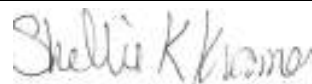


TEST REPORT
EN 60601 -1
Medical electrical equipment
Part 1: General requirements for safety

Report reference No. : 3168173DEN-001

Compiled by (+ signature) : Shellie Kramer



Reviewed by (+ signature)..... : Claudia Sirch



Number of Pages: 51

Date of issue : 23 March 2009

Testing laboratory : Intertek

Address..... : 5541 Central Ave. Suite 110, Boulder, CO 80301 USA

Testing location..... : as above

Applicant : Frye Electronics, Inc.

Address..... : 9826 SW Tigard St.
Tigard, OR 97223 USA

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..... :

Procedure deviation..... : N/A

Non-standard test method : N/A

Type of test object : Hearing Evaluation Unit

Trademark : Frye Electronics, Inc.

Model/type reference : HearLab

Manufacturer..... : Frye Electronics, Inc.

Address..... : 9826 SW Tigard St.
Tigard, OR 97223 USA

Rating : 100-240 V 0.5 A 50-60 Hz, Type BF applied parts

Copy of marking plate:



GENERAL INFORMATION	
Test item particulars (see also clause 5):	
Classification of installation and use.....	: Portable
Supply connection	: appliance coupler
Accessories and detachable parts included in the evaluation :	Microphone. Computer. All applied parts. (Headphones, and sensing electrodes {no current or energy in electrodes}). These were used to evaluate the unit itself, but were not part of this evaluation.
Options included	: None.
Possible test case verdicts:	
- test case does not apply to the test object	:N / A N
- test object does meet the requirement	:Pass P
- test object does not meet the requirement.....	:Fail F
Abbreviations used in the report:	
- normal condition	:N.C.
- operational insulation	:OP
- basic insulation between parts of opposite polarity	:BOP
- double insulation.....	:DI
- single fault condition	:S.F.C.
- basic insulation	:BI
- supplementary insulation.....	:SI
- reinforced insulation	:RI
General remarks:	
<p>"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".</p> <p>"(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.</p>	
Note 1:	
Checklist for IEC 60601-2-40: Located from page 44 to page 50 in this report	
Note 2:	
A power cord and plug acceptable for the country of use will be provided with each unit.	
General product information and considerations:	
<p>HEARLab™ ACA device is indicated for use in the recording and analysis of human electro-physiological data as an aid in the assessment of hearing and hearing-related functions. The data is obtained with electrodes attached to the scalp of the subject to detect the presence or absence of electro-physiological signals that may be evoked in response to auditory stimulus. These electro-physiological signals being monitored are not intended to indicate signals vital to life or health or state of well being of the patient</p>	

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

3	GENERAL REQUIREMENTS		P
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.)	No safety hazards can be reasonably foreseen from the conditions described.	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	An alternative means of construction to the details of this standard are not used.	N/A

5	CLASSIFICATION		P
5.1	Type of protection against electric shock		--
	Class I equipment	Equipment is Class I.	P
	Class II equipment	Equipment is Class I.	N/A
	Internally powered equipment	Equipment is not internally powered.	N/A
5.2	Degree of protection against electric shock		--
	Type B applied part	BF applied parts.	N/A
	Type BF applied part	BF applied parts.	P
	Type CF applied part	BF applied parts.	N/A
	Not classified - no applied parts	BF applied parts.	N/A
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).....:	Equipment is IPX0.	N/A
5.4	Methods of sterilization or disinfection	The equipment is not sterile or disinfected. It is cleaned. Applied parts are single use components and the operator is instructed to dispose of the applied parts after each use.	N/A
5.5	Equipment not suitable for use in the presence of flammable mixtures	Equipment is for not for use in the presence of flammable mixture.	P
	Category AP equipment	Equipment is not AP or APG.	N/A
	Category APG equipment	Equipment is not AP or APG.	N/A
5.6	Mode of operation:		--
	-continuous operation	Equipment is for continuous operation.	P
	-short-time operation, specified operation; period ...:		—

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

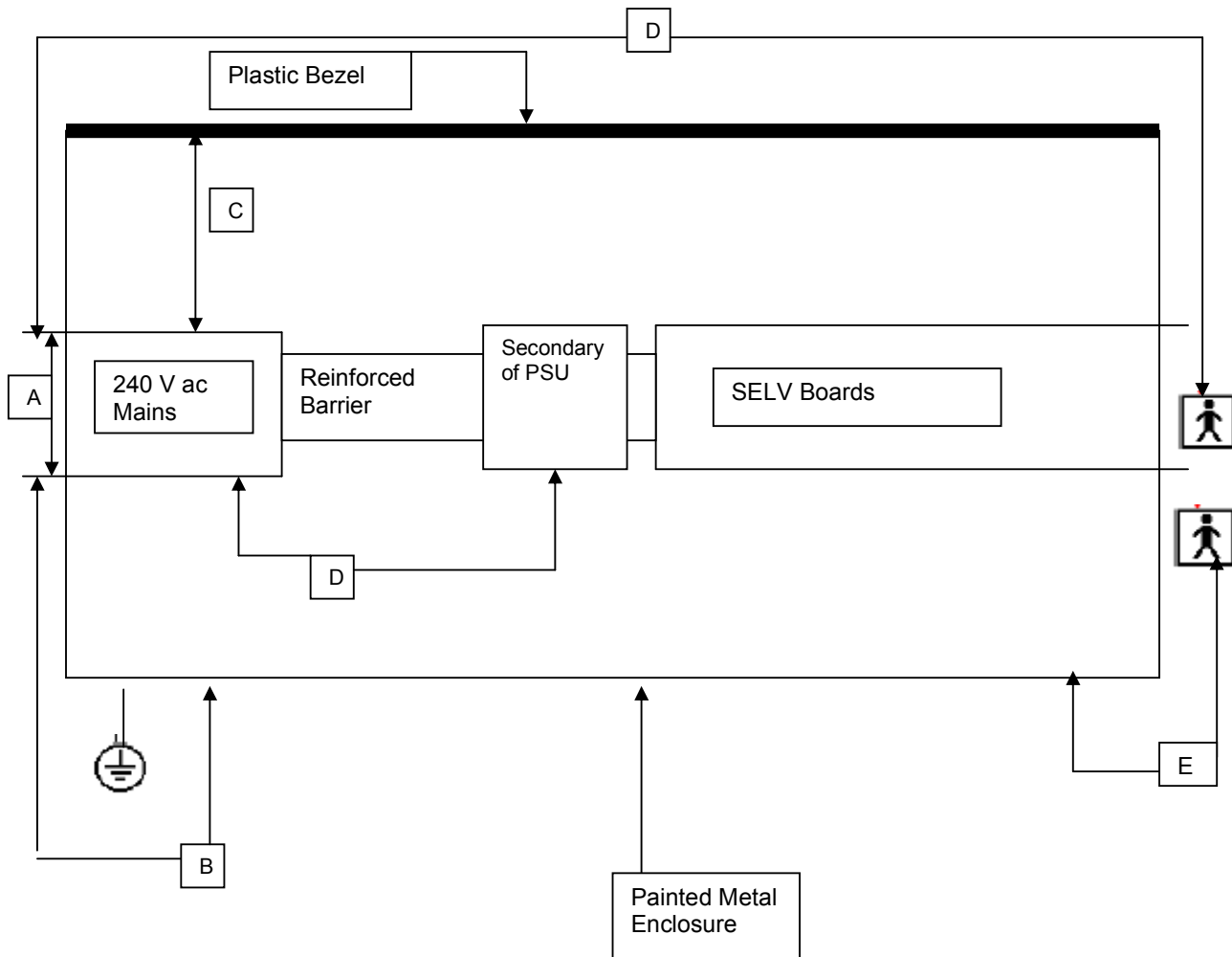
INSULATION DIAGRAM

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	BOP (A-f)	240 V ac	3.0 mm	1.6 mm	> 3.0 mm	> 1.6 mm	Maintained by the use of Recognized components.
B	Basic(A- a1)	240 V ac	4.0 mm	2.5 mm	> 4.0 mm	> 2.5 mm	Maintained by the use of Recognized components.
C	Double/Reinforced (A-a2)	240 V ac	8.0 mm	5.0 mm	> 8.0 mm	> 5.0 mm	Values are much greater then required.
D	Double/Reinforced (B-a)	240 V ac	8.0 mm	5.0 mm	> 8.0 mm	> 5.0 mm	Maintained by approved medical grade power supply
E	Basic(B-d)	240 V ac	4.0 mm	2.5 mm	> 4.0 mm	> 2.5 mm	
Applied parts are headphones and sensing pads Entirely of insulating material. No electrical connections in applied parts. B-b does not apply for this unit. Refer to Clause 20 of IEC 60601-2-40							

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

6	IDENTIFICATION, MARKING AND DOCUMENTS		P
6.1	Marking on the outside of equipment or equipment parts		--
	c) Markings of the specific power supply affixed	No specific power supply.	N/A
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents	Markings are provided on the equipment.	N/A
	e) Name and/or trademark of the manufacturer or supplier	Equipment is marked Frye Electronics.	P
	f) Model or type reference	HearLab.	P
	g) Rated supply voltages or voltage range(s)	100-240 V	P
	Number of phases	Single phase	P
	Type of current.....	Equipment is AC and is marked with Hz. Plus, ac symbol is used.	P
	h) Rated frequency or rated frequency range(s) (Hz)	50-60 Hz	P
	j) Rated power input (VA, W or A)	0.5 A.	P
	k) Power output of auxiliary mains socket-outlets	No mains socket outlets.	N/A
	l) Class II symbol	Equipment is Class I.	N/A
	Symbol for degree of protection against ingress of water provided	Equipment is IPX0.	N/A
	Symbol for protection against electric shock	Provided (type BF)	P
	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	Only BF applied parts	N/A
	Symbol for protection of defibrillation-proof applied parts	Equipment is not defibrillation proof.	N/A
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable	Equipment is not defibrillation proof.	N/A
	m) Mode of operation (if no marking, suitable for continuous operation)	Equipment is for continuous operation	N/A
	n) Types and rating of external accessible fuses ...	Provided. 250 V, 0.5 A Time Delay	P
	p) Ratings of external output	No such output.	N/A
	q) Symbol for physiological effect(s):		--
	- attention, consult accompanying documents	No physiological effects.	N/A
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 60417	No non-ionizing radiation.	N/A
	r) Anaesthetic-proof symbol: AP or APG	Equipment is not AP or APG	N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	s) Dangerous voltage symbol	No dangerous voltage by definition.	N/A
	t) Special cooling requirements	No special cooling requirements.	N/A
	u) Limited mechanical stability	Equipment is mechanically stable.	N/A
	v) Protective packing requirement(s)	No protective packaging requirements.	N/A
	- Marking(s) for unpacking safety hazard(s)	No safety hazards while unpacking.	N/A
	- Equipment or accessories supplied sterile, marked as sterile	Equipment is not supplied or marked as sterile. Accessories that are supplied as sterile and are marked as such.	N/A
	y) Potential equalization terminal	No potential equalization terminal.	N/A
	- Functional earth terminal	No functional earth terminals.	N/A
	z) Removable protective means	No removable protective means.	N/A
	Durability of marking test	UL Recognized Marking and Labeling System used, or etched. Labels pass required tests.	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	No heating elements.	N/A
	c) Dangerous voltage symbol	No dangerous voltage by definition.	N/A
	d) Type of battery and mode of insertion	No batteries.	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 fuses.	N/A
	f) Protective earth terminal	Marked accordingly.	P
	g) Functional earth terminal	No functional earth terminals.	N/A
	h) Supply neutral conductor in permanently installed equipment (N)	Not permanently connected.	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	See 6.2.f), h), k), and l).	P
	- Markings comply with IEC 60445		N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)	Not permanently connected.	N/A
	l) Statement for suitable wiring materials at temperatures over 75 °C	Not permanently connected.	N/A
	n) Capacitors and/or circuit parts marked as required in Sub-clause 15c	No such circuits.	N/A
6.3	Marking of controls and instruments		--
	a) Mains switch clearly identified	Mains switch is clearly identified.	P
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light	Mains switch is marked with a I and O.	P
	b) Indication of different positions of control devices and switches	No controls or switches.	N/A
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device	No such controls.	N/A
	f) The functions of operator controls and indicators are identified	No such controls.	N/A
	g) Numeric indications of parameters are in SI units except for units listed in Am. 2	SI units are indicated when necessary.	P
6.4	Symbols		--
	Used symbols comply with Appendix D or IEC 60417 and/or IEC 60878 or ISO publications (if applicable)	Symbols used comply with applicable appendix and/or standard.	P
6.5	Colors of the insulation of conductors		--
	a) Protective earth conductor has green/yellow insulation	Protective earthing conductors are green with yellow strips.	P
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations	All internal protective earthing conductors are green with a yellow stripe.	P
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow	Only protective earthing conductors are green with a yellow stripe.	P
	d) Color of neutral conductor..... :	Blue	P
	e) Colors of phase conductor(s) :	Brown.	P
	- Compliance with IEC 60227 and IEC 60245	Wiring complies with the appropriate standards.	P
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors	No such cord.	N/A
6.6	Medical gas cylinders and connections		--

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	a) In accordance with ISO ISO/R 32	No medical gas cylinders or connections.	N/A
	b) Identification of connection point	No medical gas cylinders or connections.	N/A
6.7	Indicator lights and push-buttons		N/A
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action	No red indicator lights.	N/A
	- Yellow used to indicate caution or attention required	No yellow indicator lights.	N/A
	- Yellow used to indicate caution or attention required	No yellow indicator lights.	N/A
	b) Color red used only for push-buttons by which a function is interrupted in case of emergency	No red push buttons.	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	Instructions of use, technical information, and contact information are provided in the manual.	P
	Classifications specified in Clause 5 included in both the instructions for use and the technical description	Provided.	P
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	Markings are permanently fixed to equipment.	N/A
	Warning statements and the explanation of warning symbols provided in the accompanying documents	Warnings statements and the explanation of symbols are provided.	P
6.8.2	Instructions for use		P
	a) General information provided in instructions for use	General information on use provided.	P
	- state the function and intended application of the equipment	The intended function of the equipment is provided.	P
	- include an explanation of: the function of controls, displays and signals	Provided.	P
	- the sequence of operation	Provided.	P
	- the connection and disconnection of detachable parts and accessories	Provided.	P
	- the replacement of material which is consumed during operation	Provided.	P
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	Provided.	P

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	Provided.	P
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	Provided.	P
	General information provided in instructions:		P
	- information for the safe performance or routine maintenance	Information is provided.	P
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	Provided.	P
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	Provided.	P
	c) Signal output or signal input parts intended only for connection to specified equipment described	Provided.	P
	d) Details about acceptable cleaning, disinfection or sterilization methods included	Provided.	P
	e) Warning statement for mains operated equipment with additional power source	No additional power sources.	N/A
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	No batteries.	N/A
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	No batteries.	N/A
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 60601-1	No batteries.	N/A
	j) Identification of any risks associated with the disposal of waste products, residues, etc.	Provided.	P
	- Advice in minimizing these risks	Provided.	P
6.8.3	Technical description		P
	a) All characteristics essential for safe operation provided	Provided.	P
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	Not permanently connected.	N/A
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	Provided.	P
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	Provided.	P

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Provided.	P
7	POWER INPUT		P
	Power Input Measurements		P
10	ENVIRONMENTAL CONDITIONS		P
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer	Not part of the investigation	-
10.2.2a	Rated voltage not exceeding 250 V for hand-held equipment	Equipment is not hand-held.	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	Equipment is single phase and does not exceed 250 V.	P
	Rated voltage not exceeding 500 V for all other equipment		N/A
	Rated input frequency not more than 1kHz	Rated input frequency is 50-60 Hz.	P
10.2.2b	Internal replaceable electrical power source specified	No internal power source.	N/A
14	REQUIREMENTS RELATED TO CLASSIFICATION		P
14.4a	Class I and Class II equipment in addition to basic insulation provided with an additional protection	Class I: BI and grounding. DI/RI provided between primary and secondary circuits.	P
14.4b	Equipment supplied from external dc source of reverse polarity results in no safety hazard	Equipment is supplied from an AC 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	Equipment is not internally powered.	N/A
14.6c	Applied parts intended for direct cardiac application are of type CF	Equipment is not for direct cardiac application.	N/A
15	LIMITATION OF VOLTAGE AND/OR ENERGY		
15b	Voltage measured one sec after disconnection of the mains plug does not exceed 60V	No excessive voltages.	P
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	Marking not required.	N/A

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

16	ENCLOSURES AND PROTECTIVE COVERS		P
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	Live parts cannot be contacted.	P
	Insertion or removal of lamps - protection against contact with live parts provided	No lamps.	N/A
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented	No openings in top cover.	N/A
16c	Conductive parts accessible after the removal of handles, knobs, levers		N/A
	- have a resistance of not more than 0.2 Ω	No handles, knobs, or levers for removal.	N/A
	- separated from live parts by one of the means described in Sub-clause 17g	No handles, knobs, or levers for removal.	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 components.	N/A
16e	Removable enclosures protecting against contact with live parts		P
	- Removal possible only with the aid of a tool	Removable cover requires the use of a tool.	P
	- Use of automatic device making parts not live when the enclosure is opened or removed	No automatic devices.	N/A
	- Exception 16e applied to the following parts :	No exceptions.	N/A
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	No such adjustable controls.	N/A

17	SEPARATION		P
17a	Separation method of the applied part from live parts:		P
	1) basic insulation: applied part earthed	Applied parts are not 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	Applied parts are separated from live parts by double/ reinforced insulation	P
	5) by protective impedances limiting current to applied part		N/A
	- Additional leakage current test in single fault conditions		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)	Equipment is not hand-held.	N/A
17g	Separation method of accessible parts other than applied parts from live parts:		P
	1) basic insulation: accessible part earthed	Accessible conductive parts are protectively earthed or provided with double/reinforced insulation.	P
	2) by protectively earthed conductive part (e.g. screen)	A protectively earthed screen or such is not used.	N/A
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure	No such circuit used.	N/A
	4) by double or reinforced insulation	Double/reinforced insulation is used.	P
	5) by protective impedances limiting current to accessible part	Protective impedance is not used.	N/A
	- Additional leakage current test in single fault conditions		N/A
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	Equipment is not defibrillation-proof.	N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function	Equipment is not defibrillation-proof.	N/A
18	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION		P
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal	Accessible conductive parts are protectively earthed.	P
18b	Protective earth terminals suitable for connection to the protective earth conductor	The protective earth terminal is suitable for the conductors.	P
18e	Potential equalization conductor		N/A
	- Readily accessible	No potential equalization conductors	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 $\leq 0.1 \Omega$	Equipment is provided with an appliance inlet.	N/A
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $\leq 0.1 \Omega$	Impedance does not exceed 0.1Ω	P
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part $\leq 0.2 \Omega$	Power cord is detachable.	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	Impedance does not exceed 0.1Ω .	N/A
18k	Functional earth terminal not used to provide protective earthing	No functional earth terminals.	N/A
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	Equipment is Class I.	N/A
	- functional earth terminal clearly marked	Equipment is Class I.	N/A
	- explanation of functional earth terminal provided in the accompanying documents	Equipment is Class I.	N/A
19	CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS		P
19.1b	Leakage currents	(see appended table 19)	P
	- earth leakage current		P
	- enclosure leakage current		P
	- patient leakage current		P
	- patient auxiliary current		P
20	DIELECTRIC STRENGTH		P
	Overall compliance with Clause 20	(see appended table 20)	P
21	MECHANICAL STRENGTH		P
21a	Sufficient rigidity of an enclosure tested by: force of 45 N	See appended tables.	P
21b	Sufficient strength of an enclosure tested by: impact hammer	See appended tables.	P
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test	Not this type	N/A
21.3	No damage to parts of patient support and/or immobilization system after the loading test	Not this type of equipment.	N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
21.5	Hand held equipment or equipment parts are safe after drop test	Equipment is not hand-held.	N/A
21.6	Portable and mobile equipment is able to withstand rough handling	Equipment withstands rough handling.	P
22	MOVING PARTS		N/A
22.2a	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment	No such 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		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 such parts.	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	No such parts.	N/A
22.6	Parts of equipment subject to mechanical wear are accessible for inspection	No parts subject to mechanical wear.	N/A
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard	No emergency switches necessary.	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		P
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	No rough surfaces, sharp corners or edges.	P
24	STABILITY IN NORMAL USE (see appended table 24)		P
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°	Equipment does not overbalance.	P
24.3	Equipment overbalances when tilted through an angle of 10°		N/A
	- does not overbalance when tilted through an angle of 5° in any position excluding transport	Equipment is stable at 10°	N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- 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	Equipment is less than 20 kg.	N/A
	- instructions for lifting and handling during assembly	Equipment is less than 20 kg.	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	Equipment is less than 20 kg.	N/A
25	EXPELLED PARTS		N/A
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	No expelled parts.	N/A
28	SUSPENDEE MASSES		N/A
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

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
29	X-RADIATION		N/A
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5 mR)	Equipment does not produce X-rays.	N/A
36	ELECTROMAGNETIC COMPATIBILITY		N/A
	Equipment complies with IEC 60601-1-2	Not part of this investigation	N/A
37	COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT		N/A
	Requirements for category AP and APG equipment (Cl. 37 - 41)	Equipment is not AP or APG.	N/A
42	EXCESSIVE TEMPERATURES		P
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	No excessive temperatures	P
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient		P
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C		P
42.5	Guards to prevent contact with hot surfaces removable only with a tool		P
43	FIRE PREVENTION		P
	Strength and rigidity necessary to avoid a fire hazard	Equipment has adequate strength and rigidity to avoid fire hazards.	P
44	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION		P
44.2	Equipment contain a liquid reservoir:		N/A
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min	Equipment does not have reservoirs.	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)	Equipment does not have reservoirs.	N/A
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)	No liquid in equipment.	N/A
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard	No liquid in equipment.	N/A

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

44.5	Equipment sufficiently protected against the effects of humidity	(see appended table 44)	P
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 60529	IPX0	N/A
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	(see appended table 44)	P

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

48	BIOCOMPATIBILITY		N/A
	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	Applied parts that are in contact with the patient have been approved separately. Not part of this investigation.	--

49	INTERRUPTION OF THE POWER SUPPLY		P
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IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
49.1	Thermal cut-outs and overcurrent releases with automatic resetting not used if they may cause a safety hazard	No thermal cutouts.	N/A
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function	Interruptions and restoration of the power supply does not present a safety hazard.	P
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure	No mechanical constraints.	N/A
51	PROTECTION AGAINST HAZARDOUS OUTPUT		N/A
51.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally	No such outputs.	N/A
52	ABNORMAL OPERATION AND FAULT CONDITIONS		P
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	P
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 60601-1-4	Equipment is not being evaluated to IEC 60601-1-4. Safety of equipment is not software dependent.	N/A
52.5.2	Failure of thermostats presents no safety hazards	No thermostats in equipment.	N/A
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard		N/A
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C		N/A
52.5.6	Locking of moving parts presents no safety hazard	No such moving parts.	N/A
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	No motors in equipment.	N/A
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8	No motors.	N/A
52.5.9	Failure of one component at a time presents no safety hazard		N/A
52.5.10	Overload of heating elements presents no safety hazard	No heating elements in equipment.	N/A
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	No motors.	N/A
	h) Equipment with three-phase motors can safely operate with one phase disconnected	No motors.	N/A

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

56	COMPONENTS AND GENERAL ASSEMBLY		P
	List of critical components	(see appended table 56)	P
56.1b	Ratings of components not in conflict with the conditions of use in equipment	Rating of components do not conflict the rating of the equipment.	P
	Ratings of mains components are identified	Ratings of mains components are identified.	P
56.1d	Components, movements of which could result in a safety hazard mounted securely	No such components.	N/A
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard	Conductors and connectors are adequately secured to prevent a safety hazard.	P
56.3a	Connectors provide separation required by Sub-clause 17g	Provided.	P
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	No such circuits.	N/A
	Medical gas connections not interchangeable	No gas connections	N/A
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken	Accessible metal parts are protectively earthed or separated from live parts by double/reinforced insulation.	P
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.	Leads are adequately protected.	P
56.4	Connections of capacitors		P
	Not connected between live parts and non-protectively earthed accessible parts	No capacitors in equipment except in approved power supply.	P
	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	No thermal cutouts.	N/A
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	No such components.	P
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 thermal cutouts.	N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits	No thermal safety devices.	N/A
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard	No thermal cutouts.	N/A
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard	No thermal cutouts.	N/A
	Self-resetting thermal cut-outs and self-resetting overcurrent releases operated 200 times	No thermal cutouts.	N/A
	Non-self resetting overcurrent releases operated 10 times	No self resetting overcurrent releases.	N/A
56.6b	Thermostats with varying temperature settings clearly indicated	No thermostats.	N/A
	Operating temperature of thermal cut-outs indicated	No thermal cutouts.	N/A
56.7	Batteries		N/A
	a) Battery compartments:		N/A
	- adequately ventilated	No batteries	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):		P
	- to indicate that equipment is energized	Green light provided.	P
	- 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	No hazard from output.	N/A
	- charging mode indicator provided	No charging mode.	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	No actuating parts.	N/A
	Controls are secured to prevent the movement relative to scale marking (safety related only)	No actuating parts.	N/A
	Detachable indicating devices are prevented from incorrect connection without the use of tool	No actuating parts.	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 rotating controls.	N/A
	- to prevent damage to wiring		N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
56.11	Cord-connected hand-held and foot-operated control devices		N/A
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g	Not a hand-held or foot operated device.	N/A
	b) Hand-held control devices comply with the requirement and test of Sub-clause 21.5	See above.	N/A
	- Foot-operated control devices designed to support the weight of an adult human being	See above.	N/A
	c) Devices not change their setting when inadvertently placed	See above.	N/A
	d) Foot-operated control devices are at least IP X1	See above.	N/A
	- For surgical use, electrical switching parts are IP X8	See above.	N/A
	e) Adequate strain relief at the cord entry provided	See above.	N/A
57	MAINS PARTS, COMPONENTS AND LAYOUT		P
57.1	Isolation from supply mains		P
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	Fuses provided.	P
	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	A switch is provided, but appliance inlet is considered the disconnect device.	N/A
	f) Mains switches not incorporated in a power supply cord	No switch in power cord.	P
	h) Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a	Approved appliance inlet provided.	P
	m) Fuses and semiconductor devices not used as isolating devices	Such components are not used as isolating devices.	P
57.2	Mains connectors and appliance inlets		P
	e) Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug	No mains socket outlets.	N/A
	g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment	No functional earth terminals.	N/A
57.3	Power supply cords		P
	a) Not more than one connection to a particular supply mains	Only one connection.	P

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously	No alternate supply.	N/A
	The mains plug has only one power supply cord	Only one mains plug.	P
	Non-permanently connected equipment provided with power supply cord or appliance inlet	Appliance inlet provided.	P
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 60227, designation 53 and IEC 60245, designation 53	Suitable power cord is provided.	P
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C	No external temperatures exceed 75 °C.	N/A
	c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV	The cross sectional area of the conductors is adequate.	P
	d) Stranded conductors not soldered if fixed by any clamping means	Soldering not used.	N/A
57.4	Connection of power supply cords		N/A
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	Appliance inlet provided.	N/A
	Tying the cord into a knot or tying the ends with string not used	Appliance inlet provided.	N/A
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation	Appliance inlet provided.	N/A
	Cord anchorages made of metal provided with an insulating lining	Appliance inlet provided.	N/A
	Clamping screws do not bear directly on the cord insulation	Appliance inlet provided.	N/A
	Screws associated with cable replacement are not used to secure other components	Appliance inlet provided.	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	Appliance inlet provided.	N/A
57.4b	Power supply cord protected against excessive bending	Appliance inlet provided.	N/A
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected	Appliance inlet provided.	N/A
57.5	Mains terminal devices and wiring of mains part		N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Mains connected equipment other than those with a detachable supply cord provided with mains terminals, where connections are made with screws, nuts or equally effective methods	Appliance inlet provided.	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	Appliance inlet provided.	N/A
	Mains terminal devices accessible only with use of a tool	Appliance inlet provided.	N/A
	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	Appliance inlet provided and fast on connectors used.	N/A
	c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened	Appliance inlet provided.	N/A
	d) Cord terminals not require special preparation of the conductor	No specially prepared cord.	N/A
57.6	Mains fuses and overcurrent releases		P
	Fuses or overcurrent releases provided accordingly for Class I and Class II	Fuses provided.	P
	Current rating of mains fuses and overcurrent releases such that they reliably carry the normal operating current	Fuses are adequately rated.	P
	Protective earth conductor not fused	Protective earth is not fused.	P
	Neutral conductor not fused for permanently installed equipment	Not permanently connected.	N/A
57.8	Wiring of the mains part		P
	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	Wires are adequate.	P
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord	Wires are adequate.	P
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard	Wires are adequate, and so are traces on the printed wiring boards.	P
57.9	Mains supply transformers		N/A
57.9.1	Overheating	Transformers are in approved power supply unit only.	N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	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		N/A
57.9.1b	Overload of secondary windings not caused excessive temperature		N/A
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests		N/A
57.9.4	Construction		N/A
	a) Separation of primary and secondary windings	Transformers are in approved power supply unit only.	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		N/A
	- 1 insulation layer with thickness of at least 1 mm	Transformers are in approved power supply unit only.	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		P
	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	No motors.	N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	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	Minimum spacings between parts of opposite polarity are maintained before fuse	P
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts	Equipment is not defibrillation-proof.	N/A

58	PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS		P
58.1	Clamping means of the protective earth terminal		P
	Not be able to loosen without the aid of a tool	Connections require the use of a tool for removal.	P
	Screws for internal earth connections are covered or protected against loosening from outside	Screws used for internal connections are not able to be removed from the exterior of the equipment.	P
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal	Appliance inlet earth pin is regarded as the protective earth terminal.	P
58.8	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing	The protective earthing terminal is secured independently and not used for any other connection.	P
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	The earth pin makes first and breaks last.	P

59	CONSTRUCTION AND LAYOUT		P
59.1	Internal wiring		P
	a) Cables and wiring protected against contact with a moving part	Cable and wiring are adequately secured away from moving parts.	P
	Wiring having basic insulation only protected by additional fixed sleeving	No need for additional sleeving,	N/A
	Components are not likely to be damaged in the normal assembly or replacement of covers	Components are not likely to be damaged during normal assembly and replacement of covers.	P
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead	No movable leads.	N/A
	c) Insulating sleeving adequately secured	Insulating sleeving not required or used.	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	Sheathing of a flexible cord is not used as supplementary insulation.	N/A

IEC 60601 + Am. 1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	dielectric test		
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material	Temperatures do not exceed 70 °C.	P
	d) Aluminum wires of less than 16 mm ² cross-section not used	Aluminum wires not used.	N/A
	f) Connecting cords between equipment parts considered as belonging to the equipment	No connecting cords.	N/A
59.2	Insulation		P
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation	Insulation is resistant to heat and fire and mechanical damage.	P
	c) Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts	Insulation not likely to be impaired by dirt, dust, or wear.	P
	Parts of rubber resistant to ageing	No rubber parts.	N/A
59.3	Excessive current and voltage protection		N/A
	Internal electrical power source provided with device for protection against fire hazard	No internal power sources used.	N/A
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuse holder	No 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 devices.	N/A
59.4	Oil containers		N/A
	Oil containers adequately sealed	No oil or oil containers in equipment.	N/A
	Container allow for the expansion of the oil	No oil or oil containers in equipment.	N/A
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport	No oil or oil containers in equipment.	N/A
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level	No oil or oil containers in equipment.	N/A

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

TEST EQUIPMENT LIST					
Item	Equipment Type	Make	Model No.	ITS Asset No.	Cal. Due Date
1	Multimeter	HP	34401A	18649	12/15/09
2	ITS 601 measuring circuit (MD)	--	--	0008395	VBU
3	Stop watch	Radio Shack	19-VU3A0-1-1	000173	12/15/09
4	Environmental Chamber and Controller	Envirotronics	SH27	18648	12/15/09
5	Power Analyzer	Valhalla	2100	18641	12/15/09
6	High Current Sourcing Milliohm Meter	Hypatia	309	18945	12/15/09
7	Master Mechanic Angle Finder	Master Mechanic	--	8411	05/04/10
8	Calipers	Starrett	96481073	18657	12/15/09
9	Creepage & Clearance gauges	SPI - Tronic	CC-23	18923	12/15/09
10	Multimeter	Fluke	87	18652	12/15/09
11	Dielectric Tester	Associated Research	3560D	18642	12/15/09
12	Ball Pressure Tester	ED&D	BPA-01	98002	04/19/11
13	Force Gauge	Chatillon	DPPH50	18650	12/15/09
14	Thermometer	Fluke	52 II	18941	12/15/09
15	Impact Hammer	ED&D	5110-0.5J	18930	12/15/09
16	Oscilloscope	Phillips	PM3382	18644	12/15/09

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

6.1	TABLE: marking durability	P
Marking tested		Remarks
Identification label		No edges curl, label remains legible.
Supplementary information:		

7	TABLE: power input					P
Operating condition		Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks
Normal		90	50	0.251	12.9	
		90	60	0.251	12.9	
		100	50	0.235	13.0	
		100	60	0.231	13.0	
		240	50	0.151	14.0	
		240	60	0.154	14.0	
		264	50	0.147	14.1	
		264	60	0.147	14.1	
Supplementary information:						

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

15b	TABLE: residual voltage in attachment plug										P
Voltage measured between:	Measurements [V]										Remarks
	1	2	3	4	5	6	7	8	9	10	
supply pins (pin 1 & pin 2)	0	0	0	0	0	0	0	0	0	0	
line pin 1 and enclosure	0	0	0	0	0	0	0	0	0	0	
line pin 2 and enclosure	0	0	0	0	0	0	0	0	0	0	

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

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	
Not defibrillation proof.						
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	
Not defibrillation proof.					
Supplementary information:					

18	TABLE: protective earthing				P	
Test location			Test current (A)	Calculated voltage (V)	Measured Resistance (mohms)	Remarks
Front			25 A	0.20	8.054 mΩ	
Back			25 A	0.18	7.191 mΩ	
Supplementary information:						

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

19	TABLE: leakage current				P
Type of leakage current and test condition (including single faults)		Supply voltage	Supply frequency	Measured max. value (mA)	Remarks
ER, B, 1, NC		264	60	0.020	
ER, B, 1, SFC		264	60	0.212	
ER, B, 0, NC		264	60	0.040	
ER, B, 0, SFC		264	60	0.222	
EN, B, 1, NC		264	60	0	
EN, B, 1, SFC		264	60	0	
EN, B, 0, NC		264	60	0	
EN, B, 0, SFC		264	60	0	
P, B, 1, NC		264	60	0	
P, B, 1, SFC		264	60	0	
P, B, 0, NC		264	60	0	
P, B, 0, SFC		264	60	0	
PA, B, 1, NC		264	60	0	
PA, B, 1, SFC		264	60	0	
PA, B, 0, NC		264	60	0	
PA, B, 0, SFC		264	60	0	
PM, B, 1, NC		264	60	0	
PM, B, 1, SFC		264	60	0	
PM, B, 0, NC		264	60	0	
PM, B, 0, SFC		264	60	0	
ER, A, 1, NC		264	60	0.020	
ER, A, 1, SFC		264	60	0.210	
ER, A, 0, NC		264	60	0.039	
ER, A, 0, SFC		264	60	0.223	
EN, A, 1, NC		264	60	0	
EN, A, 1, SFC		264	60	0	
EN, A, 0, NC		264	60	0	
EN, A, 0, SFC		264	60	0	
P, A, 1, NC		264	60	0	
P, A, 1, SFC		264	60	0	
P, A, 0, NC		264	60	0	
P, A, 0, SFC		264	60	0	

IEC 60601 + Am. 1& 2				
Clause	Requirement + Test		Result - Remark	
PA, A, 1, NC	264	60	0	
PA, A, 1, SFC	264	60	0	
PA, A, 0, NC	264	60	0	
PA, A, 0, SFC	264	60	0	
PM, A, 1, NC	264	60	0	
PM, A, 1, SFC	264	60	0	
PM, A, 0, NC	264	60	0	
PM, A, 0, SFC	264	60	0	
(Record at least maximum measured value for each test required by Clause 19 and the specific conditions of the test circuit and equipment).				
<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				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 (A-f)	Operational (BOP)	240 V	N/A	(spacings checked)	
B (A- a1)	Basic	240 V	1500 V ac		
C (A-a2)	Double/Reinforced	240 V	4000 V ac		
E (B-d)	Basic	240 V	1500 V ac		
Supplementary information: D is maintained by the use of a recognized power supply. Barrier does not need retested.					

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

21	TABLE: mechanical strength		P
Part under test		Test (impact, drop, force, handle, rough handling, mobile)	Remarks
Front Bezel/Enclosure		Impact, force, drop, ball pressure	Ball pressure measured less than 1.5 mm
Front Bezel/Enclosure		Impact - 0,5 J ± 0,05	No crack or reduction in spacings
Front Bezel/Enclosure		Force - 45 N applied over an area of 625 mm2	No crack or reduction in spacings
Front Bezel/Enclosure		Drop (5 cm)	No crack or reduction in spacings
Supplementary information:			

24	TABLE: - stability		P
Part under test		Test condition	Remarks
Whole unit.		10 degree tilt.	
Supplementary information:			

29	TABLE: X - radiation			N/A
Part under test		Test condition	Measured radiation (mR)	Remarks
Not X-Ray equipment.				
Supplementary information:				

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

42	TABLE: normal temperature				P
Supply voltage: 90V 50 Hz Ambient temperature :23.4 °C		Test Condition: Normal operating condition			
Measuring location	t_m °C	t_c °C	t_{max} °C	Verdict	Remarks
Cap 1 (PSU)	38.0	54.6	85	P	
Cap 2 (PSU)	41.6	58.2	85	P	
Transformer (PSU)	42.5	59.1	105	P	
Cap (secondary side PSU)	41.6	58.2	85	P	
Top Board (closed to heat sink)	36.7	53.3	90	P	
Touch surface	27.9	44.5	85	P	
Enclosure	28.4	45	85	P	
Front panel (touch surface)	27.4	44	60	P	
Ambient	23.4	40	--	--	
Supplementary information: No temperature rise on any of the applied parts.					

52	TABLE: abnormal temperature				N/A
Supply voltage . : V Hz Ambient temperature. : °C		Test Condition:			
Measuring location	t_m °C	t_c °C	t_{max} °C	Verdict	Remarks
Supplementary information:					

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

44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		P
Test type and condition	Part under test	Remarks	
Enclosure	Cleaning	No water entry.	
Entire Unit	Humidity 48hrs	No effects.	
Supplementary information:			

45	TABLE: hydrostatic pressure and pressure-relief device cycling test			N/A
Test type and condition		Part under test	Test pressure	Remarks
No pressure within equipment.				
Supplementary information:				

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

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

56.1	Critical Components List			P
Object/part No	Manufacturer/ trademark	Type/model	Technical data	Mark(s) of conformity ¹⁾
Enclosure	CHI MEI Corp.	PA-758R	ABS, Minimum HB, minimum 1.5 mm thick. Ball pressure test completed on enclosure.	UR
Appliance Inlet	Schurter	4303.0001	Medical Grade, 250 V, 10 A.	UR, CSA, VDE
Power Supply	MEPOS	SMFA60-S05-1	Medical Grade, Input 100-240, 47-63 Hz, Output: 11-13 V dc, 4.09-3.46 A	UR, TUV, DE, (CB Supply)
Switch	Marquardt	1852.1128	250 V, 4 A,	UR, CSA, VDE
Fuse	Littlefuse	313.5	0.5 A, 250 V Time Delay	UR, CSA
Opto-Isolator	Avago	HCNW2611-300E	5000 V isolation	UR, CSA, UR
Opto-Isolator	Avago	HCPL7840#300	5000 V isolation	UR, CSA, UR
DC-DC Converter	Traco	THI 0511	3000 V isolation	UR, CSA, TUV
Primary Wiring	Various	Various	Minimum 1.5 mm ² (18 AWG), 300 V, 80 °C. Minimum Flammability of FV-1.	VDE, UR,
Secondary Wiring	Various	Various	Minimum 0.33 mm ² (22 AWG), 300 V, 80 °C. Minimum Flammability of FV-1.	VDE, UR,
Connectors	Any	Any	Rated minimum 250 V	UL, UR

56.10	TABLE: actuating parts and controls		N/A
Part under test		Torque applied	Remarks
No such controls			
Supplementary information:			

56.11b	TABLE: foot operated control devices-loading		N/A
Part under test		Observed results	Remarks
No such controls.			
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
Appliance inlet provided.					
Supplementary information:					

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

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

57.9.1a	TABLE: transformer short circuit					N/A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
						Transformers are in approved power supply.
Supplementary information:						

57.9.1b	TABLE: overload						N/A
Winding under test	Protection	Measured temperatures (°C)			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:					

Photos





APPENDIX 2

TEST REPORT IEC 60601 - 2- 40 Medical electrical equipment Part 2: Particular requirements for the safety of electromyographs and evoked response equipment
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Testing Laboratory	Intertek
Address.....	5541 Central Ave, Suite # 110, Boulder CO, 80301
Applicant's name	See Main Body of Report.
Address.....	See Main Body of Report.
Test specification:	
Standard	IEC 60601-2-40: 1998 (First Edition) for use in conjunction with IEC 60601-1:1988 + A1:1991 + A2:1995
Test procedure.....	
Non-standard test method.....	N/A
Test Report Form No.	IEC60601_2_40B
Test Report Form(s) Originator.....	Underwriters Laboratories Inc.
Master TRF	Dated 2006-07
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Test item description.....	See Main Body of Report.
Trade Mark.....	See Main Body of Report.
Manufacturer.....	See Main Body of Report.
Model/Type reference.....	See Main Body of Report.
Ratings.....	See Main Body of Report.

Testing procedure and testing location:	
CCA Testing Laboratory:	Intertek
Testing location/ address.....	5541 Central Ave. Suite 110 Boulder, CO 80301 USA

Tests performed (name of test and test clause): See main body of this report for details.

Summary of compliance with National Differences: None	
Copy of marking plate See main body of this report for details.	
Tests performed (name of test and test clause): See the main body of this report for details on testing completed on the unit.	

Test item particulars	
Classification of installation and use.....	See main body of this report for details.
Type of STIMULATOR	AUDITORY STIMULATOR
Options included.....	See main body of this report for details.
Accessories and detachable parts included in the evaluation (See also IEC 601-1 Report)	See main body of this report for details.
Possible test case verdicts:	
- test case does not apply to the test object.....	N/A
- test object does meet the requirement.....	P (Pass)
- test object does not meet the requirement.....	F (Fail)
Testing	
Date of receipt of test item	1 December 2008
Date (s) of performance of tests	1 December 2008 to 24 December 2008
General remarks:	
<p>The test 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 Issuing testing laboratory. "(see Enclosure #)" refers to additional information appended to the report. "(see appended table)" refers to a table appended to the report.</p> <p>Throughout this report, a point (coma) is used as the decimal separator. List of test equipment must be kept on file and available for review.</p> <p>This Test Report Form is intended for the investigation of electromyographs and evoked response equipment in accordance with IEC 60601-2-40. It can only be used together with IEC 60601-1 Test Report.</p>	
General product information: See main body of this report for details.	

5	IDENTIFICATION, MARKING AND DOCUMENTS		P
5.2	TYPE B APPLIED PART not applicable	Type BF applied part.	N/A
5.6	Only CONTINUOUS OPERATION allowed	Unit is for continuous operation.	P

6	IDENTIFICATION, MARKING AND DOCUMENTS		P
6.1	Marking on the outside of EQUIPMENT or EQUIPMENT parts		P
6.1j	The marked RATED power input is the maximum power input averaged over any period of 5 s under the conditions set out in item aa) of 7.1.....	See main body of this report.	P
6.1p	EQUIPMENT marked near the electrode connections with the symbol No. 14 in accordance with annex D of Part 1.		P
6.8.2	INSTRUCTIONS FOR USE		
	aa) Information on the output WAVE FORM(S), including any d.c. component, PULSE DURATION, pulse repetition frequencies, maximum amplitude of output voltage and/or current, and the effect of load impedance on the demanded parameters	Not this type.	N/A
	bb) Advice on the size of electrodes to be used and the method of application for each particular type of examination for which the ELECTRICAL STIMULATOR is intended	Not this type. Stimulator is acoustic.	N/A
	cc) Advice on any necessary precautions to be taken when the output contains a d.c. component	Not this type.	N/A
	dd) Advice that a PATIENT with an implanted electronic device should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained	Provided.	P
	ee) Advice to avoid trans-thoracic stimulation, for example maintenance of anode and cathode stimulating sites in close proximity	Stimulator is acoustic.	N/A
	ff) Warnings on the potential SAFETY HAZARDS: "Connection of a PATIENT to an h.f. surgical equipment and an ELECTROMYOGRAPH or EVOKED RESPONSE EQUIPMENT may result in burns at the site of the ELECTRICAL STIMULATOR or BIOPOTENTIAL INPUT PART electrodes and possible damage to the ELECTRICAL STIMULATOR or biological amplifiers	Unit will not be used during surgery. It is to conduct hearing tests.	N/A
	- "Operation in proximity of short wave or microwave therapy equipment may produce instability in the ELECTRICAL STIMULATOR output"	Stimulator is acoustic.	N/A
	gg) EQUIPMENT delivering output higher than 10 mA r.m.s. or 10 V r.m.s. averaged over 1 s, or having an energy greater than 10 mJ per pulse into the specified load impedance	No electrical stimulation. Stimulator is acoustic.	N/A
	- Information on the max. output allowed for the electrodes recommended by the manufacturer for use with the ELECTRICAL STIMULATOR.	No output for electrodes. Stimulator is acoustic.	N/A

	- Advice that current densities for any electrodes exceeding 2 mA r.m.s./cm ² may require the special attention of the OPERATOR	No output for electrodes. Stimulator is acoustic.	N/A
	hh) When a mains powered video monitor, not complying with IEC 60601-1, is to be used as part of the VISUAL STIMULATOR, the instructions for use explain how to comply with IEC 60601-1	Not a visual stimulator.	N/A
	ii) Warning to avoid accidental contact between connected but unused APPLIED PARTS and other conductive parts including those connected to protective earth	Provided.	P
6.8.3	Technical description		N/A
	aa) Technical description specifies the parameters mentioned in 6.8.2 aa) and the range of load impedance for which these parameters are valid	See 6.8.2 aa.	N/A

7	POWER INPUT		P
7.1	aa) The power input measured with a load resistance of the lowest value specified in the technical description, and with any output controls set to give maximum power input	See main body of report.	P

14	REQUIREMENTS RELATED TO CLASSIFICATION		P
14.6	APPLIED PARTS of ELECTRICAL STIMULATORS, VISUAL STIMULATORS, and AUDITORY STIMULATORS are TYPE BF or CF APPLIED PARTS	Type BF	P

20	DIELECTRIC STRENGTH		N/A
20.2	(B-b) - DOUBLE or REINFORCED INSULATION used between BIOPOTENTIAL INPUT PARTS and other energized APPLIED PARTS	Applied parts are not biopotential applied parts. Double reinforced insulation provided between applied parts.	N/A
	(B-b) - Insulation not required between different BIOPOTENTIAL PARTS when intended for use on a single PATIENT	Applied parts are not biopotential applied parts. Double reinforced insulation provided between applied parts.	N/A
	(B-b) - DOUBLE or REINFORCED INSULATION used between stimulator APPLIED PARTS of differing modalities	Applied parts are not biopotential applied parts. Double reinforced insulation provided between applied parts.	N/A

36	ELECTROMAGNETIC COMPATIBILITY		--
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	EQUIPMENT complies with IEC 60601-1-2	Conformance to IEC 60601-1-2 was not investigated under the scope of this evaluation. The unit under went EMC testing as described in the main body of this report, but unable to verify that part requirements of IEC 60601-2-40 were considered.	--
36.201	EMISSIONS		--
36.201.1.7	For the radiated radiofrequency emissions test, all relevant electrodes connected and applied to the contents of a 1 000 ml capacity, normal saline filled phantom, positioned within 400 mm of the EQUIPMENT in accordance with Fig. 101.....:	Conformance to IEC 60601-1-2 was not investigated under the scope of this evaluation. The unit under went EMC testing as described in the main body of this report, but unable to verify that part requirements of IEC 60601-2-40 were considered.	--
36.202	IMMUNITY		--
	The EQUIPMENT did not deliver stimuli exceeding more than ± 10 % of those set by the OPERATOR for intensity, amplitude, PULSE DURATION, or repetition rate when subjected to requirements in clauses 36.202.1 through 36-202.6 of this standard.	Not all parameters of EMC (60601-1-2) have been considered for IEC 60601-2-40, This unit is not intended for critical monitoring of physiological parameters. Risk of delivering an excessive stimuli is minimal. The unit under went EMC testing as described in the main body of this report, but unable to verify that part requirements of IEC 60601-2-40 were considered.	--
	Disturbance of the display during tests of 36.202.2.1 does not constitute a non-compliance	Conformance to IEC 60601-1-2 was not investigated under the scope of this evaluation. The unit under went EMC testing as described in the main body of this report, but unable to verify that part requirements of IEC 60601-2-40 were considered.	--

	After completion of the immunity tests, the EQUIPMENT continued to comply with the PATIENT, PATIENT AUXILIARY, and EARTH LEAKAGE CURRENT requirements	Not all parameters of EMC (60601-1-2) have been considered for IEC 60601-2-40. This unit is not intended for critical monitoring of physiological parameters. Leakage currents of the device measure 0 in normal use. Minimal risk of leakage after immunity testing of the device. The unit under went EMC testing as described in the main body of this report, but unable to verify that part requirements of IEC 60601-2-40 were considered.	--
36.202.1	ELECTROSTATIC DISCHARGE		--
	Electrostatic discharge tests included all connectors and terminals intended to form part of the PATIENT circuit during NORMAL USE and all other accessible surfaces, control knobs, etc.	Conformance to IEC 60601-1-2 was not investigated under the scope of this evaluation. The unit under went EMC testing as described in the main body of this report, but unable to verify that part requirements of IEC 60601-2-40 were considered.	--
36.202.2	Radiated radiofrequency electromagnetic fields		--
	d) For the radiated radiofrequency electromagnetic field test, all relevant electrodes connected and applied to the contents of a 1 000 ml capacity, normal saline filled phantom, positioned within 400 mm of the EQUIPMENT according to Fig. 101..... :	Conformance to IEC 60601-1-2 was not investigated under the scope of this evaluation. The unit under went EMC testing as described in the main body of this report, but unable to verify that part requirements of IEC 60601-2-40 were considered.	--

42	EXCESSIVE TEMPERATURES		P
	The maximum temperatures allowed in Part 1 checked under the conditions specified in 7.1 aa)	See Table 42 in Part 1 Report	P

46	HUMAN ERRORES		N/A
	The ELECTRICAL STIMULATOR did not become unsafe when the output was switched on inadvertently with open- or short-circuit electrodes	Not an electrical stimulator.	N/A
	The ELECTRICAL STIMULATOR did not become unsafe after operating at maximum output settings for 5 minutes with the electrodes open-circuited and with the electrodes short-circuited	Not an electrical stimulator.	N/A

50	ACCURACY OF OPERATING DATA		P
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50.1	Marking of controls and instruments		N/A
	An output control incorporated in the ELECTRICAL STIMULATOR	No electrical stimulators.	N/A
	- controlling of the output from minimum to maximum of the range continuously, or in discrete increments of not more than 1 mA amplitude or 5 V amplitude per increment		N/A
	At its minimum setting, the output did not exceed 2% of that available at the maximum setting of the control (%).....:		N/A
50.2	Accuracy of controls and instruments		N/A
	The specified values of PULSE DURATIONS, pulse repetition frequencies, and amplitudes did not deviate by more than 30 % when measured with an error of ± 10 % into a load resistance within the range specified in the ACCOMPANYING DOCUMENTS	No electrical stimulators.	N/A

51	Protection against hazardous output		P
51.101	Supply voltage fluctuations	See below.	P
	Supply voltage fluctuations of ± 10 % of the NOMINAL voltage did not affect the ELECTRICAL STIMULATOR output amplitude, PULSE DURATION, or pulse repetition frequency by more than ± 10 %	Supply fluctuation does not affect unit.	P
51.102	ELECTRICAL STIMULATOR output indicator	See below.	P
	Visual indicator provided for EQUIPMENT delivering an output in excess of 10 mA r.m.s., 10 V r.m.s., or pulses having energy exceeding 10 mJ per pulse	Not applicable.	N/A
	- color of visual indicators is of yellow	See above.	N/A
51.103	Limitation of ELECTRICAL STIMULATOR output parameters	See below.	P
	The pulse energy with a load resistance of 1000 Ω did not exceed 50 mJ per pulse (mJ):	Not	P
51.104	Limitation of VISUAL STIMULATOR output parameters	Not this type.	N/A
	The radiation density of light-emitting diodes (LEDs) in the transducer of the VISUAL STIMULATOR does not exceed the limits of IEC 60825-1.....:	Not this type.	N/A
51.105	Limitation of AUDITORY STIMULATOR output parameters	See below.	N/A
	The overall sound level for a continuous output did not exceed 125 dB HTL.....:	Not a continuous output.	N/A