Test Report issued under the responsibility of:





#### IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance Report Reference No.....: 140900434SHA-001 Date of issue .....: 2014-11-10 Modification 1: 2017-07-17 Total number of pages ..... 14 CB Testing Laboratory..... Intertek Testing Services Shanghai Building No.86, 1198 Qinzhou Road (North), 200233 Shanghai, Address ..... China Applicant's name..... GlobTek, Inc. Address ..... 186 Veterans Dr. Northvale, NJ 07647 USA Test specification: Standard ..... IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint) Test procedure.....: **CB** Scheme Non-standard test method...... N/A Test Report Form No..... IEC60601 1J Test Report Form Originator .....: UL(US) Master TRF.....: 2014-07 Copyright © 2014 Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE), Geneva, Switzerland. All rights reserved. This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context. If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed. This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02. General disclaimer: The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB. responsible for this Test Report. Test item description ..... Medical Power Supply Trade Mark .....: GlobTek Manufacturer ..... Same as applicant

Model/Type reference...... GT\*43007-\*\*\*\*\* (Refer to page 6 for details.)

Output: Refer to page 6 for details.



Testing procedure and testing location:				
CB Testing Laboratory:				
Testing location/ address	Intertek Testing Services Shanghai			
	Building No.86, 1198 Qinzhou Ro Shanghai, China	oad (North), 200233		
Associated CB Testing Laboratory:				
Testing location/ address				
Tested by (name + signature):	Francis Cai (Engineer)	Francis Cari Dean D		
Approved by (name + signature) :	Justin Yu (Mandated Reviewer)	Jun V		
Testing procedure: TMP/CTF Stage 1:				
Testing location/ address:				
Tested by (name + signature)				
Approved by (name + signature)				
Testing procedure: WMT/CTF Stage 2:				
Testing location/ address:				
Tested by (name + signature)				
Witnessed by (name + signature)				
Approved by (name + signature)				
Testing procedure: SMT/CTF Stage 3 or 4:				
Testing location/ address:				
Tested by (name + signature)				
Witnessed by (name + signature)				
Approved by (name + signature)				
Supervised by (name + signature):				



ist of Attachments (including a total number of pages in each attachment):
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See original report

# Summary of testing

# Tests performed (name of test and test clause):

### 4.11 POWER INPUT

11.1 EXCESSIVE TEMPERATURE

# **Testing location:**

Intertek Testing Services Shanghai

Building No. 86, 1198 Qinzhou Road (North), 200233 Shanghai, China

### Summary of compliance with National Differences

List of countries addressed:

See original report

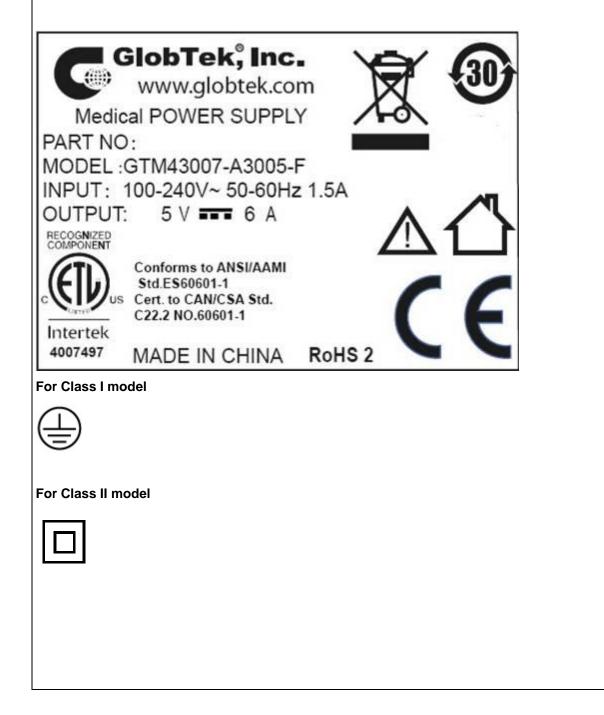
 $\boxtimes$  The product fulfils the requirements of IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012.



#### Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks. Note:

The marking plates of the other models listed in this report are identical with below except model name and output parameter. The below marking is complying with the minimum requirements required by the safety standard. For the final production samples, the additional markings which do not give rise to misunderstanding may be added.





GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use:	Final determination in end product evaluation for open frame model
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location) :	PSU (internal power supply board)
Mode of operation:	Continuous
Supply connection	Final determination in end product evaluation for open frame model
Accessories and detachable parts included	None
Other options include	None
Testing	
Date of receipt of test item(s):	2017-07-03
Dates tests performed	2017-07-03 to 2017-07-17
Possible test case verdicts:	
- test case does not apply to the test object	N/A
- test object does meet the requirement	Pass (P)
- test object was not evaluated for the requirement:	N/E (collateral standards only)
- test object does not meet the requirement	Fail (F)
Abbreviations used in the report:	
- normal condition: N.C.	- single fault condition: S.F.C.
- means of Operator protection: MOOP	- means of Patient protection: MOPP
General remarks:	
Before starting to use the TRF please read carefully the 4 in report on how to complete the new version "J" of TRF for I Amendment 1. "(See Attachment #)" refers to additional information appended "(See appended table)" refers to a table appended to the report The tests results presented in this report relate only to the object This report shall not be reproduced except in full without the wr List of test equipment must be kept on file and available for rev Additional test data and/or information provided in the attachment <b>Throughout this report a Comma / Section Description Description</b>	<b>IEC for 60601-1 3<sup>rd</sup> edition with</b> to the report. t. ct tested. itten approval of the testing laboratory. iew. ents to this report.
Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02	:2012
sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided	applicable
When differences exist; they shall be identified in the Genera	al product information section.



Name and address of factory (ies):	Factory 1 GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 USA
	Factory 2 GlobTek (Suzhou) Co., Ltd Building 4, No. 76, Jin Ling East Rd., Suzhou Industrial Park, Suzhou, JiangSu 215021, China

### General product information:

Product covered by this report is medical power supply module, which can be used as a part of medical equipment.

The installation and use for the insulation construction shall be finally determined in the end product.

All the types are designed for continuous operation and no applied part is defined.

The product is designed to be operated at max. 5000m above sea level.

The insulation between primary and secondary circuits of EUT is evaluated as 2MOPP in this report as customer's request.

#### Model similarity:

GT\*43007-\*\*\*\*\*

The 1st "\*" can be 'M' or '-'or 'H' for market identification and not related to safety.

The 2nd "\*" is A, B, or C and is related to PCB size: A= 2"x3", B=2"x4", C=3"x5". The different PCB sizes are only for installation purpose in end product with no safety spacing modification.

The 3rd "\*" denote the rated output wattage designation, which can be "01" to "60", with interval of 1.

The 4th "\*" denote the standard rated output voltage designation, which can be "05", "07", "09", "12", "15", "18", "24", "36" or "48". Each standard rated output voltage designation corresponds to a transformer model. Each transformer model is identical in insulation construction including clearance and creepage except number of turns per coil.

The 5th "\*" is optional deviation, subtracted from standard output voltage, which can be "-0.1" to "-11.9" with interval of 0.1, or blank to indicate no voltage different.

The 4th and 5th asterisks together denote the output voltage with a range of 5-48 volts.

The 6th "\*" can be "-F" or "-FW". "-F" represents Class I model and "-FW" represents Class II model. **Model list** 

Model	Output Voltage	Max. output current	Max. output power	Transformer
GT*43007-**05*	5 V	6A	30W	
GT*43007-**07**	5.1-7V	6A	30W	TF024 for 5-6.5Vdc
GT*43007-**09**	7.1-9V	5A	45W	TF025 for 6.6-8.9Vdc
GT*43007-**12**	9.1-12V	5.0A	60W	TF026 for 9-13Vdc
GT*43007-**15**	12.1-15V	5.0A	60W	TF027 for 13.1-17Vdc
GT*43007-**18**	15.1-18V	4.0A	60W	TF028 for 17.1-24.9Vdc
GT*43007-**24**	18.1-24V	3.31A	60W	TF029 for 25-34.9Vdc
GT*43007-**36**	24.1-36V	2.50A	60W	TF032 for 35-48Vdc
GT*43007-**48**	36.1-48V	1.66A	60W	



### **Modification 1:**

The original report ref. No. 140900434SHA-001, dated 2014-11-10, was modified on 2017-07-17 to include the following changes and/or additions:

- 1. Increase the max. output power for model GT\*43007-\*\*12\*\* from 45W to 60W.
- 2. Added alternative PCB, fuse and heatsink in critical component list.

Concerning above change, power input and excessive temperature test were performed on model GT\*43007-\*6012\*\*.

### Technical Considerations:

Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:

- a) Clause 7.9 (Accompanying Documents of power adapter model are provided for some critical issue like technical data, safety warnings, necessary information to set up. Further evaluation is needed for both power adapter model and open frame model on end product level.),
- b) Clause 8.11.5 (Mains Fuse with High Breaking Capacity),
- c) Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
- d) Clause 10 (Radiation),
- e) Clause 11.7 (Biocompatibility),
- f) Clause 14 (PEMS),
- g) Clause 16 (ME Systems),
- h) Clause 17 (EMC)

Open frame model

• Suitability of the enclosure should be evaluated when installed in the end product including access to energized parts, clearance & creepage distance measurement and mechanical strength.

• Temperature Testing should be performed on this component when installed in the end product.



Clause	Requirement + Test	Result - Remark	Verdict
4.11	Power input		
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%	See appended Table 4.11	P

11.1	Excessive temperatures in ME EQUIPMENT		
11.1.1	Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and	See appended Table 11.1.1	Р
	Surfaces of test corner did not exceed 90 °C		Р
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION		Р
	RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Final determination in end product.	N/A
11.1.2	Temperature of APPLIED PARTS		
11.1.2.1	APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply:	No APPLIED PARTS.	N/A
	Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use		N/A
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in NORMAL CONDITION and SINGLE FAULT CONDITION. :		N/A
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:		N/A
	Maximum Temperature:		—
	Conditions for safe contact, e.g. duration or condition of the PATIENT:		_
	Clinical effects with respect to characteristics taken or surface pressure documented in the RISK MANAGEMENT FILE (ISO 14971 CI. 4.2-4.4, 5, 6.2-6.5)		N/A
	APPLIED PARTS surface temperature of equal to or less than 41°C		N/A



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Clause	Requirement + Test	Result - Remark	Verdict
	Analysis documented in the RISK MANAGEMENT FILE show that APPLIED PART temperatures are not affected by operation of the ME EQUIPMENT including SINGLE FAULT CONDITIONS. Measurement of APPLIED PART temperature according to 11.1.3 is not conducted		N/A
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS		N/A
11.1.3	Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE: (ISO 14971 CI. 4.2-4.4, 5, 6.2-6.5)	No such temperature limits.	N/A
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE	Test corner used	N/A
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE	No such guards.	N/A
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE	No alternative method	N/A
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	No such guards.	N/A



	IEC 60601-1						
Clause	Requirement + Test Result - Remark				·k	Verdict	
4.11	TABLE: Power Input						
Operat	Operating Conditions / RatingsVoltage (V)Frequency (Hz)Current (A)Power (W)					Power factor (cos φ)	
Tested on model GTM43007-A6012-F, 12Vdc output, 5A							
	Normal condition	264	50/60	0.44	69.5	<0.9	

Normal condition	264	50/60	0.44	69.5	<0.9		
Normal condition	240	50/60	0.47	69.3	<0.9		
Normal condition	100	50/60	1.08	70.6	<0.9		
Normal condition	90	50/60	1.24	70.9	<0.9		
Supplementary Information:							

8.10 T	ABLE: List of critical	components			Р
Component Part No.	/ Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity <sup>1</sup>
PCB	PACIFIC WIN INDUSTRIAL LTD	PW-02 PW-03	Min. V-0, min 1.6 mm thickness, 130°C	IEC/EN 60601-1 UL 796	Tested with appliance UL E228070
Alt.	YILIHUA	YLH-1 YLH-2	Min. V-0, min 1.6 mm thickness, 130°C	IEC/EN 60601-1 UL 796	Tested with appliance UL E251781
Alt.	AREX	02V0 04V0	Min. V-0, min 1.6 mm thickness, 130°C	IEC/EN 60601-1 UL 796	Tested with appliance UL E186016
Alt.	BRITE PLUS ELECTRONICS (SUZHOU) CO LTD	DKV0-3A DGV0-3A	Min. V-0, min 1.6 mm thickness, 130°C	IEC/EN 60601-1 UL 796	Tested with appliance UL E177671
Alt.	SHENZHEN TONGCHUANGXI N ELECTRONICS CO LTD	тсх	Min. V-0, min 1.6 mm thickness, 130°C	IEC/EN 60601-1 UL 796	Tested with appliance UL E250336
Alt.	WALEX ELECTRONIC (WUXI) CO LTD	T2, T2A, T2B T4	Min. V-0, min 1.6 mm thickness, 130°C	IEC/EN 60601-1 UL 796	Tested with appliance UL E154355
Alt.	DONGGUAN HE TONG ELECTRONICS CO LTD	CEM1 2V0 FR4	Min. V-0, min 1.6 mm thickness, 130°C	IEC/EN 60601-1 UL 796	Tested with appliance UL E243157



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		IEC 6	0601-1			
Clause R	Requirement + Test	Result -			Remark	Verdict
Alt.	CHEERFUL ELECTRONIC (HK) LTD	02 03 03A	Min. V-0, mm thick 130°C		IEC/EN 60601-1 UL 796	Tested with appliance UL E199724
Alt.	DONGGUAN DAYSUN ELECTRONIC CO LTD	DS2	Min. V-0, mm thick 130°C		IEC/EN 60601-1 UL 796	Tested with appliance UL E251754
Alt.	KUOTIANG ENT LTD	C-2 C-2A	Min. V-0, min 1.6 mm thickness, 130°C		IEC/EN 60601-1 UL 796	Tested with appliance UL E227299
Alt.	YUANMAN PRINTED CIRCUIT CO LTD	1V0	Min. V-0, mm thick 130°C		IEC/EN 60601-1 UL 796	Tested with appliance UL E74757
Alt.	SUZHOU XINKE ELECTRONICS CO LTD	XK-2, XK-3	Min. V-0, min 1.6 mm thickness, 130°C		IEC/EN 60601-1 UL 796	Tested with appliance UL E213590
Alt.	KUNSHAN CITY HUA SHENG CIRCUIT BOARD CO LTD	HS-S	Min. V-0, min 1.6 mm thickness, 130°C		IEC/EN 60601-1 UL 796	Tested with appliance UL E229877
Alt.	JIANGSU DIFEIDA ELECTRONICS CO LTD	DFD-1	Min. V-0, min 1.6 mm thickness, 130°C		IEC/EN 60601-1 UL 796	Tested with appliance UL E213009
Alt.	HUIZHOU SHUNJIA ELECTRONICS CO LTD	SJ-B	Min. V-0, mm thick 130°C		IEC/EN 60601-1 UL 796	Tested with appliance UL E320884
Alt.	SHANGHAI H- FAST ELECTRONIC CO LTD	211001, 411001	Min. V-0, mm thick 130°C		IEC/EN 60601-1 UL 796	Tested with appliance UL E337862
Alt.	Interchangeable	Interchangeable	Min. V-0, min 1.6 mm thickness, 130°C		IEC/EN 60601-1 UL 796	Tested with appliance UL Approved.
Fuse (F1, F2) (F2 is optional.)	Conquer Electronics Co., Ltd.	MST	T2A, 250 V, Rated breaking capacity 100A		IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40017118 UL E82636
Alt.	Ever Island Electric Co., Ltd. and Walter Electric	2010, <b>ICP</b>	T2A, 250 Rated bre capacity 7	eaking	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40018781 UL E220181
Alt.	Bel Fuse Ltd.	RST	T2A, 250 breaking 100A		IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40011144 UL E20624



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IEC 60601-1							
Clause Requirement + Te			Result -	Remark	Verdict		
Alt.	Das & Sons International Ltd.	385T series	T2A, 250V, Rated breaking capacity 35A		VDE 40008524 UL E205718		
Alt.	Shenzhen Lanson Electronics Co. Ltd.	SMT	T2A, 250V, Rated breaking capacity 35A		VDE 40012592 UL E221465		
Alt.	Walter Electronic Co. Ltd.	ICP series	T2A, 250V, Rated breaking capacity 50A.		VDE 40012824 UL E56092		
Alt.	Zhongshan Lanbao Electrical Appliances Co., Ltd.	RTI-10 series	T2A, 250V, Rated breaking capacity 50A		VDE 40017009 UL E213695		
Alt.	Sun Electric Co.	5T	T2A, 250V, Rated breaking capacity 100A		VDE 40027241 UL E166522		
Alt.	Bel Fuse Ltd.	5ST	T2A, 250V, Rated breaking capacity 35A		VDE 40000507 UL E20624		
Alt.	Copper Bussmann LLC	SS-5	T2A, 250V, Rated breaking capacity 50A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40015513 UL E19180		
Alt.	Dongguan Better Electronics Technology Co., Ltd.	932	T2A, 250V, Rated breaking capacity 100A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40033369 UL E300003		
Alt.	Hollyland Compoany Limited	5ET	T2A, 250V, Rated breaking capacity 63A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40015669 UL E156471		
Alt.	Sunny East Enterprise Co. Ltd.	CFD-Serie(s)	T2A, 250V, Rated breaking capacity 50A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40030246 UL E133774		
Alt.	Conquer Electronics Co., Ltd.	MET series	T2A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40017157 UL E82636		
Heatsink (HS2) (for 9V)	5-	Interchangeable	Aluminum. Approximate overall dimension 50mm by 22mm by 38mm, min.1.0mm thick, secured to PWB by soldering	IEC/EN 60601-1	Tested with appliance		



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IEC	6060	1-1
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Clause	Requirement + Test		Result -	Verdict	
Alt.	Interchangeable	Interchangeabl e	Aluminum. Approximate overall dimension 50mm by 22mm by 38mm, min.1.2mm thick, secured to PWB by soldering	IEC/EN 60601-1	Tested with appliance
Alt.	Interchangeable	Interchangeabl e	SPCC. Approximate overall dimension 50mm by 14mm by 38mm, min.1.2mm thick, secured to PWB by soldering	IEC/EN 60601-1	Tested with appliance
Heatsink (HS2) (for 9.1-48V)	Interchangeable	Interchangeable	Aluminum. Approximate overall dimension 50mm by 6mm by 18mm, min.1.4mm thick, secured to PWB by soldering	IEC/EN 60601-1	Tested with appliance
Alt.	Interchangeable	Interchangeabl e	SPCC. Approximate overall dimension 50mm by 14mm by 38mm, min.1.2mm thick, secured to PWB by soldering	IEC/EN 60601-1	Tested with appliance



#### IEC 60601-1

Clause Requirement + Test

**Result - Remark** 

Verdict

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT						Р	
Model No:			GTM43007-A6012-F					
Test ambient (°C):			40					
Test supply voltage/frequency (V/Hz) <sup>4</sup> :			9	0V/60HZ				
Model No.	Thermo- couple No.	Thermocouple loc	cation <sup>3</sup>	temperature <sup>1</sup> fr Table 22, 23 or 2	Max allowable emperature <sup>1</sup> from able 22, 23 or 24 or M file for AP <sup>5</sup> (°C)		neasured erature <sup>2</sup> , °C)	Remarks
	1 LF1 winding			130			9.7	
	2	CX1 body	X1 body				5.4	
	3	C8 body		105		8	8.2	
	4	T1 winding		130-10=120	)	1	09.5	COR method not used
	5	T1 core		130		1	08.6	
	6	PCB near Q1 (HS1)		130	8		37.7	
	7	PCB near Q2 (HS2)		130		1	09.5	
	8	PCB near U2		130		8	3.8	
	9	C9 body		105		8	8.7	

#### Supplementary information:

<sup>1</sup> Maximum allowable temperature on surfaces of test corner is 90 °C

<sup>2</sup> Max temperature determined in accordance with 11.1.3e)

<sup>3</sup>When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.

<sup>4</sup> Supply voltage:

- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;

- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.

- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

<sup>5</sup> APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

Information from Risk Management, as applicable: N/A