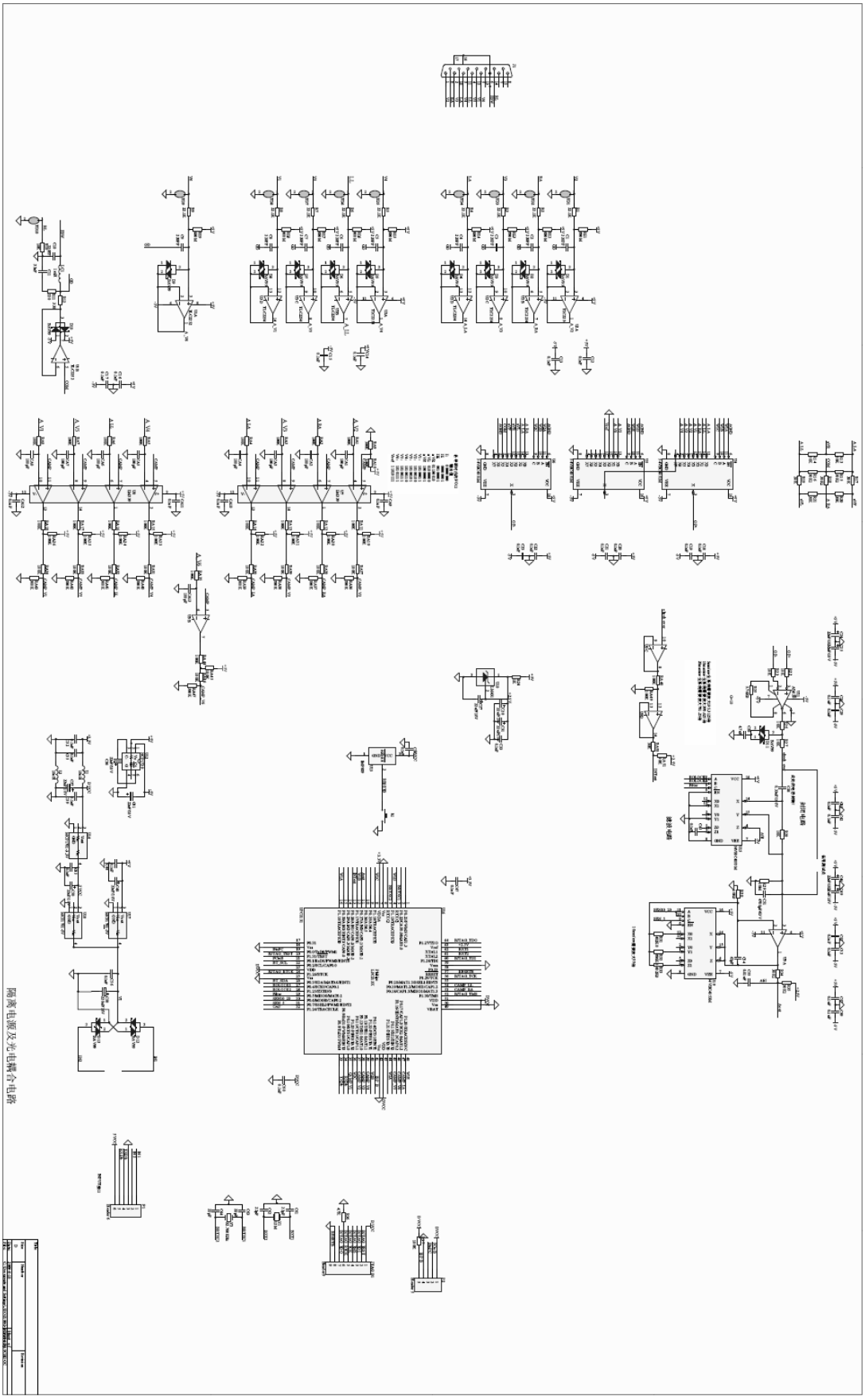
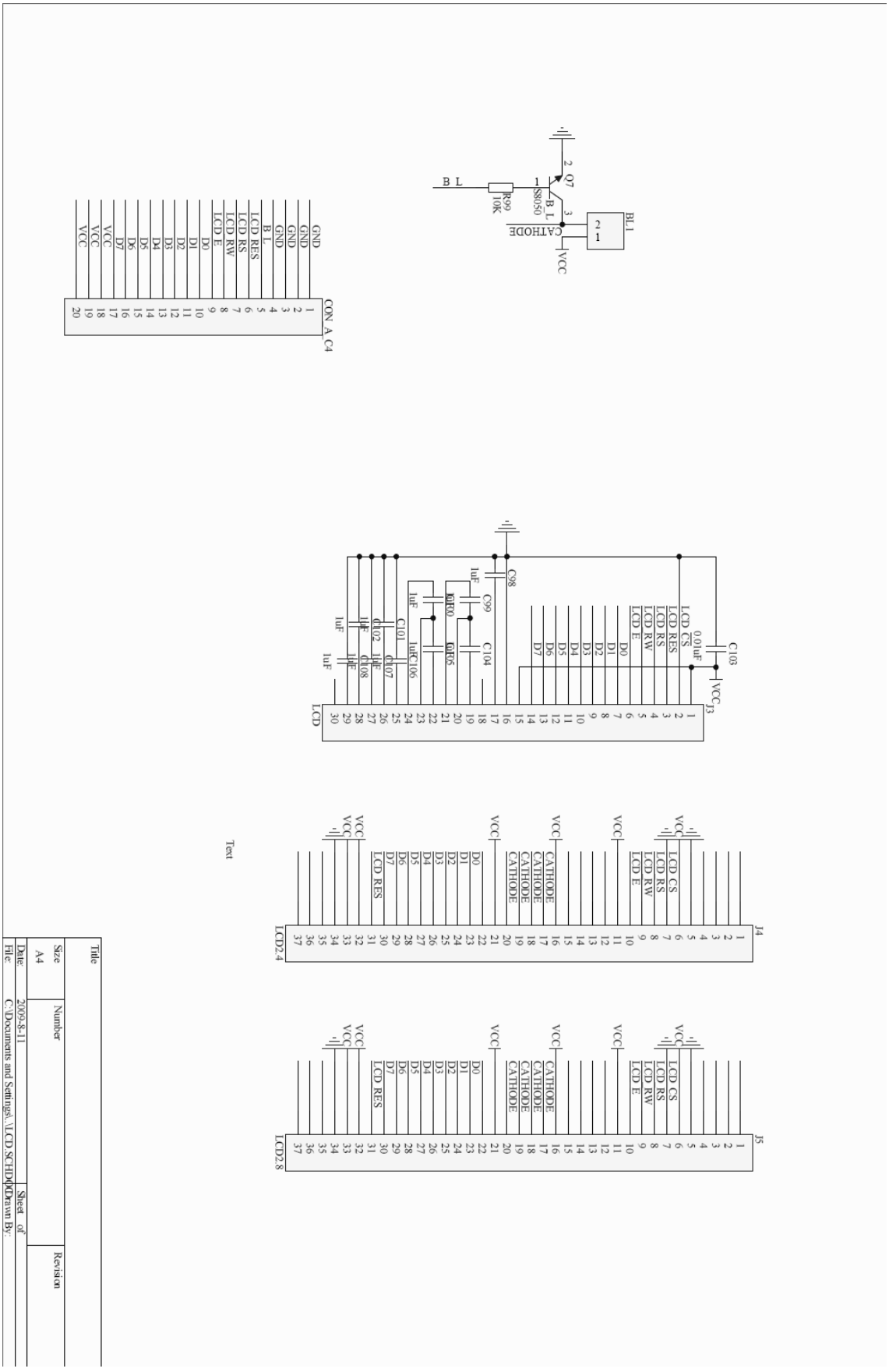

隔离电源及光电耦合电路


CON_A C4
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GND
GND
GND
GND
B_L
LCD RES
LCD RS
LCD RW
LCD E
D0
D1
D2
D3
D4
D5
D6
D7
VCC
VCC
VCC
VCC
VCC
Q7
SS8050
R99
10K
B_L
CATHODE
BL1
VCC
LCD
C98
C99
C101
C104
C106
C103
0.01uF
LCD CS
LCD RES
LCD RS
LCD RW
LCD E
D0
D1
D2
D3
D4
D5
D6
D7
VCC3
LCD2.4
J4
LCD2.8
J5
CATHODE
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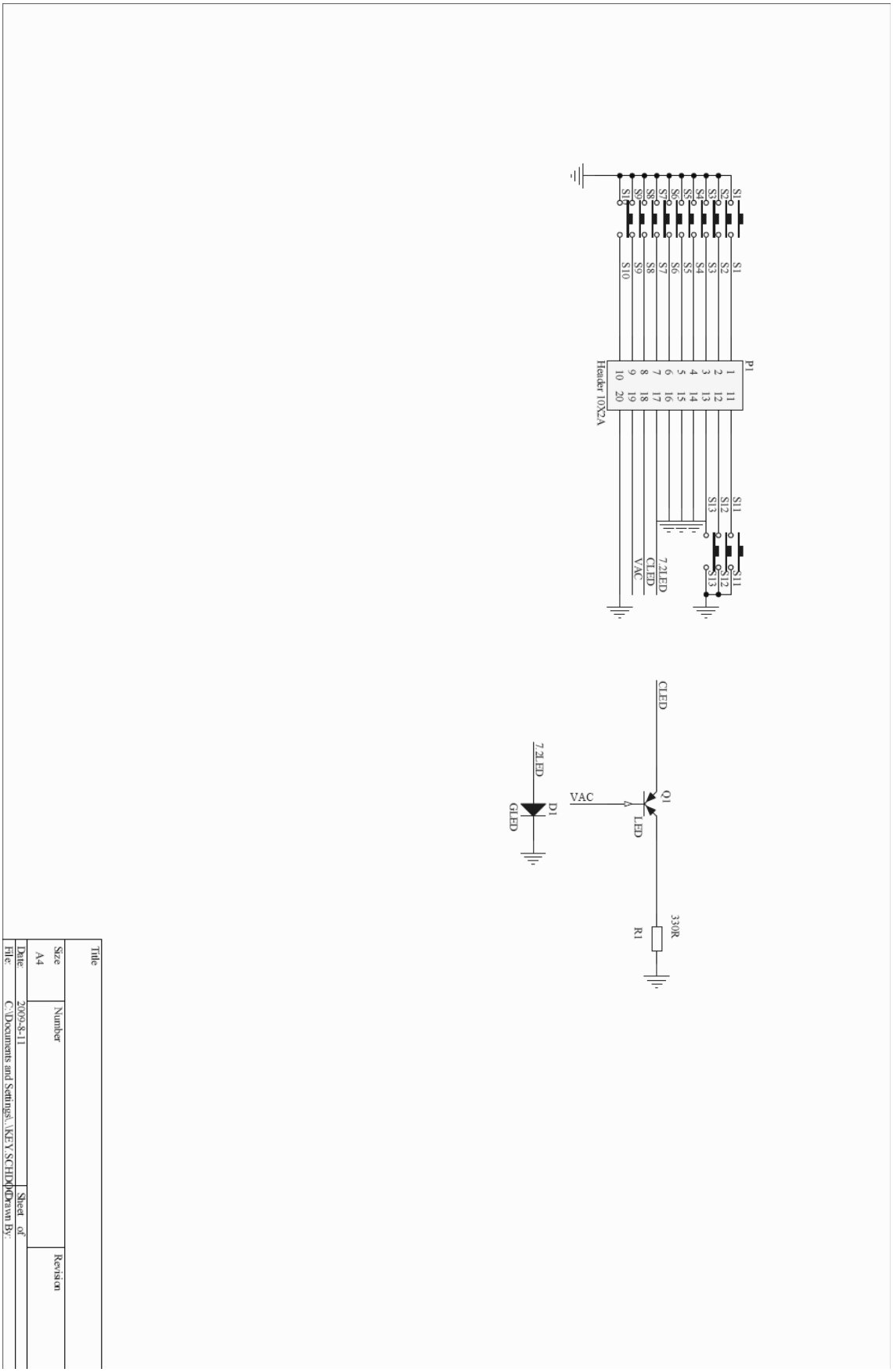
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S2
S3
S4
S5
S6
S7
S8
S9
S10
S11
S12
S13
P1
Header 10X2A
7.2LED
CLED
VAC
GLED
D1
Q1
LED
330R
R1
Title
Size
A4
Number
Revision
Date:
2009-8-11
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Comment	Description	Type	Designator	Footprint	LibRef	Quantity
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晶振	32.768KHz	Crystal	Y2	XTAL-2	CRYSTAL	2
电感	220uH	Inductor	L1, L2, L3	L-T	Inductor	3
电感	10uH	Inductor	L4, L5	CR3225-1210	Inductor	2
电感	10uH	Inductor	L1, L2	CR3225-1210	Inductor	2
电感	1mH		LC1	CR3225-1210	INDUCTOR1	1
小磁环	Φ3.5-5.0mm					
大磁环	Φ10.5-12.5mm					
磁珠	500mA	0603				

Appendix C

Photo documents

Photo documents

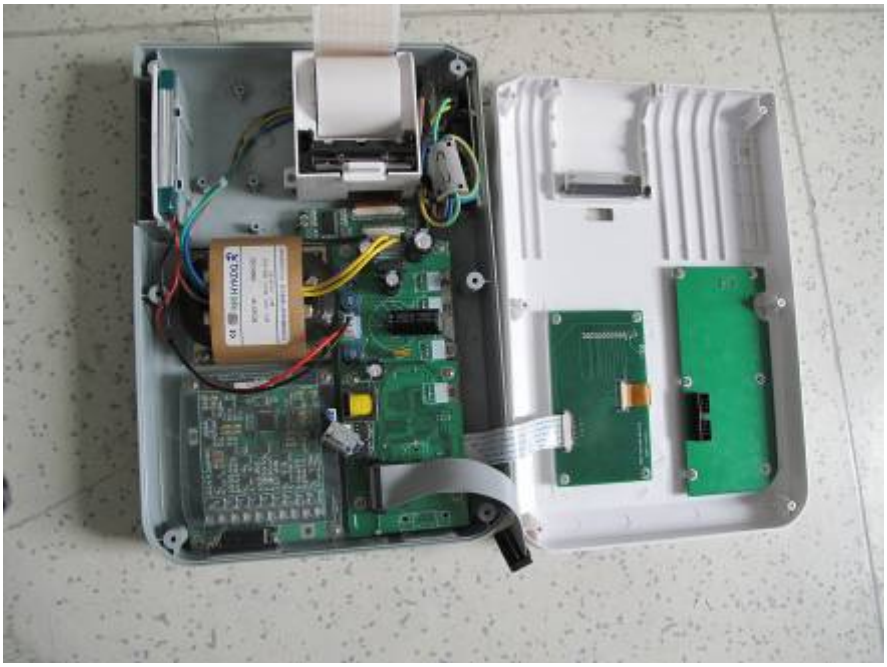

Photo documents

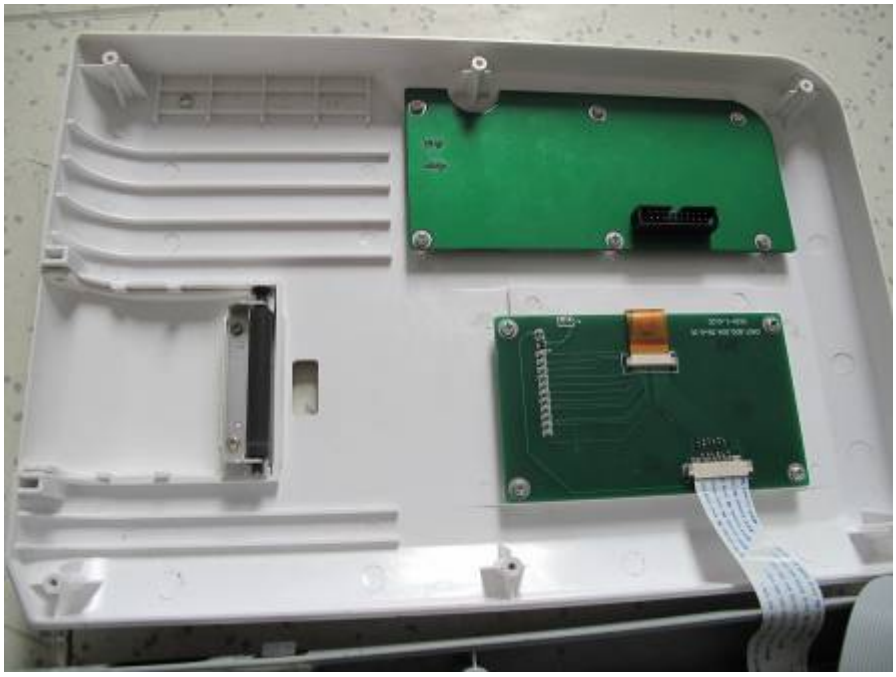

Photo documents

Photo documents

Photo documents