TEST REPORT **IEC 60601-1 / EN 60601 -1** **Medical electrical equipment** **Part 1: General requirements for safety**	
Report reference No. ..... :	ETS-060065
Testled by (+ signature)..... :	Arthur Sun
Approved by (+ signature) ..... :	Una Tseng
Date of issue..... :	February 27, 2006
Contents .....:	Test report, 38 pages + Photo, 1 page
Testing laboratory..... :	Intertek Testing Service Taiwan Ltd.
Address..... :	5F, No. 423, Ruiguang Rd., Neihu District, Taipei 114, Taiwan
Testing location..... :	as above
Applicant..... :	Recom Development & Trading GmbH & Co KG
Address..... :	Technologiezentrum Salzkammergut Krottenseestr. 45 4810 Gmunden AUSTRIA
Standard ..... :	IEC 60601-1:1988 + 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..... :	E&E Test Report
Procedure deviation..... :	N/A
Non-standard test method ..... :	N/A
Type of test object ..... :	DC/DC Converter
Trademark ..... :	RECOM
Model/type reference..... :	REC2.2-xxxx, REC3-xxxx, REC5-xxxx, REC7.5-xxxx, REC3-XXXXDRWIA Dual, and RW dual output
Rating ..... :	Input: 5, 12, 24, 48 Vdc Output: 3.3, 5, 9, 12, 15Vdc, ±3.3, ±5, ±9, ±12, ±15 Vdc

Copy of marking plate:

REPRESENTATIVE

RECOM
REC7.5-4815DRW/AM
0305

GENERAL INFORMATION	
Test item particulars (see also clause 5):	
Classification of installation and use..... :	Component
Supply connection ..... :	Permanently installed
Accessories and detachable parts included in the evaluation :	N/A
Options included ..... :	N/A

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 IECEE 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:

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
3	**GENERAL REQUIREMENTS**		
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.)		P
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		N/A
5	**CLASSIFICATION**		
5.1	Type of protection against electric shock		
	Class I equipment		N/A
	Class II equipment		N/A
	Internally powered equipment		N/A
5.2	Degree of protection against electric shock		
	Type B applied part		N/A
	Type BF applied part		N/A
	Type CF applied part		N/A
	Not classified - no applied parts		P
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 60529 (see 6.1.1).....::	Component	N/A
5.4	Methods of sterilization or disinfection		N/A
5.5	Equipment not suitable for use in the presence of flammable mixtures		P
	Category AP equipment		N/A
	Category APG equipment		N/A
5.6	Mode of operation:		
	-continuous operation		P
	-short-time operation, specified operation; period ..:		—
	-intermittent operation, specified operation; rest period .....:		—
	-continuous operation with short-time, stated		—

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	permissible loading time .....::		
	-continuous operation with intermittent, stated permissible loading/rest time .....:		—

INSULATION DIAGRAM

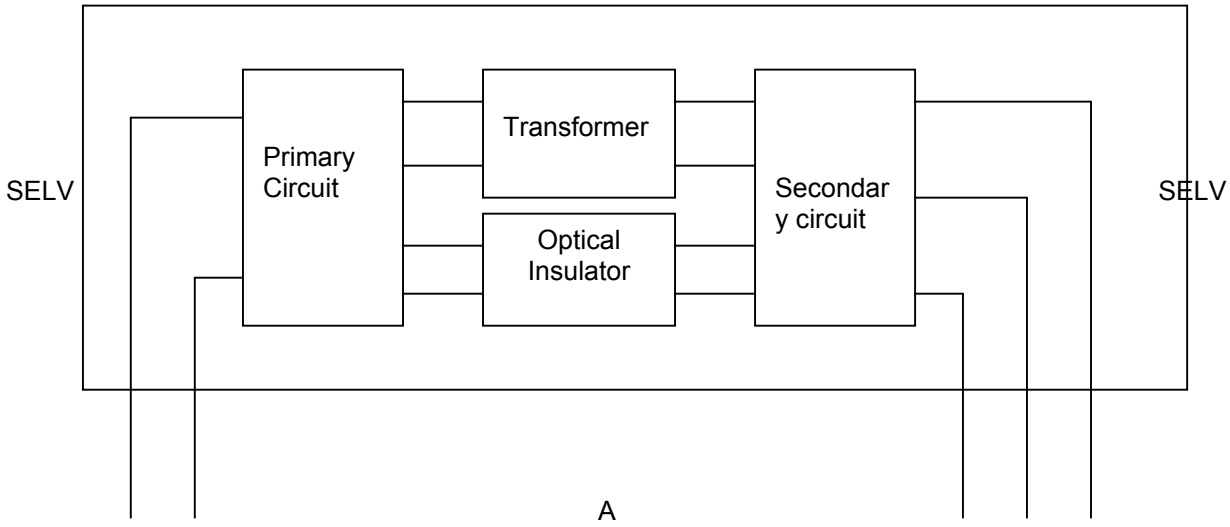

	Table: to insulation diagram						P
Area	Insulation type: operational / basic / supplementary / double / reinforced	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A B C D E F G H I J K L M N O	basic	48 dc	0.7	1.3	>0.7	>1.3	Pass

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			
Clause	Requirement + Test	Result - Remark	Verdict

6	**IDENTIFICATION, MARKING AND DOCUMENTS**		
6.1	Marking on the outside of equipment or equipment parts		
	c) Markings of the specific power supply affixed		N/A
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		P
	e) Name and/or trademark of the manufacturer or supplier ..... :		P
	f) Model or type reference ..... :		P
	g) Rated supply voltages or voltage range(s)		N/A
	Number of phases ..... :		N/A
	Type of current ..... :		N/A
	h) Rated frequency or rated frequency range(s) (Hz) ..... :		N/A
	j) Rated power input (VA, W or A) ..... :		N/A
	k) Power output of auxiliary mains socket-outlets		N/A
	l) Class II symbol		N/A
	Symbol for degree of protection against ingress of water provided ..... :		N/A
	Symbol for protection against electric shock ..... :		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		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	P
	n) Types and rating of external accessible fuses ... :		N/A
	p) Ratings of external output ..... :		N/A
	q) Symbol for physiological effect(s):		
	- attention, consult accompanying documents		N/A
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 60417		N/A
	r) Anaesthetic-proof symbol: AP or APG ..... :		N/A
	s) Dangerous voltage symbol		N/A

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	t) Special cooling requirements		N/A
	u) Limited mechanical stability		N/A
	v) Protective packing requirement(s)		N/A
	- Marking(s) for unpacking safety hazard(s)		N/A
	- Equipment or accessories supplied sterile, marked as sterile		N/A
	y) Potential equalization terminal		N/A
	- Functional earth terminal		N/A
	z) Removable protective means		N/A
	Durability of marking test		P
6.2	Marking on the inside of equipment or equipment parts		
	a) Nominal voltage of permanently installed equipment		N/A
	b) Maximum power loading for heating elements or holders for heating lamps		N/A
	c) Dangerous voltage symbol		N/A
	d) Type of battery and mode of insertion		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		N/A
	f) Protective earth terminal		N/A
	g) Functional earth terminal		N/A
	h) Supply neutral conductor in permanently installed equipment (N)		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 60445		N/A
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)		N/A
	l) Statement for suitable wiring materials at temperatures over 75 °C		N/A
	n) Capacitors and/or circuit parts marked as required in Sub-clause 15c		N/A
6.3	Marking of controls and instruments		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Mains switch clearly identified		N/A
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light		N/A
	b) Indication of different positions of control devices and switches		N/A
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device		N/A
	f) The functions of operator controls and indicators are identified		N/A
	g) Numeric indications of parameters are in SI units except for units listed in Am. 2		N/A
6.4	Symbols		
	Used symbols comply with Appendix D or IEC 60417 and/or IEC 60878 or ISO publications (if applicable)		N/A
6.5	Colors of the insulation of conductors		
	a) Protective earth conductor has green/yellow insulation		N/A
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		N/A
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow		N/A
	d) Color of neutral conductor ..... :		N/A
	e) Colors of phase conductor(s) ..... :		N/A
	- Compliance with IEC 60227 and IEC 60245		N/A
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N/A
6.6	Medical gas cylinders and connections		
	a) In accordance with ISO ISO/R 32		N/A
	b) Identification of connection point		N/A
6.7	Indicator lights and push-buttons		
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action		N/A
	- Yellow used to indicate caution or attention required		N/A

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- Yellow used to indicate caution or attention required		N/A
	b) Color red used only for push-buttons by which a function is interrupted in case of emergency		N/A
6.8	ACCOMPANYING DOCUMENTS		
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		P
	Classifications specified in Clause 5 included in both the instructions for use and the technical description		N/A
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment		N/A
	Warning statements and the explanation of warning symbols provided in the accompanying documents		N/A
6.8.2	Instructions for use		
	a) General information provided in instructions for use		P
	- state the function and intended application of the equipment		P
	- include an explanation of: the function of controls, displays and signals		N/A
	- the sequence of operation		N/A
	- the connection and disconnection of detachable parts and accessories		N/A
	- the replacement of material which is consumed during operation		N/A
	- information regarding potential electromagnetic or other interference and advice regarding avoidance		N/A
	- 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		N/A
	General information provided in instructions:		

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- information for the safe performance or routine maintenance		N/A
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied		N/A
	- explanation of figures, symbols, warning statements and abbreviations on the equipment		N/A
	c) Signal output or signal input parts intended only for connection to specified equipment described		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		N/A
	f) A warning to remove primary batteries if equipment is not likely to be used for some time		N/A
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries		N/A
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 60601-1		N/A
	j) Identification of any risks associated with the disposal of waste products, residues, etc.		N/A
	- Advice in minimizing these risks		N/A
6.8.3	Technical description		
	a) All characteristics essential for safe operation provided		P
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment		N/A
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use		N/A
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided		N/A
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging		N/A
7	**POWER INPUT**		
	Power Input Measurements		N/A

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
10	**ENVIRONMENTAL CONDITIONS**		
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer		N/A
10.2.2a	Rated voltage not exceeding 250 V for 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		N/A
	Rated voltage not exceeding 500 V for all other equipment		P
	Rated input frequency not more than 1kHz		P
10.2.2b	Internal replaceable electrical power source specified		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		N/A
14.4b	Equipment supplied from external dc source of reverse polarity results in no safety hazard		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		N/A
14.6c	Applied parts intended for direct cardiac application are of type CF		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)	N/A
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	(see appended table 15c)	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)		N/A
	Insertion or removal of lamps - protection against contact with live parts provided		N/A
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented		N/A
16c	Conductive parts accessible after the removal of handles, knobs, levers		
	- have a resistance of not more than 0.2 Ω	(see appended table 18)	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		N/A
16e	Removable enclosures protecting against contact with live parts		
	- Removal possible only with the aid of a tool		N/A
	- Use of automatic device making parts not live when the enclosure is opened or removed		N/A
	- Exception 16e applied to the following parts ..... :		N/A
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts		N/A

17	**SEPARATION**		
17a	Separation method of the applied part from live parts:		
	1) basic insulation: applied part earthed		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	(see appended table 19)	N/A

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
17c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		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:		
	1) basic insulation: accessible part earthed		N/A
	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		N/A
	5) by protective impedances limiting current to accessible part		N/A
	- Additional leakage current test in single fault conditions	(see appended table 19)	N/A
17h	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 17h1)	N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function	(see appended table 17h2)	N/A
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		N/A
18b	Protective earth terminals suitable for connection to the protective earth conductor		N/A
18e	Potential equalization conductor		
	- Readily accessible		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

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
18f	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1\ \Omega$	(see appended table 18)	N/A
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $\leq 0.1\ \Omega$	(see appended table 18)	N/A
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part $\leq 0.2\ \Omega$	(see appended table 18)	N/A
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1 Ω, the allowable value of the enclosure leakage current is not exceeded in single fault condition	(see appended table 19)	N/A
18k	Functional earth terminal not used to provide protective earthing		N/A
18l	Class II equipment with isolated internal screens		
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		N/A
	- functional earth terminal clearly marked		N/A
	- explanation of functional earth terminal provided in the accompanying documents		N/A
19	**CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS**		
19.1b	Leakage currents	(see appended table 19)	N/A
	- earth leakage current		N/A
	- enclosure leakage current		N/A
	- patient leakage current		N/A
	- patient auxiliary current		N/A
20	**DIELECTRIC STRENGTH**		
	Overall compliance with Clause 20	(see appended table 20)	P
21	**MECHANICAL STRENGTH**		
21a	Sufficient rigidity of an enclosure tested by: force of 45 N		N/A
21b	Sufficient strength of an enclosure tested by: impact hammer		N/A
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test	(see appended table 21)	N/A

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
21.3	No damage to parts of patient support and/or immobilization system after the loading test	(see appended table 21)	N/A
21.5	Hand held equipment or equipment parts are safe after drop test	(see appended table 21)	N/A
21.6	Portable and mobile equipment is able to withstand rough handling	(see appended table 21)	N/A
22	**MOVING PARTS**		
22.2a	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment		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		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		N/A
	Guides or other safeguards are removable only with a tool		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		N/A
22.6	Parts of equipment subject to mechanical wear are accessible for inspection		N/A
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard		N/A
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard		N/A
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents		N/A
	Means for stopping of movements operate as a result of one single action		N/A
23	**SURFACES, CORNERS AND EDGES**		
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered		P

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
24	**STABILITY IN NORMAL USE** (see appended table 24)		
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10º		N/A
24.3	Equipment overbalances when tilted through an angle of 10º		
	- does not overbalance when tilted through an angle of 5º in any position excluding transport		N/A
	- 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 10º		N/A
24.6a	Equipment or its parts with a mass of more than 20 kg is provided with:		
	- suitable handling devices (grips etc.), or		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		N/A
25	**EXPELLED PARTS**		
25.1	Protective means are provided where expelled parts of the equipment could be a hazard		N/A
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		N/A
28	**SUSPENDED MASSES**		
28.3	Suspension system with safety device		
	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		N/A
	Safety device has safety factors complying with Sub-clause 28.4.2		N/A
	Clear indication to the operator that the safety device has been activated after failure of suspension means		N/A
28.4	Suspension systems of metal without safety devices		
	1) Total load does not exceed the safe working load		N/A

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
	2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired		N/A
	3) Safety factors not less than 8 where impairment is expected		N/A
	4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%		N/A
	5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement		N/A
29	**X-RADIATION**		
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5 mR)	(see appended table 29)	N/A
36	**ELECTROMAGNETIC COMPATIBILITY**		
	Equipment complies with IEC 60601-1-2		N/A
37	**COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT**		
	Requirements for category AP and APG equipment (Cl. 37 - 41)	(see Attachment #)	N/A
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)	P
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25ºC ambient		p
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41ºC		N/A
42.5	Guards to prevent contact with hot surfaces removable only with a tool		N/A
43	**FIRE PREVENTION**		
	Strength and rigidity necessary to avoid a fire hazard		N/A

IEC 60601+ Am. 1 & 2			
Clause	Requirement + Test	Result - Remark	Verdict
44	**OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION**		
44.2	Equipment contain a liquid reservoir:		
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min	(see appended table 44)	N/A
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15º in the least favorable direction(s) (if necessary with refilling)	(see appended table 44)	N/A
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)	(see appended table 44)	N/A
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard	(see appended table 44)	N/A
44.5	Equipment sufficiently protected against the effects of humidity	(see appended table 44)	N/A
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 60529	(see appended table 44)	N/A
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	(see appended table 44)	N/A
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	(see appended table 45)	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

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Clause	Requirement + Test	Result - Remark	Verdict
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	(see appended table 45)	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	(see Attachment #)	N/A
49	**INTERRUPTION OF THE POWER SUPPLY**		
49.1	Thermal cut-outs and overcurrent releases with automatic resetting not used if they may cause a safety hazard		N/A
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function		N/A
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure		N/A
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 #)	N/A
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 60601-1-4	(see Attachment #)	N/A
52.5.2	Failure of thermostats presents no safety hazards	(see appended table 52)	N/A
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard	(see appended table 19)	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5ºC	(see appended table 52)	N/A
52.5.6	Locking of moving parts presents no safety hazard	(see appended table 52)	N/A
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	(see appended table 52)	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)	N/A
52.5.10	Overload of heating elements presents no safety hazard	(see appended table 52)	N/A
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection		N/A
	h) Equipment with three-phase motors can safely operate with one phase disconnected	(see appended table 52)	N/A
56	**COMPONENTS AND GENERAL ASSEMBLY**		
	List of critical components	(see appended table 56)	P
56.1b	Ratings of components not in conflict with the conditions of use in equipment		P
	Ratings of mains components are identified		N/A
56.1d	Components, movements of which could result in a safety hazard mounted securely		N/A
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard		P
56.3a	Connectors provide separation required by Sub-clause 17g		N/A
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment		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		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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.		N/A
56.4	Connections of capacitors		
	Not connected between live parts and non-protectively earthed accessible parts		N/A
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 60384-14		N/A
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts		N/A
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs		N/A
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment		N/A
56.6	Temperature and overload control devices		
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment		N/A
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits		N/A
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		N/A
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		N/A
	Self-resetting thermal cut-outs and self-resetting overcurrent releases operated 200 times		N/A
	Non-self resetting overcurrent releases operated 10 times		N/A
56.6b	Thermostats with varying temperature settings clearly indicated		N/A
	Operating temperature of thermal cut-outs indicated		N/A
56.7	Batteries		
	a) Battery compartments:		
	- adequately ventilated		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- 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):		
	- to indicate that equipment is energized		N/A
	- to indicate the operation of non-luminous heaters if a safety hazard could result		N/A
	- to indicate when output exists if a safety hazard could result		N/A
	- charging mode indicator provided		N/A
56.10	Actuating parts of controls	(see appended table 56.10)	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:		
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard		N/A
	- to prevent damage to wiring		N/A
56.11	Cord-connected hand-held and foot-operated control devices		
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g		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	(see appended table 56.11b)	N/A
	c) Devices not change their setting when inadvertently placed		N/A
	d) Foot-operated control devices are at least IP X1	(see appended table 44)	N/A
	- For surgical use, electrical switching parts are IP X8		N/A
	e) Adequate strain relief at the cord entry provided	(see appended table 57.4)	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
57	**MAINS PARTS, COMPONENTS AND LAYOUT**		
57.1	Isolation from supply mains		
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously		N/A
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents		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 60328		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		N/A
	m) Fuses and semiconductor devices not used as isolating devices		N/A
57.2	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/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		
	a) Not more than one connection to a particular supply mains		N/A
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously		N/A
	The mains plug has only one power supply cord		N/A
	Non-permanently connected equipment provided with power supply cord or appliance inlet		N/A
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 60227, designation 53 and IEC 60245, 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		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	d) Stranded conductors not soldered if fixed by any clamping means		N/A
57.4	Connection of power supply cords		
57.4a	Cord anchorages		
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting	(see appended table 57.4)	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	(see appended table 57.4b)	N/A
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		N/A
57.5	Mains terminal devices and wiring of mains part		
	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/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		N/A
	Mains terminal devices accessible only with use of a tool		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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/A
	c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened		N/A
	d) Cord terminals not require special preparation of the conductor		N/A
57.6	Mains fuses and overcurrent releases		
	Fuses or overcurrent releases provided accordingly for Class I and Class II		N/A
	Current rating of mains fuses and overcurrent releases such that they reliably carry the normal operating current		N/A
	Protective earth conductor not fused		N/A
	Neutral conductor not fused for permanently installed equipment		N/A
57.8	Wiring of the mains part		
	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 60227 or 60245, treated as bare conductor		N/A
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord		N/A
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard		N/A
57.9	Mains supply transformers		
57.9.1	Overheating		
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		N/A
57.9.1a	Short-circuit of secondary windings not caused excessive temperature	(see appended table 57.9.1a)	N/A
57.9.1b	Overload of secondary windings not caused excessive temperature	(see appended table 57.9.1b)	N/A
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests	(see appended table 57.9.2)	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
57.9.4	Construction		
	a) Separation of primary and secondary windings		N/A
	- separate bobbins or formers		N/A
	- one bobbin with insulating partition		N/A
	- 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		N/A
	d) Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn		N/A
	e) Insulation between the primary and secondary in transformers with double insulation		
	- 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		N/A
	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		N/A
57.10	Creepage distances and air clearances		
	a) Values: compliance with at least the values of Table XVI	(see table for insulation diagram)	P
	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-circuting does not produce a safety hazard	(see appended table 52)	P
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other 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		
	Not be able to loosen without the aid of a tool		N/A
	Screws for internal earth connections are covered or protected against loosening from outside		N/A
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal		N/A
58.8	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing		N/A
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		N/A

59	**CONSTRUCTION AND LAYOUT**		
59.1	Internal wiring		
	a) Cables and wiring protected against contact with a moving part		N/A
	Wiring having basic insulation only protected by additional fixed sleeving		N/A
	Components are not likely to be damaged in the normal assembly or replacement of covers		N/A
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead		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 60227 and IEC 60245 and dielectric test	(see appended table 20)	N/A
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material		N/A
	d) Aluminum wires of less than 16 mm^2 cross-section not used		N/A
	f) Connecting cords between equipment parts considered as belonging to the equipment		N/A
59.2	Insulation		
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		P
	Parts of rubber resistant to ageing		N/A
59.3	Excessive current and voltage protection		
	Internal electrical power source provided with device for protection against fire hazard		N/A
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuse holder		N/A
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		N/A
59.4	Oil containers		
	Oil containers adequately sealed		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

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Clause	Requirement + Test	Result - Remark	Verdict

6.1	TABLE: marking durability	P
Marking tested	Remarks	
Housing	Clearly legible after test	
Supplementary information:		

7	TABLE: power input					N/A
Operating condition	Voltage	Frequency	Current	Power	Remarks	
Supplementary information:						

15b	TABLE: residual voltage in attachment plug										N/A
Voltage measured between:	Measurements [V]										Remarks
	1	2	3	4	5	6	7	8	9	10	
supply pins (pin 1 & pin 2)											
line pin 1 and enclosure											
line pin 2 and enclosure											
pin 1 and earth pin											
pin 2 and earth pin											

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:					

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

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:					

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				N/A
Test location	Test current (A)	Measured voltage (V)	Resistance (ohms)	Remarks	
Supplementary information:					

19	TABLE: leakage current				N/A
Type of leakage current and test condition (including single faults)	Supply voltage	Supply frequency	Measured max. value	Remarks	
(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 to 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	

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

20	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)	Test voltage (V)	Remarks
A	BI	48 Vdc	3000 Vdc	No breakdown
Supplementary information:				

21	TABLE: mechanical strength	N/A
Part under test	Test (impact, drop, force, handle, rough handling, mobile)	Remarks
Supplementary information:		

24	TABLE: - stability	N/A
Part under test	Test condition	Remarks
Supplementary information:		

29	TABLE: X - radiation		N/A
Part under test	Test condition	Measured radiation (mR)	Remarks
Supplementary information:			

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

42	TABLE: normal temperature		P
Supply voltage . : 32.4 Vdc Ambient temperature. : 22.1 ºC		Test Condition: Output ±250 mA	
Measuring location		Measured temperature [ºC]	Remarks
Transformer winding		79	Pass

42	TABLE: normal temperature		P
Supply voltage . : 79.2 Ambient temperature. : 21.8 ºC		Test Condition: Output ±250 mA	
Measuring location		Measured temperature [ºC]	Remarks
Transformer winding		68	Pass

44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		N/A
Test type and condition		Part under test	Remarks
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:				

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

52	TABLE: abnormal operation		N/A
Test type, condition and clause reference		Observed results	Remarks
Supplementary information:			

56.1	TABLE: lists of critical component parts				
Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
Transformer windings	various	UEW	105°C	IEC 60601	Tested with the appliance
Optical Isolator	various	TLP181	3000 Vdc	IEC 60601	Tested with the appliance
Epoxy	various	various	105°C	IEC 60601	Tested with the appliance
[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:			

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

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						N/A
Winding under test	Protection	Measured temperatures (ºC)			Test duration	Remarks	
		Primary	Secondary	Ambient			
Supplementary information:							

57.9.1b	TABLE: overload							N/A
Winding under test	Protection	Measured temperatures (ºC)			Test duration	Test current or thermal cutout temp.	Remarks	
		Primary	Secondary	Ambient				
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:					

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

	TABLE: additional tests		N/A
Clause	Test type and condition	Remarks and observed results	

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

SUMMARY OF CONTENTS:

The equipment has been tested according to standard IEC 60601-1 (1988) Second Edition and IEC 60601-2-.. .

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

These tests fulfill the requirements of standard EN 45001.

This test report comprises 39 pages of CB Test Report and the following Attachments:

Attachment #	Description	Pages

Note:

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


RECOM
REC7.5-4815DRW/AM
0526
REC3-4815DRW/H6/A
RECOM
0550
RECOM
REC3-480515DRWI/A
0513
REC5-4815DRW/H6/A
RECOM
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RECOM
RW-4815D
0529