Test Report issued under the responsibility of:

TEST REPORT

IEC 60601-1

Medical Electrical Equipment

Part 1: General requirements for basic safety and essential performance

Report Number. .....:	T223-0536/24
Date of issue .....:	2024-09-30
Total number of pages.....:	313 pages
Name of Testing Laboratory preparing the Report.....:	SIQ Ljubljana *SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number LP-009 in the field of testing (SIST EN ISO/IEC 17025).* Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia
Applicant's name.....:	GlobTek, Inc.
Address .....:	186 Veterans Drive Northvale, NJ 07647, USA
Test specification:	
Standard .....:	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Test procedure .....:	CB Scheme
Non-standard test method .....:	N/A
TRF template used .....:	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No.....:	IEC60601_1U
Test Report Form(s) Originator ....:	UL(US)
Master TRF.....:	2023-08-24

Copyright © 2023 IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System). 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 IECEE 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 NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description .....:	Desk-top Power supply for Medical use
Trade Mark(s).....:	GlobTek, Inc.
Manufacturer.....:	GlobTek, Inc. 186 Veterans Drive, Northvale, NJ 07647, USA
Model/Type reference .....:	GTM21097-X-Y.Y series X=2003, 3005, 4509, 5012, 5015, 5018, 5024 or 5048 Y.Y=0.1V min. to 23.9V max or blank See general product information for details.
Ratings .....:	**Input:** 100-240 V a.c.; 50-60 Hz; 1,6 Amax.; Class I **Output:** See general product information for details.

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
☒	**CB Testing Laboratory:**	SIQ Ljubljana	
Testing location/ address.....:		Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia	
Tested by (name, function, signature).....:		Elvis Pučko (Service Provider)	
Approved by (name, function, signature)...:		Janez Vidmar (Approved Signatory)	
☐	**Testing procedure: CTF Stage 1:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
Supervised by (name, function, signature) :			

List of Attachments (including a total number of pages in each attachment):

1. Test Report (182 pages)
2. National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020 – Enclosure No. 1 (34 pages)
3. Photo Documentation – Enclosure No. 2 (5 pages)
4. PCB layouts, electrical schemes, transformer drawings – Enclosure No. 3 (92 pages)

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
Clause 4.11: Power input	SIQ Ljubljana
Clause 5.7: Humidity preconditioning treatment	Tržaška cesta 2, SI-1000 Ljubljana, Slovenia
Clause 5.9.2: Determination of accessible parts	
Clause 7.1.2: Legibility of marking	**Revision 1.0:**
Clause 7.1.3: Durability of marking plate	SIQ Ljubljana
Clause 8.4.2: Working voltage / power measurement	Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia
Clause 8.4.3: ME equipment for connection to a power source by a plug	
8.6.4. Impedance and current- carrying capability of protective earth connections	
Clause 8.7: Leakage current	
Clause 8.8.3: Dielectric strength test of solid insulating materials with safety function	
Clause 11.1.1: Excessive temperatures in ME equipment	
Clause 13.2: Single fault conditions in accordance with 13.2.2 to 13.2.13, inclusive	
Clause 15.3: Mechanical strength tests	
Clause 15.5.1.2: Transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under single fault condition	
Clause 15.5.1.3: Transformer overload test – conducted only when protective device under short-circuit test operated	
Evaluation of voltage limiting components in SELV circuits	

Summary of compliance with National Differences:

List of countries addressed:

Standard IEC 60601-1:2005 + A1:2012 + A2:2020

CANADA NATIONAL DIFFERENCES

National standard CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14

US NATIONAL DIFFERENCES

National standard AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021

JAPAN NATIONAL DIFFERENCES

National standard JIS T 0601-1:2023

Standard IEC 60601-1:2005 + A1:2012

REPUBLIC OF KOREA NATIONAL DIFFERENCES:

Notification of MFDS No. 2020-12, Annex 1

☒ **The product fulfils the requirements of EN 60601-1:2006 + A1:2013 + A12:2014 + A2:2021 (BS EN 60601-1:2006 + A2:2021).**

Statement concerning the uncertainty of the measurement systems used for the tests

(may be required by the product standard or client)

☐ **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

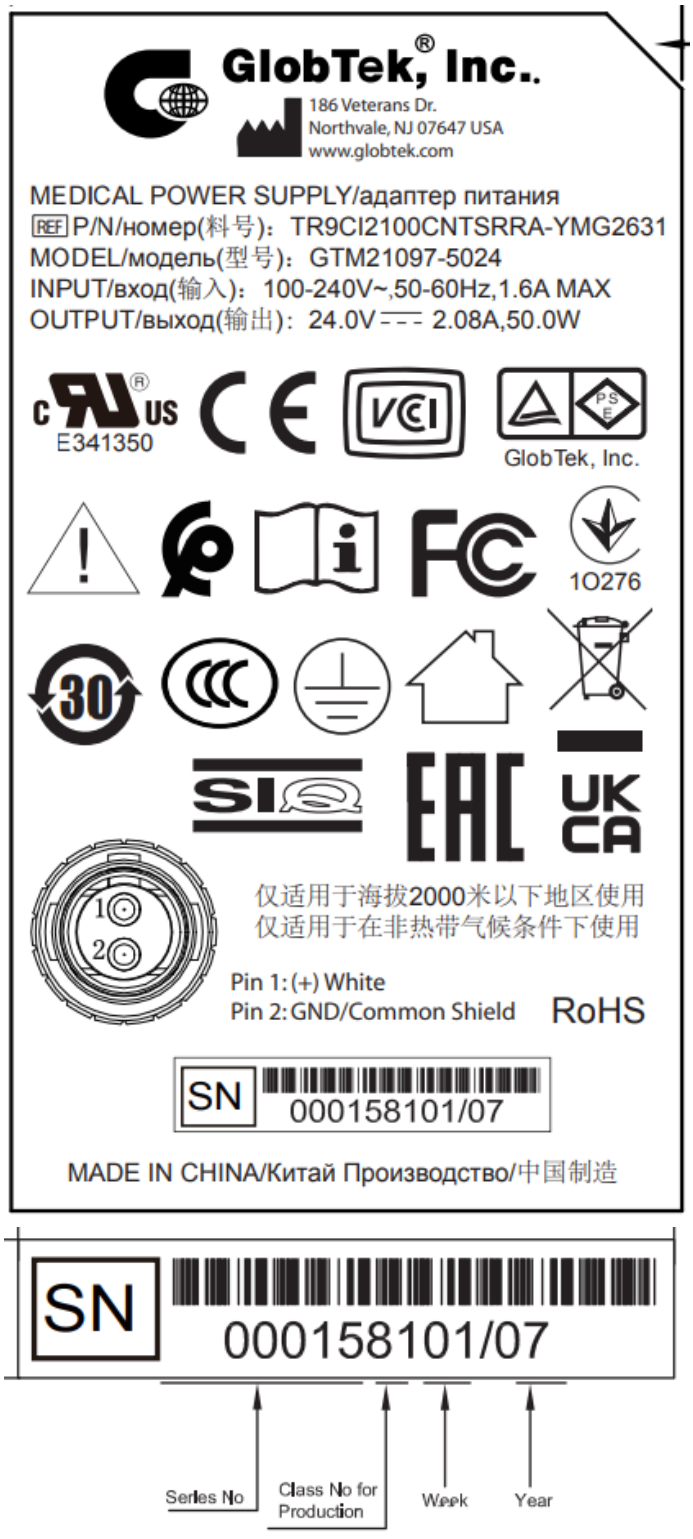
Procedure number, issue date and title:

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

☒ **Statement not required by the standard used for type testing**

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.



Test item particulars.....:	
Classification of installation and use.....:	Portable equipment (desk-top version).
Supply Connection.....:	Appliance coupler.
Device type (component/sub-assembly/ equipment/ system)……..:	Component level power supply.
Intended use (Including type of patient, application location)……:	EUT is intended to provide power to medical devices with isolation grade MOOP (Means of Operator Protection).
Mode of operation……:	Continuous operation.
Accessories and detachable parts included……...:	No accessories and detachable parts included.
Other options include……..:	No other options included.
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 was not evaluated for the requirement……..:	N/E (collateral standards only)
- test object does not meet the requirement.....:	F (Fail)
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
Testing.....:	
Date of receipt of test item .....:	2010-02-01 **(Initial testing)** 2019-07-23 **(Revision 1.0)** 2024-08-30 **(Revision 2.0)**
Date (s) of performance of tests.....:	From 2011-06-27 to 2012-01-05 **(Initial testing)** From 2019-07-24 to 2019-07-26 **(Revision 1.0)** From 2024-09-02 to 2024-09-10 **(Revision 2.0)**
General remarks:	
"(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. **Throughout this report a ☒ comma / ☐ point is used as the decimal separator.**	

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☒ **Yes** ☐ **Not applicable**
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) ..... :	1) GlobTek Inc. 186 Veterans Drive, Northvale, NJ 07647, New Jersey, USA 2) GlobTek (Suzhou) Co., Ltd. Building 4, No. 76, Jinling East Road, Suzhou Industrial Park, Jiangsu CN-215021, China

General product information and other remarks:

Desk-top Power Supply GTM21097 series has been designed for the supplying various medical devices with integrated MOOP isolation (means of operator protection between mains and secondary accessible parts).

Model / Type reference:

GTM21097-X-Y.Y series

X=2003, 3005, 4509, 5012, 5015, 5018, 5024 or 5048

Y.Y=0.1V min. to 23.9V max or blank

Variable	Range of Variable	Content
X	2003, 3005, 4509, 5012, 5015, 5018, 5024 or 5048	The former two bits of figures indicate max. output power, 20-50W, Max 50 Watt and the latter two bits of figures indicate standard model output voltage, 3.3V min. to 48V,max.
Y.Y	0.1V min. to 23.9V max or blank	Optional variable for specifying output voltage deviation from standard model; which means subcontracting volts from standard output voltage in 0.1V increments or blank; 0.1V min. to 23.9V max. the detailed value scope refer to the above model list

Ratings:

Input: 100-240 V a.c.; 50-60 Hz; 1,6 Amax.; Class I

Output: see table below:

Model	Standard model	Standard model output voltage (Vdc)	Standard model rated output current (A)	Y.Y scope	Output voltage range(V)	Max output power (W)
GTM21097-2003-Y.Y	GTM21097-2003	3.3	6	0.1-0.3 or blank	3-3,3	20
GTM21097-3005-Y.Y	GTM21097-3005	5	6	0.1-1.6 or blank	3,4-5	30
GTM21097-4509-Y.Y	GTM21097-4509	9	5	0.1-3.9 or blank	5,1-9	45
GTM21097-5012-Y.Y	GTM21097-5012	12	4,17	0.1-2.9 or blank	9,1-12	50
GTM21097-5015-Y.Y	GTM21097-5015	15	3,3	0.1-6.9 or blank	12,1-15	50
GTM21097-5018-Y.Y	GTM21097-5018	18	2,8	0.1-6.9 or blank	15,1-18	50
GTM21097-5024-Y.Y	GTM21097-5024	24	2,1	0.1-5.9 or blank	18,1-24	50
GTM21097-5048-Y.Y	GTM21097-5048	48	1,0	0.1-23.9 or blank	24,1-48	50

Power supply is not intended for direct patient connection.

Power supply is not intended to be used inside patient environment (contact with patient is unlikely).

Power supply is designed for desk-top use. Power is delivered to the medical device via secondary SELV wire with the DC plug at the end.

Power supply unit is provided with appliance inlet used for connection to the mains. Appliance power supply cord not part of the investigation.

Power supply is provided with green LED indicator indicating operating condition on the top side of the PSU.

Power supply in maintenance free.

Power supply is intended for operating at ambient temperature up to 40°C.

Power supply shall not be used for use in an oxygen rich environment.

Power supply is not intended to be use with flammable anaesthetics and not intended for use in conjunction with flammable agents.

Essential performance shall be determined within the end medical equipment; however for this medical power supply essential performance is considered MOOP. MOOP is tested within this test report.

Desk-top power supply is provided with appliance coupler used for connection to the mains.

Power supply cord is not part of the investigation.

Power supply provides internally two primary fuses F1 and F2 (in both supply leads).

Power supply was evaluated only for Means of Operator Protection:

- 2 x MOOP between primary and secondary circuit
- 2 x MOOP between primary and external plastic enclosure surface
- 2 x MOOP between primary and functional earth
- 1 x MOOP between primary and protective earth

Secondary output circuit is separated from mains by reinforced insulation and rated SELV. The output does not provide hazard energy level.

Power supply is provided with technical specification.

Power supply is rated as class I with functional earth (reinforced insulation provided between primary and secondary, between primary and outer enclosure, and between primary and functional earthing).

The transformer T1 provides reinforced insulation. This transformer is built up to fulfil the requirement of insulation class B. See also list of safety critical components.

Power supply has been evaluated for use in a Pollution Degree 2 and overvoltage category II environment and a maximum altitude of 2000 m.

Power supply is provided with plastic enclosure made by non-flammable material Min. V-0. See also list of safety critical components.

Cleaning and other applicable tests shall be considered within end system investigation. Approval within the end product:

Technical Considerations:

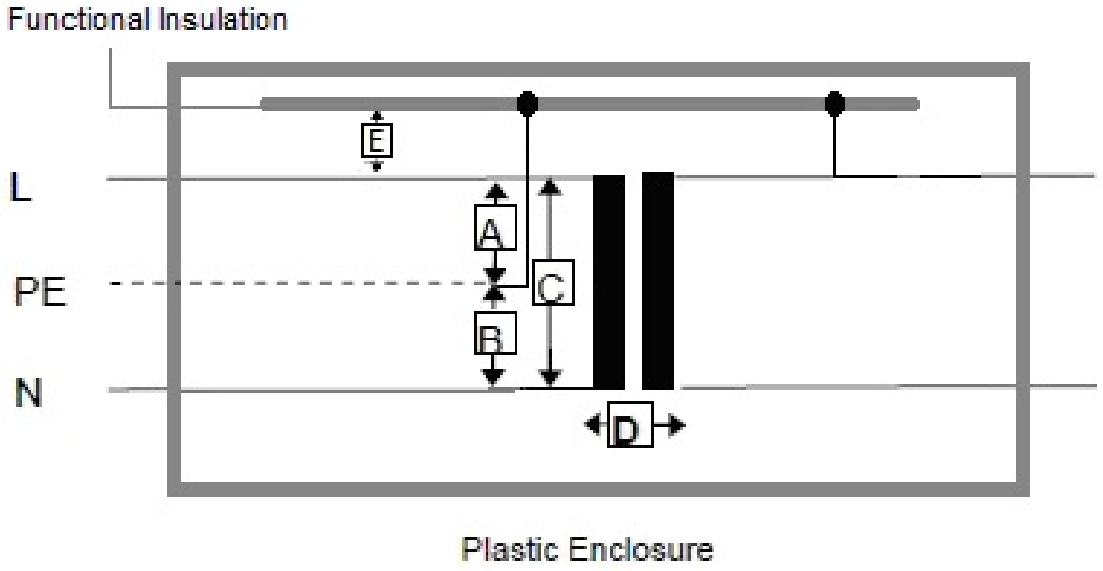
Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:

- Clause 7.5 (Safety Signs),
- Clause 7.9 (Accompanying Documents),
- Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
- Clause 10 (Radiation),
- Clause 14 (PEMS),
- Clause 16 (ME Systems)

History Sheet			
Date	**Report Number**	**Change**	**Revision No.**
2012-03-19	T223-0079/12	Initial Test Report issued.	—
2019-11-04	T223-0553/19	Test report updated from IEC 60601-1:2005 (3rd Edition) to IEC 60601-1:2005 (3rd Edition) + A1:2012. No changes on the product since initial approval. After review, the following tests were considered required: - Clause 8.7: Leakage current (measured with frequency-non-weighted measuring device) Power supply unit additionally evaluated for the latest National Differences to IEC 60601-1: 2005 + AM1: 2012. Added new user manual in Enclosure No. 3. - RMF review - Update table 8.10: List of critical components	1.0
2024-09-30	T223-0536/24	Test report updated due to new version of the IEC 60601-1 standard. Test report rewritten to the latest version of TRF and according to the latest standard IEC 60601-1:2005 + A1:2012 + A2:2020. Updated Critical components information (Table 8.10). Schematics updated with better specification of component EC1. Latest versions of the documentation reviewed and considered during preparation of the test report. No changes on the medical device itself. After review, the following test was considered required: - Clause 8.6.4: Impedance and current- carrying capability of protective earth connections (test with recommended power supply cord by the manufacturer).	2.0

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM



IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

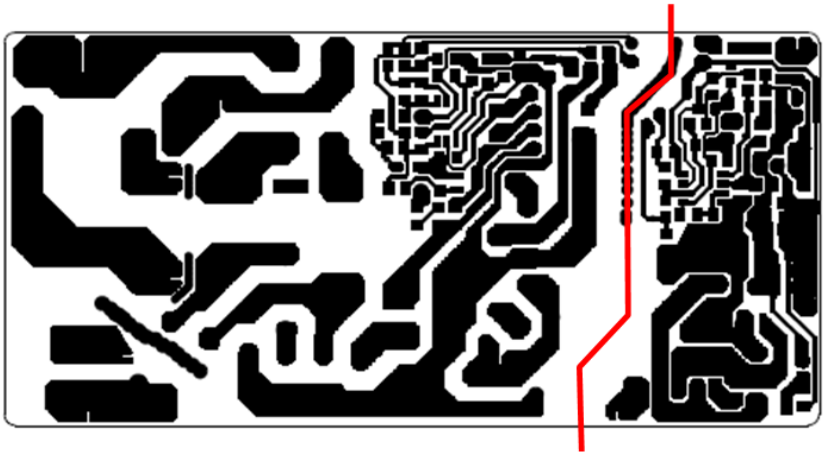
TABLE: INSULATION DIAGRAM		P
Pollution degree ..... :	PD 2	—
Overvoltage category ..... :	OVC 2	—
Altitude..... :	Up to 2.000 meters	—
Additional details on parts considered as applied parts ..... :	☒ None ☐ Areas _____ (See Clause 4.6 for details)	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			V_{rms}	V_{pk}					
A1	2 x MOOP	IIIb	240	340	4,8	4,0	8,0	5,5	Measured on PCB.
A2	2 x MOOP	IIIb	240	340	4,8	4,0	5,0	5,0	Measured on appliance inlet pins.
A3	2 x MOOP	IIIb	240	340	4,8	4,0	10,5	6,9	Measured between primary components and heat sink
B1	2 x MOOP	IIIb	240	340	4,8	4,0	8,0	6,3	Measured on PCB.
B2	2 x MOOP	IIIb	240	340	4,8	4,0	5,0	5,0	Measured on appliance inlet pins.
C1	1 x MOOP	IIIb	240	340	Verified via short-circuiting. See TABLE: abnormal operation (after fuse)				
C2	1 x MOOP	IIIb	240	340	3,0	1,6	4,4	4,4	Measured on PCB before both fuses.
D1	2 x MOOP	IIIa	265	484	5,0	4,2	8,0	8,0	On PCB.
D2	2 x MOOP	IIIb	250	368	5,0	4,0	8,0	8,0	Via U2 body
D3	2 x MOOP	IIIb	265	484	5,0	4,2	6,0	5,9	Between transformer core and secondary pins.
D4	2 x MOOP	IIIb	265	484	5,0	4,2	5,0	4,2	Between secondary components and transformer T1 core

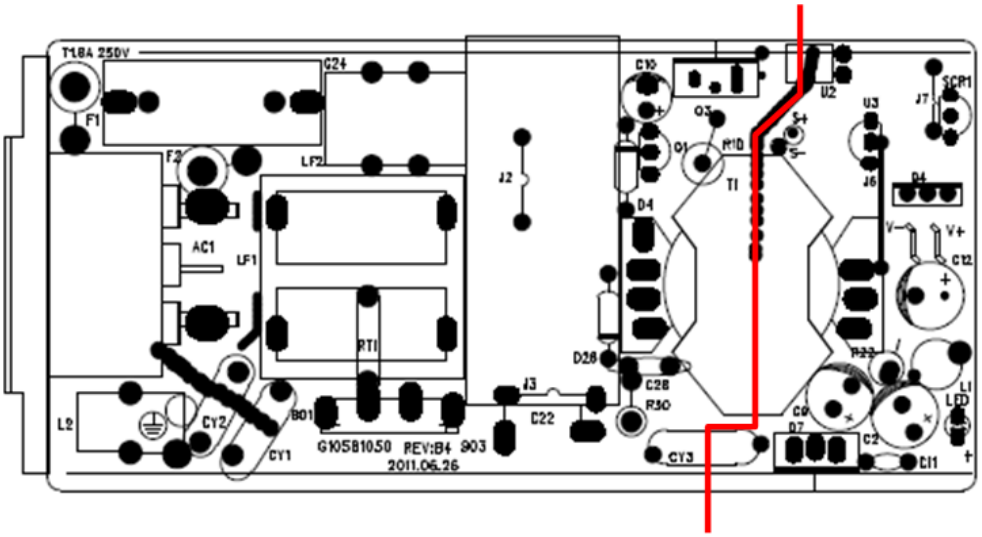
IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

E1	2 x MOOP	IIIb	265	484	5,0	4,2	5,0	5,0	Between primary and earthed shield.

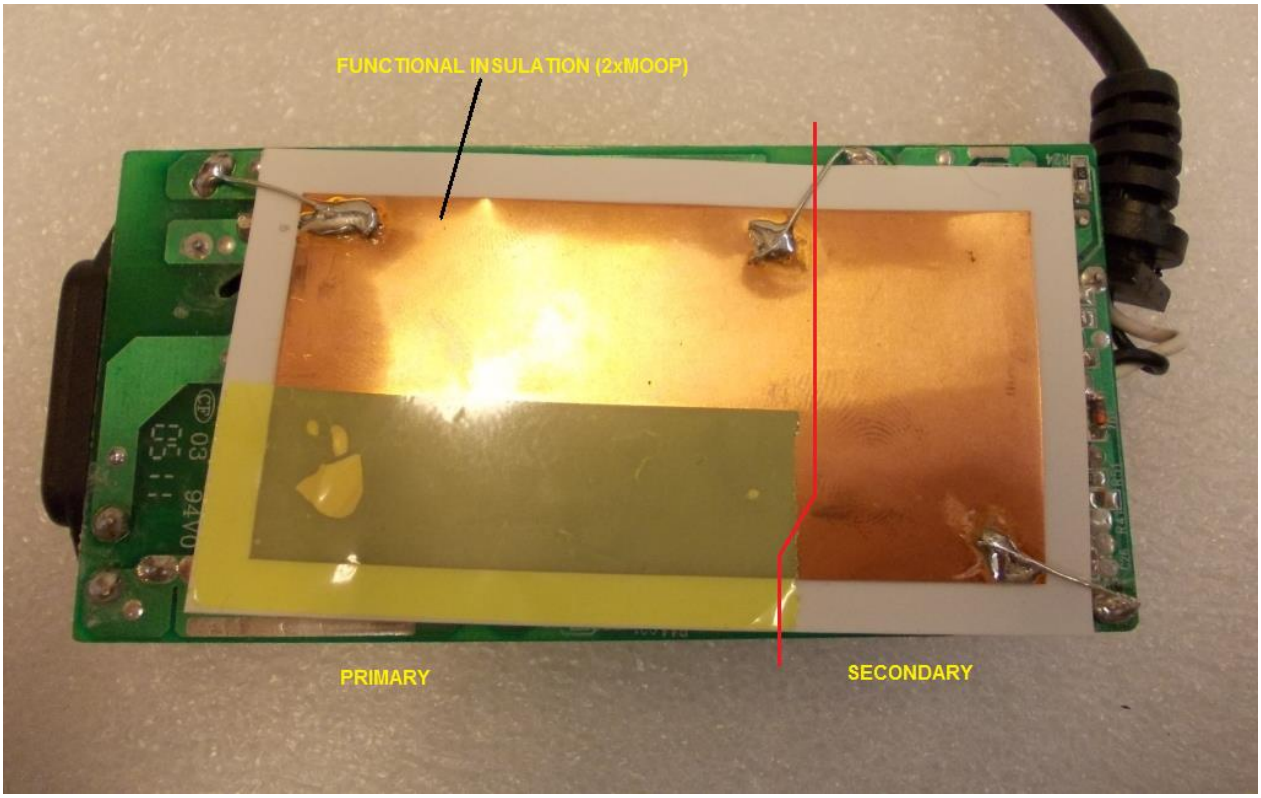
Primary Secondary



Primary Secondary



IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict



Supplementary Information:

1) Both sides of the enclosure are fixed together by adhesive (ultrasonic welding).

Complete creepage distance between PCB and outer enclosure:

1mm + 10,5 mm + 2,4 mm = 13,9 mm

Complete clearance distance between bottom of C24 to outer enclosure:

2,3 mm + 1,3 mm + 7,0 mm = 10,6 mm

2) Transformer core is considered as primary.

3) Approved triple insulated wire used for secondary windings.

4) Approved optocoupler between primary and secondary side provide. Refer to list of critical components for details.

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

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:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure but are not terminated with an arrow.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4	**GENERAL REQUIREMENTS**		**P**
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse	--	**P**
4.2	**RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS**		**P**
4.2.2	General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2019)…….:	See Appended RM Results Table 4.2.2.	**P**
4.2.3	Evaluating RISK		**P**
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level	--	**P**
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN……:	RISK MANAGEMENT PLAN Document: Attachment B Risk Management Plan (GT-RMPLAN203-009)	**P**
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.	--	**P**
	– HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.	--	**P**
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.	Manufacturer addressed all hazards and hazardous situations during risk analysis.	**P**
4.3	Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.	Power supply unit is not end medical product; therefore no clinical functions specified by the manufacturer.	**N/A**
	– Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.	--	**N/A**
	– Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated	--	**N/A**
	– Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE……:	Power supply unit is not end medical product; therefore no clinical functions specified by the manufacturer.	**N/A**
	– RISK CONTROL measures implemented	--	**N/A**
	– Methods used to verify the effectiveness of RISK CONTROL measures implemented	--	**N/A**
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE……:	The expected service life is specified by the manufacturer: 10 years.	**P**
4.5	Alternative RISK CONTROL methods utilized:	No equivalent safety used.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific risks: (ISO 14971 Cl. __) No equivalent safety used.	**N/A**
	Alternative means based scientific data or clinical opinion or comparative studies ……..:	--	**N/A**
4.6	RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10 ……...:	See Appended Insulation Diagram Table No such parts.	**N/A**
	MANUFACTURER assesses the risk of accessible parts coming into contact with the patient: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. __) No such parts. No RM considered necessary.	**N/A**
	Assessment identified the APPLIED PART TYPE requirements ……..:	Type B requirements considered for power supply output and power supply accessible enclosure.	**N/A**
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2……:	Short circuit or open circuit of relevant single components performed. See Table 13.2: Single fault conditions in accordance with 13.2.2 to 13.2.13, inclusive.	**P**
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested……: (ISO 14971 Cl. 5.2-5.5)	RISK ANALYSIS reference: Risk management report (EL1 to EL7, H1, H2, M1, OP1 to OP4) (ISO 14971 Cl. 5.2-5.5)	**P**
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically……..:	See appended Table 13.2 for simulated physical test.	**P**
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified ……..:	All components are suitable and used within their rating. See appended table 8.10.	**P**
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS	--	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings ……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) All components used according to their applicable ratings.	**N/A**
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION ……..:	All components are suitable and used within their ratings.	**N/A**
	Components determined to be acceptable where used as a MEANS OF PROTECTION ……:	All components are suitable and used within their ratings.	**N/A**
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following	--	**P**
	a) Applicable safety requirements of a relevant IEC or ISO standard	Approved critical components used. See Table 8.10: List of critical components.	**P**
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard	--	**P**
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately……..:	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	**N/A**
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:	See Table 8.10 b	**N/A**
4.10	**Power supply**		**P**
4.10.1	ME EQUIPMENT is suitable for connection to indicated power source (select applicable) ……:	Power supply unit is suitable for connection to supply mains (appliance coupler used for connection to the mains).	**P**
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:	--	**P**
	– 250 V for HAND-HELD ME EQUIPMENT (V) ……:	Not hand-held equipment.	**N/A**
	– 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V) ……:	100-240 Vac	**P**
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS	--	**N/A**
4.11	**Power input**		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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**
5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		**P**
5.1	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods ……..:	Type test performed according to all applicable clauses of standard IEC 60601-1:2005 (3rd Ed.) + A1:2012 + A2:2020.	**P**
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. (ISO 14971 Cl. 5.2-5.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
5.3	Tests conducted within the environmental conditions specified in technical description	--	**P**
	Temperature (ºC), Relative Humidity (%) ……:	Operating temperature: 0-40°C Operating relative humidity: Up to 90% RH.	**—**
	Atmospheric Pressure (kPa) ……:	Operating atmospheric pressure: 800 hPa to 1060 hPa	**—**
5.5	a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V)……..:	--	**P**
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz).....:	50-60 Hz	**P**
	c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current.....:	Supply voltage: 100-240 Vac Only AC supply voltage used for supplying power supply unit.	**P**
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered .....:	AC supply voltage only.	**N/A**
	e) ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions .....:	No accessories provided.	**N/A**
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	Mains operated equipment.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3……..:	Complete power supply unit was subject to humidity preconditioning treatment.	**P**
	ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +30°C for indicated time	**Revision 1.0:** 2 days (48h): T = 27,8°C RH= 94,6 %	**—**
5.9	**Determination of APPLIED PARTS and ACCESSIBLE PARTS**		**P**
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS.....:	See clause 4.6 Remark No applied parts provided.	**N/A**
5.9.2	**ACCESSIBLE PARTS**		**P**
5.9.2.1	Accessibility determined using standard test finger of Fig. 6	See Appended Table 5.9.2 Power supply unit is provided with plastic enclosure without openings.	**P**
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s	No openings provided.	**N/A**
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS……:	No actuating mechanism.	**N/A**
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL……:	No actuating mechanism.	**N/A**
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		**P**
6.2	CLASS I ME EQUIPMENT, externally powered	Power supply unit is Class I equipment.	**P**
	CLASS II ME EQUIPMENT, externally powered	--	**N/A**
	INTERNALLY POWERED ME EQUIPMENT	Equipment is not internally powered equipment.	**N/A**
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements	--	**N/A**
	TYPE B APPLIED PART	No applied parts provided.	**N/A**
	TYPE BF APPLIED PART	--	**N/A**
	TYPE CF APPLIED PART	--	**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529 ..... …:	IP20 (ordinary equipment). No protection against ingress of water provided.	**N/A**
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use .....:	No such parts.	**N/A**
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2	Power supply not investigated for OXYGEN RICH ENVIRONMENT.	**N/A**
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION .....:	The equipment is intended for continuous operation.	**P**
7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		**P**
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6……:	See Appended Table 7.1.2	**P**
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE	See appended Tables 7.1.3 and 8.10	**P**
7.2	**Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**		**P**
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ……..:	See attached copy of Marking Plate All required markings are provided on the marking plate.	**P**
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS ……:	See above.	**N/A**
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT	Packaging not part of the investigation.	**N/A**
	Single use item marked……..:	Power supply is not intended for single use.	**N/A**
7.2.2	ME EQUIPMENT marked with:	--	**P**
	– the name or trademark and contact information of the MANUFACTURER	See copy of marking plate for details.	**P**
	– a MODEL OR TYPE REFERENCE	See copy of marking plate for details.	**P**
	– a serial number or lot or batch identifier; and	See copy of marking plate for details.	**P**
	– the date of manufacture or use by date	See copy of marking plate for details.	**P**
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	No detachable parts provided.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.3)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and	--	**N/A**
	– a MODEL OR TYPE REFERENCE	--	**N/A**
	Software forming part of a PEMS identified with a unique identifier……..:	No software incorporated.	**N/A**
7.2.3	Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS	Symbol not required. EUT is medical in power supply unit.	**N/A**
	SAFETY SIGN 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	--	**N/A**
7.2.4	ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and….:	No accessories provided.	**N/A**
	– with a MODEL or TYPE REFERENCE	--	**N/A**
	– a serial number or lot or batch identifier	--	**N/A**
	– the date of manufacture or use by date	--	**N/A**
	Markings applied to individual packaging when not practical to apply to ACCESSORIES	--	**N/A**
7.2.5	ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following	Mains operated equipment.	**N/A**
	– the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or	--	**N/A**
	– Table D.2, SAFETY SIGN No. 10 adjacent to the relevant connection point and listing of the required details in the instructions for use; or	--	**N/A**
	– Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use.	--	**N/A**
7.2.6	**Connection to the Supply Mains**		**P**
	Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point	Marking plate provided on the bottom side of the plastic enclosure.	**P**
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT	EUT is not permanently installed equipment.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V)……:	100-240 Vac Markings provided on the marking plate.	**P**
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)……..:	--	**N/A**
	– Nature of supply and type of current……..:	Symbol ‘’ ~ ‘’ provided near rated supply voltage.	**P**
	Symbols 1-5, Table D.1 (used for same parameters……:	Symbol No. 1 from table D.1 used for input voltage. Symbol No. 4 from table D.1 used for output voltage.	**P**
	– RATED supply frequency or RATED frequency range in hertz……:	50-60 Hz	**P**
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT……..:	Provided on the marking plate of power supply unit.	**P**
7.2.7	RATED input in amps or volt-amps, (A, VA)……:	Rated input expressed in Amperes: 1,6 Amax.	**P**
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W)……..:	Rated input expressed in Amperes.	**P**
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W)…..:	Rated input expressed in Amperes: 1,6 Amax.	**P**
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W)……:	--	**N/A**
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA)……..:	--	**N/A**
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W)……..:	--	**N/A**
7.2.8	**Output connectors**		**P**
7.2.8.2	Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment	Rating of the output provided on the marking plate.	**P**
	Rated Voltage (V), Rated Current (A)……:	See attached copy of Marking Plate.	**—**
	Rated Power (W), Output Frequency (Hz)……:	DC output voltage.	**—**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.2.9	ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2), marking optional for ME EQUIPMENT or parts rated IPX0….:	--	**N/A**
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols ……..:	No applied parts provided.	**N/A**
	TYPE B APPLIED PARTS with symbol 19 of Table D.1.:	--	**N/A**
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1:	--	**N/A**
	TYPE CF APPLIED PARTS with symbol 21 of Table D...:	--	**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1…….:	--	**N/A**
	Proper symbol marked adjacent to or on connector for APPLIED PART……..:	--	**N/A**
	SAFETY SIGN 2 of Table D.2 placed near relevant outlet……..:	--	**N/A**
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use…….:	--	**N/A**
7.2.11	ME EQUIPMENT suitable for CONTINUOUS OPERATION	No marking provided, therefore Power supply unit is suitable for continuous operation.	**P**
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum “on” and “off” time……..:	EUT is designed for continuous operation.	**N/A**
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder	Top and bottom part of enclosure are fixed together by means of ultrasonic welding; therefore mains fuses not accessible.	**N/A**
	Fuse type…….:	--	**—**
	Voltage (V) and Current (A) rating…….:	--	**—**
	Operating speed (s) and Breaking capacity…….:	--	**—**
7.2.13	Physiological effects – SAFETY SIGN and warning statements ……..:	Equipment does not produce physiological effects.	**N/A**
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use…….: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	RMF Reference to specific RISKS: (ISO 14971 Cl. __) Equipment does not produce physiological effects. No RM considered necessary.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1	No high voltage terminal devices provided.	**N/A**
7.2.15	Requirements for cooling provisions marked……:	Not provided.	**N/A**
7.2.17	Packaging marked with special handling instructions for transport and/or storage……:	No special handling requirements.	**N/A**
	Permissible environmental conditions marked on outside of packaging……..:	--	**N/A**
	Packaging marked with a suitable SAFETY SIGN indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK……..:	--	**N/A**
	RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK…: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization	--	**N/A**
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and ……..:	--	**N/A**
	– the RATED flow rate also marked	--	**N/A**
7.2.19	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL……..:	Internal metal shield is connected to protective earth and considered as functional earth (reinforced insulation between primary and metal shield provided). Connection to internal metal plate performed by the manufacturer during assembling of the power supply unit.	**N/A**
7.2.20	Removable protective means marked to indicate the necessity for replacement when the function is no longer needed……..:	--	**N/A**
7.2.21	MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms……:	Not mobile equipment.	**N/A**
7.3	**Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts**		**P**
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W)……:	No heating elements provided.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL	--	**N/A**
7.3.2	Symbol 24 of Table D.1, or SAFETY SIGN No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts……:	No such parts within the equipment.	**N/A**
7.3.3	Type of battery and mode of insertion marked…….:	No battery provided.	**N/A**
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL……..:	--	**N/A**
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK……:	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an HAZARDOUS SITUATION if replaced incorrectly……: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Neither batteries nor battery compartments incorporated. No RM considered necessary.	**N/A**
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARDOUS SITUATION……:	--	**N/A**
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified ……..……:	Unit put together by ultrasonic welding and therefore not serviceable.	**N/A**
	Voltage (V) and Current (A) rating…….	--	**—**
	Operating speed(s), size & breaking capacity….:	--	**—**
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1	Approved appliance inlet used for connection to the mains.	**P**
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made	--	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.3.6	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS	Internal metal shield is connected to protective earth and considered as functional earth (reinforced insulation between primary and metal shield provided). Connection to internal metal plate performed by the manufacturer during assembling of the power supply unit. No external functional earth provided.	**N/A**
7.3.7	Terminals for supply conductors marked adjacent to terminals……:	No such terminals provided. Appliance coupler used for connection to the mains.	**N/A**
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	--	**N/A**
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3	--	**N/A**
	Marking for connection to a 3-phase supply, complies with IEC 60445	--	**N/A**
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made	--	**N/A**
7.3.8	"For supply connections, use wiring materials suitable for at least X °C" or equivalent, marked at the point of supply connections	--	**N/A**
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made	--	**N/A**
7.4	**Marking of controls and instruments**		**N/A**
7.4.1	The "on" & "off" positions of switch to control power to ME EQUIPMENT, including mains switch, marked with symbols 12 and 13 of Table D.1 or	--	**N/A**
	– indicated by an adjacent indicator light, or	--	**N/A**
	– indicated by other unambiguous means	--	**N/A**
	The "on" & "off" positions of switch to control power to parts of ME EQUIPMENT, marked with symbols 12 and 13 of Table D.1 or	--	**N/A**
	– marked with symbols 16 and 17 of Table D.1 or	--	**N/A**
	– indicated by an adjacent indicator light, or	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– indicated by other unambiguous means	--	**N/A**
	Switches that brings ME EQUIPMENT into “stand-by” may be indicated by symbol 29 of Table D.1	--	**N/A**
	The “on/off” positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, and	--	**N/A**
	– status indicated by adjacent indicator light	--	**N/A**
	– status indicated by other unambiguous means	--	**N/A**
	The “on/off” positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or	--	**N/A**
	– status indicated by adjacent indicator light	--	**N/A**
	– status indicated by other unambiguous means	--	**N/A**
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means	No control devices provided.	**N/A**
	RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK…….: (ISO 14971 Cl. 5.2-5.5, 6, 7.1, 7.2)	RMF Reference to specific RISKS: List of controls: (ISO14971 Cl.__) No control devices/switches provided. No RM considered necessary.	**N/A**
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE……..:	--	**N/A**
	– or an indication of direction in which magnitude of the function changes	--	**N/A**
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units	--	**N/A**
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units	--	**N/A**
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3……:	See Appended Tables 7.1.2 and 7.1.3.	**N/A**
7.5	**SAFETY SIGNS**		**N/A**
	SAFETY SIGN with established meaning used	No safety signs used.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR……: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	RMF Reference to specific RISK & Marking: SAFETY SIGN Used: (ISO 14971 Cl.__) No safety signs provided. No RM considered necessary.	**N/A**
	Affirmative statement together with SAFETY SIGN placed in instructions for use if insufficient space on ME EQUIPMENT	--	**N/A**
	Specified colours in ISO 3864-1 used for SAFETY SIGNs……..:	--	**N/A**
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)	--	**N/A**
	SAFETY SIGNS including any supplementary text or symbols described in instructions for use	--	**N/A**
	– and in a language acceptable to the intended OPERATOR	--	**N/A**
7.6	**Symbols**		**P**
7.6.1	Meanings of symbols used for marking described in instructions for use……:	Provided within the user manual, see enclosed.	**P**
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable	--	**N/A**
7.7	Colours of the insulation of conductors		**P**
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation	Green/yellow insulation used (Between PE pin of appliance inlet and internal PCB connection).	**P**
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations	Whole conductor has green/yellow insulation.	**N/A**
7.7.3	Green and yellow insulation identify only following conductors:	--	**P**
	– PROTECTIVE EARTH CONDUCTORS	--	**P**
	– conductors specified in 7.7.2	--	**N/A**
	– POTENTIAL EQUALIZATION CONDUCTORS	--	**N/A**
	– FUNCTIONAL EARTH CONDUCTORS	--	**N/A**
7.7.4	Neutral conductors of POWER SUPPLY CORDS are “light blue”	Power supply cord is not part of the investigation.	**N/A**
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1	--	**N/A**
7.8	Indicator lights and controls		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.8.1	Red indicator lights, not flashing used only for Warning	No red indicator light provided.	**N/A**
	Yellow indicator lights, not flashing used only for Caution	No yellow indicator light provided.	**N/A**
	Green indicator lights used only for Ready for use	A green LED is illuminated power on. Provided on the top side of the enclosure.	**P**
	Red flashing used only for HIGH PRIORITY ALARM CONDITION, interruption of current workflow needed	--	**N/A**
	Yellow flashing used only MEDIUM PRIORITY ALARM CONDITION, re-planning of workflow needed	--	**N/A**
	Yellow or Cyan, not flashing used for LOW PRIORITY ALARM CONDITION, planning of future workflow needed.	--	**N/A**
	Other colours: Meaning other than red, yellow, cyan or green (colour, meaning)……:	--	**N/A**
7.8.2	Red used only for emergency control	--	**N/A**
7.9	**ACCOMPANYING DOCUMENTS**		**P**
7.9.1	ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description	Technical description and user instruction provided by the manufacturer.	**P**
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:	--	**P**
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to……..:	GlobTek, Inc.	**P**
	– MODEL or TYPE REFERENCE……:	GTM21097 series	**P**
	When ACCOMPANYING DOCUMENTS provided electronically, USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT	Documents are provided in hard copy.	**N/A**
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	No special skills required. Environmental conditions specified in technical documentation.	**P**
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	--	**P**
7.9.2	Instructions for use include the required information		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.1	– use of ME EQUIPMENT as intended by the MANUFACTURER:	EUT is medical in power supply unit intended for supplying end medical product by its output voltage (polarized output cable provided).	**P**
	– frequently used functions,	EUT is medical in power supply unit intended for supplying end medical product by its output voltage (polarized output cable provided).	**P**
	– known contraindication(s) to use of ME EQUIPMENT	EUT is medical power supply unit; therefore no contraindications to use of the equipment.	**N/A**
	– parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient	No such parts.	**N/A**
	– name or trademark and address of the MANUFACTURER	--	**P**
	– MODEL OR TYPE REFERENCE	--	**P**
	Instruction for use included the following when the PATIENT is an intended OPERATOR:	End product consideration. Power supply unit is not end medical product.	**N/A**
	– the PATIENT is an intended OPERATOR	--	**N/A**
	– warning against servicing and maintenance while the ME EQUIPMENT is in use	--	**N/A**
	– functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and	--	**N/A**
	– maintenance the PATIENT can perform	--	**N/A**
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of SAFETY SIGNS and symbols marked on ME EQUIPMENT	Provided within the user manual, see enclosed.	**P**
	Instructions for use are in a language acceptable to the intended operator	English version evaluated.	**P**
7.9.2.2	Instructions for use include all warning and safety notices	Provided within the user manual, see enclosed.	**P**
	Warning statement for CLASS I ME EQUIPMENT included	--	**P**
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	Not specified. EUT is medical in power supply unit. Shall be evaluated during end medical product approval.	**N/A**
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	No multiple socket-outlet provided.	**N/A**
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	--	**N/A**
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions	Mains operated equipment.	**N/A**
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source	No additional power source provided. Mains operated equipment.	**N/A**
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries……: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	Specific RISKS: (ISO 14971 Cl.__) Neither batteries nor battery compartments incorporated. RM considered necessary.	**N/A**
	Where the RISK is unacceptable, the IFU includes a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time..... :	No batteries provided.	**N/A**
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided……:	No internal replaceable power source provided. Power supply unit is desk-top equipment.	**N/A**
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK……:	Power supply unit is not end medical product; shall be considered during end medical product approval.	**N/A**
7.9.2.5	Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE	Provided within the user manual, see enclosed.	**P**
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to	--	**N/A**
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected	No signal input/signal output parts provided.	**N/A**
	APPLIED PARTS specified	No applied parts provided.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.6	Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation	--	**N/A**
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device	EUT is desk-top power supply unit.	**N/A**
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation	--	**N/A**
7.9.2.9	Information provided to operate ME EQUIPMENT	--	**N/A**
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	--	**N/A**
7.9.2.10	A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message	Not messages provided.	**N/A**
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	Green LED for functional indication only.	**N/A**
7.9.2.12	Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified	No applied parts provided.	**N/A**
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	No such parts.	**N/A**
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	Power supply is maintenance free.	**N/A**
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	--	**N/A**
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	--	**N/A**
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	--	**N/A**
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	No such parts.	**N/A**
	Other equipment providing power to ME SYSTEM sufficiently described	Mains operated equipment.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.15	Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for use……..:	Provided within the user manual: The power supply has to be disposed appropriately. Please refer to local regulations (Waste Electrical and Electronic Equipment).	**P**
7.9.2.16	Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)	--	**N/A**
7.9.2.17	Instruction for use for ME EQUIPMENT emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation	Equipment does not emit radiation for medical purposes.	**N/A**
7.9.2.18	The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile indicate that they have been sterilized and the method of sterilization	No parts supplied sterile.	**N/A**
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization	--	**N/A**
7.9.2.19	The instructions for use contain a unique version identifier……..:	User manual, GTM21097 series, versions.01	**P**
7.9.3	**Technical description**		**P**
7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use including	--	**P**
	– information required in 7.2	--	**P**
	– permissible environmental conditions of use including conditions for transport and storage……:	--	**P**
	– characteristics of the ME EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found	--	**N/A**
	– special installation requirements such as the maximum permissible apparent impedance of SUPPLY MAINS	--	**N/A**
	– permissible range of values of inlet pressure and flow, and the chemical composition of cooling liquid	--	**N/A**
	– description of the means for checking the oil level in partially sealed oil filled ME EQUIPMENT or its parts	--	**N/A**
	– warning statement that addresses the HAZARDS that can result from unauthorized modification of the ME EQUIPMENT	The following WARNING provided within the user manual: Modification of the power supply is not allowed.	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– information pertaining to ESSENTIAL PERFORMANCE and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency	--	**N/A**
	Technical description separable from instructions for use contains required information, as follows		**P**
	– information required by 7.2		**P**
	– applicable classifications in Clause 6, warning and safety notices, and explanation of SAFETY SIGNS marked on ME EQUIPMENT	--	**P**
	– brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and	--	**N/A**
	a unique version identifier……..:	--	**P**
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description	--	**N/A**
7.9.3.2	**The technical description contains the following required information**		**N/A**
	– type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT:	Power supply unit is not permanently installed equipment.	**N/A**
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and	--	**N/A**
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	No replaceable or detachable parts provided.	**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine if replacement of components results in any unacceptable RISKS……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No replaceable components specified by the manufacturer. No RM considered necessary.	**N/A**
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component	Unit not serviceable – ultrasonic welding used.	**N/A**
7.9.3.3	Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description	Appliance coupler is considered as disconnecting device.	**P**
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		**P**
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS	--	**P**
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION……..: (ISO 14971 Cl. 5.4)	RMF Reference to specific RISKS: Risk management report (EL7) (ISO 14971 Cl. 5.4)	**P**
8.2	**Requirements related to power sources**		**N/A**
8.2.1	**Connection to a separate power source**		**N/A**
	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM	Equipment is intended for connection to the supply mains. No separate power source specified.	**N/A**
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified	--	**N/A**
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined	--	**N/A**
8.2.2	**Connection to an external d.c. power source**		**N/A**
	No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source	Equipment is intended for connections to the AC mains.	**N/A**
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE	--	**N/A**
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset	--	**N/A**
8.3	**Classification of APPLIED PARTS**		**N/A**
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	No applied parts provided.	**N/A**
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART	--	**N/A**
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.4	**Limitation of voltage, current or energy**		**P**
8.4.2	**ACCESSIBLE PARTS and APPLIED PARTS**		**P**
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT…:	No applied parts provided.	**N/A**
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT……:	See appended Table 8.7 Measured on the outer plastic enclosure (metal foil used) and on the output.	**P**
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed	Power supply unit is not end medical product. The likelihood of the current flowing through body of OPERATOR to be determined in end-product evaluation.	**N/A**
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.)……:	See appended Table 8.4.2	**P**
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J)……..:	See appended Table 8.4.2	**P**
	Limits in b) does not apply to SIP/SOP connectors and separate power supply connectors if the voltage measured is less than or equal to 60 V d.c. or 42,4 V peak a.c	--	**N/A**
	d) Voltage and energy limits specified in c) above also applied to the following:	--	**N/A**
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	No such parts.	**N/A**
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL	No such parts.	**N/A**
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N	No openings provided.	**P**
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N	No pre-set controls provided.	**P**
	Test repeated with a TOOL specified in instructions for use	--	**N/A**
	Test rod freely and vertically suspended through openings on top of ENCLOSURE	No top openings provided.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION	--	**N/A**
	A TOOL is required when it is possible to prevent the devices from operating	--	**N/A**
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one sec after disconnecting the plug of ME EQUIPMENT or its parts (V)…… ……:	See appended Table 8.4.3	**P**
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45µC….:	See appended Table 8.4.3	**N/A**
8.4.4	Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC….:	See appended Table 8.4.4	**N/A**
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL	--	**N/A**
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description……:	--	**N/A**
8.5	**Separation of parts**		**P**
8.5.1	**MEANS OF PROTECTION (MOP)**		**P**
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4	2 x MOOP provided between primary and accessible parts and between primary and secondary circuit within the equipment. 2 x MOOP provided between primary and internal functional earth.	**P**
	A MEANS OF PROTECTION protecting APPLIED PARTS or parts identified by 4.6 as parts subject to the same requirements, considered as MEANS OF PATIENT PROTECTION……..:	--	**N/A**
	Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10	--	**P**
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)	Protection categorized as operator protection.	**N/A**
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test.:	See appended Table 8.8.3	**N/A**
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12	--	**N/A**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6	--	**N/A**
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION ……..:	See appended Tables 8.8.3 and 8.10	**N/A**
	Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c……..:	See appended Tables 8.8.3 and 8.10	**N/A**
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	--	**N/A**
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF)…….:	--	**—**
	Optocouplers complying with IEC 60747-5-5:2007, or a later edition. Considered equivalent to requirements in 8.8.2 and 8.9.3	See table 8.10	**N/A**
	Measurement of Air Clearance and Creepage distance on the outside	See insulation table	**N/A**
	Dielectric strength test across optocoupler	See table 8.8.3	**N/A**
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	--	**P**
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:	--	**P**
	– dielectric strength test ……..:	See appended Table 8.8.3	**P**
	– requirements of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for INSULATION CO-ORDINATION	--	**N/A**
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:	--	**P**
	– limits of Tables 13 to 16 (inclusive); or	--	**P**
	– requirements of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for INSULATION CO-ORDINATION	--	**N/A**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6	--	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– or with requirements and tests of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for protective earthing……:	--	**N/A**
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION……:	See Appended Tables 8.8.3 and 8.10 Y1 type capacitor (CY1, CY2) provided between primary and functional earth.	**P**
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION……:	See Appended Tables 8.8.3 and 8.10 Y1 type capacitor (CY1, CY2) provided between primary and functional earth.	**P**
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	--	**N/A**
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (μF)……..:	--	**—**
	Optocouplers complying with IEC 60747-5-5:2007, or a later edition. Considered equivalent to requirements in 8.8.2 and 8.9.3	See table 8.10	**P**
	Measurement of Air Clearance and Creepage distance on the outside	See insulation table.	**P**
	Dielectric strength test across optocoupler	See table 8.8.3	**P**
	Points and applied parts at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 were examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION	--	**N/A**
8.5.2	**Separation of PATIENT CONNECTIONS**		**N/A**
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAX. MAINS VOLTAGE……:	No patient connections provided.	**N/A**
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART	--	**N/A**
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function	--	**N/A**
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS……:	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	--	**N/A**
	LEAKAGE CURRENT tests conducted per 8.7.4….:	See appended Table 8.7	**N/A**
	Dielectric strength test conducted per 8.8.3…….:	See appended Table 8.8.3	**N/A**
	CREEPAGE and CLEARANCES measured ……:	Refer to Insulation Diagram	**N/A**
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s	--	**N/A**
8.5.2.2	PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED…:	--	**N/A**
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and	--	**N/A**
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low. In this case 8.7.4.7 d) does not apply	--	**N/A**
	LEAKAGE CURRENT tests conducted per 8.7.4…:	See appended Table 8.7	**N/A**
	Dielectric strength test conducted per 8.8.3 …..:	See appended Table 8.8.3	**N/A**
	Relevant CREEPAGE and CLEARANCES measured	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISK of metal ACCESSIBLE PARTS contacting a source of voltage or LEAKAGE CURRENT above the limits……: (ISO 14971 Cl. 5.2-5.5, 6)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	**N/A**
8.5.2.3	**A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable distal from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE**		**N/A**
	– cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT……:	No patient leads provided.	**N/A**
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter	--	**N/A**
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– conductive part pluggable into a mains socket protected from contacting parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1	--	**N/A**
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,	--	**N/A**
	Test finger test (10 N)……..:	See appended Table 5.9.2	**N/A**
	Except when RISK MANAGEMENT PROCESS includes an assessment of RISKS resulting from contact with objects other than mains sockets or flat surfaces.: (ISO 14971 Cl. 5.2-5.5, 6)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
8.5.4	**WORKING VOLTAGE**	--	**P**
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V)……..:	240 Vac	**P**
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V)……..:	--	**N/A**
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V)……	See Insulation Diagram and Insulation Table.	**P**
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth	No applied parts in power supply.	**N/A**
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V)…… ……..:	No applied parts in power supply.	**N/A**
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	No applied parts in power supply.	**N/A**
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V)……..:	No motors provided.	**N/A**
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	No defibrillation-proof applied parts provided.	**N/A**
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:	--	**N/A**
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ……...:	See appended Table 8.5.5.1a	**N/A**
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS……..:	See appended Table 8.5.5.1b	**N/A**
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load……:	See appended Table 8.5.5.2	**N/A**
8.6	**Protective and functional earthing and potential equalization of ME EQUIPMENT**		**P**
8.6.1	Requirements of 8.6.2 to 8.6.8 applied	EUT is Class I equipment.	**P**
	Parts complying with IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 or IEC 62368-1:2018 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8	--	**N/A**
8.6.2	PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR……:	Protective earth terminal considered as functional earth terminal.	**P**
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL	--	**N/A**
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside……..:	--	**N/A**
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL	--	**P**
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing	--	**N/A**
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part,	No moving parts.	**N/A**
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE ……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to proof of reliability: (ISO 14971 Cl.__)	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop……:	See appended Table 8.6.4	**P**
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits……..:	See appended Table 8.6.4 & Clause 8.7	**P**
	DETACHABLE POWER SUPPLY CORD specified by manufacturer or delivered with product	Power supply cord specified within the user manual: Specified power supply cord: 3 x 0,75mm^2, maximum length 3 meters	**P**
8.6.5	**Surface coatings**		**N/A**
	Poorly conducting surface coatings on conductive elements removed at the point of contact	--	**N/A**
	Coating not removed when requirements for impedance and current-carrying capacity met	--	**N/A**
8.6.6	**Plugs and sockets**		**N/A**
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections	--	**N/A**
	– applied also where interchangeable parts are PROTECTIVELY EARTHED	--	**N/A**
8.6.7	**Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR**		**N/A**
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE	No potential equalization conductor provided.	**N/A**
	– accidental disconnection avoided in NORMAL USE	--	**N/A**
	– Terminal allows conductor to be detached without a TOOL	--	**N/A**
	– Terminal not used for a PROTECTIVE EARTH CONNECTION	--	**N/A**
	– Terminal marked with symbol 8 of Table D.1	--	**N/A**
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard	--	**N/A**
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION	Internal metal screen is considered as functional earth. There is reinforced insulation between primary and internal metal screen.	**P**
8.6.9	**Class II ME EQUIPMENT**		**N/A**
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow	--	**N/A**
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.	--	**N/A**
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS	Two means of protection between primary parts and functional earthing.	**N/A**
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		**P**
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3….:	See appended Tables 8.7	**P**
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7…….:	See appended Tables 8.7	**P**
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except	--	**P**
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)	--	**N/A**
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time	--	**P**
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION	Considered.	**P**
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE	No applied parts provided. EUT is medical power supply unit.	**N/A**
8.7.3	**Allowable Values**		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b……:	See appended Table 8.7 Leakage current meter with frequency characteristics as specified on Fig. 12 b) used.	**P**
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz……:	See appended Table 8.7 No applied parts provided.	**N/A**
	c) TOUCH CURRENT did not exceed 100µA in NORMAL CONDITION and 500µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC})…… ……..:	See appended Table 8.7 Measured on output and on the plastic enclosure surface (metal foil used).	**P**
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC})…… ……..:	See appended Table 8.7	**P**
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710……:	See appended Table 8.7 No permanently installed equipment.	**N/A**
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device……..:	See appended Table 8.7	**N/A**
	f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION…….:	See appended Table 8.7	**P**
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements……..:	See appended Table 8.7	**P**
8.8	Insulation		**P**
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing	--	**P**
	Insulation exempted from test (complies with clause 4.8)	IEC approved optocoupler provided between primary and secondary circuit. See list of critical components for details.	**P**
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	--	**N/A**
8.8.2	**Distance through solid insulation or use of thin sheet material**		**P**
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:	--	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) 0.4 mm, min, distance through insulation, or	IEC approved optocoupler between primary and secondary provided.	**P**
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:	--	**P**
	– at least two layers of material, each passed the appropriate dielectric strength test ..... :	See appended Table 8.8.3	**N/A**
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test ..... :	See appended Table 8.8.3 Approved triple insulated wire (TIW) used for secondary windings. See list of critical components for details.	**P**
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION	Outer transformer tape.	**P**
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION	--	**N/A**
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when	--	**P**
	c) Wire with solid insulation, other than solvent based enamel, complying with a)	--	**N/A**
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L	Approved triple insulated wire (TIW) used for secondary windings. See list of critical components.	**P**
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	--	**N/A**
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer	--	**N/A**
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded	--	**N/A**
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded	--	**N/A**
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension……:	No contact between 45°and 90°.	**N/A**
	Finished component complied with routine dielectric strength tests of 8.8.3……..:	See appended Table 8.8.3	**N/A**
	Tests of Annex L not repeated since material data sheets confirm compliance……:	See Table 8.10 and Material Information Attachment Approved triple insulated wire used for secondary windings within the transformer.	**P**
8.8.3	**Dielectric Strength**		**P**
	Solid insulating materials with a safety function withstood dielectric strength test voltages ……..:	See appended Table 8.8.3	**P**
8.8.4	**Insulation other than wire insulation**		**P**
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT	Approved materials used.	**P**
	ME EQUIPMENT and design documentation examined……:	See enclosed documentation.	**P**
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) Approved components provided with adequate safety insulation. See appended Table 8.10. No RM considered necessary.	**P**
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat……..:	Manufacturer is using approved materials with adequate temperature characteristics. See Table 8.10. No additional test was considered required.	**P**
	Tests conducted in absence of satisfactory evidence for resistance to heat……..:	--	**N/A**
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus…..:	See Table 8.8.4.1	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C)……:	See Table 8.8.4.1	**N/A**
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION	--	**N/A**
8.8.4.2	**Resistance to environmental stress**		**P**
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9	EUT is provided with plastic enclosure to cover all internal insulation parts.	**P**
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	No such materials used for insulation.	**N/A**
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	--	**N/A**
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples	Rubber not used for insulation.	**N/A**
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h	--	**N/A**
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**		**P**
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive)…… ……:	Refer to Insulation Diagram.	**P**
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1	No applied parts provided.	**N/A**
8.9.1.16	Conductive coatings applied to non-metallic surfaces, do not result in flaking or peeling reducing any AIR CLEARANCE or CREEPAGE DISTANCE	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION, min CREEPAGE and CLEARANCES not applied……..:	See appended Table 8.9.2 Sufficient creepage and clearance distances provided between parts of opposite polarity before mains fuses. Short circuit performed after primary fuses. No hazardous situation.	**N/A**
8.9.3	**Spaces filled by insulating compound**		**N/A**
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound	No parts filled with insulation compounds. There are only approved optocoupler connected between primary and secondary circuit. See list of critical components.	**N/A**
	Thermal cycling, humidity preconditioning, and dielectric strength tests	--	**N/A**
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage)…… ……:	See appended Table 8.9.3.2	**N/A**
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur	--	**N/A**
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint	--	**N/A**
	A winding of solvent-based enamelled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:	--	**N/A**
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage ……..:	See appended Table 8.9.3.4	**N/A**
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage	--	**N/A**
8.9.4	Minimum spacing of grooves transvers to the CREEPAGE DISTANCES considered a MEANS OF OPERATOR PROTECTION adjusted based on pollution degree ……:	Pollution degree:2	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES	Refer to Insulation Diagram supplemental information for location and force used.	**P**
8.10	**Components and wiring**		**P**
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely……:	All components mounted securely. Unwanted movement of single component not result unacceptable risk. Glue used for additional fixing of some components**.**	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: Risk management report (EL3) (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	**P**
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment……:	Accidental detachment prevented. Output cable is provided with cord anchorage to prevent displacement of the secondary wires in case of accidental displacement. Internal PE conductor is fixed with glue in additionally to the soldering (through the hole method used).	**N/A**
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS	--	**N/A**
8.10.3	Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken …:	See Appended Table 5.9.2 No such flexible cords provided.	**N/A**
8.10.4	**Cord-connected HAND-HELD parts and cord-connected foot-operated control devices**		**N/A**
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION	No cord-connected hand-held parts and cord-connected foot-operated control device provided.	**N/A**
8.10.4.2	Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3	--	**N/A**
8.10.5	**Mechanical protection of wiring**		**N/A**
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges……..:	No moving parts provided.	**N/A**
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS	--	**N/A**
8.10.6	Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead	--	**N/A**
8.10.7	a) Insulating sleeve adequately secured……..:	See appended Table 8.10 No insulation sleeve used.	**N/A**
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics	--	**N/A**
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C……..:	See appended Table 8.10 No such high temperature rises obtained during normal use of the equipment.	**N/A**
8.11	**MAINS PARTS, components and layout**		**P**
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles……..:	See appended Table 8.10 Appliance coupler is considered as disconnecting device.	**P**
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	EUT is not permanently installed poly-phase equipment.	**N/A**
	PERMANENTLY INSTALLED ME EQUIPMENT provided with means to isolate its circuits electrically from the SUPPLY MAINS are capable of being locked in the off position	EUT is not permanently installed equipment.	**N/A**
	– the isolation device specified in the ACCOMPANYING DOCUMENTS	Final determination in the end product.	**N/A**
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description ……..:	See appended Table 8.10	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV……:	See appended Table 8.10 No switch used as disconnect device.	**N/A**
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	--	**N/A**
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447	--	**N/A**
	f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH……:	See appended Table 8.10 Appliance coupler is considered as disconnecting device.	**P**
	g) A fuse or a semiconductor device not used as an isolating means	--	**N/A**
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device	Appliance coupler is considered as disconnecting device.	**P**
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering	--	**N/A**
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage	--	**N/A**
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause	--	**N/A**
	Standard test finger applied	--	**N/A**
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	No multiple-socket outlet provided.	**N/A**
8.11.3	**POWER SUPPLY CORDS**		**N/A**
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD	Power supply cord is not part of the investigation and is end product consideration.	**N/A**
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design 53):	See appended Table 8.10	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE ……:	See appended Table 8.10	**N/A**
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17……:	--	**N/A**
	For ME EQUIPMENT utilizing POWER SUPPLY CORDS and operating at currents greater than 63 A, apply the electrical regulations appropriate for the jurisdiction in which the ME EQUIPMENT is to be used.	--	**N/A**
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6 ……:	See appended Table 8.10	**N/A**
8.11.3.5	**Cord anchorage**		**N/A**
	a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage	Power supply cord not part of the investigation.	**N/A**
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or	--	**N/A**
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or	--	**N/A**
	– metal provided with an insulating lining affixed to cord anchorage	--	**N/A**
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation	--	**N/A**
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components	--	**N/A**
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals	--	**N/A**
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR	--	**N/A**
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18.....:	See appended Table 8.11.3.5	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests	--	**N/A**
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position	--	**N/A**
	CREEPAGE and CLEARANCES not reduced below limits in 8.9	--	**N/A**
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged	--	**N/A**
8.11.3.6	POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment	Power supply cord not part of the investigation.	**N/A**
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or	--	**N/A**
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram attached to the free end of cord (g)……..:	See appended Table 8.11.3.6	**N/A**
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance	--	**N/A**
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D ……..:	See appended Table 8.11.3.6	**N/A**
8.11.4	**MAINS TERMINAL DEVICES**		**N/A**
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection	--	**N/A**
	Terminals alone are not used to keep conductors in position	--	**N/A**
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors	--	**N/A**
	Screws and nuts clamping external conductors do not serve to secure any other component	--	**N/A**
8.11.4.2	**Arrangement of MAINS TERMINAL DEVICES**		**N/A**
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection	--	**N/A**
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	e) MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction	--	**N/A**
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced after fastening and loosening a conductor of largest cross-sectional area 10 times	No internal wirings on the primary side.	**N/A**
8.11.4.4	Terminals with clamping means for a rewireable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened	--	**N/A**
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewireable POWER SUPPLY CORD to allow for connection of conductors	--	**N/A**
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test	--	**N/A**
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		**P**
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection……..:	See appended Table 8.10. Two primary fuses used (in line and neutral).	**P**
	– in at least one supply lead for other single-phase CLASS II ME EQUIPMENT……..:	See appended table 8.10. Two primary fuses used (in line and neutral). EUT is Class I equipment. Short circuit tests performed and when components were failing, the test was repeated two times.	**P**
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	Not permanently installed equipment.	**N/A**
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART	--	**N/A**
	Protective devices have adequate breaking capacity based on MANUFACTURER'S expectation of the highest branch circuit current and/or prospective short circuit current:	See appended Table 8.10	**P**
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR	Not fused.	**P**
	Justification for omission of fuses or OVER-CURRENT RELEASES documented……..:	--	**N/A**
8.11.6	**Internal wiring of the MAINS PART**		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable .....:	No internal wiring in a mains part provided. Only PCB tracks provided.	**N/A**
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient……:	See appended Table 8.10 PCB tracks provided.	**P**
9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		**P**
9.2	**HAZARDS associated with moving parts**		**N/A**
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level……:	No moving parts provided.	**N/A**
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)	--	**N/A**
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and	--	**N/A**
	RISK CONTROLS implemented……..:	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	All RISKS associated with moving parts have been reduced to an acceptable level	--	**N/A**
9.2.2	**TRAPPING ZONE**		**N/A**
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:	--	**N/A**
	– Gaps in Clause 9.2.2.2, or	--	**N/A**
	– Safe distances in Clause 9.2.2.3, or	--	**N/A**
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or	--	**N/A**
	– Continuous activation in Clause 9.2.2.5	--	**N/A**
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM	--	**N/A**
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20……..:	See appended Table 9.2.2.2	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008……:	See appended Table 9.2.2.2	**N/A**
9.2.2.4	**GUARDS and other RISK CONTROL measures**		**N/A**
9.2.2.4.1	A TRAPPING ZONE do not to present a MECHANICAL HAZARD when GUARDS or other RISK CONTROL measures are of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK……..:	See appended Table 15.3 No trapping zones.	**N/A**
9.2.2.4.2	FIXED GUARDS held in place by systems that can only be dismantled with a TOOL	--	**N/A**
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open	--	**N/A**
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,	--	**N/A**
	– absence or failure of one of their components prevents starting, and stops moving parts	--	**N/A**
	Movable GUARDS complied with any applicable tests	--	**N/A**
9.2.2.4.4	Other RISK CONTROL designed and incorporated into to the control system stops movement and	--	**N/A**
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or	--	**N/A**
	ME EQUIPMENT is SINGLE FAULT SAFE	--	**N/A**
9.2.2.5	**Continuous activation**		**N/A**
	Continuous activation used as a RISK CONTROL, complies with the following	--	**N/A**
	a) movement was in OPERATOR'S field of view	--	**N/A**
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR	--	**N/A**
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or	--	**N/A**
	– the continuous activation system is SINGLE FAULT SAFE	--	**N/A**
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement	--	**N/A**
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.2.3	**Other MECHANICAL HAZARDS associated with moving parts**		**N/A**
9.2.3.1	Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated	No moving parts.	**N/A**
	– unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or	--	**N/A**
	– activation does not result in an unacceptable RISK	--	**N/A**
9.2.3.2	Over travel past range limits of the ME EQUIPMENT prevented……:	--	**N/A**
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse……:	See appended Table 9.2.3.2	**N/A**
9.2.4	**Emergency stopping devices**		**N/A**
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power……:	No emergency stopping device provided.	**N/A**
	a) Emergency stopping device reduced RISK to an acceptable level	--	**N/A**
	RISK MANAGEMENT FILE indicates the use of an emergency stopping device reduces the RISK to an acceptable level……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __) No emergency stopping device provided. No RM considered necessary.	**N/A**
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM	--	**N/A**
	c) Emergency stopping device actuator was readily accessible to OPERATOR	--	**N/A**
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT	--	**N/A**
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD	--	**N/A**
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like	--	**N/A**
	g) Means for stopping of movements operate as a result of one single action	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls	--	**N/A**
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or "STOP"	--	**N/A**
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed	--	**N/A**
	k) Emergency stopping device is suitable for its application	--	**N/A**
9.2.5	Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping .....:	Equipment does not require fixation of patient.	**N/A**
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented	--	**N/A**
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented	--	**N/A**
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT ……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No moving parts provided. Equipment does not require fixation of patient. No RM considered necessary.	**N/A**
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered……..:	No rough surfaces, no sharp corners and no sharp edges.	**P**
9.4	**Instability HAZARDS**		**N/A**
9.4.1	ME EQUIPMENT and its parts, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE	Power supply is desk-top equipment, stability tests not applicable.	**N/A**
9.4.2	**Instability – overbalance**		**N/A**
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested ……..:	See appended Table 9.4.2.1	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.4.2.2	**Instability excluding transport**		**N/A**
	ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE,.....:	See appended Table 9.4.2.2	**N/A**
	A warning provided when overbalance occurred during 10° inclined plane test	--	**N/A**
9.4.2.3	**Instability from horizontal and vertical forces**		**N/A**
	a) ME EQUIPMENT or its parts with a mass of 25kg or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it	Mass of equipment less than 25 kg.	**N/A**
	Surfaces of ME EQUIPMENT or its parts where a RISK of overbalancing exists from pushing, etc., permanently marked with a warning of the RISK	--	**N/A**
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)	See appended Table 9.4.2.3	**N/A**
	b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping	--	**N/A**
	ME EQUIPMENT or its parts, for use on the floor or on a table, where RISK of overbalancing exists, permanently marked with the RISK warning.....:	--	**N/A**
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b)……:	See appended Table 9.4.2.3	**N/A**
9.4.2.4	**Castors and wheels**		**N/A**
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE	Not a mobile equipment.	**N/A**
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT did not exceed 200 N ……:	See appended Table 9.4.2.4.2	**N/A**
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold ……:	See appended Table 9.4.2.4.3	**N/A**
9.4.3	**Instability from unwanted lateral movement (including sliding)**		**N/A**
9.4.3.1	a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control	Not a mobile equipment.	**N/A**
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements	--	**N/A**
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1	See appended Table 9.4.3.1	**N/A**
9.4.3.2	**Instability excluding transport**		**N/A**
	a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test .....:	See appended Table 9.4.3.2	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test	See appended Table 9.4.3.2	**N/A**
9.4.4	**Grips and other handling devices**		**N/A**
	a) ME EQUIPMENT with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method	--	**N/A**
	Handles, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS	--	**N/A**
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying	--	**N/A**
	c) Carrying handles and grips and their means of attachment withstood loading test .....:	See appended Table 9.4.4	**N/A**
9.5	**Expelled parts HAZARD**		**N/A**
9.5.1	Suitability of means of protecting against expelled parts determined by assessment and examination of RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No risk of expelled parts. No RM considered necessary.	**N/A**
	All identified RISKS associated with expelled parts mitigated to an acceptable level	--	**N/A**
9.5.2	Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965 .....:	See appended Table 8.10 No cathode ray tubes.	**N/A**
9.6	**Acoustic energy (including infra- and ultrasound) and vibration**		**N/A**
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and	Equipment does not produce significant acoustic energy or vibration.	**N/A**
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity .....:	--	**N/A**
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Equipment does not produce significant acoustic energy or vibration. No RM considered necessary.	**N/A**
	All identified RISKS mitigated to an acceptable level	--	**N/A**
9.6.2	**Acoustic energy**		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE	Equipment does not produce significant acoustic energy.	**N/A**
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA) .....:	--	**—**
	– 83 dBA (when halving the cumulative exposure time) (dBA) .....:	--	**—**
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB).....:	--	**—**
9.6.2.2	RISK MANAGEMENT FILE examined .....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Equipment does not produce infrasound and ultrasound.	**N/A**
9.6.3	**Hand-transmitted vibration**		**N/A**
	Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values	Equipment does not produce vibration.	**N/A**
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2) .....:	--	**N/A**
	– Accelerations for different times, inversely proportional to square root of time (m/s^2).....:	--	**N/A**
9.7	**Pressure vessels and parts subject to pneumatic and hydraulic pressure**		**N/A**
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No pneumatic and hydraulic parts within the equipment.	**N/A**
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum	--	**N/A**
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure	--	**N/A**
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects	--	**N/A**
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply	--	**N/A**
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity	--	**N/A**
9.7.4	MAXIMUM EQUIPMENT PRESSURE did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for the part, except allowed for pressure relief devices in 9.7.7confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests.....:	--	**N/A**
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when MAXIMUM EQUIPMENT PRESSURE was more than 50 kPa, and product of MAXIMUM EQUIPMENT PRESSURE and volume was more than 200 kPa.....:	See appended Table 9.7.5	**N/A**
9.7.6	Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE .....:	--	**N/A**
9.7.7	Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests .....:	--	**N/A**
	a) Connected as close as possible to pressure vessel or parts of system it is to protect	--	**N/A**
	b) Installed to be readily accessible for inspection, maintenance, and repair	--	**N/A**
	c) Could be adjusted or rendered inoperative without a TOOL	--	**N/A**
	d) With discharge opening located and directed as to not to release material towards any person	--	**N/A**
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK	--	**N/A**
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE EQUIPMENT PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure	--	**N/A**
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the risks associated with the discharge opening of the pressure relief device .....: ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No pressure-relief devices provided. No RM considered necessary.	**N/A**
9.8	**HAZARDS associated with support systems**		**N/A**
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK ..... :	See appended Table 8.10 No support system provided.	**N/A**
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD	--	**N/A**
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK	--	**N/A**
	– RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No support system provided.	**N/A**
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES	--	**N/A**
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials	--	**N/A**
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to	--	**N/A**
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest	No support system provided.	**N/A**
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing.....:	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment of the structural integrity of support system .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No support system provided.	**N/A**
	All identified RISKS are mitigated to an acceptable level	--	**N/A**
	When test was conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK.....:	See appended Table 8.10	**N/A**
	Where the equipment is not at equilibrium after 1 min, the RISK MANAGEMENT FILE includes an assessment of the test results .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISK: (ISO 14971 Cl.__) No support system provided.	**N/A**
9.8.3	**Strength of PATIENT or OPERATOR support or suspension systems**		**N/A**
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints:	--	**N/A**
	RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No support system provided.	**N/A**
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts	--	**N/A**
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER	--	**N/A**
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications	--	**N/A**
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS	--	**N/A**
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance ..... :	See copy of Marking Label	**N/A**
9.8.3.2	a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m^2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR..... :	--	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests ..... :	See appended Tables 8.10 and 9.8.3.2	**N/A**
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK	--	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test ..... :	See appended Tables 8.10 and 9.8.3.2	**N/A**
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE maintained BASIC SAFETY and ESSENTIAL PERFORMANCE confirmed test	See appended Table 9.8.3.3	**N/A**
9.8.4	**Systems with MECHANICAL PROTECTIVE DEVICES**		**N/A**
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided for the support system	--	**N/A**
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:	--	**N/A**
	– Designed based on TOTAL LOAD	--	**N/A**
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7	--	**N/A**
	– Activated before travel produced an unacceptable RISK	--	**N/A**
	– Considers Clauses 9.2.5 and 9.8.4.3	--	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests ..... :	See appended Table 8.10	**N/A**
9.8.4.2	Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE	--	**N/A**
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced	--	**N/A**
9.8.4.3	**MECHANICAL PROTECTIVE DEVICE intended to function once**		**N/A**
	– use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE . :	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal	--	**N/A**
	– ME EQUIPMENT permanently marked with SAFETY SIGN 2 of Table D.	--	**N/A**
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE	--	**N/A**
	– Compliance confirmed by examination and following test .....:	See appended Table 8.10	**N/A**
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT	--	**N/A**
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR	--	**N/A**
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function	--	**N/A**
9.8.5	**Systems without MECHANICAL PROTECTIVE DEVICES**		**N/A**
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES .....:	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No support system provided.	**N/A**
10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		**N/A**
10.1	**X-Radiation**		**N/A**
10.1.1	The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT.....:	See Table 10.1.1 Equipment does not produce X-radiations.	**N/A**
	Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE	--	**N/A**
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or :	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Equipment does not produce diagnostic or therapeutic X-radiation.	**N/A**
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) EUT not produces alpha, beta, gamma, neutron and other radiation.	**N/A**
10.3	The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2	EUT not produces microwave radiation.	**N/A**
	Microwave radiation is propagated intentionally	--	**N/A**
10.4	Relevant requirements of IEC 60825-1:2014 applied to lasers including laser diodes, laser light barriers or similar with a wavelength range of 180nm to 1 mm.	No such components incorporated within the equipment.	**N/A**
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .. : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Equipment does not produce other visible electromagnetic radiation.	**N/A**
10.6	RISK associated with infrared radiation other than emitted by lasers addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .. : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Equipment does not produce other visible electromagnetic radiation.	**N/A**
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Equipment does not produce other visible electromagnetic radiation.	**N/A**
11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		**P**
11.1	**Excessive temperatures in ME EQUIPMENT**		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.1.1	Temperatures on ACCESSIBLE PARTS did not exceed values in Tables 22 and.....:	See appended Table 11.1.1 Enclosure of the power supply is not intended to be touched by the operator; therefore top side of the power supply considered for non-intentional contact with the operator (duration less than 1 second, therefore limit 86°C applied). Shall be considered during end medical product approval.	**P**
	Surfaces of test corner did not exceed 90 °C	Temperature of test corner does not exceed 90°C in normal conditions.	**P**
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	No thermal cut-outs provided.	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISK: Risk management report (H2) (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	**P**
11.1.2	**Temperature of APPLIED PARTS**		**N/A**
11.1.2.1	APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply .....:	See appended Table 11.1.2.1 and appended. No applied parts provided.	**N/A**
	Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**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..:	See appended Table 11.1.2.2 No applied parts provided.	**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 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	APPLIED PARTS surface temperature of equal to or less than 41°C	--	**N/A**

IEC 60601-1			
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 ..... : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**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 Cl. 5.3-5.5, 6, 7.1-7.4)	See appended Table 11.1.3d and RMF Reference to specific RISKS: (ISO 14971 Cl.__) Temperature measurement was performed. No heating effect of nearby surfaces. No RM considered necessary.	**P**
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No heating effect of nearby surfaces. No RM considered necessary.	**N/A**
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: Risk management report (H2) (ISO 14971 Cl5.3-5.5, 6, 7.1-7.4)	**P**
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE.....:	RMF Reference to specific RISKS: Temperature measurement was performed.	**N/A**
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	--	**N/A**
11.2	**Fire prevention**		**P**
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3	See clause 15.3.	**P**
11.2.2	**Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS**		**N/A**
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of..... :	See appended Table 8.10 Component, not evaluated for use with Oxygen Rich Environment	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions	--	**N/A**
	1) when temperature of material raised to its ignition temperature	--	**N/A**
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature	--	**N/A**
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating	--	**N/A**
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton	--	**N/A**
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton	--	**N/A**
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE……..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) ME Equipment is not intended to be used in an oxygen rich environment.	**N/A**
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively……:	See appended Table 11.2.2.1	**N/A**
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three.....:	--	**N/A**
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination ……..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) ME Equipment is not intended to be used in an oxygen rich environment.	**N/A**
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3……:	See appended Tables 4.11, 11.1.1, 11.2.2.1 and 13.2	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%)……:	--	**N/A**
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes	--	**N/A**
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE……..:	--	**N/A**
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases ……..:	--	**N/A**
11.2.2.2	RISK of ignition did not occur, and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT	--	**N/A**
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks	--	**N/A**
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques	--	**N/A**
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means	--	**N/A**
11.2.3	**SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered**		**N/A**
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2)…… ……:	Component, not evaluated for use with Oxygen Rich Environment	**N/A**
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3)…… ……:	--	**N/A**
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a)……...:	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a)…… …….:	--	**N/A**
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas……..:	--	**N/A**
11.3	**Constructional requirements for fire ENCLOSURES of ME EQUIPMENT**		**P**
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2…….:	EUT complies with the construction requirements for fire enclosure. In addition, single fault as specified within the standard performed.	**P**
	Constructional requirements were met, or	Power supply unit is provided with plastic enclosure without openings (Flammability min. V-0). All internal components are mounted on the PCB rated min. V-0. Output cable is classified as VW-1. Short circuit on the cable output performed. No deformation of the cable, no hazard.	**P**
	– constructional requirements specifically analysed in RISK MANAGEMENT FILE …….. : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: Specific Requirements not met: (ISO 14971 Cl.__) Power supply unit complies with the constructional requirements for fire enclosure.	**P**
	Justification, when requirement not met…….:	EUT fulfils the constructional requirements of the standard.	**P**
	a) Flammability classification of insulated wire and connectors within fire ENCLOSURE is minimum V-2, , when test in accordance with IEC 60695-11-10 or :	See appended Table 8.10 Output cable is classified as VW-1. Short circuit on the cable performed. No deformation of the cable, no fire, no emission of flames, no hazard.	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	insulated with PVC, TFE, PTFE, FEP, polychloroprene or polyimide as determined by examination of data on materials……..:	--	**P**
	Flammability classification of printed circuit boards, and insulating material on which components are mounted is V-2, or better, based on IEC 60695-11-10 as decided by examination of materials data…:	See appended Table 8.10 PCB is rated min. V-0.	**P**
	If no Certification, V tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings	--	**N/A**
	b) Fire ENCLOSURE met following:	--	**P**
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm	Power supply unit is provided with plastic enclosure without openings.	**P**
	2) No openings on the sides within the area included within the inclined line C in Fig 39 or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm	Power supply unit is provided with plastic enclosure without openings.	**P**
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials……..:	See appended Table 8.10 Plastic enclosure is classified min. V-0	**P**
11.4	**ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics**		**N/A**
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G	Not evaluated for use in the presence of flammable anaesthetics.	**N/A**
11.5	**ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents**		**N/A**
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE ……..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Equipment is not intended to be used in conjunction with flammable agents.	**N/A**
11.6	**Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT**		**N/A**
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT ..... :	See Appended Table 11.6.1	**N/A**
11.6.2	**Overflow in ME EQUIPMENT**		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT incorporates a reservoir or liquid storage that did not wet any MEANS OF PROTECTION, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE……:	See Appended Table 11.6.1 Equipment does not contain a reservoir or liquid storage chamber.	**N/A**
	Maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.	--	**N/A**
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.	--	**N/A**
11.6.3	**Spillage on ME EQUIPMENT and ME SYSTEM**		**N/A**
	ME EQUIPMENT and ME SYSTEMS handling liquids constructed that spillage does not wet parts as determined by review of the RISK MANAGEMENT FILE and test……..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	See appended Tables 11.6.1; 8.7, 8.8.3 and RMF Reference to specific RISK: (ISO 14971 Cl. __) Equipment does not require handling of liquids in normal or foreseeable misuse.	**N/A**
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill……:	--	**N/A**
11.6.5	**Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**		**N/A**
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)…… ……..:	See Appended Table 11.6.1 No protection against ingress of water provided (classified IP20).	**N/A**
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION ..... :	See appended Tables 8.7 8.8.3	**N/A**
11.6.6	**Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS**		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use……:	See Appended Tables 11.6.1, 8.7, and 8.8.3 Cleaning or disinfection process not specified by the manufacturer.	**N/A**
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER……:	--	**N/A**
11.6.7	**Sterilization of ME EQUIPMENT and ME SYSTEMS**		**N/A**
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests……:	See appended Tables 8.7 8.8.3, and 11.6.1 Component, to be determined in end-product evaluation.	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISKS associated with any deterioration following sterilization……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No parts subjected to sterilization.	**N/A**
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No special substances used in conjunction with the equipment.	**N/A**
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented	--	**N/A**
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	Shall be evaluated during end medical product approval.	**N/A**
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		**N/A**
12.1	RISKS associated with accuracy of controls and instruments stated ..... : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No controls and instruments provided.	**N/A**
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING……:	USABILITY ENGINEERING PROCESS not applied for power supply.	**N/A**
12.3	MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020……..:	No alarm system incorporated.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
12.4	**Protection against hazardous output**		**N/A**
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS…….: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
12.4.2	– need for indication associated with hazardous output addressed in RISK MANAGEMENT PROCESS ... : (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit addressed in RISK MANAGEMENT PROCESS.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No multi-purpose equipment.	**N/A**
12.4.4	RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No multi-purpose equipment.	**N/A**
12.4.5	**Diagnostic or therapeutic radiation**		**N/A**
12.4.5.1	Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation	--	**N/A**
	Radiation safety ensured by compliance with requirements of appropriate standards	--	**N/A**
12.4.5.2	ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3.....:	Equipment does not produce diagnostic or therapeutic radiation.	**N/A**
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as .....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Equipment does not produce diagnostic or therapeutic radiation.	**N/A**
12.4.5.4	RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as .....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Equipment does not produce diagnostic or therapeutic radiation.	**N/A**
12.4.6	RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Equipment does not produce diagnostic or therapeutic radiation.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		**P**
13.1	**Specific HAZARDOUS SITUATIONS**		**P**
13.1.2	**Emissions, deformation of ENCLOSURE or exceeding maximum temperature**		**P**
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur	No fire, emission of molten metal or ignition of substances was noted during the tests.	**P**
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur	No deformation of the enclosure occurs.	**P**
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 ..... :	No applied parts.	**N/A**
	– Temperatures of Accessible PARTS THAT ARE LIKELY TO BE TOUCHED, but not intended to be touched did not exceed limits in Table 34 ..... :	See appended Table 11.1.1	**P**
	– Temperatures of ACCESSIBLE PARTS intended to be touched did not exceed limits in Table 23	Considered.	**P**
	– Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C were not exceeded	Considered.	**P**
	Limits for windings in Tables 26, 27, and 31 not exceeded	Temperature of transformer windings not exceeded.	**P**
	Table 22 not exceeded in all other cases	--	**P**
	Temperatures measured according to 11.1.3	--	**P**
	SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where:	No such parts or components provided.	**N/A**
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit in SINGLE FAULT CONDITION ..... :	See appended Table 13.1.2	**N/A**
	– or secondary circuits mounted on materials with a minimum flame rating of -V1, and	--	**N/A**
	– Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and	--	**N/A**
	– Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and	--	**N/A**
	– Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide	--	**N/A**
	– or components in the circuit have HIGH INTEGRITY CHARACTERISTICS..... :	See appended Table 4.9	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– or parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation	--	**N/A**
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function	See appended Table 13.1.2	**N/A**
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed……..:	See appended Table 8.7	**P**
	– voltage limits for ACCESSIBLE PARTS and APPLIED PARTS did not exceed……..:	See appended Table 8.7 Output voltage of the medical power supply.	**P**
13.2	**SINGLE FAULT CONDITIONS**		**P**
13.2.1	During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination	See appended Table 13.2 Considered.	**P**
	ME EQUIPMENT complied with 13.2.2 -13.2.12…..:	See appended Table 13.2	**P**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION.....…….....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. __) Equipment does not contain liquids.	**N/A**
	RISK MANAGEMENT FILE defines the appropriate test conditions..... …….....:	Equipment does not contain liquids.	**N/A**
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of test environment temperature	No heating elements or motors provided. EUT is intended for continuous operation.	**N/A**
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted	--	**N/A**
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION, the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).	--	**N/A**
13.2.13.2	**ME EQUIPMENT with heating elements**		**N/A**
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	No heating elements provided.	**N/A**
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a 3) other ME EQUIPMENT with heating elements met test	--	**N/A**
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively	--	**N/A**
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration	--	**N/A**
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part	--	**N/A**
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself	--	**N/A**
	b) ME EQUIPMENT with heating elements without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V) .....:	--	**N/A**
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY	--	**N/A**
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted	--	**N/A**
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION	--	**N/A**
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and	--	**N/A**
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS	--	**N/A**
	2) When more than one control provided, they were disabled in turn	--	**N/A**
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time	--	**N/A**
13.2.13.3	**ME EQUIPMENT with motors**		**N/A**
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable	No motors provided.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test	--	**N/A**
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition	--	**N/A**
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT	--	**N/A**
	b) Motor met running overload protection test of this clause when:	--	**N/A**
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or	--	**N/A**
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended	--	**N/A**
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C) ..... :	--	**N/A**
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps	--	**N/A**
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload	--	**N/A**
	Test not conducted where electronic drive circuits maintained a substantially constant drive current	--	**N/A**
	Test not conducted based on other justifications (justification) ..... :	--	**N/A**
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10	--	**N/A**
13.2.13.4	**ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION**		**N/A**
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated	EUT is designed for continuous operation.	**N/A**
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Motor winding temperatures did not exceed values in 13.2.10……..:	--	**N/A**
	Insulation Class……:	--	**—**
	Maximum temperature measured (°C)……..:	--	**—**
14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		**N/A**
14.1	Requirements in 14.2 to 14,12 not applied to PEMS when it provides no functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE, or	EUT is not programmable electrical medical system. EUT is medical power supply unit.	**N/A**
	– when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK……..:	--	**N/A**
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 5.2-5.5, 6)	RMF Reference to specific RISKS: ISO 14971 Cl. __)	**N/A**
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK	Equipment not connected to such network.	**N/A**
	When the requirements of 14.2 to 14.13 apply, the requirements of IEC 62304:2006 and IEC 62304:2006/AMD1:2015 clause 4.3, 5, 7, 8 and 9 apply for the development or modification of software of each PESS	--	**N/A**
	Software development process for Software Classification applied in accordance with Clause 4.3 and 4.4 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015……..:	Software Class: __	**N/A**
	Software development process applied according to Clause 5 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015……:	Refer to Attachment- Software	**N/A**
	Software development process for Software risk management applied according to Clause 7 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015……:	Refer to Attachment-Software	**N/A**
	Software development process Configuration Management applied according to Clause 8 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015……:	Refer to Attachment-Software	**N/A**
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015……..:	Refer to Attachment-Software	**N/A**
14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process……:	--	**N/A**
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented	--	**N/A**
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	--	**N/A**
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	--	**N/A**
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones	--	**N/A**
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	--	**N/A**
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained	--	**N/A**
14.6	**RISK MANAGEMENT PROCESS**		**N/A**
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS……..:	--	**N/A**
	RISK MANAGEMENT FILE includes known or foreseeable HAZARDS associated with software, hardware, incorporation of the PEMS into an IT-NETWORK, components of 3rd party origin and legacy subsystems……..: (ISO 14971 Cl. 5.3)	RMF Reference to specific HAZARDS: (ISO 14971 Cl. __)	**N/A**
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2…:	--	**N/A**
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure……: (ISO 14971 Cl. 7.1)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	**N/A**
14.7	A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem……: (ISO 14971 Cl. 7.2)	RMF Reference to specific RISK CONTROLS: (ISO 14971 Cl. __)	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems …..: (ISO 14971 Cl. 7.2)	RMF Reference to specific RISK CONTROLS: (ISO 14971 Cl. __)	**N/A**
14.9	Design is broken up into sub systems and descriptive data on design environment documented……:	--	**N/A**
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures……..: (ISO 14971 Cl. 7.2)	RMF Reference to specific RISK CONTROLS: (ISO 14971 Cl. __)	**N/A**
	– milestone(s) when VERIFICATION is to be performed for each function	--	**N/A**
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION	--	**N/A**
	– selection and utilization of VERIFICATION tools	--	**N/A**
	– coverage criteria for VERIFICATION	--	**N/A**
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented	--	**N/A**
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE .....:	--	**N/A**
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented	--	**N/A**
	The person with overall responsibility for PEMS VALIDATION is independent	--	**N/A**
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 7.2)	RMF Reference to specific RISK CONTROLS: (ISO 14971 Cl. __)	**N/A**
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE	--	**N/A**
	Software Classification for Software changes applied in accordance with Clause 4.3 and 4.4 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015:	Software Class:__	**N/A**
	Software Process for Software changes applied according to Clause 5 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015 ..... :	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015.....:	--	**N/A**
	Configuration management of software changes applied per Clause 8 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015.....:	--	**N/A**
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015.....:	--	**N/A**
14.13	For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following.....:	Equipment not connected to such network.	**N/A**
	a) Purpose of the PEMS connection to an IT-NETWORK	--	**N/A**
	b) required characteristics of the IT-NETWORK	--	**N/A**
	c) required configuration of the IT-NETWORK	--	**N/A**
	d) technical specifications of the network connection, including security specifications	--	**N/A**
	e) intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK	--	**N/A**
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the required characteristics (ISO 14971 Cl. 5.2-5.5, 6, 7.1, 7.2)	RMF Reference to specific hazardous situations: (ISO 14971 Cl. __) Equipment not connected to such network. No RM considered necessary.	**N/A**
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		**N/A**
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties	--	**N/A**
	– Notification that the RESPONSIBLE ORGANIZATION identify, analyse, evaluate and control these RISKS	--	**N/A**
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis	--	**N/A**
	– Changes to the IT-NETWORK include: - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15	**CONSTRUCTION OF ME EQUIPMENT**		**P**
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS……..:	A green LED is illuminated when the unit is operating. No other controls or indicators provided.	**N/A**
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance	No such parts provided.	**N/A**
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring	--	**N/A**
15.3	**Mechanical strength**		**P**
15.3.1	Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	See below.	**P**
15.3.2	Push test conducted ……..:	See Appended Table 15.3	**P**
	No damage resulting in an unacceptable RISK sustained	Equipment does not sustain any damage during testing.	**P**
15.3.3	Impact test conducted……:	See Appended Table 15.3	**P**
	No damage resulting in an unacceptable RISK sustained	Equipment does not sustain any damage during testing.	**P**
15.3.4	**Drop test**		**P**
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested ……..:	See Appended Table 15.3	**N/A**
	No unacceptable RISK resulted	--	**N/A**
15.3.4.2	Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test……:	See Appended Table 15.3.	**P**
	No damage resulting in an unacceptable RISK sustained	EUT is provided with enclosure with adequate strength and rigidity.	**P**
15.3.5	MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests…….:	See Appended Table 15.3 EUT is not mobile equipment.	**N/A**
	No damage resulting in an unacceptable RISK sustained	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.3.6	Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK	EUT is provided with enclosure with adequate strength and rigidity.	**P**
	Mould-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C……:	Test was performed at 94,0°C ambient temperature. Maximum temperature rise measured on the enclosure top during normal operation: 83,7°C at 40°C ambient temperature. No damage of the enclosure.	**P**
	No damage resulting in an unacceptable RISK	No risk of shrinkage or distortion on enclosures due to release of internal stresses.	**P**
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT	--	**N/A**
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK	--	**N/A**
15.4	**ME EQUIPMENT components and general assembly**		**P**
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists,…… ……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Output cable is soldered to the PCB through the hole within the equipment by the manufacturer. It cannot be connected or disconnected without the use of tool.	**N/A**
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions,……:	--	**N/A**
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection……:	--	**N/A**
15.4.2	**Temperature and overload control devices**		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.2.1	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION……: (ISO 14971 Cl. 5.2-5.5, 6)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No automatic resetting thermal cut-out or over-current release provided.	**N/A**
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT	No thermal cut-out that is reset by soldering provided.	**N/A**
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided……..: (ISO 14971 Cl. 5.2-5.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __) No thermostat provided.	**N/A**
	d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION or loss of ESSENTIAL PERFORMANCE ……..: (ISO 14971 Cl. 5.2-5.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No thermal cut-out or over current release provided.	**N/A**
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS	No thermal cut-out provided.	**N/A**
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests	No thermal cut-out or over current release provided.	**N/A**
	– Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17	--	**N/A**
	– ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13……:	See appended Table 13.2	**N/A**
	– SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards……:	--	**N/A**
	– In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions operated 200 times	--	**N/A**
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards	--	**N/A**
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times	--	**N/A**
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating	No fluid filled container with heating means provided.	**N/A**
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating……..: (ISO 14971 Cl. 5.2-5.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No tubular heating elements provided.	**N/A**
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS	No thermostats incorporated.	**N/A**
15.4.3	**Batteries**		**N/A**
15.4.3.1	Battery housings provided with ventilation……..: (ISO 14971 Cl. 5.2-5.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Neither batteries nor battery compartments incorporated..	**N/A**
	Battery compartments designed to prevent accidental short circuiting	--	**N/A**
15.4.3.2	Means provided to prevent incorrect connection of polarity	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries……: (ISO 14971 Cl. 5.2-5.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Neither batteries nor battery compartments incorporated.	**N/A**
15.4.3.3	Overcharging of battery prevented by virtue of design……:	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries…: (ISO 14971 Cl. 5.2-5.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Neither batteries nor battery compartments incorporated.	**N/A**
15.4.3.4	Primary lithium batteries comply with IEC 60086-4	No primary lithium battery used.	**N/A**
	Secondary lithium batteries comply with IEC 62133 or IEC 62133-2	No secondary lithium battery used.	**N/A**
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire……..:	--	**N/A**
	Protective device has adequate breaking capacity	--	**N/A**
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPS provided, or	--	**N/A**
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION	--	**N/A**
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for……:	A green LED is illuminated when the unit is operating or ready for operation (delivering output voltage).	**P**
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,	--	**N/A**
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational	No heaters provided.	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with the use of indicator lights for EQUIPMENT incorporating non-luminous heaters…..: (ISO 14971 Cl. 5.2-5.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No heaters provided.	**N/A**
	Requirement not applied to heated stylus-pens for recording purposes	--	**N/A**
	Indicator lights provided on ME EQUIPMENT to indicate an output exists	--	**N/A**
	Colours of indicator lights complied with 7.8.1	Only green LED is illuminated when the unit is operating.	**P**
	Charging mode visibly indicated	No charging mode incorporated.	**N/A**
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No pre-set controls provided.	**N/A**
15.4.6	**Actuating parts of controls of ME EQUIPMENT**		**N/A**
15.4.6.1	a) Actuating parts cannot be pulled off or loosened during NORMAL USE	No actuating parts of controls provided.	**N/A**
	b) Controls secured so that the indication of any scale always corresponds to the position of the control	--	**N/A**
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	When torque values per Table 30 applied knobs did not rotate ……..:.	See appended Table 15.4.6	**N/A**
	Tests conducted with no unacceptable RISK …..:	See appended Table 15.4.6	**N/A**
15.4.6.2	Stops on rotating/ movable parts of controls are of adequate mechanical strength …….:	See appended Table 15.4.6	**N/A**
	Torque values in Table 30 applied…….:	See appended Table 15.4.6	**N/A**
	No unexpected change of the controlled parameter when tested……:	See appended Table 15.4.6	**N/A**
15.4.7	**Cord-connected HAND-HELD and foot-operated control devices**		**N/A**
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1	No hand held control device provided.	**N/A**
	b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage……..:	No foot operated control device provided.	**N/A**
15.4.7.2	Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface……..:	No inadvertent change of control device possible.	**N/A**
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position	--	**N/A**
15.4.7.3	a) Foot-operated control device is at least rated IPX1……..:	See appended Table 11.6.1	**N/A**
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6……:	See appended Table 11.6.1	**N/A**
15.4.8	Aluminium wires less than 16 mm^2 in cross-sectional area are not used	Aluminium wires not used.	**P**
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed	No oil container provided.	**N/A**
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport	--	**N/A**
	A pressure-release device operating during NORMAL USE is provided	--	**N/A**
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage	--	**N/A**
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements	--	**N/A**
15.5	**MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5**		**P**
15.5.1	**Overheating**		**P**
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating……..:	See appended Tables 15.5.1.2 and 15.5.1.3	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31	--	**P**
	Dielectric strength test conducted after short circuit and overload tests ……:	See appended Table 15.5.2 Switch mode transformer incorporated within the equipment. Dielectric strength test according to Clause 8.8.3 performed.	**P**
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved ……..:	See appended Table 15.5.1.2	**P**
	Short circuit applied directly across output windings	Short circuit performed on transformer output windings.	**P**
15.5.1.3	Multiple overload tests conducted on windings:	See appended Table 15.5.1.3	**P**
15.5.2	Transformers operating at a frequency above 1kHz tested according to clause 8.8.3……:	Switch mode transformer provided. Therefore this test is not applicable.	**N/A**
	Transformer windings provided with adequate insulation	Switch mode transformer provided. Therefore this test is not applicable.	**N/A**
	Dielectric strength tests were conducted ……:	See appended Table 15.5.2 Switch mode transformer provided. Therefore this test is not applicable.	**N/A**
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with……..:	See appended Table 8.10 Transformer tested within the equipment.	**P**
	– Means provided to prevent displacement of end turns	--	**P**
	– Protective earth screens with a single turn have insulated overlap	--	**N/A**
	– Exit of wires form internal windings of toroid transformers protected with double sleeving	No toroid transformer construction.	**N/A**
	– Insulation between primary and secondary windings complies with 8.8.2	--	**N/A**
	– CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4	--	**N/A**
16	**ME SYSTEMS**		**N/A**
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with installation and modification of an ME SYSTEM……..: (ISO 14971 Cl. 5.2-5.5, 6)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No different configurations specified. ME Equipment is not intended to be combined with other equipment to create a system.	**N/A**
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered	--	**N/A**
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard	--	**N/A**
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards	--	**N/A**
	– tests performed in NORMAL CONDITION, except as specified	--	**N/A**
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM	--	**N/A**
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated	--	**N/A**
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR	--	**N/A**
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards	--	**N/A**
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM	--	**N/A**
16.2	**ACCOMPANYING DOCUMENTS of an ME SYSTEM**		**N/A**
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM	--	**N/A**
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM	--	**N/A**
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER	--	**N/A**
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER	--	**N/A**
	c) the required information is provided:	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM	--	**N/A**
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard	--	**N/A**
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM	--	**N/A**
	– additional safety measures to be applied during installation of ME SYSTEM	--	**N/A**
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT	--	**N/A**
	– additional measures to be applied during preventive maintenance	--	**N/A**
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor	--	**N/A**
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM	--	**N/A**
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM	--	**N/A**
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM	--	**N/A**
	– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM	--	**N/A**
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer	--	**N/A**
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET	--	**N/A**
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage	--	**N/A**
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT	--	**N/A**
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES	--	**N/A**
	– assembly of ME SYSTEMS and modifications during actual service life evaluated based on the requirements of this standard	--	**N/A**
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements	--	**N/A**
	Transient currents restricted to allowable levels for the specified IPS or UPS .....:	--	**N/A**
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified	--	**N/A**
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)	--	**N/A**
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed	--	**N/A**
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION	--	**N/A**
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V).....:	--	**N/A**
16.6	**LEAKAGE CURRENTS**		**N/A**
16.6.1	TOUCH CURRENT in NORMAL CONDITION did not exceed 100µA.....:	See appended Table 16.6.1	**N/A**
	TOUCH CURRENT did not exceed 500µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR .....:	See appended Table 16.6.1	**N/A**
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA.....:	--	**N/A**
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values .....:	See appended Tables 8.7 8.7.4.7 and 16.6.1	**N/A**
16.7	ME SYSTEM complied with applicable requirements of Clause 9.....:	See applicable appended Tables in section 9	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
16.8	Interruption and restoration power to the ME SYSTEM or any part of the ME SYSTEM did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	--	**N/A**
16.9	**ME SYSTEM connections and wiring**		**N/A**
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result……:	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with plugs for connection of PATIENT leads or cables likely to be located in the PATIENT ENVIRONMENT……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	– Plugs for connection of PATIENT leads or PATIENT cables could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no unacceptable RISK results	--	**N/A**
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable	--	**N/A**
16.9.2	**MAINS PARTS, components and layout**		**N/A**
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or	--	**N/A**
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or	--	**N/A**
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer	--	**N/A**
	b) – MULTIPLE SOCKET-OUTLET marked with SAFETY SIGN 2 of Table D.2 visible in NORMAL USE, and	--	**N/A**
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or	--	**N/A**
	– marked to indicate the equipment or equipment parts it may safely be attached to	--	**N/A**
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT	--	**N/A**
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:	--	**N/A**
	– CREEPAGE and CLEARANCES complied with 8.9	--	**N/A**
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:	--	**N/A**
	– ENCLOSURE complied with 8.4.2 d)	--	**N/A**
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable	--	**N/A**
	– RATINGS of components are not in conflict with conditions of use ……:	See appended Table 8.10	**N/A**
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL	--	**N/A**
	– POWER SUPPLY CORD complied with 8.11.3	--	**N/A**
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:	--	**N/A**
	– Separating transformer complied with this standard or IEC 61558-2-1……:	See appended Table 8.10	**N/A**
	– Separating transformer is CLASS I	--	**N/A**
	– Degree of protection against ingress of water specified as in IEC 60529	--	**N/A**
	– Separating transformer assembly marked according to 7.2 and 7.3	--	**N/A**
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083	--	**N/A**
16.9.2.2	The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED and protected by only the SUPPLY MAINS circuit over-current release, did not exceed 200 mΩ	--	**N/A**
	The impedance of an earth pathway protected by an additional intermediate circuit breaker or fuse rated 13A or lower, did not exceed 400 mΩ	--	**N/A**
	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part	--	**N/A**
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL	--	**N/A**
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage	--	**N/A**
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		**P**
	RISKS associated confirmed by review……:	--	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment of risks associated with the introduction of electromagnetic phenomena into the environment by the EQUIPMENT or SYSTEM……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: Risk management report (M1) (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	**P**

ANNEX G	**PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		**N/A**
G.2	**Locations and basic requirements**		**N/A**
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5	EUT was not tested against hazard of ignition of flammable anaesthetic mixtures.	**N/A**
G.2.2	FLAMMABLE AESTHETIC MIXTURE WITH	--	**N/A**
G.2.3	A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE	--	**N/A**
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5	--	**N/A**
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE comply with G.4 and G.6	--	**N/A**
	ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.6 conducted after tests of 11.6.6 and 11.6.7	--	**N/A**
G.3	**Marking, ACCOMPANYING DOCUMENTS**		**N/A**
G.3.1	CATEGORY APG ME EQUIPMENT prominently marked "APG" (symbol 23 in Table D.1)..... :	See copies of Marking Labels	**N/A**
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case	--	**N/A**
	When above marking not possible, relevant information included in instructions for use ..... :	--	**N/A**
	Marking complied with tests and criteria of 7.1.2 and 7.1.3	--	**N/A**
G.3.2	CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle "AP" (symbol 22 in Table D.1)..... :	See copies of Marking Labels	**N/A**
	Marking is as large as possible for the particular case	--	**N/A**
	When above marking not possible, the relevant information included in instructions for use ..... :	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Marking complied with tests and criteria of 7.1.2 and 7.1.3	--	**N/A**
G.3.3	The marking placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts	--	**N/A**
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts	--	**N/A**
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG	--	**N/A**
G.4	**Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT**		**N/A**
G.4.1	a) CREEPAGE and CLEARANCES are according to Table 12 for one MEANS OF PATIENT PROTECTION	--	**N/A**
	b) Connections protected against accidental disconnection	--	**N/A**
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD,	--	**N/A**
G.4.2	**Construction details**		**N/A**
	a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL	--	**N/A**
	b) ENCLOSURE complies with.....:	See appended Table 8.10	**N/A**
	– no openings on top covers of ENCLOSURE,	--	**N/A**
	– openings in side-covers prevented penetration of a solid cylindrical test rod	--	**N/A**
	– openings in base plates prevented penetration of a solid cylindrical test	--	**N/A**
	c) Short circuiting conductor(s) to a conductive part (when no explosive gasses) did not result in loss of integrity of the part, an unacceptable temperature, or any HAZARDOUS SITUATION	--	**N/A**
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures	--	**N/A**
	– Use of antistatic materials with a limited electrical resistance.....:	See appended Table 8.10	**N/A**
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor	--	**N/A**
	b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882 .....:	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5	--	**N/A**
G.5	**Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components**		**N/A**
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5	--	**N/A**
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5 ..... :	--	**N/A**
G.5.2	Temperature limits ..... :	See appended Tables 11.1.1 and 11.2.2.1	**N/A**
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:	--	**N/A**
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1 .....:	--	**N/A**
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 .....:	--	**N/A**
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 .....:	--	**N/A**
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3 .....:	--	**N/A**
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1	--	**N/A**
	No extrapolation made for voltages above 42 V	--	**N/A**
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2	--	**N/A**
	No extrapolation made for voltages above 242V	--	**N/A**
	U_{max} determined using actual resistance R	--	**N/A**
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3	--	**N/A**
	No extrapolation made for inductances larger than 900 mH	--	**N/A**
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed	--	**N/A**
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks	--	**N/A**
	– Peak value considered when a.c. supplied	--	**N/A**
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit .....:	--	**N/A**
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max} , and C_{max} determined with application of Figs G.1-G.3.....:	See appended Table 11.1.1	**N/A**
	Alternatively, compliance was verified by examination of design data..... :	--	**N/A**
G.5.4	**External ventilation with internal overpressure**		**N/A**
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:	--	**N/A**
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR t removed by ventilation before EQUIPMENT energized,	--	**N/A**
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa) .....:	--	**N/A**
	Overpressure maintained at the site of potential ignition	--	**N/A**
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE	--	**N/A**
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present	--	**N/A**
	c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa) .....:	--	**N/A**
	d) External surface of ENCLOSURE did not exceed 150 °C in 25 °C.....:	--	**N/A**
G.5.5	**ENCLOSURES with restricted breathing**		**N/A**
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:	--	**N/A**
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h . :	See appended Table 8.10	**N/A**
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained	--	**N/A**
	Cords are fitted with adequate anchorages to limit stresses as determined by test	--	**N/A**
	Overpressure not reduced below 200 Pa	--	**N/A**
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)	--	**N/A**
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C).....:	--	**N/A**
	Steady state operating temperature of ENCLOSURE also measured (°C) .....:	--	**N/A**
G.6	**CATEGORY APG ME EQUIPMENT, parts and components thereof**		**N/A**
G.6.1	ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION	--	**N/A**
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test	--	**N/A**
G.6.2	Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION..... :	--	**N/A**
G.6.3	Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS..... :	--	**N/A**
	a) no sparks produced and temperatures did not exceed 90 °C, or	See Tables 11.1.1, 11.2.2.1 and 13.2	**N/A**
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U_{max} and I_{max} occurring in their circuits complied with requirements, taking C_{max} and L_{max} into consideration:	See Tables 11.1.1 and 13.2	**N/A**
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 .....:	--	**N/A**
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5.....:	--	**N/A**
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 .....:	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 ..... :	--	**N/A**
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated	--	**N/A**
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in Cl. 4.10	--	**N/A**
	– I_{max} was the highest current flowing in the circuit under investigation, considering MAINS VOLTAGE variations as in Cl. 4.10	--	**N/A**
	– C_{max} and L_{max} are values occurring in relevant circuit	--	**N/A**
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω	--	**N/A**
	– Peak value considered when a.c. supplied	--	**N/A**
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :	--	**N/A**
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components	--	**N/A**
	– requirement not applied to transformers complying with this standard	--	**N/A**
	– requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture	--	**N/A**
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or	--	**N/A**
	Temperature measurements made in accordance with 11.1..... :	See Table 11.1.1	**N/A**
	– or U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6 ..... :	--	**N/A**
	Alternatively, compliance verified by comparison with design data ..... :	--	**N/A**
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1 ..... :	See appended Table 8.10	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE	--	**N/A**
G.7	Test apparatus for flammable mixtures according to this Clause and Fig G.7	--	**N/A**

ANNEX L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**		**N/A**
L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex	Separately approved triple insulated wire used within the transformer, refer to Table 8.10.	**N/A**
L.2	**Wire construction**		**N/A**
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component	--	**N/A**
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap	--	**N/A**
L.3	**Type Test**		**N/A**
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified	--	**N/A**
	Temperature (°C) .....:	---	**—**
	Humidity (%) .....:	--	**—**
L.3.1	Dielectric strength		**N/A**
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted with no breakdown:	--	**N/A**
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V) .....:	--	**N/A**
	– 6000 V for REINFORCED INSULATION (V) .....:	--	**N/A**
L.3.2	**Flexibility and adherence**		**N/A**
	Sample subjected to flexibility and adherence	--	**N/A**
	Sample examined per IEC 60851-3: 1997, cl. 5.1.1.4, followed by dielectric test of cl. 8.8.3, with no breakdown	--	**N/A**
	Test voltage was at least the voltage in Tables 6 and 7 but not less than the following:	--	**N/A**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) .....:	--	**N/A**
	– 3000 V for REINFORCED INSULATION (V) .....:	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa ..... :	--	**N/A**
L.3.3	**Heat Shock**		**N/A**
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3	--	**N/A**
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	--	**N/A**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :	--	**N/A**
	– 3000 V for REINFORCED INSULATION (V) ..... :	--	**N/A**
	Oven temperature based on Table L.2 (°C) ..... :	--	**—**
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm^2) ..... :	--	**N/A**
	Dielectric strength test conducted at room temperature after removal from the oven	--	**N/A**
L.3.4	**Retention of electric strength after bending**		**N/A**
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests	--	**N/A**
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	--	**N/A**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :	--	**N/A**
	– 3000 V for REINFORCED INSULATION (V) ..... :	--	**N/A**
	Test voltage applied between the shot and conductor	--	**N/A**
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm^2) ..... :	--	**N/A**
L.4	**Tests during manufacture**		**N/A**
L.4.1	Production line dielectric strength tests done by the manufacture per L.4.2 and L.4.3..... :	--	**N/A**
L.4.2	Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:	--	**N/A**
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V)..... :	--	**N/A**
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V)..... :	--	**N/A**
L.4.3	Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1) ..... :	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:	--	**N/A**
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION.....:	--	**N/A**
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION .....:	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
4.1	GT-RM2013-002 GTQPR05000 GT-RMPLAN2013-002	—	Risk Management Process (excluding production and post-production)	P
4.2	GT-RM2013-002 GTQPR05000 GT-RMPLAN2013-002	—	Adequate Resources	P
4.2	GT-RM2013-002 GTQPR05000 GT-RMPLAN2013-002	—	Assignment of qualified personnel	P
4.2	GT-RM2013-002 GTQPR05000 GT-RMPLAN2013-002	—	Policy for determining criteria for risk acceptability	P
4.3	—	GT-RM2013-002, Clause 3.4	Competence of personnel	P
4.4a	—	GT-RMPLAN2013-002, Chapter 1.1	Risk Management Plan - the scope of the planned risk management activities	P
4.4b	—	GT-RMPLAN2013-002, Chapter 1.2	Risk Management Plan - assignment of responsibilities and authorities	P
4.4c	—	GT-RMPLAN2013-002, Chapter 1.2	Risk Management Plan - requirements for review of risk management activities	P
4.4d	—	GT-RMPLAN2013-002, Chapter 1.3	Risk Management Plan - criteria for risk acceptability	P
4.4e	—	GT-RMPLAN2013-002, Chapter 1.4	Risk Management Plan - a method to evaluate the overall residual risk, and criteria for acceptability of the overall residual risk	P
4.4f	—	GT-RMPLAN2013-002, Chapter 1.5	Risk Management Plan - activities for verification of the implementation and effectiveness of risk control measures	P
4.5	—	GT-RM2013-002 GTQPR05000	Risk Management File	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

5.1	—	GT-RM2013-002, Chapter 6	Risk Analysis - Process	P
5.2	—	GT-RM2013-002, Chapter 6.1	Risk Analysis - Intended use and reasonably foreseeable misuse	P
5.3	—	GT-RM2013-002, Chapter, Chapter 6.1	Risk Analysis - Identification of characteristics related to safety	P
5.4	—	GT-RM2013-002, Chapter 6.2	Risk Analysis - Identification of hazards and hazardous situations	P
5.5	—	GT-RM2013-002, Chapter 6.3, 6.4	Risk Analysis - Risk estimation	P
6	—	GT-RM2013-002, Chapter 7	Risk Evaluation	P
7.1	—	GT-RM2013-002, Chapter 8	Risk Control - Risk control option analysis	P
7.2	—	GT-RM2013-002, Chapter 8	Risk Control - Implementation of risk control measures	P
7.3	—	GT-RM2013-002, Chapter 8.2	Risk Control - Residual risk evaluation	P
7.4	—	GT-RM2013-002, Chapter 8.3	Risk Control - Benefit-risk analysis	P
7.5a	—	GT-RM2013-002, Chapter 8.1	Risk Control - Risks arising from risk control measures (new hazards or hazardous situations introduced)	P
7.5b	—	GT-RM2013-002, Chapter 8.1, 9	Risk Control - Risks arising from risk control measures (estimated risks for previously identified hazardous situations affected)	P
7.6	—	GT-RM2013-002, Chapter 10.1	Risk Control - Completeness of risk control	P
8	—	GT-RM2013-002, Chapter 10.2	Evaluation of overall residual risk	P
9	—	GT-RM2013-002, Chapter 11	Risk management review	P

Supplementary Information:

Document Ref should be with regards to the policy/procedure documents and documents containing Risk Management Process -specific output.

4.3	**TABLE: ESSENTIAL PERFORMANCE**	**N/A**
List of ESSENTIAL PERFORMANCE functions	**MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)**	**Remarks**
--	--	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary Information:

ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.

Power supply unit is not end medical product; therefore no essential performance defined by the manufacturer.

4.11	TABLE: Power input					P
Operating Conditions / Ratings		**Voltage (V)**	**Frequency (Hz)**	**Current (A)**	**Power (W)**	**Power factor (cos φ)**
Model: GTM21097-2003						
Rated output load (6 A @ 3,3 Vdc)		90	50/60	0,56/0,57	--	--
Rated output load (6 A @ 3,3 Vdc)		100	50/60	0,53/0,54	--	--
Rated output load (6 A @ 3,3 Vdc)		120	50/60	0,46/0,46	--	--
Rated output load (6 A @ 3,3 Vdc)		132	50/60	0,42/0,43	--	--
Rated output load (6 A @ 3,3 Vdc)		180	50/60	0,30/0,31	--	--
Rated output load (6 A @ 3,3 Vdc)		200	50/60	0,26/0,27	--	--
Rated output load (6 A @ 3,3 Vdc)		220	50/60	0,24/0,24	--	--
Rated output load (6 A @ 3,3 Vdc)		230	50/60	0,23/0,23	--	--
Rated output load (6 A @ 3,3 Vdc)		240	50/60	0,22/0,22	--	--
Rated output load (6 A @ 3,3 Vdc)		264	50/60	0,20/0,20	--	--
Model: Model: GTM21097-3005						
Rated output load (6 A @ 5 Vdc)		90	50/60	0,71/0,72	--	--
Rated output load (6 A @ 5 Vdc)		100	50/60	0,65/0,66	--	--
Rated output load (6 A @ 5 Vdc)		120	50/60	0,57/0,58	--	--
Rated output load (6 A @ 5 Vdc)		132	50/60	0,53/0,55	--	--
Rated output load (6 A @ 5 Vdc)		180	50/60	0,44/0,45	--	--
Rated output load (6 A @ 5 Vdc)		200	50/60	0,41/0,42	--	--
Rated output load (6 A @ 5 Vdc)		220	50/60	0,39/0,39	--	--
Rated output load (6 A @ 5 Vdc)		230	50/60	0,38/0,38	--	--
Rated output load (6 A @ 5 Vdc)		240	50/60	0,37/0,37	--	--
Rated output load (6 A @ 5 Vdc)		264	50/60	0,35/0,35	--	--
Model: GTM21097-4509						
Rated output load (5 A @ 9 Vdc)		90	50/60	1,04/1,05	--	--
Rated output load (5 A @ 9 Vdc)		100	50/60	0,65/0,67	--	--
Rated output load (5 A @ 9 Vdc)		120	50/60	0,83/0,84	--	--

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
Rated output load (5 A @ 9 Vdc)	132	50/60	0,76/0,78	--	--
Rated output load (5 A @ 9 Vdc)	180	50/60	0,61/0,62	--	--
Rated output load (5 A @ 9 Vdc)	200	50/60	0,57/0,58	--	--
Rated output load (5 A @ 9 Vdc)	220	50/60	0,53/0,53	--	--
Rated output load (5 A @ 9 Vdc)	230	50/60	0,51/0,52	--	--
Rated output load (5 A @ 9 Vdc)	240	50/60	0,50/0,50	--	--
Rated output load (5 A @ 9 Vdc)	264	50/60	0,46/0,46	--	--
Model: GTM21097-5048					
Rated output load (1,0 A @ 48 Vdc)	90	50/60	1,00/1,02	--	--
Rated output load (1,0 A @ 48 Vdc)	100	50/60	0,98/0,98	--	--
Rated output load (1,0 A @ 48 Vdc)	120	50/60	0,92/0,92	--	--
Rated output load (1,0 A @ 48 Vdc)	132	50/60	0,87/0,86	--	--
Rated output load (1,0 A @ 48 Vdc)	180	50/60	0,62/0,61	--	--
Rated output load (1,0 A @ 48 Vdc)	200	50/60	0,57/0,57	--	--
Rated output load (1,0 A @ 48 Vdc)	220	50/60	0,52/0,51	--	--
Rated output load (1,0 A @ 48 Vdc)	230	50/60	0,50/0,50	--	--
Rated output load (1,0 A @ 48 Vdc)	240	50/60	0,49/0,49	--	--
Rated output load (1,0 A @ 48 Vdc)	264	50/60	0,48/0,47	--	--
Model: GTM21097-5024					
Rated output load (2,1 A @ 24 Vdc)	90	50/60	1,08/1,09	--	--
Rated output load (2,1 A @ 24 Vdc)	100	50/60	0,99/1,00	--	--
Rated output load (2,1 A @ 24 Vdc)	120	50/60	1,00/0,90	--	--
Rated output load (2,1 A @ 24 Vdc)	132	50/60	0,88/0,80	--	--
Rated output load (2,1 A @ 24 Vdc)	180	50/60	0,65/0,66	--	--
Rated output load (2,1 A @ 24 Vdc)	200	50/60	0,60/0,61	--	--
Rated output load (2,1 A @ 24 Vdc)	220	50/60	0,57/0,57	--	--
Rated output load (2,1 A @ 24 Vdc)	230	50/60	0,55/0,56	--	--
Rated output load (2,1 A @ 24 Vdc)	240	50/60	0,54/0,54	--	--
Rated output load (2,1 A @ 24 Vdc)	264	50/60	0,50/0,51	--	--
Model: GTM21097-5012					
Rated output load (4,17 A @ 12 Vdc)	90	50/60	1,09/1,11	--	--
Rated output load (4,17 A @ 12 Vdc)	100	50/60	0,99/1,02	--	--
Rated output load (4,17 A @ 12 Vdc)	120	50/60	0,86/0,88	--	--
Rated output load (4,17 A @ 12 Vdc)	132	50/60	0,83/0,81	--	--
Rated output load (4,17 A @ 12 Vdc)	180	50/60	0,66/0,68	--	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Rated output load (4,17 A @ 12 Vdc)	200	50/60	0,62/0,63	--	--
Rated output load (4,17 A @ 12 Vdc)	220	50/60	0,58/0,59	--	--
Rated output load (4,17 A @ 12 Vdc)	230	50/60	0,56/0,58	--	--
Rated output load (4,17 A @ 12 Vdc)	240	50/60	0,55/0,56	--	--
Rated output load (4,17 A @ 12 Vdc)	264	50/60	0,52/0,53	--	--

Supplementary information:

Rated input voltage: 100-240 Vac ; 50-60Hz

Rated input current: 1,6 Amax.

See copy of marking plate for details.

5.9.2	TABLE: Determination of ACCESSIBLE parts	P

Location	Determination method (NOTE1)	Comments
EUT enclosure	Visual	Live parts not accessible. Enclosure without openings provided to cover all live parts. No doubts; therefore only visual inspection performed.

Supplementary information:

[1)] NOTE: The determination methods are: visual; rigid test finger; jointed test finger; test hook.

7.1.2	TABLE: Legibility of Marking	P

Markings tested	Ambient Illuminance (lx)	Remarks
Outside Markings (Clause 7.2) .....:	900 lx	Marking plate
Inside Markings (Clause 7.3) .....:	--	No markings to be read inside
Controls & Instruments (Clause 7.4).....:	--	No controls & instruments
SAFETY SIGNS (Clause 7.5) .....:	--	No safety signs
Symbols (Clause 7.6).....:	900 lx	Present on Marking plate

Supplementary information:

Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR or if not defined at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.

7.1.3	TABLE: Durability of marking test	P

Characteristics of the Marking Label tested:		Remarks
Material of Marking Label .....:	Ink-print method.	Pass
Ink/other printing material or process .....:	Laser printing.	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Material (composition) of Warning Label .....:	--	N/A
Ink/other printing material or process .....:	--	N/A
Other .....:	--	N/A
Marking Label Tested:		**Remarks**
In-print method (printing on outer plastic enclosure)		--
Supplementary information: Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96%, and then for 15 s with a cloth rag soaked with isopropyl alcohol.		

8.4.2	**TABLE: TABLE: Working Voltage / Power Measurement**					**P**
Test supply voltage/frequency (V/Hz)[1] .....:						240 Vac / 50 Hz
Location From/To	**Measured values**					**Remarks**
	Vrms	**Vpk or Vdc**	**Peak-to-peak ripple[2]**	**Power W/VA**	**Energy (J)**	
Model: GTM21097-2003 (overload)						
Measured between output minus and output plus	--	3,47 Vdc	--	56,7 VA	--	Maximum output current achieved: 16,35 A
Model: GTM21097-3005 (input current limitation disabled, R10 short)						
Measured between output minus and output plus	--	3,47 Vdc	--	78,4 VA	--	Maximum output current achieved: 22,6 A
Model: GTM21097-5024 (overload)						
Measured between output minus and output plus	--	24,1 Vdc	--	111 VA	--	Maximum output current achieved: 4,6 A
Model: GTM21097-5024 (input current limitation disabled, R10 short)						
Measured between output minus and output plus	--	24,1 Vdc	--	185,6 VA	--	Maximum output current achieved: 11,6 A
GTM21097-5048 Transformer T1						
Pin 1 to PE	214	348	--	--	--	*
Pin 2 to PE	213	352	--	--	--	*
Pin 3 to PE	264	484	--	--	--	*
Pin 4 to PE	218	442	--	--	--	*

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Pin3 To Pin 5	168	418	--	--	--	*
Pin3 To Pin 6/7	200	484	--	--	--	*
Optocoupler U2						
Pin 3 to pin 1	222	368	--	--	--	*
Pin 3 to pin 2	222	368	--	--	--	*
Pin 4 to pin 1	230	368	--	--	--	*
Pin 4 to pin 2	228	368	--	--	--	*

Supplementary Information:

[1)]The input supply voltage to the ME EQUIPMENT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4.

[2)]. If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2

[3)] Voltage measurement of all conductive ACCESSIBLE PARTS of the SIP/SOP connection or separate power supply output connections to earth used a resistor of 10 kΩ + 500 Ω. See clause 8.4.2

Power measurements:

Output voltage during single fault conditions was recorded. Output voltage was below SELV limit. See table 13.2: TABLE: single fault conditions in accordance with 13.2.2 to 13.2.13, inclusive.

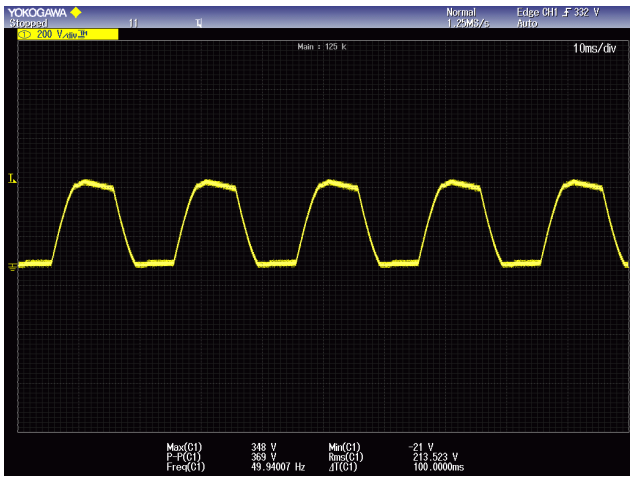
In additional, evaluation of voltage limiting components in SELV circuits performed. See table: evaluation of voltage limiting components in SELV circuits.

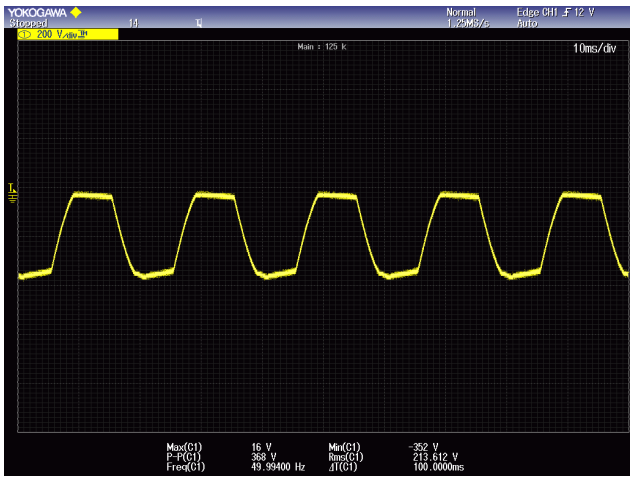
The energy on the output did not exceed 240 VA.

Working voltage:

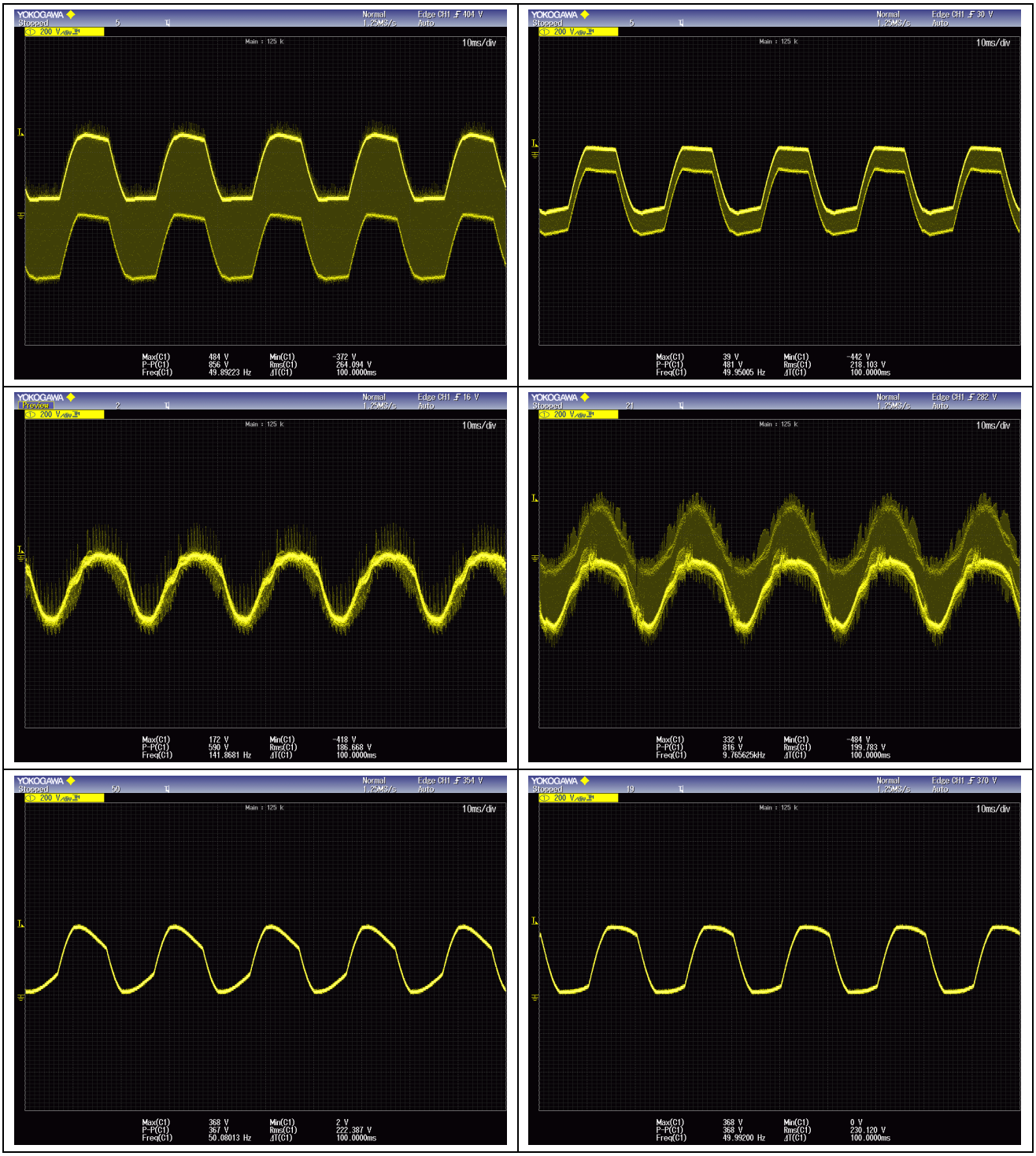
*: Input voltage: 240 Vac; Rated output load.

Protective earth, minus of the output and input N were connected and marked as PE.

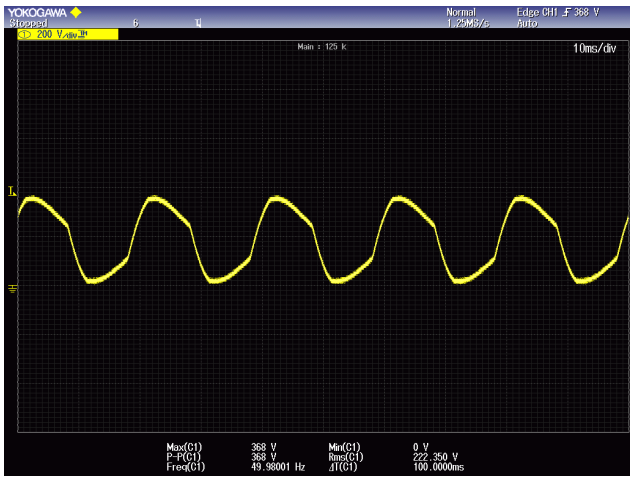


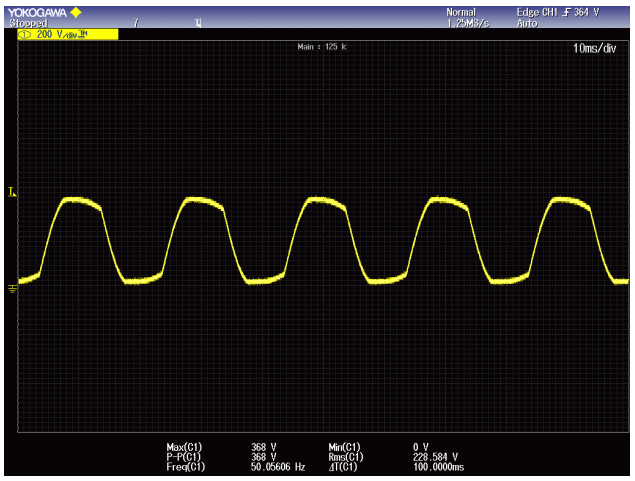


IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict



IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict





8.4.3	**TABLE: ME EQUIPMENT for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply**	**P**

Maximum allowable voltage (V) .....: 60

Voltage measured (V)

Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2	31	34	--	--	--	--	--	--	--	--
Plug pin 1 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and enclosure	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and enclosure	--	--	--	--	--	--	--	--	--	--

Maximum allowable stored charge when measured voltage exceeded 60 v (μc) .....: 45

Calculated stored charge (μc)

Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and enclosure	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and enclosure	--	--	--	--	--	--	--	--	--	--

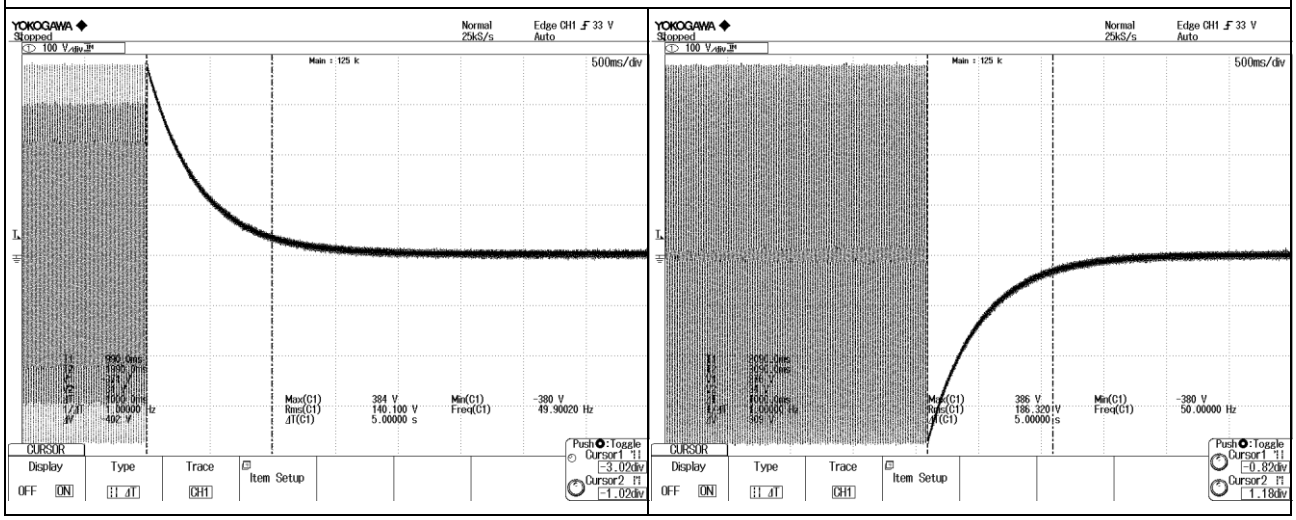
IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

Discharge performed at peak supply voltage; therefore performed only 2 times (upper peak, lower peak).

Supply voltage: 264 Vac.

See oscillograms below.



8.4.4	TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT	N/A

Maximum allowable residual voltage (V) .....:	60 V
Maximum allowable stored charge when residual voltage exceeded 60 V .....:	45 µC

Description of the capacitive circuit (i.e., accessible capacitor or circuit parts)	Measured residual voltage (V)	Calculated stored charge (µC)	Remarks
--	--	--	--

Supplementary information: /

8.5.5.1a	TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies	N/A

Test Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
--	--	--	--	--	--

Supplementary information: /

8.5.5.1b	TABLE: defibrillation-proof applied parts – verification of recovery time	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Applied part with test voltage	Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks
--	--	--	--	--
Supplementary information: /				

8.5.5.2	**TABLE: DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load**	N/A

Test Voltage applied to	Measured Energy E1 (mJ)	Measured Energy E2 (mJ)	Energy E1 as % of E2 (%)
PATIENT CONNECTION 1 or APPLIED PART with PATIENT CONNECTIONS 2, 3, and 4 of the same APPLIED PART connected to earth	--	--	--
PATIENT CONNECTION 2 or APPLIED PART with PATIENT CONNECTIONS 1, 3, and 4 of the same APPLIED PART connected to earth	--	--	--
PATIENT CONNECTION 3 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 4 of the same APPLIED PART connected to earth	--	--	--
PATIENT CONNECTION 4 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 3 of the same APPLIED PART connected to earth	--	--	--

Supplementary information:

For compliance: E1 must at least 90% of E2
E1= Measured energy delivered to 100 Ω with ME Equipment connected;
E2= Measured energy delivered to 100 Ω without ME equipment connected.

8.6.4	**TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS**	P

Type of ME EQUIPMENT & impedance measured between parts	Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part	25 Aac / 60	0,60	24	100
	25 Adc / 60	0,36	14	100
	40 Adc / 60	1,21	30	100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part **(Revision 2.0)**	25 Adc / 60	0,787	31,5	100
	40 Adc / 60	1,720	43,0	100

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

ME equipment with an appliance inlet, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a protectively earthed part **(Revision 2.0)**	25 Adc	3,559	142,4	200

Supplementary information:

Permanently installed ME equipment, impedance between protective earth terminal and a protectively earthed part - Limit 100 mΩ

ME equipment with an appliance inlet, impedance between earth pin in the appliance inlet and a protectively earthed part - Limit 100 mΩ

ME equipment with an appliance inlet, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a protectively earthed part - Limit 200 mΩ

ME equipment with a non-detachable power supply cord, impedance between the protective earth pin in the mains plug and a protectively earthed part - Limit 200 mΩ

Recommended power supply specified within the user manual: 3 x 0,75 mm^2, 3 metres long.

8.7	TABLE: leakage current				P
Type of leakage current and test condition (including single faults)	**Supply voltage (V)**	**Supply frequency (Hz)**	**Measured max. value (µA)**	**Remarks**	
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC	
Before humidity treatment (Frequency weighted)					
Normal condition, normal polarity, before humidity treatment;	264	60	660,0	--	
Normal condition, reverse polarity, before humidity treatment;	264	60	25,3	--	
Single fault condition (supply interruption), normal polarity, before humidity treatment;	264	60	692.0	--	
Single fault condition (supply interruption), reverse polarity, before humidity treatment;	264	60	49,1	--	
Revision 1.0					
Before humidity treatment (Frequency weighted)					
Normal condition, normal polarity, before humidity treatment;	264	60	417,0	--	
Normal condition, reverse polarity, before humidity treatment;	264	60	411,0	--	
Single fault condition (supply interruption), normal polarity, before humidity treatment;	264	60	780,0	--	

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Single fault condition (supply interruption), reverse polarity, before humidity treatment;	264	60	778,0	--
After humidity treatment (Frequency weighted)				
Normal condition, normal polarity, before humidity treatment;	264	60	405,2	--
Normal condition, reverse polarity, before humidity treatment;	264	60	398,7	--
Single fault condition (supply interruption), normal polarity, before humidity treatment;	264	60	766,0	--
Single fault condition (supply interruption), reverse polarity, before humidity treatment;	264	60	764,0	--
Before humidity treatment (Non-frequency weighted)				
Normal condition, normal polarity, before humidity treatment;	264	60	414,0	--
Normal condition, reverse polarity, before humidity treatment;	264	60	418,0	--
Single fault condition (supply interruption), normal polarity, before humidity treatment;	264	60	790,0	--
Single fault condition (supply interruption), reverse polarity, before humidity treatment;	264	60	789,0	--
After humidity treatment (Non-frequency weighted)				
Normal condition, normal polarity, before humidity treatment;	264	60	418,0	--
Normal condition, reverse polarity, before humidity treatment;	264	60	408,0	--
Single fault condition (supply interruption), normal polarity, before humidity treatment;	264	60	779,0	--
Single fault condition (supply interruption), reverse polarity, before humidity treatment;	264	60	777,0	--
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC
With frequency weighted device (before humidity treatment)				
Normal condition, normal polarity, before humidity treatment	264	60	6,7	Measured on output
Normal condition, reverse polarity, before humidity treatment	264	60	5,8	Measured on output

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Single fault condition (supply interruption), normal polarity, before humidity treatment	264	60	8,8	Measured on output
Single fault condition (supply interruption), reverse polarity, before humidity treatment	264	60	6,8	Measured on output
Single fault condition (PE interruption), normal polarity, before humidity treatment	264	60	9,3	Measured on output
Single fault condition (PE interruption), reverse polarity, before humidity treatment	264	60	8,6	Measured on output
Normal condition, normal polarity, before humidity treatment	264	60	1,5	Measured on plastic enclosure (metal foil used)
Normal condition, reverse polarity, before humidity treatment	264	60	1,7	Measured on plastic enclosure (metal foil used)
Single fault condition (supply interruption), normal polarity, before humidity treatment	264	60	2,3	Measured on plastic enclosure (metal foil used)
Single fault condition (supply interruption), reverse polarity, before humidity treatment	264	60	2,2	Measured on plastic enclosure (metal foil used)
With frequency weighted device (after humidity treatment)				
Normal condition, normal polarity, after humidity treatment	264	60	8,3	Measured on output
Normal condition, reverse polarity, after humidity treatment	264	60	7,1	Measured on output
Single fault condition (supply interruption), normal polarity, after humidity treatment	264	60	9,5	Measured on output
Single fault condition (supply interruption), reverse polarity, after humidity treatment	264	60	10,2	Measured on output
Normal condition, normal polarity, after humidity treatment	264	60	2,3	Measured on plastic enclosure (metal foil used)
Normal condition, reverse polarity, after humidity treatment	264	60	3,1	Measured on plastic enclosure (metal foil used)
Single fault condition (supply interruption), normal polarity, after humidity treatment	264	60	5,3	Measured on plastic enclosure (metal foil used)

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Single fault condition (supply interruption), reverse polarity, after humidity treatment	264	60	4,6	Measured on plastic enclosure (metal foil used)
Revision 1.0				
With frequency weighted device (before humidity treatment)				
Normal condition, normal polarity, before humidity treatment	264	60	5,4	Measured on output plus
Normal condition, reverse polarity, before humidity treatment	264	60	5,6	Measured on output plus
Single fault condition (supply interruption), normal polarity, before humidity treatment	264	60	8,1	Measured on output plus
Single fault condition (supply interruption), reverse polarity, before humidity treatment	264	60	8,1	Measured on output plus
Single fault condition (PE interruption), normal polarity, before humidity treatment	264	60	6,0	Measured on output plus
Single fault condition (PE interruption), reverse polarity, before humidity treatment	264	60	6,2	Measured on output plus
Normal condition, normal polarity, before humidity treatment	264	60	5,4	Measured on output minus
Normal condition, reverse polarity, before humidity treatment	264	60	5,6	Measured on output minus
Single fault condition (supply interruption), normal polarity, before humidity treatment	264	60	8,0	Measured on output minus
Single fault condition (supply interruption), reverse polarity, before humidity treatment	264	60	8,0	Measured on output minus
Single fault condition (PE interruption), normal polarity, before humidity treatment	264	60	5,9	Measured on output minus
Single fault condition (PE interruption), reverse polarity, before humidity treatment	264	60	6,2	Measured on output minus
Normal condition, normal polarity, before humidity treatment	264	60	4,9	Measured on plastic enclosure (metal foil used)
Normal condition, reverse polarity, before humidity treatment	264	60	5,4	Measured on plastic enclosure (metal foil used)

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Single fault condition (supply interruption), normal polarity, before humidity treatment	264	60	7,0	Measured on plastic enclosure (metal foil used)
Single fault condition (supply interruption), reverse polarity, before humidity treatment	264	60	7,3	Measured on plastic enclosure (metal foil used)
Single fault condition (PE interruption), normal polarity, before humidity treatment	264	60	5,7	Measured on plastic enclosure (metal foil used)
Single fault condition (PE interruption), reverse polarity, before humidity treatment	264	60	6,2	Measured on plastic enclosure (metal foil used)
With frequency weighted device (after humidity treatment – 2 days)				
Normal condition, normal polarity, after humidity treatment	264	60	5,9	Measured on output plus
Normal condition, reverse polarity, after humidity treatment	264	60	6,0	Measured on output plus
Single fault condition (supply interruption), normal polarity, after humidity treatment	264	60	8,7	Measured on output plus
Single fault condition (supply interruption), reverse polarity, after humidity treatment	264	60	8,7	Measured on output plus
Single fault condition (PE interruption), normal polarity, after humidity treatment	264	60	8,7	Measured on output plus
Single fault condition (PE interruption), reverse polarity, after humidity treatment	264	60	6,6	Measured on output plus
Normal condition, normal polarity, after humidity treatment	264	60	5,9	Measured on output minus
Normal condition, reverse polarity, after humidity treatment	264	60	6,0	Measured on output minus
Single fault condition (supply interruption), normal polarity, after humidity treatment	264	60	8,7	Measured on output minus
Single fault condition (supply interruption), reverse polarity, after humidity treatment	264	60	8,7	Measured on output minus
Single fault condition (PE interruption), normal polarity, after humidity treatment	264	60	6,5	Measured on output minus

IEC 60601-1					
Clause	Requirement + Test			Result - Remark	Verdict
Single fault condition (PE interruption), reverse polarity, after humidity treatment	264	60	6,6	Measured on output minus	
Normal condition, normal polarity, after humidity treatment	264	60	6,2	Measured on plastic enclosure (metal foil used).	
Normal condition, reverse polarity, after humidity treatment	264	60	6,0	Measured on plastic enclosure (metal foil used).	
Single fault condition (supply interruption), normal polarity, after humidity treatment	264	60	8,2	Measured on plastic enclosure (metal foil used).	
Single fault condition (supply interruption), reverse polarity, after humidity treatment	264	60	8,2	Measured on plastic enclosure (metal foil used).	
Single fault condition (PE interruption), normal polarity, after humidity treatment	264	60	6,9	Measured on plastic enclosure (metal foil used).	
Single fault condition (PE interruption), reverse polarity, after humidity treatment	264	60	6,7	Measured on plastic enclosure (metal foil used).	
With non-frequency weighted device (before humidity treatment)					
Normal condition, normal polarity, before humidity treatment	264	60	216,0	Measured on output plus	
Normal condition, reverse polarity, before humidity treatment	264	60	218,8	Measured on output plus	
Single fault condition (supply interruption), normal polarity, before humidity treatment	264	60	191,4	Measured on output plus	
Single fault condition (supply interruption), reverse polarity, before humidity treatment	264	60	12,3	Measured on output plus	
Single fault condition (PE interruption), normal polarity, before humidity treatment	264	60	190,6	Measured on output plus	
Single fault condition (PE interruption), reverse polarity, before humidity treatment	264	60	194,2	Measured on output plus	
Normal condition, normal polarity, before humidity treatment	264	60	219,6	Measured on output minus	
Normal condition, reverse polarity, before humidity treatment	264	60	222,0	Measured on output minus	

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Single fault condition (supply interruption), normal polarity, before humidity treatment	264	60	189,3	Measured on output minus
Single fault condition (supply interruption), reverse polarity, before humidity treatment	264	60	12,2	Measured on output minus
Single fault condition (PE interruption), normal polarity, before humidity treatment	264	60	191,9	Measured on output minus
Single fault condition (PE interruption), reverse polarity, before humidity treatment	264	60	197,3	Measured on output minus
Normal condition, normal polarity, before humidity treatment	264	60	213,3	Measured on plastic enclosure (metal foil used)
Normal condition, reverse polarity, before humidity treatment	264	60	215,4	Measured on plastic enclosure (metal foil used)
Single fault condition (supply interruption), normal polarity, before humidity treatment	264	60	178,2	Measured on plastic enclosure (metal foil used)
Single fault condition (supply interruption), reverse polarity, before humidity treatment	264	60	12,4	Measured on plastic enclosure (metal foil used)
Single fault condition (PE interruption), normal polarity, before humidity treatment	264	60	192,7	Measured on plastic enclosure (metal foil used)
Single fault condition (PE interruption), reverse polarity, before humidity treatment	264	60	194,7	Measured on plastic enclosure (metal foil used)
With non-frequency weighted device (after humidity treatment – 2 days)				
Normal condition, normal polarity, after humidity treatment	264	60	212,5	Measured on output plus
Normal condition, reverse polarity, after humidity treatment	264	60	209,7	Measured on output plus
Single fault condition (supply interruption), normal polarity, after humidity treatment	264	60	11,9	Measured on output plus
Single fault condition (supply interruption), reverse polarity, after humidity treatment	264	60	11,9	Measured on output plus
Single fault condition (PE interruption), normal polarity, after humidity treatment	264	60	192,2	Measured on output plus

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Single fault condition (PE interruption), reverse polarity, after humidity treatment	264	60	189,9	Measured on output plus
Normal condition, normal polarity, after humidity treatment	264	60	212,3	Measured on output minus
Normal condition, reverse polarity, after humidity treatment	264	60	209,5	Measured on output minus
Single fault condition (supply interruption), normal polarity, after humidity treatment	264	60	11,9	Measured on output minus
Single fault condition (supply interruption), reverse polarity, after humidity treatment	264	60	11,9	Measured on output minus
Single fault condition (PE interruption), normal polarity, after humidity treatment	264	60	191,3	Measured on output minus
Single fault condition (PE interruption), reverse polarity, after humidity treatment	264	60	189,1	Measured on output minus
Normal condition, normal polarity, after humidity treatment	264	60	201,9	Measured on plastic enclosure (metal foil used).
Normal condition, reverse polarity, after humidity treatment	264	60	200,1	Measured on plastic enclosure (metal foil used).
Single fault condition (supply interruption), normal polarity, after humidity treatment	264	60	11,7	Measured on plastic enclosure (metal foil used).
Single fault condition (supply interruption), reverse polarity, after humidity treatment	264	60	11,7	Measured on plastic enclosure (metal foil used).
Single fault condition (PE interruption), normal polarity, after humidity treatment	264	60	183,4	Measured on plastic enclosure (metal foil used).
Single fault condition (PE interruption), reverse polarity, after humidity treatment	264	60	182,4	Measured on plastic enclosure (metal foil used).
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
--	--	--	--	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 µA Type CF AP: 50 µA
--	--	--	--	--
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
--	--	--	--	--
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 µA Type CF: N/A
--	--	--	--	--
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current)
--	--	--	--	--
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
--	--	--	--	--
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC;1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
--	--	--	--	--
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000 µA Type CF: 100 µA
--	--	--	--	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 µA Type CF: N/A
--	--	--	--	--
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
--	--	--	--	--

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

Touch current measured after 2 days and 5 days on humidity treatment.

ER - Earth leakage current
TC – Touch current
P - Patient leakage current
PA – Patient auxiliary current
TP – Total Patient current
PM - Patient leakage current with mains on the applied parts
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

8.8.3	**TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)**	**P**

Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1)]	Dielectric breakdown after 1 minute Yes/No[2)]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
Area C (primary to plastic enclosure (metal foil used)	2xMOOP	340 V_{peak}	--	3000 Vac	No
Area C (primary to FG)	2xMOOP	340 V_{peak}	--	3000 Vac	No
Area D (primary to secondary)	2xMOOP	484 V_{peak}	--	3000 Vac	No
Area D (primary to secondary – mains transformer)	2xMOOP	484 V_{peak}	--	3000 Vac	No

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.
[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

8.8.4.1	TABLE: Resistance to heat - Ball pressure test of thermoplastic parts		N/A
	Allowed impression diameter (mm) ..... :	≤ 2 mm	—
	Force (N) ..... :	20	—

Part/material	Test temperature (°C)	Impression diameter (mm)
--	--	--

Supplementary information:

Resistance to heat for insulation of thermoplastic materials that used as SUPPLEMENTARY INSULATION or REINFORCED INSULATION established by performing the ball-pressure test in at a temperature 25 °C higher than the temperature of the insulation measured during the tests of 13.2.2 to 13.2.13 (inclusive).

8.9.2	TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4		N/A

Specific areas of circuits short-circuited and test conditions	Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE[1)]	HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No	Remarks
--	--	--	--

Supplementary information:

[1)] Note: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE

8.9.3.2	Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts			N/A
Part Test	8.9.3.4 - Test duration and temperature for 10 cycles after which the sample was subjected to Humidity Preconditioning per Cl. 5.7	Dielectric test voltage	Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No	Crack or voids in the insulating compound: Yes/No
	68 h at T1 ± 2 °C = ___°C [1)]	--	--	--
	1 h at 25 °C ± 2 °C			
	2 h at 0 °C ± 2 °C			
	1 or more h at 25 °C ± 2 °C			

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

1) T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

8.9.3.3	**Table: Thermal cycling tests on one sample of cemented joint with other insulating parts (see 8.9.3.3)**			**N/A**
Part tested	**Sample**	**Each test duration and temperature**	**Dielectric test voltage**	**Dielectric strength test Breakdown: Yes/No**
	1	10 Cycles conducted of the following:	--	--
		1 - 68 h at T1 ± 2 °C = ___ °C[1]		
		2 - 1 h at 25 °C ± 2 °C		
		3 - 2 h at 0 °C ± 2 °C		
		4 - 1 or more h at 25 °C ± 2 °C		
	2	Humidity Conditioning per 5.7		--
	3	Humidity Conditioning per 5.7		--

Supplementary information:

1) T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

8.10	**TABLE: Critical components information**				**P**
Object / part No.	**Manufacturer/ trademark**	**Type / model**	**Technical data**	**Standard**	**Mark(s) of conformity[1)]**
Enclosure (Electrical, Fire)	SABIC	SE1X, SE1, HF500R	Plastic overall. Dimensions: 118,0 mm (W) by 60,0 mm (L) 43,0 mm (H) (without pins), min. 1,5 mm thick. Top and bottom parts are glued together with adhesive. V-0, 105°C	IEC/EN 60601-1 (QMFZ2)	Checked with appliance. UR E45329

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Enclosure (Electrical, Fire) (alternative)	TEIJIN	LN-1250	Plastic overall. Dimensions: 118,0 mm (W) by 60,0 mm (L) 43,0 mm (H) (without pins), min. 1,5 mm thick. Top and bottom parts are glued together with adhesive. V-0, 115°C	IEC/EN 60601-1 (QMFZ2)	Accepted. UR E244324
Enclosure (Electrical, Fire) (alternative) **(Revision 1.0)**	SABIC	945	Plastic overall. Dimensions: 118,0 mm (W) by 60,0 mm (L) 43,0 mm (H) (without pins), min. 1,5 mm thick. Top and bottom parts are glued together with adhesive. V-0, 120°C	IEC/EN 60601-1 (QMFZ2)	Accepted. UR E45329 UR E207780
Enclosure (Electrical, Fire) (alternative) **(Revision 1.0)**	SABIC	C2950	Plastic overall. Dimensions: 118,0 mm (W) by 60,0 mm (L) 43,0 mm (H) (without pins), min. 1,5 mm thick. Top and bottom parts are glued together with adhesive. V-1, 85°C	IEC/EN 60601-1 (QMFZ2)	Accepted. UR E207780
Appliance inlet	Inalways	0707-1	10A, 250V	IEC 60320 (AXUT2)	VDE 40022412 UR E94191
Appliance inlet (alternative)	Rich bay	R-301	10A, 250V	IEC 60320 (AXUT2)	VDE 40029319 UR E184638
Appliance inlet (alternative)	BEJ	ST-A01 series	10A, 250V	IEC 60320 (AXUT2)	VDE 40013388 UR E225980

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Appliance inlet (alternative)	TECX	TU-301	10A, 250V	IEC 60320 (AXUT2)	VDE 40025582 UR E220004
Appliance inlet (alternative)	Sun Fair	S-03	10A, 250V	IEC 60320 (AXUT2)	VDE 40012607 UR E226643
Appliance inlet (alternative)	Supercom	SC-8R	10A, 250V	IEC 60320 (AXUT2)	VDE 40014286 UL
Appliance inlet (alternative)	Shenzhen Delikang Electronics	CDJ-3	10A, 250V	IEC 60320 (AXUT2)	VDE 40010513 UR E217394
Appliance inlet (alternative) **(Revision 2.0)**	LECI Electronics Co., Ltd.	DB-14	10A, 250V	IEC 60320 (AXUT2)	VDE 40032137 UR E302229
PCB	Interchangeable	Interchangeable	Min. V-0 Min. 130°C, Dimensions: 111 mm by 54 mm by 1,0 mm thickness.	IEC/EN 60601-1 (ZPMV2)	Accepted. UL
Fuse (F1)	Walter Electronics	TSD	T1.6A, 250V 5x20mm	IEC 60127-2 (JDYX)	VDE 40016851 UL E56092
Fuse (F1) (alternative)	Bel	5ST	T1.6A, 250Vac, 5x20mm	IEC 60127-2 (JDYX2)	VDE 40000507 UR E20624
Fuse (F1) (alternative)	Cooper Ind.	S506	T1.6A, 250Vac, 5x20mm	IEC 60127-2 (JDYX2)	VDE 40011926 UR E19180
Fuse (F1) (alternative)	Conquer Electronics	UTE, UTE-A, UDA-A	T1.6A, 250Vac, 5x20mm	IEC 60127-2 (JDYX2)	VDE 40008019 VDE 40008022 UR E82636
Fuse (F1) (alternative)	Littelfuse	218	T1.6A, 250Vac, 5x20mm	IEC 60127-2 (JDYX2)	VDE 40013496 UR E10480
Fuse (F1) (alternative)	SUNNY EAST ENTERPRISE CO LTD	GTL	T1.6A, 250Vac, 5.2x20mm	IEC 60127-2 (JDYX2)	VDE 40003683 UR E133774
Fuse (F2)	HollyLand	32S	1,6A, 250V, 3,6x10mm	IEC 60127-2 (JDYX)	VDE 40011830 UR E156471
Fuse (F2) (alternative)	SUNNY EAST ENTERPRISE CO LTD	TDP, CFD	1,6A, 250V, 3,6x10mm	IEC 60127-2 (JDYX2)	VDE 40024676 VDE 40030246 UL E133774
Fuse (F2) (alternative)	Bel	RST	1,6A, 250V, 3,6x10mm	IEC 60127-2 (JDYX2)	VDE 40000507 UR E20624

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Fuse (F2) (alternative)	Walter Electronics	ICP	1,6A, 250V, 3,6x10mm	IEC 60127-2 (JDYX)	VDE 40012824 UL E56092
Fuse (F2) (alternative)	Conquer Electronics	PTU	1,6A, 250V, 3.6x10mm	IEC 60127-2 (JDYX2)	VDE 40001462 UR E82636
Bleeder Resistors (R11, R16)	Interchangeable	Interchangeable	470kΩ, 1/4 W	IEC/EN 60601-1	Accepted.
Diode Bridge (BD1)	Interchangeable	Interchangeable	Min. 4A Min. 600V	IEC/EN 60601-1	Accepted.
Tubing on F1, F2, C10, CY3, C9, L2, R10	Interchangeable	Interchangeable	VW-1 Min. 130°C Min. 0,4 mm thickness	IEC/EN 60601-1 (YDPU2)	Accepted. UL approved
Insulation tape on/around heatsink, transformer T1	3M COMPANY	Polyester film	Min. 130°C	IEC/EN 60601-1 (OANZ2)	Accepted. UL E17385
Insulation tape on/around heatsink, transformer T1 (alternative)	Interchangeable	Interchangeable	Min. 130°C	IEC/EN 60601-1 (OANZ2)	Accepted. UL approved
Insulation cap on Q3 & D7	Great Holding Industrial Co Ltd	TFS	Min. 600V Min. 200°C	IEC/EN 60601-1 (OANZ2)	Accepted. UL E156256
Insulation cap on Q3 & D7 (alternative)	Interchangeable	Interchangeable	Min. 600V Min. 200°C	IEC/EN 60601-1 (OANZ2)	Accepted. UL approved
X capacitor (C24) (Optional)	Ultra tech xiphi enterprise	HQX	Max. 0,47uF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40015608 UR E183780
X capacitor (C24) (Optional) (alternative)	Okaya	RE	Max. 0,47uF 250 Vac	IEC 60384-14 (FOWX2)	VDE 094750X UR E47474
X capacitor (C24) (Optional) (alternative)	Pilkor	PCX2 335	Max. 0,47uF 250 Vac	IEC 60384-14 (FOWX2)	VDE UR E165646
X capacitor (C24) (Optional) (alternative)	Cheng Tung Industrial Co., Ltd.	CTX	Max. 0,47uF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40026382 UR E193049
X capacitor (C24) (Optional) (alternative)	Winday Electronic Industrial Co., Ltd.	MPX	Max. 0,47uF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40018071 UR E302125

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

X capacitor (C24) (Optional) (alternative)	VISHAY Capacitors Belgium N V	F1772	Max. 0,47uF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40005120 UR E100682
X capacitor (C24) (Optional) (alternative) X capacitor (C24) (Optional) (alternative)	Tenta Electric Industrial Co., Ltd.	MEX	Max. 0,47uF 250 Vac	IEC 60384-14 (FOKY2)	VDE 119119 UR E186475
X capacitor (C24) (Optional) (alternative)	Dain Electronics Co., Ltd.	MEX, MPX, NPX	Max. 0,47uF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40018798 UR E147776
X capacitor (C24) (Optional) (alternative)	Sinhua Electronics (Huzhou) Co. Ltd.	MPX	Max. 0,47uF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40014686 UR E237560
X capacitor (C24) (Optional) (alternative)	Foshan Shunde Chuang Ge Electronic Industrial Co., Ltd.	MKP-X2	Max. 0,47uF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40008922 UR E308832
X capacitor (C24) (Optional) (alternative)	Shun De Dahua Electric Co., Ltd.	HD	Max. 0,47uF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40001126 UR E227157
X capacitor (C24) (Optional) (alternative) **(Revision 2.0)**	Shantou High-new Technology Development Zone Songtian Enterprise Co., Ltd.	MPX	Max. 0,47uF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40034679 UR E208107
Y Capacitors (CY1, CY2, CY3) (Optional)	Murata	KH, KX	Max. 4700pF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40002796 VDE 40002831 UR E37921
Y Capacitors (CY1, CY2, CY3) (Optional) (alternative)	Walsin Technology Corp.	AC, AH	Max. 4700pF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40001804 VDE 40001829 UR E146544
Y Capacitors (CY1, CY2, CY3) (Optional) (alternative)	Welson Industrial Co., Ltd.	WD	Max. 4700pF 250 Vac	IEC 60384-14 (FOWX2)	VDE 115455 UR E104572
Y Capacitors (CY1, CY2, CY3) (Optional) (alternative)	Success	SF, SE, SB	Max. 4700pF 250 Vac	IEC 60384-14 (FOWX2)	VDE 089780 VDE 40008996 VDE 094680 UR E114280

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Y Capacitors (CY1, CY2, CY3) (Optional) (alternative)	TDK	CS, CD	Max. 4700pF 250 Vac	IEC 60384-14 (FOWX2)	VDE 122006 VDE124321 UR E37861
Y Capacitors (CY1, CY2, CY3) (Optional) (alternative)	Jya-Nay Co., Ltd.	JN	Max. 4700pF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40001831 UR E201384
Y Capacitors (CY1, CY2, CY3) (Optional) (alternative)	Haohua Electronic	CT 7	Max. 4700pF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40003902 UR E233106
Y Capacitors (CY1, CY2, CY3) (Optional) (alternative)	Chyun Fuh Electronic Co., Ltd.	CE	Max. 4700pF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40001233 UR E202835
Y Capacitors (CY1, CY2, CY3) (Optional) (alternative)	Jyh Chung Electronic Co., Ltd.	JD	Max. 4700pF 250 Vac	IEC 60384-14 (FOWX2)	VDE 137027 UR E187963
Y Capacitors (CY1, CY2, CY3) (Optional) (alternative)	Kunshan Wansheng Electronics Co., Ltd.	CT7	Max. 4700pF 250 Vac	IEC 60384-14 (FOWX2)	VDE 40012143 UR E249006
Bulk Capacitor (C22)	Interchangeable	Interchangeable	100uF for 50-48W 68uF for 45-36W 47uF for 30-27W 33uF for 20W Min. 400V Min. 105°C	IEC/EN 60601-1	Checked with appliance.
Switching Transistor (Q3)	Interchangeable	Interchangeable	Min. 4A Min. 600V	IEC/EN 60601-1	Acceptable.
Optical Isolator (U2)	Sharp corp. Electronic components and devices group	PC817, PC123	External clearance / creepage distance: Min. 6,4 mm Min. 110°C Isolation voltage: 5.000 Vac	IEC/EN 60747-5-5 (FPQU2)	VDE 40008087 UR E64380

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Optical Isolator (U2) (alternative)	Lite on Technology	LTV-817	External clearance / creepage distance: Min. 8,0 mm Min. 115°C Isolation voltage: 5.000 Vac	IEC/EN 60747-5-5 (FPQU2)	VDE 40015248 UR E113898
Optical Isolator (U2) (alternative)	Bright Led Electronics	BPC-817, BPC-817M, BPC-817S	External clearance / creepage distance: Min. 8,0 mm Min. 110°C Isolation voltage: 5.000 Vac	IEC/EN 60747-5-5 (FPQU2)	VDE 40007240 UR E236324
Optical Isolator (U2) (alternative)	Cosmo	K1010; KP1010	External clearance / creepage distance: Min. 6,5 mm Min. 115°C Isolation voltage: 5.000 Vac	IEC/EN 60747-5-5 (FPQU2)	VDE 101347 UR E169586
Optical Isolator (U2) (alternative)	Fairchild	H11A817B, H11A817C, F0D817B	External clearance / creepage distance: Min. 8,0 mm Min. 115°C Isolation voltage: 5.000 Vac	IEC/EN 60747-5-5 (FPQU2)	VDE 40026857 UR E90700
Optical Isolator (U2) (alternative)	Everlight	EL817	External clearance / creepage distance: Min. 7,6 mm Min. 110°C Isolation voltage: 5.000 Vac	IEC/EN 60747-5-5 (FPQU2)	VDE 132249 UR E214129

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Transformer (T1)	SUNNY or GlobTek Inc. or Wuxi Haopuwei Electronics Co.,Ltd. or WEICHI Electronic Co., Ltd. HaiNing or Shan Dong BOAM Co., Ltd. 04-B273 (3-7,5V) 04-B1733 (7,6-8,99V) 04-B167 (9-13V) 04-B1731 (13-17,99V) 04-B172 (18-21,99V) 04-B171 (22-24V) 04-B212 (24-36V) 04-B1713 (36-48/V) Construction: Open type construction approx. 36 mm 32 mm by 26 mm. Ferrite Core: RM10 Bobbin: See below. Windings: Approved primary wires (OBMW2) are used (UR E102761 & UR E214423 or equivalent) Outerwrap around transformer, functional insulation between shielding and primary windings (see below). Secondary wires are TIW (see below). Outlets are tubed with Teflon tubes. Class B			IEC/EN 60601-1	Checked with appliance.
Bobbin	CHANG CHUN PLASTICS CO LTD	T373J, T375J, T375HF	Min. V-0, Min. 150°C	IEC/EN 60601-1 UL 746 (QMFZ2)	Accepted. UL E59481
Bobbin (alternative) **(Revision 1.0)**	Sumitomo	PM-9820	Min. V-0 Min. 150°C	IEC/EN 60601-1 UL746 (QMFZ2)	Accepted. UR E41429
Insulation tape – Outerwrap around transformer, functional insulation between shielding and primary windings	Jingjiang Yahua Pressure Sensitive Glue Co.	CT series (Polyester film tape)	130°C Min.	IEC/EN 60601-1 (OANZ2)	Accepted. UR E165111

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Isulation tape – outerwrap around transformer, functional insulation between shelding and primary windings (alternative) **(Revision 1.0)**	3M	1350F-1, 1350T-1; 44	130°C Min.	IEC/EN 60601-1 (OANZ2)	Accepted. UR E17385
Triple insulated wire	Furukawa Electric co Ltd	TEX-E	130°C Min. Class B	IEC/EN 60601-1 Annex L UL 1446 (OBJT2)	VDE 006735 UR E206440
Triple insulated wire (alternative) **(Revision 1.0)**	Cosmolink	TIW-M	130°C Min. Class B	IEC/EN 60601-1 Annex L UL 1446 (OBJT2)	VDE 138053 UR E258545
Triple insulated wire (alternative) **(Revision 2.0)**	Hoi Luen Electrical Mfr Co., Ltd.	THL-F-xx, THL-F-SB-xx	130°C Min. Class B	IEC/EN 60601-1 Annex L UL 1446 (OBJT2)	VDE 40020365 UR E257525
Triple insulated wire (alternative) **(Revision 2.0)**	Great Leoflon	TRW(B)-M series	130°C Min. Class B	IEC/EN 60601-1 Annex L UL 1446 (OBJT2)	VDE 136581 UR E211989
Triple insulated wire (alternative) **(Revision 2.0)**	Great Leoflon	TRW(F) series	155°C Min. Class F	IEC/EN 60601-1 Annex L UL 1446 (OBJT2)	VDE 136581 UR E211989
Choke (L2)	Wuxi Haopuwei Electronics Co., Ltd. or GlobTek, Inc. Part No.: 04C117 Diameter 20 mm. Class B			IEC/EN 60601-1	Checked with appliance.
Choke (L2) (alternative)	BOAM Part No.: 04C117 Diameter 20 mm. Class B			IEC/EN 60601-1	Accepted.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Line Filter (LF1)	WUXI HAOPUWEI Electronics Co., Ltd. Or GlobTek, Inc. Part No: 04A052 Diameter 18 mm. Class B	IEC/EN 60601-1	Accepted.
Line Filter (LF1) (alternative)	BOAM Part No: 04A052 Diameter 18 mm. Class B	IEC/EN 60601-1	Accepted.
Supplementary information: 1) Provided evidence ensures the agreed level of compliance. See OD-CB2039.			

8.10 b	**TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS**				**N/A**
Object / part No.	**Manufacturer/ trademark**	**Type / model**	**Technical data**	**Standard**	**Mark(s) of conformity1)**
--	--	--	--	--	--
Supplementary information: 1) Provided evidence ensures the agreed level of compliance. See OD-CB2039.					

8.11.3.5	**TABLE: Cord anchorages**			**N/A**
Cord under test	**Mass of equipment (kg)**	**Pull (N)**	**Torque Nm)**	**Remarks**
--	--	--	--	--
Supplementary information: /				

8.11.3.6	**TABLE: Cord guard**		**N/A**
Cord under test	**Test mass**	**Measured curvature**	**Remarks**
--	--	--	--
Supplementary information: /			

9.2.2.2	**TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996)**			**N/A**
Part of body	**Allowable adult gap1), mm**	**Measured adult gap, mm**	**Allowable children gap1), mm**	**Measured children gap, mm**
Body	> 500	--	> 500	--
Head	> 300 or < 120	--	> 300 or < 60	--
Leg	> 180	--	> 180	--
Foot	> 120 or < 35	--	> 120 or < 25	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Toes	> 50	--	> 50	--
Arm	> 120	--	> 120	--
Hand, wrist, fist	> 100	--	> 100	--
Finger	> 25 or < 8	--	> 25 or < 4	--

Supplementary information:

[1)] In general, gaps for adults used, except when the device is specifically designed for use with children, values for children applied.

9.2.3.2	TABLE: Over-travel End Stop Test	N/A
ME EQUIPMENT end stop	Test Condition (cycles, load, speed)	Remarks
--	--	--
Supplementary information: /		

9.4.2.1	TABLE: Instability—overbalance in transport position	N/A
ME EQUIPMENT preparation	Test Condition (transport position)	Remarks
--	--	--
Supplementary information: /		

9.4.2.2	TABLE: Instability—overbalance excluding transport position	N/A
ME EQUIPMENT preparation	Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)	Remarks
--	--	--
Supplementary information: /		

9.4.2.3	TABLE: Instability—overbalance from horizontal and vertical forces	N/A
ME EQUIPMENT preparation	Test Condition (force used, direction of force, weight of equipment, location of force)	Remarks
--	--	--
Supplementary information: /		

9.4.2.4.2	TABLE: Castors and wheels – Force for propulsion	N/A
ME EQUIPMENT preparation	Test Condition (force location and height)	Remarks
--	--	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information: /

9.4.2.4.3	TABLE: Castors and wheels – Movement over a threshold	N/A
ME EQUIPMENT preparation	**Test Condition (speed of movement)**	**Remarks**
--	--	--
Supplementary information: /		

9.4.3.1	TABLE: Instability from unwanted lateral movement (including sliding) in transport position	N/A
ME EQUIPMENT Preparation	**Test Condition (transport position, working load, locking device(s), caster position)**	**Remarks**
--	--	--
Supplementary information: /		

9.4.3.2	TABLE: Instability from unwanted lateral movement (including sliding) excluding transport position	N/A
ME EQUIPMENT Preparation	**Test Condition (working load, locking device(s), caster position, force, force location, force direction)**	**Remarks**
--	--	--
Supplementary information: /		

9.4.4	TABLE: Grips and other handling devices	N/A
Clause and Name of Test	**Test Condition**	**Remarks**
--	--	--
Supplementary information: /		

9.7.5	TABLE: Pressure vessels					N/A
Hydraulic, Pneumatic or Suitable Media and Test Pressure	**Vessel Burst**	**Permanent Deformation**	**Leaks**	**Vessel fluid substance**	**Remarks**	
--	--	--	--	--	--	
Supplementary information: /						

9.8.3.2	TABLE: PATIENT support/suspension system - Static forces	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

ME equipment part or area	Position	Load	Area	Remarks
--	--	--	--	--

Supplementary Information: /

9.8.3.3	TABLE: Support/Suspension System – Dynamic forces due to loading from persons	N/A

ME EQUIPMENT part or area	Position	Safe Working Load	Area	Remarks
--	--	--	--	--

Supplementary Information: /

10.1.1	TABLE: Measurement of X - radiation	N/A

Maximum allowable radiation pA/kg (µSv/h) (mR/h)	36 (5 µSv/h) (0.5 mR/h)	
Surface area under test Surface no./ Description[1)]	**Measured Radiation, pA/kg (µSv/h) (mR/h)**	**Remarks**
1/ /	--	--
2/ /	--	--
3/ /	--	--
4/ /	--	--
5/ /	--	--
6/ /	--	--
7/ /	--	--
8/ /	--	--
9/ /	--	--
10/ /	--	--

Supplementary information:

[1)] Measurements made at 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				P
Model No. .....:	1)	2)	3)	4)	--
Test ambient (°C) .....:	28,4	27,9	40,0	40,0	--
Test supply voltage/frequency (V/Hz)[4)] .....:	90/60	264/50	90/60	264/50	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
GTM21097-3005					
1)	1.	Bottom on PCB	130	85,4	--
1)	2.	D7 diode	130	108,2	--
1)	3.	T1 core	120	93,6	--
1)	4.	LF1 inductor	130	77,5	--
1)	5.	T1 winding	120	97,2	--
1)	6.	BD1 Bridge	130	94,3	--
1)	7.	Q3 Mosfet	130	80,6	--
1)	8.	Enclosure top	86	59,8	--
1)	9.	L2 inductor	130	63,2	--
1)	10.	Appliance Inlet	70	50,7	--
1)	11.	CY3 Capacitor	105	81,6	--
1)	12.	Corner under EUT	90	58,3	--
2)	1.	Bottom on PCB	130	88,6	--
2)	2.	D7 diode	130	108,2	--
2)	3.	T1 core	120	101,6	--
2)	4.	LF1 inductor	130	72,0	--
2)	5.	T1 winding	120	104,5	--
2)	6.	BD1 Bridge	130	79,8	--
2)	7.	Q3 Mosfet	130	85,7	--
2)	8.	Enclosure top	86	60,7	--
2)	9.	L2 inductor	130	62,7	--
2)	10.	Appliance Inlet	70	49,6	--
2)	11.	CY3 Capacitor	105	83,0	--
2)	12.	Corner under EUT	90	59,1	--
3)	1.	Bottom on PCB	130	97,0	--
3)	2.	D7 diode	130	119,8	--
3)	3.	T1 core	120	105,2	--
3)	4.	LF1 inductor	130	89,1	--
3)	5.	T1 winding	120	108,8	--

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
3)	6.	BD1 Bridge	130	105,9	--
3)	7.	Q3 Mosfet	130	92,2	--
3)	8.	Enclosure top	86	71,4	--
3)	9.	L2 inductor	130	74,8	--
3)	10.	Appliance Inlet	70	62,3	--
3)	11.	CY3 Capacitor	105	93,2	--
3)	12.	Corner under EUT	90	69,9	--
4)	1.	Bottom on PCB	130	100,7	--
4)	2.	D7 diode	130	120,3	--
4)	3.	T1 core	120	113,7	--
4)	4.	LF1 inductor	130	84,1	--
4)	5.	T1 winding	120	116,6	--
4)	6.	BD1 Bridge	130	91,9	--
4)	7.	Q3 Mosfet	130	97,8	--
4)	8.	Enclosure top	86	72,8	--
4)	9.	L2 inductor	130	74,8	--
4)	10.	Appliance Inlet	70	61,7	--
4)	11.	CY3 Capacitor	105	95,1	--
4)	12.	Corner under EUT	90	71,2	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

1) Maximum allowable temperature on surfaces of test corner is 90 °C
2) Max temperature determined in accordance with 11.1.3e)
3) When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
4) 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.

5) 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: Risk management report (H2)

Model 1):
- Output current: 6,0 A
- Output voltage: 5,0 Vdc
- Duration:140 min

Model 2):
- Output current: 6,0 A
- Output voltage: 5,0 Vdc
- Duration:120 min

Model 3):
- Output current: 6,0 A
- Output voltage: 5,0 Vdc
- Duration:140 min

Model 4):
- Output current: 6,0 A
- Output voltage: 5,0 Vdc
- Duration:120 min

Temperature rises of the transformer was measured with thermocouples (Class B transformer provided inside the unit, 130°C - 10°C= 120°C).

The printed circuit board (PCB) is rated 130°C.

Enclosure of the power supply is not intended to be touched by the operator; therefore top side of the power supply considered for non-intentional contact with the operator (duration less than 1 second, therefore limit 86°C applied). Shall be considered during end medical product approval.

* It is not possible to state compliance using a 95% coverage probability for the expanded uncertainty. Expanded uncertainty: U = 3°C (coverage factor kp = 2; confidence level: 95 %).

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT**				**P**
Model No. .....:	1)	2)	3)	4)	--
Test ambient (°C) .....:	28,4	27,9	40,0	40,0	--
Test supply voltage/frequency (V/Hz)4) .....:	90/60	264/50	90/60	264/50	--

Model No.	Thermo-couple No.	Thermocouple location3)	Max allowable temperature1) from Table 22, 23 or 24 or RM file for AP5) (°C)	Max measured temperature2), (°C)	Remarks

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

GTM21097-5012					
1)	1.	Bottom on PCB	130	95,1	--
1)	2.	D7 diode	130	116,2	--
1)	3.	T1 core	120	103,7	--
1)	4.	LF1 inductor	130	87,6	--
1)	5.	T1 winding	120	106,9	--
1)	6.	BD1 Bridge	130	101,7	--
1)	7.	Q3 Mosfet	130	114,4	--
1)	8.	Enclosure top	86	62,9	--
1)	9.	L2 inductor	130	66,7	--
1)	10.	Appliance Inlet	70	58,7	--
1)	11.	CY3 Capacitor	105	91,1	--
1)	12.	Corner under EUT	90	65,4	--
2)	1.	Bottom on PCB	130	91,4	--
2)	2.	D7 diode	130	112,5	--
2)	3.	T1 core	120	103,6	--
2)	4.	LF1 inductor	130	73,9	--
2)	5.	T1 winding	120	106,5	--
2)	6.	BD1 Bridge	130	81,5	--
2)	7.	Q3 Mosfet	130	104,8	--
2)	8.	Enclosure top	86	59,5	--
2)	9.	L2 inductor	130	61,8	--
2)	10.	Appliance Inlet	70	54,7	--
2)	11.	CY3 Capacitor	105	87,9	--
2)	12.	Corner under EUT	90	61,7	--
3)	1.	Bottom on PCB	130	106,7	--
3)	2.	D7 diode	130	127,8*	--
3)	3.	T1 core	120	115,3	--
3)	4.	LF1 inductor	130	99,2	--
3)	5.	T1 winding	120	118,5*	--
3)	6.	BD1 Bridge	130	113,3	--
3)	7.	Q3 Mosfet	130	126,0	--
3)	8.	Enclosure top	86	74,5	--

IEC 60601-1					
Clause	Requirement + Test			Result - Remark	Verdict
3)	9.	L2 inductor	130	78,3	--
3)	10.	Appliance Inlet	70	70,3	--
3)	11.	CY3 Capacitor	105	102,7*	--
3)	12.	Corner under EUT	90	77,0	--
4)	1.	Bottom on PCB	130	103,5	--
4)	2.	D7 diode	130	124,6	--
4)	3.	T1 core	120	115,7	--
4)	4.	LF1 inductor	130	86,0	--
4)	5.	T1 winding	120	118,6*	--
4)	6.	BD1 Bridge	130	93,6	--
4)	7.	Q3 Mosfet	130	116,9	--
4)	8.	Enclosure top	86	71,6	--
4)	9.	L2 inductor	130	73,9	--
4)	10.	Appliance Inlet	70	66,8	--
4)	11.	CY3 Capacitor	105	100,0	--
4)	12.	Corner under EUT	90	73,8	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

1) Maximum allowable temperature on surfaces of test corner is 90 °C
2) Max temperature determined in accordance with 11.1.3e)
3) When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
4) 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.

5) 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: Risk management report (H2)

Model 1):
- Output current: 4,17 A
- Output voltage: 12,0 Vdc
- Duration:140 min

Model 2):
- Output current: 4,17 A
- Output voltage: 12,0 Vdc
- Duration:120 min

Model 3):
- Output current: 4,17 A
- Output voltage: 12,0 Vdc
- Duration:140 min

Model 4):
- Output current: 4,17 A
- Output voltage: 12,0 Vdc
- Duration:120 min

Temperature rises of the transformer was measured with thermocouples (Class B transformer provided inside the unit, 130°C - 10°C= 120°C).

The printed circuit board (PCB) is rated 130°C.

Enclosure of the power supply is not intended to be touched by the operator; therefore top side of the power supply considered for non-intentional contact with the operator (duration less than 1 second, therefore limit 86°C applied). Shall be considered during end medical product approval.

* It is not possible to state compliance using a 95% coverage probability for the expanded uncertainty. Expanded uncertainty: U = 3°C (coverage factor kp = 2; confidence level: 95 %).

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT**				**P**
Model No. .....:	1)	2)	3)	4)	--
Test ambient (°C) .....:	28,4	27,9	40,0	40,0	--
Test supply voltage/frequency (V/Hz)4) .....:	90/60	264/50	90/60	264/50	--

Model No.	Thermo-couple No.	Thermocouple location3)	Max allowable temperature1) from Table 22, 23 or 24 or RM file for AP5) (°C)	Max measured temperature2), (°C)	Remarks

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

GTM21097-5024					
1)	1.	Bottom on PCB	130	86,5	--
1)	2.	D7 diode	130	103,7	--
1)	3.	T1 core	120	96,7	--
1)	4.	LF1 inductor	130	68,3	--
1)	5.	T1 winding	120	99,0	--
1)	6.	BD1 Bridge	130	98,8	--
1)	7.	Q3 Mosfet	130	92,4	--
1)	8.	Enclosure top	86	59,2	--
1)	9.	L2 inductor	130	63,1	--
1)	10.	Appliance Inlet	70	54,9	--
1)	11.	CY3 Capacitor	105	78,4	--
1)	12.	Corner under EUT	90	65,6	--
2)	1.	Bottom on PCB	130	87,3	--
2)	2.	D7 diode	130	100,8	--
2)	3.	T1 core	120	105,3	--
2)	4.	LF1 inductor	130	70,0	--
2)	5.	T1 winding	120	102,3	--
2)	6.	BD1 Bridge	130	78,1	--
2)	7.	Q3 Mosfet	130	85,6	--
2)	8.	Enclosure top	86	60,2	--
2)	9.	L2 inductor	130	57,5	--
2)	10.	Appliance Inlet	70	50,3	--
2)	11.	CY3 Capacitor	105	74,3	--
2)	12.	Corner under EUT	90	62,9	--
3)	1.	Bottom on PCB	130	98,1	--
3)	2.	D7 diode	130	115,3	--
3)	3.	T1 core	120	108,3	--
3)	4.	LF1 inductor	130	79,9	--
3)	5.	T1 winding	120	110,6	--
3)	6.	BD1 Bridge	130	110,4	--
3)	7.	Q3 Mosfet	130	104,0	--
3)	8.	Enclosure top	86	70,8	--

IEC 60601-1					
Clause	Requirement + Test			Result - Remark	Verdict
3)	9.	L2 inductor	130	74,7	--
3)	10.	Appliance Inlet	70	66,5	--
3)	11.	CY3 Capacitor	105	90,0	--
3)	12.	Corner under EUT	90	77,2	--
4)	1.	Bottom on PCB	130	99,4	--
4)	2.	D7 diode	130	112,9	--
4)	3.	T1 core	120	117,4*	--
4)	4.	LF1 inductor	130	82,1	--
4)	5.	T1 winding	120	114,4	--
4)	6.	BD1 Bridge	130	90,2	--
4)	7.	Q3 Mosfet	130	97,7	--
4)	8.	Enclosure top	86	72,3	--
4)	9.	L2 inductor	130	69,6	--
4)	10.	Appliance Inlet	70	62,4	--
4)	11.	CY3 Capacitor	105	86,4	--
4)	12.	Corner under EUT	90	75,0	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

1) Maximum allowable temperature on surfaces of test corner is 90 °C
2) Max temperature determined in accordance with 11.1.3e)
3) When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
4) 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.

5) 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: Risk management report (H2)

Model 1):
- Output current: 2,1 A
- Output voltage: 24,0 Vdc
- Duration:140 min

Model 2):
- Output current: 2,1 A
- Output voltage: 24,0 Vdc
- Duration:120 min

Model 3):
- Output current: 2,1 A
- Output voltage: 24,0 Vdc
- Duration:140 min

Model 4):
- Output current: 2,1 A
- Output voltage: 24,0 Vdc
- Duration:120 min

Temperature rises of the transformer was measured with thermocouples (Class B transformer provided inside the unit, 130°C - 10°C= 120°C).

The printed circuit board (PCB) is rated 130°C.

Enclosure of the power supply is not intended to be touched by the operator; therefore top side of the power supply considered for non-intentional contact with the operator (duration less than 1 second, therefore limit 86°C applied). Shall be considered during end medical product approval.

* It is not possible to state compliance using a 95% coverage probability for the expanded uncertainty. Expanded uncertainty: U = 3°C (coverage factor kp = 2; confidence level: 95 %).

11.1.1	**TABLE: Excessive temperatures in me equipment**				**P**
Model No. .....:	1)	2)	3)	4)	--
Test ambient (°C) .....:	28,4	27,9	40,0	40,0	--
Test supply voltage/frequency (V/Hz)4) .....:	90/60	264/50	90/60	264/50	--

Model No.	**Thermo-couple No.**	**Thermocouple location3)**	**Max allowable temperature1) from Table 22, 23 or 24 or RM file for AP5) (°C)**	**Max measured temperature2), (°C)**	**Remarks**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

GTM21097-5048					
1)	1.	Bottom on PCB	130	88,2	--
1)	2.	D7 diode	130	90,1	--
1)	3.	T1 core	120	106,9	--
1)	4.	LF1 inductor	130	90,2	--
1)	5.	T1 winding	120	108,2	--
1)	6.	BD1 Bridge	130	94,2	--
1)	7.	Q3 Mosfet	130	93,6	--
1)	8.	Enclosure top	86	72,1	--
1)	9.	L2 inductor	130	67,4	--
1)	10.	Appliance Inlet	70	58,0	--
1)	11.	CY3 Capacitor	105	83,7	--
1)	12.	Corner under EUT	90	67,3	--
2)	1.	Bottom on PCB	130	84,6	--
2)	2.	D7 diode	130	71,1	--
2)	3.	T1 core	120	102,1	--
2)	4.	LF1 inductor	130	76,1	--
2)	5.	T1 winding	120	103,9	--
2)	6.	BD1 Bridge	130	72,2	--
2)	7.	Q3 Mosfet	130	89,2	--
2)	8.	Enclosure top	86	70,5	--
2)	9.	L2 inductor	130	62,1	--
2)	10.	Appliance Inlet	70	55,3	--
2)	11.	CY3 Capacitor	105	78,5	--
2)	12.	Corner under EUT	90	65,8	--
3)	1.	Bottom on PCB	130	99,8	--
3)	2.	D7 diode	130	101,7	--
3)	3.	T1 core	120	118,5*	--
3)	4.	LF1 inductor	130	101,8	--
3)	5.	T1 winding	120	119,8 *	--
3)	6.	BD1 Bridge	130	105,8	--
3)	7.	Q3 Mosfet	130	105,2	--
3)	8.	Enclosure top	86	83,7 *	--

IEC 60601-1					
Clause	Requirement + Test			Result - Remark	Verdict
3)	9.	L2 inductor	130	79,0	--
3)	10.	Appliance Inlet	70	69,6*	--
3)	11.	CY3 Capacitor	105	95,3	--
3)	12.	Corner under EUT	90	78,9	--
4)	1.	Bottom on PCB	130	96,7	--
4)	2.	D7 diode	130	83,2	--
4)	3.	T1 core	120	114,2	--
4)	4.	LF1 inductor	130	88,2	--
4)	5.	T1 winding	120	116,0	--
4)	6.	BD1 Bridge	130	84,3	--
4)	7.	Q3 Mosfet	130	101,3	--
4)	8.	Enclosure top	86	82,6 *	--
4)	9.	L2 inductor	130	74,2	--
4)	10.	Appliance Inlet	70	66,9*	--
4)	11.	CY3 Capacitor	105	90,6	--
4)	12.	Corner under EUT	90	77,9	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

1) Maximum allowable temperature on surfaces of test corner is 90 °C
2) Max temperature determined in accordance with 11.1.3e)
3) When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
4) 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.

5) 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: Risk management report (H2)

Model 1):
- Output current: 1,0 A
- Output voltage: 48,0 Vdc
- Duration:140 min

Model 2):
- Output current: 1,0 A
- Output voltage: 48,0 Vdc
- Duration:120 min

Model 3):
- Output current: 1,0 A
- Output voltage: 48,0 Vdc
- Duration:140 min

Model 4):
- Output current: 1,0 A
- Output voltage: 48,0 Vdc
- Duration:120 min

Temperature rises of the transformer was measured with thermocouples (Class B transformer provided inside the unit, 130°C - 10°C= 120°C).

The printed circuit board (PCB) is rated 130°C.

Enclosure of the power supply is not intended to be touched by the operator; therefore top side of the power supply considered for non-intentional contact with the operator (duration less than 1 second, therefore limit 86°C applied). Shall be considered during end medical product approval.

* It is not possible to state compliance using a 95% coverage probability for the expanded uncertainty. Expanded uncertainty: U = 3°C (coverage factor kp = 2; confidence level: 95 %).

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT – Output overload**				**P**
Model No. .....:	1)	2)	--	--	--
Test ambient (°C) .....:	27,1	40,0	--	--	--
Test supply voltage/frequency (V/Hz)4) .....:	90/60	90/60	--	--	--

Model No.	Thermo-couple No.	Thermocouple location3)	Max allowable temperature1) from Table 22, 23 or 24 or RM file for AP5) (°C)	Max measured temperature2), (°C)	Remarks

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

GTM21097-3005					
1)	1.	Bottom on PCB	182,5	105,5	--
1)	2.	D7 diode	182,5	134,0	--
1)	3.	T1 core	165	116,0	--
1)	4.	LF1 inductor	165	95,9	--
1)	5.	T1 winding	165	122,1	--
1)	6.	BD1 Bridge	182,5	111,6	--
1)	7.	Q3 Mosfet	182,5	100,2	--
1)	8.	Enclosure top	--	76,8	--
1)	9.	L2 inductor	165	76,8	--
1)	10.	Appliance Inlet	92,5	57,3	--
1)	11.	CY3 Capacitor	145	102,7	--
1)	12.	Corner under EUT	--	64,4	--
2)	1.	Bottom on PCB	182,5	117,1	--
2)	2.	D7 diode	182,5	145,6	--
2)	3.	T1 core	165	127,6	--
2)	4.	LF1 inductor	165	107,5	--
2)	5.	T1 winding	165	133,7	--
2)	6.	BD1 Bridge	182,5	123,2	--
2)	7.	Q3 Mosfet	182,5	111,8	--
2)	8.	Enclosure top	--	88,4	--
2)	9.	L2 inductor	165	88,4	--
2)	10.	Appliance Inlet	92,5	68,9	--
2)	11.	CY3 Capacitor	145	114,3	--
2)	12.	Corner under EUT	--	76,0	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] 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.

[5] 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: Risk management report (H2)

Model 1):
- Output current: 8,0 A
- Output voltage: 3,6 Vdc
- Duration:60 min

Model 2):
- Output current: 8,0 A
- Output voltage: 3,6 Vdc
- Duration:60 min

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT – Output overload**				**P**
Model No. .....:	1)	2)	--	--	--
Test ambient (°C) .....:	27,1	40,0	--	--	--
Test supply voltage/frequency (V/Hz)[4] .....:	90/60	90/60	--	--	--

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
GTM21097-5024					
1)	1.	Bottom on PCB	182,5	111,2	--
1)	2.	D7 diode	182,5	133,5	--
1)	3.	T1 core	165	125,2	--
1)	4.	LF1 inductor	165	100,2	--
1)	5.	T1 winding	165	130,0	--
1)	6.	BD1 Bridge	182,5	122,0	--
1)	7.	Q3 Mosfet	182,5	138,2	--
1)	8.	Enclosure top	--	73,6	--
1)	9.	L2 inductor	165	78,7	--
1)	10.	Appliance Inlet	92,5	66,9	--
1)	11.	CY3 Capacitor	145	100,3	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

1)	12.	Corner under EUT	--	79,2	--
2)	1.	Bottom on PCB	182,5	122,8	--
2)	2.	D7 diode	182,5	145,1	--
2)	3.	T1 core	165	136,8	--
2)	4.	LF1 inductor	165	113,1	--
2)	5.	T1 winding	165	141,6	--
2)	6.	BD1 Bridge	182,5	133,6	--
2)	7.	Q3 Mosfet	182,5	149,8	--
2)	8.	Enclosure top	--	85,2	--
2)	9.	L2 inductor	165	90,3	--
2)	10.	Appliance Inlet	92,5	78,5	--
2)	11.	CY3 Capacitor	145	111,9	--
2)	12.	Corner under EUT	--	90,8	--

Supplementary information:

[1)] Maximum allowable temperature on surfaces of test corner is 90 °C
[2)] Max temperature determined in accordance with 11.1.3e)
[3)] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4)] 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.

[5)] 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: Risk management report (H2)

Model 1):
- Output current: 3,1 A
- Output voltage: 18,0 Vdc
- Duration:60 min

Model 2):
- Output current: 3,1 A
- Output voltage: 18,0 Vdc
- Duration:60 min

11.1.3d	TABLE: Temperature of windings by change-of-resistance method	N/A

Temperature T of winding:	t_1 (°C)	R_1 (Ω)	t_2 (°C)	R_2 (Ω)	T (°C)	Allowed T_{max} (°C)	Insulation class
--	--	--	--	--	--	--	--

Supplementary information: /

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.2.2.1	TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source		N/A
Areas where sparking might cause ignition:		**Remarks**	
1.		--	
2.		--	
3.		--	
4.		--	
5.		--	
6.		--	
Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):		**Remarks**	
1.		--	
2.		--	
3.		--	
4.		--	
5.		--	
6.		--	
Test parameters selected representing worst case conditions for ME EQUIPMENT:		**Remarks**	
Oxygen concentration (%) ..... :	--	--	
Fuel..... :	--	--	
Current (A)..... :	--	--	
Voltage (V) ..... :	--	--	
Capacitance (μF) ..... :	--	--	
Inductance or resistance (h or Ω)..... :	--	--	
No. of trials (300 Min)..... :	--	--	
Sparks resulted in ignition (Yes/No) .... :	--	--	

Supplementary information:

Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst-case values with other parameters set at worst case values to determine if ignition can occur.

Information from Risk Management, as applicable: N/A

11.6.1	TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause / Test Name	Test Condition	Part under test	Remarks
--	--	--	--

Supplementary information:

Information from Risk Management, as applicable: N/A

13.1.2	**TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances**	**N/A**

Power dissipated less than (W) ..... :	**15**
Energy dissipated less than (J) .....:	**900**

Part or component tested	Measured power dissipated (W)	Calculated energy dissipated (J)	SINGLE FAULT CONDITIONS waived (Yes/No)	Remarks
--	--	--	--	--

Supplementary information:

13.2	**TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive**		**P**
Clause No.	**Description of SINGLE FAULT CONDITION**	**Results observed**	**HAZARDOUS SITUATION (Yes/No)**
13.2.2	**Electrical SINGLE FAULT CONDITIONS per Cl. 8.1:**	**—**	**—**
	1) D107 (Short circuit) Supply voltage: 264 Vac	Diode D7 damaged after 2s, Q3 damaged, unit damaged. No output voltage peaks, output down immediately. No fire, no hazard.	NO
	2) U2 (Shorted pin 1 to pin 2) Supply voltage: 264 Vac	Unit damaged immediately. Some smoke occurred. No fire, no hazard, no output voltage peaks. Same results with load and no load.	NO
	3) U2 (Shorted pin 3 to pin 4) Supply voltage: 264 Vac	No load. In 20 ms output down to zero. No defect, no hazard, no output voltage peaks.	NO
	4) Output (Shorted + to -) Supply voltage: 264 Vac	Unit go in hiccup mode. No heating of components, no defect, no hazard. After removing of short unit operate normally.	NO
	5) T1 (Shorted secondary pin 5 – pin 6) Supply voltage: 264 Vac	After 15 min unit shut down. Max. temp. on T1 winding 45,1°C. Fuse F2 opened. No fire, no hazard, no high temperature rises observed.	NO

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	6) T1 (Shorted primary pin 1 – pin 3) Supply voltage: 264 Vac	After 2s fuse F2 opened. Output slowly down to 0V. No fire, no hazard. Unit damaged.	NO
	7) T1 (Shorted primary pin 2 – pin 4) Supply voltage: 264 Vac	No load. Output voltage 23,75V. No high temperature rises observed, no defect, no hazard.	NO
	8) BD1 (Short circuit + to -) Supply voltage: 264 Vac	Fuses F1/F2 opened immediately. No fire, no hazard.	NO
	9) Capacitor C22 (short circuit) Supply voltage: 264 Vac	Fuses F1/F2 opened immediately. No fire, no hazard.	NO
	10) Capacitor C10 (Short circuit) Supply voltage: 264 Vac	Output slowly down to 0V. After removing of short unit operate normally. Same results with load and no load.	NO
	11) Transistor Q3 (Short D-S) Supply voltage: 264 Vac	Unit damaged immediately. Q3,U1,F2 damaged. No fire, no hazard.	NO
	12) Output Overload Supply voltage: 264 Vac	Model GTM21097-5024 See next pages for details. Over temperature protection activate. Unit shut down, no hazard, no damage.	NO
	13) Output Overload Supply voltage: 264 Vac	Model GTM21097-3005 See next pages for details. Over temperature protection activate, unit shut down, no hazard, no damage.	NO
	14) Transformer T1 overload Supply voltage: 90V	Model GTM21097-2003 Temperatures stabilized. Max temp. on winding 105,8°C	NO
	15) Transformer T1 overload Supply voltage: 264V	Model GTM21097-2003 Unit in hiccup mode after 15 min. Max. temp. on winding 115,3°C.	NO
13.2.3	**Overheating of transformers per Clause 15.5:**	**—**	**—**
	Transformer short circuit test	Refer to Table 15.5.1.2 for details.	NO
	Transformer overload test	Refer to table 15.5.1.3 for details.	NO

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
13.2.4	**Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:**	**—**	**—**
	No thermostats incorporated.	--	--
13.2.5	**Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:**	**—**	**—**
	No temperature limiting devices incorporated.	--	--
13.2.6	**Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)**	**—**	**—**
	No liquid used.	--	--
13.2.7	**Impairment of cooling that could result in a HAZARD using test method of 11.1:**	**—**	**—**
	Single ventilation fans locked consecutively	No fan provided.	--
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls	No opening provided	--
	Simulated blocking of filters	No such filter used.	--
	Flow of a cooling agent interrupted	No cooling agent provided.	--
13.2.8	**Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:**	**—**	**—**
	--	--	--
13.2.9	**Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10**	**—**	**—**
	--	--	--
13.2.10	**Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:**	**—**	**—**
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or upper limit of RATED voltage range for specified time:	No motors provided.	--
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices	No motors provided.	--
	Temperatures measured as specified in 11.1.3 d)	No motors provided.	--
	Temperatures did not exceed limits of Table 26	No motors provided.	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

13.2.11	**Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:**	**—**	**—**
	--	--	--
13.2.12	**Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):**	**—**	**—**
	--	--	--

Supplementary information:

[1)] Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.

Information from Risk Management, as applicable: N/A

There was no flame, extensive smoke or melted metal during single fault testing.

When components were failing, the test was repeated two times.

15.3	**TABLE: Mechanical Strength tests [1)]**		**P**
Clause	**Name of Test**	**Test conditions**	**Observed results/Remarks**
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	Test performed on external parts of the enclosure. No damage of the enclosure, no cracks.
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	Test performed all sides of the enclosure. No damage of the enclosure, no cracks.
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5 cm	No damage of the enclosure, no cracks.
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) = 93,7°C	Whole equipment placed into the circulating air oven for 7 hours. Maximum temperature measured on the enclosure during normal use of the equipment: 83,7°C. No damage of the enclosure.

Supplementary information: [1)]

As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows or state N/A in Remarks field).

15.4.6	**TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests**				**N/A**
Rotating control under test	**Gripping diameter "d" of control knob (mm)[1)]**	**Torque from Table 30 (Nm)**	**Axial force applied (N)**	**Unacceptable RISK occurred Yes/No**	**Remarks**
--	--	--	--	--	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

1) Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)

15.5.1.2	TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION	P
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)1)....:	253 Vac	—
RATED input frequency (Hz).....:	50 Hz	—

Winding tested	Class of insulation (A, B, E, F, or H)	Type of protective device (fuse, circuit breaker) /Ratings	Protective device operated Yes/No	Time to THERMAL STABILITY (when protective device did not operate)(Min)	Maximum allowed temp from Table 31 (ºC)	Maximum winding temp measured (ºC)	Ambient (ºC)
1) T1 (Shorted secondary winding pin 5 – pin 6)	Class B	Primary fuses	No	60 min	165	61,1	40,0
2) T1 (Shorted primary winding pin 1 – pin 3)	Class B	Primary fuses	Yes	60 min	165	See 1)* below	40,0
3) T1 (Shorted primary winding pin 2 – pin 4)	Class B	Primary fuses	No	60 min	165	44,4	40,0

Supplementary information:

1) Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.

1)* Unit shut down. No heating of T1. No high temperature rises observed. No fire, no smoke.

See table 13.2: TABLE: Single fault conditions in accordance with 13.2.2 to 13.2.13, inclusive for details.

15.5.1.3	TABLE: transformer overload test – conducted only when protective device under short-circuit test operated	P
Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)1).....:		90Vac/264Vac
RATED input frequency (Hz).....:		50 Hz
Test current just below minimum current that would activate protective device and achieve THERMAL STABILITY under method a) (A).....:		Considered
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A).....:		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Winding tested	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (ºC)	Maximum winding temp measured (ºC)	Ambient (ºC)
Model GTM21097-2003					
Transformer T1 (Pin 5 to Pin 6; Input: 90V)	Class B	Primary fuses	165	105,8	24,0
Transformer T1 (Pin 5 to Pin 6; Input: 264V)	Class B	Primary fuses	165	115,3	24,0

Supplementary information:

[1)] Loads on other windings between no load and their NORMAL USE load.
Time durations: - IEC 60127-1 fuse: 30 min at current from Table 32.
Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved.
- Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a). This portion concluded at specified time or when a second protective device opened.

Protective device not operated.

Limit in accordance to Annex C is 175°C – 10°C= 165°C. 10°C were subtracted because of the measurement with the thermo probes.

See table 13.2: TABLE: Single fault conditions in accordance with 13.2.2 to 13.2.13, inclusive for details.

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7				N/A
Transformer Model/Type/ Part No	**Test voltage applied between**	**Test voltage, (V)**	**Test frequency (Hz)**	**Breakdown Yes/No**	**Deterioration Yes/No**
--	Primary & secondary windings	--	--	--	--
--	Primary winding & frame	--	−−	--	--
--	Secondary winding & frame	--	−−	--	--

Supplementary information:

Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details

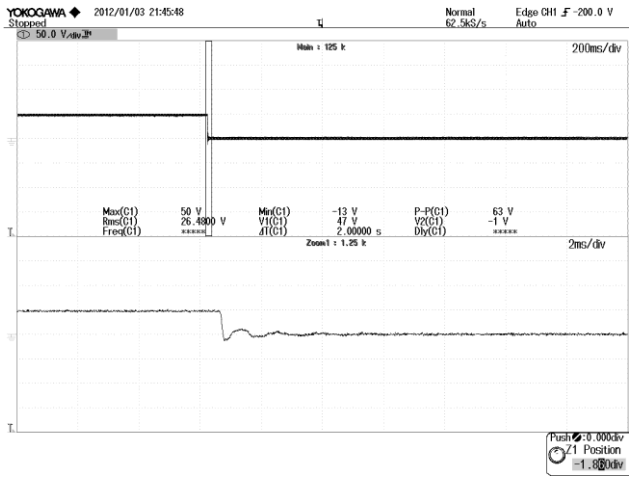
16.6.1	TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS			N/A
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	**Allowable TOUCH CURRENT in NORMAL CONDITION (μA)**	**Measured TOUCH CURRENT in NORMAL CONDITION (μA)**	**Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (μA)**	**Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (μA)**
--	100	--	500	--

Supplementary information:

Not treated as electrical medical system.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

SP	TABLE: Additional or special tests conducted		P
Clause and Name of Test	**Test type and condition**	**Observed results**	
Evaluation of voltage limiting components in SELV circuits	See table below	See table below	
Supplementary information: See Table below.			

	TABLE: evaluation of voltage limiting components in SELV circuits			P
Component (measured between)	**max. voltage (V) (normal operation)**		**Voltage Limiting Components**	
	V peak	**V d.c.**		
Input voltage: 264 Vac				
Transformer T1 (between pin 5 and pin 6/7)	322	--	--	
Transformer T1 (across C2)	48,7	46,7	D7	
Fault test performed on voltage limiting components	**Voltage measured (V) in SELV circuits (V peak or V d.c.)**			
Short circuit of diode D7 (No load)	**Output voltage dropped to 0 V immediately. No hazard.** 			
Supplementary information: /				

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

	Attachment - Software – IEC 62304:2006+AMD1:2015		**—**
4.3	**[A, B, C] Software safety classification**		**—**
	a) The MANUFACTURER assigns to each SOFTWARE SYSTEM a software safety class according to the RISK of HARM to the patient, operator, or other people resulting from a HAZARDOUS SITUATION to which the SOFTWARE SYSTEM can contribute in a worst-case-scenario	No software incorporated.	**N/A**
	The SOFTWARE SYSTEM is software safety class A if:		**—**
	– the SOFTWARE SYSTEM not contribute to a HAZARDOUS SITUATION; or	--	**N/A**
	– the SOFTWARE SYSTEM contribute to a HAZARDOUS SITUATION which does not result in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM	--	**N/A**
	The SOFTWARE SYSTEM is software safety class B if:		**—**
	– the SOFTWARE SYSTEM contribute to a HAZARDOUS SITUATION which results in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM and the resulting possible HARM is non-SERIOUS INJURY	--	**N/A**
	The SOFTWARE SYSTEM is software safety class C if:		**—**
	– the SOFTWARE SYSTEM contribute to a HAZARDOUS SITUATION which results in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM and the resulting possible HARM is death or SERIOUS INJURY	--	**N/A**
	For a SOFTWARE SYSTEM initially classified as software safety class B or C, the MANUFACTURER has implemented additional RISK CONTROL measures external to the SOFTWARE SYSTEM and subsequently has assigned a new software safety classification to the SOFTWARE SYSTEM	--	**N/A**
	c) The MANUFACTURER documents the software safety class assigned to each SOFTWARE SYSTEM in the RISK MANAGEMENT FILE	--	**N/A**
	d) When a SOFTWARE SYSTEM is decomposed into SOFTWARE ITEMS, and when a SOFTWARE ITEM is decomposed into further SOFTWARE ITEMS, such SOFTWARE ITEMS inherit the software safety classification of the original SOFTWARE ITEM (or SOFTWARE SYSTEM) unless the MANUFACTURER documents a rationale for classification into a different software safety class	--	**N/A**
	A rationale explains how the new SOFTWARE ITEMS are segregated so that they may be classified separately	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	e) The MANUFACTURER documents the software safety class of each SOFTWARE ITEM if that class is different from the class of the SOFTWARE ITEM from which it was created by decomposition	--	**N/A**
	f) When applied to a group of SOFTWARE ITEMS, the MANUFACTURER uses the PROCESSES and TASKS which are required by the classification of the highest-classified SOFTWARE ITEM in the group unless the MANUFACTURER documents in the RISK MANAGEMENT FILE a rationale for using a lower classification	--	**N/A**
	g) Class C requirements apply for each SOFTWARE SYSTEM, until a software safety class is assigned	--	**N/A**
4.4	**[A, B, C] LEGACY SOFTWARE**		**—**
	Clauses 5 through 9 have applied to demonstrate the compliance of LEGACY SOFTWARE	--	**N/A**
	As alternative, clauses 4.4.2 through 4.4.5 have applied to demonstrate the compliance of LEGACY SOFTWARE	--	**N/A**
4.4.2	[A, B, C] RISK MANAGEMENT ACTIVITIES		**—**
	The MANUFACTURER:		**N/A**
	a) assesses any feedback, including post-production information, on LEGACY SOFTWARE regarding incidents and / or near incidents, both from inside its own organization and / or from users	--	**N/A**
	b) performs RISK MANAGEMENT ACTIVITIES associated with continued use of the LEGACY SOFTWARE	--	**N/A**
	Considering the following aspects:		**N/A**
	– integration of the LEGACY SOFTWARE in the overall MEDICAL DEVICE architecture	--	**N/A**
	– continuing validity of RISK CONTROL measures, implemented as part of the LEGACY SOFTWARE	--	**N/A**
	– identification of HAZARDOUS SITUATIONS associated with the continued use of the LEGACY SOFTWARE	--	**N/A**
	– identification of potential causes of the LEGACY SOFTWARE contributing to a HAZARDOUS SITUATIONS	--	**N/A**
	– definition of RISK CONTROL measures for each potential cause of the LEGACY SOFTWARE contributing to a HAZARDOUS SITUATIONS	--	**N/A**
4.4.3	[A, B, C] Gap analysis		**N/A**
	Based on the software safety class of the LEGACY SOFTWARE, the MANUFACTURER performs a gap analysis of available DELIVERABLES against those required according to 5.2, 5.3, 5.7, and Clause 7	--	**N/A**
	a) The MANUFACTURER assesses the continuing validity of available DELIVERABLES	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) Where gaps are identified, the MANUFACTURER EVALUATES the potential reduction in RISK resulting from the generation of the missing DELIVERABLES and associated ACTIVITIES	--	**N/A**
	c) Based on this evaluation, the MANUFACTURER determines the DELIVERABLES to be created and associated ACTIVITIES to be performed	--	**N/A**
	SOFTWARE SYSTEM test records are the minimum DELIVERABLES to be created	--	**N/A**
4.4.4	[A, B, C] Gap closure activities		**N/A**
	a) The MANUFACTURER establishes and executes a plan to generate the identified DELIVERABLES	--	**N/A**
	Objective evidences have used to generate required DELIVERABLES without performing ACTIVITIES required by 5.2, 5.3, 5.7 and Clause 7	--	**N/A**
	b) The plan addresses the use of the problem resolution PROCESS for handling problems detected in the LEGACY SOFTWARE and DELIVERABLES in accordance with Clause 9	--	**N/A**
	c) Changes to the LEGACY SOFTWARE have performed in accordance with Clause 6.	--	**N/A**
4.4.5	[A, B, C] Rationale for use of LEGACY SOFTWARE		**N/A**
	The MANUFACTURER documents the VERSION of the LEGACY SOFTWARE together with a rationale for the continued use of the LEGACY SOFTWARE	--	**N/A**
5	**SOFTWARE DEVELOPMENT PROCESS**		—
5.1	**Software development planning**		—
5.1.1	[A, B, C] The MANUFACTURER establishes a software development plan (or plans) for conducting the ACTIVITIES of the software development PROCESS appropriate to the scope, magnitude, and software safety classifications of the SOFTWARE SYSTEM to be developed.	--	**N/A**
	The SOFTWARE DEVELOPMENT LIFE CYCLE MODEL is either fully defined or be referenced in the plan (or plans).	--	**N/A**
	The plan addresses the following:		**N/A**
	a) the PROCESSES to be used in the development of the SOFTWARE SYSTEM	--	**N/A**
	b) the DELIVERABLES (includes documentation) of the ACTIVITIES and TASKS	--	**N/A**
	c) TRACEABILITY between SYSTEM requirements, software requirements, SOFTWARE SYSTEM test, and RISK CONTROL measures implemented in software	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	d) software configuration and change management, including SOUP CONFIGURATION ITEMS and software used to support development	--	**N/A**
	e) software problem resolution for handling problems detected in the MEDICAL DEVICE SOFTWARE, DELIVERABLES and ACTIVITIES at each stage of the life cycle	--	**N/A**
5.1.2	[A, B, C] The MANUFACTURER updates the plan, as appropriate, as development proceeds	--	**N/A**
5.1.3	[A, B, C] Software development plan reference to SYSTEM design and development		**N/A**
	a) As inputs for software development, SYSTEM requirements are referenced in the software development plan by the MANUFACTURER	--	**N/A**
	b) In the software development plan, the MANUFACTURER includes or references procedures for coordinating the software development with the system development necessary to satisfy 4.1 (such as system integration, verification, and validation)	--	**N/A**
5.1.4	[C] Associated with the development of SOFTWARE ITEMS of class C, in the software development plan are included or referenced:		**N/A**
	a) standards	--	**N/A**
	b) methods	--	**N/A**
	c) tools	--	**N/A**
5.1.5	[B, C] The MANUFACTURER includes or references in the software development plan, a plan to integrate the SOFTWARE ITEMS (including SOUP) and performs testing during integration	--	**N/A**
5.1.6	[A, B, C] In the software development plan, the following VERIFICATION information are included or referenced:		**N/A**
	a) DELIVERABLES requiring VERIFICATION	--	**N/A**
	b) the required VERIFICATION TASKS for each life cycle ACTIVITY	--	**N/A**
	c) milestones at which the DELIVERABLES are VERIFIED	--	**N/A**
	d) the acceptance criteria for VERIFICATION of the DELIVERABLES	--	**N/A**
5.1.7	[A, B, C] In the software development plan the MANUFACTURER includes or references a plan to conduct the ACTIVITIES and TASKS of the software RISK MANAGEMENT PROCESS, including the management of RISKS relating to SOUP	--	**N/A**
5.1.8	[A, B, C] In the software development plan the MANUFACTURER includes or references information about the documents to be produced during the software development life cycle	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	For each identified document or type of document the following information has included or referenced:		**N/A**
	a) title, name or naming convention	--	**N/A**
	b) purpose	--	**N/A**
	c) procedures and responsibilities for development, review, approval and modification	--	**N/A**
5.1.9	[A, B, C] The MANUFACTURER includes or references software configuration management information in the software development plan	--	**N/A**
	The software configuration management information includes or references:		**N/A**
	a) the classes, types, categories or lists of items to be controlled	--	**N/A**
	b) the software configuration management ACTIVITIES and TASKS	--	**N/A**
	c) the organization(s) responsible for performing software configuration management and ACTIVITIES	--	**N/A**
	d) their relationship with other organizations, such as software development or maintenance	--	**N/A**
	e) when the items are to be placed under configuration control	--	**N/A**
	f) when the problem resolution PROCESS is to be used	--	**N/A**
5.1.10	[B, C] The items to be controlled include tools, items or settings, used to develop the MEDICAL DEVICE SOFTWARE, which could impact the MEDICAL DEVICE SOFTWARE	--	**N/A**
5.1.11	[B, C] The MANUFACTURER plans to place CONFIGURATION ITEMS under documented configuration management control before they are VERIFIED	--	**N/A**
5.1.12	[B, C] In the software development plan the MANUFACTURER includes or references a procedure for:		**N/A**
	a) identifying categories of defects that may be introduced based on the selected programming technology that are relevant to their SOFTWARE SYSTEM	--	**N/A**
	b) documenting evidence that demonstrates that these defects do not contribute to unacceptable RISK	--	**N/A**
5.2	**Software requirements analysis**		—
5.2.1	[A, B, C] For each SOFTWARE SYSTEM of the MEDICAL DEVICE, the MANUFACTURER defines and documents SOFTWARE SYSTEM requirements from the SYSTEM level requirements	--	**N/A**
5.2.2	[A, B, C] As appropriate to the MEDICAL DEVICE SOFTWARE, the MANUFACTURER includes in the software requirements:		**N/A**
	a) functional and capability requirements	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) SOFTWARE SYSTEM inputs and outputs	--	**N/A**
	c) interfaces between the SOFTWARE SYSTEM and other SYSTEMS	--	**N/A**
	d) software-driven alarms, warnings, and operator messages	--	**N/A**
	e) SECURITY requirements	--	**N/A**
	f) user interface requirements implemented by software	--	**N/A**
	g) data definition and database requirements	--	**N/A**
	h) installation and acceptance requirements of the delivered MEDICAL DEVICE SOFTWARE at the operation and maintenance site or sites	--	**N/A**
	i) requirements related to methods of operation and maintenance	--	**N/A**
	j) requirements related to IT-network aspects	--	**N/A**
	k) user maintenance requirements	--	**N/A**
	l) regulatory requirements	--	**N/A**
5.2.3	[B, C] The MANUFACTURER includes RISK CONTROL measures implemented in software in the requirements as appropriate to the MEDICAL DEVICE SOFTWARE	--	**N/A**
5.2.4	[A, B, C] The MANUFACTURER re-EVALUATES the MEDICAL DEVICE RISK ANALYSIS when software requirements are established and update it as appropriate	--	**N/A**
5.2.5	[A, B, C] The MANUFACTURER ensures that existing requirements, including SYSTEM requirements, are re-EVALUATED and updated as appropriate as a result of the software requirements analysis ACTIVITY	--	**N/A**
5.2.6	[A, B, C] The MANUFACTURER verifies and documents that the software requirements:		**N/A**
	a) implement SYSTEM requirements including those relating to RISK CONTROL	--	**N/A**
	b) do not contradict one another	--	**N/A**
	c) are expressed in terms that avoid ambiguity	--	**N/A**
	d) are stated in terms that permit establishment of test criteria and performance of tests	--	**N/A**
	e) can be uniquely identified	--	**N/A**
	f) are traceable to SYSTEM requirements or other source	--	**N/A**
5.3	**Software ARCHITECTURAL design**		**N/A**
5.3.1	[B, C] The MANUFACTURER transforms the requirements for the MEDICAL DEVICE SOFTWARE into a documented ARCHITECTURE that describes the software's structure and identifies the SOFTWARE ITEMS	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.3.2	[B, C] The MANUFACTURER develops and documents an ARCHITECTURE for the interfaces between the SOFTWARE ITEMS and the components external to the SOFTWARE ITEMS (both software and hardware), and between the SOFTWARE ITEMS	--	**N/A**
5.3.3	[B, C] If a SOFTWARE ITEM is identified as SOUP, the MANUFACTURER specifies functional and performance requirements for the SOUP item that are necessary for its intended use	--	**N/A**
5.3.4	[B, C] If a SOFTWARE ITEM is identified as SOUP, the MANUFACTURER specifies the SYSTEM hardware and software necessary to support the proper operation of the SOUP item	--	**N/A**
5.3.5	[C] The MANUFACTURER identifies any segregation between SOFTWARE ITEMS that is necessary for RISK CONTROl, and states how to ensure that such segregation is effective	--	**N/A**
5.3.6	[B, C] The MANUFACTURER verifies and documents that:		**N/A**
	a) the ARCHITECTURE of the software implements SYSTEM and software requirements including those relating to RISK CONTROL	--	**N/A**
	b) the software ARCHITECTURE is able to support interfaces between SOFTWARE ITEMS and between SOFTWARE ITEMS and hardware	--	**N/A**
	c) the MEDICAL DEVICE ARCHITECTURE supports proper operation of any SOUP items	--	**N/A**
5.4	**Software detailed design**		**N/A**
5.4.1	[B, C] The MANUFACTURER subdivides the software until it is represented by SOFTWARE UNITS	--	**N/A**
5.4.2	[C] The MANUFACTURER documents a design with enough detail to allow correct implementation of each SOFTWARE UNIT	--	**N/A**
5.4.3	[C] The MANUFACTURER documents a design for any interfaces between the SOFTWARE UNIT and external components (hardware or software), as well as any interfaces between SOFTWARE UNITS, detailed enough to implement each SOFTWARE UNIT and its interfaces correctly	--	**N/A**
5.4.4	[C] The MANUFACTURER verifies and documents that the software detailed design:		**N/A**
	a) implements the software ARCHITECTURE	--	**N/A**
	b) is free from contradiction with the software ARCHITECTURE	--	**N/A**
5.5	**SOFTWARE UNIT implementation**		**N/A**
5.5.1	[A, B, C] The MANUFACTURER implements each SOFTWARE UNIT	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.5.2	[B, C] The MANUFACTURER establishes strategies, methods and procedures for verifying the SOFTWARE UNITS	--	**N/A**
	Where VERIFICATION is done by testing, the test procedures are EVALUATED for adequacy	--	**N/A**
5.5.3	[B, C] The MANUFACTURER establishes acceptance criteria for SOFTWARE UNITS prior to integration into larger SOFTWARE ITEMS as appropriate, and ensures that SOFTWARE UNITS meet acceptance criteria	--	**N/A**
5.5.4	[C] When present in the design, the MANUFACTURER includes additional acceptance criteria as appropriate for:		**N/A**
	a) proper event sequence	--	**N/A**
	b) data and control flow	--	**N/A**
	c) planned resource allocation	--	**N/A**
	d) fault handling (error definition, isolation, and recovery)	--	**N/A**
	e) initialisation of variables	--	**N/A**
	f) self-diagnostics	--	**N/A**
	g) memory management and memory overflows	--	**N/A**
	h) boundary conditions	--	**N/A**
5.5.5	[B, C] The MANUFACTURER performs the SOFTWARE UNIT VERIFICATION and documents the results	--	**N/A**
5.6	**Software integration and integration testing**		**N/A**
5.6.1	[B, C] The MANUFACTURER integrates the SOFTWARE UNITS in accordance with the integration plan	--	**N/A**
5.6.2	[B, C] The MANUFACTURER verifies that the SOFTWARE UNITS have been integrated into SOFTWARE ITEMS and/or the SOFTWARE SYSTEM in accordance with the integration plan and retains records of the evidence of such verification	--	**N/A**
5.6.3	[B, C] The MANUFACTURER tests the integrated SOFTWARE ITEMS in accordance with the integration plan and documents the results	--	**N/A**
5.6.4	[B, C] For software integration testing, the MANUFACTURER addresses whether the integrated SOFTWARE ITEM performs as intended	--	**N/A**
5.6.5	[B, C] The MANUFACTURER EVALUATES the integration test procedures for adequacy	--	**N/A**
5.6.6	[B, C] When software items are integrated, the MANUFACTURER conducts REGRESSION TESTING appropriate to demonstrate that defects have not been introduced into previously integrated software	--	**N/A**
5.6.7	[B, C] The MANUFACTURER:		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) documents the test result (pass/fail and a list of ANOMALIES)	--	**N/A**
	b) retains sufficient records to permit the test to be repeated	--	**N/A**
	c) identifies the tester	--	**N/A**
5.6.8	[B, C] The MANUFACTURER enters ANOMALIES found during software integration and integration testing into a software problem resolution PROCESS	--	**N/A**
5.7	**SOFTWARE SYSTEM testing**		**N/A**
5.7.1	[A, B, C] Establish tests for software requirements		**—**
	a) The MANUFACTURER establishes and performs a set of tests, expressed as input stimuli, expected outcomes, pass/fail criteria and procedures, for conducting SOFTWARE SYSTEM testing, such that all software requirements are covered	--	**N/A**
	b) The MANUFACTURER EVALUATES the adequacy of VERIFICATION strategies and test procedures.	--	**N/A**
5.7.2	[A, B, C] The MANUFACTURER enters ANOMALIES found during software system testing into a software problem resolution PROCESS	--	**N/A**
5.7.3	[A, B, C] When changes are made during SOFTWARE SYSTEM testing, the MANUFACTURER:		**N/A**
	a) repeats tests, performs modified tests or performs additional tests, as appropriate, to verify the effectiveness of the change in correcting the problem	--	**N/A**
	b) conducts testing appropriate to demonstrate that unintended side effects have not been introduced	--	**N/A**
	c) performs relevant RISK MANAGEMENT ACTIVITIES as defined in 7.4	--	**N/A**
5.7.4	[A, B, C] Evaluate SOFTWARE SYSTEM testing		**N/A**
	The MANUFACTURER EVALUATES the appropriateness of VERIFICATION strategies and test procedures	--	**N/A**
	The MANUFACTURER verifies that:		**N/A**
	a) all software requirements have been tested or otherwise VERIFIED	--	**N/A**
	b) the TRACEABILITY between software requirements and tests or other VERIFICATION is recorded	--	**N/A**
	c) test results meet the required pass/fail criteria	--	**N/A**
5.7.5.	[A, B, C] In order to support the repeatability of tests, the MANUFACTURER documents:		**N/A**
	a) a reference to test case procedures showing required actions and expected results	--	**N/A**
	b) the test result (pass/fail and a list of ANOMALIES)	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) the version of software tested	--	**N/A**
	d) relevant hardware and software test configurations	--	**N/A**
	e) relevant test tools	--	**N/A**
	f) date tested	--	**N/A**
	g) the identity of the person responsible for executing the test and recording the test results	--	**N/A**
5.8	**Software RELEASE for utilization at a SYSTEM level**		**N/A**
5.8.1	[A, B, C] The MANUFACTURER ensures that all software VERIFICATION ACTIVITIES has been completed and the results EVALUATED before the software is released	--	**N/A**
5.8.2	[A, B, C] The MANUFACTURER documents all known residual ANOMALIES	--	**N/A**
5.8.3	[B, C] The MANUFACTURER ensured that all known residual ANOMALIES have been EVALUATED to ensure that they do not contribute to an unacceptable RISK	--	**N/A**
5.8.4	[A, B, C] The MANUFACTURER documented the VERSION of the MEDICAL DEVICE SOFTWARE that is being released	--	**N/A**
5.8.5	[B, C] The MANUFACTURER documents the procedure and environment used to create the released software	--	**N/A**
5.8.6	[B, C] The MANUFACTURER ensures that all software development plan (or maintenance plan) ACTIVITIES and TASKS are complete along with the associated documentation	--	**N/A**
5.8.7	[A, B, C] For at least a period of time determined as the longer of: the life time of the MEDICAL DEVICE SOFTWARE as defined by the MANUFACTURER or a time specified by relevant regulatory requirements, the MANUFACTURER archives:		**N/A**
	a) the MEDICAL DEVICE SOFTWARE and CONFIGURATION ITEMS	--	**N/A**
	b) the documentation	--	**N/A**
5.8.8	[A, B, C] The MANUFACTURER establishes procedures to ensure that the released MEDICAL DEVICE SOFTWARE can be reliably delivered to the point of use without corruption or unauthorised change	--	**N/A**
	These procedures address the production and handling of media containing the MEDICAL DEVICE SOFTWARE including as appropriate:		**N/A**
	– replication	--	**N/A**
	– media labelling	--	**N/A**
	– packaging	--	**N/A**
	– protection	--	**N/A**
	– storage	--	**N/A**
	– delivery	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

7	**SOFTWARE RISK MANAGEMENT PROCESS**		—
7.1	**Analysis of software contributing to hazardous situations**		—
7.1.1	[B, C] The MANUFACTURER identifies SOFTWARE ITEMS that could contribute to a hazardous situation identified in the MEDICAL DEVICE RISK ANALYSIS ACTIVITY of ISO 14971	No software incorporated.	**N/A**
7.1.2	[B, C] The MANUFACTURER identifies potential causes of the SOFTWARE ITEM identified above contributing to a hazardous situation	--	**N/A**
	The MANUFACTURER considers potential causes including, as appropriate:		**N/A**
	a) incorrect or incomplete specification of functionality	--	**N/A**
	b) software defects in the identified SOFTWARE ITEM functionality	--	**N/A**
	c) failure or unexpected results from SOUP	--	**N/A**
	d) hardware failures or other software defects that could result in unpredictable software operation	--	**N/A**
	e) reasonably foreseeable misuse	--	**N/A**
7.1.3	[B, C] If failure or unexpected results from SOUP is a potential cause of the SOFTWARE ITEM contributing to a hazardous situation, the MANUFACTURER EVALUATES as a minimum any ANOMALY list published by the supplier of the SOUP item relevant to the VERSION of the SOUP item used in the MEDICAL DEVICE to determine if any of the known ANOMALIES result in a sequence of events that could result in a hazardous situation	--	**N/A**
7.1.4	[B, C] The MANUFACTURER documents in the RISK MANAGEMENT FILE potential causes of the SOFTWARE ITEM contributing to a hazardous situation	--	**N/A**
7.2	**RISK CONTROL measures**		—
7.2.1	[B, C] For each case documented in the RISK MANAGEMENT FILE where a SOFTWARE ITEM could contribute to a HAZARDOUS SITUATION, the MANUFACTURER defines and documents RISK CONTROL measures in accordance with ISO 14971	--	**N/A**
7.2.2	[B, C] If a RISK CONTROL measure is implemented as part of the functions of a SOFTWARE ITEM, the MANUFACTURER:		**N/A**
	a) includes the RISK CONTROL measure in the software requirements	--	**N/A**
	b) assigns to each SOFTWARE ITEM that contributes to the implementation of a RISK CONTROL measure a software safety class based on the RISK that the RISK CONTROL measure is controlling	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) develops the SOFTWARE ITEM in accordance with Clause 5	--	**N/A**
7.3	**VERIFICATION of RISK CONTROL measures**		—
7.3.1	[B, C] The implementation of each RISK CONTROL measure documented in 7.2 is VERIFIED, and this VERIFICATION is documented	--	**N/A**
	The MANUFACTURER reviewers the RISK CONTROL measure and determines if it could result in a new HAZARDOUS SITUATION	--	**N/A**
7.3.3	[B, C] The MANUFACTURER documents TRACEABILITY of software HAZARDS as appropriate:		**N/A**
	a) from the hazardous situation to the SOFTWARE ITEM	--	**N/A**
	b) from the SOFTWARE ITEM to the specific software cause	--	**N/A**
	c) from the software cause to the RISK CONTROL measure	--	**N/A**
	d) from the RISK CONTROL measure to the VERIFICATION of the RISK CONTROL measure	--	**N/A**
7.4	**RISK MANAGEMENT of software changes**		—
7.4.1	[A, B, C] The MANUFACTURER analyses changes to the MEDICAL DEVICE SOFTWARE (including SOUP) to determine whether:		**N/A**
	a) additional potential causes are introduced contributing to a hazardous situation	--	**N/A**
	b) additional software RISK CONTROL measures are required	--	**N/A**
7.4.2	[B, C] The MANUFACTURER analyses changes to the software, including changes to SOUP, to determine whether the software modification could interfere with existing RISK CONTROL measures	--	**N/A**
7.4.3	[B, C] The MANUFACTURER performs relevant RISK MANAGEMENT ACTIVITIES defined in 7.1, 7.2 and 7.3 based on these analyses	--	**N/A**

8	**SOFTWARE CONFIGURATION MANAGEMENT PROCESS**		—
8.1	**Configuration identification**		—
8.1.1	[A, B, C] The MANUFACTURER establishes a scheme for the unique identification of CONFIGURATION ITEMS and their VERSIONS to be controlled according to the development and configuration planning specified in 5.1	--	**N/A**
8.1.2	[A, B, C] For each SOUP CONFIGURATION ITEM being used, including standard libraries, the MANUFACTURER documents:		**N/A**
	a) the title	--	**N/A**
	b) the MANUFACTURER	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) the unique SOUP designator	--	**N/A**
8.1.3	[A, B, C] The MANUFACTURER documents the set of CONFIGURATION ITEMS and their VERSIONS that comprise the SOFTWARE SYSTEM configuration	--	**N/A**
8.2	**Change control**		**—**
8.2.1	[A, B, C] The MANUFACTURER changes CONFIGURATION ITEMS identified to be controlled according to 8.1 only in response to an approved CHANGE REQUEST	--	**N/A**
8.2.2	[A, B, C] The MANUFACTURER implements the change as specified in the CHANGE REQUEST	--	**N/A**
	The MANUFACTURER identifies and performs any ACTIVITY that needs to be repeated as a result of the change, including changes to the software safety classification of SOFTWARE SYSTEMS and SOFTWARE ITEMS	--	**N/A**
8.2.3	[A, B, C] The MANUFACTURER verifies the change, including repeating any VERIFICATION that has been invalidated by the change and taking into account 5.7.3 and 9.7	--	**N/A**
8.2.4	[A, B, C] The MANUFACTURER maintains records of the relationships and dependencies between:		**N/A**
	a) CHANGE REQUEST	--	**N/A**
	b) relevant PROBLEM REPORT	--	**N/A**
	c) approval of the CHANGE REQUEST	--	**N/A**
8.3	[A, B, C] The MANUFACTURER retains retrievable records of the history of controlled CONFIGURATION ITEMS including SYSTEM configuration	--	**N/A**

9	**SOFTWARE PROBLEM RESOLUTION PROCESS**		—
9.1	[A, B, C] The MANUFACTURER prepares a PROBLEM REPORT for each problem detected in the MEDICAL DEVICE SOFTWARE	No software incorporated.	**N/A**
	PROBLEM REPORTS include a statement of criticality (for example, effect on performance, SAFETY, or SECURITY) as well as other information that may aid in the resolution of the problem (for example, devices affected, supported accessories affected)	--	**N/A**
9.2	[A, B, C] The MANUFACTURER:		**N/A**
	a) investigates the problem and if possible identify the causes	--	**N/A**
	b) EVALUATES the problem's relevance to SAFETY using the software RISK MANAGEMENT PROCESS	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) documents the outcome of the investigation and evaluation	--	**N/A**
	d) creates a CHANGE REQUEST(S) for actions needed to correct the problem, or document the rationale for taking no action	--	**N/A**
9.3	[A, B, C] The MANUFACTURER advises relevant parties of the existence of the problem, as appropriate	--	**N/A**
9.4	[A, B, C] The MANUFACTURER approves and implements all CHANGE REQUESTS, observing the requirements of the change control PROCESS	--	**N/A**
9.5	[A, B, C] The MANUFACTURER maintains records of PROBLEM REPORTS and their resolution including their VERIFICATION	--	**N/A**
	The MANUFACTURER updates the RISK MANAGEMENT FILE as appropriate	--	**N/A**
9.6	[A, B, C] The MANUFACTURER performs analysis to detect trends in PROBLEM REPORTS	--	**N/A**
9.7	[A, B, C] The MANUFACTURER verifies resolutions to determine whether:		**N/A**
	a) problem has been resolved and the PROBLEM REPORT has been closed	--	**N/A**
	b) adverse trends have been reversed	--	**N/A**
	c) CHANGE REQUESTS have been implemented in the appropriate MEDICAL DEVICE SOFTWARE and ACTIVITIES	--	**N/A**
	d) additional problems have been introduced	--	**N/A**
9.8	[A, B, C] When testing, retesting or REGRESSION TESTING SOFTWARE ITEMS and SYSTEMS following a change, the MANUFACTURER includes in the test documentation:		**N/A**
	a) test results	--	**N/A**
	b) ANOMALIES found	--	**N/A**
	c) the VERSION of software tested	--	**N/A**
	d) relevant hardware and software test configurations	--	**N/A**
	e) relevant test tools	--	**N/A**
	f) date tested	--	**N/A**
	g) identification of the tester	--	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Attachment	**Software - Mapping of required evidence and manufacturer documents**			**N/A**
Standard Clause	Deliverables	Title	Revision #	Date
4.3	Software safety classification document	--	--	--
4.3	Specification of risk control measures external to software system	--	--	--
4.3	Rationale of classification for decomposed software system	--	--	--
4.4.2	Risk management activities for legacy software	--	--	--
4.4.3	Gap analysis for legacy software	--	--	--
4.4.4	Gap closure plan for legacy software	--	--	--
4.4.5	Rationale for use of legacy software	--	--	--
5.1.1	Software development plan	--	--	--
5.1.3	Software requirements reference to software design and development document	--	--	--
5.1.4	Development standards, methods and tools records for class C software	--	--	--
5.1.5	Software integration and integration testing plan	--	--	--
5.1.6	Software verification plan	--	--	--
5.1.7	Software risk management plan	--	--	--
5.1.8	Document management procedures	--	--	--
5.1.9	Software configuration management procedures	--	--	--
5.2	Software system requirements specification	--	--	--
5.2.3	Specification of risk control measure implemented in software	--	--	--
5.3	Software system architecture design specification	--	--	--
5.3	Software item architecture design specification	--	--	--
5.4	Software item detailed design specification	--	--	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Attachment	**Software - Mapping of required evidence and manufacturer documents**			**N/A**
Standard Clause	Deliverables	Title	Revision #	Date
5.4	Software unit detailed design specification	--	--	--
5.5.1	Software unit implementation records	--	--	--
5.5.2	Software unit verification process	--	--	--
5.5.3	Software unit acceptance criteria	--	--	--
5.5.5	Software unit verification records	--	--	--
5.6.1	Software unit integration process	--	--	--
5.6.2	Software unit integration records	--	--	--
5.6.4	Software unit integration testing records	--	--	--
5.6.5	Evaluation of software unit integration test	--	--	--
5.6.6	Software unit regression testing process	--	--	--
5.6.7	Software unit regression testing records	--	--	--
5.6.8	Software problem resolution process	--	--	--
5.7	Software system testing process	--	--	--
5.7	Software system testing records	--	--	--
5.8	Software system release process	--	--	--
5.8	Software system release record	--	--	--
5.8	Statement of known residual anomalies	--	--	--
7.1	Software hazard analysis process	--	--	--
7.1	SOUP anomaly lists	--	--	--
7.2	Risk control process	--	--	--
7.3	Risk control verification process	--	--	--
7.4	Risk management of software change process	--	--	--
8.1	Configuration identification record	--	--	--
8.2	Change control process	--	--	--
8.2	Records for traceability of change	--	--	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Attachment	**Software - Mapping of required evidence and manufacturer documents**			**N/A**
Standard Clause	Deliverables	Title	Revision #	Date
9	Software problem resolution process	--	--	--
9	Software problem resolution records	--	--	--
Supplementary information: /				

Enclosure No. 1

National Differences to
IEC 60601-1:2005 + A1:2012 + A2:2020

(34 pages including this cover page)

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT

IEC 60601-1:2005 + AMD 1:2012
US NATIONAL DIFFERENCES
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Differences according to.....:	National standard AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021
TRF template used: ..... :	IECEE OD-2020-F3, Ed. 1.1
Attachment Form No. .....:	US_ND_IEC60601_1U
Attachment Originator.....:	UL(US)
Master Attachment .....:	2022-07-01

Copyright © 2022 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.

	National Differences		P
4.8	Components of ME EQUIPMENT		P
	b) where there is no relevant IEC/ISO standard, the relevant ANSI standard applied; if no relevant ANSI standard exists, the requirements of this standard were applied. (*Replacement of clause 4.8 b*)	Considered.	P
4.10.2	SUPPLY MAINS FOR ME EQUIPMENT AND ME SYSTEMS		P
	(Replacement to reflect agreement with the National Electrical Code (NEC): The reference to "500 V" replaced with "600 V" in the second and third dashes.	Considered.	P
	(Addition to reflect agreement with the NEC) In the text of the second-to-last dash of this sub-clause, "and the NEC" added after reference to "IEC 60364-4-41"	Considered.	P
6.0	**Classification of ME EQUIPMENT and ME SYSTEMS**		P
6.6	Mode of operation	Continuous mode of operation considered.	P
	(Addition to reflect agreement with NFPA 70) X-Ray systems are classified as long time operation (> 5 min) or momentary operation (< 5 sec).	Not X-ray equipment.	N/A
7.0	**ME EQUIPMENT identification, marking and documents**		P
7.2.11	Mode of operation	Continuous mode of operation considered.	P
	(Addition to reflect agreement with NFPA 70) X-Ray systems are marked as long time operation or momentary operation.	Not X-ray equipment.	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
7.2.22	(*Addition of new item*) Colours of medical gas cylinders	No medical gas cylinders provided.	N/A
	To reflect agreement with NFPA 99: Cylinders containing medical gases and their connection points are coloured in accordance with the requirements of NFPA 99.	--	N/A
8.0	**Protection against electrical hazards from ME EQUIPMENT**		P
8.2	Requirements related to power sources	--	N/A
	(Addition to reflect agreement with the NEC) All FIXED ME EQUIPMENT and PERMANENTLY INSTALLED ME EQUIPMENT are CLASS I ME EQUIPMENT.	EUT is not fixed or permanently installed equipment.	N/A
8.6.1	Application of requirements	--	N/A
	(Addition to reflect agreement with NFPA 99) The enclosure of X-ray ME EQUIPMENT operating over 600 Vac, 850 Vdc MAINS VOLTAGE, or containing voltages up to 50 V peak and enclosed in protectively earthed enclosure as well as connections to X-ray tubes and other high voltage components that include high voltage shielded cables are PROTECTIVELY EARTHED.	Not X-ray equipment.	N/A
	(Addition to reflect agreement with NFPA 99) Non-current carrying conductive parts of X-Ray ME EQUIPMENT likely to become energized are PROTECTIVELY EARTHED	--	N/A
8.7.3	Allowable values	--	P
	(Deletion to reflect agreement with NFPA 99 which does not allow for allowance greater than the stated values) Delete the second sentence and note to sub-clause 8.7.3 d) so that it reads: d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION	Considered.	P
8.11	MAINS PARTS, components and layout	--	N/A
	(Addition to reflect agreement with the NEC) Permanently connected ME EQUIPMENT has provision for the connection of one of the wiring systems that is in accordance with the NEC.	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	Exception: Fixed and stationary X-ray ME EQUIPMENT supplied from a branch circuit rated at 30 A or less, and ME EQUIPMENT that is not strictly portable but obviously is intended to be stationary, may be acceptable if provided with a length of attached hard service flexible cord - such as Type S, or the equivalent, for supply connection.	--	N/A
	The installation of connecting cords between EQUIPMENT parts meets the requirements of the NEC, as applicable. Cable used as external interconnection between units are as follows:	No connecting cord between equipment parts provided. Only output cable provided.	N/A
	1) If exposed to abuse, the cables are Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord or similar multiple-conductor appliance-wiring material such as computer cable	--	N/A
	2) If not exposed to abuse, the cables are as indicated in item 1) above or are: i) Type SPT-2, SP-2, or SPE-2, or equivalent, ii) Type SVr, SVRO, SVE, or equivalent flexible cord or similar multiple-conductor appliance wiring material, or iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more, enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more.	--	N/A
	Receptacles provided as part of ME EQUIPMENT or ME SYSTEMS for use in the patient care areas of paediatric wards, rooms, or areas are listed tamper resistant or employ a listed tamper resistant cover in accordance with the NEC.	--	N/A
	b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, 250 V/20 A “Hospital Grade” mains plug is provided and the POWER SUPPLY CORD is marked.	--	N/A
8.11.3.2	*(Addition to reflect agreement with the NEC)* The flexible cord is of a type that is acceptable for the particular application. It is acceptable for use at a voltage not less than the rated voltage of the appliance and has an ampacity, as given in the NEC, not less than the current rating of the appliance .....:	Power supply cord not part of the investigation.	N/A
8.11.3.3	Cross-sectional area of POWER SUPPLY CORDS	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	(Addition to reflect agreement with NFPA 99) For X-Ray ME EQUIPMENT with an attachment plug, the current rating on a hospital grade plug should be 2X the maximum input current of the equipment.	Not X-Ray equipment.	N/A
	1) If exposed to abuse, the cables are Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord or similar multiple-conductor appliance-wiring material such as computer cable.	--	N/A
	2) If not exposed to abuse, the cables are as indicated in item 1) above or are: i) Type SPT-2, SP-2, or SPE-2, or equivalent, ii) Type SVr, SVRO, SVE, or equivalent flexible cord or similar multiple-conductor appliance wiring material, or iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more, enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more.	--	N/A
	Receptacles provided as part of ME EQUIPMENT or ME SYSTEMS for use in the patient care areas of paediatric wards, rooms, or areas are listed tamper resistant or employ a listed tamper resistant cover in accordance with the NEC.	--	N/A
	b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, 250 V/20 A “Hospital Grade” mains plug is provided and the POWER SUPPLY CORD is marked.	--	N/A

ATTACHMENT TO TEST REPORT

IEC 60601-1:2005, COR1:2006, COR2:2007, AMD:1:2012.
CANADIAN NATIONAL DIFFERENCES
Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

Differences according to..... :	Canadian National standard: CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14
TRF template used:..... :	IECEE OD-2020-F3, Ed. 1.1
Attachment Form No. ..... :	CA_ND_IEC60601_1U
Attachment Originator..... :	CSA Group
Master Attachment..... :	2022-08-12

Copyright © 2022 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict

Note *: IEC CANADIAN NATIONAL DIFFERENCES in Canada are called CANADIAN DEVIATIONS.

	Canadian National Differences		P
1	**Scope, object and related standards**		P
1.1	**Scope**		P
	[Replace the first paragraph with the following] This Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be used in accordance with CSA C22.1 (Canadian Electrical Code, Part I) and CSA Z32.	Considered.	P
	[Add the following note] Note 1A: In the IEC 60601 Standards series adopted for use in Canada, the Canadian standards may modify, replace, or delete requirements contained in the IEC standard as appropriate to the ME EQUIPMENT and ME SYSTEMS under evaluation, and they may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements		P
1.3	**Collateral standards**		P
	[Replace this clause with the following] Applicable Canadian 60601 collateral standards become normative at the date of their publication and apply together with this Standard.	Considered.	P
1.4	**Particular standards**		P
	[Replace this clause with the following] Applicable Canadian 60601/80601 particular standards may modify, replace, or delete requirements contained in this Standard. The requirement of a Canadian 60601/80601 particular safety standard takes priority over this Standard.	Considered.	P
2	**Normative references**		P
	In this CSA Group adoption, any reference to International Standards shall be replaced by the relevant National Standard of Canada. **Note 1DV:** *For additional information about normative Standards in Canada, refer to the* Canadian Electrical Code, Part I, *Appendix A.* Where reference is made to CSA Group Standards, such reference are considered to refer to the latest edition and all amendments published to that edition. This Standard refers to the following Standards, and the years shown indicate the latest editions available at the time of printing: **CSA Group** B51-09 Boiler, pressure vessel, and pressure piping code	Considered.	P

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	C22.1-21 Canadian Electrical Code, Part I C22.2 No. 0:20 General requirements — Canadian Electrical Code, Part II C22.2 No. 0.4-17 *Bonding of electrical equipment* C22.2 No. 21-95 (R2009) Cord sets and power supply cords C22.2 No. 42-10 General use receptacles, attachment plugs, and similar wiring devices C22.2 No. 49-10 Flexible cords and cables C22.2 No. 100:14 (R2019) *Motors and generators* C22.2 No. 248 series of Standards Low-voltage fuses C22.2 No. 308-18 Cord reels and multi-outlet assemblies CAN/CSA-E61558-2-1-03 (R2012) Safety of power transformers, power supply units and similar — Part 2: Particular requirements for separating transformers for general use CSA C22.2 No. 62368-1:19 Audio/video, information and communication technology equipment — Part 1: Safety requirements Z32-09 Electrical safety and essential electrical systems in health care facilities CAN/CSA-Z305.8-03 (R2013) Medical supply units Z305.12-06 (R2012) Safe storage, handling, and use of portable oxygen systems in residential buildings and health care facilities Z305.13-09 Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings CAN/CSA-Z5359-10 Low-pressure hose assemblies for use with medical gases CAN/CSA-Z9170-1-11 Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases, vacuum, and anaesthetic gas scavenging systems		

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	CAN/CSA-Z10524-1:12 Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices CAN/CSA-Z15002:12 Flow-metering devices for connection to terminal units of medical gas pipeline systems **ASME (American Society of Mechanical Engineers)** PTC 25-2008 Pressure Relief Devices **CGA (Compressed Gas Association)** V-1-2013 Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections V-5-2008 (reaffirmed 2013) Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications) **ISO (International Organization for Standardization)** 32:1977 Gas cylinders for medical use — Marking for identification of content 407:2004 Small medical gas cylinders — Pin-index yoke-type valve connections 9170-2:2008 Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems		
3	**Terminology and definitions**		N/A
3.41	**HIGH VOLTAGE**		N/A
	[Replace this Clause in the Canadian deviations in the adopted Standard with the following] voltage above 1000 V ac for ac circuits or voltage above 1060 V dc for dc circuits, as defined in the *Canadian Electrical Code, Part I*	No such high voltage within the equipment.	N/A
4.	**General requirements**		P
4.1A	*[Add the following clause]* General requirements applicable to ME EQUIPMENT and ME SYSTEMS are provided in CAN/CSA-C22.2 No. 0.	Considered.	P
4.8	**Components of ME EQUIPMENT**		P
	[Replace Items a) and b) and Note 2 with the following]	--	P

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	a) The applicable safety requirements of a relevant CSA Group, IEC, or ISO Standard; or	Considered.	P
	b) where there is no relevant CSA Group, IEC, or ISO Standard, the requirements of this Standard shall be applied	Considered.	P
	Note 2: If there are neither requirements in this Standard nor in a CSA Group, IEC, or ISO Standard, any other applicable source (e.g., standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.		--
4.10.2	**SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS**		P
	[Replace the first sentence with the following] ME EQUIPMENT intended to be connected to SUPPLY MAINS shall be in accordance with the Canadian Electrical Code, Part I, and the following RATED voltages shall not be exceeded:	--	P
7.	**ME EQUIPMENT identification, marking and documents**		P
7.5	**Safety signs**		N/A
	[Replace the paragraph starting with "When supplementary text" in IEC Amendment 1 with the following] When supplementary text is placed together with safety signs, the supplementary text shall be in English and French for the intended OPERATOR.	No such safety signs provided.	N/A
7.7	**Colours of the insulation of conductors**		P
7.7.1	**PROTECTIVE EARTH CONDUCTOR**		P
	[Replace Clause 7.7.1 in the adopted Standard with the following] A PROTECTIVE EARTH CONDUCTOR shall be identified throughout its length by green or green and yellow coloured insulation.	Protective conductor within the power supply.	P
7.7.2	**PROTECTIVE EARTH CONNECTIONS**		N/A
	[Replace Clause 7.7.2 in the adopted Standard with the following] A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION of any insulation on conductors shall be identified by either green or green and yellow colours at least at the termination of the conductors.	--	N/A
7.7.3	**Green or green and yellow insulation**		P
	[Replace Clause 7.7.3 in the adopted Standard, as modified by IEC Amendment 1, with the following]		P
	Identification by green or green and yellow insulation shall only be used for:		P

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	- PROTECTIVE EARTH CONDUCTORS (see Clause 8.6.2);	--	P
	- conductors as specified in Clause 7.7.2; **Note:** In other safety Standards such as CSA C22.2 No. 62368-1, internal connections between conductive parts and the main protective earth are called "protective bonding conductors".	--	N/A
	- POTENTIAL EQUALIZATION CONDUCTORS (see Clause 8.6.7);	--	N/A
	- FUNCTIONAL EARTH CONDUCTORS (see Clause 8.6.9).	--	P
7.7.4	**Neutral conductor**		N/A
	[Replace Clause 7.7.4 in the adopted Standard with the following] Colours of neutral conductors and POWER SUPPLY CORD conductors shall be in accordance with the *Canadian Electrical Code, Part I*, CSA C22.2 No. 21, and CSA C22.2 No. 49.	Power supply cord not part of the investigation.	N/A
7.7.5	**POWER SUPPLY CORD conductors**		N/A
	[Replace Clause 7.7.5 in the adopted Standard with the following] Colours of conductors in POWER SUPPLY CORDS shall be in accordance with the Canadian Electrical Code, Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49.	Power supply cord not part of the investigation.	N/A
	Compliance with the requirements of Clause 7.7 is checked by inspection.	--	N/A
7.9	**ACCOMPANYING DOCUMENTS**		N/A
7.9.2.1	**General**		N/A
	[Replace the last paragraph in the adopted Standard with the following] The instructions for use shall be in English and French for the intended OPERATOR.	--	N/A
8	**Protection against electrical HAZARDS from ME EQUIPMENT**		P
8.6	**Protective earthing, functional earthing and potential equalization of ME EQUIPMENT**		P
8.6.4	**Impedance and current-carrying capability**		P
	[Replace Clause 8.6.4 in the adopted Standard, as modified by IEC Amendments 1 and 2, with the following]		P
	PROTECTIVE EARTH CONNECTIONS shall be able to carry fault currents reliably and without excessive voltage drop.	Testing performed.	P

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	Impedance and current-carrying capability shall comply with CSA C22.2 No. 0.4.	--	P
	For PERMANENTLY INSTALLED ME EQUIPMENT and ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, the impedance between the PROTECTIVE EARTH TERMINAL (inside the ME EQUIPMENT) and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ. For ME EQUIPMENT with an APPLIANCE INLET, the impedance between the earth pin of the APPLIANCE INLET and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ……..:	--	N/A
	In addition to the test above, for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD or any DETACHABLE POWER SUPPLY CORD (supplied or specified by the MANUFACTURER), the impedance between the protective earth pin of the MAINS PLUG and the PROTECTIVE EARTH TERMINAL (inside the ME EQUIPMENT) shall not exceed 100 mΩ…….:	Testing performed.	P
	Where an APPLIANCE INLET forms the supply connection to ME EQUIPMENT, the earth pin of the APPLIANCE INLET is regarded as the PROTECTIVE EARTH TERMINAL. The combined testing requirements above are equivalent to 200 mΩ impedance testing requirements as described in IEC 60601-1. Separate testing is required to comply with CSA C22.2 No. 0.4.	Considered.	P
	Testing shall be carried out using a DETACHABLE POWER SUPPLY CORD as provided or specified (length and cross-sectional area as per the Canadian Electrical Code, Part I) by the MANUFACTURER.	Specified by the manufacturer.	P
	The test current shall have the following characteristics: — for cord-connected equipment, twice the rating of the attachment plug cap, but not less than 40 A; — for equipment for permanent connection to the supply, twice the rating of the fuse that is required by the *Canadian Electrical Code*, *Part I* for the branch circuit to which the equipment is connected, up to 250 A; and — 500 A for equipment for permanent connection to the supply when a branch circuit fused at over 250 A is required.	Test current: 40 A	P

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	Compliance is checked by the following test: — for test currents up to 500 A, the measured potential drop shall not exceed 4 V; — for equipment that requires branch circuit fusing over 250 A, the measured potential drop multiplied by the required fusing and divided by 250 shall not exceed 4 V; — there shall be no melting of any metal in the bond and no heating or burning that is likely to create a fire hazard; and — the time duration— the time duration for testing is indicated in Table 8.6.4A:	Voltage drop below 4 V.	P
	Table 8.6.4A **Time duration of impedance test current** **Fusing of branch circuit required for equipment (A)** / **Time (min)** 0–30 / 2 31–60 / 4 61–100 / 6 101–200 / 8 201 and over / 10 **Note:** *Additional information can be found in CSA C22.2 No. 0.4.*	--	P
	Alternatively, dc may be used for this test, if the ME EQUIPMENT is rated dc.	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	Note: When protective earth is relied on as a MEANS OF PROTECTION, the test current is determined based on the location where a fault could occur. If the prospective fault is in the mains supply circuit prior to the overcurrent protection included in the ME EQUIPMENT, the test current for that part of the protective earth circuit is based on the rating of the external overcurrent protection included in the building infrastructure or specified in the ACCOMPANYING DOCUMENTS (two times the interrupt rating of the external overcurrent protection). If the prospective fault is in the mains supply circuit after the overcurrent protection included in the ME EQUIPMENT, the test current is based on the rating of the overcurrent protection included in the ME EQUIPMENT (two times the interrupt rating of the ME EQUIPMENT overcurrent protection). In either case, the minimum test current is 40 A. The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop. If the measured impedance is within the permitted limit, either the impedance measurement is then repeated using a current source with a no-load voltage sufficient to deliver the specified current into the total impedance, or the current-carrying ability of the relevant protective earth conductor and protective earth connection is confirmed by checking that their cross-sectional area is at least equal to that of the relevant current-carrying conductors.	--	N/A
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		P
8.7.3	**Allowable values**		P
	[Add the following paragraph] Allowable values shall be in accordance with the Canadian Electrical Code, Part I.	Considered.	P
8.11	**MAINS PARTS, components and layout**		N/A
8.11.3.2	**Types**		N/A
	[Replace this clause with the following]		N/A
	The following requirements for POWER SUPPLY CORDS shall apply:		N/A
	a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENt shall be:		N/A
	i) if moulded-on type, a hospital-grade mains plug complying with CSA C22.2 No. 21;	Power supply cord not part of the investigation.	N/A
	ii) a hospital-grade disassembly attachment plug type complying with CSA C22.2 No. 42; or	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	iii) Class II equipment having fuses on the line side(s), and the neutral may use a non-polarized attachment plug or a polarized attachment plug. CSA configuration type 1-15P shall be required and meets all applicable requirements in CSA C22.2 No. 21 and CSA C22.2 No. 42. Where a polarized attachment plug is used, the POWER SUPPLY CORD is connected to the wiring of the EQUIPMENT on the ungrounded side of the line when any of the following devices are used in the primary circuit:	--	N/A
	1) the centre contact of an Edison base lampholder;	--	N/A
	2) a single pole switch;	--	N/A
	3) an automatic control with a marked off position;	--	N/A
	4) a solitary fuse/fuse holder; or	--	N/A
	5) any other single pole overcurrent protective device.	--	N/A
	b) A detachable POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) shall be of a type:		N/A
	i) that can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety HAZARD to a PATIENT or OPERATOR;	Power supply cord not part of the investigation.	N/A
	ii) for which it can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety HAZARD to a PATIENT or OPERATOR; and	--	N/A
	iii) that has a terminal configuration or other constructional feature that will minimize the possibility of its replacement by a detachable POWER SUPPLY CORD which could create a HAZARDOUS SITUATION.	--	N/A
	c) The detachable POWER SUPPLY CORD shall:		N/A
	i) comply with the applicable requirements of CSA C22.2 No. 21; and	Power supply cord not part of the investigation.	N/A
	ii) not be smaller than No. 18 AWG, and the mechanical serviceability is not less than:	--	N/A
	1) Type SJ or equivalent for ME EQUIPMENT that is mobile or exposed to abuse; and	--	N/A
	2) Type SV or equivalent for ME EQUIPMENT that is not exposed to abuse (or Type HPN if required because of temperature). **Note:** See CSA C22.2 No. 49 for requirements for the cord types mentioned in Sub-item 2).	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	d) Installation of POWER SUPPLY CORDS shall meet the requirements of the Canadian Electrical Code, Part I, as applicable.	--	N/A
	[Add the following to this Canadian deviation in the adopted Standard] The POWER SUPPLY CORD used with the ME EQUIPMENT shall be in accordance with the temperature rating to which it has been RATED. **Note 1DV:** Refer to the Canadian Electrical Code, Part I, Tables 11 and 12 for additional information.	--	N/A
	Compliance is checked by inspection and measurement……..:	--	N/A
8.11.3.3	**Cross-sectional area of POWER SUPPLY CORD conductors**		N/A
	[Replace Clause 8.11.3.3 in the adopted Standard, as modified by Amendment 2, with the following] The NOMINAL cross-sectional area of conductors of any POWER SUPPLY CORD of ME EQUIPMENT shall be not less than the requirements of the Canadian Electrical Code, Part I, and CSA C22.2 No. 21. **Note:** Table 17 can be used for European countries or other countries where the nominal cross-sectional area is measured in mm2 (HAR); American Wire Gauge (AWG) is the nominal cross-sectional area used in Canada as per the Canadian Electrical Code, Part I.	Power supply cord not part of the investigation.	N/A
	Compliance is checked by inspection……..:	--	N/A
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		P
	[Replace Clause 8.11.5 in the Canadian deviations in the adopted Standard with the following] Installation of overcurrent protective devices shall be in accordance with the Canadian Electrical Code, Part I	See list of critical components.	P
9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**		N/A
9.7	**Pressure vessels and parts subject to pneumatic and hydraulic pressure**		N/A
9.7.5	**Pressure vessels**		N/A
9.7.5	*[Replace this clause with the following]* Pressure vessels shall comply with the requirements of CSA B51, as applicable	No pressure vessels provided.	N/A
9.7.7	**Pressure-relief device**		N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	[Add the following as the first paragraph of this Clause] A pressure-relief device shall comply, as applicable, with the requirements of ASME PTC 25 or equivalent Canadian requirements.	No pressure-relief devices provided.	N/A
13	**HAZARDOUS SITUATIONS and fault conditions**		N/A
13.2	**SINGLE FAULT CONDITIONS**		N/A
13.2.9	**Interruption and short circuiting of motor capacitors**		N/A
	[Replace the second paragraph of the compliance statement in the adopted Standard with the following] The test with a short-circuited capacitor is not performed if the motor is provided with a capacitor that complies with IEC 60252-1 or is included as part of the evaluation of the motor in accordance with CSA C22.2 No. 100, and the ME EQUIPMENT is not intended for unattended use (including automatic or remote control).	No motors incorporated.	N/A
	For additional test criteria, see Clause 13.2.10.	--	N/A
15	**Construction of ME EQUIPMENT**		P
15.4	**ME EQUIPMENT components and general assembly**		P
15.4.1	**Construction of connectors**		P
	[Add the following item]		N/A
	bA) The point of connection of gas cylinders to ME EQUIPMENT is gas-specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on ME EQUIPMENT shall be:		N/A
	i) gas-specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1380 kPa (200 psi); or	No gas cylinders provided.	N/A
	ii) DISS type complying with CGA V-5 for pressures 1380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA-Z5359	--	N/A
	Note: Users of this Standard should consult the CSA Z305 series of Standards, CAN/CSA-Z9170-1, ISO 9170-2, CAN/CSA-Z10524, and CAN/CSA-Z15002 for further information regarding inlet connectors; ISO 407 for requirements addressing yoke type valve connections; and ISO 32 for colour coding.		--
15.4.8	**Internal wiring of ME EQUIPMENT**		P
	[Replace this Clause with the following]		P
	Internal wiring of ME EQUIPMENT shall be in accordance with the Canadian Electrical Code, Part I.	--	P

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	Except for flexible cord, equipment wire, control circuit insulated conductors, and cable, insulated conductors shall be not smaller than No. 14 AWG when made of copper and not smaller than No. 12 AWG when made of aluminium. **Note 1:** See the Canadian Electrical Code, Part I, Rule 4-002.	--	N/A
	The maximum current that an equipment wire of a given size may carry shall be as specified in Table 12 of the Canadian Electrical Code, Part I. **Note 2:** For additional information refer to the Canadian Electrical Code, Part I, Rule 4-014.	--	N/A
15.5	**MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5**		N/A
15.5.1.3	**Overload test**		N/A
	[Replace the second and third dashed items of Item b) of Clause 15.5.1.3 in the adopted Standard with the following]		N/A
	- Fuses not in accordance with IEC 60127-1 but in accordance with the CSA C22.2 No. 248 series of Standards: 30 min at the current according to the characteristics supplied by the fuse manufacturer, specifically the 30 min clearing-time current. If no 30 min clearing-time current data is available, the test current from Table 32 is used until THERMAL STABILITY is achieved.	IEC approved fuses provided.	N/A
	- Other protective device as per the Canadian Electrical Code, Part I: until THERMAL STABILITY at a current just below that which caused the device to operate in Item a).	--	N/A
	This portion of the overload test is concluded at the specified time or when a second protective device opens.	--	N/A
16	**ME SYSTEMS**		N/A
16.1	**General requirements for the ME SYSTEMS**		N/A
	*[Replace the paragraph that starts with "*An ME SYSTEM shall provide:*" with the following]*		N/A
	An ME SYSTEM shall be provided:		N/A
	- within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this CSA Group Standard; and	Not treated as electrical medical system.	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	- outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA Group, IEC, or ISO safety Standards.	--	N/A
	[Replace the third-last paragraph with the following] Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with the CSA Group, IEC, or ISO safety Standards that are relevant to that equipment.	--	N/A
16.9	**ME SYSTEM connections and wiring**		N/A
16.9.2.1	**MULTIPLE SOCKET-OUTLET**		N/A
	[Replace the first sentence of Item c) of Clause 16.9.2.1 in the adopted Standard with the following]		N/A
	c) The MULTIPLE SOCKET-OUTLET shall comply with CSA C22.2 No. 308 as applicable and the following requirements.	No multiple socket outlets provided.	N/A
	[Add the following note to Item d) in the Canadian deviations in the adopted Standard]		N/A
	d) If the MULTIPLE SOCKET OUTLET is combined with a separating transformer, the following additional requirements shall apply:		N/A
	The separating transformer complies with this Standard.	--	N/A
	Alternatively, the separating transformer may comply with the requirements of CAN/CSA-E61558-2-1, except that the requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 do not apply.	--	N/A
	Note 1: As a separating transformer is not a MAINS SUPPLY TRANSFORMER, it does not require more than BASIC INSULATION. Note 2: Limitation of output power is not explained in CAN/CSA-E61558-2-1 and the RATED output power is defined by the fuse in the installation and by the allowable power supply cable used. However, the characteristics of the separating transformer need to be carefully selected, taking into account the variations in the load current of the ME SYSTEM to ensure that the voltage supplied to the various items of the ME SYSTEM remains within the limits specified for the equipment. Note 3: For additional details refer to the Canadian Electrical Code, Part I, Diagrams 1 and 2.		N/A
	The separating transformer assembly shall be a CLASS I construction.	--	N/A
	The degree of protection against ingress of water as given in IEC 60529 is specified.	--	N/A
	The separating transformer assembly shall be marked according to the requirements of 7.2 and 7.3.	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
	The MULTIPLE SOCKET OUTLET is permanently connected to the separating transformer or,	--	N/A
	The socket-outlet of the separating transformer assembly shall be of a type that cannot accept MAINS PLUGS of any of the kinds identified in Canadian Electrical Code, Part I (see Figure I.1 and Figure I.2 of this Standard)	--	N/A
	[Add the following item] dA) The MULTIPLE SOCKET OUTLET complies with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and Item d) of this Standard, as applicable.	--	N/A

ATTACHMENT TO TEST REPORT

IEC 60601-1

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
JAPAN NATIONAL DIFFERENCES
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Differences according to.....:	National standard JIS T 0601-1:2023
TRF template used .....:	IECEE OD-2020-F3:2022, Ed. 1.2
Attachment Form No.....:	JP_ND_IEC60601_1U
Attachment Originator .....:	TÜV Rheinland Japan Ltd.
Master Attachment.....:	Dated 2023-08-22

Copyright © 2023 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.

	National Differences		**N/A**
1.3	In NOTE 3, add the following: In Japan, to check the corresponding Japanese Industrial Standard(s) is required.	--	N/A
1.4	At the end of NOTE, add the following: In Japan, to check the corresponding Japanese Industrial Standard(s) is required.	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
2	Replace the listed standards with the followings: JIS B 7761-3, Hand-transmitted vibration - Part 3: General requirements for measurement and evaluation NOTE: ISO 5349-1, Mechanical vibration - Measurement and evaluation of human exposure to hand-transmitted vibration - Part 1: General requirements (IDT) JIS B 9718:2013, Safety of machinery - Safety distances to prevent hazard zone being reached by upper and lower limbs NOTE: ISO 13857:2008, Safety of machinery -- Safety distances to prevent hazard zones being reached by upper and lower limbs (IDT) JIS C 0445, Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system NOTE: IEC 60445, Basic and safety principles for man-machine interface, marking and identification - Identification of equipment terminals, conductor terminations and conductors (IDT) JIS C 0447, Man-machine interface (MMI) - Actuating principles NOTE: IEC 60447, Basic and safety principles for man-machine interface, marking and identification - Actuating principles (IDT) JIS C 0920:2003, Degrees of protection provided by enclosures (IP Code) NOTE 1: IEC 60529:2001, Degrees of protection provided by enclosures (IP Code) (IDT) NOTE 2: According to IEC60601-1:2005, IEC 60529:1989 and Amendment 1:1999 are listed as Normative references, however, the latest edition is edition 2.1 issued in 2001 and the corresponding Japanese Industrial standard was listed as normative reference. JIS C 1509-1, Electroacoustitcs - Sound level meters - Part 1: Specifications NOTE: IEC 61672-1, Electroacoustics - Sound level meters - Part 1: Specifications (IDT) JIS C 1509-2, Electroacoustics - Sound level meters - Part 2: Pattern evaluation tests NOTE: IEC 61672-2, Electroacoustics - Sound level meters - Part 2: Pattern evaluation tests (IDT)	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
2	JIS C 2134, Method for the determination of the proof and the comparative tracking indices of solid insulating materials NOTE: IEC 60112, Method for the determination of the proof and the comparative tracking indices of solid insulating materials (IDT) JIS C 3301:2000, Rubber insulated flexible cords NOTE: IEC 60245-4:1994, Rubber insulated cables - Rated voltages up to and including 450/750 V - Part 4: Cords and flexible cables, Amendment 1:1997 (NEQ) JIS C 3306:2000, Polyvinyl chloride insulated flexible cords NOTE: IEC 60227-5:1997, Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V - Part 5: Flexible cables (cords) (NEQ) JIS C 4003, Electrical insulation - Thermal evaluation and designation NOTE: IEC 60085, Electrical insulation - Thermal evaluation and designation (MOD) JIS C 5101-14:2009, Fixed capacitors for use in electronic equipment - Part 14: Sectional specification - Fixed capacitors for electromagnetic interference suppression and connection to the supply mains NOTE: IEC 60384-14:2005, Fixed capacitors for use in electronic equipment - Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains (IDT) JIS C 6065:2013, Audio, video and similar electronic apparatus - Safety requirements NOTE: IEC 60065:2001, Audio, video and similar electronic apparatus - Safety requirements, Amendment 1:2005 and Amendment 2:2010 (MOD) JIS C 6802:2011, Safety of laser products NOTE: IEC 60825-1:2007, Safety of laser products - Part 1: Equipment classification and requirements (IDT) JIS C 6950-1:2012, Information technology equipment - Safety - Part 1: General requirements NOTE: IEC60950-1:2005, Information technology equipment - Safety - Part 1: General requirements (MOD) JIS C 6965, Mechanical safety of cathode ray tubes NOTE: IEC 61965, Mechanical safety of cathode ray tubes (IDT)	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
2	JIS C 8282-1, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements NOTE: IEC 60884-1, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements (MOD) JIS C 8303, Plugs and receptacles for domestic and similar general use NOTE: No corresponding International standard exists. This standard has been listed as normative reference corresponding to IEC/TR 60083, Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC, which has been listed in IEC 60601-1:2005. Refer to JIS T 1021, too. JIS C 60068-2-2:2010, Environmental testing - Part 2-2: Tests - Test B: Dry heat NOTE: IEC 60068-2-2:2007, Environmental testing - Part 2-2: Tests - Tests B: Dry heat (IDT) JIS C 60079-0, Explosive atmospheres - Part 0: Equipment - General requirements NOTE: IEC 60079-0, Explosive atmospheres - Part 0: Equipment - General requirements (IDT) JIS C 60079-2, Electrical apparatus for explosive gas atmospheres - Part 2: Pressurized enclosure "p" NOTE: IEC 60079-2, Explosive atmospheres - Part 2: Equipment protection by pressurized enclosures “p” (IDT) JIS C 60079-6, Electrical apparatus for explosive gas atmospheres - Part 6: Oil immersion "o" NOTE: IEC 60079-6, Explosive atmospheres - Part 6: Equipment protection by oil immersion “o” (IDT) JIS C 60364-4-41, Low-voltage electrical installations - Part 4-41: Protection for safety - Protection against electric shock NOTE: IEC 60364-4-41, Low- voltage electrical installations - Part 4-41: Protection for safety - Protection against electric shock (IDT) JIS C 60664-1:2009, Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests NOTE: IEC 60664-1:2007, Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests (IDT)	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
2	JIS C 60695-11-10, Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods NOTE: IEC 60695-11-10, Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods (IDT) JIS T 0601-1-3, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment NOTE: IEC60601-1-3, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment (IDT) JIS T 0801-1:2010, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices NOTE: ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT) JIS T 0806-1:2010, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices NOTE: ISO 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT) JIS T 0816-1:2010, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices NOTE: ISO 17665-1:2006, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (IDT) JIS T 2304:2012, Medical device software - Software life cycle processes IEC62304:2006, Medical device software - Software life cycle processes (IDT) JIS T 14971:2012, Medical devices - Application of risk management to medical devices NOTE: ISO 14971:2007, Medical devices - Application of risk management to medical devices (IDT)	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
2	JIS T 60601-1-8, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems NOTE: IEC60601-1-8, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IDT) JIS Z 8000 (all parts), Quantities and units NOTE: ISO 80000-1, Quantities and units - Part 1: General JIS Z 8736-1, Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1: Measurement at discrete points NOTE: ISO 9614-1, Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1: Measurement at discrete points (IDT) JIS Z 9101:2005, Safety colours and safety signs - Design principles for safety signs in workplaces and public areas NOTE: ISO 3864-1:2002, Graphical symbols - Safety colours and safety signs - Part 1: Design principles for safety signs in workplaces and public areas (IDT) ISO 780, Packaging - Distribution packaging - Graphical symbols for handling and storage of packages NOTE: JIS Z 0150 Packaging - Distribution packaging - Graphical symbols for handling and storage of packages (MOD) ISO 1853, Conducting and dissipative rubbers, vulcanized or thermoplastic - Measurement of resistivity NOTE: JIS K 6271-2 Rubber, vulcanized or thermoplastic - Determination of resistivity – Part 2: Parallel terminal electrode system (MOD) ISO 2878, Rubber, vulcanized or thermoplastic - Antistatic and conductive products - Determination of electrical resistance ISO 2882:1979, Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
2	ISO 3746, Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane ISO 7000-DB:2004, Graphical symbols for use on equipment - Index and synopsis NOTE: “DB” indicated ISO-IEC jointed online database. ISO 7010:2011, Graphical symbols - Safety colours and safety signs - Registered safety signs ISO 10993 (all parts), Biological evaluation of medical devices NOTE: JIS T 0993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (MOD). However, other Parts than Part 1 and Part 7 have still not been published as JIS. ISO 15223-1:2012 , Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements ISO 23529, Rubber -- General procedures for preparing and conditioning test pieces for physical test methods NOTE: JIS K 6250, Rubber -- General procedures for preparing and conditioning test pieces for physical test methods (MOD) IEC 60079-5, Explosive atmospheres — Part 5: Equipment protection by powder filling “q” IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries NOTE: JIS C 8513 Safety of primary lithium batteries (MOD) IEC 60127-1, Miniature fuses - Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links NOTE: JIS C 6575-1 Miniature fuses - Part 1: Definitions of miniature fuses and general requirements for miniature fuse-links (MOD)	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
2	IEC 60227-1:2007, Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements NOTE: JIS C 3662-1:2009 Polyvinyl chloride insulated cables of rated voltages up to and including 450/750V - Part 1: General requirements (MOD) IEC 60245-1:2003, Rubber insulated cables - Rated voltages up to and including 450/750 V - Part 1: General requirements and Amendment 1:2007 NOTE: The corresponding JIS standard: None JIS C 3663-1:2010 Rubber insulated cables - Rated voltages up to and including 450/750 V - Part 1: General requirements (MOD) corresponds to IEC 60245-1:2008. IEC 60252-1, AC motor capacitors - Part 1: General - Performance, testing and rating - Safety requirements - Guidance for installation and operation IEC 60320-1, Appliance couplers for household and similar general purposes - Part 1: General requirements NOTE: JIS C 8283-1 Appliance couplers for household and similar general purposes - Part 1: General requirements (MOD) IEC 60335-1:2010, Household and similar electrical appliances - Safety - Part 1: General requirements NOTE: The corresponding JIS standard: None JIS C 9335-1:2003 Household and similar electrical appliances - Safety - Part 1 : General requirements (MOD) corresponds to IEC 60335-1:2001. IEC 60417, Graphical symbols for use on equipment IEC 60601-1-2:2001, Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests NOTE 1: The current “JIS T 0601-1-2:2012 Medical electrical equipment - Part 1-2: General requirements for safety - Electromagnetic compatibility - Requirements and tests” corresponds to IEC 60601-1-2:2001 and Amendment 1:2004. NOTE 2: Currently, IEC 60601-1-2 Ed 2.1:2004 or IEC 60601-1-2 Ed 3:2007 is used in other countries.	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
2	IEC 60601-1-6, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability NOTE: As the corresponding international standard, IEC 62336 is applicable. IEC 60730-1:2010, Automatic electrical controls for household and similar use - Part 1: General requirements NOTE: The corresponding JIS standard: None JIS C 9730-1:2010 Automatic electrical controls for household and similar use - Part 1:General requirements (MOD) corresponds to IEC 60730-1:1999, Amendment 1: 2003 and Amendment 2:2007 IEC 60851-3:2009, Winding wires - Test methods - Part 3: Mechanical properties NOTE: JIS C 3216-3:2011, Winding wires - Test methods - Part 3: Mechanical properties (MOD) IEC 60851-5:2008, Winding wires - Test methods - Part 5: Electrical properties NOTE: JIS C 3216-5:2011, Winding wires - Test methods - Part 5: Electrical properties (MOD) IEC 60851-6:1996, Methods of test for winding wires - Part 6: Thermal properties and Amendment 1:1997 IEC 61058-1:2000, Switches for appliances - Part 1: General requirements, Amendment 1:2001 and Amendment 1:2007 NOTE: The corresponding JIS standard: None JIS C 4526-1:2013 Switches for appliances - Part 1: General requirements (MOD) corresponds to IEC 61058-1:2008 IEC 61558-2-1, Safety of power transformers, power supplies, reactors and similar products - Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications NOTE: JIS C 61558-2-1 Safety of power transformers, power supplies, reactors and similar products - Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications (MOD)	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
2	IEC 62133, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications. NOTE: JIS C 8712:2015 Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications (MOD) was created changing the technical contents of IEC 62133:2012. IEC 62366:2014, Medical devices - Application of usability engineering to medical devices	--	N/A
3.9	Add NOTE as follows: NOTE 2 IEV stands for International Electrotechnical Vocabulary	--	N/A
3.50	Replace NOTE 2 as follows: NOTE 2 See also JIS C 8303 and IEC 60309-1 and JIS T 1021.	--	P
3.61	Add NOTE as follows: NOTE In this standard, MECHANICAL HAZARD is suitably understandable by replacing mechanical HAZARD with mechanical HAZARDOUS SITUATION, HARM or unacceptable RISK.	--	N/A
3.70	Replace the existing text with: condition in which all means provided for protection against HAZARDOUS SITUATIONS or HARM are intact	--	N/A
4.10.1	In the existing text, replace “a separate power supply” with “a separate power supply (e.g. a power supply of other equipment)”.	No separate power supply used.	N/A
7.3.3	Replace the third paragraph with: Where lithium batteries or fuel cells are incorporated and where incorrect replacement would result in an unacceptable RISK, a warning indicating that replacement by inadequately trained personnel could result in a HAZARDOUS SITUATION (such as excessive temperatures, fire or explosion) shall be given in addition to the identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS.	No battery provided.	N/A
7.3.4	Add the following NOTE NOTE Corresponding Japanese Industrial Standard for IEC 60127-1: JIS C 6575-1:2009	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
7.4.3	Replace the existing first paragraph with the following: Numeric indications of parameters on ME EQUIPMENT shall be expressed in SI units according to JIS Z 8000 (all parts) except the base quantities listed in Table 1 may be expressed in the indicated units, which are used in conjunction with the SI units system or as the approved combination. Replace the title of Table 1 with the following: Units which are used in conjunction with the SI units system or as the approved combination Replace “a” of Table 1 with the following note: Note: For consistency, in international standards only the symbol “l” is used for litre, although the symbol “L” is also given in JIS Z 8000 (all parts).	--	N/A
7.7.4	Under the existing text, add the following: If polyvinyl chloride insulated flexible cord of JIS C 3306 or rubber insulated flexible cord of JIS C 3301 is used, the conductor may be coloured "white".	Approved appliance inlet used for connection to the mains.	N/A
7.7.5	Under the existing text, add the following: If polyvinyl chloride insulated flexible cord of JIS C 3306 or rubber insulated flexible cord of JIS C 3301 is used, conductors may be of the colour specified in the these standards.	Power supply cord is not provided with the equipment.	N/A
7.9.3.2	Replace the fourth dash with: – where replacement of a component could result in an unacceptable RISK, appropriate warnings that identify the nature of the HAZARDOUS SITUATION and, if the MANUFACTURER specifies the component as replaceable by SERVICE PERSONNEL, all information necessary to safely replace the component.	Replacement of a component could not result in an unacceptable risk. No warning required.	N/A
8.8.2	For a), add the following NOTE: NOTE – Generally, “distance through insulation” means the thickness of insulation. However, for example, if a transformer installed into a metal case is insulated by filler, the thickness is not always uniformly. Therefore, such expression was used.	--	N/A
8.8.3	Between the third dash and the paragraph of “Initially, not more than --”, add the following new paragraph. During the above-mentioned tests, the state of the power switch shall be kept closed.	--	N/A
8.9.1.2	At the end of the title of this sub-clause, add “(Apply to MOOP)”.	Distances were not evaluated according to IEC 60950-1.	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
8.9.1.3	At the end of the title of this sub-clause, add "(Apply to MOOP)".	No such insulation material.	N/A
8.9.1.4	At the end of the title of this sub-clause, add "(Apply to MOOP)".	--	N/A
8.9.1.5	At the end of the title of this sub-clause, add "(Apply to MOOP and MOPP)".	--	N/A
8.9.1.6	At the end of the title of this sub-clause, add "(Apply to MOOP and MOPP)".	--	N/A
8.9.1.7	At the end of the title of this sub-clause, add "(Apply to MOOP)".	--	N/A
8.9.1.8	At the end of the title of this sub-clause, add "(Apply to MOOP)".	--	N/A
8.9.1.9	At the end of the title of this sub-clause, add "(Apply to MOOP)".	--	N/A
8.9.1.10	At the end of the title of this sub-clause, add "(Apply to MOOP)".	--	N/A
8.9.1.11	At the end of the title of this sub-clause, add "(Apply to MOOP)".	--	N/A
8.9.1.12	At the end of the title of this sub-clause, add "(Apply to MOOP)".	--	N/A
8.9.1.13	At the end of the title of this sub-clause, add "(Apply to MOOP)".	Working voltage did not exceed 1800 V peak.	N/A
8.9.1.14	At the end of the title of this sub-clause, add "(Apply to MOOP)".	--	N/A
8.11.3.2	Add the following between the first paragraph and the second paragraph: And, rubber insulated flexible cords of JIS C 3301, polyvinyl chloride insulated flexible cords of JIS C 3306 or cords of which the robustness is equal to or more than those are usable. Add the following between the second paragraph and the last paragraph: And, in the case of cords of JIS C 3306, shall not use; for polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 60 °C, and; for grade heat-resistant polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 75 °C.	Power supply cord not part of the investigation.	N/A
9.2.2.2	In the bottom column of Table 20, replace the existing text with the following: [a] The values in this table are taken from JIS B 9718:2013.	No trapping zones.	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
9.2.4	In e), replace a further “MECHANICAL HAZARD” and the original “HAZARD” with a further “HAZARDOUS SITUATION” and the original “HAZARDOUS SITUATION”, respectively.	Equipment has no emergency stopping devices.	N/A
9.3	Replace the NOTE 2: A sharp edge MECHANICAL HAZARD could cut wire insulation which could lead to an electrical HAZARDOUS SITUATION. This requirement is intended to cover all these HAZARDS.	No sharp edges, no sharp corners, no sharp surfaces.	P
9.8.3.3	Figure 33: Replace the fourth sentence of the existing NOTE with the following and change “NOTE” to “NOTE 1”: The resiliency or spring factor of the foam (ILD or IFD ratings) has not been specified. Add the following NOTE: NOTE 2: NOTE 1 above stated that in the corresponding international standards, "when dropping the weight, the characteristics of the foam are probably not important, therefore The resiliency or spring factor of the foam (ILD or IFD ratings) is not specified." However, This expression is confusing, and it was modified.	Not intended to support loads.	N/A
10.1.1	Add in NOTE 1 “Current irradiation dose unit is not R unit, but Gy unit (air kerma), which corresponds to 1 mR/h ≈ 10 μGy/h.” Replace (0,1 mR/h) with (0.1 mR/h ≈ 1 μGy/h) in NOTE 2.”	Equipment does not produce X-radiations.	N/A
10.5	Replace “other than that produced by lasers and light emitting diodes” with “other than that produced by lasers”	--	N/A
10.6	Replace “other than that produced by lasers and light emitting diodes” with “other than that produced by lasers”	--	N/A
10.7	Replace “other than that produced by lasers and light emitting diodes” with “other than that produced by lasers”	--	N/A
11.1.1	To the existing text of a in the Table 22, add the following: (For example, the maximum temperature limit of a transformer with three insulating materials of Class A, Class B and Class E shall be the lowest limit 105 °C of Class A.)	Transformer incorporated in separately approved power supply unit.	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
13.2.10	In Table 26, replace the existing NOTE with the following: NOTE The temperature limits in this table were derived from Table B.1 of JIS C 6950-1:2012 (in the corresponding international standard, IEC 61010-1:2001 [22]).	No motor provided.	N/A
16.1	Replace the last two paragraphs with the following: Otherwise, non-ME EQUIPMENT shall be those which are in compliance with relevant JIS standards or the Technical Requirements of the Electrical Appliance and Material Safety Act or which ensure safety equivalent to the said standards/technical requirements. Equipment in which protection against electric shock relies only on BASIC INSULATION shall not be used in an ME SYSTEM. For the measures for ensuring safety, e.g. the case combined with a separating transformer with DOUBLE INSULATION or RAINFORCED INSULATION, equipment only with BASIC INSULATION may be used. *Compliance is checked by inspection of appropriate documents or certificates.*	Not treated as electrical medical system.	N/A
16.6.4.1	In NOTE, replace “no possibility of any HAZARD” with “no possibility of any HAZARDOUS SITUATION”.	--	N/A
16.9.2.1	In the text of c), replace “IEC 60884-1” with “IEC 60884-1 or JIS C 8282-1”.	--	N/A

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
Annex I	In I.1.3, replace the first dash with the following: - PATIENTS should only be connected to APPLIED PARTS of ME EQUIPMENT complying with this standard. Other equipment should comply with relevant IEC or ISO standards or comply with relevant JIS safety standards or the Technical Requirements of the Electrical Appliance and Material Safety Act, or ensure safety equivalent to the said standards/technical requirements. Replace the existing NOTE 2 with the following: NOTE 2 IEC 60601: MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601 (all parts) or JIS T 0601 (all parts). Replace the existing NOTE 3 with the following: NOTE 3 IEC xxxxx: Non-medical equipment in compliance with relevant IEC safety standards. Include non-medical equipment in compliance with relevant JIS safety standards or the Technical Requirements of the Electrical Appliance and Material Safety Act, or non-medical equipment ensuring safety equivalent to the said standards/technical requirements.	--	P
Annex L	In the first paragraph, replace “wound components” with “wound components (e.g. transformers, motors, etc.)”	--	N/A

ATTACHMENT TO TEST REPORT

IEC 60601-1

REPUBLIC OF KOREA NATIONAL DIFFERENCES

(Medical electrical equipment - Part 1 : General requirements for basic safety and essential performance)

Differences according to .....: Notification of MFDS No. 2020-12, Annex 1

Attachment Form No.....: KR_ND_ IEC60601_1S

Attachment Originator .....: KTR

Master Attachment.....: 2020-12-17

Copyright © 2020 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.

	Special national conditions (if any)		—
Voltage	National supply voltages are 110, 220 V and 380 V.	The rated voltage range is covering Korea mains voltage.	P
Frequency	Only appliances having supply frequency of 60 Hz or a frequency range including 60 Hz are accepted.	The rated frequency is covering 60 Hz.	P

National Differences to IEC 60601-1:2005 + A1:2012 + A2:2020			
Clause	Requirement + Test	Result - Remark	Verdict
Instruction	Instruction manuals and appliance markings related safety, including nameplate shall be in Korean or graphical symbols in accordance with IEC Publication 417.	Must be verified during national approval.	N/A
Plug	Plugs for connection of the equipment to the supply mains shall comply with the Korean Standard (KSC 8305 and 8300)	Must be verified during national approval.	N/A

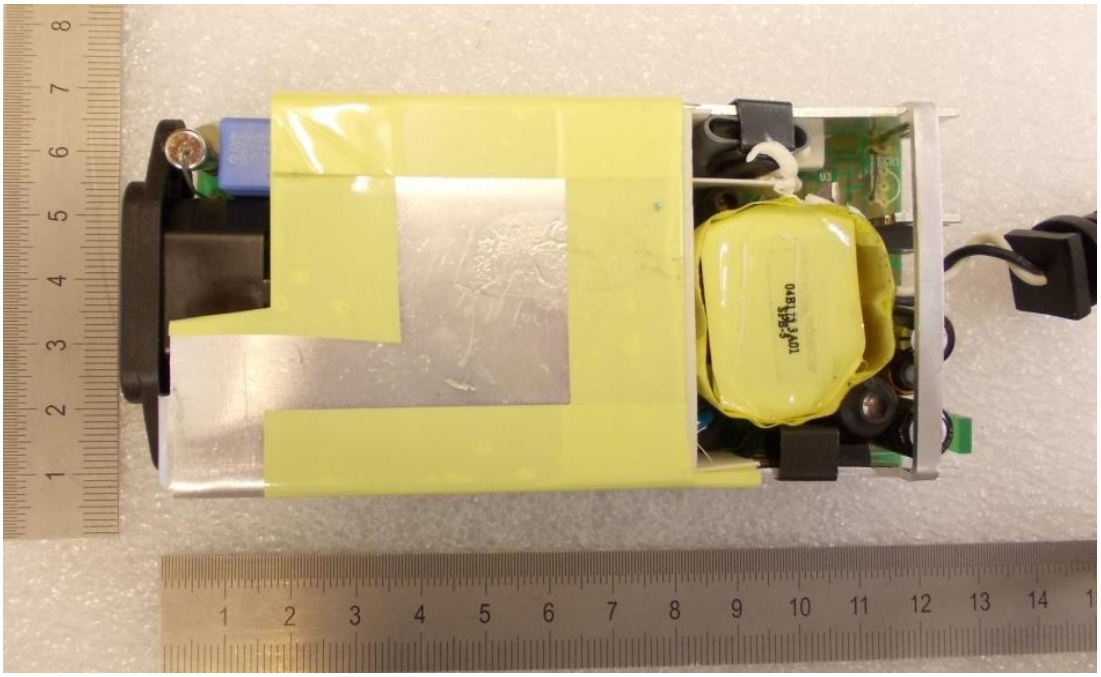
Enclosure No. 2

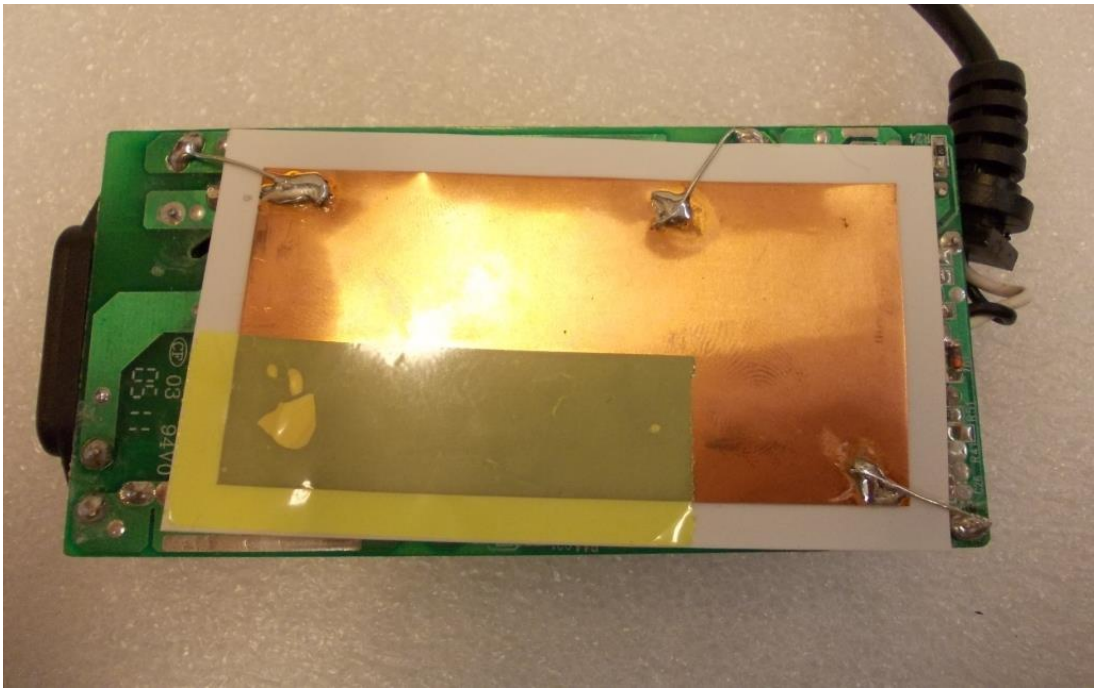
Photo Documentation

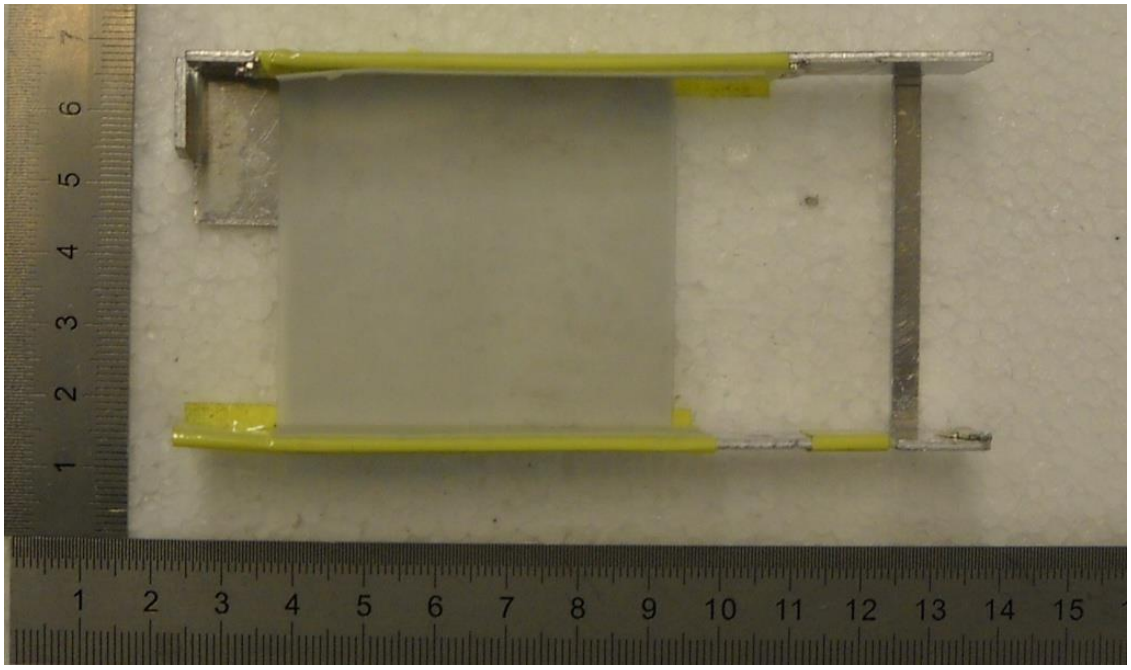
(5 pages including this cover page)

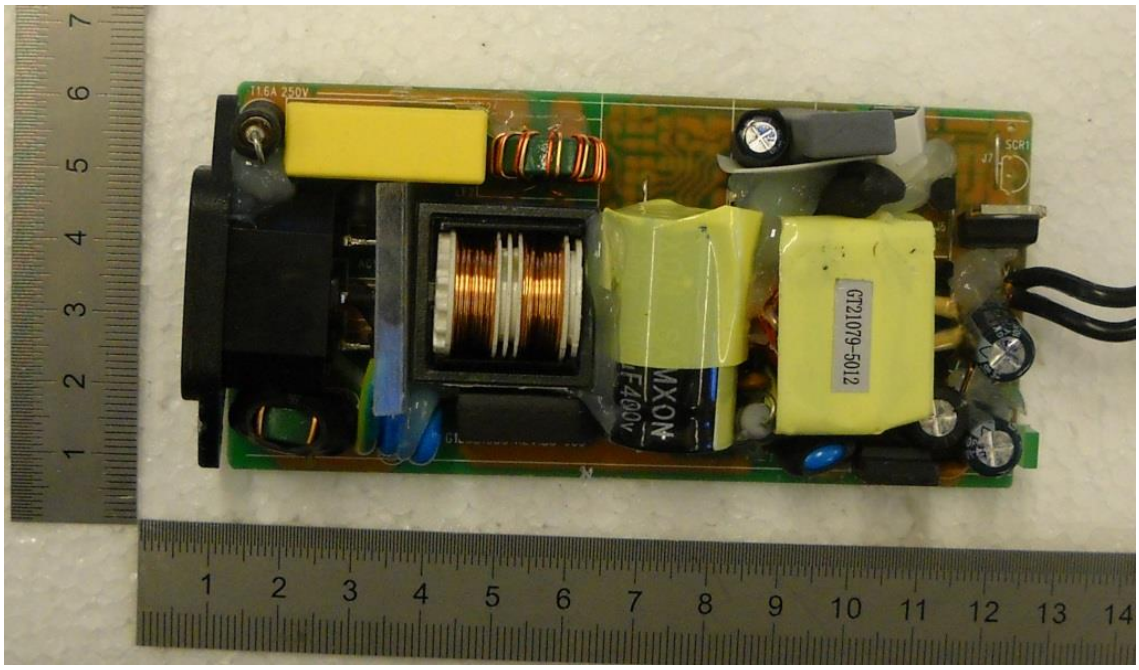


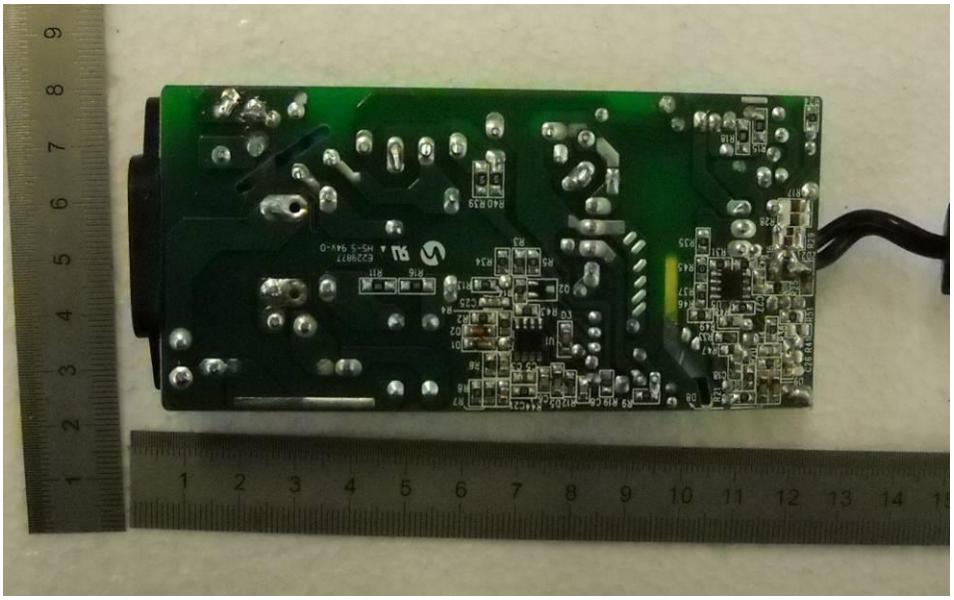

1 2 3 4 5 6 7 8 9 10 11 12 13







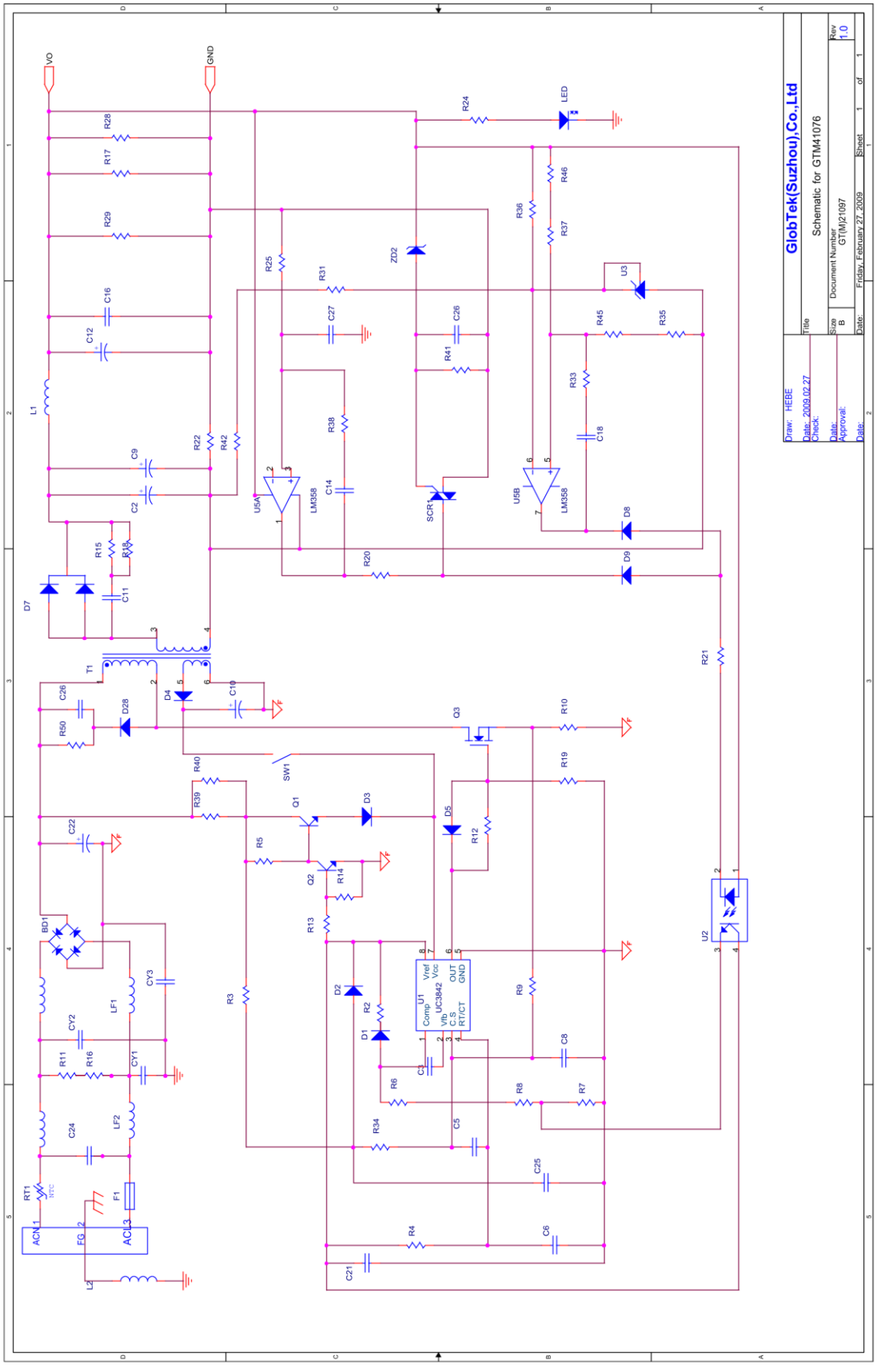

MXON
F400V
GT21079-6012

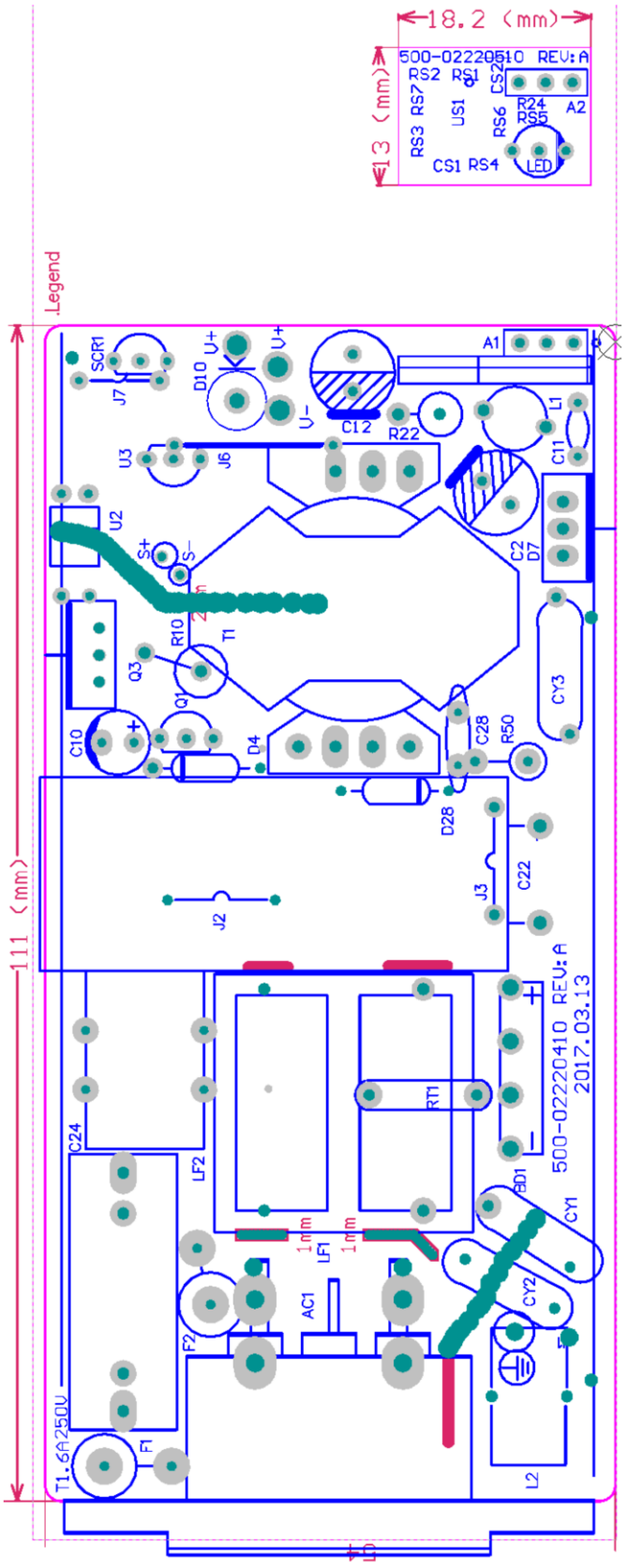


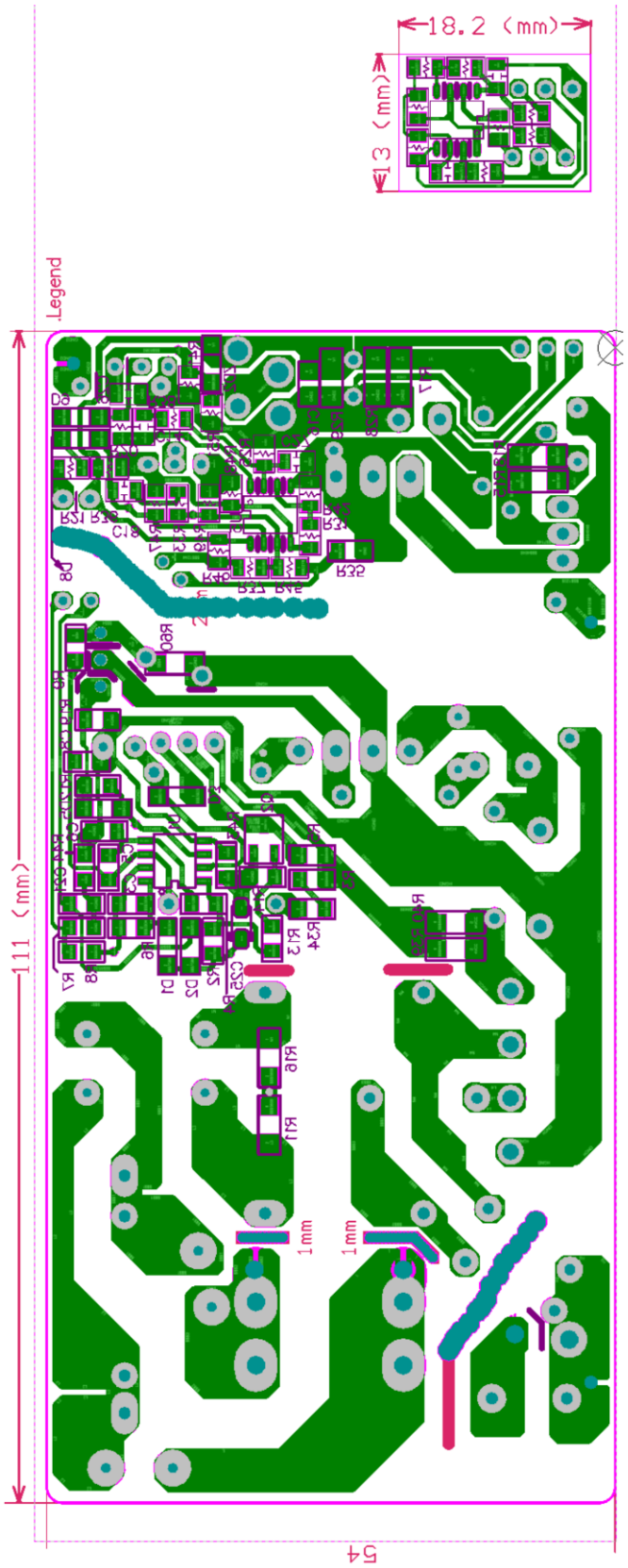
Enclosure No. 3

PCB layouts, electrical schemes, transformer drawings

(92 pages including this cover page)


GlobTeK(Suzhou),Co.,Ltd
Schematic for GTM41076
Document Number
GTM21097
Rev
1.0
Sheet
1
of
1
Size
B
Date:
Friday, February 27, 2009
Title
Draw: HEBE
Date: 2009.02.27
Check:
Date:
Approval:
Date:
VO
GND
LED
U1
UC3842
Vref
Vcc
OUT
GND
Comp
VFB
C.S
RT/CT
U2
U3
U5A
U5B
LM358
SCR
Q1
Q2
Q3
BD1
T1
L1
L2
LF1
LF2
SW1
F1
RT1
ACN
FG
ACL
D1
D2
D3
D4
D5
D7
D8
D9
D28
ZD2


18.2 (mm)
13 (mm)
500-02220510 REV:A
111 (mm)
Legend
500-02220410 REV:A
2017.03.13
T1.6A250V
1mm
1mm


18.2 (mm)
13 (mm)
Legend
111 (mm)
54
1mm
1mm

确 认 书
APPROVAL SHEET

客 户
CUSTOMER : GlobTek

型 号
MODEL : GTM21079

名 称
ITEM : CHOKE

部 品 号
PART NO : 321-02161502(R)

中通部品号
ZT SPEC NO :

承制方:
MANUFACTURE:

使用方:
USER:

拟 制 DESIGN	审 核 CHECK	批 准 APPRO.

主 管 CHIEF	核 准 CONFIRM

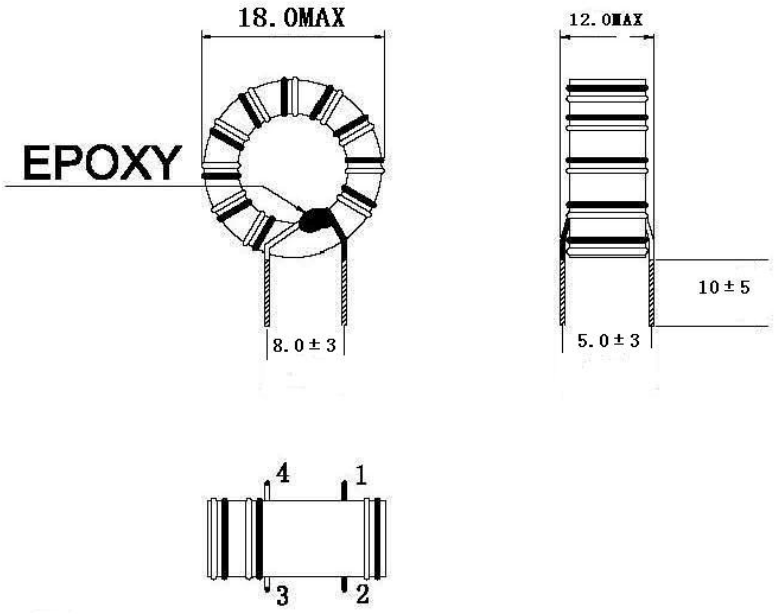
*请确认后及时回签,自接定单后,本确认书将自动生效

*Please sign and return back after you approval.The specification will come into force automatically when is received the purchase.

无 锡 中 通 电 子 有 限 公 司
WUXI ZHONGTONG ELECTRONICS CO.,LTD

中国江苏省无锡市东港镇工业园区（A 区）
Industry Zone(A Zone) Donggang Town Wuxi City Jiangsu Province China
电话(Tel): (0510) 88351365
传真(Fax): (0510) 88351363
邮编(Post code): 214199

1. DIMENSION&SCHEMATIC(UNIT : mm)



WUXI ZHONGTONG ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	CM CHOKE		
			ZT SPEC NO	DATE	2009.03.06
				PAGE	2/5

2. ELECTRICAL CHARACTERISTICS

NO	ITEM	TERMINAL	SPECIFICATION	REMARKS
3-1	CHOKE	1-2	150uH Min	GainKaiTa3250 @1KHz,0.25Vrms
		4-3		

3. WINDING SPEC

NO	TERMINAL		TURNS	WIRE	STRANDS	INSULATION MATERIAL	INSULATION LAYERS
N1	1	2	14	2UEW Φ 0.50	1	n/a	n/a
N2	4	3					

4. MATERIAL LIST.

NO.	NAME	SPEC	MANUFACTURER	NOTE
1.	CORE	T14*9*5C M5K	CHANGSHU TIANMING	
2.	WIRE	2UEW	WUXI JUFENG	E206882
3.	EPOXY		WUXI CHANGFENG	

*DATA SHEET

TESTING INST	GainKaiTa3250		TEMP/HUMIDITY	25℃/60℃		
QUANTITY	5EA		DATA OF MEAS	2009.03.06		
ITEM		INDUCTANCE				
PIN NO	S.T.D	#1	#2	#3	#4	#5
LS-F	150uH min.	397.4	348.8	371.4	309.1	442.2

WUXI ZHONGTONG ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	CM CHOKE		
			ZT SPEC NO	DATE	2009.03.06
				PAGE	3/5

***UL CARD**

1)COIL

WUXI JUFENG COMPOUND LINE CO LTD E206882

MEI CUN TOWN

XISHAN, JIANGSU 214112 CHINA

Mtl Dsg	Coat Type		ANSI Type	Temp Class
	BC	OC		
xEIW,	Polyester-	?/TD>	MW30#	180
QZY-x/180	imide			
xEIW,	Polyester-	?/TD>	MW74	200
QZY-x/200	imide			
xUEWH*,	Poly-	?/TD>	MW82	180
QA-x/180*	urethane			
xUEW*,	Poly-	?/TD>	MW75	130
QA-x/130*	urethane			
xUEWF*,	Poly-	?/TD>	MW79#	155
QA-x/155*	urethane			
xPEW,	Polyester	?/TD>	MW5	155
QZ(G)-x/155				
xUEWNF*,	Poly-	Polyamide	MW80	155
QAN-x/155*	urethane			
xUEWN*,	Poly-	Polyamide	MW28#	130
QAN-x/130*	urethane			
xUEWNF*A (Aluminum),	Poly-	Polyamide	@	155
QAN-x/155* A	urethane			
xEI/AIW,	Polyester-	Polyamide-	MW35#,	200
Q(ZY/XY)-x/200	amideimide	imide	MW73#	
xEI/AIWC,	Polyester-	Polyamide-	@	220
Q(ZY/XY)-x/220	amideimide	imide		
xEI/AIWA (Aluminum),	Polyester-	Polyamide-	@	200

WUXI ZHONGTONG ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	CM CHOKE		
			ZT SPEC NO	DATE	2009.03.06
				PAGE	4/5

2) VARNISH

WU JIANG TAIHU INSULATING MATERIAL CO LTD E228349

BEI SHI

WUJIANG, JIANGSU 215214 CHINA

Varnish Dsg	ANSI Magnet Wire Type	Varnish Thermal Class C		
		TP	HC	CE
ET-90(a)	MW35	180	200	—
	MW28	130	—	—
	MW24	155	180	—
	MW76	180	200	—
T-4260(a)	MW 28	130	—	—

(a) - May be followed by an alphanumeric suffix indicating viscosity.

Marking: Company name and varnish designation on shipping container.

WUXI ZHONGTONG ELECTRONICS CO.,LTD.			TITLE	UNIT	mm
DESIGN	CHECK	APPRO.	CM CHOKE		
			ZT SPEC NO	DATE	2009.03.06
				PAGE	5/5

GlobTek® (Suzhou) Co., Ltd

车载、特种电源

QC PASS

零件承认书
Material Approval

Manufacture	
供应商： Supplier	山东宝岩电气有限公司 SHAN DONG BOAM CO.,LTD
供应商料号： Supplier P/N	703-02081204
名称： Part Name	
品名/规格： SPEC	GT(M)21097
GlobTek料号： GlobTek P/N	703-02081204
Edition No: 版本	1

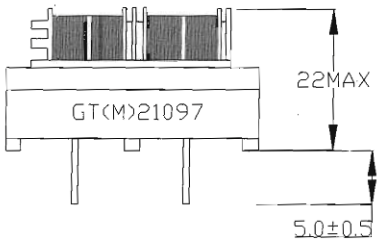
作成： Made by	确认： Check	承认： Approval
PS承认章： Approval Stamp	RD承认章： Approval Stamp	QC承认章： Approval Stamp

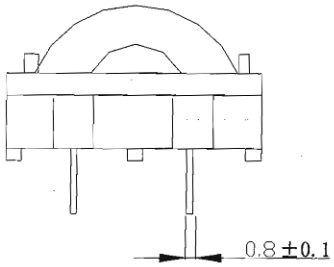
GLOBTEK SUZHOU 2009.7.30 受控文件 发行章

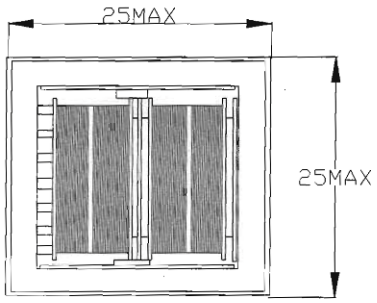
SPECIFICATION

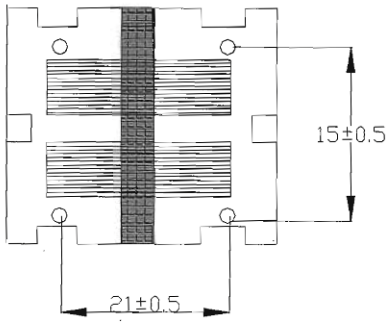
CUSTOMER	GLOBTEK(SUZHOU)	PART NAME	S/W TRANSFORMER
MODEL NO.	SQ2424	PART NO.	703-02081204

1.DIMENSION(mm)

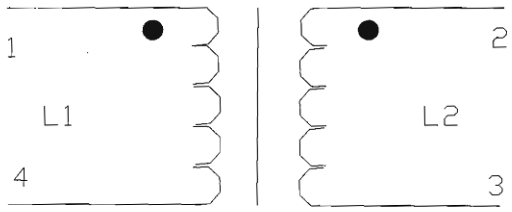








2. EQUIVALENT CIRCUIT (BOTTOM VIEW)





SPEC NO.	KF-09072101-A	DATE	2009.07.21	SHEET NO.	1	
NO.	DATE	REVISION	CHECKED	DESIGN	CHECK	APPROVAL
				于海霞	潘秀丽	孙恩国

SHANDONG BOAM ELECTRIC CO.,LTD

SPECIFICATION

CUSTOMER	GLOBTEK(SUZHOU)	PART NAME	S/W TRANSFORMER
MODEL NO.	SQ2424	PART NO.	703-02081204

3 ELECTRICAL CHARACTERISTICS

NO.	ITEM	TERMINAL	SPECIFICATION	REMARKS
1	INDUCTANCE	1-4	12mH MIN	HIOKI 3531 Z HITESTER (1KHz,1V)
		2-3		

4 WINDING SPEC

NO	S-F	WIRE	TURNS
1	1-4	2UEW 0.60	52
2	2-3	2UEW 0.60	52

5. LIST OF MATERIALS

NO.	COMPONENT	MATERIALS	MANUFACTURES	REMARKS
1	CORE	SQ2424,	FERRITE CORE	
2	BOBBIN	SQ2424,2F	CHANG CHUN PLASTICS CO LTD or equiv	E59481(S)
3	WIRE	2UEW Φ0.60	DONG YANG ELECTRONIC ., LTD	E102761(S)

SPEC NO.	KF-09072101-A	DATE	2009.07.21	SHEET NO.	2	
NO.	DATE	REVISION	CHECKED	DESIGN	CHECK	APPROVAL
				于海霞	潘秀丽	孙恩国

SHANDONG BOAM ELECTRIC CO.,LCD

FROM : FAX NO. : 657 Sep. 28 2004 08:27 P1

呈威電子廠

Sunny

地址:東莞市橫瀝鎮新城工業區 TEL: (0769)3377756-9 3377358

零件承認書

SPECIFCATION FOR APPROVAL

品名 Part Name	变压器		
機種名稱 Model Name	6TS109		
廠商 Manufacture	曜威		
料品規格 Material Spec	RM-10		
承認代號 Part No	G104B1671B01X		
日期 Date	2005.04.03	版本 Rev	V.1

No. : CR11203060015

簽名	品管 QC	批准 APPROVE	覆核 REVIEW	審核 VIEW	工程印章 ISSUED STAMP
日期	04/3	2005.P.5	9/3	9/3	GP

FROM : FAX NO. : 657 Sep. 28 2004 08:28 P2

承認書工程測試基本資料

料號: G104B167IB01* 型號: AM-10 X'FMR廠商: 日耀威电子

机种: SYS1097-4812 測試時間: 9/28 負責人: 谭才富

一.外觀及尺寸測試:

1.長: 22.29mm 寬: 29.7 高: 19.37 其他:

2.外觀:

二:机械性能:

1.

2.

3.

三.電氣測試:

1. 感量. 425.9uH 漏感 10.58uH

2. 高压测试 P-S. 4.3KVAC. 10mA. 60sec 测试OK

3. 装机测试 OK

4. 温升测试中. 室温为32℃时. 变压器温度为 100℃.

5.

6.

四.其他:

五.测试結論: 可用于 SYS1097-4812中

FROM : FAX NO. : 657 Sep. 28 2004 08:28 P3

規格承認書

SPECIFICATION FOR APPROVAL

Customer: 呈威

Customer Model: SYS1097(醫療)

Sample No. G104B1671B01*

Description: TRANSFORMER

Issued Date: 2005/09/01

	"V"	Customer's Signatures	Signature
Full Approved			
Conditional Approved			
Rejected			

DRAWER	CHECKED	QC	APPROVED
陳秀平 2005/09/01			

Sunny 曜威電子廠
中國廣東省東莞市橫瀝鎮新城工業區
Hengli New Town zone Dong Guan City Guang Dong China.
TEL:(0769) 3377756-9,3377358 FAX:(0769) 3721585
E-mail: sales@sunny-group.com
Web Site: http://www.sunny-group. com.

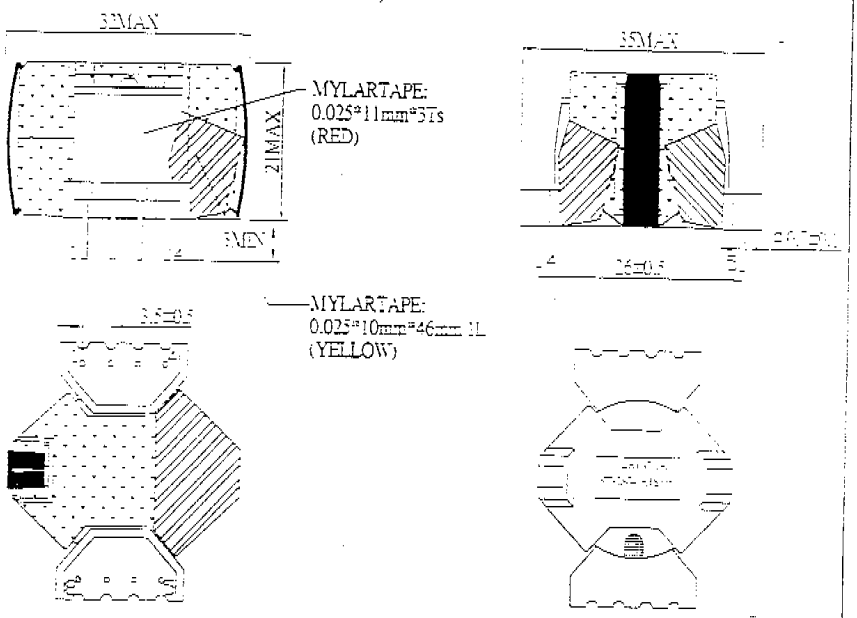
FROM : FAX NO. : 657 Sep. 28 2004 08:29 P4

SPECIFICATION FOR APPROVAL

曜威電子厂

PART NO.	G104B1671B01*	SUNNY NO.	
PART NAME	RM-10 XFMR	CUSTOMER MODEL	SYS1097(聲寶)
REV. NO.	A	ISSUE DATE	2005/09/01

1.PHYSICAL DIMENSION(UNIT:mm)



NOTE:

1.PIN8 CUT OFF.PIN耳外插入軸心繞線;
2.所有繞組進出線必須穿 TEFLON TUBE;
3.繞線須平整緊密,繞制銅箔焊點朝下;
4.三層絕緣線須先剝皮再鍍錫;
5.GAP CORE置於PIN部.成品在底部PIN4-5側貼瑪拉:0.025*10mm*1L.
6.成品包 T*W=0.025*22mm*2Ts MYLAR TAPE.

APPROVED BY	CHECKED BY	REPORTED BY
		陳秀平 2005/09/01

FROM : FAX NO. : 657 Sep. 28 2004 08:29 P5

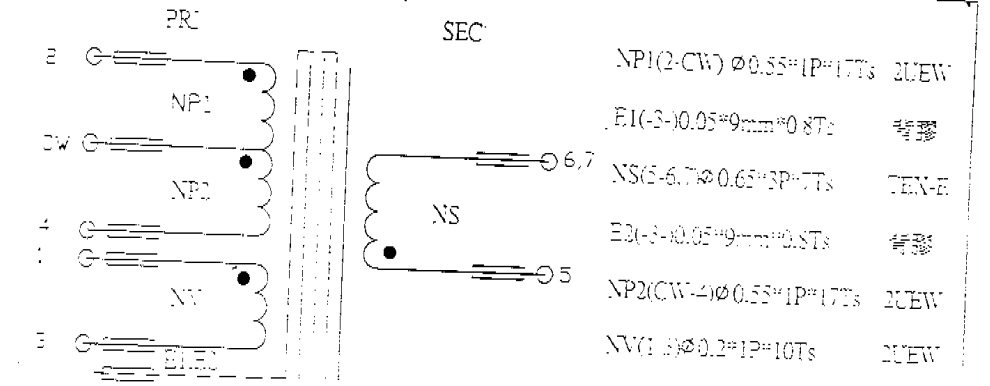
Sunny

SPECIFICATION FOR APPROVAL

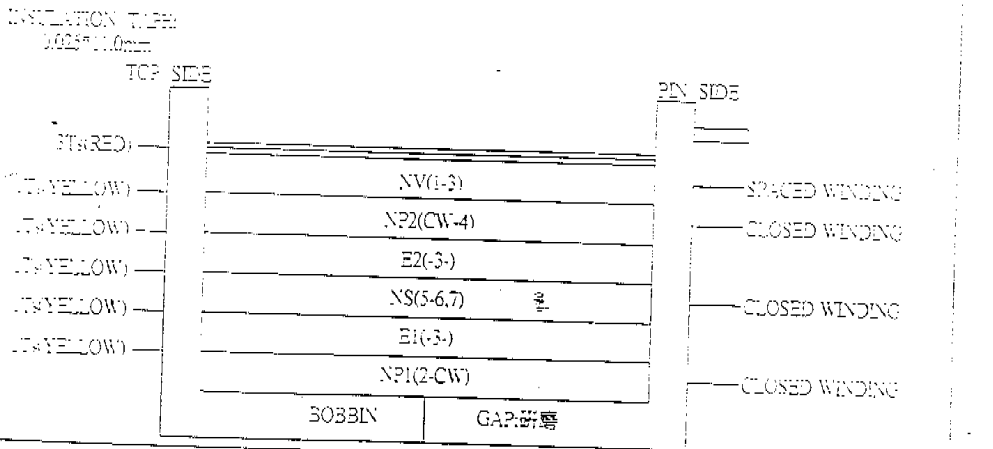
曜威電子厂

PART NO.	G104B1671B01*	SUNNY NO.	
PART NAME	RM-10 XFMR	CUSTOMER MODEL	SYS1097(醫療)
REV. NO.	A	ISSUE DATE	2005/09/01

2.SCHEMATIC:



3.WINDING CONSTRUCTION:



APPROVED BY	CHECKED BY	REPORTED BY
		陳秀平 2005/09/01

FROM : FAX NO. : 657 Sep. 28 2004 08:30 P6

Sunny

SPECIFICATION FOR APPROVAL

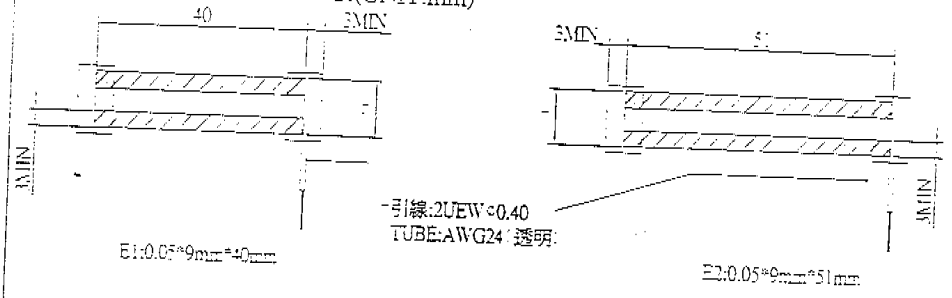
曜威電子厂

PART NO.	G104B1671B01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097(客戶)
REV. NO.	A	ISSUE DATE	2005/09/01

4.WINDING TABLE:

Winding No. (繞組)	Margin Tape (擋墻)	Pin (腳位)	Copper Wire (銅線)	Turns (圈數)	Winding Method (繞線方式)	Tape Turns (膠帶圈數)	Tube (套管)
NP1	0	2-CW	Φ0.55*1P	17Ts	密繞	1Ts	25*16mm/2*17mm
S1	1	-5-	0.05*9mm	0.8Ts	散繞	1Ts	-24*14mm-
NS	0	5-6.7	Φ0.65*3P	7Ts	密繞	1Ts	13*16mm/13*16mm
S2	1	-3-	0.05*9mm	0.8Ts	散繞	1Ts	-24*12mm-
NP2	0	CW-4	Φ0.55*1P	17Ts	密繞	1Ts	22*17mm/25*14mm
NF	0	1-3	Φ0.2*1P	10Ts	亂繞	3Ts	30*15mm/30*15mm

5.MATERIAL PROCESSING:(UNIT:mm)



APPROVED BY	CHECKED BY	REPORTED BY
		陳秀平 2005/09/01

FROM : FAX NO. : 657 Sep. 28 2004 08:30 P7

SPECIFICATION FOR APPROVAL
曜威電子厂

PART NO.	G104B1671B01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097(普騄)
REV. NO.	A*	ISSUE DATE	2005/09/01

6.ELECTRICAL CHARACTERISTIC:

TEST ITEM 測試項目	TEST CONDITION 測試條件	RESULT 規格範圍
INDUCTANCE 電感	@1KHz 0.25V (2-4)	420~450uH
LEAKAGE INDUCTANCE 漏感	@1KHz 0.25V (2-4) SHORTED PIN1.3.5.6.7	15uH MAX
TURN RATIO 匝數比	20KHz 1.0V NP(2-4):34Ts NV:(1-3) NS:(5-6,7)	10±0.3Ts 7±0.3Ts
HI-POT 耐壓	@10mA 60SEC	P-S 4.3KVAC S-C 2.0KVAC P-C 0.5KVDC

APPROVED BY	CHECKED BY	REPORTED BY
		陳秀平 2005/09/01

FROM : FAX NO. : 657 Sep. 28 2004 08:31 P8

Sunny

SPECIFICATION FOR APPROVAL

曜威電子厂

PART NO.	G104B1671B01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097(醫療)
REV. NO.	A	ISSUE DATE	2005/09/01

7. MATERIAL LIST:

NO.	ITEM	MATERIAL	SUPPLIERS	UL NO.
1	BOBBIN	PHENOLIC RM-10(SUNNY) SPEC YW-470 OR EQUIV	CHANG CHUN PLASTICS CO.,LTD.	E59451(S)
2	CORE	FERITE CORE RM-10 PM7 OR EQUIV	ISU CERAMICS CO.,LTD.	
3	WIRE	POLYURETHANE ENAMELLED MW75-C 2UEW	HUIYANG GOLDEN OCEAN MAGNET WIRE FACTOR	E225143
4	TRIPLE WIRE	TRIPLE INSULATION WIRE TEX-E	FURUKAWA ELECTRIC CO.,LTD	E20344
5	INSULATION TAPE	POLYESTER FILM TAPE 1350	MINNESOTA MINING&MFG CO.,LTD	E17855(N)
6	TUBE	TEFLON TUBE	GREAT HOLDING INDUSTRIAL CO.,LTD	E156256
7	MARGIN TAPE	FIBER GLASS CLOTH 3M #44	MINNESOTA MINING&MFG CO.,LTD	E17855(N)
8	COPPER FOIL	0.05*9mm	DIANQIANG MATERIAL CO.,LTD.	
9	VARNISH	468-2FC	RIPLEY RESIN ENGINEENING CO INC	E81777(N)

APPROVED BY	CHECKED BY	REPORTED BY
		陳秀平 2005/09/01

FROM : FAX NO. : 657 Nov. 16 2006 16:07 P5

規格承認書

SPECIFICATION FOR APPROVAL

Customer: 呈威

Customer Model: SYS1097

Sample NO: G104B1710A11* 1097-3024 GT

Description: TRANSFORMER

Issued Date: 2006/11/07

	"V"	Customer's Signatures	Signature
Full Approved			
Conditional Approved			
Rejected			

REPORTED	CHECKED	QC	APPROVED

Sunny 變壓器事業處制二部

中國廣東省東莞市橫瀝鎮新城工業區
Hengli New Town zone Dong Guan City Guang Dong China
TEL:(0769)83377756-9,83377358 FAX:(0769)83793396
E-mail:sales@sunny-group.com.tw
Web Site:http://www.sunny-group.com

符合RoHS

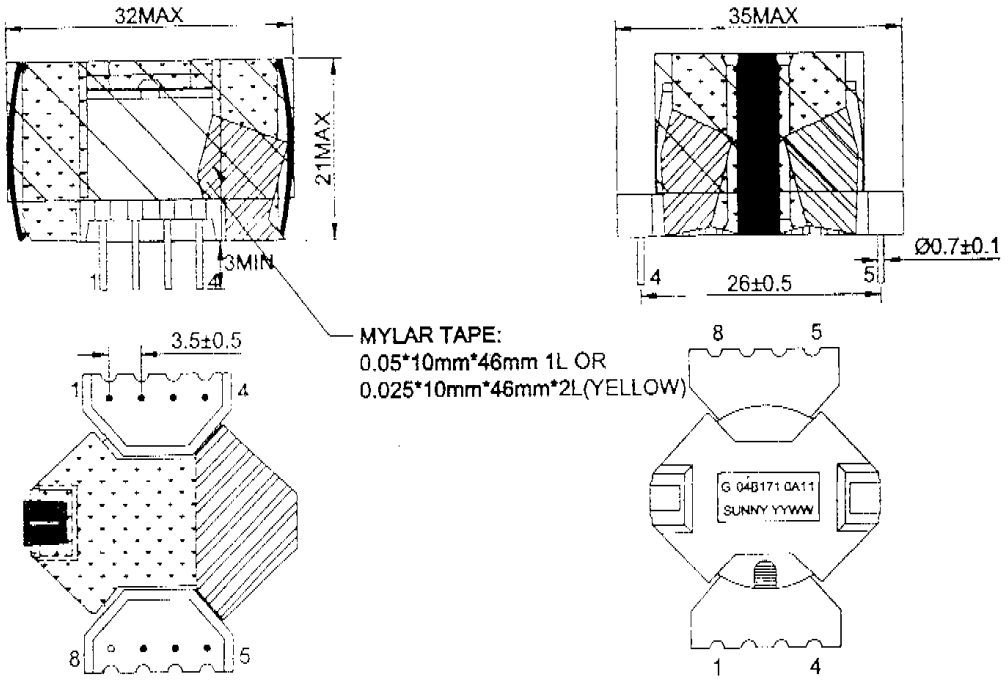
FROM : FAX NO. : 657 Nov. 16 2006 16:08 P6

SPECIFICATION FOR APPROVAL

變壓器事業處制二部

UNNY NO.	G104B1710A11*	CUSTOMER MODEL	SYS1097
REV. NO.	B	ISSUE DATE	2006/11/07

PHYSICAL DIMENSION(UNIT:mm)



NOTE:

1.PIN8,CUT OFF,PIN朝外插入軸心繞線;
2.所有繞組進出線必須穿 TEFLON TUBE;
3.繞線須平整緊密,繞制銅箔焊點朝下;
4.三層絕緣線須先剝皮再鍍錫;
5.GAP CORE置於PIN部,成品在底部PIN4-5側貼麥拉:0.05*10mm*46mm*1L . OR 0.025*10mm*46mm* 2L . 再包TAPE:0.025*13mm*1Ts.

APPROVED	CHECKED	REPORTED	PAGE
			1/5

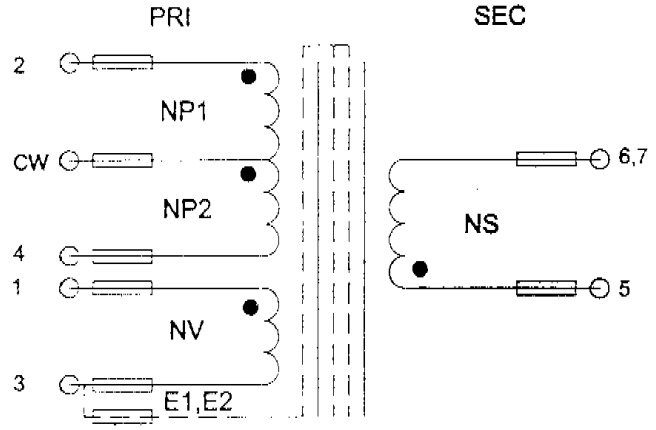
FROM : FAX NO. : 657 Nov. 16 2006 16:08 P7

SPECIFICATION FOR APPROVAL

變壓器事業處制二部

SUNNY NO.	G104B1710A11*	CUSTOMER MODEL	SYS1097
REV. NO.	B	ISSUE DATE	2006/11/07

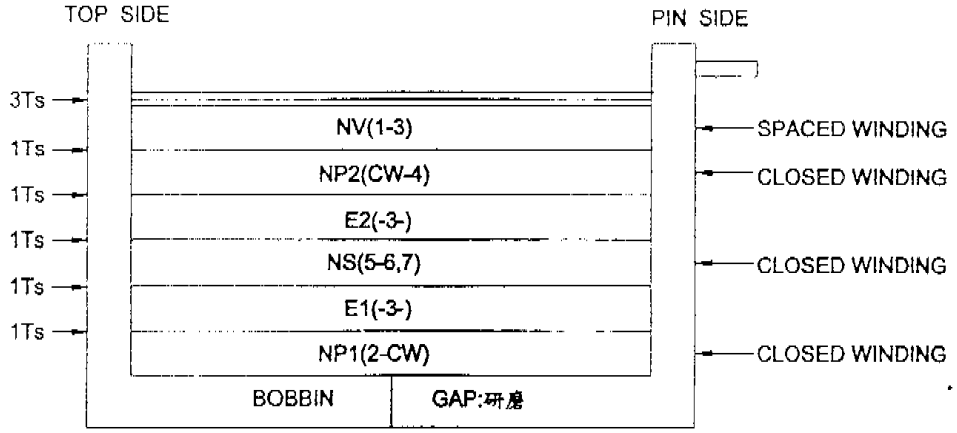
2.SCHEMATIC:



NP1(2-CW) Ø0.55*1P*17Ts 2UEW
E1(-3-)0.05*9mm*0.8Ts 背膠
NS(5-6,7)Ø0.6*2P*11Ts TEX-E
E2(-3-)0.05*9mm*0.8Ts 背膠
NP2(CW-4)Ø0.55*1P*17Ts 2UEW
NV(1-3)Ø0.2*1P*7Ts 2UEW

3.WINDING CONSTRUCTION:

INSULATION TAPE:0.025*11.0mm(YELLOW)



APPROVED	CHECKED	REPORTED	PAGE
			2/5

FROM : FAX NO. : 657 Nov. 16 2006 16:09 P8

SPECIFICATION FOR APPROVAL

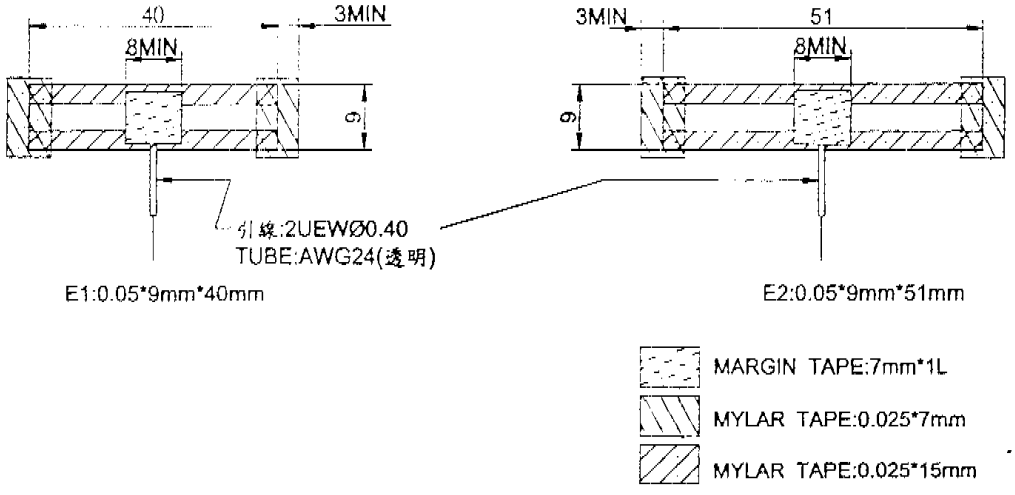
變壓器事業處制二部

SUNNY NO.	G104B1710A11*	CUSTOMER MODEL	SYS1097
REV. NO.	B	ISSUE DATE	2006/11/07

4.WINDING TABLE:

Winding No. (繞組)	Margin Tape (擋墻)	Pin (脚位)	Copper Wire (銅線)	Turns (圈數)	Winding Method (繞線方式)	Tape Turns (膠帶圈數)	Tube (套管)
NP1	0	2-CW	Ø0.55*1P	17Ts	密繞	1Ts	23L*16mm/23L*17mm
E1	0	-3-	0.05*9mm	0.8Ts	背膠	1Ts	-24L*14Lmm-
NS	0	5-6,7	Ø0.6*2P	11Ts	密繞	1Ts	15L*16mm/15L*16mm
E2	0	-3-	0.05*9mm	0.8Ts	背膠	1Ts	-24L*12Lmm-
NP2	0	CW-4	Ø0.55*1P	17Ts	密繞	1Ts	23L*17mm/23L*14mm
NV	0	1-3	Ø0.2*1P	7Ts	疏繞	3Ts	30L*15mm/30L*15mm

5.MATERIAL PROCESSING:(UNIT:mm)



E1:0.05*9mm*40mm

E2:0.05*9mm*51mm

APPROVED	CHECKED	REPORTED	PAGE
			3/5

SPECIFICATION FOR APPROVAL

變壓器事業處制二部

SUNNY NO.	G104B1710A11*	CUSTOMER MODEL	SYS1097
REV. NO.	B	ISSUE DATE	2006/11/07

3.ELECTRICAL CHARACTERISTIC:

TEST ITEM 測試項目	TEST CONDITION 測試條件	RESULT 規格範圍
INDUCTANCE 電感	@1KHz 0.25V (2-4)	420-450uH
LEAKAGE INDUCTANCE 漏感	@1KHz 0.25V (2-4) SHORTED PIN1,3,5,6,7	15uH MAX
TURN RATIO 圈數比	20KHz 1.0V NP(2-4):34Ts NV:(1-3) NS:(5-6,7)	7±0.3Ts 11±0.3Ts
HI-POT 耐壓	@10mA 60SEC	P-S 3.75KVAC S-C 2.0KVAC P-C 0.50KVDC

APPROVED	CHECKED	REPORTED	PAGE
			4/5

FROM : FAX NO. : 657 Nov. 16 2006 16:10 P10

SPECIFICATION FOR APPROVAL

變壓器事業處制二部

SUNNY NO.	G104B1710A11*	CUSTOMER MODEL	SYS1097
REV. NO.	B	ISSUE DATE	2006/11/07

7. MATERIAL LIST:

NO.	ITEM	MATERIAL	SUPPLIERS	UL NO.
1	BOBBIN	PHENOLIC RM-10 T375J	CHANG CHUN PLASTICS CO.,LTD	E59481(S)
2	CORE	FERRITE CORE RM-10 NC-2H	NICERAN FERRITE CORE SELECTION GUTDE	
3	WIRE	POLYURETHANE ENAMELLED MW75 2UEW	HUIYANG GOLDEN OCEAN MAGNET WIRE FACTOF	E225143
4	TRIPLE WIRE	TRIPLE INSULATION WIRE TEX-E	FURUKAWA ELECTRIC CO.,LTD	E206440
5	INSULATION TAPE	POLYESTER FILM TAPE 1350-1	MINNESOTA MINING&MFG CO.,LTD	E17385(N)
6	TUBE	TEFLON TUBE	GREAT HOLDING INDUSTRIAL CO.,LTD	E156256(S)
7	COPPER FOIL	0.05*9mm	DIANQIANG MATERIAL CO.,LTD.	
8	VARNISH	468-2FC+	RIPLEY RESIN ENGINEENING CO INC	E81777(N)

APPROVED	CHECKED	REPORTED	PAGE
			5/5

FROM : FAX NO. : Sep. 01 2002 06:07 P1

呈威電子廠

SUNNY

地址:東莞市橫瀝鎮新城工業區 TEL: (0769)3377756-9 3377358

零件承認書

SPECIFCATION FOR APPROVAL

品名 Part Name	变压器		
機種名稱 Model Name	S/S1097		
廠商 Manufacture	曜威		
料品規格 Material Spec	RM-10.		
承認代號 Part No	104B1720B01X		
日期 Date	2003.07.26	版本 Rev	V.0.

No.: CR112030702

簽名	品管 QC	批准 APPROVE	覆核 REVIEW	審核 VIEW	工程印章 ISSUED STAMP
	彭家勇	Paul	丁竹惟	2003.7.30 胡貴融文件用	呈威電子 工程部專用章 文件發行 2003.7.30
日期	7/29	7.30.	03.7.26	7/26	

FROM : FAX NO. : Sep. 01 2002 06:07 P2

承認書工程測試基本資料

料號: 10LB1720B01 型號: Transformer 廠商: 耀威

機種: LY51097 測試時間: 2002.7.26 負責人: 王守恒

一:外觀及尺寸測試:

1.長: 24.30mm 寬: 22.10mm 高: 19.21mm 其他: 腳寬: 0.7mm 排距: 24.30mm 腳長: 6.7mm

2.外觀: 要求LABEL印字清晰,貼正,磁芯无破裂現象

二:機械性能:

1. OK
2.
3.

三:電氣測試:

1. 电感值测试 <4.7±3.2%H第二脚去第四脚> OK
2. 漏感值测试 <±7%H> OK
3. 耐压测试 <3.7KVAC, 60SEC 10mA> OK
4. 外观 OK
5.
6.

四:其他: 去PCB板时客户

五:測試結論: 已经做样测试OK,可以接受

FROM : FAX NO. : Sep. 01 2002 06:08 P3

規格承認書

SPECIFICATION FOR APPROVAL

Customer : 呈威

Customer Model: SYS1097

Sample No : 104B1720B01*

Description : Transformer

Issued Date : 2003/07/07

	"V"	Customer's Signatures	Signature
Full Approved			
Conditional Approved			
Rejected			

DRAWER	CHECKED	APPROVED
楊秀 2003/07/07	歐陽論	

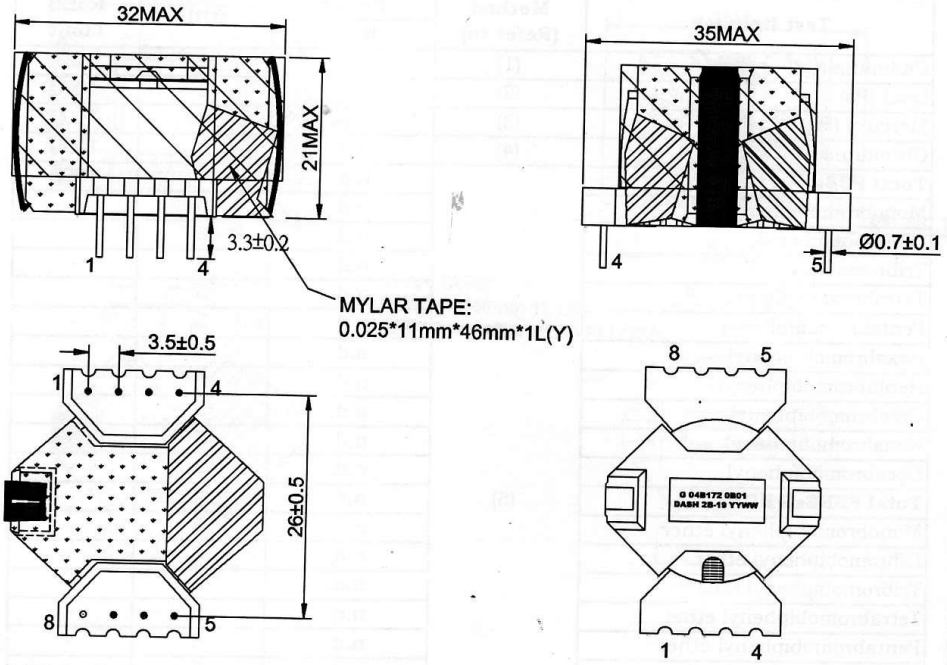
SUNNY 曜威電子廠
中國廣東省東莞市橫瀝鎮新城工業區
Hengli New Town zone Dong Guan City Guang Dong China.
TEL:(0769) 3377756-9,3377358 FAX:(0769) 3721585
E-mail: sales@sunny-group.com.tw
Web Site: http://www.super- sunny.com.

SPECIFICATION FOR APPROVAL

變壓器事業處制二部

SUNNY NO.	G104B1720B01*	CUSTOMER MODEL	SYS1097
REV. NO.	B	ISSUE DATE	2010/10/19

1.PHYSICAL DIMENSION(UNIT:mm)



NOTE:

1.PIN8,CUT OFF,PIN朝外插入軸心繞線;
2.所有繞組進出線必須穿 TEFLON TUBE;
3.繞線須平整緊密,繞制銅箔焊點朝下;
4.三層絕緣線須先剝皮再鍍錫;
5.GAP CORE置於PIN部,成品在底部PIN4-5側貼麥拉:0.025*11mm*1L .
再包TAPE:0.025*13mm*1Ts.

APPROVED	CHECKED	REPORTED	PAGE
經理 10.OCT.19 劉傑	工程部 10.OCT.19 劉維忠	工程部 10.OCT.19 唐湘	1/5

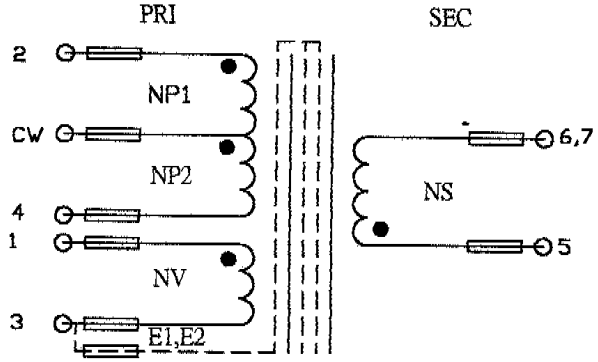
FROM : FAX NO. : Sep. 01 2002 06:09 P5

SUNNY SPECIFICATION FOR APPROVAL

曜威電子厂

PART NO.	104B1720B01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097
REV. NO.	A	ISSUE DATE	2003/07/07

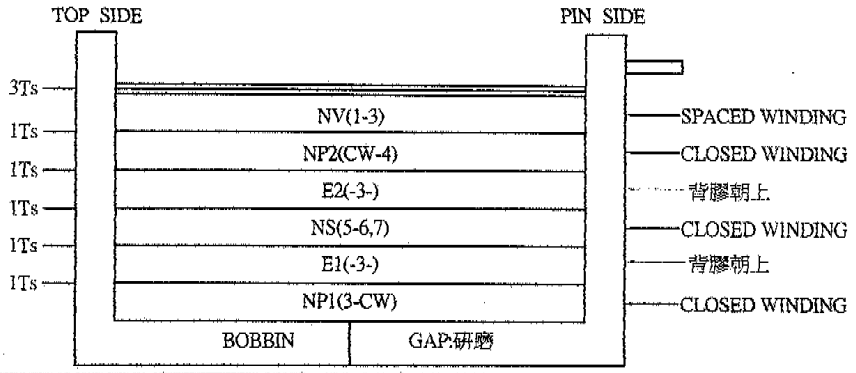
2.SCHEMATIC:



NP1(2-CW) ø0.55*1P*17Ts 2UEW
E1(-3-)0.05*10mm*0.8Ts 背膠
NS(5-6,7)ø0.65*2P*10Ts TEX-E
E2(-3-)0.05*10mm*0.8Ts 背膠
NP2(CW-4)ø0.55*1P*17Ts 2UEW
NV(1-3)ø0.2*1P*9Ts 2UEW

3.WINDING CONSTRUCTION:

INSULATION TAPE:
0.025*11.0mm(YELLOW)



APPROVED BY	CHECKED BY	REPORTED BY

FROM : FAX NO. : Sep. 01 2002 06:09 P6

SUNNY SPECIFICATION FOR APPROVAL

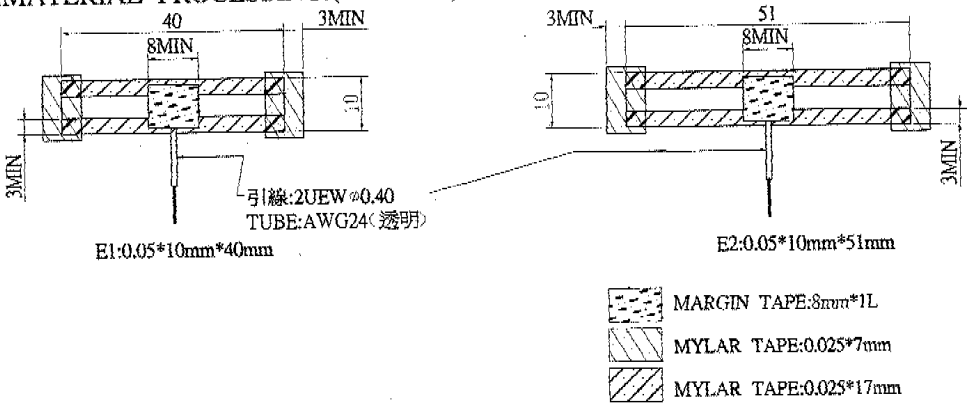
曜威電子厂

PART NO.	104B1720B01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097
REV. NO.	A	ISSUE DATE	2003/07/07

4.WINDING TABLE:

Winding No. (繞組)	Margin Tap (檔腳)	Pin (腳位)	Copper Wire (銅線)	Turns (圈數)	Winding Method (繞線方式)	Tape Turns (膠帶圈數)	Tube (套管)
NP1	0	2-CW	ø0.55*1P	17Ts	密繞	1Ts	23*16mm/23*17mm
E1	0	-3-	0.05*10mm	0.8Ts	背膠	1Ts	-24*14mm-
NS	0	5-6,7	ø0.65*2P	10Ts	密繞	1Ts	15*16mm/15*16mm
E2	0	-3-	0.05*10mm	0.8Ts	背膠	1Ts	-24*12mm-
NP2	0	CW-4	ø0.55*1P	17Ts	密繞	1Ts	23*17mm/23*14mm
NV	0	1-3	ø0.2*1P	9Ts	疏繞	3Ts	30*15mm/30*15mm

5.MATERIAL PROCESSING:(UNIT:mm)



APPROVED BY	CHECKED BY	REPORTED BY

FROM : FAX NO. : Sep. 01 2002 06:10 P7

SUNNY SPECIFICATION FOR APPROVAL

曜威電子厂

PART NO.	104B1720B01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097
REV. NO.	A	ISSUE DATE	2003/07/07

6.ELECTRICAL CHARACTERISTIC:

TEST ITEM 測試項目	TEST CONDTION 測試條件	RESULT 規格範圍
INDUCTANCE 電感	@1KHz 0.25V (2-4)	420-450uH
LEAKAGE INDUCTANCE 漏感	@1KHz 0.25V (2-4) SHORTED PIN1,3,5,6,7	15uH MAX
HI-POT 耐壓	@10mA 60SEC	P-S 3.75KVAC S-C 2.0KVAC P-C 0.5KVDC

APPROVED BY	CHECKED BY	REPORTED BY
		2003/07/07

FROM : FAX NO. : Sep. 01 2002 06:10 P8

SUNNY SPECIFICATION FOR APPROVAL

曜威電子厂

PART NO.	104B1720B01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097
REV. NO.	A	ISSUE DATE	2003/07/07

7. MATERIAL LIST:

NO.	TEM	MATERIAL	SUPPLIERS	UL NO.
1	BOBBIN	PHENOLIC RM-10(SUNNY) 8PIN YW-470 OR EQUIV	CHANG CHUN PLASTICS CO.,LTD.	E59481(S)
2	CORE	FERRITE CORE RM-10 PM7 OR EQUIV	ISU CERAMICS CO.,LTD	
3	WIRE	POLYURETHANE ENAMELLED COPPER WIRE 2UEW	WAN MON INDUSTRIAL CORP	E104091(S)
4	TRIPLE WIRE	TRIPLE INSULATION WIRE TEX-E	GREAT LEOFLON INDUSTRIAL CO.,LTD	E211989
5	INSULATION TAPE	POLYESTER FILM TAPE CT-280	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO.,LTD	E165111
6	TUBE	TEFLON TUBE	FLUO TECH INDUSTRIES CO.,ITD	E175982(S)
7	MARGIN TAPE	POLYESTER FILM TAPE WF-2902	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CL.,LTD.	E165111
8	COPPER FOIL	0.05*10mm	DIANQIANG MATERIAL CO.,LTD.	
9	VARNISH	WA-238A	HITACHI CHEMICAL CO.,LTD	E72979
10	SOLDER	BAR 63/37	SOLNET METAL INDUSTRY CO.,LTD.	

APPROVED BY	CHECKED BY	REPORTED BY
		2003/07/07

FROM : FAX NO. : Sep. 01 2002 06:11 P9

SUNNY SAMPLES TEST DATA

CUSTOMER	呈威		TEMPERATURE		25℃		DESCRIPTION		TRANSFORMER	
MODEL	SYS1097		HUMIDITY		75%		SPECIFICATION		RM-10	
SUNNY NO.	104B1720B01*		SAMPLE		5PCS		DATE		2003/07/07	
TEST ITEM	L	LK	TR	TR	HI-POT	HI-POT	HI-POT			
PIN NO.	2-4	2-4 SHORTED PIN1,3,5,6,7	1-3 NP(2-4) 34TS	5-6,7 NP(2-4) 34TS	P-S	S-C	P-C			
SPEC.	420-450uH	15uH MAX	9±0.3Ts	10±0.3Ts	3750V	2000V	500V			
TEST CONDITION	1KHz/0.25V	1KHz/0.25V	20KHz/1.0V	20KHz/1.0V	10mA/1MIN	10mA/1MIN	10mA/1MIN			
1	440	6.3	OK	OK	OK	OK	OK			
2	440	6.5	OK	OK	OK	OK	OK			
3	438	6.7	OK	OK	OK	OK	OK			
4	446	6.9	OK	OK	OK	OK	OK			
5	444	6.5	OK	OK	OK	OK	OK			
6										
7										
8										
9										
10										
TEST ITEM										
PIN NO.										
SPEC.										
TEST CONDITION										
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

PHYSICAL DIMENSIONS				TEST INSTRUMENTS	
LENGTH	OK	PIN LENGTH	OK	INDUCTANCE:	CH100;CH3250
WIDTH	OK	PIN DISTANCE	OK	TURNS:	CH3250
HIGH	OK	ROW DISTANCE	OK	DCR:	/
PIN DIAMETER	OK	OTHER	/	HI-POT:	HY-7112
APPROVED:		CHECKED:		TESTER:	2003/07/07

FROM : FAX NO. : Apr. 10 2002 00:22 P1

呈威電子廠

SUNNY COMPUTER TECHNOLOGY CO., LTD

地址:東莞市橫瀝鎮新城工業區 TEL:(0769)3377756-9 3377358

零件承認書

SPECIFICATION FOR APPROVAL

品名 Part Name	变压器		
機種名稱 Model Name	SIS 1097		
廠商 Manufacture	銘威		
料品規格 Material Spec	RM-10		
承認代號 Part No	104B2730A01*		
日期 Date	03/01/03	版本 Rev	V1.0

No.: B2112030105

簽名	品管 QC	批准 APPROVE	复核 REVIEW	審核 VIEW	工程印章 ISSUED STAMP
	陈沛德			杨先生	呈威電子廠 工程部專用章
日期	02.3.4	2003.3.6.	01/03	01/03	管制文件 2002.1.08 發行

FROM : FAX NO. : Apr. 10 2002 00:22 P2

規 格 承 認 書

SPECIFCATION FOR APPROVAL

Customer : 呈 威

Part No : 104B2730A01*

Sample No : SYS1097

Deseription : Transformer

Issued Date : 2002/12/23

	"V"	Customer's Signatures	Signature
Full Approved			
Conditional Approved			
Rejected			

DRAWER	CHECKED	APPROVED
欧阳海波 12/23	欧阳海波 12/23	12/23

SUNNY COMPUTER TECHNOLOGY CO., LTD.

銘 威 電 子 廠

中國廣東省東莞市橫瀝鎮新城工業區
Hengli New Townzone Dong Guan City Guang Dong China.
TEL:(0769)3377756-9, 3377358 FAX:(0769)3377351-2
E-mail:sales@sunny-group.com.tw
Web Site:http://www.super- sunny.com.

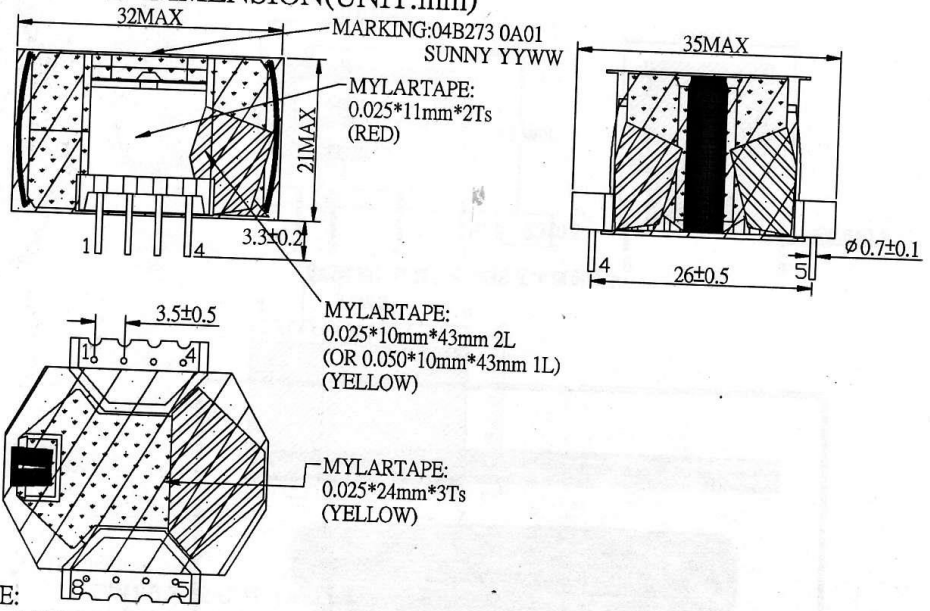
Sunny

SPECIFICATION FOR APPROVAL

曜威電子厂

PART NO.	104B2730A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	
REV. NO.	A	ISSUE DATE	2010/10/19

1.PHYSICAL DIMENSION(UNIT:mm)



NOTE:

1.PIN8,CUT OFF;
2.所有繞組進出線必須穿 TEFLON TUBE;
3.繞線須平整緊密,絕緣膠帶均需依規格指定層數字包足,不可有少包,多包,及反折現象以防耐壓不良及超胖;
4.三層絕緣線須先剝皮再鍍錫;
5.CORE爲RM型,GAP CORE置於PIN部,成品在底部PIN4-5 側貼:0.025*10mm*2L (或0.05*10mm*1L),然后包CORE TAPE0.025*24mm*3Ts;
6.成品包三層T*W=0.025*24mm MYLAR.

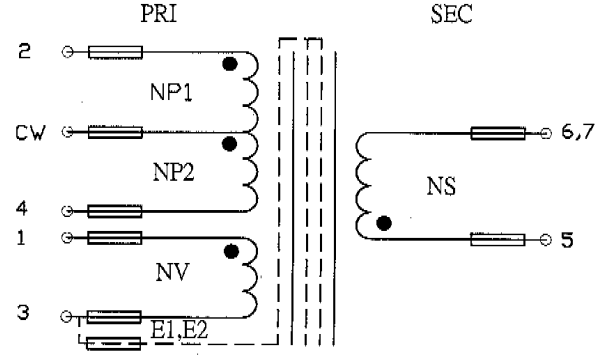
APPROVED BY	CHECKED BY	REPORTED BY
劉傑2010/10/19	歐陽海歡2010/10/19	唐湘2010/10/19

FROM : FAX NO. : Apr. 10 2002 00:23 P4

SUNNY COMPUTER TECHNOLOGY CO.,LTD.
銘威電子厂

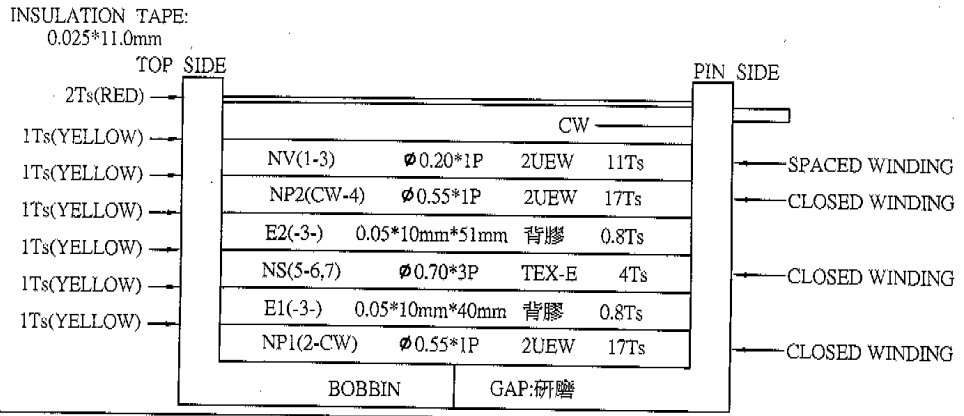
PART NO.	104B2730A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	
REV. NO.	A	ISSUE DATE	2002/12/23

2.SCHEMATIC:



NP1(2-CW) ø0.55*1P*17Ts 2UEW
E1(-3-)0.05*10mm*0.8Ts 背膠
NS(5-6,7)ø0.75*3P*4Ts TEX-E
E2(-3-)0.05*10mm*0.8Ts 背膠
NP2(CW-4)ø0.55*1P*17Ts 2UEW
NV(1-3)ø0.20*1P*11Ts 2UEW

3.WINDING CONSTRUCTION:



APPROVED BY	CHECKED BY	REPORTED BY
	欧阳海欢 12/23	欧阳海欢 12/23

FROM : FAX NO. : Apr. 10 2002 00:24 P5

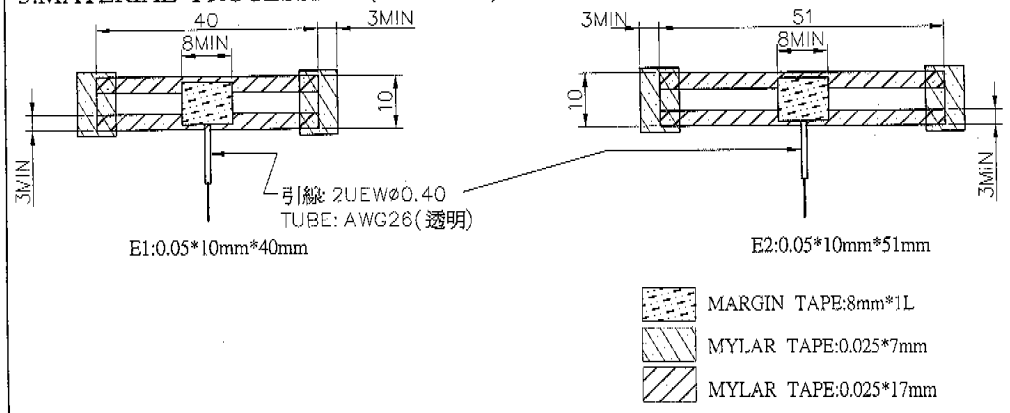
SUNNY COMPUTER TECHNOLOGY CO.,LTD.
銘威電子厂

PART NO.	104B2730A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	
REV. NO.	A	ISSUE DATE	2002/12/23

4.WINDING TABLE:

Winding No. (繞組)	Margin Tap (檔牆)	Pin (腳位)	Copper Wire (銅線)	Turns (圈數)	Winding Methed (繞線方式)	Tape Turns (膠帶圈數)	Tube (套管)
NP1	0	2-CW	ø0.55*1P	17Ts	密繞	1Ts	23*14mm/23*14mm
E1	0	-3-	0.05*10mm	0.8Ts	背膠	1Ts	-26*13mm-
NS	0	5-6,7	ø0.75*3P	4Ts	密繞	1Ts	12*14mm/12*14mm
E2	0	-3-	0.05*10mm	0.8Ts	背膠	1Ts	-26*12mm-
NP2	0	CW-4	ø0.55*1P	17Ts	密繞	1Ts	23*12mm/23*12mm
NV	0	1-3	ø0.20*1P	11Ts	疏繞	1Ts	30*13mm/30*13mm
將"CW"絞線鍍錫后折回線包內						2Ts	

5.MATERIAL PROCESSING:(UNIT:mm)



APPROVED BY	CHECKED BY	REPORTED BY

FROM : FAX NO. : Apr. 10 2002 00:24 P6

SUNNY COMPUTER TECHNOLOGY CO.,LTD.

銘威電子厂

PART NO.	104B2730A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	
REV. NO.	A	ISSUE DATE	2002/12/23

6.ELECTRICAL CHARACTERISTIC:

TEST ITEM 測試項目	TEST CONDTION 測試條件	RESULT 規格範圍
INDUCTANCE 電感	@1KHz 0.25V (2-4)	410-460uH
LEAKAGE INDUCTANCE 漏感	@1KHz 0.25V (2-4) SHORTED PIN1,3,5,6,7	15uH MAX
D.C.RESISTANCE 電阻	(2-4) (1-3) (5-6,7)	0.20Ω MAX 0.50Ω MAX 0.10Ω MAX
TURN RATIO 圈數比	20KHz 1.0V NP(2-4):34Ts NV:(1-3) NS:(5-6,7)	11±0.3Ts 4±0.3Ts
HI-POT 耐壓	@10mA 60SEC	P-S 3.75KVAC S-C 0.50KVDC

APPROVED BY	CHECKED BY	REPORTED BY

FROM : FAX NO. : Apr. 10 2002 00:25 P7

SUNNY COMPUTER TECHNOLOGY CO.,LTD.

銘威電子厂

PART NO.	104B2730A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	
REV. NO.	A	ISSUE DATE	2002/12/23

7. MATERIAL LIST:

NO.	TEM	MATERIAL	SUPPLIERS	UL NO.
1	BOBBIN	PHENOLIC RM-10 8PIN YW-470 OR EQUIV	CHANG CHUN PLASTICS CO.,LTD.	E59481(S)
2	CORE	FERITE CORE RM-10 NC-2H OR EQIVE	NICERAN FERRITE CORE SELECTION GUTDE	
3	WIRE	POLYURETHANE ENAMELLED COPPER WIRE 2UEW	WAN MON INDUSTRIAL CORP	E104091(S)
4	TRIPLE WIRE	TRIPLE INSULATION WIRE TEX-E	GREAT LEOFLON INDUSTRIAL CO.,LTD	E211989
5	INSULATION TAPE	POLYESTER FILM TAPE CT-280	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO.,LTD	E165111
5	TUBE	TEFLON TUBE	FLUO TECH INDUSTRIES CO.,ITD	E175982(S)
6	MARGIN TAPE	POLYESTER FILM TAPE WF-2902	JINJIAN YAHUA PRESSURE SENSITIVE GLUE CL.,LTD.	E165111
7	COPPER FOIL	0.05*10mm	DIANQIANG MATERIAL CO.,LTD.	
8	VARNISH	WA-238A	HITACHI CHEMICAL CO.,LTD	E72979
9	SOLDER	BAR 63/37	SOLNET METAL INDUSTRY CO.,LTD.	

APPROVED BY	CHECKED BY	REPORTED BY

FROM : FAX NO. : Apr. 10 2002 00:25 P8

SUNNY COMPUTER TECHNOLOGY CO., LTD.

銘 威 電 子 廠

SAMPLES TEST DATA

CUSTOMER	呈威	PART NO:	104B2730A01*	SPECIFICATION	RM-10
ITEM	TRANSFORMER	SAMPLE	5PCS	DATE	2002/12/23
TEMP	25℃	HUM.	75% RH	TEST(f)	1.0KHZ 0.25V

RESULT OK

MANUFACTURE EXTERIOR DIMENSIONS:(OK) UNIT:mm

LENGTH 32 MAX PIN DISTANCE 3.5± 0.5
WIDTH 35 MAX ROW DISTANCE 26± 0.5
HIGH 21 MAX PIN LENGTH 3 MIN

TEST INSTRUCTMENTS

■CH100 □CH502 □CH310
□CH102 □CWV852 ■CH3250
□CH1061 □CWV902 □TF6800A3
□CH1062 ■CS2670 □CH1301A

INDUCTANCE □H ■mH ■uH ■TURNS □VOLTAGE RATIO

DC RESISTANCE □KOHM ■OHM □mOHM

SPEC	L 410-460 uH	LK 15uH MAX		11TS ± 0.3TS	4TS ± 0.3Ts			DCR 0.20Ω MAX	DCR 0.50Ω MAX	DCR 0.10Ω MAX		
PIN NO / ITEM NO	2-4	2-4		1-3	5-6,7			2-4	1-3	5-6,7		
1	425.7	12.6		OK	OK			0.135	0.411	0.003		
2	425.3	12.1		OK	OK			0.135	0.406	0.003		
3	432.2	11.0		OK	OK			0.136	0.408	0.003		
4	417.4	12.1		OK	OK			0.137	0.417	0.003		
5	442.3	12.5		OK	OK			0.138	0.414	0.003		
6												
7												
8												
9												
10												

HI-POT TEST	KV	MA	SEC	RESULT	NOTE:	TESTER	CHECKED	APPROVED
PRI-SEC	3.75AC	10	60	OK				
PRI-CORE								
SEC-CORE	0.5DC	10	60	OK				
PRI-PRI								
SEC-SEC								

FROM : FAX NO. : Apr. 10 2002 00:26 P9

333 Pfingsten Road
Northbrook, Illinois 60062-2096
United States Country Code(1)
(847) 272-8800
FAX No. (847) 272-8129
http://www.ul.com

Underwriters Laboratories Inc.®

File E181163 Vol 1 Issued 05/13/2002
Revised 07/23/2002

FOLLOW UP SERVICE PROCEDURE
(TYPE R)

COMPONENT SYSTEMS, ELECTRICAL INSULATION
(QRJY2)

Manufacturer: SUNNY COMPUTER TECHNOLOGY CO LTD
(566849-001) HENGLI NEW TOWN ZONE
DONGGUAN
GUANGDONG 523477 CHINA

Applicant: SUNNY ELECTRONICS CORP
(298510-001) 2ND FL,
125 CHUNG YING RD, SEC 2
TUCHENG CITY
TAIPEI HSIEN TAIWAN

Recognized Company: SAME AS APPLICANT
(298510-001)

This Procedure authorizes the above Manufacturer to use the marking specified by Underwriters Laboratories Inc. only on products covered by this Procedure, in accordance with the applicable Follow-Up Service Agreement.

The prescribed Mark or Marking shall be used only at the above manufacturing location on such products which comply with this Procedure and any other applicable requirements.

The Procedure contains information for the use of the above named Manufacturer and representatives of Underwriters Laboratories Inc. and is not to be used for any other purpose. It is lent to the Manufacturer with the understanding that it is not to be copied, either wholly or in part, and that it will be returned to Underwriters Laboratories Inc. upon request.

This PROCEDURE, and any subsequent revisions, is the property of UNDERWRITERS LABORATORIES INC. and is not transferable.

UNDERWRITERS LABORATORIES INC.

A.W. Schaefer
Vice President and General Manager
Laboratory Management and Operations

A not-for-profit organizatic
dedicated to public safety a

OBMW2 October 18, 1994
Component-Magnet Wire

WAN MON INDUSTRIAL CORP E104091(S)
1ST FL 31 LANE 19 HSIN SHENG NORTH RD, SEC 3 , TAIPEI TAIWAN

Mtl Dsg	Coating Type BC	TC	ANSI Typ	TI
UEW	Polyurethane	—	mw75-c	130
PEW	Polyester	—	mw5-c	155

Marking:Company name and material designation on package or reel.

See General Information Preceding These Recognitions.

For use only in equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc.

Reports:October 10, 1994: October 10, 1994.

968871001 H3108 Underwriters Laboratories Inc.® DII/0263685 29

FROM : FAX NO. : Apr. 10 2002 00:27 P11

承認書工程測試基本資料

料號：104B2730A01X 型號：變壓器 廠商：銘威電子股份

機種：SS1087 測試時間：2002.4.2 負責人：蔣良輝

一、外觀及尺寸測試：

1. 長：15mm 寬：10mm 高：_____ 其他：_____

2. 外觀：_____

二、機械性能：

1. ok.

2. _____

3. _____

三、電氣測試：

1. ARC 測試位測得 L(2-4)：420μH。

2. L(2-4)：8μH

3. 耐壓測試：2000VAC (室溫)。

4. _____

5. _____

6. _____

四、其他：_____

五、測試結論：ok.

FROM : PANASONIC PHONE NO. : 0769+3377352 AUG. 19 2005 10:42AM P1

呈威電子廠

Sunny

地址:東莞市橫瀝鎮新城工業區 TEL: (0769)3377756-9 3377358

零件承認書

SPECIFCATION FOR APPROVAL

品名 Part Name	变压器		
機種名稱 Model Name	SYS1097		
廠商 Manufacture	曜威		
料品規格 Material Spec	RM-10		
承認代號 Part No	104B1713A01*		
日期 Date	2005.06.01	版本 Rev	V1.0

No. : CR112050601 0

簽名	品管 QC	批准 APPROVE	覆核 REVIEW	審核 VIEW	工程印章 ISSUED STAMP
日期	2005.6.1	2005.6.1	2005.6.1	6/1	

FROM : PANASONIC PHONE NO. : 0769+3377352 AUG. 19 2005 10:42AM P2

承認書工程測試基本資料

料號: 1048/113A01# 型號: _____ 廠商: 曜禾

机种: STS1097 測試時間: 5/31 負責人: 伍文井

一. 外觀及尺寸測試:

1. 長: 31Max 寬: 20.6±0.1 高: 20Max 其他: _____

2. 外觀: _____

二: 机械性能:

1. ~~二~~ Pin 2 - CW 17匝 CW-4 17匝.

2. 1 - 3 9匝 5 - 6.7 17匝.

3. _____

三. 電氣測試:

1. 电感: (2-4) 430μH

2. 漏感: (2-4) 5.2μH

3. Hi-Pot. P-S 3750VAC 10mA 60SEC S-C 500VDC 1mA 60SEC

4. 通电测试 OK

5. _____

6. _____

四. 其他: _____

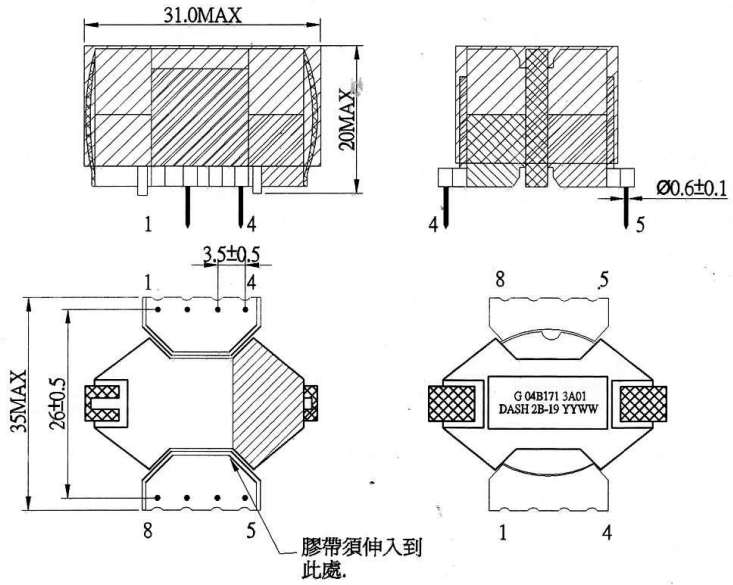
五. 測試結論: 符合1097系列机种

SPECIFICATION FOR APPROVAL

變壓器事業處

SUNNY NO.	G104B1713A01*	CUSTOMER MODEL	SYS1097(36V)
REV. NO.	A	ISSUE DATE	2010/10/19

1.PHYSICAL DIMENSION(UNIT:mm)



NOTE:

1.PIN8,CUT OFF,PIN朝外插入軸心繞線;
2.所有繞組進出線必須穿 TEFLON TUBE;
3.三層絕緣線須先剝皮再鍍錫;
4.GAP CORE置於PIN部,成品在底部PIN4-5側貼麥拉:0.025*10mm*1L,
再沿線包包TAPE:0.025*14mm*1Ts;

APPROVED	CHECKED	PROJECT	LAYOUT	PAGE
經理 10.COT.19 劉傑	工程部 10.COT.19 鄧才貴	工程部 10.COT.19 張合安	工程部 10.COT.19 胡蘭燕	1/6

FROM : PANASONIC PHONE NO. : 0769+3377352 AUG. 19 2005 10:45AM P1

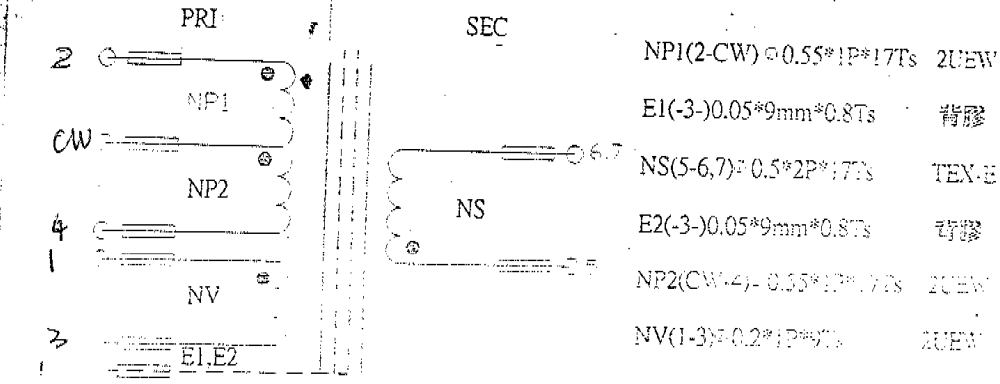
Sunny

SPECIFICATION FOR APPROVAL

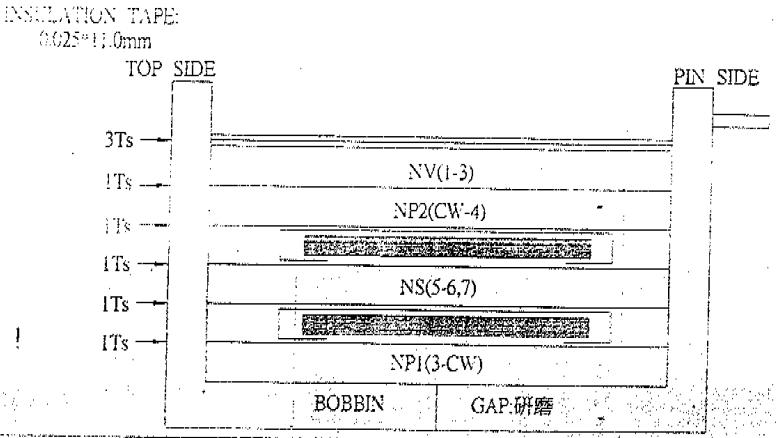
曜威電子厂

PART NO.	104B1713A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097(36V)
REV. NO.	A	ISSUE DATE	2005/05/11

2.SCHEMATIC:



3.WINDING CONSTRUCTION:



APPROVED BY	CHECKED BY	REPORTED BY
		ChenXiuPing

FROM : PANASONIC PHONE NO. : 0769+3377352 AUG. 19 2005 10:46AM P2

SUNNY

SPECIFICATION FOR APPROVAL

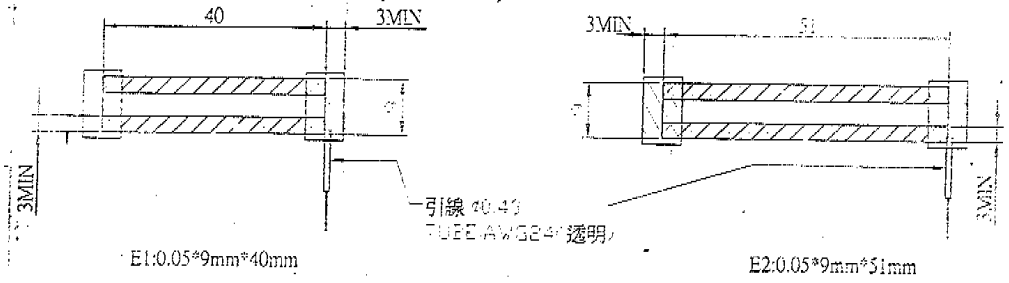
曜威電子厂

PART NO.	104B1713A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097(36V)
REV. NO.	A	ISSUE DATE	2005/05/11

4.WINDING TABLE:

Winding No. (繞組)	Margin Tape (檔牆)	Pin (腳位)	Copper Wire (銅線)	Turns (圈數)	Winding Method (繞線方式)	Tape Turns (膠帶圈數)	Tube (套管)
NP1	0	2-CW	Φ0.55*1P	17Ts	密繞	1Ts	23*17mm/23*17mm
E1	0	-3-	0.05*9mm	0.8Ts	背膠	1Ts	-24*13mm-
NS	0	5-6,7	Φ0.5*2P	17Ts	密繞	1Ts	16*16mm/16*16mm
E2	0	-3-	0.05*9mm	0.8Ts	背膠	1Ts	-24*12mm-
NP2	0	CW-4	Φ0.55*1P	17Ts	密繞	1Ts	23*17mm/23*14mm
NV	0	1-3	Φ0.2*1P	9Ts	疏繞	3Ts	28*15mm/28*15mm

5.MATERIAL PROCESSING:(UNIT:mm)



E1:0.05*9mm*40mm

E2:0.05*9mm*51mm

APPROVED BY	CHECKED BY	REPORTED BY
		ChenXiuPing

FROM : PANASONIC PHONE NO. : 0769+3377352 AUG. 19 2005 10:47AM P3

SUNNY

SPECIFICATION FOR APPROVAL

曜威電子厂

PART NO.	104B1713A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097(36V)
REV. NO.	A	ISSUE DATE	2005/05/11

6.ELECTRICAL CHARACTERISTIC:

TEST ITEM 測試項目	TEST CONDITION 測試條件	RESULT 規格範圍
INDUCTANCE 電感	@1KHz 0.25V (2-4)	420-450uH
LEAKAGE INDUCTANCE 漏感	@1KHz 0.25V (2-4) SHORTED PIN1,3,5,6,7	15uH MAX
HI-POT 耐壓	@10mA 1MIN	P-S 3750VAC S-C 500VDC

APPROVED BY	CHECKED BY	REPORTED BY
		ChenXiuPing

FROM : PANASONIC PHONE NO. : 0769+3377352 AUG. 19 2005 10:48AM P4

Sunny

SPECIFICATION FOR APPROVAL

曜威電子厂

PART NO.	104B1713A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097(36V)
REV. NO.	A	ISSUE DATE	2005/05/11

7. MATERIAL LIST:

NO.	TEM	MATERIAL	SUPPLIERS	UL NO.
1	BOBBIN	PHENOLIC RM-1 8PIN YW-470 PM9820 UL94V-0	SUMITOMO CHEMICAL CO.,LTD	E41429(M)
2	CORE	FERITE CORE RM-10 N12D	MMG BRAND CO.,LTD	
3	WIRE	POLYURETHANE ENAMELLED MW75-C 2UEW	HUIYANG GOLDEN OCEAN MAGNET WIRE FACTOR	E225143
4	TRIPLE WIRE	TRIPLE INSULATION WIRE TEX-E	FURUKAWA ELECTRIC CO.,LTD	E206440
5	INSULATION TAPE	POLYESTER FILM TAPE 1350	MINNESOTA MINING&MFG CO.,LTD	E17385(N)
6	TUBE	TEFLON TUBE	GREAT HOLDING INDUSTRIAL CO.,LTD	E156256
7	COPPER FOIL	0.05*9mm	DIANQIANG MATERIAL CO.,LTD.	
8	VARNISH	468-2FC	RIPLEY RESIN ENGINEENING CO INC	E81777(N)

APPROVED BY	CHECKED BY	REPORTED BY
		ChenXiuPing

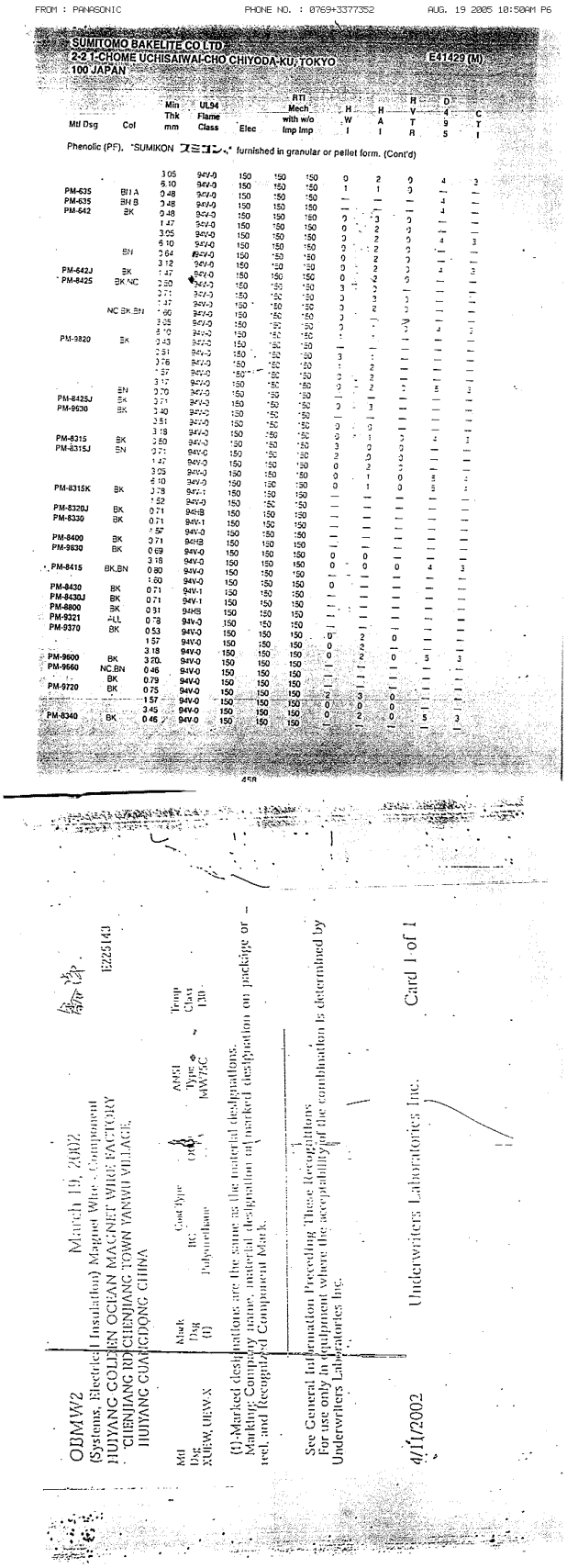
FROM : PANASONIC PHONE NO. : 0769+3377352 AUG. 19 2005 10:49AM P5

SAMPLES TEST DATA

CUSTOMER	呈威		TEMPERATURE		25℃		DESCRIPTION		TRANSFORMER	
MODEL	SYS1097(36V)		HUMIDITY		75%		SPECIFICATION		RM-10	
SUNNY NO.	104B1713A01*		SAMPLE		5PCS		DATE		2005/05/11	
TEST ITEM	L	LK	HI-POT	HI-POT						
PIN NO.	2-4	2-4 SHORTED PIN1,3,5,6,7	P-S	S-C						
SPEC.	420-450uH	15uH MAX	3750VAC	500VDC						
TEST CONDITION	1KHz/0.25V	1KHz/0.25V	10mA/1MIN	10mA/1MIN						
1	425	5.1	OK	OK						
2	429	5.2	OK	OK						
3	430	5.2	OK	OK						
4	426	5.2	OK	OK						
5	441	5.1	OK	OK						
6										
7										
8										
9										
10										
TEST ITEM										
PIN NO.										
SPEC										
TEST CONDITION										
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										

PHYSICAL DIMENSIONS				TEST INSTRUMENTS	
LENGTH	OK	PIN LENGTH	OK	INDUCTANCE:	CH1062
WIDTH	OK	PIN DISTANCE	OK	TURNS:	/
HIGH	OK	ROW DISTANCE	OK	DCR:	TH-2511
PIN DIAMETER	OK	OTHER	OK	HI-POT:	YH-7112

APPROVED: CHECKED: TESTER:陳秀平2005/05/11



FROM : PANASONIC PHONE NO. : 0769+3377352 AUG. 19 2005 10:50AM P6

SUMITOMO BAKELITE CO LTD.
2-2 1-CHOME UCHISAIWAI-CHO CHIYODA-KU, TOKYO
100 JAPAN

E41429 (M)

Mtl Dsg	Col	Min Thk mm	UL94 Flame Class	Elec	RTI Mech with w/o Imp	RTI Mech Imp	H W I	H A I	H V T R	D 4 9 5	C T I
Phenolic (PF), "SUMIKON スミコン," furnished in granular or pellet form. (Cont'd)											
		3.05	94V-0	150	150	150	0	2	0	4	3
		6.10	94V-0	150	150	150	1	1	0	—	—
PM-635	BN A	0.48	94V-0	150	150	150	—	—	—	—	—
PM-635	BN B	0.48	94V-0	150	150	150	—	—	—	—	—
PM-642	BK	0.48	94V-0	150	150	150	—	—	—	—	—
		1.47	94V-0	150	150	150	0	3	0	—	—
		3.05	94V-0	150	150	150	0	2	0	—	—
		6.10	94V-0	150	150	150	0	2	0	4	3
	BN	0.64	94V-0	150	150	150	0	2	0	—	—
		3.12	94V-0	150	150	150	0	2	0	—	—
PM-642J	BK	1.47	94V-0	150	150	150	0	2	0	4	3
PM-8425	BK,NC	2.50	94V-0	150	150	150	0	2	0	—	—
		3.71	94V-0	150	150	150	3	2	—	—	—
		1.47	94V-0	150	150	150	0	3	0	—	—
	NC,BK,BN	1.60	94V-0	150	150	150	0	2	0	—	—
		3.05	94V-0	150	150	150	0	—	—	—	—
PM-9820	BK	0.79	94V-0	150	150	150	—	—	—	—	—
		0.43	94V-0	150	150	150	—	—	—	—	—
		1.51	94V-0	150	150	150	0	2	0	—	—
		3.76	94V-0	150	150	150	1	2	0	—	—
		1.57	94V-0	150	150	150	0	2	0	—	—
		3.12	94V-0	150	150	150	0	2	0	5	3
PM-8425J	BN	0.79	94V-0	150	150	150	—	—	—	—	—
PM-9630	BK	0.71	94V-0	150	150	150	0	3	0	—	—
		3.40	94V-0	150	150	150	—	—	—	—	—
		3.51	94V-0	150	150	150	0	0	0	—	—
		3.18	94V-0	150	150	150	0	1	0	—	—
PM-8315	BK	3.50	94V-0	150	150	150	3	1	0	—	—
PM-8315J	BN	0.71	94V-0	150	150	150	3	0	0	—	—
		1.47	94V-0	150	150	150	2	0	0	—	—
		3.05	94V-0	150	150	150	0	2	0	—	—
		6.10	94V-0	150	150	150	0	1	0	—	—
PM-8315K	BK	0.78	94V-1	150	150	150	0	1	0	—	—
		1.52	94V-0	150	150	150	—	—	—	—	—
PM-8320J	BK	0.71	94HB	150	150	150	—	—	—	—	—
PM-8330	BK	0.71	94V-1	150	150	150	—	—	—	—	—
		1.57	94V-0	150	150	150	—	—	—	—	—
PM-8400	BK	0.71	94HB	150	150	150	—	—	—	—	—
PM-9830	BK	0.69	94V-0	150	150	150	—	—	—	—	—
		3.18	94V-0	150	150	150	0	0	—	—	—
PM-8415	BK,BN	0.80	94V-0	150	150	150	0	0	0	4	3
		1.60	94V-0	150	150	150	0	—	—	—	—
PM-8430	BK	0.71	94V-1	150	150	150	—	—	—	—	—
PM-8430J	BK	0.71	94V-1	150	150	150	—	—	—	—	—
PM-8800	BK	0.91	94HB	150	150	150	—	—	—	—	—
PM-9321	ALL	0.78	94V-0	150	150	150	—	—	—	—	—
PM-9370	BK	0.53	94V-0	150	150	150	—	—	—	—	—
		1.57	94V-0	150	150	150	0	2	0	—	—
		3.18	94V-0	150	150	150	0	2	0	—	—
PM-9600	BK	3.20	94V-0	150	150	150	0	2	0	5	3
PM-9660	NC,BN	0.46	94V-0	150	150	150	—	—	—	—	—
	BK	0.79	94V-0	150	150	150	—	—	—	—	—
PM-9720	BK	0.75	94V-0	150	150	150	—	—	—	—	—
		1.57	94V-0	150	150	150	2	3	0	—	—
		3.45	94V-0	150	150	150	0	0	0	—	—
PM-8340	BK	0.46	94V-0	150	150	150	0	2	0	—	—
										5	3

458

March 13, 2002

E225143

ODMW2
(Systems, Electrical Insulation) Magnet Wire - Component
HUIYANG GOLDEN OCEAN MAGNET WIRE FACTORY
CHENJIANG RD CHENJIANG TOWN YANWO VILLAGE,
HUIYANG GUANGDONG CHINA

Mtl Dsg	Mark (1)	Coat Type	AWG Type	Temp Class
XUEW, UEWX	Dsg	IEC Polyurethane	MW75C	130

(1)-Marked designations are the same as the material designations.
Marking: Company name, material designation (if marked) designation on package or reel, and Recognized Component Mark.

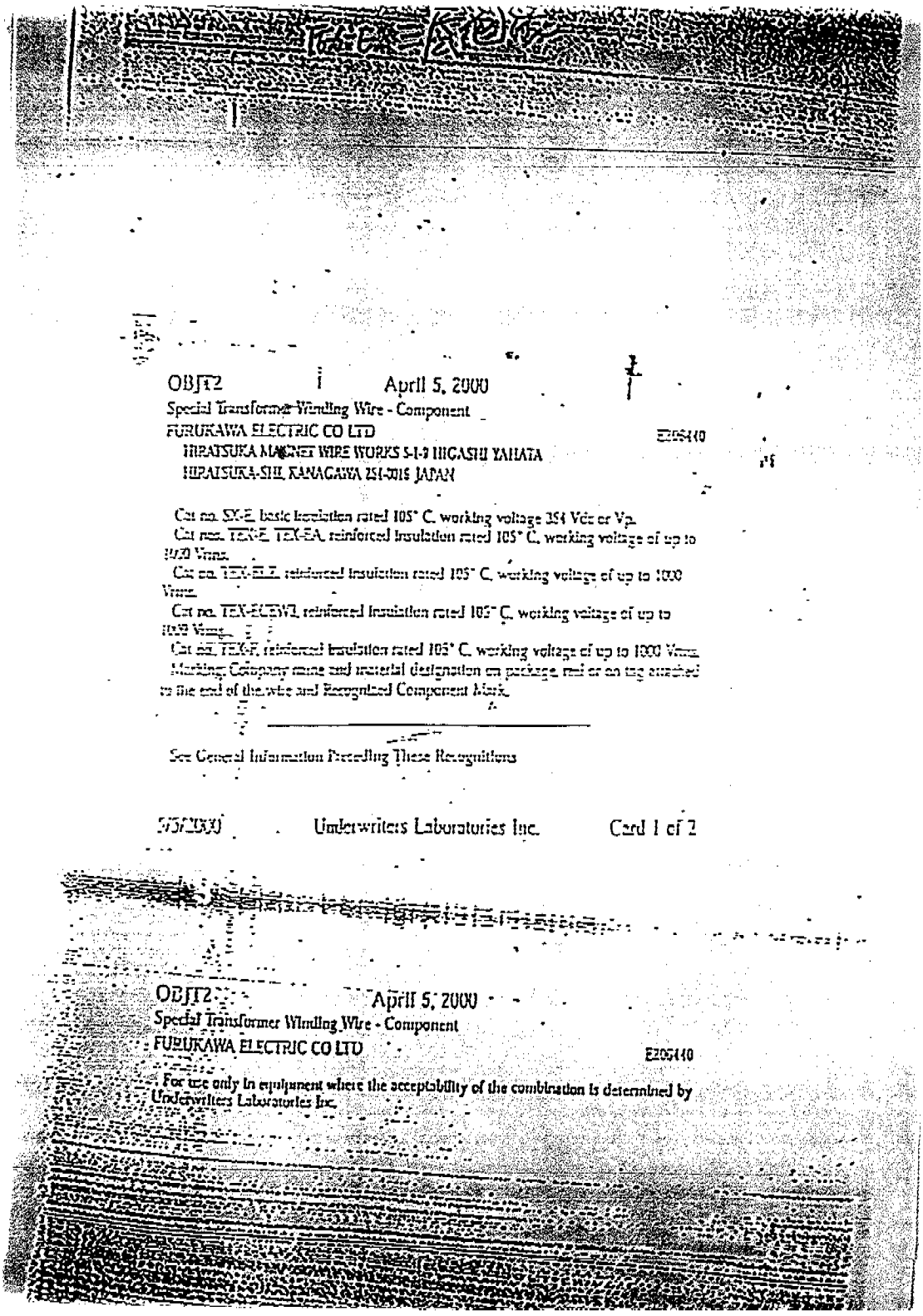
See General Information Preceding These Recognitions
For use only in equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc.

4/11/2002

Underwriters Laboratories Inc.

Card 1 of 1

FROM : PANASONIC PHONE NO. : 0769+3377352 AUG. 19 2005 10:51AM P7



OBJT2 April 5, 2000

Special Transformer Winding Wire - Component

FURUKAWA ELECTRIC CO LTD E205410

HIRATSUKA MAGNET WIRE WORKS 5-1-9 HIGASHI YAHATA

HIRATSUKA-SHI, KANAGAWA 254-0015 JAPAN

Cat no. SX-E, basic insulation rated 105° C, working voltage 354 Vdc or Vp.

Cat nos. TEX-E, TEX-EA, reinforced insulation rated 105° C, working voltage of up to 1000 Vrms.

Cat no. TEX-ELZ, reinforced insulation rated 105° C, working voltage of up to 1000 Vrms.

Cat no. TEX-ECDWZ, reinforced insulation rated 105° C, working voltage of up to 1000 Vrms.

Cat no. TEX-F, reinforced insulation rated 105° C, working voltage of up to 1000 Vrms.

Marking: Company name and material designation on package, reel or on tag attached to the end of the wire and Recognized Component Mark.

See General Information Preceding These Recognitions

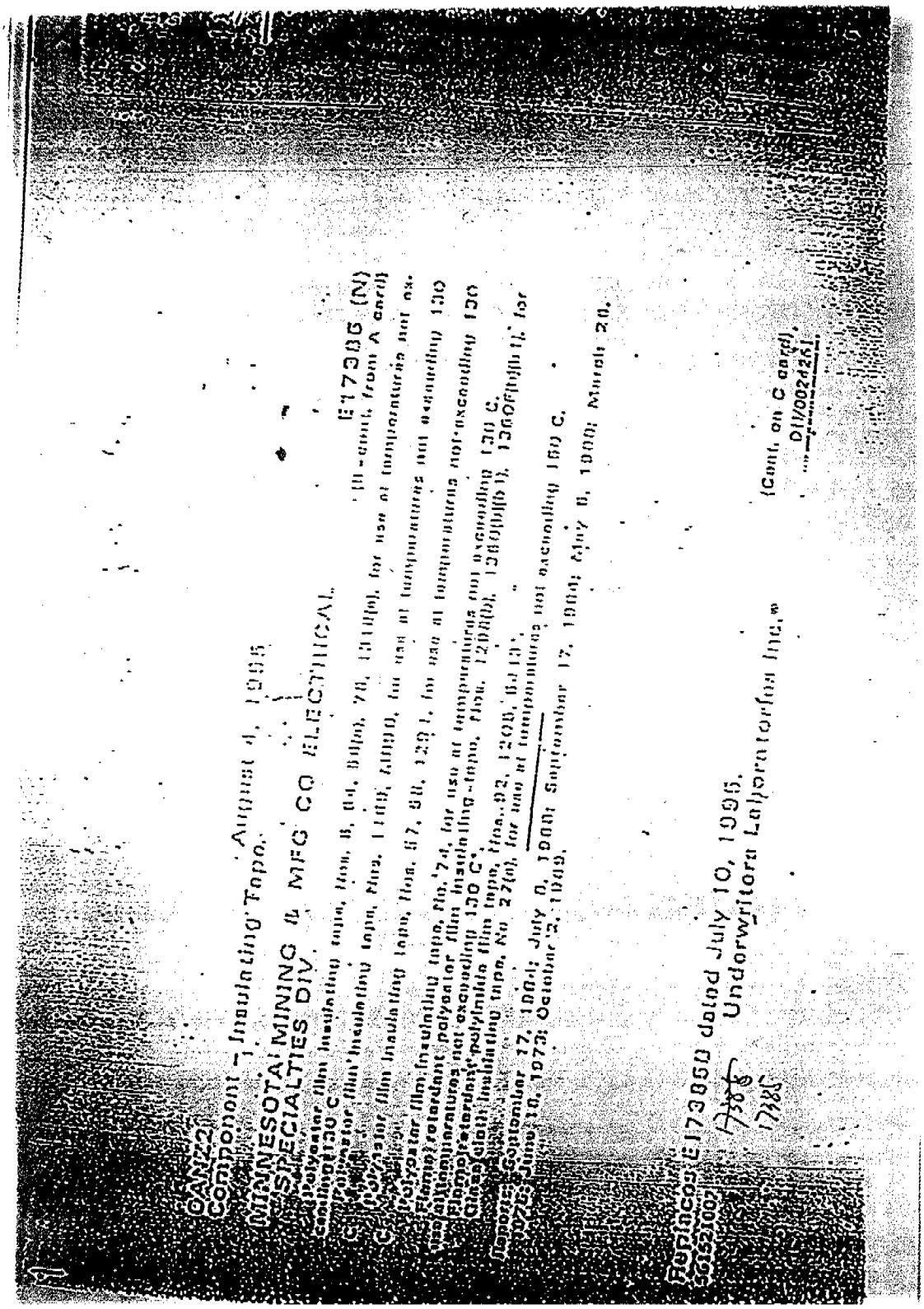
5/5/2000 Underwriters Laboratories Inc. Card 1 of 2

OBJT2 April 5, 2000

Special Transformer Winding Wire - Component

FURUKAWA ELECTRIC CO LTD E205410

For use only in equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc.



FROM : PANASONIC PHONE NO. : 0769+3377352 AUG. 19 2005 10:54AM P9

Underwriters Laboratories Inc.®

GREAT HOLDING INDUSTRIAL CO LTD
MR H WANG
618-13 CHUNG-CHENG RD
SHIN-CHUANG
TAIPEI HSIEN TAIWAN

100 a century of public safety est. 1894

Your most recent listing is shown below. Please review this information and report any inaccuracies to the UL Engineering staff member who handled your UL project.

YDPU2 May 7, 1998
Component - Extruded Tubing, Electrical

GREAT HOLDING INDUSTRIAL CO LTD
618-13 CHUNG-CHENG RD SHIN-CHUANG, TAIPEI HSIEN
TAIWAN

E156356 (S)
(A card)

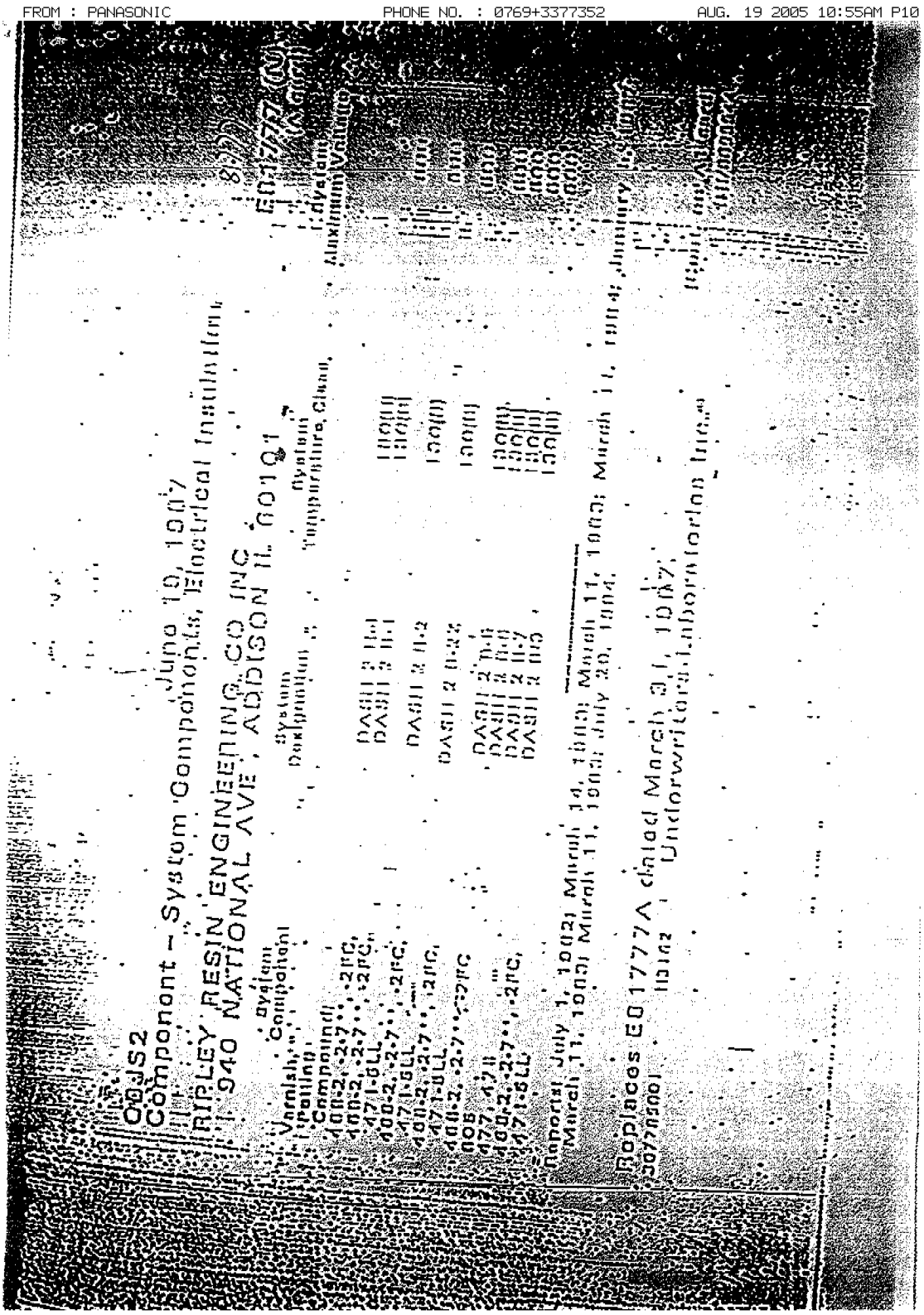
Cat. No.	Max Voltage	Max Temp, C	Cut Recognized	Max Temp Rated On Resistance	Vtm-0 Rated
Polytetrafluoroethylene (PTFE).					
775	150	250	QL,HAT	—	Yes
781	300	200	QL,HAT	—	Yes
785	600	200	QL,HAT	—	Yes

1- Tubing is considered to comply with the optional cut-resistant requirements only if so marked.
2- Tubing is considered to comply with the optional VW-1 flammability requirements only if so marked.
Report January 25, 1994.

915736001 11558 Underwriters Laboratories Inc.® (Cont. on B card)
-815021631
2/3

For information on placing an order for UL Listing Cards in a 3 x 5 inch card format, please refer to the enclosed ordering information.

UNDERWRITERS LABORATORIES INC.


FROM : PANASONIC
PHONE NO. : 0769+3377352
AUG. 19 2005 10:55AM P10

FROM : FAX NO. : 657 Nov. 14 2006 19:33 P1

呈威電子廠

地址:東莞市橫瀝鎮新城工業區 TEL: (0769)3377756-9 3377358

零件承認書

SPECIFCATION FOR APPROVAL

品名 Part Name	變壓器
機種名稱 Model Name	GG 1097 <医疗>
廠商 Manufacture	銘威
料品規格 Material Spec	CORE: 川铁 守端.
承認代號 Part No	G 102B1731A01 *
日期 Date	2006. 11. 10
版本 Rev	V1.0

No. :CR1120b11091

工程印章	核准	SGS	確認	主辦
	STEVE 11/11	11/11	11/10	11/10

FROM : FAX NO. : 657 Nov. 14 2006 19:36 P8

規格承認書

鉛

SPECIFICATION FOR APPROVAL

Customer: 星威

Customer Model: SYS1097(醫療)

Sample NO: G104B1731A01*

Description: TRANSFORMER

Issued Date: 2006/10/11

	"V"	Customer's Signatures	Signature
Full Approved			
Conditional Approved			
Rejected			

REPORTED	CHECKED	QC	APPROVED

Sunny 變壓器事業處制二部

中國廣東省東莞市橫瀝鎮新城工業區
Hengli New Town zone Dong Guan City Guang Dong China
TEL:(0769)83377756-9,83377358 FAX:(0769)83798396
E-mail:sales@sunny-group.com.tw
Web Site:http://www.sunny-group.com

符合RoHS

FROM : FAX NO. : 657 Nov. 14 2006 19:37 P9

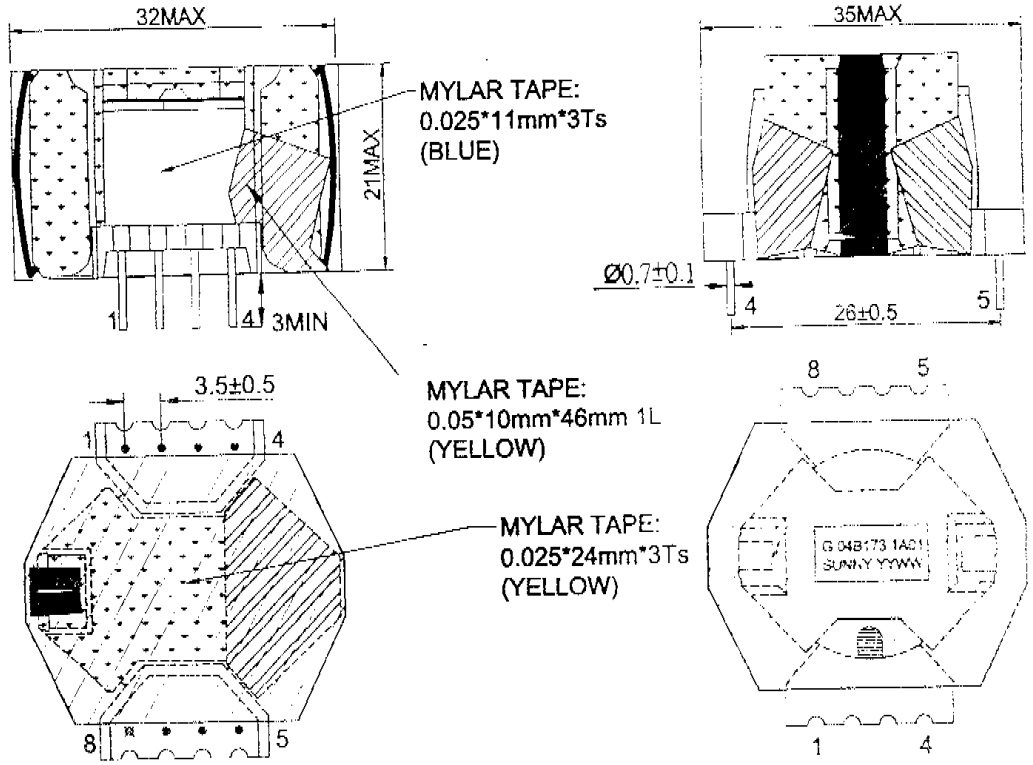
SPECIFICATION FOR APPROVAL

Sunny

變壓器事業處制二部

SUNNY NO.	G104B1731A01*	CUSTOMER MODEL	SYS1097(醫療)
REV. NO.	A	ISSUE DATE	2006/10/11

1.PHYSICAL DIMENSION(UNIT:mm)



NOTE:

1.PIN8,CUT OFF,PIN朝外插入軸心繞線;
2.所有繞組進出線必須穿TEFLON TUBE;
3.繞線須平整緊密,繞制銅箔焊點朝下;
4.三層絕緣線須先剝皮再鍍錫;
5.GAP CORE置於PIN部,成品在底部PIN4-5側貼麥拉:0.05*10mm*1L.
然後包CORE TAPE 0.025*24mm* 3Ts.

APPROVED	CHECKED	REPORTED	PAGE
	06.10.11		1/5

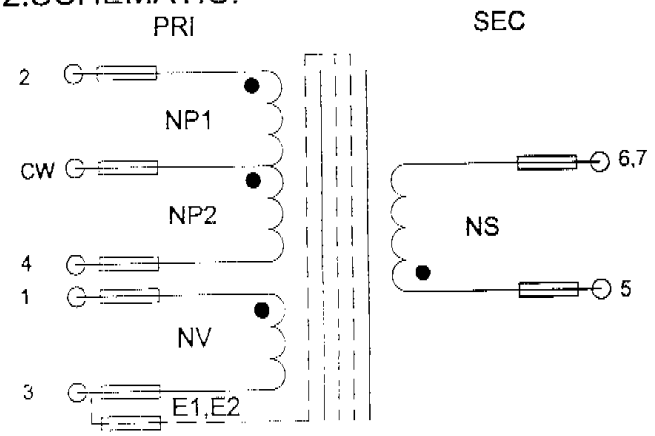
FROM : FAX NO. : 657 Nov. 14 2006 19:37 P10

SPECIFICATION FOR APPROVAL

變壓器事業處制二部

SUNNY NO.	G104B1731A01*	CUSTOMER MODEL	SYS1097(醫療
REV. NO.	A	ISSUE DATE	2006/10/11

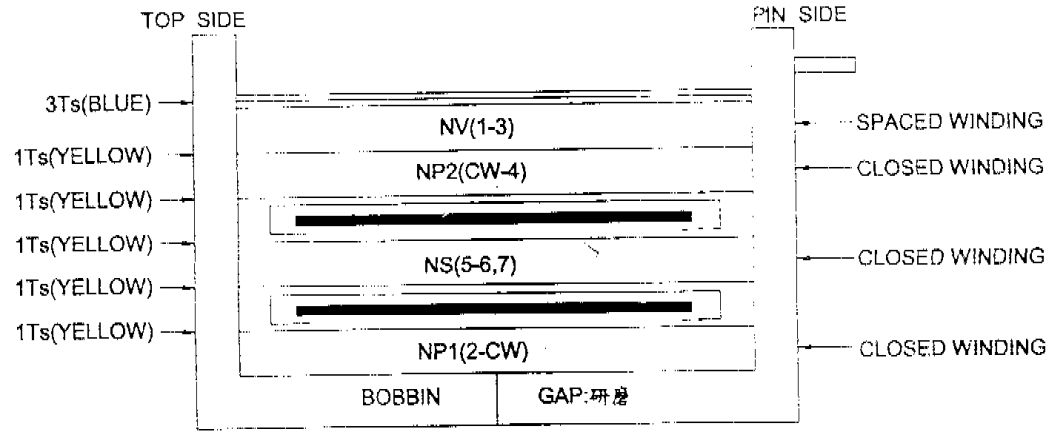
2.SCHEMATIC:



NP1(2-CW) Ø0.55*1P*17Ts	2UEW
E1(-3-)0.05*7mm*0.8Ts	背膠
NS(5-6,7)Ø0.65*2P*8Ts	TEX-E
E2(-3-)0.05*7mm*0.8Ts	背膠
NP2(CW-4)Ø0.55*1P*17Ts	2UEW
NV(1-3)Ø0.2*1P*7Ts	2UEW

3.WINDING CONSTRUCTION:

INSULATION TAPE: 0.025*11.0mm



APPROVED	CHECKED	REPORTED	PAGE
	06.10.11		2/5

Sunny SPECIFICATION FOR APPROVAL

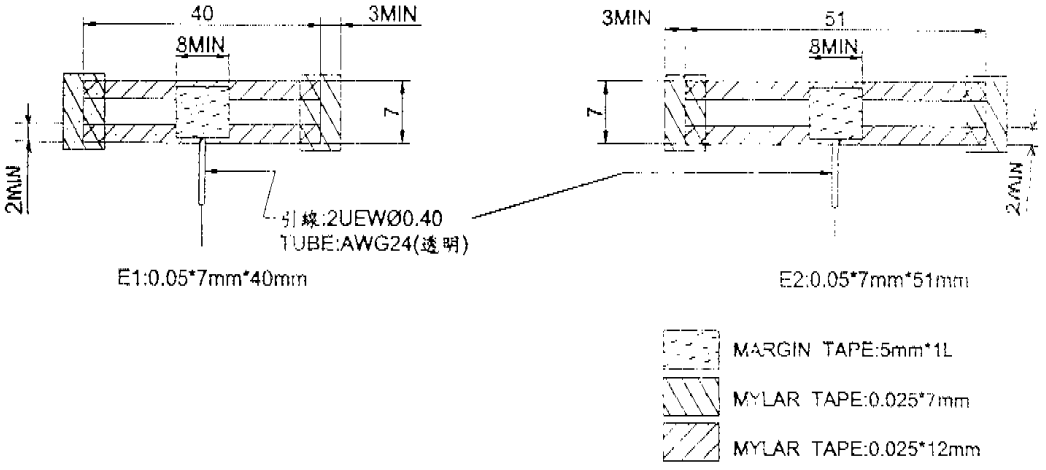
變壓器事業處制二部

SUNNY NO.	G104B1731A01*	CUSTOMER MODEL	SYS1097(醫療)
REV. NO.	A	ISSUE DATE	2006/10/11

4.WINDING TABLE:

Winding No. (繞組)	Margin Tape (擋牆)	Pin (腳位)	Copper Wire (銅線)	Turns (圈數)	Winding Method (繞線方式)	Tape Turns (膠帶圈數)	Tube (套管)
NP1	0	2-CW	Ø0.55*1P	17Ts	密繞	1Ts	23L*16mm/23L*17mm
E1	0	-3-	0.05*7mm	0.8Ts	背靠	1Ts	-24L*14 mm-
NS	0	5-6,7	Ø0.65*2P	8Ts	密繞	1Ts	15L*16mm/15L*16mm
E2	0	-3-	0.05*7mm	0.8Ts	背靠	1Ts	-24L*12 mm-
NP2	0	CW-4	Ø0.55*1P	17Ts	密繞	1Ts	23L*17mm/23L*14mm
NV	0	1-3	Ø0.2*1P	7Ts	密繞	3Ts	30L*15mm/30L*15mm

5.MATERIAL PROCESSING:(UNIT:mm)



APPROVED	CHECKED	REPORTED	PAGE
			3/5

FROM : FAX NO. : 657 Nov. 14 2006 19:38 P12

SPECIFICATION FOR APPROVAL

變壓器事業處制二部

SUNNY NO.	G104B1731A01*	CUSTOMER MODEL	SYS1097(醫療
REV. NO.	A	ISSUE DATE	2006/10/11

6.ELECTRICAL CHARACTERISTIC:

TEST ITEM 測試項目	TEST CONDITION 測試條件	RESULT 規格範圍
INDUCTANCE 電感	@1KHz 0.25V (2-4)	420-450uH
LEAKAGE INDUCTANCE 漏感	@1KHz 0.25V (2-4) SHORTED PIN1,3,5,6,7	15uH MAX
D.C.RESISTANCE 電阻	@25℃ (2-4) (1-3) (5-6,7)	0.2Ω MAX 0.5Ω MAX 0.1Ω MAX
TURN RATIO 圈數比	20KHz 1.0V NP(2-4):34Ts NV:(1-3) NS:(5-6,7)	7±0.3Ts 8±0.3Ts
HI-POT 耐壓	@10mA 60SEC	P-S 4.3KVAC S-C 0.5KVDC

APPROVED	CHECKED	REPORTED	PAGE
			4/5

SPECIFICATION FOR APPROVAL

變壓器事業處制二部

SUNNY NO.	G104B1731A01*	CUSTOMER MODEL	SYS1097(醫療
REV. NO.	A	ISSUE DATE	2006/10/11

7. MATERIAL LIST:

NO.	ITEM	MATERIAL	SUPPLIERS	UL NO.
1	BOBBIN	PHENOLIC RM-10 T375J	CHANG CHUN PLASTICS CO.,LTD	E59481(S)
2	CORE	FERRITE CORE RM-10 NC-2H	NICERAN FERRITE CORE SELECTION GUTDE	
3	WIRE	POLYURETHANE ENAMELLED MW75 2UEW	HUIYANG GOLDEN OCEAN MAGNET WIRE FACTOF	E225143
4	TRIPLE WIRE	TRIPLE INSULATION WIRE TEX-E	FURUKAWA ELECTRIC CO.,LTD	E206440
5	INSULATION TAPE	POLYESTER FILM TAPE 1350-1	MINNESOTA MINING&MFG CO.,LTD	E17385(N)
6	TUBE	TEFLON TUBE	GREAT HOLDING INDUSTRIAL CO..LTD	E156256(S)
7	COPPER FOIL	0.05*7mm	DIANQIANG MATERIAL CO.,LTD.	
8	VARNISH	468-2FC+	RIPLEY RESIN ENGINEENING CO INC	E81777(N)

APPROVED	CHECKED	REPORTED	PAGE
			5/5

FROM : FAX NO. : Apr. 22 2004 09:19 P1

呈威電子廠

Sunny

地址:東莞市橫瀝鎮新城工業區 TEL: (0769)3377756-9 3377358

零 件 承 認 書

SPECIFCATION FOR APPROVAL

品 名 Part Name	变压器		
機種名稱 Model Name	SS1097		
廠 商 Manufacture	曜威		
料品規格 Material Spec	RM-10		
承認代號 Part No	104B1733A01X		
日 期 Date	2005.03.30	版 本 Rev	V1.0

No. : CR112050 3133

簽名	品管 QC	批准 APPROVE	覆核 REVIEW	審核 VIEW	工程印章 ISSUED STAMP
日期	2005.3.30	2005.3.30	3/30	3/30	2005.3.31

FROM : FAX NO. : Apr. 22 2004 09:20 P2

承認書工程測試基本資料

料號: 104B1733A01K 型號: _____ 廠商: 日隆

机种: SYS1097(五版) 測試時間: 3/27 負責人: 任翔

一.外觀及尺寸測試:

1. 長: 32mm 寬: 26±0.5 高: 21mm 其他: _____

2. 外觀: _____

二:机械性能:

1. 良好

2. _____

3. _____

三.電氣測試:

1. OK

2. _____

3. _____

4. _____

5. _____

6. _____

四.其他: _____

五.測試結論: 為用于1097正常

FROM : FAX NO. : Apr. 22 2004 09:20 P3

規 格 承 認 書

SPECIFICATION FOR APPROVAL

Customer: 呈威

Customer Model: SYS1097(醫療)

Sample No: 104B1733A01*

Description: TRANSFORMER

Issued Date: 2005/03/22

	"V"	Customer's Signatures	Signature
Full Approved			
Conditional Approved			
Rejected			

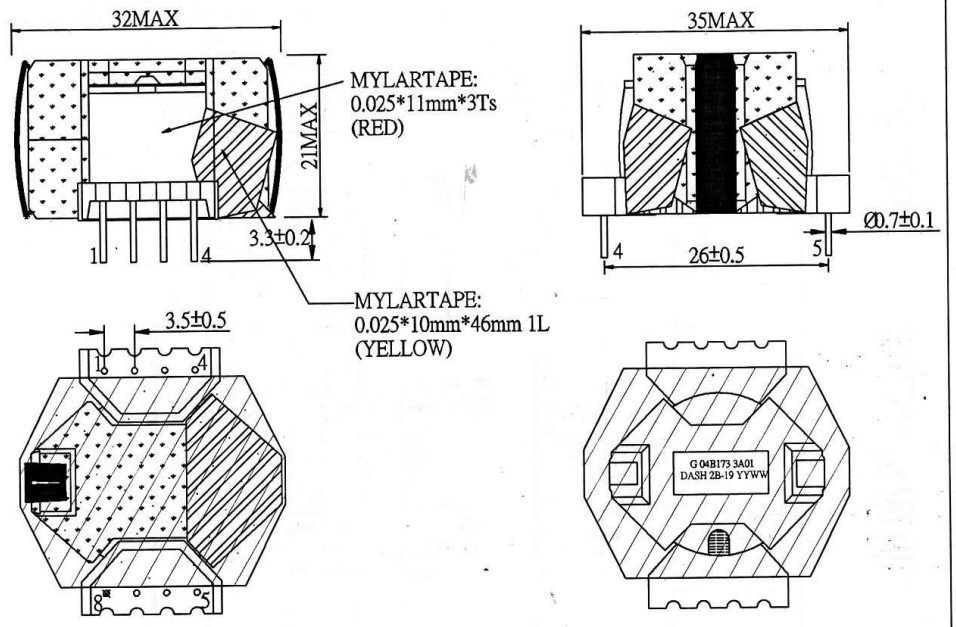
DRAWER	CHECKED	QC	APPROVED
陳秀平 2005/03/22			

Sunny 曜威電子廠
中國廣東省東莞市橫瀝鎮新城工業區
Hengli New Town zone Dong Guan City Guang Dong China.
TEL:(0769) 3377756-9,3377358 FAX:(0769) 3721585
E-mail: sales@sunny-group.com
Web Site: http://www.sunny-group. com.

SPECIFICATION FOR APPROVAL
曜威電子厂

PART NO.	G104B1733A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097(醫療)
REV. NO.	A	ISSUE DATE	2010/10/19

1.PHYSICAL DIMENSION(UNIT:mm)



NOTE:
1.PIN8 CUT OFF,PIN朝外插入軸心繞線;
2.所有繞組進出線必須穿 TEFLON TUBE;
3.繞線須平整緊密,繞制銅箔焊點朝下;
4.三層絕緣線須先剝皮再鍍錫;
5.GAP CORE置於PIN部,成品在底部PIN4-5側貼瑪拉:0.025*10mm*1L.
6.成品包 T*W=0.025*24mm*3Ts MYLAR TAPE.

APPROVED BY	CHECKED BY	REPORTED BY
劉傑2010/10/19	歐陽海歡2010/10/19	唐湘2010/10/19

FROM : FAX NO. : Apr. 22 2004 09:21 P5

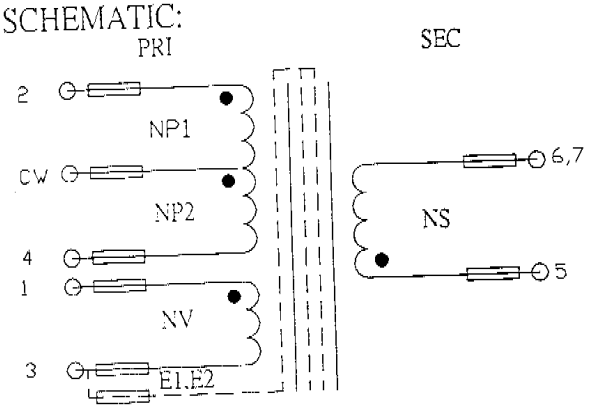
Sunny

SPECIFICATION FOR APPROVAL

曜威電子厂

PART NO.	104B1733A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097(醫療)
REV. NO.	A	ISSUE DATE	2005/03/22

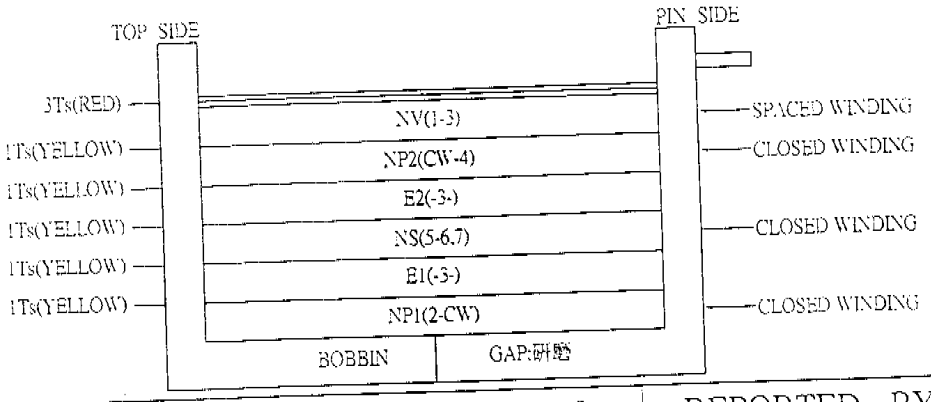
2.SCHEMATIC:



NP1(2-CW) Ø0.55*1P*17Ts 2UEW
E1(-3-)0.05*9mm*0.8Ts 背膠
NS(5-6,7)Ø0.65*3P*7Ts TEX-E
E2(-3-)0.05*9mm*0.8Ts 背膠
NP2(CW-4)Ø0.55*1P*17Ts 2UEW
NV(1-3)Ø0.2*1P*10Ts 2UEW

3.WINDING CONSTRUCTION:

INSULATION TAPE: 0.025*11.0mm



APPROVED BY	CHECKED BY	REPORTED BY
		ChenXiuPing

FROM : FAX NO. : Apr. 22 2004 09:22 P6

SPECIFICATION FOR APPROVAL

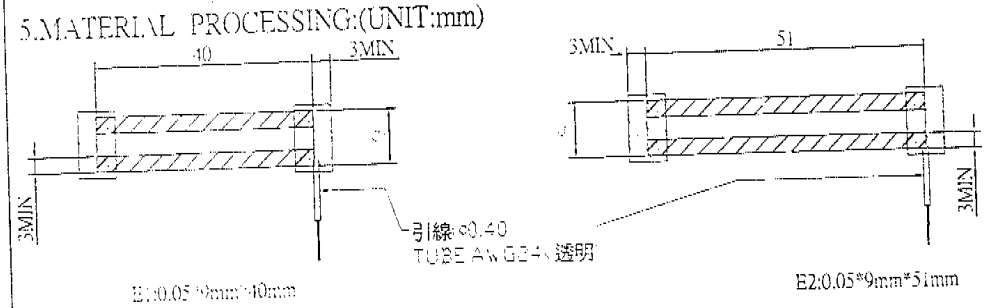
曜威電子厂

PART NO.	104B1733A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097((醫療)
REV. NO.	A	ISSUE DATE	2005/03/22

4.WINDING TABLE:

Winding No. (繞組)	Margin Tap (檔線)	Pin (腳位)	Copper Wire (銅線)	Turns (圈數)	Winding Method (繞線方式)	Tape Turns (膠帶圈數)	Tube (套管)
NP1	0	2-CW	Φ0.55*1P	17Ts	密繞	1Ts	23*16mm/23*17mm
E1	0	-3-	0.05*9mm	0.8Ts	背膠	1Ts	-24*13mm-
NS	0	5-6,7	Φ0.65*3P	7Ts	密繞	1Ts	13*16mm/13*16mm
E2	0	-3-	0.05*9mm	0.8Ts	背膠	1Ts	-24*12mm-
NP2	0	CW-4	Φ0.55*1P	17Ts	密繞	1Ts	23*17mm/23*14mm
NV	0	1-3	Φ0.2*1P	10Ts	疏繞	3Ts	30*15mm/30*15mm

5.MATERIAL PROCESSING:(UNIT:mm)



APPROVED BY	CHECKED BY	REPORTED BY
		ChenXiuPing

FROM : FAX NO. : Apr. 22 2004 09:22 P7

Sunny

SPECIFICATION FOR APPROVAL

曜威電子厂

PART NO.	104B1733A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1097(醫療)
REV. NO.	A	ISSUE DATE	2005/03/22

6.ELECTRICAL CHARACTERISTIC:

TEST ITEM 測試項目	TEST CONDITION 測試條件	RESULT 規格範圍
INDUCTANCE 電感	@1KHz 0.25V (2-4)	420-450uH
LEAKAGE INDUCTANCE 漏感	@1KHz 0.25V (2-4) SHORTED PIN1.3.5.6.7	15uH MAX
TURN RATIO 圈數比	20KHz 1.0V NP(2-4):34Ts NV:(1-3) NS:(5-6,7)	10±0.3Ts 7±0.3Ts
HI-POT 耐壓	@10mA 60SEC	P-S 4.3KVAC S-C 0.5KVDC

APPROVED BY	CHECKED BY	REPORTED BY
		ChenXiuPing

FROM : FAX NO. : Apr. 22 2004 09:23 P8

Sunny

SPECIFICATION FOR APPROVAL

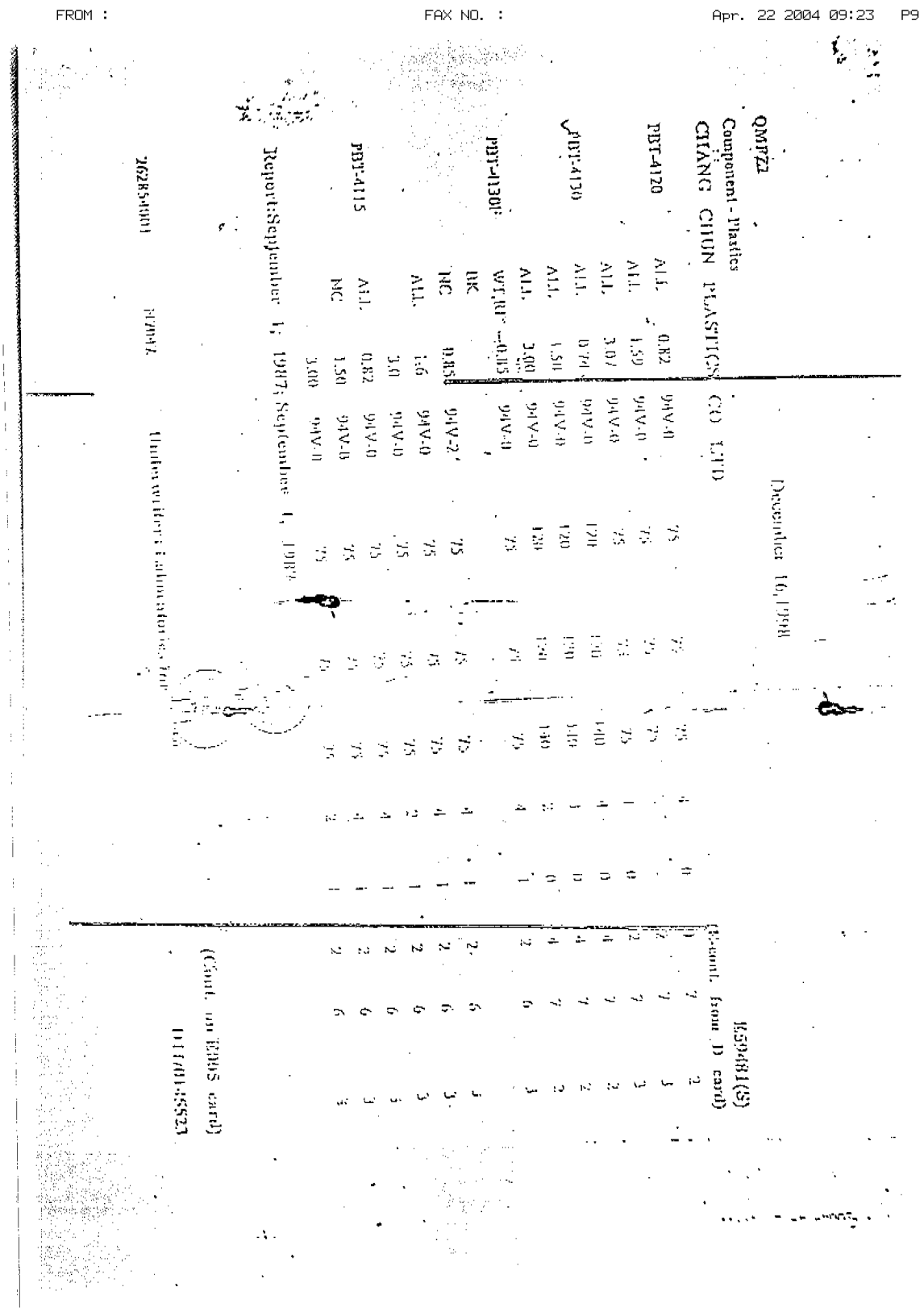
曜威電子厂

PART NO.	104B1733A01*	SUNNY NO.	
PART NAME	RM-10 X'FMR	CUSTOMER MODEL	SYS1007(醫療)
REV. NO.	A	ISSUE DATE	2005/03/22

7. MATERIAL LIST:

NO.	ITEM	MATERIAL	SUPPLIERS	UL NO.
1	BOBBIN	PHENOLIC RM-10 8PIN YW-470 OR EQUIV	CHANG CHUN PLASTICS CO.,LTD.	E59481(S)
2	CORE	FERITE CORE RM-10 NC-2H	NICERAN FERRITE CORE SELECTION GUTDE	
3	WIRE	POLYURETHANE ENAMELLED MW75-C 2UEW	HUIYANG GOLDEN OCEAN MAGNET WIRE FACTOR	E225143
4	TRIPLE WIRE	TRIPLE INSULATION WIRE TEX-E	FURUKAWA ELECTRIC CO..LTD	E206440
5	INSULATION TAPE	POLYESTER FILM TAPE 1350	MINNESOTA MINING&MFG CO..LTD	E17385(N)
6	TUBE	TEFLON TUBE	GREAT HOLDING INDUSTRIAL CO..LTD	E156256
7	MARGIN TAPE	FIBER GLASS CLOTH 3M #44	MINNESOTA MINING&MFG CO..LTD	E17385(N)
8	COPPER FOIL	0.05*9mm	DIANQIANG MATERIAL CO..LTD.	
9	VARNISH	468-2PC	RIPLEY RESIN ENGINEENING CO INC	ES1777(N)

APPROVED BY	CHECKED BY	REPORTED BY
		ChenXiuPing


FROM :
FAX NO. :
Apr. 22 2004 09:23 P9
QMFZ2
Component - Plastics
CHANG CHUN PLASTICS CO. LTD
December 16, 1998
PBT-4120
PBT-4130
PBT-4115
Report:September 1, 1987; September 1, 1989
E59481(S)
(Cont. on EBIS card)
111701155327

OIBMW2

March 19, 2002

(Systems, Electrical Insulation) Magnet Wire - Component

E225143

HUIYANG GOLDEN OCEAN MAGNET WIRE FACTORY
CHENJIANG RD CHENJIANG TOWN YANWU VILLAGE,
HUIYANG GUANGDONG CHINA

Mtl Dsg	Mark Dsg	Coat Type	ANSI Type	Temp Class
XUEW, UEWX	(1)	IIC Polyurethane	MW75C	130

(1)-Marked designations are the same as the material designations.
Marking: Company name, material designation or marked designation on package or reel, and Recognized Component Mark.

See General Information Preceding These Recognitions
For use only in equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc.

4/1/2002

Underwriters Laboratories Inc.

Card 1 of 1

FROM : FAX NO. : Apr. 22 2004 09:25 P1

T66-E 三层绝缘

April 5, 2000

OBJT2 E206440

Special Transformer Winding Wire - Component

FURUKAWA ELECTRIC CO LTD

HIRATSUKA MAGNET WIRE WORKS 5-1-9 HIGASHI YAHATA

HIRATSUKA-SHI, KANAGAWA 254-0016 JAPAN

Cat no. SX-E, basic insulation rated 105° C, working voltage 354 Vdc or Vp.

Cat nos. TEX-E, TEX-EA, reinforced insulation rated 105° C, working voltage of up to 1050 Vrms.

Cat no. TEX-ELZ, reinforced insulation rated 105° C, working voltage of up to 1000 Vrms.

Cat no. TEX-ECEWJ, reinforced insulation rated 105° C, working voltage of up to 1050 Vrms.

Cat no. TEX-F, reinforced insulation rated 105° C, working voltage of up to 1000 Vrms.

Marking: Company name and material designation on package, reel or on tag attached to the end of the wire and Recognized Component Mark.

See General Information Preceding These Recognitions

Underwriters Laboratories Inc. Card 1 of 2

5/5/2000

April 5, 2000

OBJT2 E206440

Special Transformer Winding Wire - Component

FURUKAWA ELECTRIC CO LTD

For use only in equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc.

CAHZZ
Component - Insulating Tape

MINNESOTA MINING & MFG CO ELECTRICAL SPECIALTIES DIV

E17385 (N)

(E-cont. from A card)

Polyester film insulating tape, Nos. 5, 5-1, 56hb, 76, [illegible] for use at temperatures not exceeding 130 C

Polyester film insulating tape, Nos. [illegible] for use at temperatures not exceeding 130 C

Polyester film insulating tape, Nos. 92, 99, 1291, for use at temperatures not exceeding 130 C

Polyester film insulating tape, No. 74, for use at temperatures not exceeding 130 C

Flame retardant polyester film insulating tape, Nos. 1298(b), 1360(b)(h-1), 1360(f)(h-1), for use at temperatures not exceeding 130 C.

Flame retardant polyimide film tape, Nos. 92, 1205, 1213.

Glass cloth insulating tape, No. 27(a), for use at temperatures not exceeding 150 C.

Reports: September 17, 1980; July 8, 1980; September 17, 1984; May 6, 1988; March 20, 1975; June 18, 1973; October 2, 1969.

Replaces E173850 dated July 10, 1995.

56152102

Underwriters Laboratories Inc.®

(Cont. on C card)

DIV/002.EXI

FROM : FAX NO. : Apr. 22 2004 09:26 P3

Melville, New York • (516) 271-6200
Santa Clara, California • (408) 985-2
Research Triangle Park, North Carolina • (919) 549-1400
...ham, Washington • (360) 647-55

Underwriters Laboratories Inc.®

a century of public safety est. 1894

GREAT HOLDING INDUSTRIAL CO LTD
MR H WANG
516-13 CHUNG-CHENG RD
SHIN-CHUANG
TAIPEI HSIEN TAIWAN

Your most recent listing is shown below. Please review this information and report any inaccuracies to the UL Engineering staff member who handled your UL project.

May 7, 1998

YDPU2
Component - Extruded Tubing, Electrical

E156256 (S)
(A mod)

GREAT HOLDING INDUSTRIAL CO LTD
516-13 CHUNG-CHENG RD SHIN-CHUANG, TAIPEI HSIEN
TAIWAN

Cat. No.	Max Voltage	Max Temp. C	Cal Recognized	Max Temp Rated OR Resistance *,** C	VW-1 Rated **
Polytetrafluoroethylene (PTFE),					
TFE	150	200	BL,HAT	—	Yes
TFT	300	200	BL,HAT	—	Yes
TFS	600	200	BL,HAT	—	Yes

*- Tubing is considered to comply with the optional oil-resistant requirements only if so marked.
**- Tubing is considered to comply with the optional VW-1 flammability requirements only if so marked.

Report: January 26, 1994

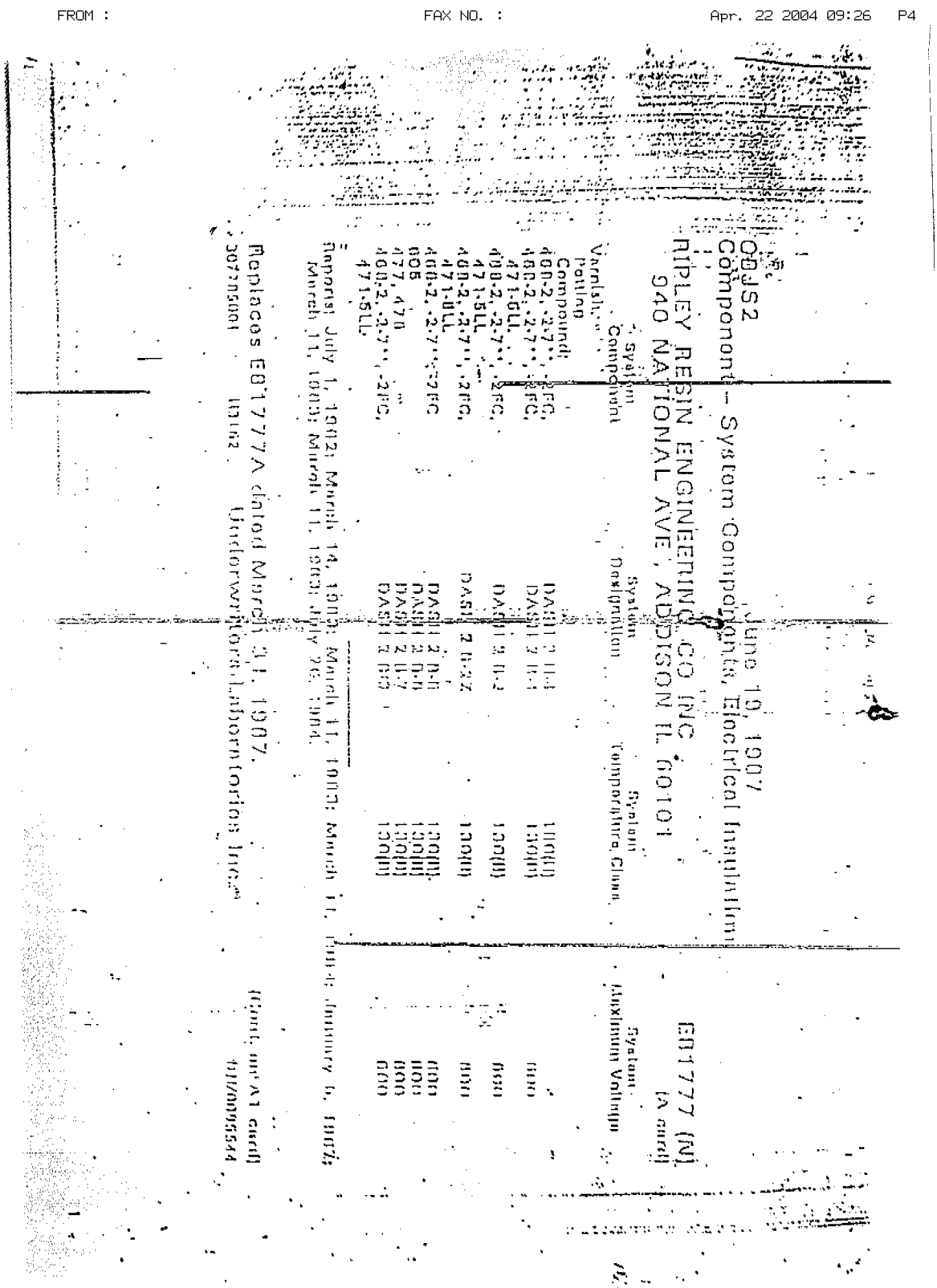
(Cont. on 2 card)
-011/02(7/5)
212

915930001 113068 Underwriters Laboratories Inc.®

For information on placing an order for UL Listing Cards in a 3 x 5 inch card format, please refer to the enclosed ordering information.

UNDERWRITERS LABORATORIES INC.

A not-for-profit organization dedicated to public safety and committed to quality service


FROM :
FAX NO. :
Apr. 22 2004 09:26 P4
OBJS2
Component – System Component, Electrical Insulation
June 10, 1997
RIPLEY RESIN ENGINEERING CO INC
940 NATIONAL AVE, ADDISON IL 60101
E81777 (N)
(A card)
Replaces E81777A dated March 24, 1997.
Underwriters Laboratories Inc.

PROPRIETARY INFORMATION:
PROPRIETARY OF GLOBTEK, INC. ANY REPRODUCTION, DISCLOSURE OR USE OF THIS DRAWING, IN WHOLE OR IN PART, IS HEREBY PROHIBITED EXCEPT AS SPECIFIED IN WRITING BY GLOBTEK, INC.

China RoHS SELF DISCLOSURE TABLE

有毒有害物质或元素名称及含量标准形式 Name and concentration of hazardous substance or element in product						
零件名 Name of part	有毒有害物质或元素 Hazardous substance or element					
	铅 Pb	汞 Hg	镉 Cd	六价铬 Cr(VI)	多溴联苯 PBB	多溴二苯醚 PBDE
输出线材料 DC CABLE	X	O	O	O	O	O
输入插座 AC SOCKET	X	O	O	O	O	O
二极管 SMD ZENER	X	O	O	O	O	O

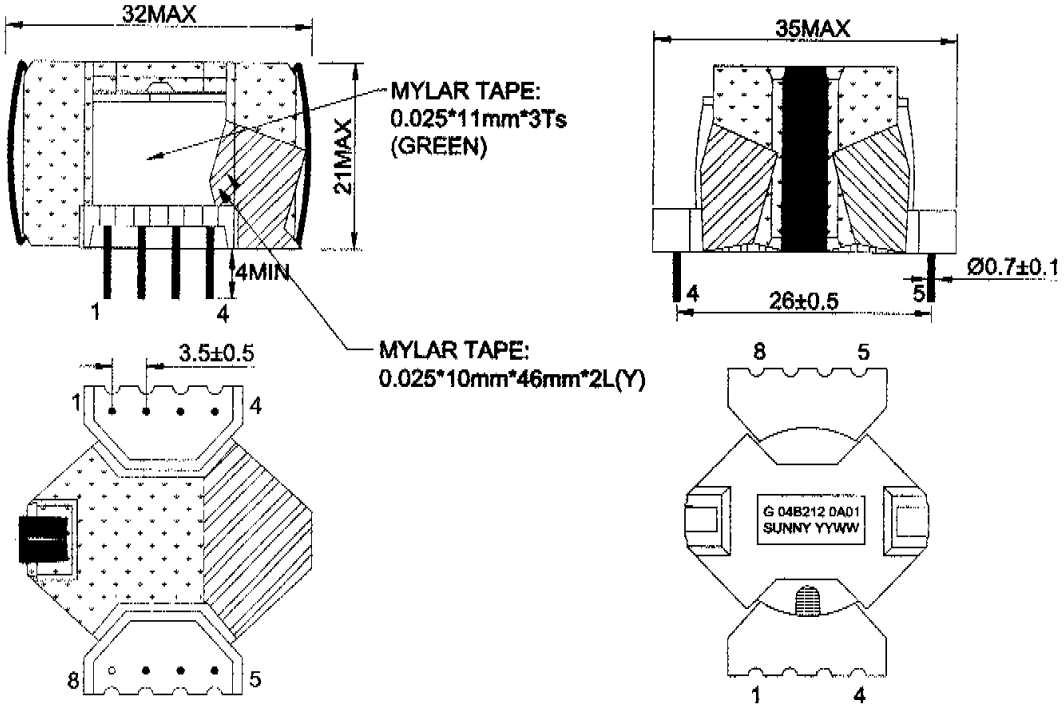
O: 表示该有害物质在这部件所有同质材料中的含量均在SJ/T 11363-2006规定的限量要求以下
O: refers to the concentration of this hazard substance in the all homogenous materials in this part is below the concentration limit as stipulated in the standard SJ/T 11363-2006.

X: 表示该有害有害物质至少在该部件中的某一均质材料中的含量超出 SJ/T 11363-2006标准的限量要求.
X: refers to the concentration of this hazard substance at least in a homogenous material is higher than the concentration limit as stipulated in the standard SJ/T 11363-2006

GlobTek, Inc. www.globtek.com	186 Veterans Dr. Northvale, NJ 07647 Tel. 201-784-1000 Fax 201.784.0111	
DWG TITLE: SWITCHER , ☐ WATT, ☐ V@ ☐ A, SINGLE OUTPUT, DESKTOP UNIVERSAL INPUT, MEDICAL, CLASS II FE		
MODEL NO: GTM21097- ☐		REV. E
PART NO: ☐		SHEET 5 OF 5

NO.	G104B2120A01*	CUSTOMER MODEL	SYS1097
REV. NO.	A	ISSUE DATE	2007/08/22

1.PHYSICAL DIMENSION(UNIT:mm)



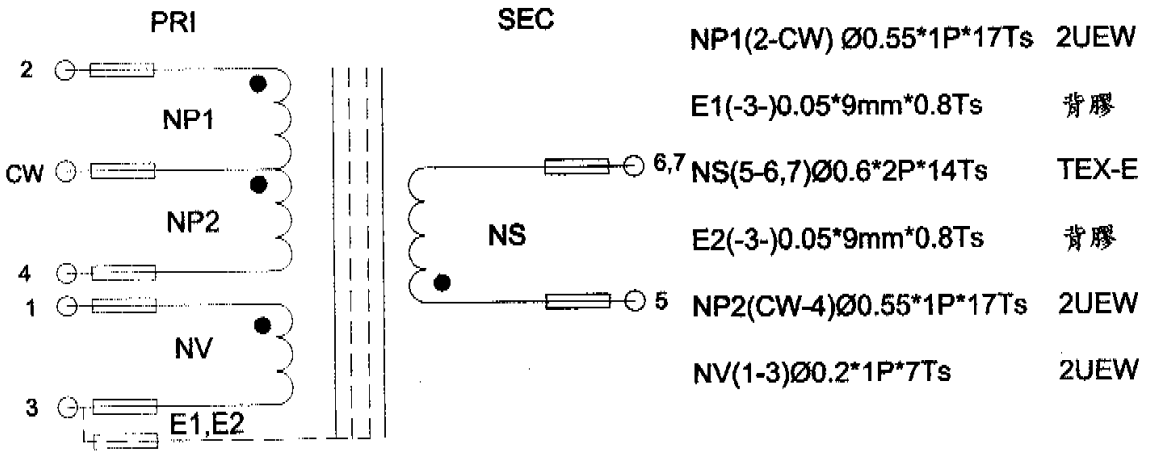
NOTE:

1.PIN8,CUT OFF,PIN朝外插入軸心繞線;
2.所有繞組進出線必須穿 TEFLON TUBE;
3.繞線須平整緊密,繞制銅箔焊點朝下;
4.三層絕緣線須先剝皮再鍍錫;
5.GAP CORE置於PIN部,成品在底部PIN4-5側貼麥拉:0.025*10mm*46mm* 2L;
6.產品含浸后需沿線包包TAPE:0.025*13mm*1Ts.

APPROVED	CHECKED	PROJECT	LAYOUT	PAGE
	邓子华 8/22	张令安 8/22	8/22	1/6

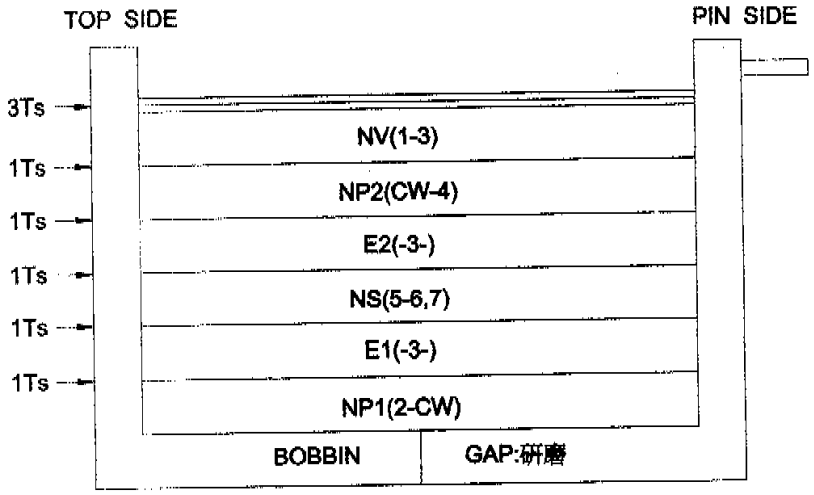
NO.	G104B2120A01*	CUSTOMER MODEL	SYS1097
REV. NO.	A	ISSUE DATE	2007/08/22

2.SCHEMATIC:



3.WINDING CONSTRUCTION:

INSULATION TAPE:0.025*11.0mm



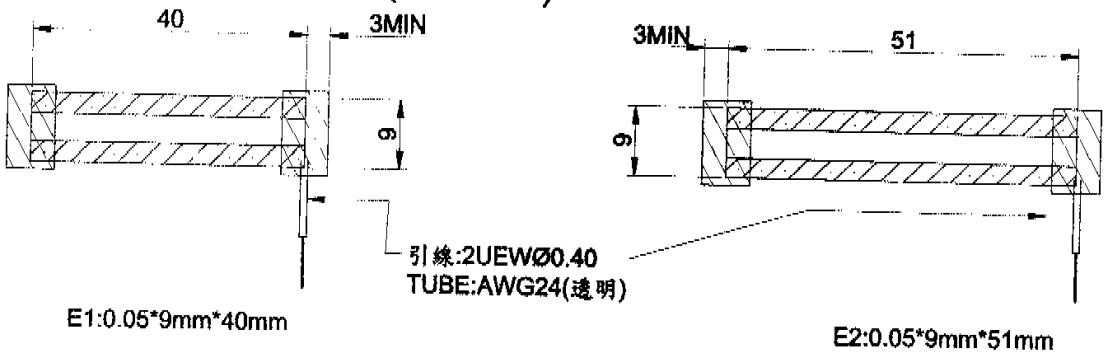
APPROVED	CHECKED	PROJECT	LAYOUT	PAGE
	8/22 8/22			2/6

NO.	G104B2120A01*	CUSTOMER MODEL	SYS1097
REV. NO.	A	ISSUE DATE	2007/08/22

4.WINDING TABLE:

Winding No. (繞組)	Margin Tape (檔腳)	Pin (腳位)	Copper Wire (銅線)	Turns (圈數)	Winding Method (繞線方式)	Tape Turns (膠帶圈數)	Tube (套管)
NP1	0	2-CW	Ø0.55*1P	17Ts	密繞	1Ts	23L*16mm/23L*17mm
E1	0	-3-	0.05*9mm	0.8Ts	背膠	1Ts	-24L*14mm-
NS	0	5-6,7	Ø0.6*2P	14Ts	密繞	1Ts	15L*16mm/15L*16mm
E2	0	-3-	0.05*9mm	0.8Ts	背膠	1Ts	-24L*12mm-
NP2	0	CW-4	Ø0.55*1P	17Ts	密繞	1Ts	(23L*17mm)/23L*14mm
NV	0	1-3	Ø0.2*1P	7Ts	疏繞	3Ts	30L*15mm/30L*15mm

5.MATERIAL PROCESSING:(UNIT:mm)



E1:0.05*9mm*40mm

E2:0.05*9mm*51mm

NO.	G104B2120A01*	CUSTOMER MODEL	SYS1097
REV. NO.	A	ISSUE DATE	2007/08/22

6.ELECTRICAL CHARACTERISTIC:

TEST ITEM 測試項目	TEST CONDITION 測試條件	RESULT 規格範圍
INDUCTANCE 電感	@1KHz 0.25V (2-4)	420-450uH
LEAKAGE INDUCTANCE 漏感	@1KHz 0.25V (2-4) SHORTED PIN1,3,5,6,7	10uH MAX
TURN RATIO 圈數比	20KHz 1.0V NP(2-4):34Ts NV:(1-3) NS:(5-6,7)	7±0.3Ts 14±0.3Ts
HI-POT 耐壓	@10mA 1MIN	P-S 3750VAC P-C 500VDC S-C 3750VAC

NO.	G104B2120A01*	CUSTOMER MODEL	SYS1097
REV. NO.	A	ISSUE DATE	2007/08/22

7. MATERIAL LIST:

NO.	ITEM	MATERIAL	SUPPLIERS	UL NO.
1	BOBBIN	PHENOLIC RM-10 8PIN YW-470	CHANG CHUN PLASTICS CO.,LTD.	E59481(S)
2	CORE	FERRITE CORE RM-10 NC-2H	NICERAN FERRITE CORE SELECTION GUTDE	
3	WIRE	POLYURETHANE ENAMELLED MW75-C 2UEW	HUIYANG GOLDEN OCEAN MAGNET WIRE FACTORY	E225143
4	TRIPLE WIRE	TRIPLE INSULATION WIRE TEX-E	FURUKAWA ELECTRIC CO.,LTD	E225143
5	INSULATION TAPE	POLYESTER FILM TAPE 1350-1	MINNESOTA MINING&MFG CO.,LTD	E17385(N)
6	TUBE	TEFLON TUBE	GREAT HOLDING INDUSTRIAL CO.,LTD	E156256(S)
7	COPPER FOIL	0.05*9mm	DIANQIANG MATERIAL CO.,LTD	
8	VARNISH	468-2FC	RIPLEY RESIN ENGINEENING CO INC	E81777(N)
單重:33.68g				

PROPRIETARY INFORMATION:
PROPRIETARY OF GLOBTEK, INC. ANY REPRODUCTION, DISCLOSURE OR USE OF THIS DRAWING, IN WHOLE OR IN PART, IS HEREBY PROHIBITED EXCEPT AS SPECIFIED IN WRITING BY GLOBTEK, INC.

REVISION			
REV	DESCRIPTION	DATE	APPROVED
A	INITIALRELEASE, RFS. 5931, 6135, 6970, 8328	08/26/05	DMR
B	UPDATE OVERLOAD, ADD VCCI, ROHS, RFS. 9693, JB	11/06/06	HM
C	UPDATE SPEC., RFS. 16421, JB	06/10/09	HM
D	UPDATE LEAKAGE CURRENT, RFS.16145,HM	07/31/09	HM
E	UPDATE INPUT CURRENT, RFS.17182,HM	10/01/09	HM

All models under this series are Certified to be in compliance with all the applicable requirements of UL60601-1 2nd Edition, CSA 22.2 No.601.1-M90 and EN 60601-1:A2. Globtek's Medical power supplies are designed to be used in applications that do not connect the output to Patient Circuits directly. The power supply can be used in systems with patient applied parts only when appropriate system level isolation is provided by the end user.
For medical units used in the USA and Canada, a UL/CSA approved hospital grade AC cord of type SV or better (AWG18 or bigger) shall be used (ie. Globtek PN: 1191068F0701). This is required to comply with the relevant standards and ensure proper grounding reliability.

1. ELECTRICAL SPECIFICATIONS:

INPUT:

INPUT VOLTAGE:	90Vac TO 264Vac
INPUT CURRENT:	<1.6Arms AT 90Vac INPUT
INPUT FREQUENCY:	47HZ - 63HZ

OUTPUT

OUTPUT VOLTAGE:	____ V
OUTPUT CURRENT:	____ A, NO LOAD TO FULL LOAD, NO MINIMUM LOAD REQUIRED
RATED OUTPUT POWER:	____ WATTS, MAXIMUM
OUTPUT REGULATION:	+/- 5% MEASURED AT THE OUTPUT CONNECTOR
LINE VOLTAGE REGULATION:	+/- 1% TYPICAL MEASURED AT FULL LOAD
HIGH FREQ. OUTPUT RIPPLE:	1% OF OUTPUT VOLTAGE , PEAK TO PEAK, TYPICAL
TURN-ON/TURN-OFF OVERSHOOT:	5% MAXIMUM, 1mS TYPICAL RECOVERY TIME FOR 25% STEP LOAD
TURN-ON DELAY:	1 SECOND, TYPICAL
HOLD-UP TIME:	10mS TYPICAL AT NOMINAL INPUT VOLTAGE AND FULL LOAD
INRUSH CURRENT:	20A TYPICAL AT 115Vac INPUT AND 30A TYPICAL AT 230Vac INPUT
SWITCHING FREQUECNCY:	100KHZ TYPICAL
EFFICIENCY:	75% TYPICAL AT NOMINAL INPUT AND FULL LOAD
OUTPUT INDICATOR:	GREEN LED FOR OUTPUT INDICATOR

PROTECTION

OVER-VOLTAGE:	VOLTAGE LIMITED BY CROWBAR METHOD, OUTPUT WILL AUTORECOVER UPON REMOVAL OF OVER VOLTAGE
OVERLOAD:	HICCUP MODE OUTPUT WILL AUTO-RECOVERY UPON REMOVAL OF OVERLOAD
SHORT CIRCUIT:	HICUP MODE, OUTPUT WILL AUTORECOVER UPON REMOVAL OF SHORT
INPUT PROTECTION:	INPUT LINE AND NEUTRAL FUSING

Foot Note:
Globtek Inc. will not be liable for the safety and performance of these power supplies if unauthorized access and repair occurs. End user should consult for the proper installation instruction the applicable UL,CSA and EN standards.

Limitation of Use:
Globtek product are not authorized for use as mission critical components in life support, hazardous environment, nuclear or aircraft applications without prior written approval from the CEO of Globtek Inc.

Contents of this document are subject to change without prior notice

C	PART NO	REV.	DESCRIPTION	NOTES
	TABULATION BLOCK			

TOLERANCES:
DECIMALS .xx +/- 0.1 .xxx +/- .005 ANGULAR +/- 1°
MILLIMETERS .xx +/- 0.3 .xxx +/- .013 ANGULAR +/- 1°

GlobTek, Inc.
www.globtek.com
186 Veterans Dr. Northvale, NJ 07647
Tel. 201-784-1000 Fax 201.784.0111

DWG TITLE: SWITCHER , ____ WATT, ____ V@ ____ A, SINGLE OUTPUT, DESKTOP UNIVERSAL INPUT, MEDICAL, CLASS II FE

INIT.BY: DMR	DATE: 10/22/03				
DRAWN: NF	DATE: 10/22/03	FSCN No.: G, N	SIZE A	MODEL NO: GTM21097- ____	REV. E
APRVD : DMR	DATE: 10/22/03	SCALE: NONE		PART NO: ____	SHEET 1 OF 5

PROPRIETARY INFORMATION:
PROPRIETARY OF GLOBTEK, INC. ANY REPRODUCTION, DISCLOSURE OR USE OF THIS DRAWING IN WHOLE OR IN PART, IS HEREBY PROHIBITED EXCEPT AS SPECIFIED IN WRITING BY GLOBTEK, INC.

SAFETY

TYPE OF PROTECTION AGAINST ELECTRIC SHOCK:	CLASS II WITH FUNCTIONAL EARTH
DEGREE OF PROTECTION AGAINST ELECTRIC SHOCK:	NOT CLASSIFIED (NO APPLIED PART)
DEGREE OF PROTECTION AGAINST INGRESS OF WATER:	IPX0 (ORDINARY)
DEGREE OF SAFETY OF APPLICATION IN THE PRESENCE OF FLAMMABLE ANESTHETIC:	NOT EVALUATED
MODE OF OPERATION:	CONTINUOUS
DIELECTRIC WITHSTAND VOLTAGE:	5656Vdc FROM PRIMARY TO SECONDARY
EARTH LEAKAGE CURRENT:	< 100uA at 264Vac INPUT VOLTAGE

APPROVALS

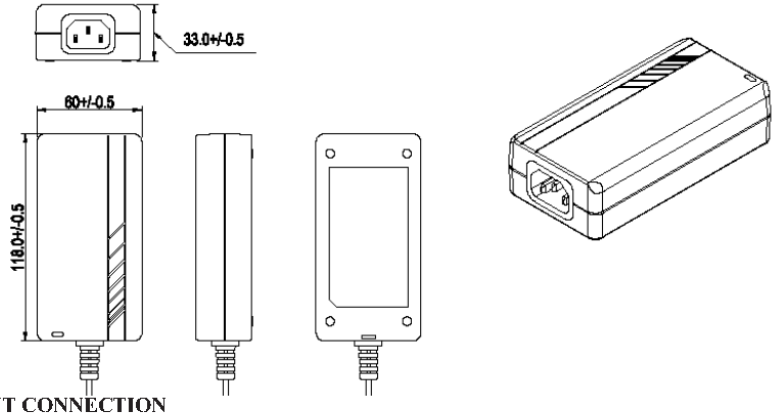
MEDICAL UNITS:	UL 60601-1, CUL TO 22.2NO.601, TUV TO EN60601 cTUVus CE FOR EMC, PSE TO J60950
EMI:	COMPLIES WITH EN55022 CLASS B AND FCC PART 15 CLASS B, VCCI WHEN TESTED WITH RESITIVE LOAD, BOTH CONDUCTED AND RADIATED EMI
CE MARK:	TESTED TO COMPLY WITH EN61000-3-2 EN610003-3 AND EN50082-1 INCLUDING EN61000-4-2, EN61000-4-3, EN61000-4-4, EN61000-4-5, EN61000-4-6, EN61000-4-11
MTBF:	200,000 HOURS AT 2°5C AMBIENT TEMPERATURE
OPERATING TEMPERATURE:	0°C TO 40°C AMBIENT TEMPERATURE
HUMIDITY:	0% TO 90% RELATIVE HUMIDITY
STORAGE TEMPERATURE:	-40°C TO 80°C
ROHS:	COMPLIES WITH EU 2002/95/EC AND CHINA SJ/T 11363-2006

GlobTek, Inc. www.globtek.com	186 Veterans Dr. Northvale, NJ 07647 Tel. 201-784-1000 Fax 201.784.0111	
DWG TITLE: SWITCHER , ☐ WATT, ☐ V@☐ A, SINGLE OUTPUT, DESKTOP UNIVERSAL INPUT, MEDICAL, CLASS II FE		
MODE NO: GTM21097- ☐		REV. E
PART NO: ☐		SHEET 2 OF 5

PROPRIETARY INFORMATION:
PROPRIETARY OF GLOBTEK, INC. ANY REPRODUCTION, DISCLOSURE OR USE OF THIS DRAWING, IN WHOLE OR IN PART, IS HEREBY PROHIBITED EXCEPT AS SPECIFIED IN WRITING BY GLOBTEK, INC.

2. MECHANICAL SPECIFICATION

ENCLOSURE:
UPPER HOUSING: HIGH IMPACT PLASTIC, 94V0 POLYCARBONATE, NON-VENTED, COLOR BLACK
LOWER HOUSING: HIGH IMPACT PLASTIC 94V0 POLYCARBONATE, NON- VENTED, COLOR BLACK
SIZE: 118 x 60 x 33 ± 0.5 mm

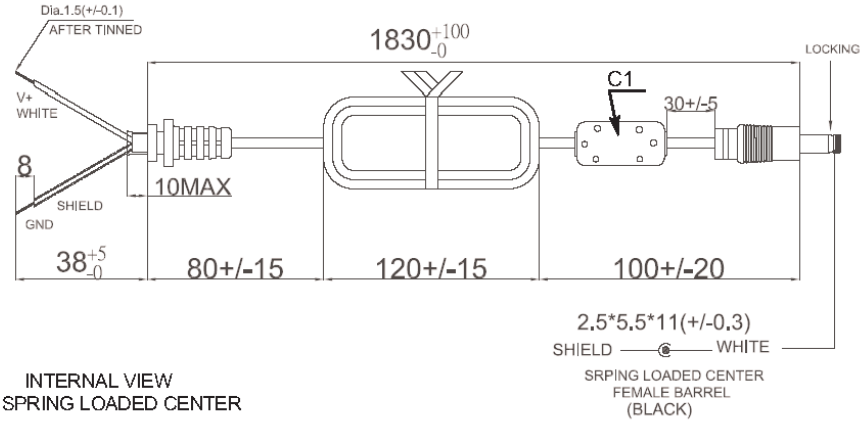


3. INPUT AND OUTPUT CONNECTION

INPUT :
CONFIGURATION: IEC320 / C14, AC POWER INLET WITH 3 MALE PRONGS

OUTPUT CORD:
1 CONDUCTOR+SHIELD, 18 AWG STRANDED WIRE, ROUND UL 1185 CORD TYPE, COLOR BLACK , LENGTH OF CORD: 1830+100, -0 mm. CORD IS MEASURED FROM THE HOUSING TO THE END OF OVERMOLD OF THE CONNECTOR. CABLE IS TO BE MARKED WITH WIRE GAUGE, AND ALL APPLICABLE RATING AND SAFETY APPROVALS.
CABLE HAS FERRITE BEAD C1 (10.5 x 20.0 x 5.6 mm) WITH OVERMOLD (15.5 x 26.0 x 8.5 mm).

OUTPUT CONNECTOR:
STANDARD, STRAIGHT FEMALE BARREL 5.5 x 2.5 x 11 mm (SPRING LOADED WITH LOCKING NOTCH) CENTER POSITIVE



INTERNAL VIEW
SPRING LOADED CENTER



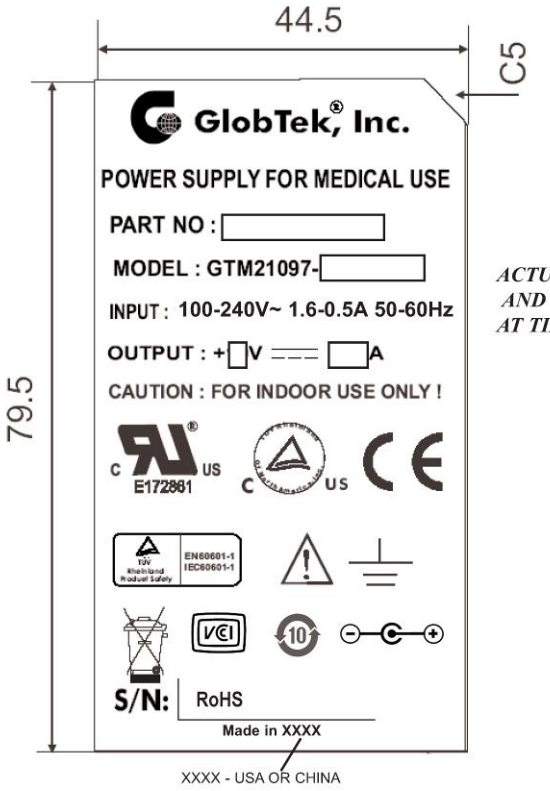
NOTE: FOR OUTPUT PLUG/CORD OPTIONS SEE OUTPUT PLUG / CORD OPTIONS, CATALOG ACCESSORIES.

GlobTek, Inc. www.globtek.com	186 Veterans Dr. Northvale, NJ 07647 Tel. 201-784-1000 Fax 201.784.0111	
DWG TITLE: SWITCHER, ☐ WATT, ☐ V@ ☐ A, SINGLE OUTPUT, DESKTOP UNIVERSAL INPUT, MEDICAL, CLASS II PS		
MODEL NO: GTM21097- ☐		REV. E
PART NO: ☐		SHEET 3 OF 5

PROPRIETARY INFORMATION:
PROPRIETARY OF GLOBTEK, INC. ANY REPRODUCTION, DISCLOSURE OR USE OF THIS DRAWING, IN WHOLE OR IN PART, IS HEREBY PROHIBITED EXCEPT AS SPECIFIED IN WRITING BY GLOBTEK, INC.

4. LABEL:

MATERIAL: .007 (0.18) THICK FLAT THERMAL TRANSFER, IMPRINTABLE, BLACK POLYESTER SHEET WITH WHITE NOMENCLATURE.
MANUFACTURER: STEVEN LABEL, MATERIAL I.D. NO.3302-33, UL FILE NO. MH12821(N), UL MATERIAL DESIGNATION FILE NO. GHW332RL. OPTIONAL LABEL MATERIAL CAN BE SUBSTITUTED PROVIDING MATERIAL IS UL LISTED AND COMPLIES WITH APPLICABLE SAFETY REQUIREMENTS.



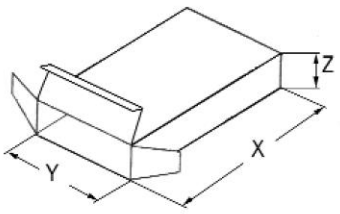
ACTUAL POSITIONING OF SYMBOLS AND TEXT IS SUBJECT TO CHANGE AT TIME OF MANUFACTURE

→ **AVAILABLE UPON REQUEST**

CAUTION: FOR INDOOR USE ONLY
→ **ATTENTION: POUR UTILASATION A L'INTERUR SEULAMENT**

5. INDIVIDUAL PACKING BOX:

MATERIAL: CORRUGATED FIBERBOARD, F-FLUTE 0.8 (2.0) THICK, DOUBLE WALL CONSTRUCTION.
EXTERNAL FINISH: WHITE, COATED WITH GLOSS FINISH (AQUEOUS OR VARNISH) STYLE: TUCK SIDES WITH LOCKING TABS ON BOTH SIDES OF BOX. NO PRINTING ON THE OUTSIDE OF BOX.



X = 147 mm
Y = 100 mm
Z = 33 mm

GlobTek, Inc. www.globtek.com	186 Veterans Dr. Northvale, NJ 07647 Tel. 201-784-1000 Fax 201.784.0111	
DWG TITLE: SWITCHER, WATT, V@ A, SINGLE OUTPUT, DESKTOP UNIVERSAL INPUT, MEDICAL, CLASS II FE		
MODEL NO: GTM21097-		REV. E
PART NO:		SHEET 4 OF 5

Versions.01

User manual for Model No.:

GTM21097 series

ELECTRICAL SPECIFICATIONS:

Input: 100-240Vac 50-60Hz 1.6A MAX

Output: 3.3 – 48V；max.6A；max.50W；details refer to making label.

MTBF: 200,000 HOURS AT 25°C ambient temperature

Operating Temperature: 0°C TO 40° C

Storage Temperature: -40°C TO 80° C

Humidity: 0% TO 90% relative humidity

Atmospheric pressure: 800hPa to 1060hPa

Weight: 255g

Enclosure Size: 58x 117 x 33mm

Input connector: IEC 60320 / C14, AC power receptacle with 3 male prongs

Output cord: No. 24 AWG min., VW-1, 105 degrees C, min.30 V;

---

1. Please read these safety instructions carefully.
2. This unit is for indoor use only.
3. Please refer to the marking label on the unit for input and output ratings. Do not overload the power supply.
4. The socket-out shall be installed near the equipment and shall be easily accessible.
5. A readily accessible disconnect device shall be incorporated in the fixed wiring.
6. Disconnect the appliance coupler to separate the unit from mains supply.
7. The apparatus shall not be exposed to dripping or splashing.
8. Output polarity: 
9. Class I equipment: 
10. Indoor use: 
11. Attention, Consult Accompanying Documents- as applicable) 
12. Do not throw this electronic device into the trash when discarding. To minimize pollution and ensure utmost protection of the global environment, please recycle it.



13. The power supply has to be disposed appropriately: Please refer to local regulations (Waste Electrical and Electronic Equipment).
14. The LED is operating indicator
15. **Modification of the power supply is not allowed.**
16. **Specified power supply cord: 3 x 0,75mm2, maximum length 3 meters**
16. Regardless to the legal warranty the manufacturer grants in accordance with the laws of its country, at least 1 year (in Germany 2 years). Begin of warranty is the sales date of the equipment to the final consumer.

The warranty covers only defects/deficiencies, which are to due to failures of material or manufacturing.

Versions.01

Warranty repairs may be accomplished exclusively by an authorized customer service. In order to make your warranty claim the original (sales voucher) receipt (with sales date) must be attached.

Excluded from warranty are:

- Usual abrasion
- Inappropriate applications, like for example overloading of the equipment and not certified accessories
- Damages by foreign effects, use of force or by foreign objects
- Damage, which results from neglect of the user manual, for example connection to a wrong voltage or neglect of the assembly instructions
- Complete or partly dismantled devices