



MEDICAL DIRECTIVE—SAFETY TEST REPORT

For

Beauty massager

Model: BP-008, BP-010, BP-010 PLUS, BP-010E, BP-012, BP-015, BP-028

Brand Name: BEPERFECT

Report No.: ENC170811GZ57L1

Date of Issue: Aug. 11, 2017

Prepared For

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Prepared By

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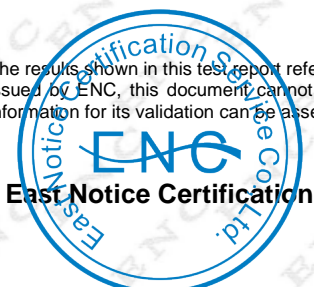
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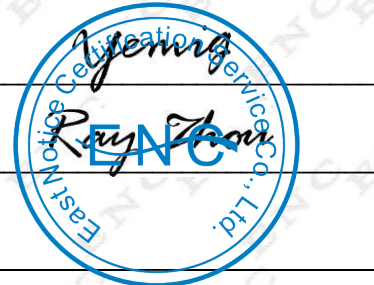
TEST REPORT

EN 60601-1

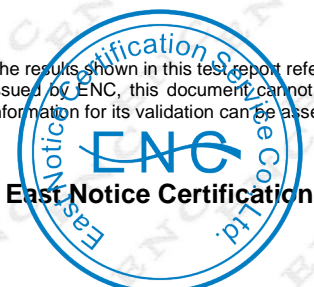
Medical electrical equipment --

Part 1: General requirements for basic safety and essential performance

Report reference No.	: ENC170811GZ57L1
Tested by	: Sam Liu
Review by (+ Signature)	: Yemig
Approved by (+ signature)	: Ray Zhou
Date of issue	: Aug. 11, 2017
Contents	: Total 31 pages
Testing laboratory	
Name	: East Notice Certification Service Co., Ltd.
Address	: 1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City, China
Testing location	: Same as above
Application	
Name	: Shenzhen Perfect Idea Tech. Co., Ltd.
Address	: 4F, Building 1, Fuhua Industrial Park, Tangwei, Fuyong, Bao'an, Shenzhen, China 518103
Manufacturer	
Name	: Shenzhen Perfect Idea Tech. Co., Ltd.
Address	: 4F, Building 1, Fuhua Industrial Park, Tangwei, Fuyong, Bao'an, Shenzhen, China 518103
Test specification	
Standard	: EN 60601-1:2006+A11:2011+A1:2013+A12:2014, EN 62471: 2008
Test procedure	: CCA
Procedure deviation	: N/A
Non-standard test method	: N/A
Test Report Form/blank test report	
Test Report Form No.	: ENC60601-1-A14
TRF originator.	: ENC
Test item	
Description	: Beauty massager
Brand name	: BEPERFECT
Model and/or type reference	: BP-010
Series models	: BP-008, BP-010, BP-010 PLUS, BP-010E, BP-012, BP-015, BP-028
Rating(s)	: DC 15V, 0.4A by adapter (100-240V~, 50/60Hz)



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Test case verdicts

Test case does not apply to the test object.....: N(/A)
Test item does meet the requirement: P(ass)
Test item does not meet the requirement.....: F(ail)

Testing

Date of receipt of test item: Aug. 3, 2017
Date(s) of performance of test: Aug. 3, 2017 –Aug. 11, 2017

General remarks

This test report shall not be reproduced except in full without the written approval of the testing laboratory.
The test results presented in this report relate only to the item tested.
"(see remark #)" refers to a remark appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report a comma is used as the decimal separator.
When determining the test result, measurement uncertainty has been considered.
Note:
This report shall not be altered, increase and deleted.
The results relate only to the items tested.
This report shall not be published as advertisement without the approval of ENC.
This report shall not be copied partly without the written approval of ENC.
Should any objections to the test reports occurred, should submit it to the Company within ten days since the issuing of the report, Fail to accept.




Special description:

1. All tests are basic on model BP-010.
2. Model Difference: POWER SUPPLY: 15V, 0.4A ; 15V,0.8A; 3.7V; 9V
3. Specified maximum ambient temperature is 40°C.

Summary of testing

All tests were found satisfactory in accordance with EN 60601-1:2006+A11:2011+A1:2013+A12:2014
The product was classified as Exempt group LED Product according to EN 62471: 2008.

Marking on the appliance:

Beauty massager
Model: BP-010
Input: 15V  0.4 A  
Shenzhen Perfect Idea Tech. Co., Ltd.

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
4.11	POWER INPUT AND CURRENT		--
	Power input Measurement	(see appended table 4.11)	P


5	GENERAL REQUIREMENTS		--
5.1	Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.)		P
5.2	An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained		N

6	CLASSIFICATION		--
6.1	General		--
	For purposes of this standard, equipment shall be classified as follows.		P
6.2	Type of protection against electric shock	Adaptor: Class II Application Part: Class III	N
	Class I equipment		N
	Class II equipment		N
	Internally powered equipment		N
6.3	Protection against harmful ingress of water or particulate matter (see 6.1.1)	IP X0	N
6.4	Methods of sterilization or disinfection	Absolute alcohol.	P
6.5	Suitability for use in an oxygen rich environment		--
	Category AP equipment		N
	Category APG equipment		N
6.6	Mode of operation:		--
	-continuous operation		P
	-short-time operation, specified operation; period		N
	-intermittent operation, specified operation; rest period		N
	-continuous operation with short-time, stated permissible loading time		N
	-continuous operation with intermittent, stated permissible loading/rest time		N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict

7	IDENTIFICATION, MARKING AND DOCUMENTS		--
7.1	General		P
7.1.1	Usability of the identification, marking and documents		P
7.1.2	Legibility of markings	Legibility.	P
7.1.3	Durability of markings	Durability.	P
7.2	Marking on the outside of equipment or equipment parts		P
7.2.1	Minimum requirements for marking on equipment and on interchangeable parts		P
7.2.2	Identification	Shenzhen Perfect Idea Tech. Co., Ltd.	P
7.2.3	Consult accompanying documents		P
7.2.4	Accessories shall be marked with the name or trade-mark of their manufacturer or supplier, and with a model or type reference.		P
7.2.5	Equipment intended to receive power from other equipment		P
7.2.6	Connection to the supply mains shall be marked with the following information:		--
	– the rated supply voltage(s)	100-240V	P
	– nature of supply	~	P
	– the rated supply frequency	50/60Hz	P
	– For class II equipment, symbol IEC 60417-5172	For adapter: 	P
7.2.7	Electrical input power from the supply mains		N
7.2.8	Output connectors		--
7.2.8.1	Mains power output		N
7.2.8.2	Other power sources		N
7.2.9	IP classification	IP X0	N
7.2.10	Applied parts		P
7.2.11	Mode of operation		N
7.2.12	Fuses		N
7.2.13	Physiological effects (safety signs and warning statements)		N
7.2.14	High voltage terminal devices		N

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Clause	Requirement - Test	Result	Verdict
7.2.15	Cooling conditions		N
7.2.16	Mechanical stability		N
7.2.17	Protective packaging		P
7.2.18	External pressure source	Normal	N
7.2.19	Functional earth terminals		N
7.2.20	Removable protective means		N
7.3	Marking on the inside of equipment or equipment parts		--
7.3.1	Heating elements or lampholders	Not such equipment	N
7.3.2	High voltage parts	Not such equipment	N
7.3.3	Batteries		N
7.3.4	Fuses, thermal cut-outs and over-current releases		N
7.3.5	Protective earth terminals		N
7.3.6	Functional earth terminals		N
7.3.7	Supply terminals		N
7.3.8	Temperature of supply terminals		N
7.4	Marking of controls and instruments		--
7.4.1	Power switches		--
	– marked with symbols IEC 60417-5007 (DB:2002-10) and IEC 60417-5008		N
	– indicated by an adjacent indicator light; or		N
	– indicated by other unambiguous means.		N
7.4.2	Control devices		P
7.4.3	Units of measure		N
7.5	Safety signs		--
	a) Constructing a safety sign according to ISO 3864-1:2002,		N
	b) Using the general warning sign ISO 7010:2003-W001		N
	c) Using the general prohibition sign ISO 7010:2003-P001		N
	d) Using the general mandatory action sign ISO 7010:2003-M001		N
7.6	Symbols		--
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)		P

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
7.7	Colors of the insulation of conductors		--
	a) Protective earth conductor has green/yellow insulation		N
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		N
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow		N
	d) Color of neutral conductor		N
	e) Colors of phase conductor(s)	Single phases	N
	- Compliance with IEC 227 and IEC 245		P
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N
7.8	Indicator lights and push -buttons		N
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action		N
	-Yellow used to indicate caution or attention required		N
	b) Color red used only for push-buttons by which a function is in case of emergency		N
7.9	Accompanying documents		P
7.9.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Integrally contained all that required document.	P
	Classifications specified in Clause 5 included in both the instructions for use and the technical description	Technical description include in instruction	N
	Markings specified in Sub-clause 7.1 included in the accompanying documents if they have not been permanently affixed to equipment		N
	Warnings statements and the explanation of warning symbols provided in the accompanying documents		N
7.9.2	Instructions for use		--
	a) General information provided in instructions for use		P
	-state the function and intended applications for use		P
	-include an explanation of: the function of controls, displays and signals		P
	-the sequence of operation		P
	-the connection and disconnection of detachable Parts and accessories		P

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Clause	Requirement - Test	Result	Verdict
	-the replacement of material which is consumed during operation		N
	-information regarding potential electromagnetic or other interference and advice regarding avoidance		P
	-include: indications of recognized accessories detachable parts and materials, if the use of other Parts or materials can degrade minimum safety		P
	-instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance		P
	General information provided in instructions:		--
	-information for the safe performance or routine maintenance		P
	-parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied		P
	-explanation of figures, symbols, warning statements and abbreviations on the equipment		P
	c)Signal output or signal input parts intended only for connection to specified equipment described		P
	d)Details about acceptable cleaning, disinfection or sterilization methods include		P
	e)Warning statement for mains operated equipment with additional power source	No additional power source.	N
	f)A warning to remove primary batteries if equipment is not likely to be used for some time		N
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries		P
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1		P
	j) Identification of any risks associated with the disposal of waste products, residues, etc.		N
	- Advice in minimizing these risks		N
7.9.3	Technical description		--
	a)All characteristics essential for safe operation	Technical description included in insulation	P
	b)Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment		N

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Clause	Requirement - Test	Result	Verdict
	-Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided		N
	c)Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided		N
	d)Environmental conditions for transport or storage specified in accompanying documents and marked on packaging		P

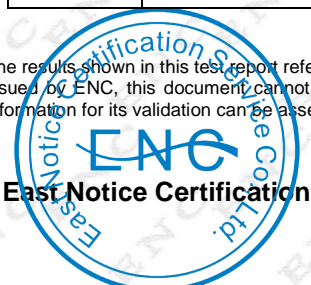
8	PROTECTION AGAINST ELECTRICAL HAZARDS FROM EQUIPMENT		--
8.1	Fundamental rule of protection against electric shock		P
	The limits specified in 8.4 shall not be exceeded for accessible parts and applied parts in normal condition or single fault condition.	See Clause 8.4	P
8.2	Requirements related to power sources	~	P
8.2.1	Connection to a separated power source	No separated power source.	N
8.2.2	Connection to an external d.c. power source		P
8.3	Requirements related to classification		P
	Class I and Class II equipment in addition to basic insulation provided with an additional protection	For adapter: Class II equipment	P
	Equipment supplied from external d.c. source of reverse polarity results in no safety hazard		N
	Internally powered equipment complies with requirements for Class I Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected		N
	Applied parts intended for direct cardiac application are of type CF		N
8.4	Limitation of voltage , current or energy		N
8.4.1	Patient connections intended to deliver current		N
8.4.2	Accessible parts including applied parts		N
8.4.3	Equipment intended to be connected to a power source by a plug		N
8.4.4	Internal capacitive circuits	(See appended table 8.4.4a and 8.4.4b)	N
8.5	Separation of parts		N
	Separation method of the applied part from live parts:		--

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Clause	Requirement - Test	Result	Verdict
	1) Basic insulation: applied part earthed.	No such parts.	N
	2)by protectively earthed intermediate circuit limiting leakage current to applied part in event of insulation failure	No protectively earthed circuit	N
	3)by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N
	4)by double or reinforced insulation		N
	5)by protective impedances limiting current to applied part		N
	-Additional leakage current test single fault conditions	(see appended table 8.5)	N
	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		N
	Supplementary insulation between hand-held flexible shafts and motor shafts(Class I)		N
	Separation method of accessible parts other than applied parts from live parts:		P
	1)basic insulation: accessible part earthed		N
	2)by protectively earthed conductive part(e.g.screen)		N
	3)by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N
	4)by double or reinforced insulation		P
	5)by protective impedances limiting current to accessible part		N
	-Additional leakage current test in single fault conditions	(see appended table 8.5)	N
	Arrangements used to isolate defibrillation-proof applied parts so designed that:		--
	-no hazardous electrical energies appear during a discharge of a cardiac defibrillator	(see appended table 8.5a)	N
	-after exposure to the defibrillation voltage, the equipment continues to perform its intended function	(see appended table 8.5b)	N
8.6	protective earthing, functional earthing and potential		--
	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal		N
	Protective earth terminals suitable for connection to the protective earth conductor		N

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Clause	Requirement - Test	Result	Verdict
	Potential equalization conductor		--
	-Readily accessible		N
	-Accidental disconnection prevented in normal use		N
	-Conductor detachable without the use of a tool		N
	-Accidental disconnection prevented in normal use		N
	-Connection means marked with Symbol9, Table DI		N
	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1\Omega$		N
	-For equipment with an appliance inlet, impedance between protective earth terminal and accessible metal part $\leq 0.1\Omega$	(see appended table 8.6)	N
	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.2\Omega$		N
	If the impedance of protective earth connections Other than in Cl.18f) exceed 0.1Ω , the allowable value of the enclosure leakage current is not exceeded in single fault condition		N
	Functional earth terminal not used to provide protective earthing		N
	Class II equipment with isolated internal screens		--
	-insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		N
	-functional earth terminal clearly marked		N
	-explanation of functional earth terminal provided in the accompanying documents		N
	protective earthing-terminals and connections		N
	Clamping means of the protective earth terminal		N
	Not be able to loosen without the aid of a tool		N
	Screws for internal earth connections are covered or protective against loosening from outside		N
	Earth pin of the appliance inlet regarded as the protective earth terminal		N
	The protective earth connections are covered or protected against loosening from outside		N

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Clause	Requirement - Test	Result	Verdict
	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting		N
8.7	continuous leakage currents and patient auxiliary currents		--
	Leakage currents	(see appended table 8.7)	P
	-earth leakage current		N
	-enclosure leakage current		P
	-patient leakage current		N
	-patient auxiliary current		N
8.8	Dielectric strength		--
	Overall compliance with Clause 20	(see appended table 8.8)	P
8.11	Mains parts, components and layout		P
8.11.1	Isolation from supply mains		P
	a)Equipment provides means to isolate its circuits electrically from the supple mains on all poles simultaneously	Connect the power with a two pins plug	P
	b)Means for isolation incorporated in equipment or ,if external, specified in the accompanying documents		N
	c)Switches used to comply with Sub-clause 57,1a comply with the creepage distances and air clearances as specified in IEC Publication 328		N
	f)Mains switches not incorporated in a power supply cord	No such switch.	N
	h)Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a		N
	m)Fuses and semiconductor devices not used as isolating devices		N
8.11.2	Mains connectors and appliance inlets		--
	e)Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug		N
	g)Unless functional earth needs to be provided ,Class I appliance inlet is not used in Class II equipment		N
8.11.3	Power supply cords		--
	a)Not more than one connection to a particular supply mains		P

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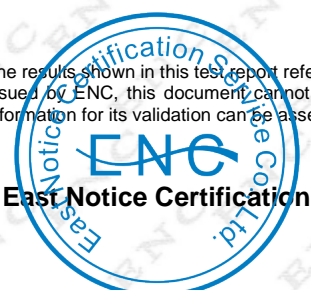
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	If alternatives supply allowed, no safety hazards when more than one connection is made simultaneously		N
	The mains plug has only one power supply cord		N
	Non-permanently connected equipment provided with power supply cord or appliance inlet		N
	b)Power supply cords sufficiently robust to comply with the requirements of IEC227,designation 53 and IEC245,designation 53	24AWG	P
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75 ⁰ C		P
	c)Nominal cross-sectional area of conductors of power supply cords not less than in Table XV		P
	d)Stranded conductors not soldered if fixed by any clamping means		N
	Connection of power supply cords		P
8.11.3.5	Cord anchorage		--
	Equipment provided with power supply cords has cord anchorage such that the conductors are relieved from strain, including twisting		N
	Tying the cord into a knot or trying the ends with string not used		N
	Cord an anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		N
	Cord anchorages made of metal provided with an insulating lining		N
	Clamping screws do not bear directly on the cord insulation		N
	Screws associated with cable replacement are not used to secure other components		N
	Conductors of the power supply cord arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminal		N
	Power supply cord protected against excessive bending		N
	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		P
8.11.4	Mains terminal devices and wiring of mains part		--

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Clause	Requirement - Test	Result	Verdict
	Mains connected equipment other than those with a detachable supply cord provided with mains terminals, where connections are made with screws ,nuts or equally effective methods		N
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced		P
	Screws and nuts which clamp external conductors not serve to fix any other component.		N
	b)Terminal closely grouped with any protective earth terminal		N
	Mains terminal devices located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact.		N
	c)Internal wiring not subject to stress when the means for clamping the conductors are tightened or loosened		N
	d)Cord terminals nor require special preparation of the conductor		N
8.11.5	Mains fuses and over current releases		N
	Fuses or over-current releases provided accordingly for Class I and Class II		N
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operation current		N
	Protective earth conductor not fused		N
	Neutral conductor not fuses for permanently installed equipment		N
8.11.6	Wiring of the mains part		--
	a)Individual conductor in the mains part with insulation not at least electrically equipment to that of the individual conductors of flexible supply cords complying with IEC227or 245,treated as bare conductor		N
	b)Cross-section area of conductors up to protective device not less than the minimum required for the power supply cord		P
	Cross-sectional area of other wiring and the sizes of ranks on printed wiring circuits sufficient to prevent any fire hazard		N
	Mains supply transformers	Compliance	P

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	construction and layout		P
	Internal wiring		--
	a)Cables and wiring protected against contact with a moving part		N
	Wiring having basic insulation only protected by additional fixed sleeving		P
	Components are not likely to be damaged in the normal assembly or replacement of covers		P
	b)Movable leads are not bent around a radius of less than five times the outer diameter of the lead		N
	c)Insulating sleeving adequate		N
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC245 and dielectric test	None	N
	Conductors subjected to temperatures exceeding 70 ⁰ C have an insulation of heat-resistant material		N
	d)Aluminum wires of less than 16mm ² cross section not used	No any aluminum wire	N
	f)Connecting cords between equipment parts considered as belonging to the equipment		P
	Insulation		--
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation	Ball-pressure test for enclosure at a temperature of 75 ⁰ C	P
	c)Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		N
	Parts of rubber resistant to ageing	No such part.	N

9	MECHANICAL STRENGTH		--
9.1	Mechanical hazards of equipment		P
	Sufficient rigidity of an enclosure tested by: force of 45 N	(see appended table 9)	P
	Sufficient strength of an enclosure tested by: impact hammer	(see appended table 9)	P
	On portable equipment carrying handles or grips withstand the requirements of the loading test	No such equipment.	N
	No damage to parts of patient support and/or immobilization system after the loading test	No such part.	N

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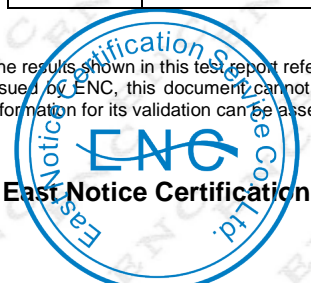
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Hand held equipment to equipment parts are safe after drop test		P
	Portable and mobile equipment is able to withstand rough handing		N
9.2	moving parts		--
	Moving parts of a transportable equipment are provided with guards which form an integral parts of the equipment		N
	Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equipment protection is separately provided during installation		N
	Cords(ropes),chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices		N
	Guides or other safeguards are removable only with a tool		N
	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator		N
	Parts of equipment subject to mechanical wear are accessible for inspection		N
	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard		N
	The means for emergency switch is readily identifiable and accessible and does not introduce a further safety hazard		N
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents		N
	Means for stopping of movements operate as a result of one single action		N
9.3	Hazard associated with surfaces, corners and edges		P
	Rough surfaces ,sharp corners and edges which may cause injury or damage avoided or covered	Edges and corners are well rounded and smooth	P
9.4	Instability hazards		N
	Equipment does not overbalance during normal Use when titled through an angle of 10 ⁰		N
	Equipment overbalance when titled through an angel of 10 ⁰		N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	-does not overbalances when titled through an angle of 5° any position excluding transport		N
	-carry a warning notice stating that transport should only be undertaken in a certain position		N
	-in the position specified for transport does not overbalance when tilted to an angle of 10°		N
	Equipment or its parts with a mass of more than 20 kg is provided with:		--
	-suitable handing devices(grips etc.),or	Not such equipment.	N
	-instructions for lifting and handing during assembly		N
	b)On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons	Less than 20kg	N
9.5	Expelled parts		N
	Protective means are provided where expelled parts of the equipment could be a hazard	No expelled parts	N
	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		N
9.8.3	Support systems		N
	Support system with safety device	No support system	N
	Safety device provided where the integrity of a suspension depends on parts which may have hidden defects ,or on parts having safety factors not complying with Sub-clause28.4		N
	Safety device has safety factors complying with Sub-clause28.4		N
	Clear indication to the operator that the safety device has been activated after failure of suspension means		N
	Suspension systems of metal		N
	1)Total load does not exceed the safe working load		N
	2)Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired		N
	3)Safety factors not less than 8 where impairment is expected		N
	4)Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%		N
	5)Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement		N

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EN 60601-1

Clause	Requirement - Test	Result	Verdict
--------	--------------------	--------	---------

10	X-RADIATION		--
	EQUIPMENT not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5Mr)	(see appended table 10)	N
10.5	electromagnetic compatibility		N
	Equipment complies with IEC 601-1-2		N

11	EXCESSIVE TEMPERATURES		--
11.1.1	Equipment does not attain temperatures exceeding the Values given in Table Xa over the range of ambient temperatures per Clause 10.2.1	(see appended table 11)	P
	Equipment does not attain temperatures exceeding the Values given in Table Xb at 25 ambient		P
	Applied parts not intended to supply heat have surface temperatures not exceeding 41 ⁰ C		N
	Guards to prevent contact with hot surfaces surface temperatures not exceeding 41 Guards to prevent contact with hot surfaces	No Guards.	N
11.2	Fire prevention		P
	Strength and rigidity necessary to avoid a fire hazard	Refer to table 10	P
11.6	overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection		P
	Equipment contain a liquid reservoir		--
	-the equipment is electrically safe after 15% overfill steadily over a period of 1 min	No liquid reservoir.	N
	-transportable equipment is electrically safe after additionally having been tilted through an angle of 15 ⁰ in the least favourable direction(s)(if necessary with refilling)		N
	Electrical properties of the equipment do not change in connection of spillage test(200 ml of water)		N
	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard	No escape.	N
	Equipment sufficiently protected against the effects of humidity		P
	Enclosure designed to give a protection against harmful ingress of water classified according to IEC Publication 529		N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Equipment capable of withstanding cleaning sterilization or disinfection without deterioration of safety provisions	(see appended table 11.6)	N
11.7	Biocompatibility		N
	Parts of equipment and accessories intended to come into contact with biological tissues, cell or body fluids are evaluated in accordance with ISO 10993-1		N
11.8	Interruption of the power supply		P
	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard	No thermal cut-outs and over-current releases.	N
	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function		P
	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure	No mechanical constraints on patient.	N

12	PROTECTION AGAINST OTHER HAZARDS		--
12.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally.		N

13	HAZARDOUS SITUATIONS AND FAULT CONDITIONS		--
	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally	(see appended table 13)	P
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC601-1-4	No such system.	N
	Failure of thermostats presents no safety hazards		N
	Short-circuiting of either part of double insulation presents no safety hazard		N
	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5		N
	Locking of moving parts presents no safety hazard		N
	Interruption and short-circuiting of motor capacitors presents no safety hazard		N
	Duration of motors locked rotor test in compliance with Cl.52.5.8		N

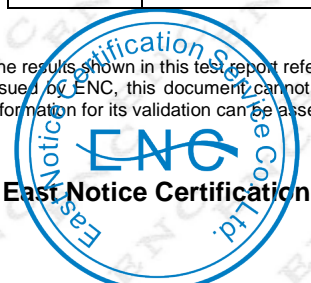
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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Failure of one component at a time presents no safety hazard		P
	Overload of heating elements presents no safety hazard		N
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection		N
	h) Equipment with three-phase motors can safety operate with one phase disconnected		N

14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)		--
14.1	General	No programmable electrical medical systems.	N
	-The PESS provides no basic safety or essential performance		N
	Essential performance - the application of ISO 14971 demonstrates that the failure of the PESS does not lead to an unacceptable		N
14.2	The documents required by Clause 14 shall be reviewed, approved, issued and changed in accordance with a formal document control		N
14.3	The risk management plan required by 3.5 of ISO 14971 shall also include a reference to the PEMS validation plan (see 14.11).		N
14.6	Risk management process		N
14.6.1	The manufacturer shall consider those hazards associated with software and hardware aspects of the PEMS including those associated with network/data coupling, components of third-party origin and legacy subsystems.		N
14.6.2	PEMS supplement Subclause 6.1 of ISO 14971.		N
14.7	For the pems and each of its subsystems (e.g. for a PESS) there shall be a documented requirement specification.		N
14.8	the architecture specification shall make use of:		N
	a) Components with high-integrity characteristics;		N
	b) fail-safe functions;		N
	c) redundancy;		N
	d) diversity;		N
	e) partitioning of functionality;		N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	f) defensive design;		N
	g) allocation of risk control measures to subsystems and components of the pems.		N
	h) failure modes of components and their effects;		N
	i) common cause failures;		N
	j) systematic failures;		N
	k) test interval duration and diagnostic coverage;		N
	l) maintainability;		N
	m) protection from reasonably foreseeable misuse;		N
	n) the network/data coupling specification, if applicable.		N
14.9	The design shall be decomposed into subsystems, each having both a design and test specification.		N
14.10	Verification is required for all functions that implement basic safety, essential or risk control measures.		N
	- at which milestone(s) verification is to be performed for each function;		N
	- the selection and documentation of verification Strategies, activities, techniques, and the appropriate level of independence of the personnel performing the verification;		N
	- the selection and utilization of verification tools;		N
	- coverage criteria for verification.		N
14.11	a pems validation include the validation of basic safety and essential, and shall require checks for unintended functioning of the pems.		N
14.12	A new design or the continued validity of any previous design documentation shall be assessed under a documented modification/change procedure.		N
14.13	Connection of pems by network/data coupling to other equipment		N
	a) specify the characteristics of the network/data coupling necessary for the pems to achieve its intended use;		N
	b) list the hazardous situations resulting from a failure of the network/data coupling to provide the specified characteristics;		N
	c) instruct the responsible organization		N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
15	COMPONENTS AND GENERAL ASSEMBLY		--
15.4.1	List of critical components	(see appended test 15)	P
	Ratings of components not in conflict with the conditions of use in equipment	Components are used according to their ratings	P
	Components, movements of which could result in a safety hazard mounted securely	Well secured.	P
	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard		P
	Connectors provide separation required by Sub-clause 17g		N
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	No patient circuit leads.	N
	Medical gas connections not interchangeable		N
	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken		N
	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.		N
	Connections of capacitors		--
	Not connected between live parts and non-protectively earthed accessible parts		N
	If connected between mains parts and non-protectively earthed metal parts comply with: IEC publication 384-14		N
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts		N
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cutouts	No thermal cut-outs.	N
	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment		N
15.4.2	Temperature and overload control devices		--
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment		N
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits		N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		N
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		N
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times		N
	Non-self resetting over-current releases operated 10 times		N
	Thermostats with varying temperature settings clearly indicated		N
	Operating temperature of thermal cut-outs indicated		N
15.4.3	Batteries		N
	a)Battery compartments;	No such component	N
	-adequately ventilated		N
	-accidentally short-circuiting is prevented		N
	b)Incorrect polarity of connection prevented		N
15.4.3.5	Excessive current and voltage protection		--
	Internal electrical power source provided with device for protection against fire hazard		N
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuse holder		N
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		N
15.4.4	Indicators-unless indication provided by other means(from the normal operation position),indicator lights are used		N
	-to indicate that equipment is energized		N
	-to indicate the operation of non-luminous heaters if a safety hazard could result		N
	-to indicate when output exists if a safety hazard could result		N
	-charging mode indicator provided		N
15.4.6	Actuating parts of controls		N
	Actuating parts are adequately secured to prevent them working loose during normal use		N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Controls are secured to prevent the movement relative to scale marking(safety related only)		N
	Detachable indicating devices are prevented from incorrect connection without the use of tool		N
	Stops are provided on rotating controls:		--
	-to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard		N
	-to prevent an unexpected change to writing		N
15.4.7	Cord-connected hand-held and foot-operated control devices		--
	a)Contain voltages not exceeding 25V a.c. or 60 V d.c. and isolated from the mains part by Cl.17g		N
	b)Hand-held control devices designed to support the weight of an adult human being		N
	-Foot-operated control devices comply with the support the weight of an adult human being	(see appended table 15.4.7)	N
	c)Devices not change their setting when inadvertently placed		N
	d)Foot-operated control devices are at least IPX1	(see appended table 15.4.7)	N
	-For surgical use, electrical switch parts are IPX8		N
	e)Adequate strain relief at the cord entry provided	(see appended table 11.3.5a and 11.3.5b)	N
15.4.9	Oil containers		--
	Oil containers adequately sealed	Not contain oil.	N
	Containers allow for the expansion of the oil		N
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		N
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N
15.5	Mains supply transformers of me equipment and transformers providing separation in accordance with 8.5		--
	Overheating		P
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		P
	Short-circuit of secondary windings not caused excessive temperature		P

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Overload of secondary windings not caused excessive temperature	(see appended table 15.5B)	N
	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests	(see appended table 15.5)	N
	Construction		N
	a) Separation of primary and secondary windings		N
	-separate bobbins or formers		N
	-one bobbin with insulating partition		N
	-one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13mm		N
	-concentrically wound on one bobbin with windings separated by double insulation		N
	c) Means provided to prevent displacement of end turns		N
	d) Insulated overlap of not less than 3mm if a protective earthed screen has only one turn		N
	e) Insulated between the primary and secondary in transformers with double insulation		N
	-1 insulation layer with thickness of at least 1mm		N
	-at least 2 insulation layer with a total thickness of at least 0.3mm		N
	-three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation	see appended table 15.5	N
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3mm extending at least 20 mm outside the winding		N
	Creepage distances and air clearances		--
	a) Values: compliance with at least the values of Table XVI	L-N:Dr.3.5 DI.3.15	P
	Creepage distances for slot insulation of motors at least 50% of the specified values		N
	b) Minimum Creepage distances and air clearances in the mains parts of opposite polarity not required if short-circuiting does not produce a safety hazard		N
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and parts	No such part.	N

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4.11	TABLE: Power input					P
Operation condition	Voltage(V)	Frequency (Hz)	Current (A)	Power(W)	Remark	
running	110	60	--	6.2	P	
running	230	50	--	6.3	P	
Supplementary information: --						

7.2	TABLE: marking durability		P
Marking tested			Remark
Rubber for 15s with a doth rage soaked with distilled water			clearly legible, not become curled at edges
Rubber for 15s with a doth rage soaked with mentholated spirit			Ditto
Rubber for 15s with a doth rage soaked with isopropyl alcohol			Ditto
Supplementary information: --			

8.4.4a	TABLE: residual voltage in attachment plug										N
Voltage measured between	Measurements[V]										Remark
	1	2	3	4	5	6	7	8	9	10	
Supply pins (pin1&pin2)	--	--	--	--	--	--	--	--	--	--	*
Line pin1 and enclosure	--	--	--	--	--	--	--	--	--	--	*
Line pin1 and enclosure	--	--	--	--	--	--	--	--	--	--	*
Pin 1 and earth pin	--	--	--	--	--	--	--	--	--	--	*
Pin 2 and earth pin	--	--	--	--	--	--	--	--	--	--	*
Supplementary information : *) The capacitor connected between supply pins is less than 45uF, so the test between lines needs not to be done.											
8.4.4b	TABLE: residual voltage or energy in capacitors					N					
Capacitor and its location	Residual voltage(v)	Time after disconnection (s)	Capacitor value (μF)	Residual energy (mJ)	Remarks						
--	--	--	--	--	--						
--	--	--	--	--	--						
Supplementary information: --											

8.5a	TABLE: defibrillation-proof applied parts				N
Test Condition: Fig.50 or 51	Accessible part of measurements	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2(mV)	Remarks
--	--	--	--	--	--
Supplementary information: --					

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8.5b	TABLE: defibrillation-proof recovery time				N
Applied part with test voltage	Test voltage polarity	Recovery time from accompanying documents(s)	Measured recovery time(s)	Remarks	
--	--	--	--	--	
--	--	--	--	--	
--	--	--	--	--	

Supplementary information: --

8.6	TABLE: protective earthing				N
Test location	Test current (A)	Measured voltage	Resistance(ohms)	Remarks	
--	--	--	--	--	

Supplementary information: Class I unit

8.7	TABLE: leakage current				P
Type of leakage current and test condition(including single faults)	Supply voltage	Supply frequency	Measured max. value	Remarks	
Enclosure leakage current of equipment (NC)	264V	50Hz	0.006mA	P	
Enclosure leakage current of control board (SFC)	264V	50 Hz	0.013mA	P	

(Record at least maximum measured value for each test required by Clause 19 and the specific conditions of the test circuit and equipment)

Abbreviations used:

ER - earth leakage current	A -After humidity conditioning
EN - Enclosure leakage current	B - Before humidity conditioning
P - Patient leakage current	1 -Switch closed or set normal polarity
PM - Patient leakage current with mains on the applied parts	0 -Switch open or set to reversed polarity
PA - Patient auxiliary current	NC -Normal condition
Fig.15 -refers to Fig.15 in IEC601-1	SFC -Single fault condition
MD -Measuring device	

8.8	TABLE: dielectric strength				P
Insulation under test (area from insulation diagram)	Insulation type(OP-operational/ BI-basic/SI -supplementary/ DI-double/RI-reinforced)	Reference Voltage(V)	Reference Voltage(V)	Remarks	
L/N-enclosure of equipment	DI	250	4000	P	
L/N-enclosure of control board	DI	250	4000	P	

Supplementary information:--

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8.11.3a	TABLE: cord anchorages					N
Cord under test	Mass of equipment	Pull	Torque	Remarks	Verdict	
--	--	--	--	--	--	
Supplementary information:--						

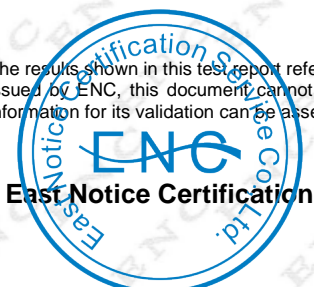
8.11.3b	TABLE: cord bending			N
Cord under test	Test mass	Measured curvature	Remarks	
--	--	--	--	
Supplementary information:--				

9.4	TABLE: stability		N
Part under test	Test condition	Remarks	
--	--	--	
Supplementary information:--			

10	TABLE: X- radiation			N
Part under test	Test condition	Measured radiation(m R)	Remarks	
--	--	--	--	
Supplementary information:--				

11	TABLE: normal temperature					P
Supply voltage: 230V, 50Hz			Test condition: Normal operation			
Monitored point:		dT (°C)	Limit dT (°C)			
AC Adaptor		26.3	65			
DC supply cord		25.2	80			
Inside wire		26.4	105			
PCB		26.0	105			
Outside enclosure near control circuit		25.3	65			
Ambient		23.1	--			
Winding temperature rise measurements:					N	
Ambient temperature t1 (°C)		22.3°C		--		
Ambient temperature t2 (°C)		22.6°C		--		
temperature rise DT of winding:	R1(Ω)	R2(Ω)	dT (K)	Required dT (K)	Insulation class	
Primary winding of mains transformer	--	--	--	--	--	
second winding 1	--	--	--	--	--	
second winding 2	--	--	--	--	--	

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11.6a	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		P
Test type and condition	Test type and condition		Remarks
Humidity 93%, 25 ⁰ C, 48h	Sample		No damage
Dearing alcohol	Main body, accessorize		No damage
Sterilization alcohol	--		--
Supplementary information:--			

11.6b	TABLE: hydrostatic pressure and pressure-relief device cycling test			N
Test type and condition	Part under test	Test pressure		Remarks
--	--	--		--
Supplementary information:--				

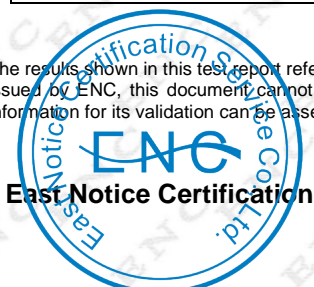
13	TABLE: abnormal operation		N
Test type, condition and clause reference	Observed results		Remarks
--	--		--

15.4.7	TABLE: list of critical components parts			P
Component	Manufacturer/trade mark	Type/model	Technical data	Mark(s) of conformity
AC Adaptor	SIMSUKIAN	SK01G-1500040V	Input: 100-240V~, 50/60Hz 0.2A, Output: DC15V, 0.4A	CE
DC supply cord	KUANWAY	24AWG	300V, 80°C	UL
Internal wiring	KUANWAY	24AWG	300V, 80°C	UL
PCB	RENZHUO	RZ100	V0, 130°C	UL
LED	--	12775W-05	Class 1	CE
1) an asterisk indicates a mark which assures the agreed level of surveillance				

15.5B	TABLE: overload					N	
Winding under test	Protection	Measured temperatures()			Test duration	Test current or thermal cutout temp	Remarks
		Primary	Secondary	Ambient			
--	--	--	--	--	--	--	--
Supplementary information:--							

15.5	TABLE: transformer dielectric strength				N
Transformer under test	Test voltage applied to	Test voltage	Test frequency	Remarks	
--	--	--	--	--	
Supplementary information:--					

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APPENDIX A
PHOTOS OF SAMPLE

Front View of EUT



Side View of EUT



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Top View of EUT



Back View of EUT



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Bottom View of EUT



Overall View of AC/DC Adapter



----END OF REPORT----

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