

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, First Edition (2003).	
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

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
	GTM91075-6012	Exempt	-	Exempt
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-A10-UL-1
Compiled by	Claire Arakaki
Reviewed by	David V. Alma
Date of issue	2006-11-09
Standards	UL 60601-1, First Edition (2003) CAN/CSA-C22.2 No.601.1-M90 with updates 1 and 2
Test procedure	Component Recognition
Non-standard test method	N/A
Test item description	Switching Power Supply
Trademark	
Model and/or type reference	GTM91075-6012
Rating(s)	Input: 120 V, 60 Hz, 0.5 A Output: 12 V, 5.0 A Max

GENERAL INFORMATION			
Test item particulars (see also clause 5):			
Classification of installation and use	Portable		
Supply connection	Direct Plug-In		
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	The product covered by this report is a direct plug-in unit intended to provide power to and intended for use with Medical 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:	CAN/CSA C22.2 No. 601.1-M90 (R1997), CAN/CSA C22.2 No. 601.1S1-94, and CAN/CSA C22.2 No. 601.1B-98 (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
CE1.5	The following accessories were investigated for use with the product:	None
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	No accompanying documents were provided.	--
CF2.1	The following tests shall be conducted in the end-product evaluation: 1) Leakage Current Measurements, 2) Temperature Tests, 3) Dielectric Voltage Withstand Tests.	--
CF2.2	This product has been judged on the basis of the required spacings in the First Edition of the standard for Medical Equipment, UL60601-1.	--

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

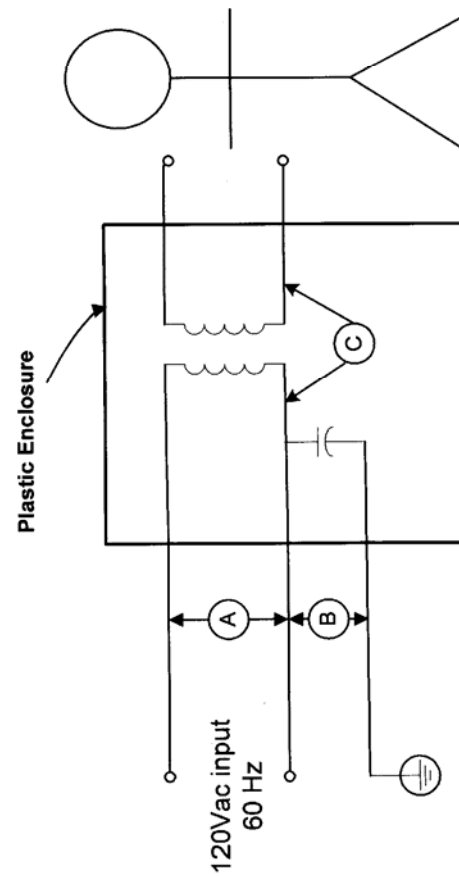
3	GENERAL REQUIREMENTS		Pass
3.1	Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (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		Pass

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	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

INSULATION DIAGRAM

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	BOP	120	2.0	1.0	3.0	3.0	Pass
B	BI	120	3.0	1.6	3.0	2.5	Pass
C	DI/RI	120	6.0	3.2	8.0	7.0	Pass

INSULATION DIAGRAM CONVENTIONS

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

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

IEC 60601			
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	Globtek Inc.	Pass
6.1f	Model or type reference	GTM91075-6012	Pass
6.1g	Rated supply voltages or voltage range(s)	120 V	Pass
	Number of phases	Single phase only; no marking required	Pass
	Type of current.....	AC	Pass
6.1h	Rated frequency or rated frequency range(s) (Hz) :	60 Hz	Pass
6.1j	Rated power input (VA, W or A)	0.5 A	Pass
6.1k	Power output of auxiliary mains socket - outlets		N/A
6.1l	Class II symbol		N/A
	Symbol for degree of protection against ingress of water provided	IPX0, no marking necessary	N/A
	Symbol for protection against electric shock	no applied parts provided	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)	No marking provided; unit is for continuous operation	N/A
6.1n	Types and rating of external accessible fuses.....		N/A
6.1p	Ratings of external output:.....	12 V, 5.0 A max for use with 12 V Halogen lamps, 60W MAx	Pass
6.1q	Symbol for physiological effect(s):		N/A
	- attention, consult accompanying documents		N/A
	- non-ionizing radiation, or symbols as adopted by		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	ISO or IEC 417		
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		Pass
6.2	Marking on the inside of equipment or equipment parts		N/A
6.2a	Nominal voltage of permanently installed equipment	Sonically welded enclosure; unit interior not accessible for users or service personnel.	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		N/A
6.2f	Protective earth terminal	Terminated at PWB	N/A
6.2g	Functional earth terminal		N/A
6.2h	Supply neutral conductor in permanently installed equipment (N)		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		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	connections are clearly marked adjacent to the terminals (or in accompanying documents for small 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		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)		Pass
6.5	Colors of the insulation of conductors		Pass
6.5a	Protective earth conductor has green/yellow insulation		Pass
6.5b	All insulations of internal protective earth conductors are green/yellow at least at their terminations		Pass
6.5c	Only protective or functional earthing, or potential equalization conductors are green/yellow		Pass
6.5d	Color of neutral conductor :		N/A
6.5e	Colors of phase conductor(s) :		N/A
	- Compliance with IEC 227 and IEC 245		N/A
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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
6.6a	In accordance with ISO ISO/R 32		N/A
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		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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance		N/A
	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		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		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	specified in accompanying documents and marked on packaging		
--	---	--	--

7	POWER INPUT		Pass
	Power Input Measurements		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		Pass
	Rated voltage not exceeding 500 V for all other equipment		N/A
	Rated input frequency not more than 1kHz		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		Pass
14.4b	Equipment supplied from external dc source of reverse polarity results in no safety hazard		N/A
14.5a	Dual classification for internally powered equipment with a means of connection to supply mains		N/A
14.5b	Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected		N/A
14.6c	Applied parts intended for direct cardiac application are of type CF		N/A

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		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		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		N/A
	- Removal possible only with the aid of a tool		N/A
	- Use of automatic device making parts not live when the enclosure is opened or removed		N/A
	- Exception 16e applied to the following parts..... :		N/A
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts		N/A

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		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		Pass
17h	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N/A
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator		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		Pass
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal		Pass
18b	Protective earth terminals suitable for connection to the protective earth conductor		Pass
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 $\leq 0.1 \text{ Ohm}$		Pass
	- 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		Pass
	- earth leakage current		Pass
	- enclosure leakage current		Pass
	- patient leakage current		N/A
	- patient auxiliary current		N/A

20	DIELECTRIC STRENGTH		Pass
	Overall compliance with Clause 20		Pass

21	MECHANICAL STRENGTH		Pass
21a	Sufficient rigidity of an enclosure tested by: force of 45 N		Pass
21b	Sufficient strength of an enclosure tested by: impact hammer		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		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°		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		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		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		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		Pass
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529		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		Pass
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard		N/A
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function		Pass
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)		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		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		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		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		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		N/A
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard		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		N/A
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs		N/A
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment		Pass
56.6	Temperature and overload control devices		N/A
56.6a	Thermal cut-outs which have to be reset by a		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	soldering not fitted in equipment		
	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 incorrect connection without the use of tool		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	Removal of power supply from receptacle disconnects all poles simultaneously.	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		N/A
57.1f	Mains switches not incorporated in a power supply cord		N/A
57.1h	Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a		N/A
57.1m	Fuses and semiconductor devices not used as isolating devices		Pass
57.2	Mains connectors and appliance inlets		N/A
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		N/A
57.3a	Not more than one connection to a particular supply mains		N/A
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously		N/A
	The mains plug has only one power supply cord		N/A
	Non-permanently connected equipment provided with power supply cord or appliance inlet		N/A
57.3b	Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53		N/A
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C		N/A
57.3c	Nominal cross-sectional area of conductors of power supply cords not less than in Table XV		N/A

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		Pass
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current	Fuses provided in both phases of the main supply.	Pass
	Protective earth conductor not fused		Pass
	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		Pass
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard		Pass
57.9	Mains supply transformers		Pass
57.9.1	Overheating		Pass
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		Pass
57.9.1a	Short-circuit of secondary windings not caused excessive temperature	(see appended table 57.9.1a)	Pass
57.9.1b	Overload of secondary windings not caused excessive temperature	(see appended table 57.9.1b)	Pass

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		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		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 Insulated Wire	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		Pass
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 not required if short-circuiting does not produce a safety hazard		N/A
57.10c	Creepage distances or clearances of at least 4 mm		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	are maintained between defibrillation-proof applied parts and other parts		
--	---	--	--

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		Pass
59.2c	Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		N/A
	Parts of rubber resistant to ageing		N/A
59.3	Excessive current and voltage protection		N/A
	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

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
Enclosure	Teijin Chemicals	LN-1250	Rated V-0. Overall 74 by 49 by 40.5 mm. Minimum 2.3 mm thick. Constructed of two parts secured together by ultrasonic welding.	QMFZ2	R/C UL	
Enclosure - Alternate	GE	SE-100	Same as above.	QMFZ2	R/C UL	
Enclosure - Alternate	Chi Mei	PA-769	Same as above.	QMFZ2	R/C UL	
Printed wiring board	--	--	Min V-1, 105°C	ZPMV2	UL/cUL R/C	
Fuses (F1, F2)	Wickmann	392	1A, 250V Time lag (Not relied on for testing)	JDXY2	R/C UL	
Alternate Fuse (F1, F2)	Littelfuse	392	250V, 1 A, Time lag	--	--	
Alternate Fuse (F1, F2)	Conquer	MST	250V, 1 A, Time lag;	--	--	
Alternate Fuse (F1, F2)	BEL	RST	250V, 1 A, Time lag;	--	--	
Across-the-line Capacitor (CX1) CX1 is an optional component	Ultra Tech	HQX	0.47uf, 275V, X2 Max.	FOKY2, or FOWX2	UL/cUL R/C	
X Capacitor (CX1) - Alternate	Arcotronics	MKP	0.47uf, 275V, X2 Max.	FOKY2, or FOWX2	UL/cUL R/C	
X Capacitor (CX1) - Alternate	Pilcor	PCX2	0.47uf, 275V, X2 Max.	FOKY2, or FOWX2	UL/cUL R/C	
X Capacitor (CX1) - Alternate	Philips Electronics Building Elements	PCX2 335	0.47uf, 275V, X2 Max.	FOKY2, or FOWX2	UL/cUL R/C	
X Capacitor (CX1) -	Okaya Electric	RE	0.47uf, 275V, X2	FOKY2, or	UL/cUL R/C	

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

Alternate	Industries Co. Ltd.		Max.	FOWX2		
X Capacitor (CX1) - Alternate	Dain	MPX	0.47uf, 275V, X2 Max.	FOKY2, or FOWX2	UL/cUL R/C	
X Capacitor (CX1) - Alternate	Europtronic	MPX	0.47uf, 275V, X2 Max.	FOKY2, or FOWX2	UL/cUL R/C	
Resistor (R3)	SAE Resistor	RSN	1 Ohm, 1/2W Metal Oxide Film Resistor (Relied on for Abnormal Testing)	--	--	
Bleeding Resistors (R1, R2) R1 and R2 are optional	--	--	470K, 1/8W, carbon	--	--	
Bulk Capacitor (C1)	--	--	1uF, 250V Min.	--	--	
Diode Bridge (BD1)	--	--	1A, 200V Min.	--	--	
Capacitor, bridging (CY1) (Optional)	Murata	KX	470pF, 250V, Y1 Max	FOKY2, or FOWX2	UL/cUL R/C	
Capacitor, bridging (CY1) -Alternate	TDK	CD	470pF, 250V, Y1 Max	FOKY2, or FOWX2	UL/cUL R/C	
Capacitor, bridging (CY1) -Alternate	Welson Industrial Co. Ltd.	WD	470pF, 250V, Y1 Max	FOKY2, or FOWX2	UL/cUL R/C	
Capacitor, bridging (CY1) -Alternate	Chyun Fuh Electronic	CD	470pF, 250V, Y1 Max	FOKY2, or FOWX2	UL/cUL R/C	
Y-Capacitors (CY2, CY3)	Pan Overseas	AC	470pF, 250V, Y2 Max	FOKY2, or FOWX2	UL/cUL R/C	
Y-Capacitors (CY2, CY3) - Alternate	Jya-Nay Co. Ltd.	JN	470pF, 250V, Y2 Max	FOKY2, or FOWX2	UL/cUL R/C	
Y-Capacitors (CY2, CY3) - Alternate	Murata	KH	470pF, 250V, Y2 Max	FOKY2, or FOWX2	UL/cUL R/C	
Y-Capacitors (CY2, CY3) - Alternate	TDK	CS	470pF, 250V, Y2 Max	FOKY2, or FOWX2	UL/cUL R/C	
Y-Capacitors (CY2, CY3) - Alternate	Success Electronics Co. Ltd.	SB	470pF, 250V, Y2 Max	FOKY2, or FOWX2	UL/cUL R/C	
Y-Capacitors (CY2, CY3)	Welson Industrial Co.	KL	470pF, 250V, Y2	FOKY2, or	UL/cUL R/C	

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

CY3) - Alternate	Ltd.		Max	FOWX2		
Transformer (T1)	--	--	Employs Triple Insulated Wire on the secondary winding. Refer to Supplement 4-01 for details.	--	(Tested in power supply.)	4-01
Triple Insulated Wire	Furukawa Electric Co. Ltd	TEX-B or TEX-E	Reinforced Insulation rated 130°C.	OBJT2	UL/cUL R/C	
Triple Insulated Wire	Rubadue Wire	FEP Teflon	Reinforced Insulation rated 155°C.	OBJT2	UL/cUL R/C	
Gate Drive Transformer (T2)	--	--	Refer to Supplement 4-02 for details.	--	(Tested in power supply.)	4-02
Transistors (Q1, Q2)	--	--	Rated 400V, 7A min. Secured to heatsink by metal screw.	--	--	
Insulator - between Heatsink and transistors	--	--	Min 0.2mm thick.	--	--	
Heatsink	--	--	Copper or Aluminum, L-shaped. 12 mm by 36 mm by 20 mm high, 1.0 mm thick. Secured to printed wiring board by soldering.	--	--	
Internal Wire	--	--	Blue and Brown; AWM, 20 AWG or greater, Vw-1, Style 1015 or equiv., min 300V, 80°C.	AVLV2	UL/cUL R/C	
Ground Wire	--	--	Green/yellow, Same as above except 18 AWG	AVLV2	UL/cUL R/C	
Output Cord	--	--	Style No. 2468, or 1185 AWM, No. 18 AWG min., VW-1, 80°C, 300V, one end soldered to pwb and the other end molded with connector barrel type or stripped and tinned.	AVLV2	UL/cUL R/C	

Issue Date: 2006-11-09

Page 4 of 4

Report Reference #

E172861-A10-UL-1

Correction 1 2006-11-28

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

6.1	TABLE: marking durability		Pass
Marking tested		Remarks	
Rating Label		Pass	
supplementary information:			
--			

7	TABLE: power input					Pass
Operating condition		Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks
Full load 60W Halogen light test load		108	60	0.402	41.2	Pass
Full load 60W Halogen light test load		120	60	0.428	49.0	Pass
Full load 60W Halogen light test load		132	60	0.450	57.3	Pass
supplementary information:						
--						

15b	TABLE: residual voltage in attachment plug										Pass	
Voltage measured between:		Measurements [V]									Remarks	
		1	2	3	4	5	6	7	8	9		10
Supply pins (pin 1 & 2)		10	10	10	10	8	8	0	0	6	8	Pass
Pin 1 and Earth Pin		0	0	16	14	14	0	16	16	0	14	Pass
Pin 2 and Earth Pin		28	36	0	14	16	10	0	36	36	12	Pass
Line pin 1 and enclosure		0	0	0	0	0	0	0	0	0	0	Pass
Pine pin 2 and enclosure		0	0	0	0	0	0	0	0	0	0	Pass
supplementary information:												
--												

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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

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

18	TABLE: protective earthing					Pass
Test location	Test current (A)	Measured voltage (V)	Resistance (ohms)	Remarks		
Ground Pin to trace pad on pwb	25	0.1413	0.0056	10 sec		
supplementary information:						
--						

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		
ER, NC, S1=1, S5=N	132	60	291	PASS		
ER, NC, S1=1, S5=R	132	60	283	PASS		

IEC 60601				
Clause	Requirement + Test	Result - Remark		Verdict
ER, SFC (NEUTRAL OPEN), S1=0, S5=N	132	60	572	PASS
ER, SFC (NEUTRAL OPEN), S1=0, S5=R	132	60	571	PASS
EN, NC, S1=1, S5=N, S7=1	132	60	0	PASS
EN, NC, S1=1, S5=R, S7=1	132	60	0	PASS
EN, SFC (NEUTRAL OPEN), S1=0, S5=N, S7=1	132	60	1	PASS
EN, SFC (NEUTRAL OPEN), S1=0, S5=R, S7=1	132	60	1	PASS
EN, SFC (GROUND OPEN), S1=1, S5=N, S7=0	132	60	0	PASS
EN, SFC (GROUND OPEN), S1=1, S5=R, S7=0	132	60	0	PASS
supplementary information:				
--				
ER - Earth leakage current EN - Enclosure leakage current P - Patient leakage current PM - Patient leakage current with mains on the applied parts PA - Patient auxiliary current Fig. 15 - refers to Fig. 15 in IEC601-1 MD - Measuring device		A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition		

20	TABLE: dielectric strength				Pass
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (V)	Test voltage (V)	Remarks	
PRI-SEC	DI/RI	120	4242Vdc	NB	
PRI-ENCL	BI	120	2121Vdc	NB	
supplementary information:					
--					

21	TABLE: mechanical strength		Pass
Part under test	Test (impact, drop, force, handle, rough handling, mobile)	Remarks	
Encl	DROP	Pass	
supplementary information:			
--			

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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

42	TABLE: normal temperature			Pass
Supply voltage: 120V, 60 Hz Ambient temperature: 21.4		Test Condition: Full load: 60 W Halogen Test load		
Measuring location			Measured temperature (°C)	Remarks
--			Horz/Vert	--
Encl top			29.1/30.1	Pass
T1 winding			72.9/68.8	Pass
L1 outerwrap			57.2/59.9	Pass
CX1 top			45.6/49.2	Pass
BD1			77.9/78.4	Pass
C1			59.7/59.0	Pass
Q1 body			65.0/66.5	Pass
Q2 heatsink			65.4/67.9	Pass
R13 (next to pwb)			68.3/67.9	Pass
Output wire: interior next to T1 winding			63.4/60.4	Pass
Ambient			21.4/20.2	Pass
COR - indicates measurements taken using change-of-resistance method				
supplementary information:				
--				

44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		Pass
Test type and condition		Part under test	Remarks
Humidity cl. 44.5		Power Supply	Pass
supplementary information:			

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

--

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

52	TABLE: abnormal operation		Pass
Test type, condition and clause reference		Observed results	Remarks
52.5.9		--	--
BD1 short "+" to "AC"		R3 opened @ < 1 sec	T1 =23.2 deg C
C1		R3 opened @ < 1 sec	T1=25.0 deg C
Q1 C - E		Unit shuts down, no damage, 1 hr duration	T1=45.8 deg C
Q1 C - B		Unit shuts down, no damage, 1 hr duration	T1=25.7 deg C
C2		Unit shuts down, no damage, 1 hr duration	T1=45.5 deg C
C6		R3 opened @ < 1 sec	T1=25.6 degC
supplementary information:			
Test repeated 3 times with same results.			

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

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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:					

57.9.1a	TABLE: transformer short circuit					Pass
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
SEC	1.0A Fuse, F1 & F2	Outerwr ap 30.3	--	20.9	4 hrs	Encl temp = 21.6
supplementary information:						
--						

57.9.1b	TABLE: overload						Pass
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current or thermal cutout temp.	Remarks
		Primary	Secondary	Ambient			
SEC	1.0A fuse F1 & F2	Outerwr ap 101.0	--	21.3	4 hrs	0.55A input	Encl temp = 44.0 Monitored input current to determine fold back
supplementary information:							
--							

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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

	TABLE: additional tests		Pass
Clause	Test type and condition	Remarks and observed results	Verdict
UL1310, Clause 41	train Relief Test	No displacement	Pass
UL1310, Clause 43	Blade Secureness Test : (Direct Plug-in Unit)	No Damage	Pass
UL1310, Clause 45	Input Contact Security test : (Direct Plug-in Unit)	No Damage	Pass
UL1310, Clause 46.2	Impact Test : (Direct Plug-in Unit)	No Damage	Pass
UL1310, Clause 46.5	Resistance to Crushing Test : (Direct Plug-in Unit)	No Damage	Pass
UL1310, Clause	Strain Relief After Mold Stress Relief Distortion Test	--	Pass
UL1310, Clause 7.11	Weight and Moment Determination : (Direct Plug-in Unit)	WX = 2951.60 g-m	Pass
supplementary information:			
--			