




TEST REPORT IEC 60601 -1 Medical electrical equipment Part 1: General requirements for safety	
Report reference No.	: TRS09030062
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Testing laboratory	: SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION Co., Ltd.
Address	: Keji Nan No.12 Road, Hi-tech Park, Shenzhen ,China
Testing location.....	: Shenzhen City ,China
Applicant	: KIRCHNER & WILHELM GmbH + Co. KG
Address	: Eberhardstr. 56 71679 Asperg GERMANY
Standard	: IEC60601-1 (1988) +A1(1991) +A2(1995)
Test Report Form No.	: I601-1_C/97-04
TRF Originator	: Underwriters Laboratories Inc.
Master TRF	: dated 97-04
Copyright blank test report.....	: the bodies participating in the Committee of Certification Bodies (CCB). This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator.
Test procedure.....	: CB Scheme
Procedure deviation	: N/A
Non-standard test method	: N/A
Type of test object.....	: Halogen medical practice light
Trademark	: 
Model/type reference	: 10.11000.002
Manufacturer	: KIRCHNER & WILHELM GmbH + Co. KG
Address	: Eberhardstr. 56 71679 Asperg GERMANY
Rating.....	: 220-240V, 50Hz, 50W

Copy of marking plate

Praxisleuchte
MASTERLIGHT®
Art.-Nr. 10.11000.002
Eingang: 220V–240V
50 Hz
Ausgang: 12 V
max.: 50 W
Klassifizierung: Klasse I

Examination lamp
MASTERLIGHT®
Art.-No. 10.11000.002
Input: 220V–240V
50 Hz
Output: 12 V
max.: 50 W
Classification: Class I



KIRCHNER & WILHELM
GmbH + Co. KG
Eberhardstr. 56
71679 Asperg
Germany

GENERAL INFORMATION	
Test item particulars (see also clause 5):	
Classification of installation and use	Mobile
Supply connection	Appliance coupler
Accessories and detachables parts included in the evaluation	None
Options included	-
Possible test case verdicts:	
- test case does not apply to the test object:N / A	
- test object does meet the requirement:Pass	
- test object does not meet the requirement:Fail	
Abbreviations used in the report:	
- normal condition.....:N.C.	- single fault condition.....:S.F.C.
- operational insulation.....:OP	- basic insulation.....:BI
- basic insulation between parts of opposite polarity:BOP	- supplementary insulation:SI
- double insulation.....:DI	- reinforced insulation.....:RI
General remarks:	
"This report is not valid as a CB Test Report unless appended to a CB Test Certificate issued by a NCB, in accordance with IECCE 02".	
"(see Attachment #)" refers to additional information appended to the report.	
"(see appended table)" refers to a table appended to the report.	
Throughout this report a point is used as the decimal separator.	
The tests results presented in this report relate only to the object tested.	
This report shall not be reproduced except in full without the written approval of the testing laboratory.	
List of test equipment must be kept on file and available for review.	
Summary of contents provided on the last page of this report.	
General product information and considerations:	
The high-quality flexible halogen examination lamp is to be used in medical practices and in medical facilities.	

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

3	GENERAL REQUIREMENTS		Pass
3.1	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.)		Pass
3.4	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	No alternative means of construction is used	N/A

5	CLASSIFICATION		Pass
5.1	Type of protection against electric shock		Pass
	Class I equipment		Pass
	Class II equipment	Class I equipment	N/A
	Internally powered equipment	Class I equipment	N/A
5.2	Degree of protection against electric shock		Pass
	Type B applied part		N/A
	Type BF applied part		N/A
	Type CF applied part		N/A
	Not classified - no applied parts		Pass
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1)..... :	Ordinarily equipment	Pass
5.4	Methods of sterilization or disinfection		Pass
5.5	Equipment not suitable for use in the presence of flammable mixtures		Pass
	Category AP equipment		N/A
	Category APG equipment		N/A
5.6	Mode of operation:		Pass
	-continuous operation		Pass
	-short-time operation, specified operation; period.. :		N/A
	-intermittent operation, specified operation; rest period..... :		N/A
	-continuous operation with short-time, stated permissible loading time..... :		N/A
	-continuous operation with intermittent, stated permissible loading/rest time		N/A

INSULATION DIAGRAM

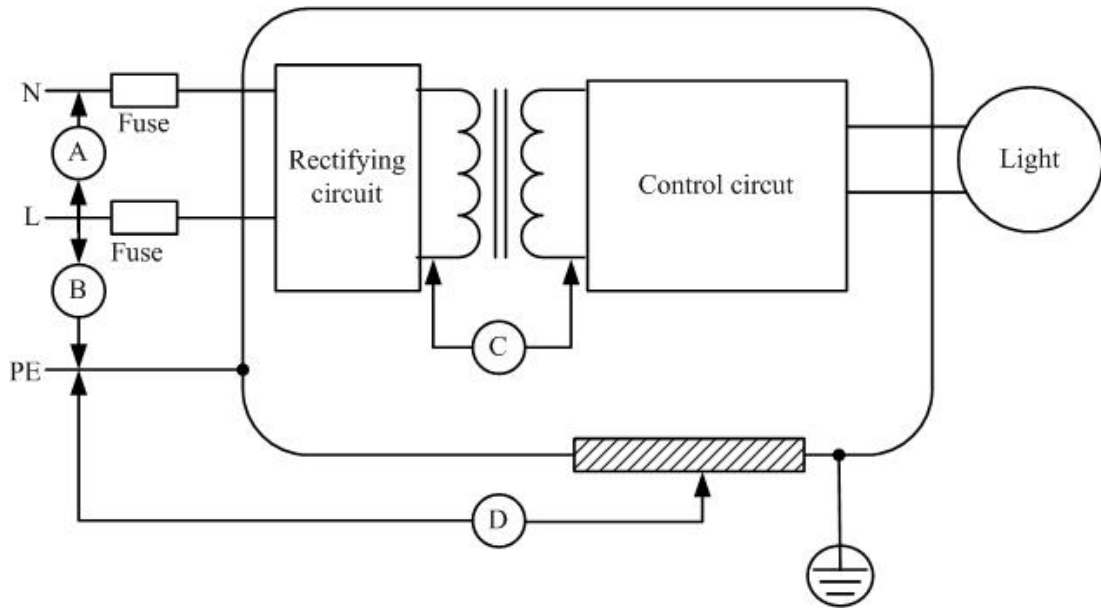



Table: to insulation diagram							Pass
Area	Insulation type: operational / basic / supplementary / double / reinforced	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A	BOP	240	3	1.6	3.2	3.2	Between L terminal and N terminal on PCB
B	BI	240	4	2.5	5.0	5.0	Mains to earthing mental part
C	DI/RI	240	8	5	1)	1)	Transformer primary to secondary
C	DI/RI	240	8	5	9	9	Transformer pri. terminal to sec.
D	DI/RI	240	8	5	>10	6	Mains to enclosure
Supplementary information:							
1) The primary wiring of the T1 is triple insulation, and the creepage and clearance on the PCB is 9mm							

INSULATION DIAGRAM CONVENTIONS

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.
5. Blocks containing the letter "Z" indicate protective impedance.
6. Operational Insulation (OP) - indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with the requirements of clauses 17, 20 and 57.

IEC 60601 + Am. 1 & 2			
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6	IDENTIFICATION, MARKING AND DOCUMENTS		Pass
6.1	Marking on the outside of equipment or equipment parts		Pass
	c) Markings of the specific power supply affixed	Not use specific power supply	N/A
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents	All marking on the equipment	N/A
	e) Name and/or trademark of the manufacturer or supplier		Pass
	f) Model or type reference.....	10.11000.002	Pass
	g) Rated supply voltages or voltage range(s)	220-240V	Pass
	Number of phases.....	Single phase	Pass
	Type of current	AC	Pass
	h) Rated frequency or rated frequency range(s) (Hz)	50Hz	Pass
	j) Rated power input (VA, W or A)	50W	Pass
	k) Power output of auxiliary mains socket-outlets	No such socket-outlets	N/A
	l) Class II symbol	Class I equipment	N/A
	Symbol for degree of protection against ingress of water provided.....	Ordinarily equipment	N/A
	Symbol for protection against electric shock.....	No applied parts	N/A
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets		N/A
	Symbol for protection of defibrillation-proof applied parts	No applied parts	N/A
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N/A
	m) Mode of operation (if no marking, suitable for continuous operation)	Continuous operation	Pass
	n) Types and rating of external accessible fuses.....	No such fuse	N/A
	p) Ratings of external output	No such output	N/A
	q) Symbol for physiological effect(s):		N/A
	- attention, consult accompanying documents		N/A
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N/A
	r) Anaesthetic-proof symbol: AP or APG.....	Not such equipment	N/A
	s) Dangerous voltage symbol		N/A
	t) Special cooling requirements	No special cooling	N/A
	u) Limited mechanical stability		N/A

IEC 60601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	v) Protective packing requirement(s)		Pass
	- Marking(s) for unpacking safety hazard(s)	All marking on the package	Pass
	- Equipment or accessories supplied sterile, marked as sterile		N/A
	y) Potential equalization terminal	No such terminal	N/A
	- Functional earth terminal		N/A
	z) Removable protective means	No such means	N/A
	Durability of marking test	See appended table 6.1	Pass
6.2	Marking on the inside of equipment or equipment parts		Pass
	a) Nominal voltage of permanently installed equipment	It's not permanently installed equipment	N/A
	b) Maximum power loading for heating elements or holders for heating lamps	No such devices	N/A
	c) Dangerous voltage symbol		N/A
	d) Type of battery and mode of insertion	No batteries used	N/A
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator		N/A
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram	No such fuse	N/A
	f) Protective earth terminal	Marked on the PCB	Pass
	g) Functional earth terminal	Marked on the PCB	Pass
	h) Supply neutral conductor in permanently installed equipment (N)	It's not permanently installed equipment	N/A
	j) Markings required in 6.2 f), h), k) ,and l) remain visible after connection and are not affixed to parts which have to be removed		N/A
	- Markings comply with IEC 445		N/A
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)	It's not permanently installed equipment	N/A
	l) Statement for suitable wiring materials at temperatures over 75 °C	Not over 75 °C	N/A
	n) Capacitors and/or circuit parts marked as required in Sub-clause 15c	Compliance with the requirement of Sub-clause 15	Pass
6.3	Marking of controls and instruments		Pass
	a) Mains switch clearly identified	By detachable plug, and switch	Pass
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light		Pass

IEC 60601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	b) Indication of different positions of control devices and switches	All marked on the equipment	Pass
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device	Indication by LED on the cable	Pass
	f) The functions of operator controls and indicators are identified	All controls are identified	Pass
	g) Numeric indications of parameters are in SI units except for units listed in Am. 2		N/A
6.4	Symbols		Pass
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	Comply with Appendix D	Pass
6.5	Colors of the insulation of conductors		Pass
	a) Protective earth conductor has green/yellow insulation	Green/yellow insulation wire	Pass
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		Pass
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow	All protective earth conductors are green/yellow	Pass
	d) Color of neutral conductor	Blue	Pass
	e) Colors of phase conductor(s)	Brown	Pass
	- Compliance with IEC 227 and IEC 245		N/A
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors	Not used additional protective earthing	N/A
6.6	Medical gas cylinders and connections		N/A
	a) In accordance with ISO ISO/R 32	No medical gas	N/A
	b) Identification of connection point		N/A
6.7	Indicator lights and push-buttons		Pass
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action	Not used	N/A
	- Yellow used to indicate caution or attention required	Not used	N/A
	- Green used to indicate ready for action	Power on	Pass
	b) Color red used only for push-buttons by which a function is interrupted in case of emergency	Not used	N/A
6.8	ACCOMPANYING DOCUMENTS		Pass
6.8.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	All the information in the operation manual	Pass

IEC 60601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Classifications specified in Clause 5 included in both the instructions for use and the technical description		Pass
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	All fixed on the equipment	N/A
	Warning statements and the explanation of warning symbols provided in the accompanying documents	All explained in the manual	Pass
6.8.2	Instructions for use		Pass
	a) General information provided in instructions for use		Pass
	- state the function and intended application of the equipment	Refer to the chapter intended use	Pass
	- include an explanation of: the function of controls, displays and signals	Refer to the chapter for instruction of product	Pass
	- the sequence of operation	Refer to the chapter for instruction of product	Pass
	- the connection and disconnection of detachable parts and accessories	Refer to the chapter for instruction of product	Pass
	- the replacement of material which is consumed during operation	Refer to the instruction of replace lamp	Pass
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	Refer to warning chapter	Pass
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety		N/A
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	In the chapter of maintenance	Pass
	General information provided in instructions:		Pass
	- information for the safe performance or routine maintenance	In all chapter of the manual	Pass
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	In the chapter of maintenance	Pass
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	In the chapter of the symbols	Pass
	c) Signal output or signal input parts intended only for connection to specified equipment described	No such devices	N/A
	d) Details about acceptable cleaning, disinfection or sterilization methods included		N/A
	e) Warning statement for mains operated equipment with additional power source	Not used additional power source	N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	No primary batteries used	N/A
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	No batteries used	N/A
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	Not use external power	N/A
	j) Identification of any risks associated with the disposal of waste products, residues, etc.		Pass
	- Advice in minimizing these risks		N/A
6.8.3	Technical description		—
	a) All characteristics essential for safe operation provided	In the whole manual	Pass
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	It's not permanently installed equipment	N/A
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	Refer to the chapter for replace lamps	Pass
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided		Pass
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	All on the packages, and description in the manual	Pass

IEC 60601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

7	POWER INPUT		—
	Power Input Measurements	See appended table 7	Pass

10	ENVIRONMENTAL CONDITIONS		—
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer		Pass
10.2.2a	Rated voltage not exceeding 250 V for hand-held equipment	None hand-held equipment	N/A
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA	Not up to 4kVA	N/A
	Rated voltage not exceeding 500 V for all other equipment	Rated voltage is 220-240Vac	Pass
	Rated input frequency not more than 1kHz	50Hz	Pass
10.2.2b	Internal replaceable electrical power source specified	No such internal power source	N/A

14	REQUIREMENTS RELATED TO CLASSIFICATION		—
14.4a	Class I and Class II equipment in addition to basic insulation provided with an additional protection	Compliance with the requirement of Class I	Pass
14.4b	Equipment supplied from external dc source of reverse polarity results in no safety hazard	Not used external dc source	N/A
14.5b	Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected	Not internally powered equipment	N/A
14.6c	Applied parts intended for direct cardiac application are of type CF	No applied parts	N/A

15	LIMITATION OF VOLTAGE AND/OR ENERGY		—
15b	Voltage measured one sec after disconnection of the mains plug does not exceed 60V	See appended table 15b	Pass
15c	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ		N/A
	Marking provided for manual discharging		N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

16	ENCLOSURES AND PROTECTIVE COVERS		—
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	All the enclosure can protective the live parts be connect	Pass
	Insertion or removal of lamps - protection against contact with live parts provided	By inspection	Pass
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented	No such opening	N/A
16c	Conductive parts accessible after the removal of handles, knobs, levers		—
	- have a resistance of not more than 0.2 Ω	No such conductive parts	N/A
	- separated from live parts by one of the means described in Sub-clause 17g		N/A
16d	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact	No such parts	N/A
16e	Removable enclosures protecting against contact with live parts		—
	- Removal possible only with the aid of a tool	Only use the specified tools can open the enclosure of live parts	Pass
	- Use of automatic device making parts not live when the enclosure is opened or removed		N/A
	- Exception 16e applied to the following parts.....:	Lamp cover, and the working voltage is 11.8Vrms	Pass
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	Not used such opening	N/A

IEC 60601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

17	SEPARATION		—
17a	Separation method of the applied part from live parts:		N/A
	1) basic insulation: applied part earthed	No applied part	N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N/A
	4) by double or reinforced insulation		N/A
	5) by protective impedances limiting current to applied part		N/A
	- Additional leakage current test in single fault conditions		N/A
17c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed	No applied part	N/A
17d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		N/A
17g	Separation method of accessible parts other than applied parts from live parts:		Pass
	1) basic insulation: accessible part earthed		Pass
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N/A
	4) by double or reinforced insulation	By double insulation	Pass
	5) by protective impedances limiting current to accessible part		N/A
	- Additional leakage current test in single fault conditions	Open protective part, refer to table 19	Pass
17h	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N/A
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator	No applied parts	N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
18	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION		—
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal	Class I equipment, refer to insulation diagram	Pass
18b	Protective earth terminals suitable for connection to the protective earth conductor	By power plug earth terminal	Pass
18e	Potential equalization conductor		N/A
	- Readily accessible	No potential equalization terminal	N/A
	- Accidental disconnection prevented in normal use		N/A
	- Conductor detachable without the use of a tool		N/A
	- Power supply cord does not incorporate a potential equalization conductor		N/A
	- Connection means marked with Symbol 9, Table DI		N/A
18f	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1 \Omega$	See appended table 18	Pass
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $\leq 0.1 \Omega$		N/A
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part $\leq 0.2 \Omega$		N/A
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1Ω , the allowable value of the enclosure leakage current is not exceeded in single fault condition	Not exceeds the limits of clause 18f)	N/A
18k	Functional earth terminal not used to provide protective earthing		Pass
18l	Class II equipment with isolated internal screens		N/A
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation	Class I equipment	N/A
	- functional earth terminal clearly marked		N/A
	- explanation of functional earth terminal provided in the accompanying documents		N/A

IEC 60601 + Am. 1& 2			
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19	CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS		—
19.1b	Leakage currents	See appended table 19	Pass
	- earth leakage current		Pass
	- enclosure leakage current		Pass
	- patient leakage current	No applied part	N/A
	- patient auxiliary current	No applied parts	N/A

20	DIELECTRIC STRENGTH		—
	Overall compliance with Clause 20	See appended table 20	Pass

21	MECHANICAL STRENGTH		—
21a	Sufficient rigidity of an enclosure tested by: force of 45 N	See appended table 21	Pass
21b	Sufficient strength of an enclosure tested by: impact hammer	See appended table 21	Pass
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test		N/A
21.3	No damage to parts of patient support and/or immobilization system after the loading test	No patient support device	N/A
21.5	Hand held equipment or equipment parts are safe after drop test	No hand held device	N/A
21.6	Portable and mobile equipment is able to withstand rough handling	See appended table 21	Pass

IEC 60601 + Am. 1& 2			
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22	MOVING PARTS		—
22.2a	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment	No moving parts	N/A
22.2b	Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation	No moving parts	N/A
22.3	Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices	No moving parts	N/A
	Guides or other safeguards are removable only with a tool	No moving parts	N/A
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator	No moving parts	N/A
22.6	Parts of equipment subject to mechanical wear are accessible for inspection	No moving parts	N/A
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard	No moving parts	N/A
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard	No moving parts	N/A
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents	No moving parts	N/A
	Means for stopping of movements operate as a result of one single action	No moving parts	N/A

23	SURFACES, CORNERS AND EDGES		—
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	Checked by inspecting	Pass

IEC 60601 + Am. 1& 2			
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24	STABILITY IN NORMAL USE		—
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°	Refer to sub-clause 24.3	N/A
24.3	Equipment overbalances when tilted through an angle of 10°		Pass
	- does not overbalance when tilted through an angle of 5° in any position excluding transport	The equipment not overbalance when tilted through an angle 5° in any position excluding transport	Pass
	- carry a warning notice stating that transport should only be undertaken in a certain position		N/A
	- in the position specified for transport does not overbalance when tilted to an angle of 10°		N/A
24.6a	Equipment or its parts with a mass of more than 20 kg is provided with:		N/A
	- suitable handling devices (grips etc.), or	The weight of the unit is 4.4Kg	N/A
	- instructions for lifting and handling during assembly		N/A
24.6b	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	Mobile equipment	N/A

25	EXPELLED PARTS		—
25.1	Protective means are provided where expelled parts of the equipment could be a hazard	No expelled parts	N/A
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		N/A

IEC 60601 + Am. 1& 2			
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28	SUSPENDED MASSES		—
28.3	Suspension system with safety device		N/A
	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-clause 28.4	No suspended masses	N/A
	Safety device has safety factors complying with Sub-clause 28.4.2	No suspended masses	N/A
	Clear indication to the operator that the safety device has been activated after failure of suspension means	No suspended masses	N/A
28.4	Suspension systems of metal without safety devices		N/A
	1) Total load does not exceed the safe working load	No suspended masses	N/A
	2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired	No suspended masses	N/A
	3) Safety factors not less than 8 where impairment is expected	No suspended masses	N/A
	4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%	No suspended masses	N/A
	5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement	No suspended masses	N/A

29	X-RADIATION		—
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5 mR)	The device will not produce X-radiation	N/A

36	ELECTROMAGNETIC COMPATIBILITY		—
	Equipment complies with IEC 601-1-2	Refer to EMC test report	N/A

37	COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT		—
	Requirements for category AP and APG equipment (Cl. 37 - 41)		N/A

IEC 60601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

42	EXCESSIVE TEMPERATURES		—
42.1	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 42	Pass
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient		Pass
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C	No applied part	N/A
42.5	Guards to prevent contact with hot surfaces removable only with a tool	No hot surfaces	N/A

43	FIRE PREVENTION		—
	Strength and rigidity necessary to avoid a fire hazard	Refer to table 21	Pass

44	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION		Pass
44.2	Equipment contain a liquid reservoir:		N/A
	- the equipment is electrically safe after 15% overflow steadily over a period of 1 min		N/A
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling)		N/A
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)		N/A
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		N/A
44.5	Equipment sufficiently protected against the effects of humidity	See appended table 44	Pass
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529	Ordinary equipment	N/A
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	See appended table 44	Pass

IEC 60601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

45	PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE		—
45.2	Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure	No such parts	N/A
45.3	Maximum pressure does not exceed the maximum permissible working pressure for individual parts		N/A
45.7	Unless excessive pressure can not occur, pressure-relief device provided		N/A
45.7a	Pressure-relief device connected as close as possible to the pressure vessel		N/A
45.7b	Readily accessible for inspection		N/A
45.7c	Not capable of being adjusted or rendered inoperative without a tool		N/A
45.7d	Discharge opening located that the released material is not directed towards person		N/A
45.7e	Discharge opening located that operation will not deposit material which may cause a safety hazard		N/A
45.7f	Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure		N/A
45.7g	No shut-off valve between a pressure-relief device and the parts intended to be protected		N/A
45.7h	Minimum number of cycles of operation: 100.000		N/A

48	BIOCOMPATIBILITY		—
	Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1	No applied part	N/A

49	INTERRUPTION OF THE POWER SUPPLY		—
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard	No such device	Pass
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function	No safety hazards	Pass
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure	No such safety risk	N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
51	PROTECTION AGAINST HAZARDOUS OUTPUT		—
51.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally		N/A
52	ABNORMAL OPERATION AND FAULT CONDITIONS		—
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13)	See appended table 52	Pass
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4		N/A
52.5.2	Failure of thermostats presents no safety hazards	No thermostats	N/A
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard	See appended table 19	Pass
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C	No cooling system	N/A
52.5.6	Locking of moving parts presents no safety hazard	No moving part	N/A
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard		N/A
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8		N/A
52.5.9	Failure of one component at a time presents no safety hazard	See appended table 52	Pass
52.5.10	Overload of heating elements presents no safety hazard		N/A
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	No such motors	N/A
	h) Equipment with three-phase motors can safely operate with one phase disconnected	Single phase device	N/A

IEC 60601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

56	COMPONENTS AND GENERAL ASSEMBLY		—
	List of critical components	See appended table 56	Pass
56.1b	Ratings of components not in conflict with the conditions of use in equipment	No confliction	Pass
	Ratings of mains components are identified	Identified	Pass
56.1d	Components, movements of which could result in a safety hazard mounted securely	All such components are mounted securely	Pass
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard	No such safety risk, all connector is inspected	Pass
56.3a	Connectors provide separation required by Sub-clause 17g	Compliance with the requirement	Pass
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	No patient circuit	N/A
	Medical gas connections not interchangeable		N/A
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken	No such safety risk, checked by inspection	Pass
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.	No such leads	N/A
56.4	Connections of capacitors		Pass
	Not connected between live parts and non-protectively earthed accessible parts	Not such connections	Pass
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14	Refer to the appended table 56	Pass
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts		Pass
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs	No such connection	N/A
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	Not used such protective devices	Pass
56.6	Temperature and overload control devices		N/A
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment	No such thermal cut-outs	N/A
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits	No thermal safety devices	N/A

IEC 60601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard	No thermal cut-outs	N/A
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard	No thermal cut-outs	N/A
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times	No thermal cut-outs	N/A
	Non-self resetting over-current releases operated 10 times	No non-self resetting over-current release	N/A
56.6b	Thermostats with varying temperature settings clearly indicated	No such devices	N/A
	Operating temperature of thermal cut-outs indicated		N/A
56.7	Batteries		N/A
	a) Battery compartments:		N/A
	- adequately ventilated	No batteries be used	N/A
	- accidentally short-circuiting is prevented		N/A
	b) Incorrect polarity of connection prevented		N/A
56.8	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):		Pass
	- to indicate that equipment is energized	By the green LED On the cable of output	Pass
	- to indicate the operation of non-luminous heaters if a safety hazard could result	No such heaters	N/A
	- to indicate when output exists if a safety hazard could result		N/A
	- charging mode indicator provided	No charger	N/A
56.10	Actuating parts of controls	No actuating parts	N/A
56.10b	Actuating parts are adequately secured to prevent them from working loose during normal use		N/A
	Controls are secured to prevent the movement relative to scale marking (safety related only)		N/A
	Detachable indicating devices are prevented from incorrect connection without the use of tool		N/A
56.10c	Stops are provided on rotating controls:		N/A
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard	No such rotating controls	N/A
	- to prevent damage to wiring		N/A
56.11	Cord-connected hand-held and foot-operated control devices		N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g	No such devices used	N/A
	b) Hand-held control devices comply with the requirement and test of Sub-clause 21.5		N/A
	- Foot-operated control devices designed to support the weight of an adult human being		N/A
	c) Devices not change their setting when inadvertently placed		N/A
	d) Foot-operated control devices are at least IPX 1		N/A
	- For surgical use, electrical switching parts are IPX 8		N/A
	e) Adequate strain relief at the cord entry provided		N/A

IEC 60601 + Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict

57	MAINS PARTS, COMPONENTS AND LAYOUT		—
57.1	Isolation from supply mains		Pass
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	By power plug	Pass
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents	No external isolation devices	N/A
	d) Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328	No mains switch	N/A
	f) Mains switches not incorporated in a power supply cord		N/A
	h) Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a		Pass
	m) Fuses and semiconductor devices not used as isolating devices	Not used as isolating devices	Pass
57.2	Mains connectors and appliance inlets		Pass
	e) Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug	Not used auxiliary mains socket-outlets	N/A
	g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment		N/A
57.3	Power supply cords		Pass
	a) Not more than one connection to a particular supply mains	Only one	Pass
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously	No alternative supply	N/A
	The mains plug has only one power supply cord	Not used mains power supply cord	N/A
	Non-permanently connected equipment provided with power supply cord or appliance inlet	Provided with appliance inlet	Pass
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53		N/A
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C		N/A
	c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV	The internal mains power supply cord's cross-sectional area is 0.77mm ²	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	d) Stranded conductors not soldered if fixed by any clamping means	Fixed by screw	Pass
57.4	Connection of power supply cords		Pass
57.4a	Cord anchorages		N/A
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting	Supply by appliance inlet	N/A
	Tying the cord into a knot or tying the ends with string not used		N/A
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		N/A
	Cord anchorages made of metal provided with an insulating lining		N/A
	Clamping screws do not bear directly on the cord insulation		N/A
	Screws associated with cable replacement are not used to secure other components		N/A
	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 terminals		N/A
57.4b	Power supply cord protected against excessive bending		N/A
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		Pass
57.5	Mains terminal devices and wiring of mains part		Pass
	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	No such cords used	N/A
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced		N/A
	Screws and nuts which clamp external conductors not serve to fix any other component		N/A
	b) Terminals closely grouped with any protective earth terminal		Pass
	Mains terminal devices accessible only with use of a tool	Only used tools can open the enclosure of the power unit	Pass
	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	No such risk	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened	Not subjected to stress	Pass
	d) Cord terminals not require special preparation of the conductor	Not special preparation	Pass
57.6	Mains fuses and overcurrent releases		Pass
	Fuses or over-current releases provided accordingly for Class I and Class II	Accordingly Class I equipment requirement, fixed fuses on L and N	Pass
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current	Reliable	Pass
	Protective earth conductor not fused	Not fused	Pass
	Neutral conductor not fused for permanently installed equipment	It's not permanently install equipment	N/A
57.8	Wiring of the mains part		Pass
	a) Individual conductor in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC 227 or 245, treated as bare conductor	Internal wiring compliance with the requirement of IEC60227	Pass
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord	All primary wirings are 18AWG	Pass
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard		Pass
57.9	Mains supply transformers		Pass
57.9.1	Overheating		Pass
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		Pass
57.9.1a	Short-circuit of secondary windings not caused excessive temperature	See appended table 57.9.1a	Pass
57.9.1b	Overload of secondary windings not caused excessive temperature	See appended table 57.9.1b	Pass
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests	See appended table 20	Pass
57.9.4	Construction		Pass
	a) Separation of primary and secondary windings	Toroidal transformer	Pass
	- separate bobbins or formers	No bobbin used	N/A
	- one bobbin with insulating partition		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm		N/A
	- concentrically wound on one bobbin with windings separated by double insulation		N/A
	c) Means provided to prevent displacement of end turns	Toroidal transformer, no such risk	N/A
	d) Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn	5mm	Pass
	e) Insulation between the primary and secondary in transformers with double insulation		Pass
	- 1 insulation layer with thickness of at least 1 mm		N/A
	- at least 2 insulation layers with a total thickness of at least 0.3 mm		N/A
	- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation		Pass
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3 mm extending at least 20 mm outside the winding		Pass
57.10	Creepage distances and air clearances		Pass
	a) Values: compliance with at least the values of Table XVI	See table for insulation diagram	Pass
	Creepage distances for slot insulation of motors at least 50% of the specified values		N/A
	b) Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuiting does not produce a safety hazard	See table for insulation diagram	Pass
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts	No such applied parts	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

58	PROTECTIVE EARTHING TERMINALS AND CONNECTIONS		—
58.1	Clamping means of the protective earth terminal		Pass
	Not be able to loosen without the aid of a tool	Loosen only by tools	Pass
	Screws for internal earth connections are covered or protected against loosening from outside	Can not loosening from outside	Pass
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal		Pass
58.8	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing		Pass
58.9	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		Pass

59	CONSTRUCTION AND LAYOUT		—
59.1	Internal wiring		Pass
	a) Cables and wiring protected against contact with a moving part	No moving part	N/A
	Wiring having basic insulation only protected by additional fixed sleeving	No such wiring	N/A
	Components are not likely to be damaged in the normal assembly or replacement of covers	No such assembly risk	Pass
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead	No such leads	N/A
	c) Insulating sleeving adequately secured		N/A
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test		Pass
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material	Not more than the limited temperature	N/A
	d) Aluminum wires of less than 16 mm ² cross-section not used	Not use aluminum wires	N/A
	f) Connecting cords between equipment parts considered as belonging to the equipment	No such connecting	N/A
59.2	Insulation		Pass
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation		Pass
	c) Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		Pass
	Parts of rubber resistant to ageing		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
59.3	Excessive current and voltage protection		N/A
	Internal electrical power source provided with device for protection against fire hazard	Not internal electrical power equipment	N/A
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder	No such fuses	N/A
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.	No such protective devices	N/A
59.4	Oil containers		N/A
	Oil containers adequately sealed	No oil containers	N/A
	Container allow for the expansion of the oil		N/A
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		N/A
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N/A

6.1	TABLE: marking durability				Pass
Marking tested				Remarks	
Rating label with distilled water				Clearly legible & durable	
Rating label with methylated spirit				Clearly legible & durable	
Rating label with isopropyl alcohol				Clearly legible & durable	
Supplementary information:					

7	TABLE: power input					Pass
Operating condition	Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks	
Max. load	198	50	0.148	26.3		
	220	50	0.159	31.3		
	240	50	0.169	36.1		
	264	50	0.181	42.1		
Supplementary information: The rating power consumption is 50W						

15b	TABLE: residual voltage in attachment plug										Pass	
Voltage measured between:		Measurements [V]									Remarks	
		1	2	3	4	5	6	7	8	9		10
supply pins (pin 1 & pin 2)		11	12	11	13	11	11	12	12	11	13	Less than 60V
line pin 1 and enclosure		/	/	/	/	/	/	/	/	/	/	/
line pin 2 and enclosure		/	/	/	/	/	/	/	/	/	/	/
pin 1 and earth pin		/	/	/	/	/	/	/	/	/	/	/
pin 2 and earth pin		/	/	/	/	/	/	/	/	/	/	/
Supplementary information: The capacitor L, N is 0.69uF, L, N to earth is 1988pF												

15c	TABLE: residual voltage or energy in capacitors				N/A	
Capacitor and its location		Residual voltage (V)	Time after disconnection (s)	Capacitance value (µF)	Residual energy (mJ)	Remarks
Supplementary information:						

17h1	TABLE: defibrillation-proof applied parts					N/A
Test Condition: Fig. 50 or 51	Accessible part of measurement:	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks	
Supplementary information: No applied parts						

17h2	TABLE: defibrillation-proof recovery time				N/A	
Applied part with test voltage		Test voltage polarity	Recovery time from accompanying documents (s)	Measured recovery time (s)	Remarks	
Supplementary information:						

18	TABLE: protective earthing				Pass	
Test location		Test current (A)	Measured voltage (V)	Resistance (ohms)	Remarks	
Earth pin to earthed screen terminal on the PCB		25	--	0.01	Less than 0.1 Ω	
Supplementary information:						

19	TABLE: leakage current			Pass
Type of leakage current and test condition (including single faults)	Supply voltage	Supply frequency	Measured max. value	Remarks
Figure 16, Earth Leakage	(V)	(Hz)	(μ A)	Limits
ER, B, NC, S1 = 1, S5 = N	264	50	132	500
ER, B, NC, S1 = 1, S5 = R	264	50	132	500
ER, B, SFC, S1 = 0, S5 = R	264	50	264	1000
ER, B, SFC, S1 = 0, S5 = N	264	50	263	1000
ER, A, NC, S1 = 1, S5 = N	264	50	133	500
ER, A, NC, S1 = 1, S5 = R	264	50	133	500
ER, A, SFC, S1 = 0, S5 = R	264	50	264	1000
ER, A, SFC, S1 = 0, S5 = N	264	50	264	1000
Figure 18, Enclosure Leakage	(V)	(Hz)	(μ A)	Limits
EN, B, NC, S1 = 1, S5 = N, S7 = 1	264	50	2	100
EN, B, NC, S1 = 1, S5 = R, S7 = 1	264	50	2	100
EN, B, SFC, S1 = 0, S5 = N, S7 = 1	264	50	2	500
EN, B, SFC, S1=0, S5=R, S7=1	264	50	2	500
EN, B, SFC, S1 = 1, S5 = N, S7 = 0	264	50	3	500
EN, B, SFC, S1 = 1, S5 = R, S7 = 0	264	50	3	500
EN, A, NC, S1 = 1, S5 = N, S7 = 1	264	50	2	100
EN, A, NC, S1 = 1, S5 = R, S7 = 1	264	50	2	100
EN, A, SFC, S1 = 0, S5 = N, S7 = 1	264	50	2	500
EN, A, SFC, S1=0, S5=R, S7=1	264	50	2	500
EN, A, SFC, S1 = 1, S5 = N, S7 = 0	264	50	3	500
EN, A, SFC, S1 = 1, S5 = R, S7 = 0	264	50	3	500
(Record at least maximum measured value for each test required by Clause 19 and the specific conditions of the test circuit and equipment).				
Supplementary information: The device is permanently installed equipment, and the protective conductor (S7) will not be disconnected				
<u>Abbreviations used:</u>				
ER - Earth leakage current EN - Enclosure leakage current P - Patient leakage current PM - Patient leakage current with mains on the applied parts PA -Patient auxiliary current Fig. 15 - refers to Fig. 15 in IEC601-1 MD - Measuring device		A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition		

20	TABLE: dielectric strength				Pass
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (V)	Test voltage (V)	Remarks	
Before humidity					
B	BI	240	1500	No breakdown	
C	DI/RI	240	4000	No breakdown	
D	DI/RI	240	4000	No breakdown	
After humidity					
B	BI	240	1500	No breakdown	
C	DI/RI	240	4000	No breakdown	
D	DI/RI	240	4000	No breakdown	
Supplementary information:					

21	TABLE: mechanical strength		Pass
Part under test	Test (impact, drop, force, handle, rough handling, mobile)	Remarks	
Power supply unit	Force, 45N	No break, no safety hazards	
Power supply unit	Impact, 0.5J	No break, no safety hazards	
Supplementary information:			

24	TABLE: - stability		Pass
Part under test	Test condition	Remarks	
Unit	5°	Stable	
Supplementary information:			

29	TABLE: X - radiation			N/A
Part under test	Test condition	Measured radiation (mR)	Remarks	
Supplementary information: None X-radiation equipment				

42	TABLE: normal temperature		Pass
Supply voltage: 264Vac, 50Hz Ambient temperature: See bellow		Test Condition: Max. load	
Measuring location		Measured temperature (adjust to 40 °C)	Remarks (limitation °C)
1.LF1		45.2/56.9	105
2.T1 core		52.4/64.1	---
3.T1 wiring		51.6/63.3	105
4.T2 core		54.1/65.8	---
5.T2 wiring		55.0/66.7	105
6.PCB nearly Q2		49.6/61.3	130
7.Power input connector		30.0/41.7	85
8.Enclosure		39.6/51.3	85
9.Light cover		83.5/95.2	Refer to IEC60958-1
10.Ambient		28.3/40.0	---
Supplementary information:			
COR - indicates measurements taken using change-of-resistance method			

44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		Pass
Test type and condition		Part under test	Remarks
Humidity (25 °C, 96%, 48hrs)		Unit	No dielectric breakdown. Leakage test see table 19.
Cleaning(wipe with a clamp cloth)		Unit	No dielectric breakdown.
Supplementary information:			

45	TABLE: hydrostatic pressure and pressure-relief device cycling test		N/A	
Test type and condition		Part under test	Test pressure	Remarks
Supplementary information:				

52	TABLE: abnormal operation		Pass
Test type, condition and clause reference	Observed results	Remarks	
Short BD1 (+, -)	Fuse open system shutdown	No safety hazards	
Short Q1 (b-e)	System protect, no output	No safety hazards	
Short Q1 (c-e)	System protect, no output	No safety hazards	
Short Q1 (b-c)	Fuse open, R7 damaged, system shutdown	No safety hazards	
Short Q2 (b-e)	System protect, no output	No safety hazards	
Short Q2 (c-e)	System protect, no output	No safety hazards	
Short Q2 (b-c)	Fuse open, R4 damaged, system shutdown	No safety hazards	
Short D6	Fuse open system shutdown	No safety hazards	
Supplementary information:			

56.1	TABLE: lists of critical component parts					Pass
Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity ¹⁾	
Enclosure	Teijin Chemicals	LN-1250	Rated V-0 Constructed of two parts Secured together by ultrasonic Welding.	UL94	UL: E50075	
Enclosure – Alternate	Various	Various	Rated V-0 Constructed of two parts Secured together by ultrasonic Welding.	UL94	Various	
Enclosure – Alternate	Chi Mei	PA-769	Rated V-0 Constructed of two parts Secured together by ultrasonic Welding	UL94	UL: E56070	
Printed wiring board	Various	Various	Min V-1, 105°C	UL94	Various	
Fuses (F1, F2)	Wickmann	392	1A, 250V Time lag	IEC60227	VDE: 126983	
Alternate Fuse (F1, F2)	Littlefuse	392	1A, 250V, Time lag	IEC60227	VDE: 126983	
Alternate Fuse (F1, F2)	Conquer Electronics Co., Ltd.	MST	1A, 250V, Time lag	IEC60227	VDE: 40017118	
Alternate Fuse (F1, F2)	Bel Fuse Ltd.	RST	1A, 250V, Time lag	IEC60227	VDE: 40011144	
Alternate Fuse (F1, F2)	Various	Various	1A, 250V, Time lag	IEC60227		
Across-the-line Capacitor (CX1) CX1 is an optional component	Ultra Tech Xiphi Enterprise Co. Ltd.	HQX	0.47uf, 275V, X2 Max.	IEC60384-14	VDE: 40015608	
X Capacitor (CX1) Alternate	Arcotronics Italia S.r.l.	MKP	0.47uf, 275V, X2 Max	IEC60384-14	VDE: 124076	
X Capacitor (CX1) Alternate	Pilkor Electronics Co., Ltd.	PCX2	0.47uf, 275V, X2 Max	UL1414	UL: E165646	
X Capacitor (CX1) Alternate	Okaya Electric Industries Co. LTD	RE	0.47uf, 275V, X2 Max	IEC60384-14	VDE: 40024816	
X Capacitor (CX1) Alternate	Dain Electronics Co., Ltd.	MPX	0.47uf, 275V, X2 Max	IEC60384-14	VDE: 094607	
X Capacitor (CX1) Alternate	Europtronic (Taiwan) Ind. Corp.	MPX	0.47uf, 275V, X2 Max	IEC60384-14	VDE: 40018238	
Resistor (R3)	Various	Various	1 Ohm, 1/2W Metal Oxide Film Resistor (Relied	--	--	

			on for Abnormal Testing)		
Bleeding Resistor (R1,R2) R1 and R2 are optional	--	--	360K, 1206	--	--
Diode Bridge (BD1)	--	--	1A Min, 600V Min	--	--
Capacitor, bridging (CY1) (Optional)	Murata Mfg. Co., Ltd.	KX	470pF, 250V, Y1 Max	IEC60384-14	VDE: 40002831
Capacitor, bridging (CY1) -Alternate	TDK Corporation, Capacitors Group	CD	470pF, 250V, Y1 Max	IEC60384-14	VDE: 124321
Capacitor, bridging (CY1) -Alternate	Welson Industrial Co. Ltd.	WD	470pF, 250V, Y1 Max	IEC60384-14	VDE: 115455
Capacitor, bridging (CY1) -Alternate	Chyun Fuh Electronic Co., Ltd.	CD	470pF, 250V, Y1 Max	IEC60384-14	VDE: 40001223
Y-Capacitors (CY2,CY3) - Alternate	Jya-Nay Co. Ltd.	JN	470pF, 250V, Y2 Max	IEC60384-14	VDE: 40001831
Y-Capacitors (CY2,CY3) - Alternate	Murata Mfg. Co., Ltd.	KH	470pF, 250V, Y2 Max	IEC60384-14	VDE: 40002796
Y-Capacitors (CY2,CY3) - Alternate	TDK Corporation, Capacitors Group	CS	470pF, 250V, Y2 Max	IEC60384-14	VDE: 122006
Y-Capacitors (CY2,CY3) - Alternate	Success Electronics Co. Ltd.	SB	470pF, 250V, Y2 Max	IEC60384-14	VDE: 121379
Y-Capacitors (CY2,CY3) - Alternate	Welson Industrial Co. Ltd.	KL	470pF, 250V, Y2 Max	IEC60384-14	VDE: 116772
Y-Capacitors (CY2,CY3) - Alternate	Walsin Technology Corp.	AC	470pF, 250V, Y2 Max	IEC60384-14	VDE: 40001829
Transformer (T1)	--	--	Employs Triple Insulated Wire On the secondary winding.	--	--
Triple Insulated Wire	Furukawa Electric Co. Ltd	TEX-B or TEX-E	Reinforced Insulation rated 130°C	UL2353	UL: E206440
Triple Insulated Wire	Rubadue Wire Co., Inc.	FEP Teflon	Reinforced Insulation rated 155°C	UL2353	UL:E206198
Triple Insulated Wire	Various	Various	Reinforced Insulation rated 130°C	UL2353	Various
Transistor (Q1,Q2)	--	--	Rated 400V Min., 7A Min. Secured to heatsink	--	--
Insulator – between	--	--	Min. 0.2mm thick	--	--

Heatsink and Transistors					
Heatsink	--	--	Copper or Aluminum	--	--
Internal Wire	Various	Various	Blue and Brown; AWM, 20 AWG or greater, Vw-1, Style 1015 or equiv., min 300V, 80°C.	UL958	Various
Ground Wire	Various	Various	Green/yellow, same as above except 18 AWG	UL958	Various
Output Cord	Various	Various	Stranded wire, AWG 22 minimum, 80°C minimum, one end soldered to PCB and the other end molded with suitable connector or stripped and tinned.	UL958	Various
Lamp	Various	Various	12V, 35W	IEC60598	Various
¹⁾ an asterisk indicates a mark which assures the agreed level of surveillance					

56.10	TABLE: actuating parts and controls			N/A
Part under test		Torque applied	Remarks	
Supplementary information:				

56.11b	TABLE: foot operated control devices-loading			N/A
Part under test		Observed results	Remarks	
Supplementary information:				

57.4	TABLE: cord anchorages					N/A
Cord under test	Mass of equipment	Pull	Torque	Remarks	Verdict	
Supplementary information:						

57.4b	TABLE: cord bending			N/A
Cord under test	Test mass	Measured curvature	Remarks	
Supplementary information:				

57.9.1a	TABLE: transformer short circuit					Pass
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
T1(2s-sf)	Fuse	-	-	26.4	1s	System shutdown, no safety hazards
Supplementary information:						

57.9.1b	TABLE: overload					Pass	
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current or thermal cutout temp.	Remarks
		Primary	Secondary	Ambient			
T1(2s-sf)	Fuse	60	76.1	26.4	1.5hrs	0.3A	When loading is more than 80W, system protected, no safety hazards
Supplementary information:							

57.9.2	TABLE: transformer dielectric strength				N/A
Transformer under test	Test voltage applied to	Test voltage	Test frequency	Remarks	
Supplementary information:					

SUMMARY OF CONTENTS:

The equipment has been tested according to standard IEC60601-1 (1988) +A1(1991) +A2(1995)

All applicable tests according to the above specified standard(s) have been carried out.

These tests fulfill the requirements of standard EN45001.

This test report comprises 46 pages of CB Test Report and the following Attachments:

Attachment #	Description	Pages
1	Photo of the DUT	4

Note:

Attachments may include Schematics, Components information, Component test Reports, Particular Standard test Reports, Standard test Reports, Information from accompanying documents and similar.

ATTACHMENT FILE 1 photo of the DUT

Photo 1

complete

internal

component

PCB

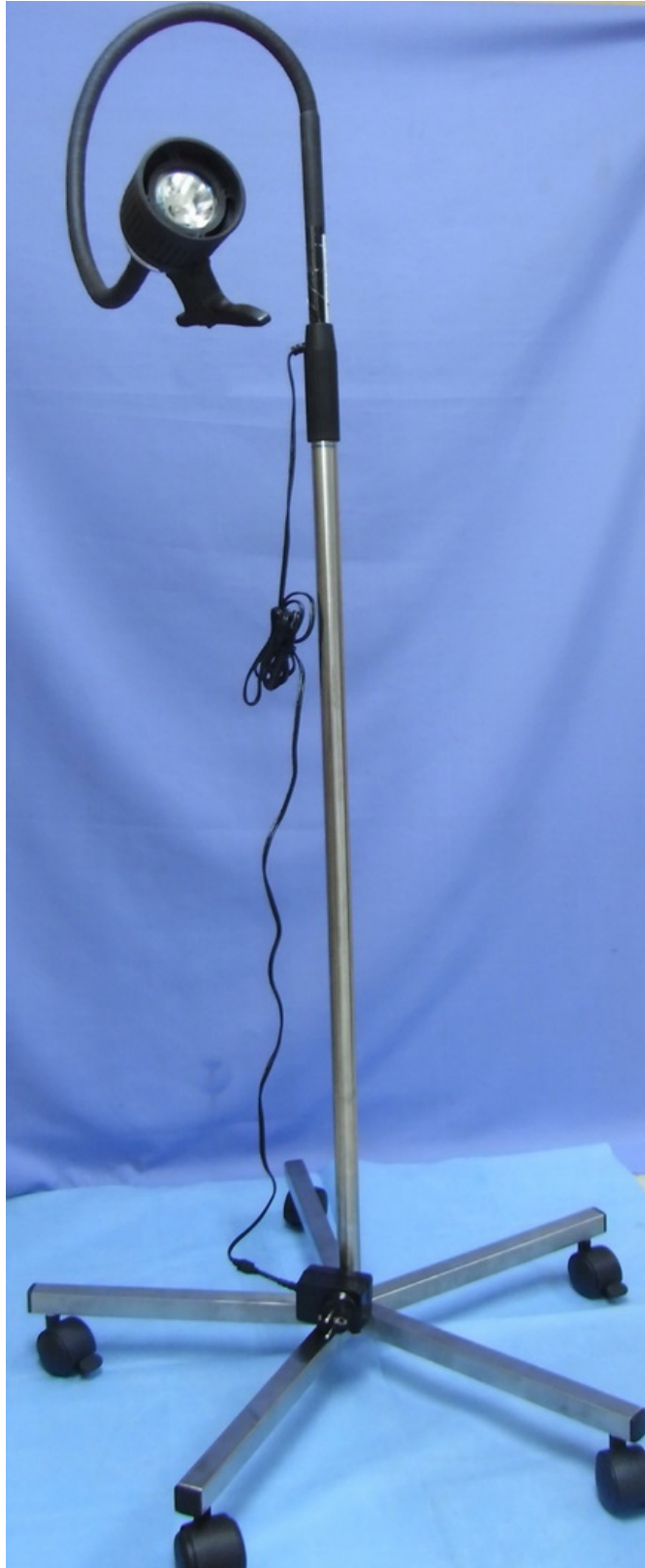


Photo 2

- complete
- internal
- component
- PCB



Photo 3

- complete
- internal
- component
- PCB



Photo 4

- complete
- internal
- component
- PCB



Photo 5

- complete
- internal
- component
- PCB

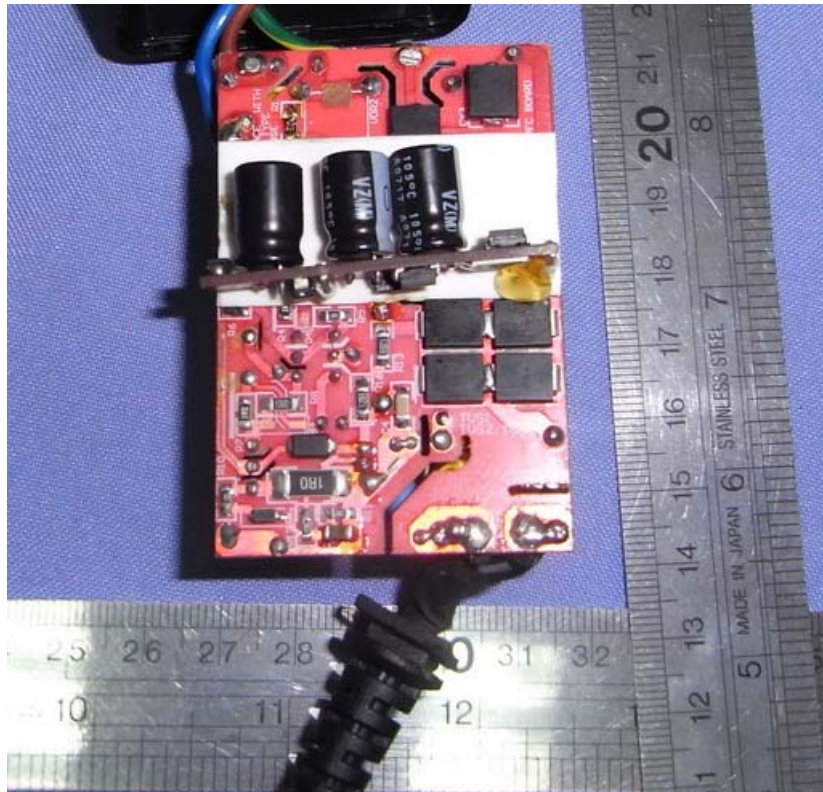


Photo 6

- complete
- internal
- component
- PCB

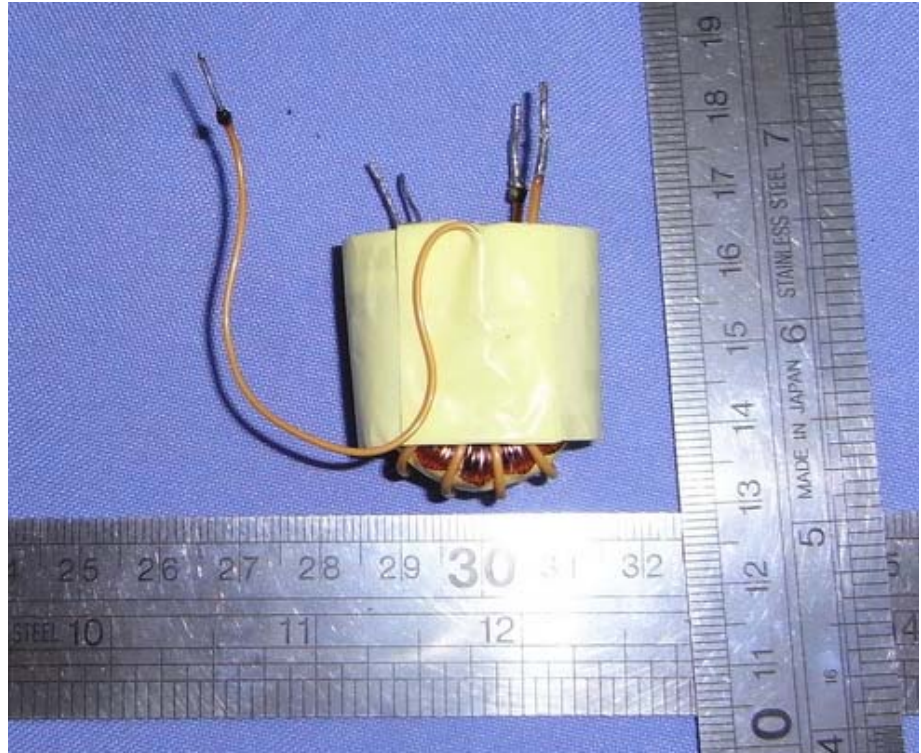


Photo 7

- complete
- internal
- component
- PCB

