

COVER PAGE FOR TEST REPORT

Product Category:	Power Supplies, Medical and Dental
Product Category CCN:	QQHM2, QQHM8
Test Procedure:	Component Recognition
Product:	Charger stand
Model/Type Reference:	GTM91094-0605-FW
Rating(s):	I/P: 100-240Vac, 50/60 Hz, 0.25 - 0.08 A
	O/P: 5Vdc, 1.2A
Standards:	UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1: General Requirements for Safety) CAN/CSA-C22.2 No. 601.1-M90, 2005 (Medical Electrical Equipment - Part 1: General Requirements for Safety)
Applicant Name and Address:	GLOBTEK INC 186 VETERANS DR NORTHVALE NJ 07647
This Report includes the following parts, in addition to this cover page:	
<ol style="list-style-type: none">1. Specific Inspection Criteria2. Specific Technical Criteria3. Clause Verdicts4. Critical Components5. Test Results6. National Differences7. Enclosures	

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of Underwriters Laboratories Inc. ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

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Test Report By:



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SPECIFIC INSPECTION CRITERIA

BA1.0	Special Instructions to UL Representative
BA1.1	N/A

BB1.0	Supporting Documentation
BB1.1	<p>The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:</p> <p>A. Authorization - The Authorization page may include additional Factory Identification Code markings.</p> <p>B. Generic Inspection Instructions -</p> <ul style="list-style-type: none">i. Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.ii. Part AE details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.iii. Part AF details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

BC1.0	Markings and instructions	
BC1.1	The following markings and instructions are provided as indicated.	
BC1.2	All clause references are from UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1: General Requirements for Safety).	
Standard Clause	Clause Title	Marking or Instruction Details
6.1e	Company identification	Classified or Recognized company's name, Trade name, Trademark or File
6.1f	Model	Model number
6.1g	Supply Connection	Voltage range, ac/dc, phases if more than single phase
	Alternating current	
6.1h	Supply Frequency	Rated frequency range in hertz
6.1j	Power Input	Amps, VA, or Watts
6.1l	Class II equipment	
6.1n	Fuses	Ratings (current and voltage) and type. (located adjacent to fuse OR as a diagram inside enclosure)
6.1p	Output	Rated output voltage, power, frequency.

BD1.0	Production-Line Testing Requirements			
BD1.1	Test Exemptions - The following models are exempt from the indicated test			
	Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
	GTM91094-0605-FW	Yes	No	Yes
BD1.2	Solid-State Component Test Exemptions - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:			
	N/A			

BE1.0	Sample and Test Specifics for Follow-Up Tests at UL			
BE1.1	The following tests shall be conducted in accordance with the Generic Inspection Instructions			
	Model	Samples	Test	Test Details
	N/A	--	--	--

SPECIFIC TECHNICAL CRITERIA

TEST REPORT UL 60601-1 Medical Electrical Equipment Part 1: General requirements for safety	
Report Reference No	E172861-A13-UL-1
Compiled by	David Shih
Reviewed by	Jimmy Deng
Date of issue	2008-01-10
Standards	UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1: General Requirements for Safety) CAN/CSA-C22.2 No. 601.1-M90, 2005 (Medical Electrical Equipment - Part 1: General Requirements for Safety)
Test procedure	Component Recognition
Non-standard test method	N/A
Test item description	Charger stand
Trademark	None
Model and/or type reference	GTM91094-0605-FW
Rating(s)	I/P: 100-240Vac, 50/60 Hz, 0.25 - 0.08 A O/P: 5Vdc, 1.2A

GENERAL INFORMATION**Test item particulars (see also clause 5):**

Classification of installation and use	N/A - Recognized Component
Supply connection	Appliance coupler
Accessories and detachable parts included in the evaluation	None
Options included	None

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) (acceptable only if a corresponding, less stringent national requirement is "Pass")

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:

- "(see Enclosure #)" refers to additional information appended to the Test Report
- "(see appended table)" refers to a table appended to the Test Report
- Throughout the Test Report a point is used as the decimal separator

General Product Information:

CA1.0	Report Summary
CA1.1	N/A
CB1.0	Product Description
CB1.1	Electronic components mounted to PWB, and housed in plastic enclosure, with Class II appliance inlet, which intended to provide electrical power to medical electrical equipment.
CC1.0	Model Differences
CC1.1	N/A
CD1.0	Additional Information
CD1.1	N/A

CE1.0	Technical Considerations	
CE1.1	The product was investigated to the following additional standards:	UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA), CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada)
CE1.2	The product was not investigated to the following standards or clauses:	Clause 52.1, Programmable Electronic Systems (IEC 601-1-4), Clause 48, Biocompatibility (ISO 10993-1), Clause 36, Electromagnetic Compatibility (IEC 601-1-2)
CE1.3	The product is Classified only to the following hazards:	Shock, Fire, Casualty
CE1.4	The degree of protection against harmful ingress of water is:	Ordinary
CE1.6	The mode of operation is:	Continuous
CE1.7	Software is relied upon for meeting safety requirements related to mechanical, fire and shock:	No
CE1.8	The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:	No
CF1.0	Engineering Conditions of Acceptability	
CF1.1	For use only in or with complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc. When installed in an end-product, consideration must be given to the following:	
CF2.0	This charger stand has been judged on the basis of the required creepage and clearances in the First Edition of the Standard for Medical Electrical Equipment, UL 60601-1, Sub clause 57.10, which covers the end-use product for which the component was designed.	--
CF2.1	This charger stand has not been evaluated for patient connected applications.	--
CF2.2	The charger stand was evaluated as Double Insulation between Primary and Secondary and, Double Insulation between Primary and Enclosure. See insulation diagram for details.	--
CF2.3	The Temperature Test was performed in an ambient of 40 Deg.C per request of applicant.	--
CF2.4	The primary transformer (T1) incorporates a Class B, 130 Deg.C insulation system.	--
CF2.5	The reference voltage for Dielectric Voltage	--

	Test in End Product: 240Vrms, 880Vpk-pk	
CF2.6	The secondary output circuit of Transformer (T1) is SELV .	--
CF2.7	This charger stand was tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.	--
CF2.8	This charger stand has been evaluated as a Class II, continuous operation, ordinary Equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. An additional evaluation shall be made if the charge stand is intended for use in other than Class II equipment.	--
CF2.9	The AC inlet of this charger stand is non-polarity type. The suitability need evaluated in the end product.	--

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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

5	CLASSIFICATION		Pass
5.1	Type of protection against electric shock		Pass
	Class I equipment		N/A
	Class II equipment		Pass
	Internally powered equipment		N/A
5.2	Degree of protection against electric shock		N/A
	Type B applied part	To be evaluated in the end product.	N/A
	Type BF applied part		N/A
	Type CF applied part		N/A
	Not classified - no 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 529 (see 6.1.1)..... :	IPX0	Pass
5.4	Methods of sterilization or disinfection		N/A
5.5	Equipment not suitable for use in the presence of flammable mixtures		Pass
	Category AP equipment		N/A
	Category APG equipment		N/A
5.6	Mode of operation:		Pass
	-continuous operation	Intended for continuous operation at rated load.	Pass
	-short-time operation, specified operation; period. :		-

IEC 60601			
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 :		-

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

TABLE: to insulation diagram							
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	A-f: BOP	250V rms	3.0	1.6	6.6	6.6	Line to Neutral
B	A-a2: DI/RI	250V rms	8.0	5.0	10.3	11.6	Primary component to outer enclosure
C	A-a2: DI/RI	250V rms	8.0	5.0	8.03	8.03	Trace distance between Primary and Secondary in the PWB
D	A-b: BI	250V rms	4.0	2.5	5.48	2.94	Primary to Core
E	A-c: SI	250V rms	4.0	2.5	7.86	2.94	Core to Secondary

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			
Clause	Requirement + Test	Result - Remark	Verdict

6	IDENTIFICATION, MARKING AND DOCUMENTS		Pass
6.1	Marking on the outside of equipment or equipment parts		Pass
6.1c	Markings of the specific power supply affixed		N/A
6.1d	If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		N/A
6.1e	Name and/or trademark of the manufacturer or supplier	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONIC CO.,LTD	Pass
6.1f	Model or type reference	GTM91094-0605-FW	Pass
6.1g	Rated supply voltages or voltage range(s)	100-240Vac	Pass
	Number of phases	Single	Pass
	Type of current.....	AC	Pass
6.1h	Rated frequency or rated frequency range(s) (Hz) :	50/60	Pass
6.1j	Rated power input (VA, W or A)	0.25 - 0.08 A	Pass
6.1k	Power output of auxiliary mains socket - outlets		N/A
6.1l	Class II symbol		Pass
	Symbol for degree of protection against ingress of water provided		N/A
	Symbol for protection against electric shock	No applied parts.	N/A
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets		N/A
	Symbol for protection of defibrillation-proof applied parts		N/A
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N/A
6.1m	Mode of operation (if no marking, suitable for continuous operation)	Continuous operation and no marking.	Pass
6.1n	Types and rating of external accessible fuses.....		N/A
6.1p	Ratings of external output:.....	5Vdc, 1.2A	Pass
6.1q	Symbol for physiological effect(s):		N/A
	- attention, consult accompanying documents		N/A
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

6.1r	Anaesthetic-proof symbol: AP or APG :		N/A
6.1s	Dangerous voltage symbol		N/A
6.1t	Special cooling requirements		N/A
6.1u	Limited mechanical stability		N/A
6.1v	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
6.1y	Potential equalization terminal		N/A
	- Functional earth terminal		N/A
6.1z	Removable protective means		N/A
	Durability of marking test	(see appended table 6.1)	Pass
6.2	Marking on the inside of equipment or equipment parts		Pass
6.2a	Nominal voltage of permanently installed equipment		N/A
6.2b	Maximum power loading for heating elements or holders for heating lamps		N/A
6.2c	Dangerous voltage symbol		N/A
6.2d	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
6.2e	Fuses accessible with a tool identified either by type and rating or by a reference to diagram	F1 and F2: T1A, 250V	Pass
6.2f	Protective earth terminal		N/A
6.2g	Functional earth terminal	No functional earth terminal.	N/A
6.2h	Supply neutral conductor in permanently installed equipment (N)	Not a permanently connected device.	N/A
6.2j	Markings required in 6.2 f), h), k), and l) remain visible after connection and are not affixed to parts which have to be removed		N/A
	- Markings comply with IEC 445		N/A
6.2k	For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	equipment)		
6.2l	Statement for suitable wiring materials at temperatures over 75°C		N/A
6.2n	Capacitors and/or circuit parts marked as required in Sub-clause 15c		N/A
6.3	Marking of controls and instruments		N/A
6.3a	Mains switch clearly identified	No switch provided.	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
6.3b	Indication of different positions of control devices and switches		N/A
6.3c	Indication of the direction in which the magnitude of the function changes, or an indicating device		N/A
6.3f	The functions of operator controls and indicators are identified		N/A
6.3g	Numeric indications of parameters are in SI units except for units listed in Am. 2		N/A
6.4	Symbols		Pass
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	In accordance with Appendix D.	Pass
6.5	Colors of the insulation of conductors		Pass
6.5a	Protective earth conductor has green/yellow insulation		N/A
6.5b	All insulations of internal protective earth conductors are green/yellow at least at their terminations		N/A
6.5c	Only protective or functional earthing, or potential equalization conductors are green/yellow		N/A
6.5d	Color of neutral conductor	UL Listed Power supply cord will be provided.	Pass
6.5e	Colors of phase conductor(s)	UL Listed Power supply cord will be provided.	Pass
	- Compliance with IEC 227 and IEC 245		Pass
6.5f	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		N/A
6.6a	In accordance with ISO ISO/R 32		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

6.6b	Identification of connection point		N/A
6.7	Indicator lights and push-buttons		N/A
6.7a	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
	- Green used to indicate ready for action		N/A
6.7b	Color red used only for push-buttons by which a function is interrupted in case of emergency		N/A
6.8	ACCOMPANYING DOCUMENTS		N/A
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	To be evaluated in the end product.	N/A
	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		N/A
6.8.2a	General information provided in instructions for use		N/A
	- state the function and intended application of the equipment		N/A
	- 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		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	including the frequency of such maintenance		
	General information provided in instructions:		N/A
	- information for the safe performance of 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	Responsibility of explanation is up to end product manufacturer.	N/A
6.8.2c	Signal output or signal input parts intended only for connection to specified equipment described		N/A
6.8.2d	Details about acceptable cleaning, disinfection or sterilization methods included		N/A
6.8.2e	Warning statement for mains operated equipment with additional power source		N/A
6.8.2f	A warning to remove primary batteries if equipment is not likely to be used for some time		N/A
6.8.2g	Instructions to ensure safe use and adequate maintenance of rechargeable batteries		N/A
6.8.2h	Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1		N/A
6.8.2j	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		N/A
6.8.3a	All characteristics essential for safe operation provided		N/A
6.8.3b	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
6.8.3c	Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided		N/A
6.8.3d	Environmental conditions for transport and storage specified in accompanying documents and marked		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	on packaging		
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7	POWER INPUT		Pass
	Power Input Measurements	(see appended table 7)	Pass

10	ENVIRONMENTAL CONDITIONS		Pass
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer		Pass
10.2.2a	Rated voltage not exceeding 250 V for hand-held equipment		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	Single phase,100-240Vac	Pass
	Rated voltage not exceeding 500 V for all other equipment		N/A
	Rated input frequency not more than 1kHz	50/60Hz	Pass
10.2.2b	Internal replaceable electrical power source specified		N/A

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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

16	ENCLOSURES AND PROTECTIVE COVERS		Pass
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)		Pass
	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	No top openings.	N/A
16c	Conductive parts accessible after the removal of handles, knobs, levers		N/A
	- have a resistance of not more than 0.2 Ohm		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		Pass
	- Removal possible only with the aid of a tool		Pass
	- Use of automatic device making parts not live when the enclosure is opened or removed		N/A
	- Exception 16e applied to the following parts..... :		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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

17	SEPARATION		Pass
17a	Separation method of the applied part from live parts:		N/A
	1) basic insulation: applied part earthed	No applied part.	N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N/A
	4) by double or reinforced insulation		N/A
	5) by protective impedances limiting current to applied part		N/A
	- Additional leakage current test in single fault conditions		N/A
17c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		N/A
17d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		N/A
17g	Separation method of accessible parts other than applied parts from live parts:		Pass
	1) basic insulation: accessible part earthed		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		Pass
	5) by protective impedances limiting current to accessible part		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		N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

18	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION		N/A
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal	Class II unit.	N/A
18b	Protective earth terminals suitable for connection to the protective earth conductor		N/A
18e	Potential equalization conductor		N/A
	- 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
18f	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1 \text{ Ohm}$		N/A
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $\leq 0.1 \text{ Ohm}$		N/A
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part $\leq 0.2 \text{ Ohm}$		N/A
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1 Ohm , the allowable value of the enclosure leakage current is not exceeded in single fault condition		N/A
18k	Functional earth terminal not used to provide protective earthing		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		N/A
	- functional earth terminal clearly marked		N/A
	- explanation of functional earth terminal provided in the accompanying documents		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

19	CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS		Pass
19.1b	Leakage currents	(see appended table 19)	Pass
	- earth leakage current		N/A
	- enclosure leakage current		Pass
	- patient leakage current		N/A
	- patient auxiliary current		N/A

20	DIELECTRIC STRENGTH		Pass
	Overall compliance with Clause 20	(see appended table 20)	Pass

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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 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		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		Pass
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered		Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

24	STABILITY IN NORMAL USE (see appended table 24)		N/A
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°	To be evaluated in the end product.	N/A
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		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 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		N/A
	- instructions for lifting and handling during assembly		N/A
24.6b	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		N/A
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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

28	SUSPENDED 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		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		N/A
	1) Total load does not exceed the safe working load		N/A
	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		N/A
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure $\leq 130 \text{ nC/kg}$ (0.5 mR)		N/A

36	ELECTROMAGNETIC COMPATIBILITY		N/A
	Equipment complies with IEC 601-1-2	Not evaluated by Underwriters Laboratories Inc.	N/A

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

42	EXCESSIVE TEMPERATURES		Pass
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures per Clause 10.2.1	(see appended table 42)	Pass
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient		Pass
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C	No applied parts.	N/A
42.5	Guards to prevent contact with hot surfaces removable only with a tool		N/A

43	FIRE PREVENTION		Pass
	Strength and rigidity necessary to avoid a fire hazard		Pass

44	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION		Pass
44.2	Equipment contain a liquid reservoir:		N/A
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min		N/A
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling)		N/A
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)		N/A
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		N/A
44.5	Equipment sufficiently protected against the effects of humidity	(see appended table 44)	Pass
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529	Ordinary protection(IPX0) considered. Other IP must be considered in the end use.	N/A
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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		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	a) Pressure-relief device connected as close as possible to the pressure vessel		N/A
45.7b	b) Readily accessible for inspection		N/A
45.7c	c) Not capable of being adjusted or rendered inoperative without a tool		N/A
45.7d	d) Discharge opening located that the released material is not directed towards person		N/A
45.7e	e) Discharge opening located that operation will not deposit material which may cause a safety hazard		N/A
45.7f	f) Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure		N/A
45.7g	g) No shut-off valve between a pressure-relief device and the parts intended to be protected		N/A
45.7h	h) Minimum number of cycles of operation: 100.000		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		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

49	INTERRUPTION OF THE POWER SUPPLY		N/A
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard	To be evaluated in the end product.	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		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		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

52	ABNORMAL OPERATION AND FAULT CONDITIONS		Pass
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13)	(see appended table 52)	Pass
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4		N/A
52.5.2	Failure of thermostats presents no safety hazards		N/A
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard		Pass
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C	(see appended table 52)	Pass
52.5.6	Locking of moving parts presents no safety hazard		N/A
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard		N/A
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8		N/A
52.5.9	Failure of one component at a time presents no safety hazard	(see appended table 52)	Pass
52.5.10	Overload of heating elements presents no safety hazard		N/A
52.5.10f	Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection		N/A
52.5.10h	Equipment with three-phase motors can safely operate with one phase disconnected		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

56	COMPONENTS AND GENERAL ASSEMBLY		Pass
	List of critical components	(see appended table 56.1)	Pass
56.1b	Ratings of components not in conflict with the conditions of use in equipment		Pass
	Ratings of mains components are identified		Pass
56.1d	Components, movements of which could result in a safety hazard mounted securely		Pass
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard	Internal wire is secured and/or insulated to prevent accidental detachment resulting in a safety hazards.	Pass
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
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		Pass
	Not connected between live parts and non-protectively earthed accessible parts		Pass
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14		N/A
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts		Pass
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs		N/A
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment		Pass
56.6	Temperature and overload control devices		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

56.6a	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
	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 over-current releases operated 200 times		N/A
	Non-self resetting over-current releases operated 10 times		N/A
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		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		N/A
56.7a	Battery compartments:		N/A
	- adequately ventilated		N/A
	- accidental short-circuiting is prevented		N/A
56.7b	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):		N/A
	- 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		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		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	incorrect connection without the use of tool		
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		N/A
	- to prevent damage to wiring		N/A
56.11	Cord-connected hand-held and foot-operated control devices		N/A
56.11a	Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g		N/A
56.11b	Hand-held control devices comply with the requirement and test of Sub-clause 21.5		N/A
	- Foot-operated control devices designed to support the weight of an adult human being		N/A
56.11c	Devices not change their setting when inadvertently placed		N/A
56.11d	Foot-operated control devices are at least IPX 1		N/A
	- For surgical use, electrical switching parts are IPX 8		N/A
56.11e	Adequate strain relief at the cord entry provided		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
57.3d	Stranded conductors not soldered if fixed by any clamping means		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		N/A
	Tying the cord into a knot or tying the ends with string not used		N/A
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		N/A
	Cord anchorages made of metal provided with an insulating lining		N/A
	Clamping screws do not bear directly on the cord insulation		N/A
	Screws associated with cable replacement are not used to secure other components		N/A
	Conductors of the power supply cord arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals		N/A
57.4b	Power supply cord protected against excessive bending		N/A
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		N/A
57.5	Mains terminal devices and wiring of mains part		N/A
	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
57.5b	Terminals closely grouped with any protective earth terminal		N/A
	Mains terminal devices accessible only with use of a tool		N/A

IEC 60601			
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
57.5c	Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened		N/A
57.5d	Cord terminals not require special preparation of the conductor		N/A
57.6	Mains fuses and overcurrent releases		Pass
	Fuses or over-current releases provided accordingly for Class I and Class II	F1 and F2 provide on "Line" and "Neuter".	Pass
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current		Pass
	Protective earth conductor not fused		N/A
	Neutral conductor not fused for permanently installed equipment		N/A
57.8	Wiring of the mains part		Pass
57.8a	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 Publications 227 or 245, treated as bare conductor		Pass
57.8b	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		Pass
57.9	Mains supply transformers		Pass
57.9.1	Overheating		Pass
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		Pass
57.9.1a	Short-circuit of secondary windings not caused excessive temperature	(see appended table 57.9.1a)	Pass
57.9.1b	Overload of secondary windings not caused excessive temperature	(see appended table 57.9.1b)	Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
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		Pass
57.9.4a	Separation of primary and secondary windings	Double insulation provided.	Pass
	- 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		Pass
57.9.4c	Means provided to prevent displacement of end turns	Margin tape used to prevent displacement.	Pass
57.9.4d	Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn		N/A
57.9.4e	Insulation between the primary and secondary in transformers with double insulation		Pass
	- 1 insulation layer having a 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	Triple insulation wire used in secondary winding and provide six layers insulation tape between primary winding and secondary winding. (see table 57.9.2)	Pass
57.9.4g	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		Pass
57.10a	Values: compliance with at least the values of Table XVI	(see insulation diagram)	Pass
	Creepage distances for slot insulation of motors at least 50% of the specified values		N/A
57.10b	Minimum creepage distances and air clearances in the mains part between parts of opposite polarity	(see insulation diagram)	Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	not required if short-circuiting does not produce a safety hazard		
57.10c	Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts		N/A

58	PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS		N/A
58.1	Clamping means of the protective earth terminal		N/A
	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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

59	CONSTRUCTION AND LAYOUT		Pass
59.1	Internal wiring		Pass
59.1a	Cables and wiring protected against contact with a moving part		N/A
	Wiring having basic insulation only protected by additional fixed sleeving		Pass
	Components are not likely to be damaged in the normal assembly or replacement of covers		Pass
59.1b	Movable leads are not bent around a radius of less than five times the outer diameter of the lead		N/A
59.1c	Insulating sleeving adequately secured		Pass
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test		N/A
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material		N/A
59.1d	Aluminum wires of less than 16 mm ² cross-section not used		N/A
59.1f	Connecting cords between equipment parts considered as belonging to the equipment		N/A
59.2	Insulation		Pass
59.2b	Mechanical strength and resistance to heat and fires retained by all types of insulation	(see appended additional test table)	Pass
59.2c	Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		Pass
	Parts of rubber resistant to ageing		N/A
59.3	Excessive current and voltage protection		Pass
	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 fuseholder		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		N/A
	Oil containers adequately sealed		N/A
	Container allow for the expansion of the oil		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

6.1	TABLE: marking durability		Pass
Marking tested		Remarks	
Rating Marking		The equipment label did not work loose and did not curl at the edges. The marking was clearly readable.	
supplementary information:			
--			

7	TABLE: power input					Pass
Operating condition		Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks
Output: 5Vdc, 1.2A/--		90	50	0.177	8.6	--
Output: 5Vdc, 1.2A/0.25A		100	50	0.165	8.5	The measured input current did not exceed 110% of the unit's ratings.
Output: 5Vdc, 1.2A/0.08A		240	50	0.078	8.2	The measured input current did not exceed 110% of the unit's ratings.
Output: 5Vdc, 1.2A/--		264	50	0.071	8.3	--
Output: 5Vdc, 1.2A/--		90	60	0.170	8.6	--
Output: 5Vdc, 1.2A/0.25A		100	60	0.157	8.5	The measured input current did not exceed 110% of the unit's ratings.
Output: 5Vdc, 1.2A/0.08A		240	60	0.086	8.3	The measured input current did not exceed 110% of the unit's ratings.
Output: 5Vdc, 1.2A/--		264	60	0.082	8.3	--
supplementary information:						
Maximum normal load: 5Vdc, 1.2A						

15b	TABLE: residual voltage in attachment plug										Pass	
Voltage measured between:		Measurements [V]									Remarks	
		1	2	3	4	5	6	7	8	9		10
Supply pins (L to N)		4	0	4	0	0	4	0	4	8	8	L-N>0.1uF
supplementary information:												
--												

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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

17h1	TABLE: defibrillation-proof applied parts				N/A
Test Condition: Fig. 50 or 51	Accessible part of measurement:	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
supplementary information:					

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:					

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

19	TABLE: leakage current				Pass
Type of leakage current and test condition (including single faults)		Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks
Fig 18		--	--	B/A	--
EN, NC, S1=1, S5=N		264	60	<1/<1	MD1 between enclosure and earth
EN, NC, S1=1, S5=R		264	60	<1/<1	MD1 between enclosure and earth
EN, SFC (Neutral Open), S1=0, S5=N		264	60	<1/<1	MD1 between enclosure and earth
EN, SFC (Neutral Open), S1=0, S5=R		264	60	<1/<1	MD1 between enclosure and earth
Fig 18		--	--	B/A	--
EN, NC, S1=1, S5=N		264	60	60.5/61.4	MD1 between output and earth
EN, NC, S1=1, S5=R		264	60	60.5/61.4	MD1 between output and earth
EN, SFC (Neutral Open), S1=0, S5=N		264	60	91.9/91.9	MD1 between output and earth
EN, SFC (Neutral Open), S1=0, S5=R		264	60	92.0/92.1	MD1 between output and earth
supplementary information:					
Output connector leakage current was measured for reference.					
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		

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

20	TABLE: dielectric strength				Pass
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (V)	Test voltage (V)	Remarks	
A-e Between primary and secondary	DI/RI	311	4250	No breakdown	
A-a2 Between primary and enclosure (with metal foil)	DI/RI	311	4250	No breakdown	
Transformer primary and secondary	DI/RI	311	4230	No breakdown	
Transformer primary and core	BI	311	1630	No breakdown	
Transformer secondary and core	SI	311	2630	No breakdown	
Triple insulation wire used in T1	DI/RI	311	6400	No breakdown	
One layer insulation tape used in T1	DI/RI	311	4250	No breakdown	
supplementary information:					
Insulation tape: (a)3M COMPANY ELECTRICAL MARKETS DIV (EMD) Model:1350f-1; (b)JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD Model: CT.					

21	TABLE: mechanical strength			Pass
Part under test	Test (impact, drop, force, handle, rough handling, mobile)	Remarks		
Enclosure (Top, Sides, Bottom)	Force Test (21a)	No damage		
Enclosure (Top, Sides, Bottom)	Impact Test (21b)	No damage		
Enclosure (Top, Sides, Bottom)	Drop Impact Test (21.5, US55)	No damage		
supplementary information:				
--				

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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			
Clause	Requirement + Test	Result - Remark	Verdict

42	TABLE: normal temperature		Pass
Supply voltage: See below Ambient temperature: See below		Test Condition: See below	
Measuring location		Measured temperature (°C)	Remarks
--		90V,60Hz/ 264V,60Hz	--
1.Input wire		46.5/42.0	80
2.AC inlet body		44.1/41.9	75
3.PWB under D5		72.3/64.1	105
4.C2 body		60.4/52.7	105
5.PWB under U1		76.3/69.2	105
6.X1 body		52.4/47.3	85
7.NF1 winding		67.8/56.0	105
8.T1 winding		87.0/85.2	120
9.T1 core		82.1/81.3	120
10.CY1 body		63.0/61.5	85
11.PC1 body		58.6/56.9	100
12.PWB under D4		86.5/83.8	105
13.C7 body		83.3/82.3	105
14.Enclosure inside near T1		51.2/46.5	70
15.Enclosure outside near T1		45.6/41.9	85
16.Ambient		25.0/25.0	--
Duration:		3.0hrs/3.2hrs	--
Shift to 40 degree C		--	--
1.Input wire		61.5/57.0	80
2.AC inlet body		59.1/56.9	75
3.PWB under D5		87.3/79.1	105
4.C2 body		75.4/67.7	105
5.PWB under U1		91.3/84.2	105
6.X1 body		67.4/62.3	85
7.NF1 winding		82.8/71.0	105
8.T1 winding		102.0/100.2	120
9.T1 core		97.1/96.3	120
10.CY1 body		78/76.5	85
11.PC1 body		73.6/71.9	100
12.PWB under D4		101.5/98.8	105
13.C7 body		98.3/97.3	105
14.Enclosure inside near T1		66.2/61.5	70
15.Enclosure outside near T1		60.6/56.9	85
16.Ambient		40.0/40.0	--
Duration:		3.0hrs/3.2hrs	--
COR - indicates measurements taken using change-of-resistance method			
supplementary information:			

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

The temperatures were measured under worst case normal mode defined in as output continuous load at 5Vdc, 1.2A. With a specified ambient temperature of 40 Deg.C, the max. temperature rise is calculated as follows: Winding components (normal condition): -Class B (T1) : $T_{max} = 130 - 10 = 120$ Deg.C Components with:
 - Max. absolute temp. of 105Deg.C (Line choke, bobbin) - Max. absolute temp. of 105Deg.C (Electrolyte capacitor) - Max. absolute temp. of 105Deg.C (PWB) - Max. absolute temp. of 70Deg.C (Enclosure) - Max. absolute temp. of 85Deg.C (Operator accessible moulded material)

44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		Pass
Test type and condition		Part under test	Remarks
93%, 25Deg.C, 48hours		Unit	No dielectric breakdown.
supplementary information:			
--			

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

52	TABLE: abnormal operation		Pass
Test type, condition and clause reference		Observed results	Remarks
D7 Short circuit		Fuse open NC.NT.NB	Test duration: 1S
C2 short circuit		Fuse open NC.NT.NB	Test duration: 1S
PC1 Primary open circuit		The unit shut down, NC.NT.NB	Test duration: 5min Input : 20mA
PC1 Secondary short circuit		The unit shut down, NC.NT.NB	Test duration: 5min Input : 20mA
U1 Pin1 to U1 Pin8 short circuit		Fuse open NC.NT.NB	Test duration: 1S
T1 Pin3 to Pin4 Short circuit		The unit shut down, NC.NT.NB	Test duration: 5min Input : 20mA
Output short circuit		The unit shut down, NC.NT.NB	Test duration: 5min Input : 19mA
Output overload		CT(T1 winding 112.9Deg.C) at 1.65A, increase to 1.7A The unit shut down, NC.NT.NB	Test duration:5.5H
Ventilation openings block		CT(T1 winding 88.1Deg.C), NC.NT.NB	Test duration:4H
supplementary information: NB - No indication of dielectric breakdown NC - Cheesecloth remained intact NT - Tissue paper remained intact CT - Constant temperatures were obtained			

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

56.1	TABLE: list of critical components					Pass
Object/part No.	Manufacturer/ trademark	type/model	technical data	Product Category CCN(s)	Required Marks of Conformity	Photo ID, Item # or other sorting identifier
01.Enclosure	SABIC INNOVATIVE PLASTICS CHINA CO LTD	C6600	V-0, min. 2.5mm thickness, 70 Deg.C, dimension: 107.5 by 76 by 45mm with six slot openings in the bottom enclosure with dimension: 26.0 by 3.0mm and 16.0 by 3.0mm.	QMFZ2	UL	3-01
02.Power Supply Cord (Optional)	Various	Various	Listed, "Hospital Grade" type, Type SJT, Min 125 V/ 250V, VW-1, Min.18AWG x 2C, with NEMA 1-15P or 2- 15Pplug. Other end with cord connected body, suitable for cord size, rating not less than that of attachment plug.	ELBZ/7, ZJCZ and RTRT and AXUT	UL, cUL	
03.Electrolytic Capacitor (C2)	--	--	22uF, 400V, Min. 105 degree C	--	--	3-04
04.Resistor (R6)	--	--	120K ohm, 1/8W	--	--	3-04
05.X Capacitor (CX1)	Various	Various	X1 or X2 Type, 250Vac, 2200pF maximum, Min. 85 degree C	FOWX2/8, FOKY2/8	UL, cUL	3-04
07.Bridge-Diodes (D5,D6,D7,D8)	--	--	1000V, 1A minimum	--	--	3-04
08.PWB	Various	Various	V-0, 105 degree C minimum	ZPMV2	UL	3-04
09.Fuse (F1, F2)	SAVE FUSETECH INC	SS-5	T1A, 250Vac	JDYX2/8	UL, cUL	3-04
09a.Fuse (F1, F2)	Various	Various	T1A, 250Vac	JDYX/7	UL, cUL	3-04

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

(alternate)						
10.Photo Coupler (PC1)	LITE-ON TECHNOLOGY CORP	LTV-817	Rated isolation minimum 5000Vac	FPQU2/8	UL, cUL	3-04
11.Appliance Inlet	TECX-UNIONS TECHNOLOGY CORP	SO-222	2.5A, 250Vac	AXUT2	UL	3-01
11a.Appliance Inlet (alternate)	SUPERCOM WIRE & CABLE CO LTD	SC-12	2.5A, 250Vac	AXUT2	UL	3-01
11c.Appliance Inlet (alternate)	SUN FAIR	S-01-01B	2.5A, 250Vac	AXUT2/8	UL, cUL	3-01
12.Transformer (T1)	--	--	See enclosure 4-01 for detail.	--	--	3-04
12-1.Insulation System	YANN SHNN CO	GH-130	Class B Insulation System	OBJY2	UL	
12-2.Core	--	--	Ferrite, overall Max. 22.0 by Max. 22.0 by 4.8	--	--	
12-3.Bobbin	CHANG CHUN PLASTICS CO LTD	T375J	Phenolic, Rated V-0, 150 degree C minimum, minimum 0.71mm thick	QMFZ2	UL	
12-4.Winding	Various	Various	Copper magnet wire wound concentrically on core.	OBMW2	UL	
12-5.Insulation Tape	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350f-1	Minimum 130 degree C	OANZ2	UL	
12-5a.Insulation Tape (alternate)	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	CT	Minimum 130 degree C	OANZ2	UL	
12-6.Varnish	P D GEORGE/VIKING	V1630FS	Minimum 130 degree C	OBOR2	UL	
12-7.Triple Insulation Wire	GREAT LEOFLON INDUSTRIAL CO LTD	TRW(B)	130 degree C	OBJT2	UL	

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

12-8.Tube	GREAT HOLDING INDUSTRIAL CO LTD	TFL	Maximum 200 degree C, maximum 150V	YDPU2	UL	
13.Varistor (ZNR) (alternate)	THINKING ELECTRONIC INDUSTRIAL CO LTD	TVR07471K	300Vac, 385Vdc	XUHT2/8	UL, cUL	3-04
13a.Varistor (ZNR) (alternate)	CENTRA SCIENCE CORP	CNR-07D471K	300Vac, 385Vdc	XUHT2/8	UL, cUL	3-04
14.DC Output Cord	Various	Various	VW-1, Min. 30V, 80 degree C	AVLV2/8	UL, cUL	3-03
15.AC Wire(input)	Various	Various	VW-1, 300V, 80 degree C	AVLV2/8	UL, cUL	3-03
16.Line Filter(NF1)	--	--	See enclosure 4-02 for detail.	--	--	3-04
16-1. Core	--	--	Ferrite, overall Max.17.5 by Max. 18.0 by 3.0 mm	--	--	
16-2.Bobbin	CHANG CHUN PLASTICS CO LTD	T375J	Phenolic, Rated V-0, 150 degree C minimum	QMFZ2	UL	
16-3.Winding	Various	Various	Copper magnet wire wound concentrically on core.	OBMW2	UL	
17.Label	AVERY (CHINA) CO LTD	72826	Min 70 Deg.C and for application to plastic enclosure.	PGJI2	UL	
18.Insulating Tubing/Sleeving	Various	Various	FEP, PTFE, PVC, TFE, neoprene, polyimide or marked VW-1; 105 degree C, 300 V	UZFT2, YDPU2, YDTU2	UL	3-04

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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

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

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

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

57.9.1a	TABLE: transformer short circuit					Pass
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
T1 Pin8-Pin7	Over power protect	--	--	--	5min	The unit shutdown, NC,NT,NB
supplementary information: NB - No indication of dielectric breakdown NC - Cheesecloth remained intact NT - Tissue paper remained intact						

57.9.1b	TABLE: overload						Pass
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current or thermal cutout temp.	Remarks
		Primary	Secondary	Ambient			
T1 After D4	Over power protect	--	112.6	25	8.5H	0.12A	CT at 0.5A, increase to 0.55A the unit shutdown, NC,NT,NB
supplementary information:							
NB - No indication of dielectric breakdown NC - Cheesecloth remained intact NT - Tissue paper remained intact CT - Constant temperatures were obtained							

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			
Clause	Requirement + Test	Result - Remark	Verdict

	TABLE: additional tests		Pass
Clause	Test type and condition	Remarks and observed results	Verdict
55(US Deviation)	Mold Stress Relief - 76.2 Deg.C, 7 Hours	Nocracking and breaking	Pass
59.2	Ball pressure Test - 1Hour	Enclosure(75 Deg.C): 0.1mm	Pass
55(US Deviation)	Ball Drop Test - 0.535 Kg, 1.3M	No cracking of the enclosure	Pass
supplementary information:			
--			

Enclosure
National Differences

Canada
USA

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict

Canada - Differences to IEC 60601-1:1988 + A1:1991 + A2:1995			
6	Canadian difference to this clause no longer applicable		N/A
6.61	Point of connection of gas cylinders:		N/A
6.61	- is gas specific		N/A
6.61	- is non-interchangeable		N/A
6.61	- is identified		N/A
56.3a	Medical gas inlet connectors:		N/A
56.3a	- are gas specific		N/A
56.3a	- are non-interchangeable		N/A
56.3a	- are DISS type complying with CGA V-5		N/A
56.3a	- are configured to permit the supply from assemblies complying with CAN/CSA - Z5359-04 (replaces Z305.2)		N/A
56.6a	Where consequential loss of function caused by operation of a thermal cut-out presents a safety hazard, both visible and audible warnings provided		N/A
57.2g	Mains plug of non-permanent installed equipment:		N/A
57.2g	- if molded on type - hospital grade complying with CSA C22.2, No. 21		N/A
57.2g	- hospital grade disassembly type complying with CSA C22.2, No. 42		N/A
57.2g	- if Class II equipment - polarized hospital grade CSA configuration 1-15P	To be evaluated in the end product.	N/A
57.3b	Detachable power supply cords:		Pass
57.3b	- unlikely to be detached accidentally		Pass
57.3b	- impedance of earth contacts presents no safety hazard		N/A
57.3b	- possibility of replacement by a cord which could make equipment hazards minimized		Pass
57.3b	- complies with CSA C22.2 NO. 21		Pass
57.3b	- not smaller than No. 18 AWG		Pass
57.3b	- minimum serviceability of Type SJ for mobile equipment or Type SV for other		Pass
57.9	Canadian difference to this clause no longer applicable		N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict

58.2	Canadian difference to this clause no longer applicable		N/A
59.1	Connecting cables comply with Canadian Electrical Code, Part I		N/A
60	Canadian difference to this clause no longer applicable		N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict

USA - Differences to IEC 60601-1:1988 + A1:1991 + A2:1995			
3.100.1a	Printed wiring boards comply with U.S. National or internationally harmonized component standards unless they are connected totally in a SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a Safety Hazard.	UL R/C PWB used.	Pass
3.100.1b	Lithium batteries comply with U.S. National or internationally harmonized component standards	No batteries.	N/A
3.100.1c	Optical isolators comply with U.S. National or internationally harmonized component standards unless they are connected totally in a SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a Safety Hazard.	UL R/C components.	Pass
3.100.1d	Wiring and tubing comply with U.S. National or internationally harmonized component standards unless they are connected totally in a SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a Safety Hazard.		Pass
3.100.1e	CRT's > 5 inches comply with U.S. National or internationally harmonized component standards	No CRT	N/A
3.101.1	Primary circuit components up to isolation transformer meet U.S. national or international harmonized component standards		Pass
6	a) All words except the signal words in "CAUTION", "WARNING", and "DANGER" markings at least 1.6 mm (1/16 inch) high		N/A
6	b) Signal words "CAUTION", "WARNING", and "DANGER" at least 2.8 mm (7/64 inch)		N/A
6	c) Letters in contrast color to the background		N/A
6	Equipment capable of emitting ionizing radiation provided with warning statement		N/A
6	If equipment produced in more than one factory, factory identification marked on the equipment		Pass
6	Multiple-voltage equipment intended for permanent connection marked with voltage for which it is connected when shipped		N/A
6.2l	Statement for suitable wiring materials at temperatures over 60 °C		N/A
6.6a	Identification of the content of gas cylinders in accordance with the color coding requirement of ANSI/NFPA99.		N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
6.8	Cord-connected equipment provided with instructions to indicate type of attachment plug for alternate voltage		N/A
10.2.2a	Rated voltage not exceeding 250 Vdc or single phase ac or 600 V polyphase ac for equipment up to 4kVA	Single phase, 100-240Vac	Pass
10.2.2a	Rated voltage not exceeding 600 V for all other equipment		N/A
14	Fixed equipment and permanent equipment is Class I		N/A
18m	Earthing of X-ray equipment: All parts operating at over 600 V ac, 850 V dc, or 850 V peak are enclosed in protectively earthed enclosures		N/A
18m	Earthing of X-ray equipment: Connections from high-voltage equipment to other high voltage components made with high voltage shielded cables		N/A
18n	Accessible non-current carrying conductive parts are protectively earthed		N/A
19	Enclosure and earth leakage currents comply with U.S. limits		Pass
22	When risk of injury can occur, end stops are provided		N/A
22	End stops have mechanical strength as determined by the test		N/A
22.4	Dangerous movements of equipment parts which may cause physical injury to the patient or operator are possible only by the continuous activation by the operator		N/A
22.7a	Emergency off switch has red actuator		N/A
22.7a	Emergency off switch: once actuated, maintains the equipment in "off" condition until action, different from that used to actuate, is performed		N/A
22.7a	Emergency off switch is readily accessible to operator		N/A
22.7b	Emergency off switch is marked with word "STOP" or symbol 5110 of IEC 878 in compliance with U.S. Clause 6		N/A
22.7b	Emergency off switch: separate and independent of		N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
	the intended movement control		
28.3	No evidence of damage to a safety catch after test		N/A
28.3	Safety catch marking provided		N/A
28.4	No damage to structural parts as a result of loading test		N/A
42	Insulation systems with measured temperatures exceeding Class A 105°C (based on 40°C ambient) comply with UL1446	Class B insulation system.	Pass
55	Polymeric enclosures and external combustible surfaces		Pass
55	Polymeric enclosures comply with: Conductive coatings applied to nonmetallic surfaces comply with UL 746C		N/A
55	External combustible surface of more than 9.47 m2 or single dimension of 3.7 m have flame spread rating not exceeding 75 (Steiner Tunnel Test)		N/A
55	External combustible surface of more than 4.74 m2 but not exceeding 9.47 m2 have flame spread rating not exceeding 75 (Radiant Panel or Steiner Tunnel Test)		N/A
55	Polymeric enclosures for transportable equipment rated 94V-2 or better	V-0 material used.	Pass
55	Polymeric enclosures for fixed or stationary equipment rated 94V-0 or better		N/A
55	Polymeric enclosures withstand 6.78 Nm impact test		Pass
55	Polymeric enclosures: no deformation after mold stress test		Pass
55	Polymeric enclosures of hand-held equipment withstands 1.22 m drop test		Pass
56.3a	Connector, pin, plug attached to patient connected lead or contact cannot engage any part on the equipment, including separable cord set		N/A
56.3a	Connector, pin, plug attached to patient connected lead or contact cannot make contact with live parts of power receptacle outlet (if product can be used without professional supervision)		N/A
57	Permanently connected equipment provided with field wiring provision in accordance with NEC, ANSI/NFPA 70		N/A
57.2	Power cord mains plug is "Hospital Grade" type		Pass

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
57.2	Grounding reliability marking provided		N/A
57.2	Plug for radiography equipment acceptable for current not less than 50 % of maximum input		N/A
57.2	Plug acceptable for use with current not less than 125 % of rated current		Pass
57.2	Plug acceptable for voltage for which the equipment is configured when shipped		Pass
57.2	Polarized plug wired such that the center contact of edison-base lampholder, single-pole switch or single-pole overcurrent device connected in ungrounded side		N/A
57.3b	Detachable power supply cord unlikely to become detached accidentally		Pass
57.3b	Flexible cord is of type acceptable for application		Pass
57.3b	Flexible cord not smaller than 18 AWG		Pass
57.3b	Flexible cord complies with serviceability requirements		N/A
57.5b	If leads are provided for connection to branch circuit, the free end is in separate compartment		N/A
57.5b	If leads are provided for connection to branch circuit, the free length of leads inside field-wiring compartment is at least 152 mm long		N/A
58.2	Connections are mechanically secured in addition to soldering		N/A
59.1	Installation of connecting cords between parts of equipment in compliance with NEC		N/A
59.1	Cable type acceptable for external interconnection		N/A
400	Oxygen		N/A
400.1	At least one of the following three requirements is satisfied:		N/A
400.1.1	Electrical components separated by barrier per 400.2		N/A
400.1.2	Compartments with electrical components ventilated per 400.3		N/A
400.1.3	Electrical components comply with 400.4 so that cannot be a source of ignition		N/A
400.2	Barrier required by 400.1 is sealed at all joints and holes		N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
400.3	Ventilation required by 400.1 is such that oxygen content does not exceed 4% above ambient		N/A
400.4	Under N.C. and S.F.C. the product of the value of no load rms voltage and short circuit rms current less than 10 VA		N/A
400.4	Surface temperature of components below 300°C in N.C. and S.F.C		N/A
400.5	External exhaust gas outlets located at least 20 cm from any electrical component mounted on the outside		N/A
400.6	Hospital beds intended for use with oxygen administering equipment provided with required markings		N/A
400.7	Pendant controls on hospital beds with oxygen administering equipment marked as required		N/A
400.8	Instructions for installation are in compliance with requirements of this clause		N/A
600.1	Separate power units packed with equipment		N/A
600.1	Separate power units provided with correlation marking		N/A
600.2.1	Direct plug-in unit construction and performance comply with required sections of UL1310		N/A
600.2.2	Direct plug-in unit external temperature rise during overheating test do not exceed 65°C		N/A
600.2.3	If direct plug-in unit provided with a mounting tab - unit marked as required by UL1310		N/A