

COVER PAGE FOR TEST REPORT

Product Category:	Power Supplies, Medical and Dental
Product Category CCN:	QQHM2, QQHM8
Complementary Product Categories:	Power Supplies for Information Technology Equipment Including Electrical Business Equipment(QQGQ2, QQGQ8)
Test Procedure:	Component Recognition
Product:	Switching Power Supply
Model/Type Reference:	GTMB1057-6010, -6012, -6015, -6018, -6019, -6020, -6022, -6024, -6030. Model numbers may be followed by an additional suffix X.X. Where X.X. represents the output deviation from the standard model; subtract X.X. from the standard output voltage to obtain the intended output voltage.
Rating(s):	Input: 100-240 VAC, 50-60Hz, 1.5A Output: 10-30 VDC, 2-6 A, 60W
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, 1st Edition, 2003-11 (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 Technical Criteria2. Clause Verdicts3. Enclosures	

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Correction 1 2007-02-19

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Report Reference #

E172861-A8-UL-1

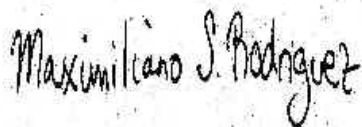
This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up 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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Reviewed By:



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SPECIFIC TECHNICAL CRITERIA

TEST REPORT UL 60601-1 Medical Electrical Equipment Part 1: General requirements for safety	
Report Reference No	E172861-A8-UL-1
Compiled by	Maximiliano S. Rodriguez
Reviewed by	David V. Alma
Date of issue	2006-09-18
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, 1st Edition, 2003-11 (Medical Electrical Equipment - Part 1: General Requirements for Safety)
Test procedure	Component Recognition
Non-standard test method	N/A
Test item description	Switching Power Supply
Trademark	
Model and/or type reference	GTMB1057-6010, -6012, -6015, -6018, -6019, -6020, -6022, -6024, -6030. Model numbers may be followed by an additional suffix X.X. Where X.X. represents the output deviation from the standard model; subtract X.X. from the standard output voltage to obtain the intended output voltage.
Rating(s)	Input: 100-240 VAC, 50-60Hz, 1.5A Output: 10-30 VDC, 2-6 A, 60W

GENERAL INFORMATION			
Test item particulars (see also clause 5):			
Classification of installation and use	Stationary		
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	The products covered by this report are switching power supplies, intended to provide power to and intended for use with Medical Electrical Equipment.
CC1.0	Model Differences
CC1.1	Differences within the Series are limited to minor component changes to determine specific output voltage and current parameters.
CD1.0	Additional Information

CD1.1	These units were evaluated to comply with both IEC/UL 60601-1 1st Edition, and IEC/UL 60950 3rd Edition. Where test procedures or acceptable limits were more stringent in one standard, data taken was considered acceptable for both standards' requirements.	
	These devices are considered component power supplies for use with other Medical Electrical equipment and therefore does not require EMC coverage.	
CE1.0	Technical Considerations	
CE1.1	The product was investigated to the following additional standards:	CAN/CSA C22.2 No. 601.1-M90 (R1997), EN 60601-1: 1990 + A1:1993 + A2:1995 + A13:1996(except EMC limitations, EN 60601-1-2, Biocompatibility, EN 10993-1, Programmable Electronic Systems, IEC 60601-1-4)
CE1.2	The product was not investigated to the following standards or clauses:	Clause 36, Electromagnetic Compatibility (IEC 601-1-2), Clause 52.1, Programmable Electronic Systems (IEC 601-1-4), Clause 48, Biocompatibility (ISO 10993-1)
CE1.3	The product is Classified only to the following hazards:	Shock, Fire Mechanical Stress
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:	N/A
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. Documentation shall be provided as part of the end product investigation.	--
CF2.1	These units are considered acceptable for use in a maximum ambient of 40°C.	--
CF2.2	The isolation transformer (T1) complies with Class B (130°C) limits.	--

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		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		-

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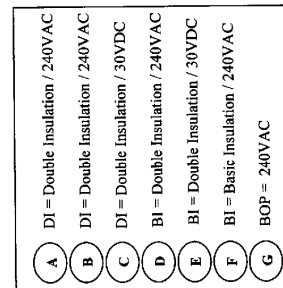
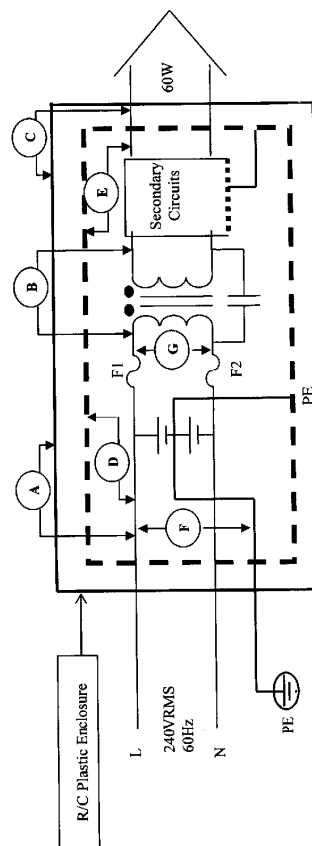
	period..... :		
	-continuous operation with short-time, stated permissible loading time :		-
	-continuous operation with intermittent, stated permissible loading/rest time :		-

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM

Insulation Diagram

Medical Equipment, GTMB1057 Series Power Supplies



Represents protective earth connections.

Represents a copper shield, copper shield is considered PE.

Represents functional earth connections.

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

TABLE: to insulation diagram							
Area	Insulation type: operational / basic / supplementary / double / reinforced	Referenc e voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A	DI	240	8	5	DTI = 1.83	DTI = 1.83	
B	DI	240	8	5	8	5.5	
C	DI	30	4	2	DTI = 1.83	DTI = 1.83	
D	BI	240	4	2.5	DTI = 0.34	DTI = 0.34	
E	BI	30	2	1	DTI = 0.34	DTI = 0.34	
F	BI	240	4	2.5	4	4	
G	BOP	240	3	1.6	4	4	

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.

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		Pass
6.1e	Name and/or trademark of the manufacturer or supplier	Globtek trademark	Pass
6.1f	Model or type reference.....	Model number provided	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
6.1g	Rated supply voltages or voltage range(s)		Pass
	Number of phases :	Single	Pass
	Type of current :	Input: AC, Output: DC	Pass
6.1h	Rated frequency or rated frequency range(s) (Hz) :	50-60 Hz	Pass
6.1j	Rated power input (VA, W or A) :	1.5A	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 :		N/A
	Symbol for protection against electric shock :		N/A
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets		N/A
	Symbol for protection of defibrillation-proof applied parts		N/A
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N/A
6.1m	Mode of operation (if no marking, suitable for continuous operation)		Pass
6.1n	Types and rating of external accessible fuses :		N/A
6.1p	Ratings of external output:..... :	10-30V, 2-6A (Rated accordingly to provide 60W)	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
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

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Clause	Requirement + Test	Result - Remark	Verdict
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		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		N/A
6.2f	Protective earth terminal		Pass
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 connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)		N/A
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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
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 : IEC320 Inlet		N/A
6.5e	Colors of phase conductor(s) : IEC320 Inlet		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
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		Pass
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	LED within the visible light range. See Supp. 7-03 for additional information.	Pass
6.7b	Color red used only for push-buttons by which a function is interrupted in case of emergency		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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
	- 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

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Clause	Requirement + Test	Result - Remark	Verdict

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 on packaging		N/A

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		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	by the manufacturer		
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		N/A
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

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		Pass

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	live parts, and with parts which can become live (finger, pin, hook test)		
	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		Pass
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

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		N/A

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	not protectively earthed		
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

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		N/A
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

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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 $\leq 0.1 \text{ Ohm}$		Pass
	- 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

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:		Pass

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	force of 45 N		
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

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

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Clause	Requirement + Test	Result - Remark	Verdict

	Means for stopping of movements operate as a result of one single action		N/A
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23	SURFACES, CORNERS AND EDGES		Pass
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered		Pass

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

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		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	hidden defects, or on parts having safety factors not complying with Sub-clause 28.4		
	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 ≤ 130 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

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

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Clause	Requirement + Test	Result - Remark	Verdict

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

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		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	withstand the hydraulic test pressure		
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

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

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Clause	Requirement + Test	Result - Remark	Verdict

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

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		Pass
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

56	COMPONENTS AND GENERAL ASSEMBLY		Pass
	List of critical components		Pass
56.1b	Ratings of components not in conflict with the		Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	conditions of use in equipment		
	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		N/A
56.3a	Connectors provide separation required by Sub-clause 17g		Pass
	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		Pass
	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		Pass
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 soldering not fitted in equipment		N/A
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	limits		
	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):		Pass
	- to indicate that equipment is energized	LED within the visible light range. See Supp. 7-03 for additional details.	Pass
	- 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
56.10c	Stops are provided on rotating controls:		N/A

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	- 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

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 detachable supply cord (not provided) disconnects all poles simultaneously.	Pass
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents		N/A
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		Pass
57.2e	Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	mains plug		
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
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		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals		
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
	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 mains 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

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Clause	Requirement + Test	Result - Remark	Verdict
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 Table 57.9.1a for details.	Pass
57.9.1b	Overload of secondary windings not caused excessive temperature	See Table 57.9.1b for details.	Pass
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

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Clause	Requirement + Test	Result - Remark	Verdict

	- 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		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 for additional details.	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 are maintained between defibrillation-proof applied parts and other parts		N/A

58	PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS		Pass
58.1	Clamping means of the protective earth terminal		Pass
	Not be able to loosen without the aid of a tool		Pass
	Screws for internal earth connections are covered or protected against loosening from outside		Pass
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal		Pass
58.8	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing		Pass
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting		Pass

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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		N/A
	Components are not likely to be damaged in the normal assembly or replacement of covers		N/A
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	No aluminum wire 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		Pass
	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

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

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Clause	Requirement + Test	Result - Remark	Verdict

	Container allow for the expansion of the oil		N/A
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		N/A
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N/A

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
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
6.1p	Output	Rated output voltage, power, frequency.
6.2f	Protective earth ground	

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
	N/A	N/A	N/A	N/A
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	N/A	N/A	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

6.1	TABLE: marking durability		Pass
Marking tested		Remarks	
Rating label		No damage.	
supplementary information:			

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7	TABLE: power input					Pass
Operating condition		Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		90	50	1.365	76.6	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		100	50	1.244	75.7	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		120	50	1.052	74.7	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		132	50	0.966	74.3	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		220	50	0.634	73.7	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		232	50	0.607	73.6	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		240	50	0.59	73.7	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		264	50	0.548	73.8	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		90	60	1.272	75.3	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		100	60	1.16	74.8	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		120	60	0.977	74.0	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		132	60	0.912	73.9	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		220	60	0.619	73.3	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		232	60	0.599	73.4	
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)		240	60	0.583	73.5	

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Clause	Requirement + Test	Result - Remark	Verdict

50-60Hz, 1.5Arms)					
GTM-B1057-6010, Output loaded to 6.0A (100-264VAC, 50-60Hz, 1.5Arms)	264	60	0.548	73.4	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	90	50	1.194	69.4	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	100	50	1.093	68.7	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	120	50	0.934	68.0	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	132	50	0.858	67.7	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	220	50	0.57	67.6	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	232	50	0.545	67.7	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	240	50	0.53	67.7	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	264	50	0.488	67.8	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	90	60	1.218	69.5	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	100	60	1.13	68.7	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	120	60	1.003	67.9	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	132	60	0.928	67.6	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	220	60	0.55	67.7	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	232	60	0.528	67.8	
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	240	60	0.515	67.8	

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

50-60Hz, 1.5Arms)					
GTM-B1057-6020, Output loaded to 3.0A (100-264VAC, 50-60Hz, 1.5Arms)	264	60	0.485	68.0	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	90	50	1.26	69.2	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	100	50	1.155	68.6	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	120	50	0.985	67.9	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	132	50	0.903	67.7	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	220	50	0.597	67.9	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	232	50	0.57	67.8	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	240	50	0.553	67.7	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	264	50	0.511	67.4	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	90	60	1.221	69.1	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	100	60	1.101	68.4	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	120	60	1.004	67.6	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	132	60	0.974	67.5	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	220	60	0.583	67.5	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	232	60	0.564	67.5	
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	240	60	0.552	67.4	

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

50-60Hz, 1.5Arms)					
GTM-B1057-6030, Output loaded to 2.0A (100-264VAC, 50-60Hz, 1.5Arms)	264	60	0.519	67.2	
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
IEC 320 Pins (Line & Neutral)		40	36	36	40	20	0	36	40	40	20	
IEC 320 Pins (Neutral & Protective Earth)		0	0	0	0	0	0	0	0	0	0	
IEC 320 Pins (Line & Protective Earth)		10	18	10	10	18	18	10	10	10	10	
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:						

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:						

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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
Model GTMB-1057-6010, ground lead termination, from foil, located on secondary side of the PWB to IEC320 ground pin		25	0.1	0.004	Duration 5 seconds
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
ER, NC, S1=1, S5=N, A		264	60	167	Model GTMB1057-6030
ER, NC, S1=1, S5=R, A		264	60	167	Model GTMB1057-6030
ER, SFC (Neutral Open), S1=0, S5=N, A		264	60	303	Model GTMB1057-6030
ER, SFC (Neutral Open), S1=0, S5=R, A		264	60	303	Model GTMB1057-6030
EN, NC, S1=1, S5=N, S7=1, A		264	60	0	Model GTMB1057-6030
EN, NC, S1=1, S5=R, S7=1, A		264	60	0	Model GTMB1057-6030
EN, SFC (NEUTRAL OPEN), S1=0, S5=N, S7=1, A		264	60	1	Model GTMB1057-6030
EN, SFC (NEUTRAL OPEN), S1=0, S5=R, S7=1, A		264	60	1	Model GTMB1057-6030
EN, SFC (GROUND OPEN), S1=1, S5=N, S7=0, A		264	60	3	Model GTMB1057-6030
EN, SFC (GROUND OPEN), S1=1, S5=R, S7=0, A		264	60	3	Model GTMB1057-6030
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		

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	
MAINS TO ENCLOSURE	DI	264	4056	Model GTMB1057-6010	
PRIMARY TO SECONDARY	DI	264	4056	Model GTMB1057-6010	
SECONDARY TO ENCLOSURE	DI	30	500	Model GTMB1057-6010	
PRIMARY TO COPPER FOIL	BI	264	1528	Model GTMB1057-6010	
SECONDARY TO COPPER FOIL	BI	30	500	Model GTMB1057-6010	
MAINS TO PROTECTIVE EARTH	BI	264	1528	Model GTMB1057-6010	
MAINS TO ENCLOSURE	DI	264	4056	Model GTMB1057-6020	
PRIMARY TO SECONDARY	DI	264	4056	Model GTMB1057-6020	
SECONDARY TO ENCLOSURE	DI	30	500	Model GTMB1057-6020	
PRIMARY TO COPPER FOIL	BI	264	1528	Model GTMB1057-6020	
SECONDARY TO COPPER FOIL	BI	30	500	Model GTMB1057-6020	
MAINS TO PROTECTIVE EARTH	BI	264	1528	Model GTMB1057-6020	
MAINS TO ENCLOSURE	DI	264	4056	Model GTMB1057-6030	
PRIMARY TO SECONDARY	DI	264	4056	Model GTMB1057-6030	
SECONDARY TO ENCLOSURE	DI	264	500	Model GTMB1057-6030	
PRIMARY TO COPPER FOIL	BI	30	1528	Model GTMB1057-6030	
SECONDARY TO COPPER FOIL	BI	264	500	Model GTMB1057-6030	
MAINS TO PROTECTIVE EARTH	BI	30	1528	Model GTMB1057-6030	
supplementary information:					
All measurements taken with secondary protective earth connection removed.					

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

21	TABLE: mechanical strength		Pass
Part under test		Test (impact, drop, force, handle, rough handling, mobile)	Remarks
Enclosure Top		Force Test	Model GTMB1057-6030, No damage
Enclosure Top		Impact Test	Model GTMB1057-6030, No damage
Enclosure Body		Drop	Model GTMB1057-6030, No damage
supplementary information:			

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

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

42	TABLE: normal temperature		Pass
Supply voltage: 90V, 50Hz Ambient temperature: 24.1		Test Condition: Worst case as indicated by the input test	
Measuring location		Measured temperature (°C)	Remarks
Outer Enclosure - Top		61.0	Model GTMB1057-6010
Outer Enclosure - Side		61.3	Model GTMB1057-6010
Between IEC320 Inlet & Fuse F2		54.9	Model GTMB1057-6010
Copper Shield Near X-Former		82.7	Model GTMB1057-6010
Fuse F1		71.1	Model GTMB1057-6010
Heat Sink Near Rectifier BD1		95.4	Model GTMB1057-6010
C5 - Top		75.2	Model GTMB1057-6010
X-Former Core - Top		97.0	Model GTMB1057-6010
X-Former Outerwrap		95.5	Model GTMB1057-6010
Output Lead "+"		70.2	Model GTMB1057-6010
Heat Sink Between D3 & D4		97.9	Model GTMB1057-6010
PWB - Bottom Near X-Former Secondary Terminals		87.1	Model GTMB1057-6010
Outer Enclosure - Top		55.7	Model GTMB1057-6020
Outer Enclosure - Side		56.5	Model GTMB1057-6020
Between IEC320 Inlet & Fuse F2		57.1	Model GTMB1057-6020
Copper Shield Near X-Former		69.1	Model GTMB1057-6020
Fuse F1		67.4	Model GTMB1057-6020
Heat Sink Near Rectifier BD1		83.4	Model GTMB1057-6020
C5 - Top		74.1	Model GTMB1057-6020
X-Former Core - Top		104.9	Model GTMB1057-6020
X-Former Outerwrap		106.9	Model GTMB1057-6020
Output Lead "+"		61.4	Model GTMB1057-6020
Heat Sink Between D3 & D4		84.2	Model GTMB1057-6020
PWB - Bottom Near X-Former Secondary Terminals		86.0	Model GTMB1057-6020
Outer Enclosure - Top		54.2	Model GTMB1057-6030
Outer Enclosure - Side		57.2	Model GTMB1057-6030
Between IEC320 Inlet & Fuse F2		54.1	Model GTMB1057-6030
Copper Shield Near X-Former		69.9	Model GTMB1057-6030
Fuse F1		59.6	Model GTMB1057-6030
Heat Sink Near Rectifier BD1		78.2	Model GTMB1057-6030
C5 - Top		72.4	Model GTMB1057-6030
X-Former Core - Top		82.7	Model GTMB1057-6030
X-Former Outerwrap		93.3	Model GTMB1057-6030
Output Lead "+"		64.1	Model GTMB1057-6030
Heat Sink Between D3 & D4		80.9	Model GTMB1057-6030
PWB - Bottom Near X-Former Secondary Terminals		73.5	Model GTMB1057-6030
COR - indicates measurements taken using change-of-resistance method			
supplementary information:			

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		Pass
Test type and condition		Part under test	Remarks
Humidity - 48hrs		Complete Sample	No Damage
supplementary information:			

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

52	TABLE: abnormal operation		Pass
Test type, condition and clause reference		Observed results	Remarks
Failure of components (52.5.9), Short C12		Both fuses opened < 1 sec	No Damage, Model GTMB1057-6030
Failure of components (52.5.9), Short BD1 ("AC" - "+")		Both fuses opened < 1 sec	No Damage, Model GTMB1057-6030
Failure of components (52.5.9), Short C5		Both fuses opened < 1 sec	No Damage, Model GTMB1057-6030
Failure of components (52.5.9), Short D3		Unit went into hic-cup mode, T1 = 34.3 dec C	No Damage, Model GTMB1057-6030
supplementary information:			

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		
S1	F1 - 3.15A, 250V / F2 - 3.15A, 250V / RT - 2.5 ohms, 5A, 170 deg C	43.5	42.1	24.0	4 hrs	Model GTMB1057-6030, Unit went into hic-cup mode, No Damage
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			
S1	F1 - 3.15A, 250V / F2 - 3.15A, 250V / RT - 2.5 ohms, 5A, 170 deg C	123.6	114.7	23.8	4 hrs	2.64A	Model GTMB1057-6030, Temps Stabalized, No Damage
supplementary information:							

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	TABLE: additional tests		Pass
Clause	Test type and condition	Remarks and observed results	Verdict
20.3	Working Voltage Measurement Test	488Vp/205.5Vrms between primary terminal 3 & secondary terminal A	Pass
49	Interruption of Power Supply	Interrupted intended function only	Pass
52.4.1	Power Availability	82.6W, 2.86A	Pass
supplementary information: Model GTMB1057-6030 was tested.			

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

56.1	TABLE: list of critical components			
Object/part No.	Manufacturer/ trademark	type/model	technical data	Product Category CCN(s)
IEC 320 Inlet	Supercom Wire & Cable Co., Ltd. or Equivalent	SC-8R or Equivalent	15A, 250V	AXUT2
Fuse (F1)	Ever Island Electric Co., Ltd.	2000+	3.15A, 250V	JDYX2
Fuse (F2)	Walter Electronic Co., Ltd.	TSD	3.15A, 250V	JDYX2
Capacitor (C1)	Ultra Tech Xiphi Enterprise Co., Ltd. or Equivalent	HQX or Equivalent	250VAC, 0.33uF, X2	FOWX2
Capacitor (C2, C3)	Success Electronics Co., Ltd. or Equivalent	SB 471K or Equivalent	250VAC, 471pF, X1, Y2	FOWX2
Capacitor (C4)	Ultra Tech Xiphi Enterprise Co., Ltd. or Equivalent	HQX or Equivalent	250VAC, 0.1uF, X2	FOWX2
Capacitor (C5)	Various	Various	Electrolytic, rated 105 deg C, 400V, 180ufds	-
Capacitor (C11)	Success Electronics Co., Ltd. or Equivalent	SE 102M or Equivalent	250VAC, 102pF, X1, Y1	FOWX2
Bridge Rectifier (BD1)	SEP Electronic Corp. or Equivalent	KBJ406 or Equivalent	600V, 4A min.	QQQX2
Line Choke (LF1)	Weasy Fortune Enterprises Ltd. or Equivalent	AM198B-LF or Equivalent	See supplement 4-01 for details	-
Alternate Line Choke (LF1)	Speedy Electronic Factory Co., Ltd. or Equivalent	AM198B-LF or Equivalent	See supplement 4-02 for details	-
Line Choke (LF2)	Speedy Electronic Factory Co., Ltd. or Equivalent	AM198B-LF2 or Equivalent	See supplement 4-03 for details	-
Transformer (T1)	Weasy Fortune Enterprises Ltd.	AM198B-T1	supplement 4-04 for details. Class B Insulation.	-
Alternate Transformer (T1)	Yidel Electronic Industry Co., Ltd.	AM198B-T1	supplement 4-05 for details. Class B Insulation.	-
Transformer (T4)	Weasy Fortune Enterprises Ltd.	AM198B-T4	supplement 4-06 for details. Class B Insulation.	-
Alternate Transformer (T4)	Yidel Electronic Industry Co., Ltd.	AM198B-T4	supplement 4-07 for details. Class B Insulation.	-

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

Class B Insulation System	Globtek	GTX-1	130 deg C	OBJY2
Alternate Class B Insulation System	Yao Sheng Electronic Co. Ltd.	YST-JC1, M7A90, M7ADEW, or M7AGHB	130 deg C	OBJY2
Mylar Barrier	Garware Polyester Ltd.	EM6	0.34 mm thick, rated VTM-2 or better, for overall dimensions see supplement 4-08 or equivalent	QMFZ2
Copper Shield	Various	Various	Copper, 173(L) x 81(W) mm, 0.21 mm thick min.	-
Enclosure	GE Plastics Japan Ltd	940	94V-0, For overall dimensions see supplement 4-11	QMFZ2
Opto-Coupler (IC1)	Everlight Electronics Co., Ltd.	EL817	5000VAC Isolation min.	FPQU2
Alternate Opto-Coupler (IC1)	Liton Electronic Co., Ltd.	LTV817	5000VAC Isolation min.	FPQU2
Alternate Opto-Coupler (IC1)	Sharp Corp.	PC817	5000VAC Isolation min.	FPQU2
Printed Wiring Board	Various	Various	V-0, 1.68 mm thick, see supplement 5-01 for details	ZPMV2
Output Cord	Various	Various	18 AWG, 80 deg C. For Models with rated outputs greater than 20 V.	AVLV2
Output Cord	Various	Various	16 AWG, 105 deg C. For Models with outputs rated less than 20v.	AVLV2
Thermal Pad	Various	T4000 or Equivalent	Rubber, 94V-0, 6000 VAC isolation. Overall 40 (L) x 18 (W) x 5 (T) mm. Located over bulk cap C5.	-

Enclosure
National Differences

Canada
United States

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		N/A
57.3b	Detachable power supply cords:		N/A
57.3b	- unlikely to be detached accidentally		N/A
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		N/A
57.3b	- complies with CSA C22.2 NO. 21		N/A
57.3b	- not smaller than No. 18 AWG		N/A
57.3b	- minimum serviceability of Type SJ for mobile equipment or Type SV for other		N/A
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

United States - 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.		Pass
3.100.1b	Lithium batteries comply with U.S. National or internationally harmonized component standards		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.		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		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 in "CAUTION", WARNING", and "DANGER" markings at least 1.6 mm (1/16 inch) high		Pass
6	b) Signal words "CAUTION", WARNING", and "DANGER" at least 2.8 mm (7/64 inch)		Pass
6	c) Letters in contrast color to the background		Pass
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		N/A
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		N/A
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

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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		Pass
55	Polymeric enclosures and external combustible surfaces		Pass
55	Polymeric enclosures comply with: Conductive coatings applied to nonmetallic surfaces comply with UL 746C		Pass
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		N/A
55	Polymeric enclosures for fixed or stationary equipment rated 94V-0 or better		Pass
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		N/A
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	Detachable cord not provided.	N/A

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SubClause	Difference + Test	Result - Remark	Verdict
57.2	Grounding reliability marking provided	`	Pass
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		N/A
57.2	Plug acceptable for voltage for which the equipment is configured when shipped		N/A
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		N/A
57.3b	Flexible cord is of type acceptable for application		N/A
57.3b	Flexible cord not smaller than 18 AWG		N/A
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		Pass
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

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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