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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. ..... :	BJ1090208-3
Date of issue ..... :	April 28, 2010
Total number of pages	62
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, China
Test specification:	
Standard..... :	IEC 60601-1-2: 2007 (Third Edition)
	IEC 60601-2-30:1999
Non-standard test method……..…..:	N/A
Test result……..……..…..:	Comply with the above standard
Test Report Form No..... :	EMC_TEST REPORT_Med2007_e
Master TRF ..... :	Dated 2009-07

Test item description .....:	
Trade Mark ..... :	Contec
Manufacturer ..... :	Contec Medical Systems Co.,Ltd.
Model/Type reference ..... :	ABPM/ Ambulatory Blood Pressure Monitor
Ratings ..... :	DC3V, ≤800mA
	Protection Class III, IPX1

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)	Ming Gu
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	N/A
Radiated Emissions	Clause 6.1.1.	Test Area - E
Harmonics Current Emissions	Clause 6.1.3	N/A
Voltage Fluctuations and Flicker	Clause 6.1.3	N/A
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	N/A
Surges	Clause 6.2.5	N/A
Conducted Disturbances	Clause 6.2.6	N/A
Voltage Dips, Interruptions	Clause 6.2.7	N/A
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 ..... :	ABPM/ Ambulatory Blood Pressure Monitor
Ratings ..... :	DC3V, ≤800mA
	Protection Class III, IPX1
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 ..... :	April 9, 2010
Date (s) of performance of tests ..... :	April 19, 2010

General remarks:

N/A

General product information:

The device is applied to Blood Pressure (BP) measure and monitor for adult, pediatric, and neonatal. It most stores 300 records of common user and 358 of ambulatory Blood Pressure data. Every record includes the detailed measure time, systolic blood pressure, diastolic blood pressure, mean blood pressure, pulse rate, error message and record number, etc.

Report Index:

Note: To update all fields in this TRF, including the Page numbers on the Index page, click Select All on the Edit menu, and then press F9.

1.1 Equipment Description

The device is applied to Blood Pressure (BP) measure and monitor for adult, pediatric, and neonatal. It most stores 300 records of common user and 358 of ambulatory Blood Pressure data. Every record includes the detailed measure time, systolic blood pressure, diastolic blood pressure, mean blood pressure, pulse rate, error message and record number, etc.

This device has friendly operation interface ,and adopts 2.4inch color LCD. It integrates data review function and display function which includes large-print single record data review ,data list ,BP data trends chart, the current time、data、power、alarm and so on.

1.1.1 Equipment Marking Plate

1.1.2 Supporting Equipment Used During Test:

Use*	Product Type	Manufacturer	Model	Comments
SIM	Non-invasive blood pressure monitor analyzer	FLUKE	BP PUMP2	None
Delete or add rows as needed except for the header.				

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	Mains	DC	—	—	None
Delete or add rows as needed except for the header.					
*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
8	--	--	--
--	--	--	--
--	--	--	--
--	--	--	--

1.1.5 Power Interface

Mode No.	Voltage (V)	Current (A)	Power (W)	Frequency (DC/AC-Hz)	Phases (No.)	Comments
Rated	3	--	--	DC	--	--

1.2 EUT Operation Modes:

Mode #	Description
1	Normal Mode: All functions are ready
2	

1.3 EUT Configuration Modes

Mode #	Description
1	

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

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		P
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		P
	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		--
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		--
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
5.2.2.7	Requirements of cables, transducers and accessories		P
a)	Documentation shall include list of ME Equipment		P

IEC 60601-1-2			
Clause	Requirement + Test	Result - Remark	Verdict
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 B	—
	Group 1 or 2 .....:	Group 1	—
	CISPR 11, 14-1, or 15.....:	CISPR 11	—
6.1.1.2	Limits of mains terminal disturbance voltage .....:		N/A
	Limits for radiated disturbance .....:		P
	Limits for disturbance power (if applicable) .....:		N/A
6.1.3.1	Harmonic Current Emissions per IEC61000-3-2..:		N/A
6.1.3.2	Voltage Fluctuations and Flicker per IEC61000-3-3		N/A
6.2	Immunity		
6.2.2	Electrostatic Discharges (ESD).....:	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	N/A
6.2.5	Surges.....:	IEC 61000-4-5: 2001	N/A
6.2.6	Conducted Disturbances, induced by RF fields ...:	IEC 61000-4-6: 2003/A2:2006	N/A
6.2.7	Voltage Dips, Interruptions, and variations .....:	IEC 61000-4-11: 2001	N/A
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.		N/A

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Delete or add rows as needed except for the header.					

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)	Gain/Loss Factor (dB)	Transducer Factor (dB)	Level dB (μV)	Limit 1 dB (μV)	Margin (dB)
Delete or add rows as needed except for the header.								
Note: This table is to be used when Gain/Loss and Transducer Factors are provided separately. Table below 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.								

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)
Delete or add rows as needed except for the header.							
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

1.8 Test Conditions and Results – Radiated Emissions

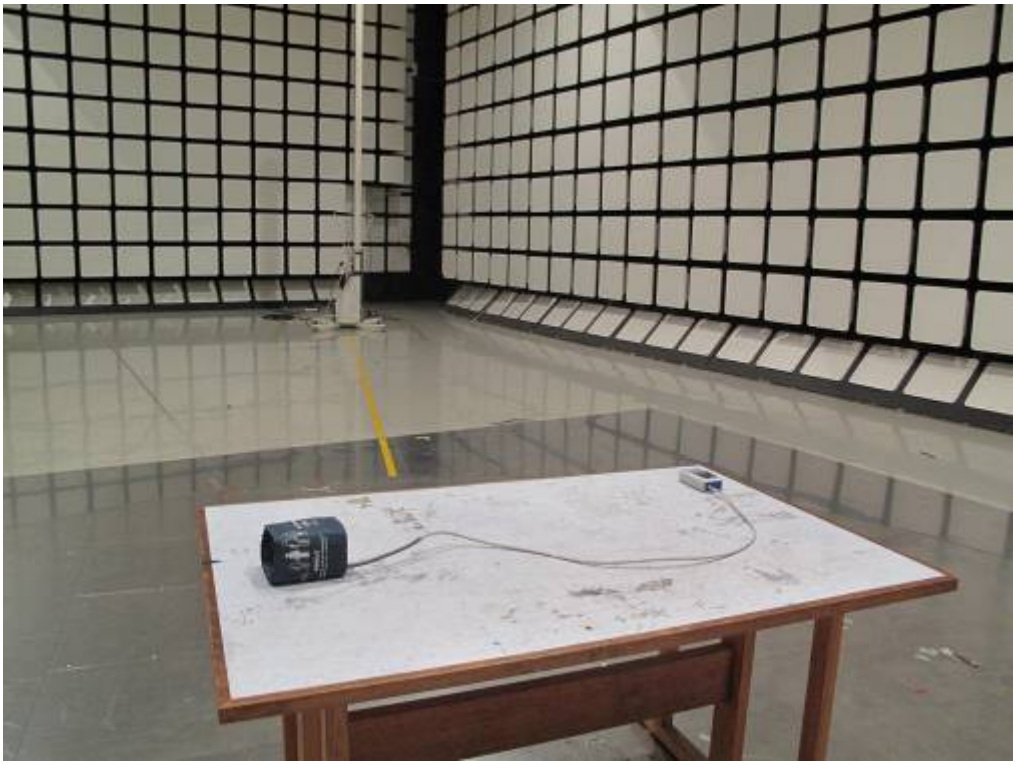
CISPR 11	**TEST:** Limits for radiated disturbance 30 MHz –1 GHz ****	**Verdict**
Method: Measurements were made in a 10-meter semi-anechoic chamber or Open Area Test Site that complies to CISPR 16. Preliminary (peak) measurements were performed at an antenna to EUT separation distance of 10 meter. The 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 %	51%
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 B *		
Frequency (MHz)	Limit dB (µV/m)	
	Quasi-Peak	Results **
30 to 230	30	P
230 to 1000	37	P

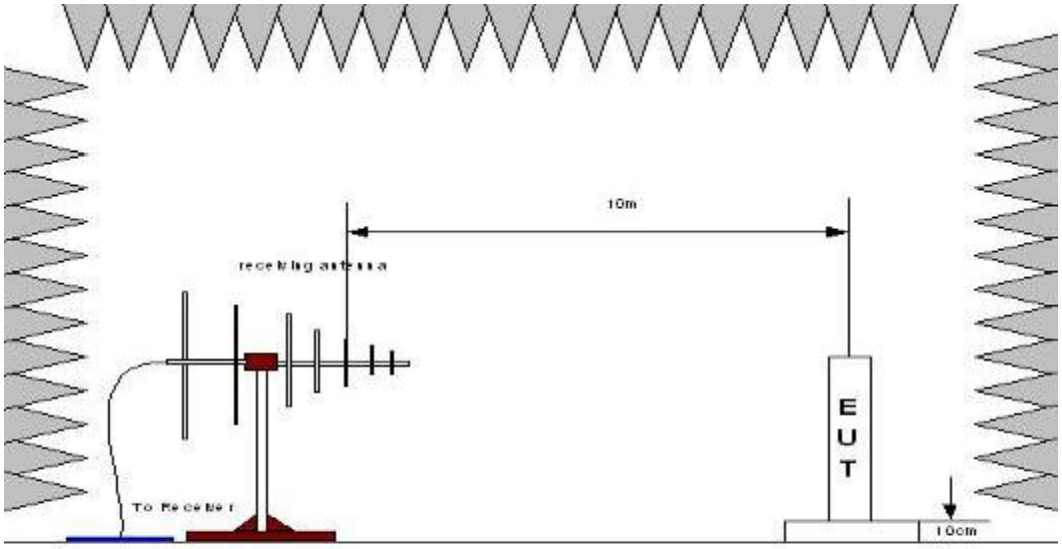
Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
EMI Receiver	Rohde & Schwarz	ESIB7	487/630408	2010.01.17	2011.01.16
Broadband Antenna	Schwarzbeck	VULB9168	487/620214	2009.12.27	2011.12.26
Anechoic Chamber	TDK	10m	487/770201	N/A	N/A

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)
30-1000	--	QP	V	- -	- -	- -	--	--	--	>6dB
30-1000	--	QP	H	--	--	- -	--	--	--	>6dB
Note: Other table formats are allowed as long as all information is included.										

Graphical representation of Radiated Disturbance Measurement



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
Delete or add rows as needed except for the headers.					

Photo of test setup for Disturbance Power Emissions

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)
Delete or add rows as needed except for the header.							
Note: Other table formats are allowed as long as all information is included.							

Graphical representation of Disturbance Power Emissions Measurement

1.10 Test Conditions And Results – Limits for Harmonic Current Emissions

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

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	°C
Relative Humidity	30 to 60 %	%
Equipment mode	Power interface mode	
	EUT configurations mode	
	Operation mode	
Classification of Equipment.....:		Class
Supplementary information:		

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Delete or add rows as needed except for the headers.					

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: - use latest edition)	Verdict
Method: The test circuit consists of a test supply voltage, reference impedance, the equipment under test and a flicker meter compliant with IEC 60868. The equipment shall be tested in the condition in which the manufacturer supplies it.		N/A

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

1 - without additional conditions

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

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

Supplementary information:

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Delete or add rows as needed except for the headers.					

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: - use latest edition)	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 %	53%

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)		

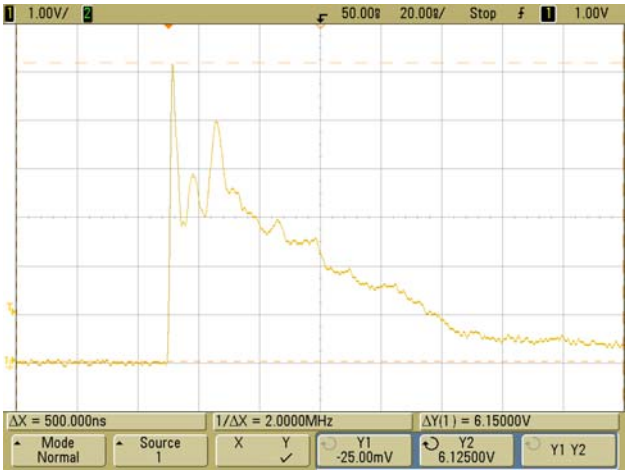
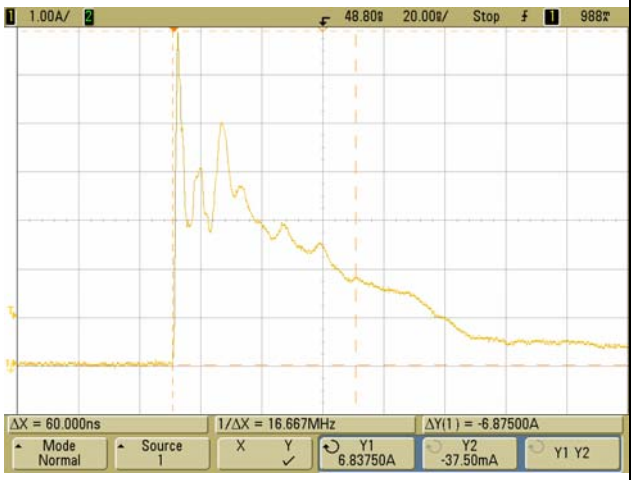
Supplementary information:

EUT powered at one of the Nominal input voltages and frequencies

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％

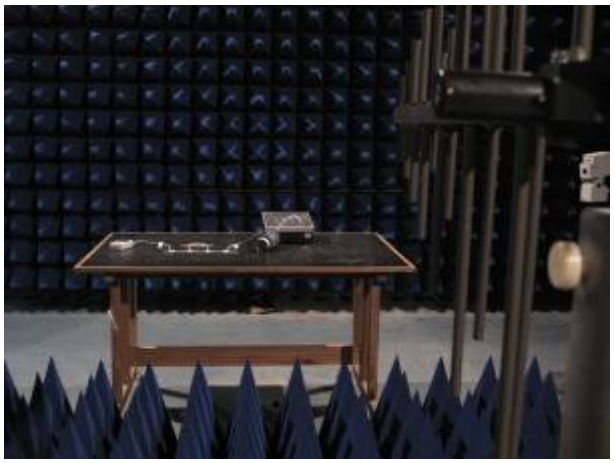
Tabulated Results for Electrostatic Discharges			
Nominal Voltage (V)..... :	3VDC		
Nominal Frequency (Hz)..... :			
Direct discharges: Air and Contact			
Discharge location	**Air discharge voltage (kV)**	**Polarity**	**Remark**
Gaps	2, 4, 8	Positive, Negative	No degradation of function
Buttons	2, 4, 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**
Connectors	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

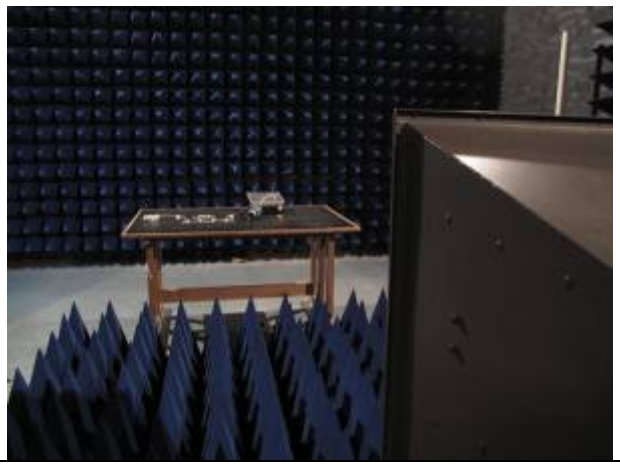
1.13 Test Conditions and Results - Immunity to Radio Frequency Electromagnetic Fields

61000-4-3	**TEST:** RF electromagnetic fields (IEC 61000-4-3: - use latest edition)		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 1000 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 %	56%	
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	3 V/ m		
Non-Life Supporting Equipment	Amplitude modulation	Controls, monitors or measures a physiological parameter, (80 % / 2 Hz)	
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	SME 06	487/390201	2009.07.20	2010.07.19
Power Amplifier	TESEQ	CBA1G-500	487/400908	2010.04.18	2011.04.17
Power Amplifier	TESEQ	CBA3G-100	487/400909	2010.04.18	2011.04.17
Power Meter	Rohde & Schwarz	NRVD	487/740224	2009.07.20	2010.07.19
Coupler	Amplifier Research	DC7144M1	487/570202	2009.07.20	2010.07.19
Coupler	Amplifier Research	DC6080	487/570203	2009.07.20	2010.07.19
Log-periodic Antenna	Amplifier Research	AT1080	487/620519	2010.04.19	2011.04.18
Horn Antenna	Amplifier Research	AT4002A	487/620621	2010.04.19	2011.04.18
Audio analyzer	Rohde & Schwarz	UPL	487/450202	2009.11.22	2010.11.21

Photo of test setup for Radio Frequency Electromagnetic Fields





Tabulated Results for RF Electromagnetic Field 80 MHz to 2500 MHz			
		Nominal Voltage (V).....:	3V
		Nominal Frequency (Hz).....:	DC
Side of the equipment under test	**Frequency (MHz)**	**Antenna polarization (V/H)**	**Remark**
Front	Full bandwidth	V	No degradation of function
	Full bandwidth	H	No degradation of function
Back	Full bandwidth	V	No degradation of function
	Full bandwidth	H	No degradation of function
Left	Full bandwidth	V	No degradation of function
	Full bandwidth	H	No degradation of function
Right	Full bandwidth	V	No degradation of function
	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: - use latest edition)	Verdict
Method: Measurements were made on a ground plane that extends 1-meter minimum beyond all sides of the system under test. Mains power tests were conducted with the product connected to a Coupling/Decoupling Network (CDN). I/O lines were tested in a Capacitive Coupling Clamp. One of each unique interface was tested for a period of one (1) minute per polarity.		N/A

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

Fully configured sample subject to the levels shown below.	Measurement Point
	Input a.c. Power Ports
	Input d.c. Power Ports
	Signal Ports longer than 3 meters

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
Signal Ports	±0.25, ±0.5, ±1	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
Delete or add rows as needed except for the header.					

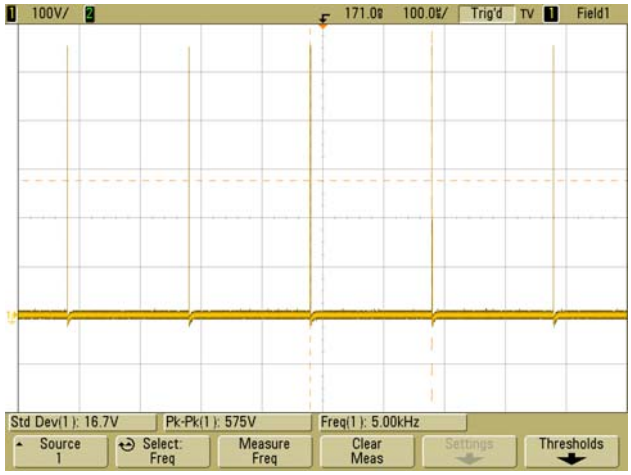
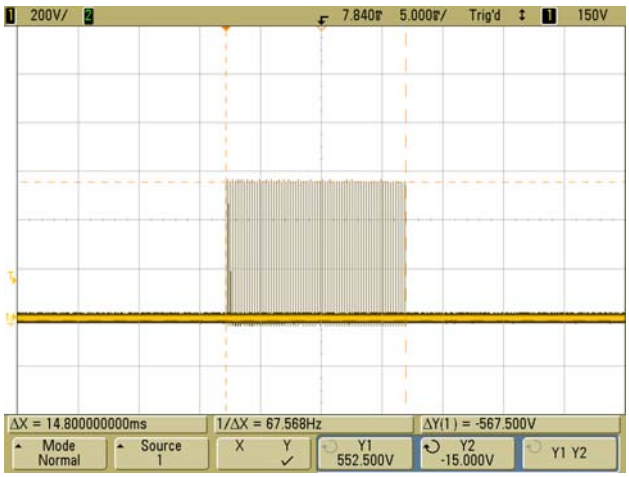
Electrical Fast Transients Waveform Verification	
Pulse Frequency: 5KHz  Test value : 5KHz	Burst duration: 15ms ± 20%  Test value : 14,8ms; Δ=1,3%

Photo of test setup for Electrical Fast Transients

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

Point of application	Comments/Results
Mains	
I/O Line 1 -	
I/O Line 2 -	
Delete or add rows as needed except for the header.	

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

Point of application	Comments/Results
Mains	
I/O Line 1 -	
I/O Line 2 -	
Delete or add rows as needed except for the header.	

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

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

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

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

Delete or add rows if not needed except for the header.

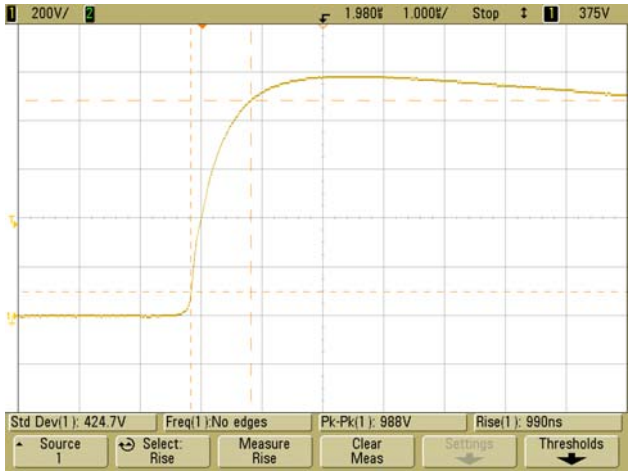
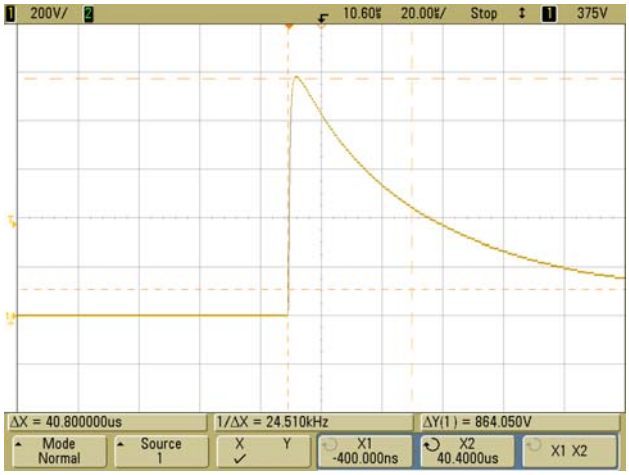
Surge Waveform Verification	
Rise time (10% - 90%): 1μs	Duration time (50% - 50%): 50μs
	
Test value: 0,99μs	Test value: 40,8μs; Δ=18.4％

Photo of test setup for Surge Immunity

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

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

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

X - Not performed
1 – Compliant – No observed response from EUT.
2 –
Note: 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 + A1:2004 + 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.		N/A

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

Test Specifications:		**Frequency range**		**Measurement Point**
Fully configured sample scanned over the following frequency range		150kHz* to 80MHz		Input a.c. Power Ports Input d.c. Power Ports Signal Ports
		Note* Verify against Clause 6.2.6.1 f)		
Level	**Non Life Supporting Equipment**	3 V rms		
		Amplitude modulation	Controls, monitors or measures a physiological parameter 80 % / 2 Hz , min. 3 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
Delete or add rows as needed except for the header.					

Photo of test setup for Conducted Disturbances

Tabulated Results for Conducted Disturbances	
Nominal Rated Voltage (V)	
Nominal Rated Frequency (Hz) .	
Point of Application	Comments/Results
I/O Line 1 - SpO_2 sensor cable	
I/O Line 2 - CO_2 sensor cable	
Delete or add rows as needed except for the header.	

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: - use latest edition)	Verdict
Method: The product was subjected to voltage dips and interruptions. Testing was performed with the product connected directly to a generator capable of simulating the voltage drops and interrupts as described.		N/A

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

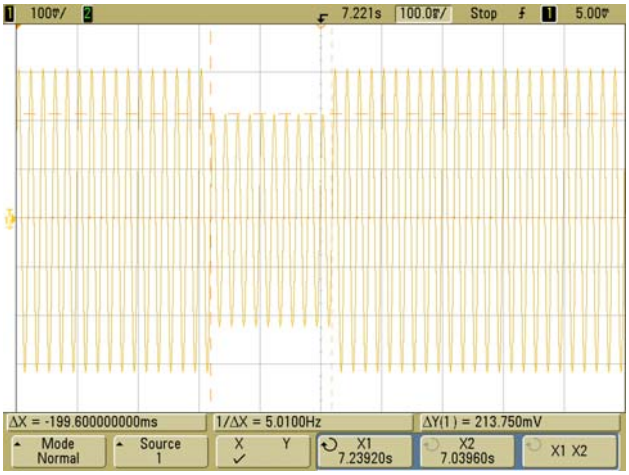
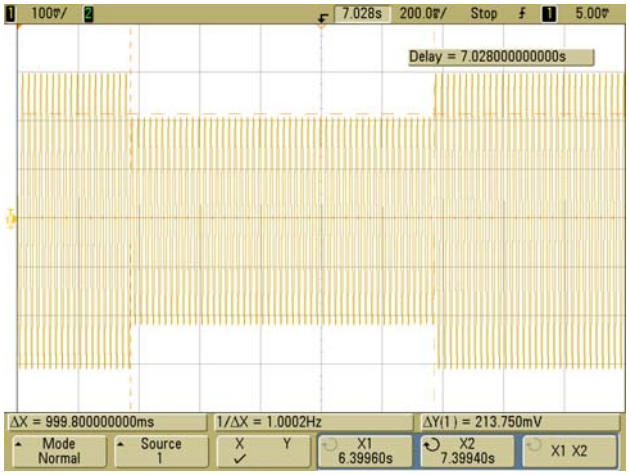
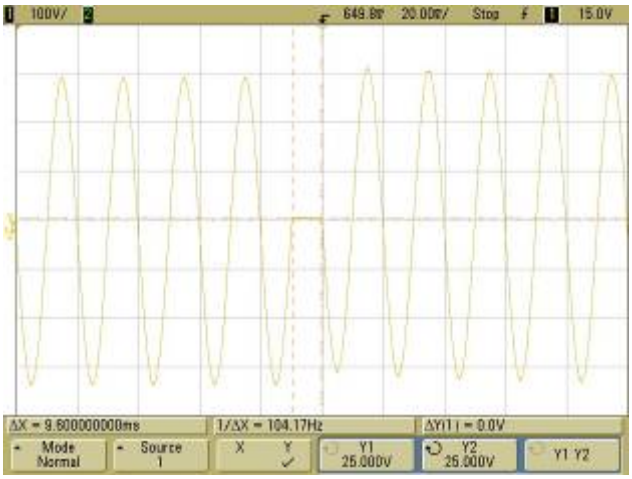
Fully configured subjected to the levels indicated below.	Measurement Point
	Input A.C. Power Ports

Applied Levels		
Voltage Dips % U_T	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
Delete or add rows as needed except the header.					

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: 10ms(0.5Cycle)  Test value: 9.6ms	Intentionally Left Blank

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

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

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: - use latest edition)	Verdict
Method: Measurements were made on a ground plane that extends 1-meter minimum beyond sides of the system under test. Tabletop EUT is located 80cm above the reference ground plane and floor-standing EUT is located 10cm above the reference ground plane. The indicated field was pre-calibrated prior to placement of the EUT under test.		P

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	22°C
Relative Humidity	10 to 90 %	56%

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	2008.06.01	2010.05.30
Induction Coil Interface	Schaffner	INA2141	487/440202	2008.06.01	2010.05.30
Power Source	California Instrument	4500L	707/689501	2008.06.01	2010.05.30

Photo of test setup for Power- Frequency Magnetic Fields


Tabulated Results for Power Frequency Magnetic Field		
Nominal Rated Voltage (V).....	3VDC	
Point of application	**Results**	
	50 Hz	**60 Hz**
X-Axis	1	1
Y-Axis	1	1
Z-Axis	1	1
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.

Appendix A

Test data sheets

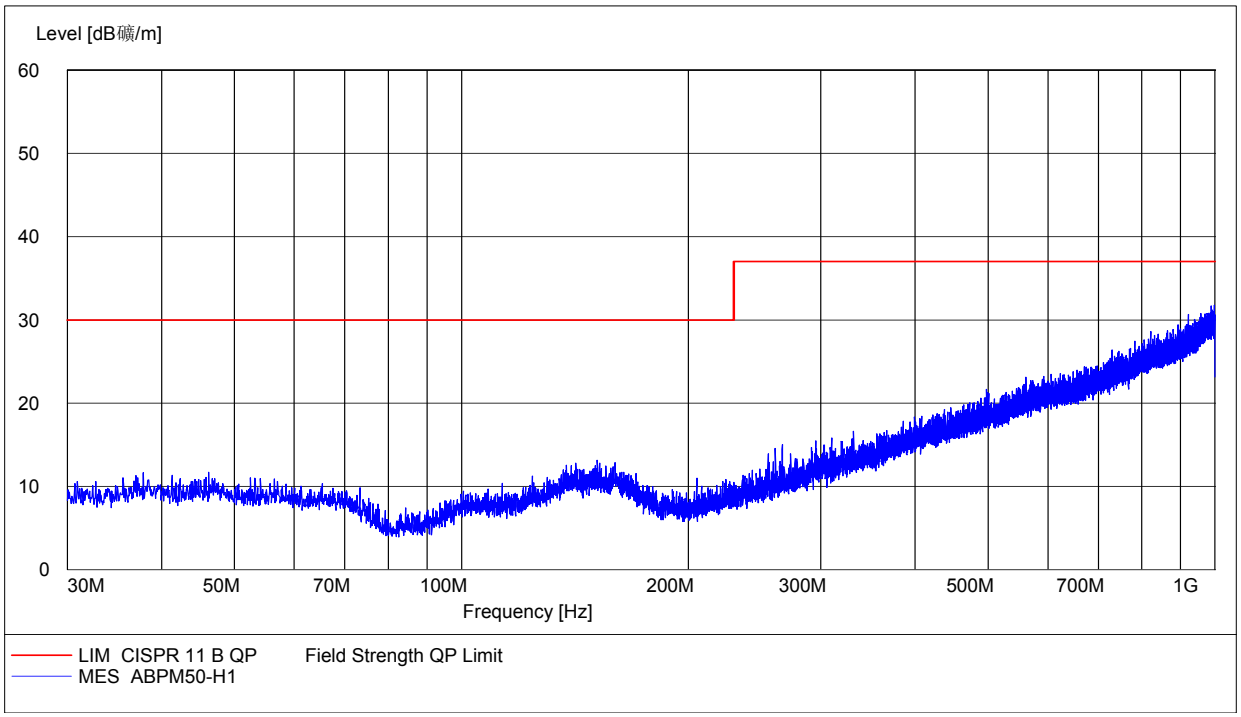
30MHz-1GHz Radiated Emission Test

ABPM50

EUT: Ambulatory Blood Pressure Monitor
Manufacturer: Contec Medical Systems Co.,Ltd.
Operating Condition: Power on
Teat Site: Jiangsu TUV 10m chamber
Operator: Ming Gu
Test Specification: CISPR 11 ,Group 1, Class B
Comment : Horizontal
Sample No.: 100323271

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_8447D10



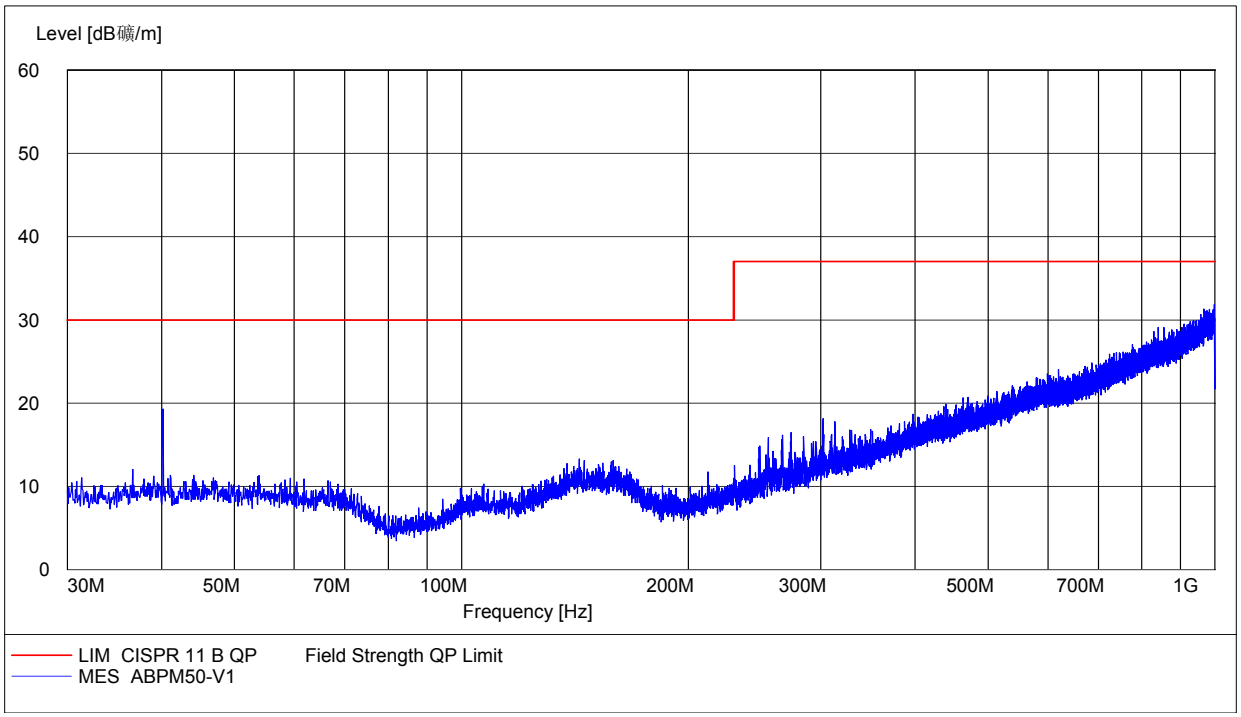
30MHz-1GHz Radiated Emission Test

ABPM50

EUT: Ambulatory Blood Pressure Monitor
Manufacturer: Contec Medical Systems Co.,Ltd.
Operating Condition: Power on
Teat Site: Jiangsu TUV 10m chamber
Operator: Ming Gu
Test Specification: CISPR 11 ,Group 1, Class B
Comment : Vertical
Sample No.: 100323271

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_8447D10



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 *ABPM50* is intended for use in the electromagnetic environment specified below. The customer of the user of the *ABPM50* should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *ABPM50* 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 B	The *ABPM50* is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

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

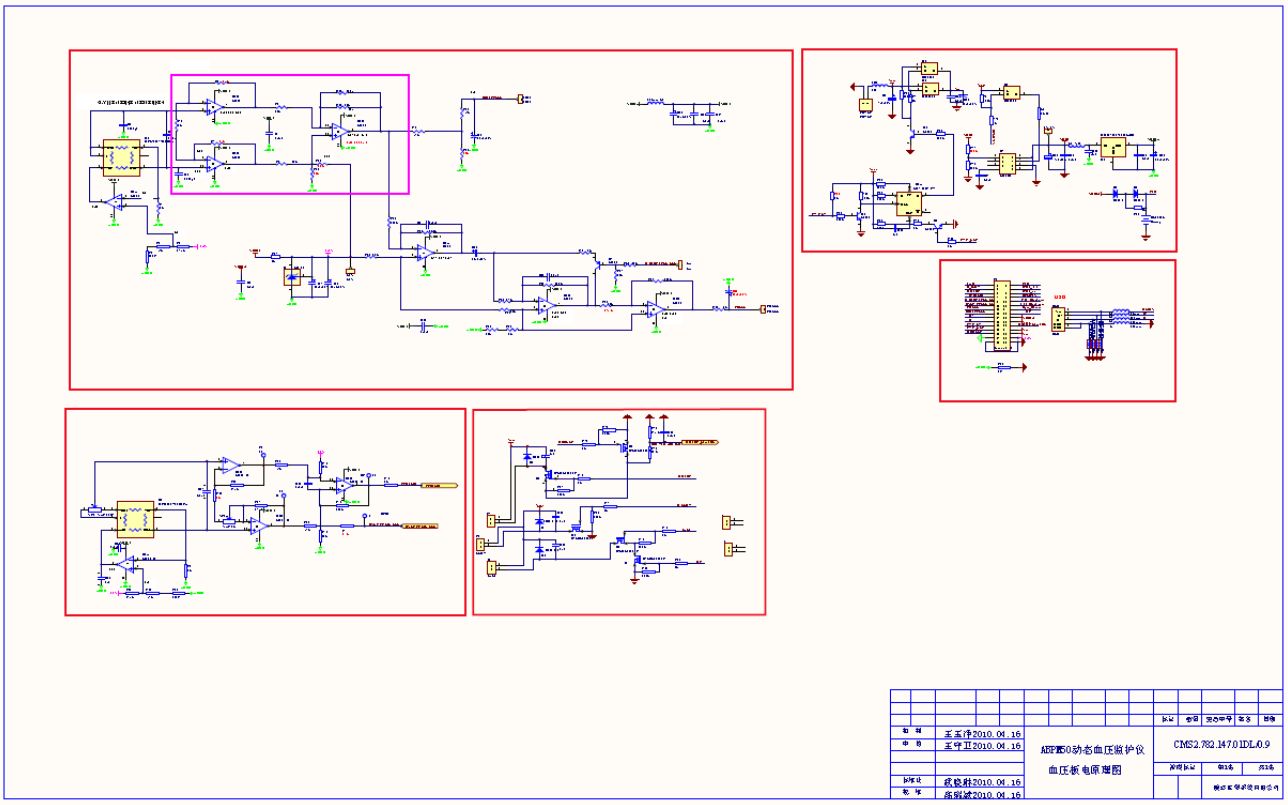
Guidance and manufacturer's declaration – electromagnetic immunity			
The *ABPM50* is intended for use in the electromagnetic environment specified below. The customer or the user of *ABPM50* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance 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%.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

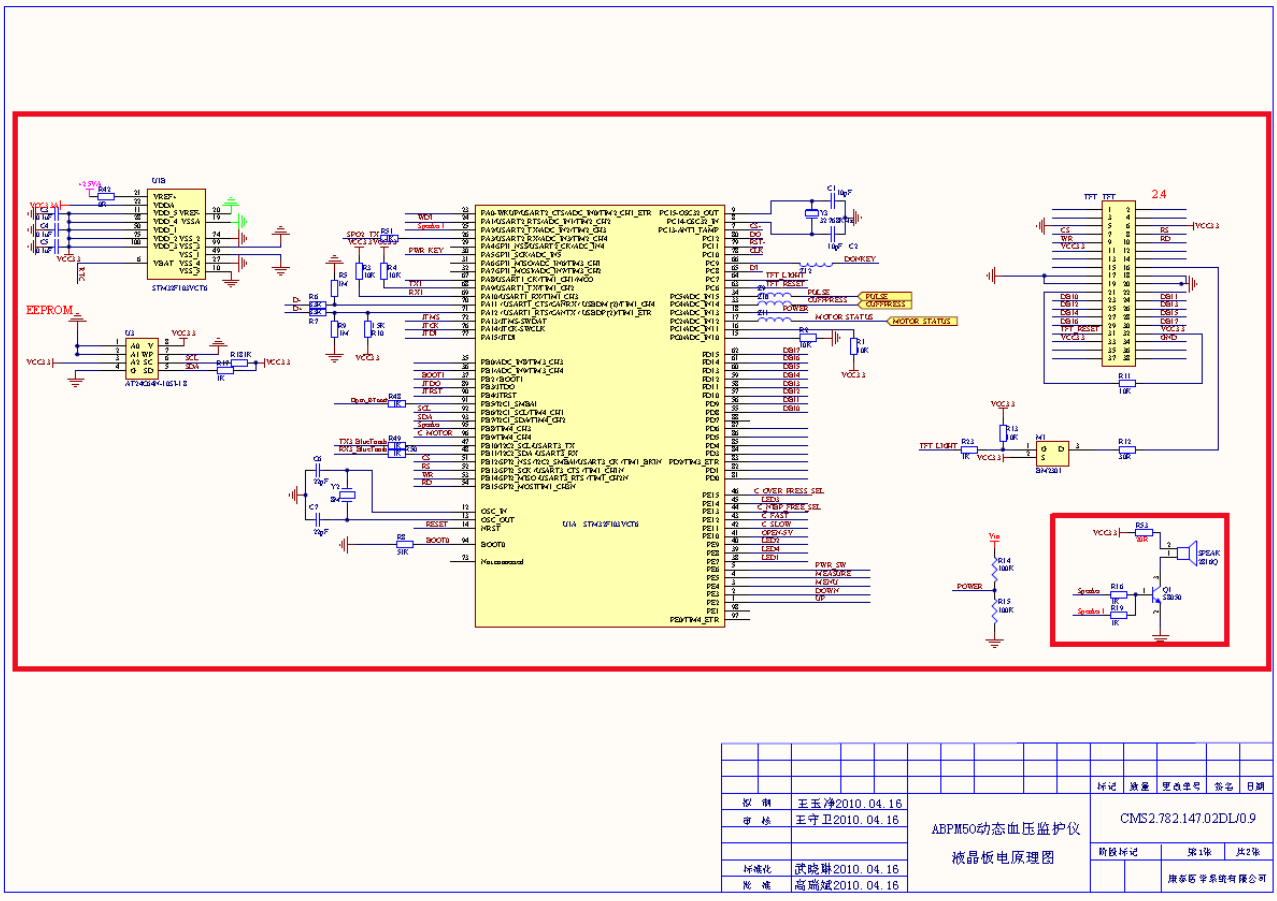
Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

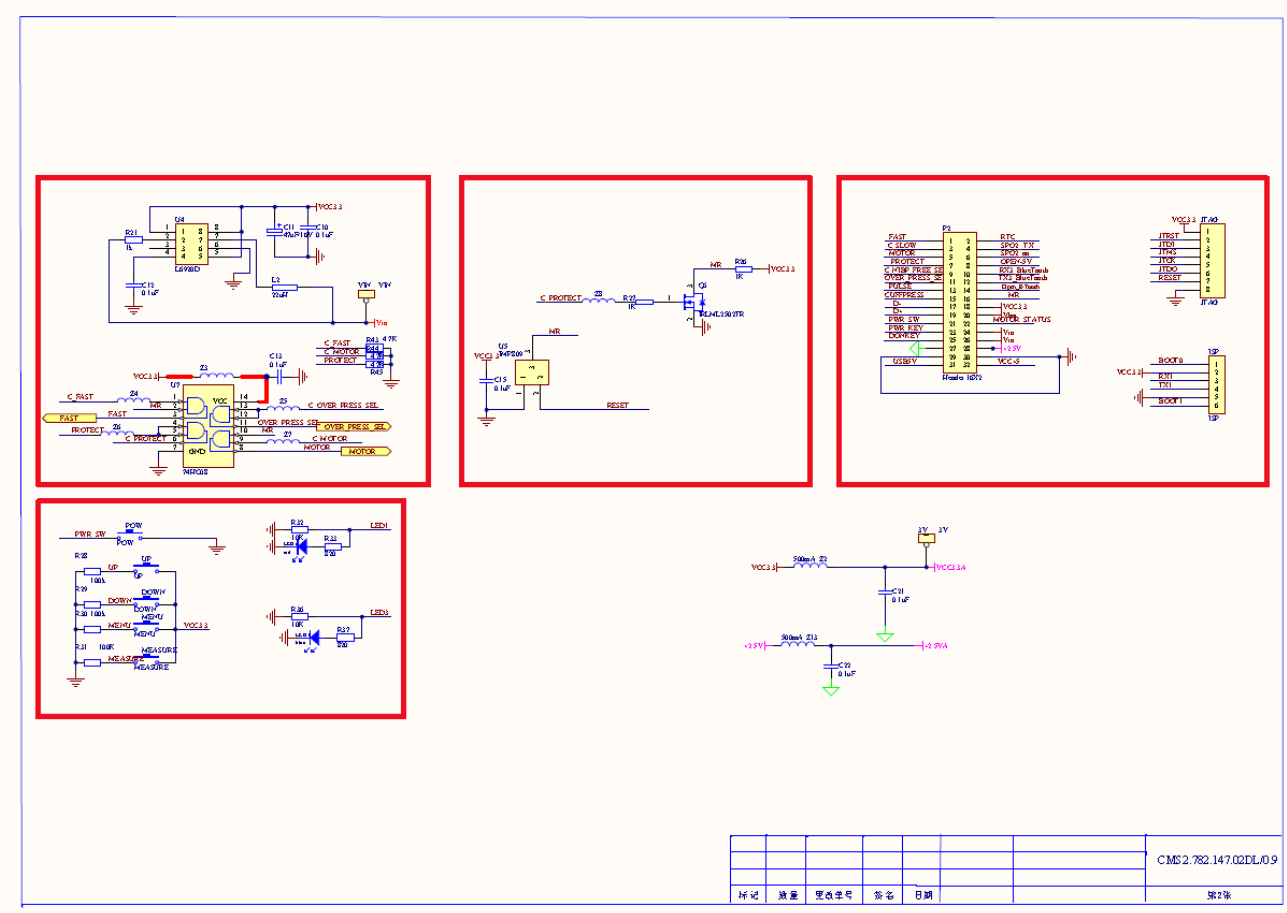
<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The ABPM50 is intended for use in the electromagnetic environment specified below. The customer or the user of ABPM50 should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the ABPM50, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 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:
  </td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">[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 ABPM50 is used exceeds the applicable RF compliance level above, the ABPM50 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ABPM50.</td></tr>
</table>

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 ABPM50		
The *ABPM50* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *ABPM50* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *ABPM50* 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)**	
	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	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.69	7.38
100	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.		


王玉伴2010.04.16
王守卫2010.04.16
武晓鹏2010.04.16
高丽斌2010.04.16
ABPM50动态血压监护仪
血压板电原理图
CMS2.782.147.01DL/0.9


EEPROM
STM32F101VCT6
2.4
王玉净2010.04.16
王守卫2010.04.16
武晓鹏2010.04.16
高丽斌2010.04.16
ABPM50动态血压监护仪
液晶板电原理图
CMS2.782.147.02DL/0.9



Critical Components BOM

object/part No.	Manufacturer/ trademark	Type/ model	Technical data	Mark(s) of conformity
Switches	DIPTRONICS MANUFACTURING INC.	TMG-533-V-T/R	50mA，DC 12V	
TFT	Truly Semiconductors Ltd.(Truly Semi.),	TFT8024-E	240RGB*320 matrix panel	
Enclosure	ZHEJIANG RONGSHENG INDUSTRIAL PLASTICS CO., LTD		ABS	
PCB	SHENZHEN BOMIN INDUSTRIAL CO.,LTD	CMS7.820.147.01/0.75 CMS7.820.147.02/0.75		
Resettable FUSE	POLYTRONICS TECHNOLOGY CORP.	SMD1206P150TS	1.5A/6V	UL
IC	ST	STM32F103VC		
crystal oscillator	Beijing Huanyu era Science and Technology Development Co., Ltd.		8MHz	
Valve	XIAMEN CONJOIN ELECTRONICS TECHNOLOGY CO.,LTD	SC0526GL		
Pump	XIAMEN CONJOIN ELECTRONICS TECHNOLOGY CO.,LTD	CJP37-C03A1		
bead	SHENZHEN HONGYEXING ELECTRONIC CO.,LTD	ACMS1608A-300	500mA 30Ω	

Appendix C

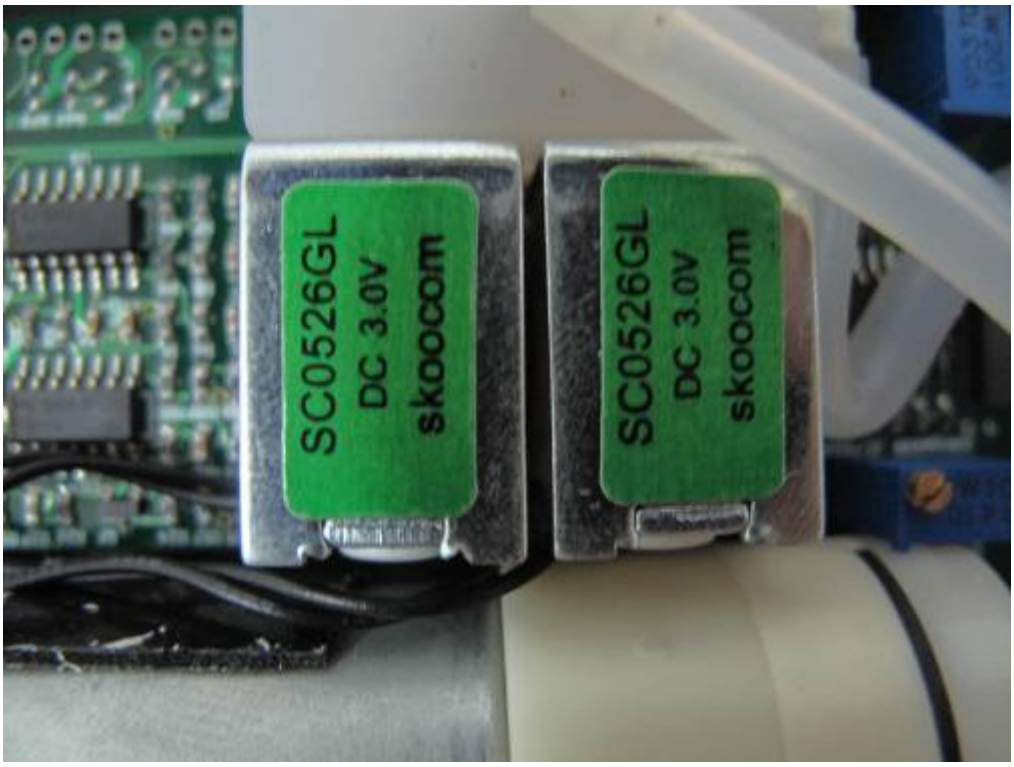
Photo documents


INDEX LINE


OK


Ambulatory Blood Pressure Monitor
Model: ABPM50
Battery Voltage:DC3V
Operating Current: ≤800mA
Safety Class: BF
SN
See Bar Code
CONTEC MEDICAL SYSTEMS CO., LTD
No.24 Huanghe West Road, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, 066004, P.R.China
SN: 100323171
P: Blood pressure monitor
Model: ABPM50
Client: Qinhuangdao Kangtai
Status on receipt
☑ In good condition ☐ Abnormal
☐ Testing ☐ Tested
Remark: GM


SC0526GL
DC 3.6V
skoocom
SC0526GL
DC 3.6V
skoocom


SC0526GL
DC 3.0V
skoocom
SC0526GL
DC 3.0V
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