CSA INTERNATIONAL

IEC 60601-1 3rd Edition
T E S T R E P O R T
M e d i c a l E l e c t r i c a l E q u i p m e n t

Master Contract-Report: 262528-70040865
Project: 70040865 (Ed.1)

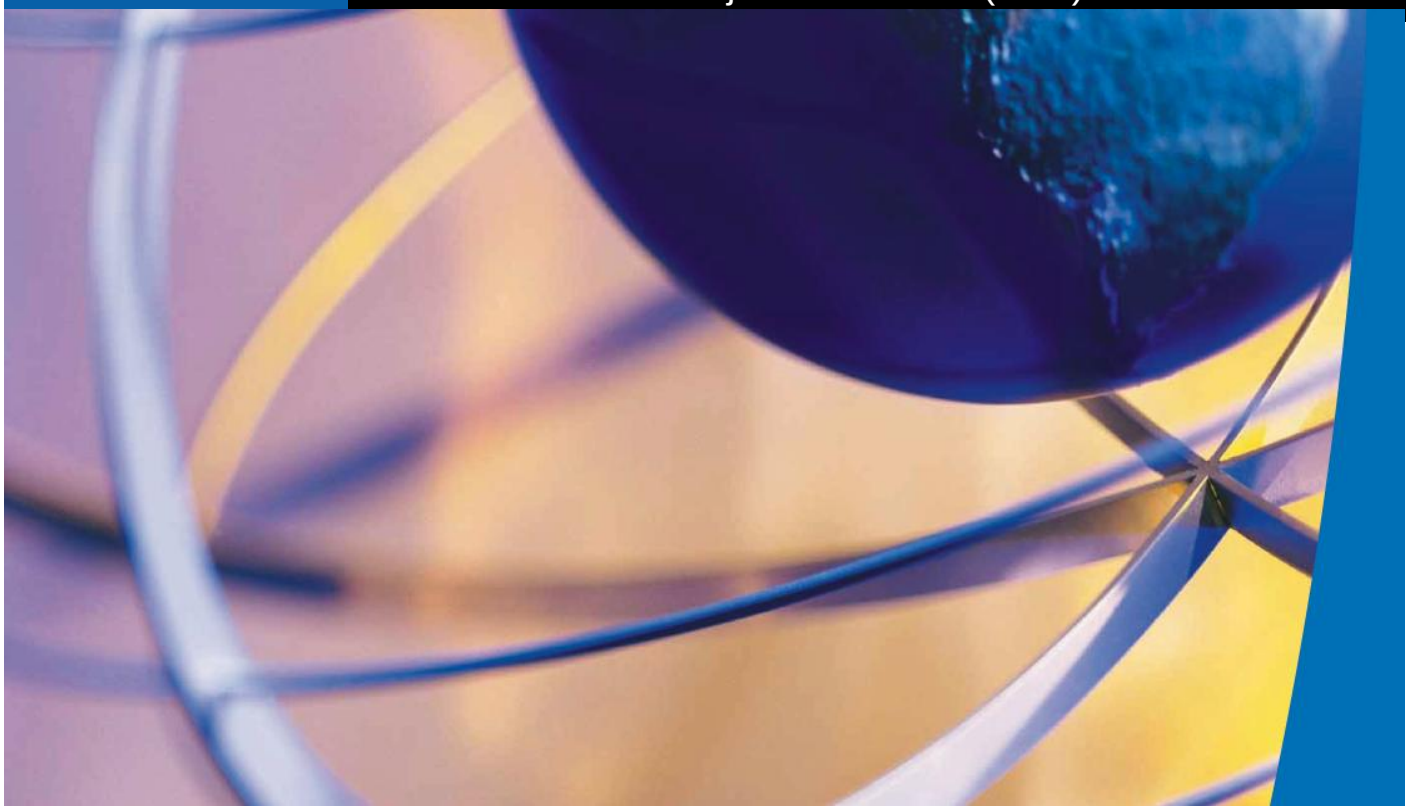


TABLE OF CONTENTS
This Report includes the following documents:

Classification Summary			
Subject		Type/Degree/Mode	Comments
1-	Type of protection against electric shock of Equipment:	Class II	
2-	Degree of protection against electric shock of Applied Part:	Type BF	
3-	Degree of protection against harmful ingress of water:	IPX0	
4-	Protection of Ignition of Flammable Anaesthetic Mixtures: Category AP/APG equipment - Equipment which is suitable for use in a Flammable Anaesthetic Mixtures with Air, Oxygen or Nitrous Oxide:	N/A	
5-	Mode of operation:	Continuous	
6-	Environmental Conditions:(Normal:10-40°C, 30-75% rH, 700-1060hPa) or Special)	Normal	

HISTORY

Edition 1: July 31, 2015; CSA Project 262528-70040865
Issued by Antonio Joo

Document No.: 70040865.

Brief Summary:

CB Testing Laboratory.....	N/A (Not CB project)
Address	N/A
Testing location	DT&C Co., Ltd.
Testing location/procedure.....	Witness Testing
Testing location/Address….	42, Yurim-ro 154 beon-gil Cheoin-gu, Yougin-si, Gyeonggi-do, Korea 449-935
Testing location	HCT Co., Ltd.
Testing location/procedure.....	Witness Testing
Testing location/Address….	74, Seoicheon-ro, 578 beon-gil, Majang-myeon, Icheon-si, Gyeonggi-do, Korea 467-811

TEST EQUIPMENT LIST
Project Edition 1

Test Equipment	Manufacturer/Model	Asset Number	Calibration date		Comments
			Last[1]	Due	
Refer to the Test Equipment List in Documentum of 2783119 project.					

1) or interval between calibrations.

Additional Considerations: **(Delete accordingly if not applicable)**
X- CSA cannot be held liable or responsible for standards/clauses which were applicable to the product but were not mandated by the submitter to be evaluated by CSA. Refer to Summary of applicable standards*/clauses* to evaluated product.
CANADIAN NATIONAL DEVIATION/DIFFERENCES
Canadian National Differences are covered by National Deviations document. These requirements are based upon CAN/CSA C22.2 No. 60601-1:09 which is technically equivalent to IEC 60601.1:2005 IEC 60601-1:2005 3rd edition
1- All safety and warning markings on the equipment are in English and French. Alternatively, the Accompanying Documents symbol appears on the unit and the text appears in the accompanying documents.
2- All symbols used on the products and in the accompanying documents are defined in the accompanying documents in English and French Languages.
UNITED STATES NATIONAL DEVIATIONS/DIFFERENCES:
United States National Deviations are based upon which is technically ANSI/AAMI ES60601:2005 which is equivalent to IEC 60601-1:2005 3rd edition
Summary of compliance with additional National Deviations/Differences:
Compliance with the National requirements of: CA (Canada), US (United States)

Test Report issued under the responsibility of:

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No.....:	**262528-70040865 (Project No.: 70040865, Ed.1)**
Date of issue .....:	**July 31, 2015**
Total number of pages.....:	**143**
CB Testing Laboratory.....:	**N/A (Not CB project)**
Address .....:	**N/A**
Applicant's name.....:	**R&L Co., Ltd.**
Address .....:	**11th Floor, B-line, ACE Gwang Myeong Tower, #1365, Soha-Dong, Gwangmyeong-Si, Gyeonggi-Do, Korea**
Test specification:	
Standard .....:	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure.....:	Witness Testing
Non-standard test method……..:	N/A
Test Report Form No.....:	IEC60601_1J
Test Report Form Originator .....:	UL(US)
Master TRF.....:	2014-07

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description .....:	Heating Mat
Trade Mark .....:	RICHWAY & LIFE CO.
Manufacturer.....:	Same as applicant
Address .....:	See above
Model/Type reference.....:	BIOMAT MINI
Ratings.....:	120 V~; 60 Hz; 100 W

Testing procedure and testing location: N/A			
☐	**CB Testing Laboratory:**		
Testing location/ address ..... :			
☐	**Associated CB Testing Laboratory:**		
Testing location/ address ..... :			
Tested by (name + signature)..... :			
Approved by (name + signature) ..... :			
☐	**Testing procedure: TMP/CTF Stage 1:**		
Testing location/ address ..... :			
Tested by (name + signature)..... :			
Approved by (name + signature) ..... :			
☐	**Testing procedure: WMT/CTF Stage 2:**		
Testing location/ address ..... :			
Tested by (name + signature)..... :			
Witnessed by (name + signature) ..... :			
Approved by (name + signature) ..... :			
☐	**Testing procedure: SMT/CTF Stage 3 or 4:**		
Testing location/ address ..... :			
Tested by (name + signature)..... :			
Witnessed by (name + signature) ..... :			
Approved by (name + signature) ..... :			
Supervised by (name + signature)..... :			

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

Att1 Photos – 4 pages

Att2 Illustrations – 4 pages

Summary of testing

- Operating environment specification of The BIOMAT MINI is following:
  - Ambient temperature range: 5 to 40 ºC
  - Relative humidity: 15 to 93 %
  - Altitude: 700 to 1 060 hPa
- For heating test was conducted with clause 201.11.1.2.1.101 of IEC 80601-2-35.

Tests performed (name of test and test clause):

Refer to appended tables

Testing location:

DT&C Co., Ltd.

42, Yurim-ro 154 beon-gil, Cheoin-gu, Yougin-si, Gyeonggi-do, Korea 449-935

Summary of compliance with National Differences

List of countries addressed: US & CA

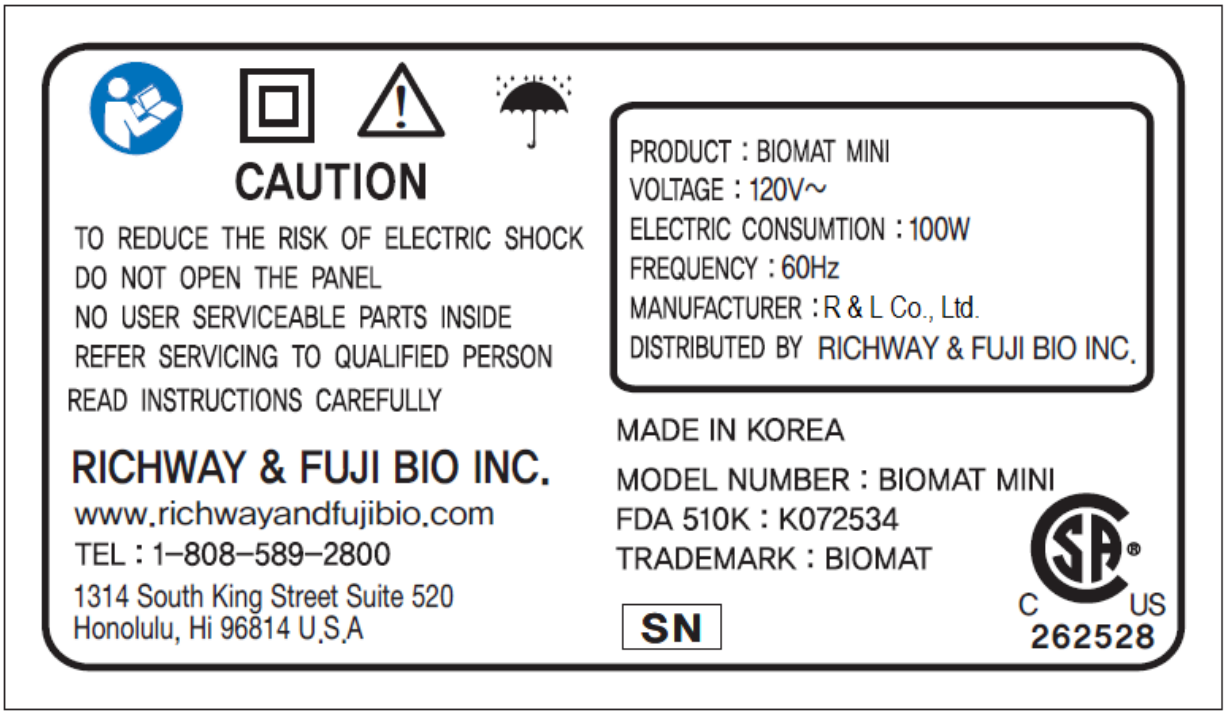
☒ The product fulfils the requirements of IEC 60601-1.

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.

- Mat label -

- Controller label -



GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	transportable / ~~portable~~ / ~~stationary~~ / ~~mobile~~ / ~~fixed / permanently installed~~ / ~~hand-held, body-worn~~
Device type (component/sub-assembly/ equipment/ system) :	Equipment
Intended use (Including type of patient, application location) :	Type BF applied parts, Home healthcare environment
Mode of operation .....:	Continuous / ~~non-continuous~~
Supply connection	~~internally powered~~ /~~permanently installed~~ / ~~appliance coupler~~ / non-detachable cord
Accessories and detachable parts included.....:	Mat
Other options include .....:	None
Testing	
Date of receipt of test item(s) .....:	January 25, 2015
Dates tests performed.....:	January 25, 2015 – March 23, 2015
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement.....:	Pass (P)
- test object was not evaluated for the requirement ..... :	N/E (collateral standards only)
- test object does not meet the requirement.....:	Fail (F)
Abbreviations used in the report:	
- normal condition.....: N.C.	- single fault condition.....: S.F.C.
- means of Operator protection .....: MOOP	- means of Patient protection ....: MOPP
General remarks:	
Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version "J" of TRF for IEC for 60601-1 3rd edition with Amendment 1. "(See Attachment #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. The tests 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 testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report. **Throughout this report a ☐ comma / ☒ point is used as the decimal separator.**	
Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012	
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)..... :

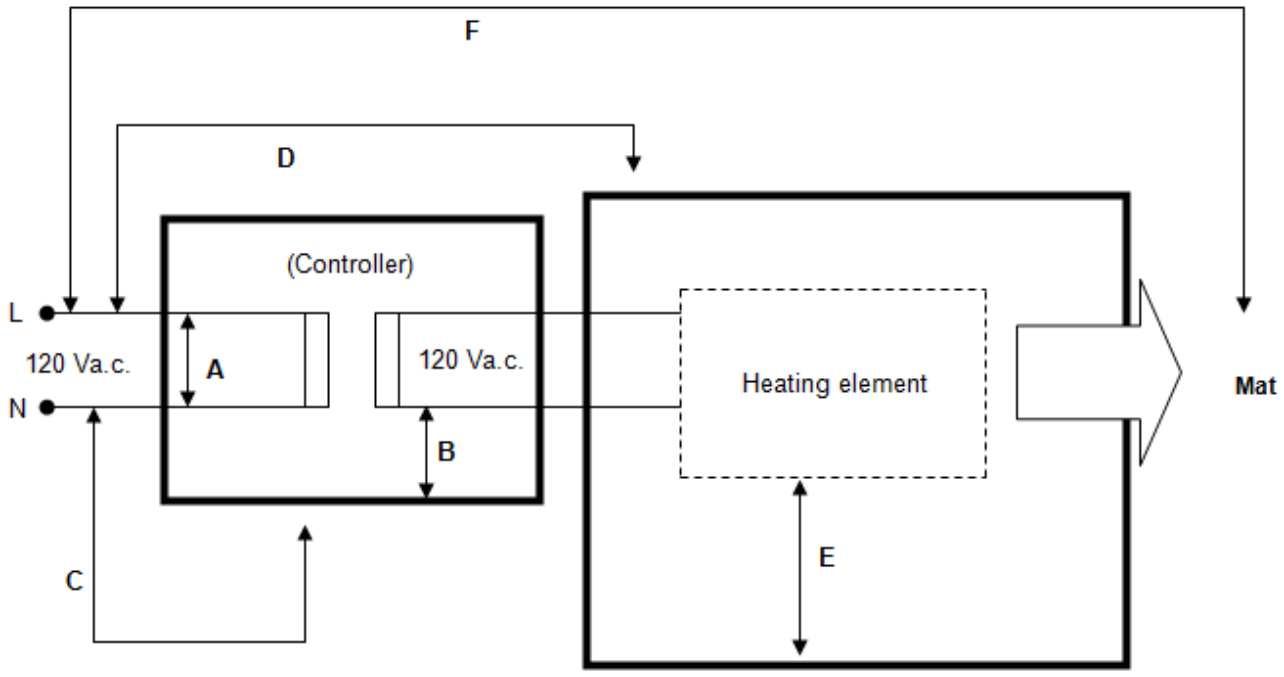
Same as manufacturer

General product information:

This equipment is indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis; the temporary relief of muscle spasms, minor sprains and strains, and minor muscular back pain; the relaxation of muscles; and the temporary increase of local circulation where applied. This equipment is intended for use in home healthcare environment.

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

INSULATION DIAGRAM



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

TABLE: INSULATION DIAGRAM		Pass
Pollution degree .....:	**II**	—
Overvoltage category .....:	**2**	—
Altitude .....:	**Up to 2 000**	—
Additional details on parts considered as applied parts .....:	☐ **None** ☒ **Areas mat** **(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}					
A	-	-	132	187	-	-	6.0	6.0	**Transformer**
B	2 MOOP	IIIb	132	187	3.2	2.0	3.2	2.0	**Secondary output to enclosure of control box**
C	2 MOOP	IIIb	132	187	3.2	2.0	3.2	2.0	**Primary to enclosure of control box**
D	2 MOPP	IIIb	132	187	8.0	5.0	8.0	5.0	**Primary to mat connector**
E	2 MOPP	IIIb	132	187	8.0	5.0	8.0	5.0	**Secondary output to mat**
F	2 MOPP	IIIb	132	187	8.0	5.0	8.0	5.0	**Primary to mat**

Supplementary Information: Refer to the Documentum of 2783119 project

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**		**Pass**
4.1	**Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse**	Applied with normal use and reasonably foreseeable misuse	**Pass**
4.2	**RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS**		**Pass**
4.2.2	**General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007) .....:**	See Appended RM Results Table 4.2.2.	**Pass**
4.2.3	**Evaluating RISK**		**Pass**
4.2.3.1	**a) Compliance with the standard reduces residual risk to an acceptable level**	Compliance with IEC 60601 series	**Pass**
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN .....:	RISK MANAGEMENT PLAN Document: RN-RMP-003 (Rev.0)	**Pass**
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.	Manufacturer has determined hazards or hazardous situations exists	**Pass**
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.	Evaluated using with risk management process	**Pass**
4.2.3.2	**MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.**	Manufacturer has addressed hazards in the risk management process	**Pass**
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.**	RM File Reference to Essential performance: Accuracy of temperature output	**Pass**
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.	Setting value ± 5 °C	**Pass**
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated	Refer to risk management file	**Pass**
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE.....:	See Appended Table 4.3	**Pass**
	- RISK CONTROL measures implemented	Temperature sensor and approved thermostats used	**Pass**
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented	Clause 201.11.1.2.1.101.1 of IEC 80601-2-35 Clause 201.13.1.2.101.2 of IEC 80601-2-35 Clause 201.12.4.101 of IEC 80601-2-35 Clause 201.12.4.102	**Pass**
4.4	**EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE .....:**	Expected Service Life: 8 years	**Pass**

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
4.5	**Alternative RISK CONTROL methods utilized:**	No such parts	**N/A**
	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. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
	Alternative means based scientific data or clinical opinion or comparative studies .....:	See above	**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.....:**	No such parts (Applied parts: Top of mat)	**N/A**
	MANUFACTURER assesses the risk of accessible parts coming into contact with the patient ....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
	Assessment identified the APPLIED PART TYPE requirements.....:	See above	**N/A**
4.7	**ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2.....:**	Remained single fault safe, or the risk remained acceptable	**Pass**
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested.....: **(ISO 14971 Cl. 4.2-4.4)**	RISK ANALYSIS reference: H1-4.7 (ISO 14971 Cl. 4.2-4.4)	**Pass**
	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	**Pass**
4.8	**All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified ....:**	Used according to their applicable ratings	**Pass**
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS	Components and wiring exception in the standard	**Pass**
	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. 4.2-4.4, 5, 6.2-6.5)**	Used according to their applicable ratings	**N/A**
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION...:	See above	**N/A**
	Components determined to be acceptable where used as a MEANS OF PROTECTION .....:	See above	**N/A**

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following	See below	**Pass**
	a) Applicable safety requirements of a relevant IEC or ISO standard	See appended Table 8.10 (Also see CA national difference)	**Pass**
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard	See appended Table 8.10 (Also see CA & US national differences)	**Pass**
4.9	**A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately.....:**	No used with component of high-integrity characteristics	**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:	See above	**N/A**
4.10	**Power supply**		**Pass**
4.10.1	**ME EQUIPMENT is suitable for connection to indicated power source** (select applicable)**.....:**	Supply mains (Also see CA national difference)	**Pass**
4.10.2	**Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:**	See below	**Pass**
	- 250 V for HAND-HELD ME EQUIPMENT (V)..... :	No hand-held ME 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)..... :	120 V~ (Also see US national difference)	**Pass**
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS	See above	**N/A**
4.11	**Power input**		**Pass**
	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	**Pass**

5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		**Pass**
5.1	**Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods .....:**	No other adequate analysis provided	**N/A**

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. **(ISO 14971 Cl. 4.2-4.4)**	No such combinations of simultaneous independent faults	**N/A**
5.3	**Tests conducted within the environmental conditions specified in technical description**	Provided in User manual	**Pass**
	Temperature (ºC), Relative Humidity (%) .....:	5 ºC to 40 ºC; 15 % to 93 %	**—**
	Atmospheric Pressure (kPa) .....:	70 kPa to 106 kPa	**—**
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) .....:**	Tests was according to 4.10.2	**Pass**
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)..... :	60 Hz	**Pass**
	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..... :	Only one rated voltage used	**N/A**
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered..... :	No such parts	**N/A**
	e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions..... :	No alternative accessories and components	**N/A**
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	No such parts	**N/A**
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..... :**		**Pass**
	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 +32°C for indicated time	T = 30 °C Time = 48 h	**—**
5.9	**Determination of APPLIED PARTS and ACCESSIBLE PARTS**		**Pass**
5.9.1	**APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS..... :**	Top of mat	**Pass**
5.9.2	**ACCESSIBLE PARTS**		**Pass**
5.9.2.1	**Accessibility determined using standard test finger of Fig. 6**	See Appended Table 5.9.2	**Pass**

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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 such parts	**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 such parts	**N/A**
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL.....:	See above	**N/A**
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		**Pass**
6.2	**CLASS I ME EQUIPMENT, externally powered**	No Class I ME equipment	**N/A**
	CLASS II ME EQUIPMENT, externally powered	Class II ME equipment	**Pass**
	INTERNALLY POWERED ME EQUIPMENT	No internally powered ME 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	No internally powered ME equipment	**N/A**
	TYPE B APPLIED PART	No B applied parts	**N/A**
	TYPE BF APPLIED PART	Top of mat	**Pass**
	TYPE CF APPLIED PART	No CF applied parts	**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS	No defibrillation-proof applied parts	**N/A**
6.3	**ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529 ..... :**	Ordinary ME equipment (IPX0)	**Pass**
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**	Not intended for use in an Oxygen rich environment	**N/A**
6.6	**CONTINUOUS or Non-CONTINUOUS OPERATION ..... :**	Continuous operation	**Pass**
7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		**Pass**
7.1.2	**Legibility of Markings Test for Markings specified in Clause 7.2-7.6.....:**	See Appended Table 7.1.2	**Pass**

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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	**Pass**
7.2	**Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**		**Pass**
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 ..... :**	All markings specified in 7.2.2 to 7.2.20 on ME equipment	**N/A**
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS ..... :	See above	**N/A**
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT	Marking applied to ME equipment	**N/A**
	Single use item marked..... :	No single use item	**N/A**
7.2.2	**ME EQUIPMENT marked with:**	See below	**Pass**
	– the name or trademark and contact information of the MANUFACTURER	Marked with name and trademark of the manufacturer	**Pass**
	– a MODEL OR TYPE REFERENCE	See attached copy of Marking Plate	**Pass**
	– a serial number or lot or batch identifier; and	Serial number used	**Pass**
	– the date of manufacture or use by date		**N/A**
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	See below	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.4)**	RMF Reference to specific RISKS: H1-7.2.2 (Mat) (ISO 14971 Cl. 4.2-4.4, 5, 6.4)	**Pass**
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and	Marked with name and trademark of the manufacturer	**Pass**
	– a MODEL OR TYPE REFERENCE	Marked with model and type reference	**Pass**
	Software forming part of a PEMS identified with a unique identifier..... :	Identified with revision level and date of release. Identified are available to designated person	**Pass**
7.2.3	**Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS**	See below	**N/A**
	Safety sign 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	Symbol (ISO 7010, M002),  is used	**Pass**

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.2.4	**ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and .....:**	No such accessories	**N/A**
	- with a MODEL or TYPE REFERENCE	See above	**N/A**
	– a serial number or lot or batch identifier	See above	**N/A**
	– the date of manufacture or use by date	See above	**N/A**
	Markings applied to individual packaging when not practical to apply to ACCESSORIES	See above	**N/A**
7.2.5	**ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following**	No such parts	**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	See above	**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	See above	**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.	See above	**N/A**
7.2.6	**Connection to the Supply Mains**		**Pass**
	Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point	Marking on the outside of part containing supply mains connection	**Pass**
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT	No permanently installed ME equipment	**N/A**
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V).....:	120 V~	**Pass**
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)...:	No multiple rated	**N/A**
	– Nature of supply and type of current.....:	See below	**Pass**
	Symbols 1-5, Table D.1 (used for same parameters.....:	Symbol (IEC 60417 No.5032),  is used	**Pass**
	– RATED supply frequency or RATED frequency range in hertz.....:	60 Hz	**Pass**
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT .....:	Symbol (IEC 60417 No.5172),  is used	**Pass**
7.2.7	**RATED input in amps or volt-amps, (A, VA) .....:**	See below	**N/A**
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) .....:	100 W	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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) .....:	Only one rated voltage (120 V~)	**N/A**
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W) .....:	See above	**N/A**
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA).....:	Not includes	**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) .....:	No such connection	**N/A**
7.2.8	**Output connectors**		**N/A**
7.2.8.2	**Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment**	Intended only for specified equipment part (Mat)	**N/A**
	Rated Voltage (V), Rated Current (A).....:	See above	**—**
	Rated Power (W), Output Frequency (Hz) .....:	See above	**—**
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....:**	IPX0 (Ordinary)	**Pass**
7.2.10	**Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols .....:**	See below	**Pass**
	TYPE B APPLIED PARTS with symbol 19 of Table D.1	No type B applied parts	**N/A**
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 .....:	Symbol (IEC 60417 No.5333),  is used	**Pass**
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 .....:	No type CF applied parts	**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 .....:	No defibrillation-proof applied parts	**N/A**
	Proper symbol marked adjacent to or on connector for APPLIED PART .....:	Marked on adjacent	**Pass**
	Safety sign 2 of Table D.2 placed near relevant outlet.....:	No such parts	**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 .....:	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.2.11	**ME EQUIPMENT suitable for CONTINUOUS OPERATION**	No marking: Continuous operation	**Pass**
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time .....:	See above	**N/A**
7.2.12	**Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder**	No accessible fuse-holder	**N/A**
	Fuse type.....:	See above	**—**
	Voltage (V) and Current (A) rating .....:	See above	**—**
	Operating speed (s) and Breaking capacity.....:	See above	**—**
7.2.13	**Physiological effects – safety sign and warning statements .....:**	No physiological effects	**N/A**
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**	See above	**N/A**
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	**N/A**
7.2.15	**Requirements for cooling provisions marked...:**	No such parts	**N/A**
7.2.17	**Packaging marked with special handling instructions for transport and/or storage.....:**		**Pass**
	Permissible environmental conditions marked on outside of packaging .....:	Temperature: -25 to 70 °C Humidity: 15 to 93 % R.H. Pressure: 700 to 1 060 hPa	**Pass**
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK .....:	No such parts	**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. 4.2-4.4, 5, 6.3-6.4)**	See above	**N/A**
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization	No such parts	**N/A**
7.2.18	**RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and .....:**	No external pressure source	**N/A**
	- the RATED flow rate also marked	See above	**N/A**
7.2.19	**Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL.....:**	No functional earth terminal	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.2.20	**Removable protective means marked to indicate the necessity for replacement when the function is no longer needed .....:**	No removable protective means	**N/A**
7.2.21	**MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms.....:**	No mobile ME equipment	**N/A**
7.3	**Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts**		**Pass**
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) .....:**	See below	**N/A**
	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	Symbol (ISO 7010, M002),  is used	**Pass**
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	**N/A**
7.3.3	**Type of battery and mode of insertion marked:**	No battery	**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 .....:	See above	**N/A**
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK.....:	See above	**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an unacceptable RISK if replaced incorrectly .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**	See above	**N/A**
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARD .....:	See above	**N/A**
7.3.4	**Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified .....:**	Specification adjacent to component	**Pass**
	Voltage (V) and Current (A) rating .....:	250 V; 3.15 A	**—**
	Operating speed(s), size & breaking capacity.:	Time-delay; 8.6 x 4.3 x 8.4 mm, Low breaking capacity	**—**
7.3.5	**PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1**	Class II ME equipment	**N/A**
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.3.6	**Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS**	No functional earth terminal	**N/A**
7.3.7	**Terminals for supply conductors marked adjacent to terminals.....:**	No supply terminals	**N/A**
	Terminals for supply connections are not marked, the RISK MANAGEMENT FILE includes an assessment of the RISKS resulting from misconnections .....: (ISO 14971 Cl. 4.3)	See above	**N/A**
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	See above	**N/A**
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3	See above	**N/A**
	Marking for connection to a 3-phase supply, complies with IEC 60445	See above	**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	See above	**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**	Not exceed 75 °C	**N/A**
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made	See above	**N/A**
7.4	**Marking of controls and instruments**		**Pass**
7.4.1	**The "on" & "off" positions of switch to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 or**	No mains switch	**N/A**
	– indicated by an adjacent indicator light, or	See above	**N/A**
	– indicated by other unambiguous means	See above	**N/A**
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, and	No such switches	**N/A**
	– status indicated by adjacent indicator light	See above	**N/A**
	– status indicated by other unambiguous means	See above	**N/A**
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or	No such switches	**N/A**
	– status indicated by adjacent indicator light	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– status indicated by other unambiguous means	See above	**N/A**
7.4.2	**Different positions of control devices/switches indicated by figures, letters, or other visual means**	No different positions of control devices/switches	**N/A**
	RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2, 6.3)**	RMF Reference to specific RISKS: H1-7.4.2 Temp. Up and Down (ISO14971 Cl. 4.2-4.4, 5, 6.2, 6.3)	**Pass**
	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 .....:	Provided with associated indicating device	**Pass**
	– or an indication of direction in which magnitude of the function changes	See above	**N/A**
	Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009	Symbol (IEC 60417 No.5009),  is used.	**Pass**
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**	SI units used	**Pass**
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units	SI units used	**Pass**
	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.	**Pass**
7.5	**Safety signs**		**Pass**
	Safety sign with established meaning used	No established meaning safety sign	**N/A**
	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. 4.2-4.4, 5, 6.3)**	RMF Reference to specific RISK & Marking: H1-7.5 Safety Sign Used: ISO 7010; W001 & M002 (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	**Pass**
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT	Provided in User manual	**Pass**
	Specified colours in ISO 3864-1 used for safety signs.....:	Specified colours in ISO 3864-1 used	**Pass**
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)	Include appropriate precautions or instructions	**Pass**
	Safety signs including any supplementary text or symbols described in instructions for use	No supplementary text	**N/A**
	- and in a language acceptable to the intended OPERATOR	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.6	**Symbols**		**Pass**
7.6.1	**Meanings of symbols used for marking described in instructions for use .....:**	Provided in User manual	**Pass**
7.6.3	**Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable**	Complied with IEC and ISO publication	**Pass**
7.7	**Colours of the insulation of conductors**		**N/A**
7.7.1	**PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation**	No protective earth conductor (Class II ME equipment)	**N/A**
7.7.2	**Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations**	See above	**N/A**
7.7.3	**Green and yellow insulation identify only following conductors:**	See above	**N/A**
	– PROTECTIVE EARTH CONDUCTORS	See above	**N/A**
	– conductors specified in 7.7.2	See above	**N/A**
	– POTENTIAL EQUALIZATION CONDUCTORS	See above	**N/A**
	– FUNCTIONAL EARTH CONDUCTORS	See above	**N/A**
7.7.4	**Neutral conductors of POWER SUPPLY CORDS are "light blue"**	See CA national difference	**N/A**
7.7.5	**Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1**	See CA national difference	**N/A**
7.8	**Indicator lights and controls**		**Pass**
7.8.1	**Red indicator lights used only for Warning**	No red indicator	**N/A**
	Yellow indicator lights used only for Caution	Yellow LED used	**Pass**
	Green indicator lights used only for Ready for use	Green LED used	**Pass**
	Other colours: Meaning other than red, yellow, or green (colour, meaning) .....:	No other colours	**N/A**
7.8.2	**Red used only for emergency control**	No emergency control device	**N/A**
7.9	**ACCOMPANYING DOCUMENTS**		**Pass**
7.9.1	**ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description**	Provided in User manual (RN-USM-003)	**Pass**
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:	See below	**Pass**
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to .....:	Provided in User manual	**Pass**
	– MODEL or TYPE REFERENCE .....:	Provided in User manual	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	When ACCOMPANYING DOCUMENTS provided electronically, USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT	Provided 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	Provided in User manual	**Pass**
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	Written	**Pass**
7.9.2	**Instructions for use include the required information**		**Pass**
7.9.2.1	**– use of ME EQUIPMENT as intended by the MANUFACTURER:**	Provided in User manual	**Pass**
	– frequently used functions,	Provided in User manual	**Pass**
	– known contraindication(s) to use of ME EQUIPMENT	Provided in User manual	**Pass**
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient	Provided in User manual	**Pass**
	– name or trademark and address of the MANUFACTURER	Provided in User manual	**Pass**
	– MODEL OR TYPE REFERENCE	Provided in User manual	**Pass**
	Instruction for use included the following when the PATIENT is an intended OPERATOR:	See below	**Pass**
	– the PATIENT is an intended OPERATOR	Provided in User manual	**Pass**
	– warning against servicing and maintenance while the ME EQUIPMENT is in use	Provided in User manual	**Pass**
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and	Provided in User manual	**Pass**
	–maintenance the PATIENT can perform	Provided in User manual	**Pass**
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	Provided in User manual	**Pass**
	Instructions for use are in a language acceptable to the intended operator	English	**Pass**
7.9.2.2	**Instructions for use include all warning and safety notices**	Provided in User manual	**Pass**
	Warning statement for CLASS I ME EQUIPMENT included	Class II ME equipment	**N/A**
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	Provided in User manual	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	Provided in User manual	**Pass**
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	No MSO	**N/A**
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	See above	**N/A**
7.9.2.3	**Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions**	No such parts	**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	**N/A**
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**	No battery	**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 battery	**N/A**
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided ..... :	No internal electrical power source	**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..... :	No such parts	**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 in User manual	**Pass**
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to	No such parts	**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 SIP/SOP	**N/A**
	APPLIED PARTS specified	Provided in User manual	**Pass**
7.9.2.6	**Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation**	Provided in User manual	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.9.2.7	**Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device**	Mains switch used	**N/A**
7.9.2.8	**Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation**	Provided in User manual	**Pass**
7.9.2.9	**Information provided to operate ME EQUIPMENT**	Provided in User manual	**Pass**
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	Provided in User manual	**Pass**
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**	Provided in User manual	**Pass**
7.9.2.11	**Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT**	Provided in User manual	**Pass**
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**	Provided in User manual	**Pass**
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	No single use parts	**N/A**
7.9.2.13	**Instructions provided on preventive inspection, calibration, maintenance and its frequency**	Provided in User manual	**Pass**
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	Provided in User manual	**Pass**
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	No such parts	**N/A**
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	No battery	**N/A**
7.9.2.14	**A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided**	Provided in User manual	**Pass**
	Other equipment providing power to ME SYSTEM sufficiently described	No such parts	**N/A**
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 in User manual	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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)**	Provided in User manual	**Pass**
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**	No such parts	**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 such parts	**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	No sterile packaging	**N/A**
7.9.2.19	**The instructions for use contain a unique version identifier.....:**	Provided in User manual (RN-USM-003, Ver.: 2.3, Date: 2015.04.20)	**Pass**
7.9.3	**Technical description**		**Pass**
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**	Provided in User manual	**Pass**
	Technical description separable from instructions for use contains required information, as follows		**N/A**
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT	Not separated	**N/A**
	– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and	See above	**N/A**
	a unique version identifier.....:	See above	**N/A**
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description	Provided in User manual	**Pass**
7.9.3.2	**The technical description contains the following required information**		**Pass**
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT.....:	No permanently installed ME 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	Not replaceable	**N/A**
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	No such parts	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RISK MANAGEMENT FILE includes an assessment to determine if replacement of components results in any unacceptable RISKS..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	Service technicians do not visit to fix or replace parts. The device must be sent to the manufacturer to be fixed or replaced.	**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	See above	**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**	No such parts	**N/A**
7.9.3.4	**Means used to comply with requirements of 8.11.1 clearly identified in technical description**	Provided in User manual	**Pass**
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		**Pass**
8.1	**Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS**	Not exceeded	**Pass**
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION ..... : **(ISO 14971 Cl. 4.3)**	RMF Reference to specific RISKS: H1-8.1b) (ISO 14971 Cl. 4.3)	**Pass**
8.2	**Requirements related to power sources**		**Pass**
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	No separate power source	**N/A**
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified	See above	**N/A**
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined	See above	**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	No such parts	**N/A**
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset	See above	**N/A**
8.3	**Classification of APPLIED PARTS**		**Pass**
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	No type CF applied parts	**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	Not intended to deliver electrical energy and an electrophysiological signal	**N/A**
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	Type BF applied parts	**Pass**
8.4	**Limitation of voltage, current or energy**		**Pass**
8.4.2	**ACCESSIBLE PARTS and APPLIED PARTS**		**Pass**
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT :	See appended Table 8.7	**Pass**
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT ..... :	See appended Table 8.7	**Pass**
	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	No such parts	**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 above	**N/A**
	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 above	**N/A**
	d) Voltage and energy limits specified in c) above also applied to the following:	No such parts	**N/A**
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	See above	**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	See above	**N/A**
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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	See above	**N/A**
	Test repeated with a TOOL specified in instructions for use	See above	**N/A**
	Test rod freely and vertically suspended through openings on top of ENCLOSURE	See above	**N/A**
	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	No such parts	**N/A**
	A TOOL is required when it is possible to prevent the devices from operating	See above	**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	**Pass**
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC .. :	Did not exceeded 60 V	**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 .. :**	No such capacitive circuits	**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	See above	**N/A**
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description ..... :	See above	**N/A**
8.5	**Separation of parts**		**Pass**
8.5.1	**MEANS OF PROTECTION (MOP)**		**Pass**
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 MOP	**Pass**
	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	Disregarded as Means of protection	**Pass**
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10	Complied with clause 8.10	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.5.1.2	**MEANS OF PATIENT PROTECTION (MOPP)**		**Pass**
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test..... :	See appended Table 8.8.3	**Pass**
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12	See insulation diagram	**Pass**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6	Class II ME equipment	**N/A**
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION ..... :	No Y-capacitor	**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. ..... :	No such parts	**N/A**
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	See above	**N/A**
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) ..... :	See above	**—**
8.5.1.3	**MEANS OF OPERATOR PROTECTION (MOOP)**		**Pass**
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:	See below	**Pass**
	– dielectric strength test ..... :	See appended Table 8.8.3	**Pass**
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION	See above	**N/A**
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:	See below	**Pass**
	– limits of Tables 13 to 16 (inclusive); or	See insulation diagram	**Pass**
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION	See above	**N/A**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6	Class II ME equipment	**N/A**
	– or with requirements and tests of IEC 60950-1 for protective earthing..... :	See above	**N/A**
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION ..... :	No Y-capacitor	**N/A**
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION ..... :	See above	**N/A**
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	See above	**N/A**
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) ..... :	See above	**—**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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	Not exceeding limits in clause 8.4	**Pass**
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION..... :	No such parts	**N/A**
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION .... :	Means of operator protection	**Pass**
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	**N/A**
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART	See above	**N/A**
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function	See above	**N/A**
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS ..... :	See above	**N/A**
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	See above	**N/A**
	LEAKAGE CURRENT tests conducted per 8.7.4 .... :	See above	**N/A**
	Dielectric strength test conducted per 8.8.3.... :	See above	**N/A**
	CREEPAGE and CLEARANCES measured ..... :	See above	**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	See above	**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 .... :**	Type B applied parts	**N/A**
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low	See above	**N/A**
	LEAKAGE CURRENT tests conducted per 8.7.4 .... :	See above	**N/A**
	Dielectric strength test conducted per 8.8.3.... :	See above	**N/A**
	Relevant CREEPAGE and CLEARANCES measured	See above	**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. 4.2-4.4, 5)**	See above	**N/A**
8.5.2.3	**A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable remote 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 lead and patient cables	**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	See above	**N/A**
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm	See above	**N/A**
	– conductive part pluggable into a mains socket protected from making contact with 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	See above	**N/A**
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,	See above	**N/A**
	Test finger test (10 N) ..... :	See above	**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. 4.2-4.4, 5)**	See above	**N/A**
8.5.4	**WORKING VOLTAGE**		**Pass**
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V) ..... :	120 V~	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– 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)..... :	No such d.c. voltage with superimposed ripple	**N/A**
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V)..... :	No such parts	**N/A**
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth	No protective earth	**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 patient connections	**N/A**
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	No defibrillation-proof applied parts	**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 such parts	**N/A**
8.5.5	**DEFIBRILLATION-PROOF APPLIED PARTS**		**N/A**
8.5.5.1	**Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety**	No defibrillation-proof applied parts	**N/A**
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:	See above	**N/A**
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ..... :	See above	**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 above	**N/A**
8.5.5.2	**Means provided to limit energy delivered to a 100 Ω load..... :**	No defibrillation-proof applied parts	**N/A**
8.6	**Protective and functional earthing and potential equalization of ME EQUIPMENT**		**N/A**
8.6.1	**Requirements of 8.6.2 to 8.6.8 applied**	Class II ME equipment	**N/A**
	Parts complying with IEC 60950-1 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	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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..... :**	No protective earth terminal	**N/A**
	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	See above	**N/A**
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside..... :	See above	**N/A**
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL	See above	**N/A**
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing	See above	**N/A**
8.6.3	**PROTECTIVE EARTH CONNECTION not used for a moving part,**	No protective earth connection	**N/A**
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
8.6.4	**a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop ..... :**	No protective earth connection	**N/A**
	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 above	**N/A**
8.6.5	**Surface coatings**		**N/A**
	Poorly conducting surface coatings on conductive elements removed at the point of contact	Class II ME equipment	**N/A**
	Coating not removed when requirements for impedance and current-carrying capacity met	See above	**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	No protective earth connection	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- applied also where interchangeable parts are PROTECTIVELY EARTHED	See above	**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	**N/A**
	–accidental disconnection avoided in NORMAL USE	See above	**N/A**
	– Terminal allows conductor to be detached without a TOOL	See above	**N/A**
	– Terminal not used for a PROTECTIVE EARTH CONNECTION	See above	**N/A**
	– Terminal marked with symbol 8 of Table D.1	See above	**N/A**
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard	See above	**N/A**
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR	See above	**N/A**
8.6.8	**FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION**	No such parts	**N/A**
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	Having two conductors	**N/A**
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.	See above	**N/A**
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS	See above	**N/A**
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		**Pass**
8.7.1	**a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3..... :**	See appended Tables 8.7	**Pass**
	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	**Pass**
8.7.2	**Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except**		**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)	No protective earth connection	**N/A**
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time	Class II ME equipment	**N/A**
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION	No such parts	**N/A**
	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 such parts	**N/A**
8.7.3	**Allowable Values**		**Pass**
	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	**Pass**
	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	**Pass**
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC})..... :	See appended Table 8.7	**Pass**
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC}) ..... :	Class II ME equipment	**N/A**
	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 ..... :	No permanently installed ME equipment	**Pass**
	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	**Pass**
	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 ..... :	No functional earth conductor	**N/A**
8.7.4	**LEAKAGE and PATIENT AUXILIARY CURRENTS measurements ..... :**	See appended Table 8.7	**Pass**
8.8	**Insulation**		**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.8.1	**Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing**	Relied upon as a MOP	**Pass**
	Insulation exempted from test (complies with clause 4.8)	See clause 4.8	**Pass**
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	No such parts	**N/A**
8.8.2	**Distance through solid insulation or use of thin sheet material**		**Pass**
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:	See below	**Pass**
	a) 0.4 mm, min, distance through insulation, or		**Pass**
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:	No such parts	**N/A**
	– at least two layers of material, each passed the appropriate dielectric strength test.....:	See above	**N/A**
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test.....:	See above	**N/A**
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION	See above	**N/A**
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION	See above	**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	See above	**N/A**
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		**Pass**
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L	No such parts	**N/A**
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	No such parts	**N/A**
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer	See above	**N/A**
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded	See above	**N/A**
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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	See above	**N/A**
	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 ..... :	See above	**N/A**
	Finished component complied with routine dielectric strength tests of 8.8.3..... :	See appended Table 8.8.3	**Pass**
	Tests of Annex L not repeated since material data sheets confirm compliance..... :	No such parts	**N/A**
8.8.3	**Dielectric Strength**		**Pass**
	Solid insulating materials with a safety function withstood dielectric strength test voltages .... :	See appended Table 8.8.3	**Pass**
8.8.4	**Insulation other than wire insulation**		**Pass**
8.8.4.1	**Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT**	During expected service life	**Pass**
	ME EQUIPMENT and design documentation examined ..... :	Considered with EUT appended table 8.10 and specification sheet	**Pass**
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: H1-8.8.4.1 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**Pass**
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat ..... :	Resistance to heat is established by tests	**N/A**
	Tests conducted in absence of satisfactory evidence for resistance to heat..... :	See below	**Pass**
	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 appended Table 8.8.4.1	**Pass**
	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 appended Table 8.8.4.1	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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	Not performed	**Pass**
8.8.4.2	**Resistance to environmental stress**		**Pass**
	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	Designed and protected	**Pass**
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	No such parts	**N/A**
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	Not used as two means of protection	**Pass**
	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	No parts of natural latex rubber	**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	See above	**N/A**
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**		**Pass**
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	**Pass**
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 defibrillation-proof applied parts	**N/A**
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	**Pass**
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 such parts	**N/A**
	Thermal cycling, humidity preconditioning, and dielectric strength tests	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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) ..... :**	No such parts	**N/A**
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur	See above	**N/A**
8.9.3.3	**Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint**	No such parts	**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:	See above	**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 above	**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	See above	**N/A**
8.10	**Components and wiring**		**Pass**
8.10.1	**Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely ..... :**	Their movements mounted securely	**Pass**
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components ..... : **(ISO 14791 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: H1-8.10.1 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**Pass**
8.10.2	**Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment ..... :**	Secured and insulated	**Pass**
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS	Not solder-coated	**Pass**
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	**Pass**
8.10.4	**Cord-connected HAND-HELD parts and cord-connected foot-operated control devices**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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 foot-operated control devices	**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**	No cord-connected hand-held parts and foot-operated control devices	**N/A**
	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	See above	**N/A**
8.10.5	**Mechanical protection of wiring**		**Pass**
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges ..... :	Protected	**Pass**
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS	Not likely to be damaged	**Pass**
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**	No such parts	**N/A**
8.10.7	**a) Insulating sleeve adequately secured..... :**	No such insulating sleeve	**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	No mechanical or thermal stresses outside its rated characteristics	**N/A**
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C ..... :	Not exceeded	**N/A**
8.11	**MAINS PARTS, components and layout**		**Pass**
8.11.1	**a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles..... :**	Mains plug used	**Pass**
	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)	No permanently installed ME 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	See above	**N/A**
	- the isolation device specified in the ACCOMPANYING DOCUMENTS	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description ..... :	Incorporated in ME equipment	**Pass**
	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 ..... :	No mains switch	**N/A**
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	No mains switch	**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 ..... :	Complied with clause 8.11.1 a)	**Pass**
	g) A fuse or a semiconductor device not used as an isolating means	Not used	**Pass**
	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	Not include	**Pass**
	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	No such parts	**N/A**
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage	See above	**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	No such parts	**N/A**
	Standard test finger applied	See above	**N/A**
8.11.2	**MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2**	No MSO	**N/A**
8.11.3	**POWER SUPPLY CORDS**		**Pass**
8.11.3.1	**MAINS PLUG not fitted with more than one POWER SUPPLY CORD**	Only one power supply cord used	**Pass**
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)... :**	Refer to CA & US national differences (Also see appended Table 8.10)	**Pass**

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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 ..... :	No such parts	**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..... :**	0.75 mm^2 Cu	**Pass**
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 ..... :**	No appliance couplers	**N/A**
8.11.3.5	**Cord anchorage**		**Pass**
	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	Cord bushing used	**Pass**
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or	Insulating material used (See appended Table 8.10)	**Pass**
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or	See above	**N/A**
	– metal provided with an insulating lining affixed to cord anchorage	See above	**N/A**
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation	No such parts	**N/A**
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components	No such screws	**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	No protective earth	**N/A**
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR	See below	**Pass**
	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	**Pass**
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests	See appended Table 8.11.3.5	**Pass**
	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	Not more than	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	CREEPAGE and CLEARANCES not reduced below limits in 8.9	Not reduced	**Pass**
	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	Not possible to push the cord	**Pass**
8.11.3.6	**POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment**	Protected	**Pass**
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or	See below	**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	**Pass**
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance	Not sensitive material	**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	**Pass**
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**	Did not replaceable by service personnel	**N/A**
	Terminals alone are not used to keep conductors in position	See above	**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	See above	**N/A**
	Screws and nuts clamping external conductors do not serve to secure any other component	See above	**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	Did not replaceable by service personnel	**N/A**
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL	See above	**N/A**
	e) A 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	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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 such parts	**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**	No such parts	**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**	Did not replaceable by service personnel	**N/A**
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test	See above	**N/A**
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		**Pass**
	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 below	**N/A**
	- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT ..... :	Provided in one supply lead (See appended Table 8.10)	**Pass**
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	See above	**N/A**
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART	See above	**N/A**
	Protective devices have adequate breaking capacity to interrupt the max. fault current ..... :	See appended Table 8.10	**Pass**
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR	No protective earth conductor	**N/A**
	Justification for omission of fuses or OVER-CURRENT RELEASES documented ..... :	Not emission	**N/A**
8.11.6	**Internal wiring of the MAINS PART**		**Pass**
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable ..... :	No such internal wiring	**N/A**
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient..... :	Sizes of tracks on printed wiring circuits are sufficient	**Pass**

9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**	**Pass**
9.2	**HAZARDS associated with moving parts**	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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	**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)	See above	**N/A**
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and	See above	**N/A**
	RISK CONTROLS implemented ..... :	See above	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
	All RISKS associated with moving parts have been reduced to an acceptable level	See above	**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:**	No moving parts	**N/A**
	– Gaps in Clause 9.2.2.2, or	See above	**N/A**
	– Safe distances in Clause 9.2.2.3, or	See above	**N/A**
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or	See above	**N/A**
	– Continuous activation in Clause 9.2.2.5	See above	**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	See above	**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 .....:**	No moving parts	**N/A**
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 ..... :**	No moving parts	**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 .....:**	No moving parts	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.2.2.4.2	**FIXED GUARDS held in place by systems that can only be dismantled with a TOOL**	No moving parts	**N/A**
9.2.2.4.3	**Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open**	No moving parts	**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,	See above	**N/A**
	– absence or failure of one of their components prevents starting, and stops moving parts	See above	**N/A**
	Movable GUARDS complied with any applicable tests	See above	**N/A**
9.2.2.4.4	**Other RISK CONTROL designed and incorporated into to the control system stops movement and**	No moving parts	**N/A**
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or	See above	**N/A**
	ME EQUIPMENT is SINGLE FAULT SAFE	See above	**N/A**
9.2.2.5	**Continuous activation**		**N/A**
	Continuous activation used as a RISK CONTROL, complies with the following	No moving parts	**N/A**
	a) movement was in OPERATOR'S field of view	See above	**N/A**
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR	See above	**N/A**
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or	See above	**N/A**
	- the continuous activation system is SINGLE FAULT SAFE	See above	**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**	No moving parts	**N/A**
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK	See above	**N/A**
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	See above	**N/A**
	activation does not result in an unacceptable RISK	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.2.3.2	**Over travel past range limits of the ME EQUIPMENT prevented .....:**	No moving parts	**N/A**
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse....:	See above	**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 moving parts	**N/A**
	a) Emergency stopping device reduced RISK to an acceptable level	See above	**N/A**
	RISK MANAGEMENT FILE indicates the use of an emergency stopping device reduces the RISK to an acceptable level .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.6)**	See above	**N/A**
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM	See above	**N/A**
	c) Emergency stopping device actuator was readily accessible to OPERATOR	See above	**N/A**
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT	See above	**N/A**
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD	See above	**N/A**
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like	See above	**N/A**
	g) Means for stopping of movements operate as a result of one single action	See above	**N/A**
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls	See above	**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"	See above	**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	See above	**N/A**
	k) Emergency stopping device is suitable for its application	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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 ..... :**	No moving parts	**N/A**
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented	See above	**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	See above	**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	See above	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
9.3	**Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered .....:**	Rough surfaces, sharp corners and edges are rounded type	**Pass**
9.4	**Instability HAZARDS**		**Pass**
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**	Not overbalance (See clause 9.4.2.1 and 9.4.2.2)	**Pass**
9.4.2	**Instability – overbalance**		**Pass**
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	**Pass**
9.4.2.2	**Instability excluding transport**		**Pass**
	ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE, ...:	See appended Table 9.4.2.2	**Pass**
	A warning provided when overbalance occurred during 10° inclined plane test	No overbalance	**N/A**
9.4.2.3	**Instability from horizontal and vertical forces**		**Pass**
	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	Not exceed 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	See above	**N/A**
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping	Did not overbalance	**Pass**
	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.....:	See above	**N/A**
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b).....:	See appended Table 9.4.2.3	**Pass**
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**	No mobile ME equipment	**N/A**
9.4.2.4.2	**Force required to move MOBILE ME EQUIPMENT did not exceed 200 N .....:**	No mobile ME equipment	**N/A**
9.4.2.4.3	**MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold .....:**	No mobile ME equipment	**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**	No mobile ME equipment	**N/A**
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements	See above	**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 above	**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 .....:	No mobile ME equipment	**N/A**
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test	See above	**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	No such parts	**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	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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	See above	**N/A**
	c) Carrying handles and grips and their means of attachment withstood loading test .....:	See above	**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. 4.3, 4.4, 5, 6.2-6.5)**	No expelled parts	**N/A**
	All identified RISKS associated with expelled parts mitigated to an acceptable level	See above	**N/A**
9.5.2	**Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965 .....:**	No expelled parts	**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**	No acoustic energy causing risk provided	**N/A**
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity .....:	See above	**N/A**
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and **(ISO 14971 Cl. 4.2-44, 5, 6.2-6.5)**	See above	**N/A**
	All identified RISKS mitigated to an acceptable level	See above	**N/A**
9.6.2	**Acoustic energy**		**N/A**
9.6.2.1	**PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE**	No component creating acoustic sound provided	**N/A**
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA).....:	See above	**—**
	- 83 dBA (when halving the cumulative exposure time) (dBA).....:	See above	**—**
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB).....:	See above	**—**
9.6.2.2	**RISK MANAGEMENT FILE examined.....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No infrasound and ultrasound	**N/A**
9.6.3	**Hand-transmitted vibration**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values	No such vibration	**N/A**
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2) .....:	See above	**N/A**
	– Accelerations for different times, inversely proportional to square root of time (m/s^2).....:	See above	**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. 4.3-4.4, 5, 6.2-6.5)**	No pneumatic and hydraulic parts	**N/A**
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum	See above	**N/A**
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure	See above	**N/A**
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects	See above	**N/A**
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply	See above	**N/A**
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible	See above	**N/A**
	– 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	See above	**N/A**
9.7.3	**Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:**	No pressure parts	**N/A**
	a) RATED maximum supply pressure from an external source	See above	**N/A**
	b) Pressure setting of a pressure-relief device provided as part of assembly	See above	**N/A**
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.7.4	**Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests.....:**	No such parts	**N/A**
9.7.5	**A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was more than 50 kPa, and product of pressure and volume was more than 200 kPal .....:**	No pressure vessel	**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 .:**	No pressure-control device	**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 .....:**	No such parts	**N/A**
	a) Connected as close as possible to pressure vessel or parts of system it is to protect	See above	**N/A**
	b) Installed to be readily accessible for inspection, maintenance, and repair	See above	**N/A**
	c) Could be adjusted or rendered inoperative without a TOOL	See above	**N/A**
	d) With discharge opening located and directed as to not to release material towards any person	See above	**N/A**
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK	See above	**N/A**
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure	See above	**N/A**
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect	See above	**N/A**
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)	See above	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the risks associated with the discharge opening of the pressure relief device .....: **(ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)**	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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 ...:**	No support systems	**N/A**
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD	See above	**N/A**
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK	See above	**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. 4.2-4.4, 5, 6.2-6.5)**	See above	**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	See above	**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	See above	**N/A**
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to	See above	**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 systems	**N/A**
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing...:	See above	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the structural integrity of support system ..: **(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**	See above	**N/A**
	All identified RISKS are mitigated to an acceptable level	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	When test were 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 above	**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. 4.3-4.4, 5, 6.2-6.5)**	See above	**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.....:**	No support and suspension systems	**N/A**
	RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**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	See above	**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	See above	**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	See above	**N/A**
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS	See above	**N/A**
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS	See above	**N/A**
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance .....:	See above	**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 .....:**	No foot rest	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests .....:	See above	**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	No such parts	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test .....:	See above	**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**	No support and suspension systems	**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**	No mechanical protective devices	**N/A**
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:	No mechanical protective devices	**N/A**
	– Designed based on TOTAL LOAD	See above	**N/A**
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7	See above	**N/A**
	– Activated before travel produced an unacceptable RISK	See above	**N/A**
	– Takes into account Clauses 9.2.5 and 9.8.4.3	See above	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests .....:	See above	**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**	No mechanical protective devices	**N/A**
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced	See above	**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 :	No mechanical protective devices	**N/A**
	– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal	See above	**N/A**
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE	See above	**N/A**
	– Compliance confirmed by examination and following test .....:	See above	**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	See above	**N/A**
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR	See above	**N/A**
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function	See above	**N/A**
9.8.5	**Systems without MECHANICAL PROTECTIVE DEVICES**		**N/A**
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES .....:	No support systems	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system .....: **(ISO 14971 Cl. 4.3,4.4,5,6.2-6.5)**	See above	**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 .....:**	No such radiation	**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	See above	**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 .....:**	No such radiation	**N/A**
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**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. 4.2-4.4, 5, 6.2-6.5)**	No alpha, beta, gamma, neutron and other particle radiation	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
10.3	**The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2**	No microwave radiation	**N/A**
	Microwave radiation is propagated intentionally	See above	**N/A**
10.4	**Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.**	No laser	**N/A**
10.5	**RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No visible electromagnetic radiation	**N/A**
10.6	**RISK associated with infrared radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No infrared 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. 4.2-4.4, 5, 6.2-6.5)**	No ultraviolet radiation	**N/A**

11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		**Pass**
11.1	**Excessive temperatures in ME EQUIPMENT**		**Pass**
11.1.1	**Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and ..... :**	See appended Table 11.1.1	**Pass**
	Surfaces of test corner did not exceed 90 °C	Test corner did not use. (No such exceed 90 °C in accessible parts)	**N/A**
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	Did not operate	**Pass**
	RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISK: H1-11.1.1 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**Pass**
11.1.2	**Temperature of APPLIED PARTS**		**Pass**
11.1.2.1	**APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply ..... :**	Heating mat	**Pass**
	Clinical effects determined and documented in the RISK MANAGEMENT FILE **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: H1-11.2.1 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use	Description in instructions for use	**Pass**
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. :**	Intended to supply heat	**N/A**
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:	See above	**N/A**
	Maximum Temperature ..... :	See above	**—**
	Conditions for safe contact, e.g. duration or condition of the PATIENT..... :	See above	**—**
	Clinical effects with respect to characteristics taken or surface pressure documented in the RISK MANAGEMENT FILE **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
	APPLIED PARTS surface temperature of equal to or less than 41°C	See above	**N/A**
	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 ..... :	See above	**N/A**
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**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. 4.2-4.4, 5, 6.2-6.5)**	No such parts	**N/A**
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: H1-11.1.3 e) (ISO 14971 Cl. 4.2-4.4, 5)	**Pass**
	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. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: H1-11.1.3 e) (ISO 14971 Cl. 4.2-4.4, 5)	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE ..... :	No such parts	**N/A**
11.1.4	**GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL**	No such guards	**N/A**
11.2	**Fire prevention**		**Pass**
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	**Pass**
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 ..... :**	Not used in an oxygen rich environment	**N/A**
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions	See above	**N/A**
	1) when temperature of material raised to its ignition temperature	See above	**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	See above	**N/A**
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating	See above	**N/A**
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton	See above	**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	See above	**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. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively ..... :	See above	**N/A**
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three ..... :	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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. 4.2-4.4, 5, 6.2-6.5)**	See above	**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 above	**N/A**
	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 (%) ..... :	See above	**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	See above	**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..... :	See above	**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 ..... :	See above	**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**	Not used in 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**	Not used in an oxygen rich environment	**N/A**
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means	See above	**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) ..... :	Not used in an oxygen rich environment	**N/A**
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) ..... :	See above	**N/A**
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) ..... :	See above	**N/A**
	– 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) ..... :	See above	**N/A**
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas ..... :	See above	**N/A**
11.3	**Constructional requirements for fire ENCLOSURES of ME EQUIPMENT**		**Pass**
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2 ..... :	See below	**Pass**
	Constructional requirements were met, or		**Pass**
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
	Justification, when requirement not met ..... :	See above	**N/A**
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials ..... :	See appended Table 8.10	**Pass**
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of materials data ..... :	See appended Table 8.10	**Pass**
	If no FV Certification, FV 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	FV certification	**N/A**
	b) Fire ENCLOSURE met following:	See below	**Pass**
	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	No opening at bottom	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	2) No openings on the sides within the area included within the inclined line C in Fig 39	No opening on the sides	**Pass**
	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	**Pass**
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 intended for use with 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. 4.2-4.4, 5, 6.2-6.5)**	Not intended for use 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**		**Pass**
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	**Pass**
11.6.2	**Overflow in ME EQUIPMENT**		**N/A**
	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 ..... :	No liquid reservoir	**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.	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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.	See above	**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. 4.2-4.4, 5, 6.2-6.5)**	No such parts	**N/A**
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill ..... :	See above	**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)..... :	Ordinary equipment: IPX0	**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 above	**N/A**
11.6.6	**Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS**		**Pass**
	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	**Pass**
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER ..... :	No multiple cleanings	**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..... :	Not intended to be sterilized	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISKS associated with any deterioration following sterilization.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
11.6.8	**RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS.....** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No such parts	**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**	Not evaluate	**N/E**
11.8	**Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**	No hazardous situation	**Pass**
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		**Pass**
12.1	**RISKS associated with accuracy of controls and instruments stated..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: H1-12.1 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**Pass**
12.2	**RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING..... :**	See Usability engineering file (RN-USE-003, Rev.0)	**Pass**
12.3	**MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8. ..... :**	No alarm system	**N/A**
12.4	**Protection against hazardous output**		**Pass**
12.4.1	**RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: H1-12.4.1 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**Pass**
12.4.2	**- need for indication associated with hazardous output addressed in RISK MANAGEMENT PROCESS..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: H1-12.4.2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**Pass**
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. 4.2-4.4, 5, 6.2-6.5)**	No multi-purpose unit	**N/A**
12.4.4	**RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: H1-12.4.4 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**Pass**
12.4.5	**Diagnostic or therapeutic radiation**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
12.4.5.1	**Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation**	No such radiation	**N/A**
	Radiation safety ensured by compliance with requirements of appropriate standards	See above	**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 ..... :**	No such radiation	**N/A**
12.4.5.3	**RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No such 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. 4.2-4.4, 5, 6.2-6.5)**	No such radiation	**N/A**
12.4.6	**RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No such acoustic pressure	**N/A**

13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		**Pass**
13.1	**Specific HAZARDOUS SITUATIONS**		**Pass**
13.1.2	**Emissions, deformation of ENCLOSURE or exceeding maximum temperature**		**Pass**
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur	Did not occur	**Pass**
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur	Did not occur	**Pass**
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24..... :	Intended to supply heat to a patient	**N/A**
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23..... :	See appended Table 11.1.1	**Pass**
	–Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 °C were not exceeded	Not exceeded (See appended Table 11.1.1)	**Pass**
	Limits for windings in Tables 26, 27, and 31 not exceeded	Not exceeded (See appended Table 11.1.1)	**Pass**
	Table 22 not exceeded in all other cases	Not exceeded (See appended Table 11.1.1)	**Pass**
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function	Did not change	**Pass**
13.1.3	**– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed..... :**	See appended Table 8.7	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS did not exceed..... :	See appended Table 8.7	**Pass**
13. 2	**SINGLE FAULT CONDITIONS**		**Pass**
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**	Applied	**Pass**
	ME EQUIPMENT complied with 13.2.2 -13.2.12 ..... :	See appended Table 13.2	**Pass**
	RISK MANAGEMENT FILE includes and assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No such parts	**N/A**
	RISK MANAGEMENT FILE defines the appropriate test conditions.....:	See above	**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 the temperature in the test environment**	Remain safe	**Pass**
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		**Pass**
	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).	No such parts	**N/A**
13.2.13.2	**ME EQUIPMENT with heating elements**		**Pass**
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, or for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	No such parts	**N/A**
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests	Continuous operation	**N/A**
	a 3) other ME EQUIPMENT with heating elements met test	See a) 1)	**N/A**
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively	Consecutively	**Pass**
	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	No such parts	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part	No such parts	**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	See above	**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) ..... :	132 V~	**Pass**
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY	See appended Table 13.2	**Pass**
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted	See above	**N/A**
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION	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	132 V~	**Pass**
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS	See appended Table 13.2	**Pass**
	2) When more than one control provided, they were disabled in turn	Only one control provided	**N/A**
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time	Continuous operation	**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	**N/A**
	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	See above	**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	See above	**N/A**
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) Motor met running overload protection test of this clause when:	No motors	**N/A**
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or	See above	**N/A**
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended	See above	**N/A**
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C)..... :	See above	**N/A**
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps	See above	**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	See above	**N/A**
	Test not conducted where electronic drive circuits maintained a substantially constant drive current	See above	**N/A**
	Test not conducted based on other justifications (justification)..... :	See above	**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	No 3-phase motors	**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	Continuous operation	**N/A**
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle	See above	**N/A**
	Motor winding temperatures did not exceed values in 13.2.10 ..... :	See above	**N/A**
	Insulation Class ..... :	See above	**—**
	Maximum temperature measured (°C)..... :	See above	**—**

14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		**Pass**
14.1	**Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE, or**	Apply to PESS	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK ..... :	See above	**N/A**
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: **(ISO 14971 Cl. 4.2-4.4, 5)**	Applying PEMS	**N/A**
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK	Not intended to be incorporated into an IT-Network	**N/A**
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304..... :	Software Class: B	**Pass**
	Software development process applied according to Clause 5 of IEC 62304..... :	See clause 9 of Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
	Software development process for Software risk management applied according to Clause 7 of IEC 62304 ..... :	See clause 17 of Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
	Software development process Configuration Management applied according to Clause 8 of IEC 62304..... :	See Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304..... :	See clause 10 of Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
14.2	**Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process ..... :**	The Software validation plan and report is reviewed, approved, issued and changed in accordance with a formal document control procedure	**Pass**
14.3	**RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan**	See Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
14.4	**A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented**	See Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	See Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	See Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules	See Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	See Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
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**	See Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
14.6	**RISK MANAGEMENT PROCESS**		**Pass**
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..... :**		**Pass**
	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. 4.3)**	See clause 17.7 of Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
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 :**		**Pass**
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure.....: **(ISO 14971 Cl. 6.1)**	See clause 17.9 of Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
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. 6.3)**	See clause 14 of Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
14.8	**An architecture satisfying the requirement is specified for PEMS and each of subsystems .... :** **(ISO 14971 Cl. 6.3)**	See clause 14.6.2 of Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
14.9	**Design is broken up into sub systems and descriptive data on design environment documented ..... :**	See Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
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. 6.3)**	See clause 16 of Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– milestone(s) when VERIFICATION is to be performed for each function	See clause 16 of Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION	See clause 16 of Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
	– selection and utilization of VERIFICATION tools	See clause 16 of Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
	– coverage criteria for VERIFICATION	See clause 16 of Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented	Performed according to the verification plan	**Pass**
14.11	**A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE ..... :**	Containing	**Pass**
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented	See clause 16 of Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
	The person with overall responsibility for PEMS VALIDATION is independent	Independent	**Pass**
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE **(ISO 14971 Cl. 6.3)**	See Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
14.12	**Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE**	See Software Validation Plan and Report (SVP-RL-S03, Rev.1)	**Pass**
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304 ..... :	Software Class: B	**Pass**
	Software Process for Software changes applied according to Clause 5 of IEC 62304 ..... :		**Pass**
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304 ..... :		**Pass**
	Configuration management of software changes applied per Clause 8 of IEC 62304 .... :		**Pass**
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304 .... :		**Pass**
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 ..... :**	Not intended	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	a) Purpose of the PEMS connection to an IT-NETWORK	See above	**N/A**
	b) required characteristics of the IT-NETWORK	See above	**N/A**
	c) required configuration of the IT-NETWORK	See above	**N/A**
	d) technical specifications of the network connection, including security specifications	See above	**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	See above	**N/A**
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the characteristics required **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)**	See above	**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	See above	**N/A**
	– Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS	See above	**N/A**
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis	See above	**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**	See above	**N/A**

15	**CONSTRUCTION OF ME EQUIPMENT**		**Pass**
15.1	**RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS..... :**	See IEC 60601-1-6 test report. See Usability engineering file (RN-USE-003, Rev.0)	**Pass**
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**	Accessible for inspection, replacement and maintenance	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring	Can easily be done without damage	**Pass**
15.3	**Mechanical strength**		**Pass**
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 clause 15.3.2, 15.3.3, 15.3.4 & 15.3.6	**Pass**
15.3.2	**Push test conducted ..... :**	See Appended Table 15.3	**Pass**
	No damage resulting in an unacceptable RISK sustained	No damage. No hazardous	**Pass**
15.3.3	**Impact test conducted..... :**	See Appended Table 15.3	**Pass**
	No damage resulting in an unacceptable RISK sustained	No damage. No hazardous	**Pass**
15.3.4	**Drop test**		**Pass**
15.3.4.1	**Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested ..... :**	No hand-held ME equipment	**N/A**
	No unacceptable RISK resulted	See above	**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	**Pass**
	No damage resulting in an unacceptable RISK sustained	No damage. No hazardous	**Pass**
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..... :**	No mobile ME equipment and parts	**N/A**
	No damage resulting in an unacceptable RISK sustained	See above	**N/A**
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**	See Appended Table 15.3	**Pass**
	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 ..... :	Outside plastic enclosure	**Pass**
	No damage resulting in an unacceptable RISK	No damage. No hazardous	**Pass**
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**		**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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	Designed and constructed (Also see clause 15.2)	**Pass**
15.4	**ME EQUIPMENT components and general assembly**		**Pass**
15.4.1	**Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, ... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: H1-15.4.1 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**Pass**
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions, ... :	No plugs for connection of patient leads or patient cables	**N/A**
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection ..... :	No medical gas connections	**N/A**
15.4.2	**Temperature and overload control devices**		**Pass**
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. 4.2-4.4, 5)**	RMF Reference to specific RISKS: H1-15.4.2.1 a) (ISO 14971 Cl. 4.2-4.4, 5) No hazardous situation	**Pass**
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT	No thermal cut-out with reset by a soldering	**N/A**
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided ..... : **(ISO 14971 Cl. 4.2-4.4)**	No hazardous situation	**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. 4.2-4.4)**	RMF Reference to specific RISKS: H1-15.4.2.1 d) (ISO 14971 Cl. 4.2-4.4)	**Pass**
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS	No such parts	**N/A**
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests:	Did not affect safety	**Pass**
	- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17	Approved thermal cut-out used	**Pass**
	- ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13 ..... :	See appended Table 13.2	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards.....	Approved self-resetting thermal cut-out used	**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	Approved self-resetting thermal cut-out used	**N/A**
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards	No manual reset thermal cut-outs and over-current	**N/A**
	manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times	See above	**N/A**
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted	Not separated	**N/A**
	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 such parts	**N/A**
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating : **(ISO 14971 Cl. 4.2-4.4)**	No tubular heating elements	**N/A**
15.4.2.2	**Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS**	No such parts	**N/A**
15.4.3	**Batteries**		**N/A**
15.4.3.1	**Battery housings provided with ventilation.... :** **(ISO 14971 Cl. 4.2-4.4)**	No battery	**N/A**
	Battery compartments designed to prevent accidental short circuiting	See above	**N/A**
15.4.3.2	**Means provided to prevent incorrect connection of polarity..... :**	No battery	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries..... : **(ISO 14971 Cl. 4.2-4.4)**	See above	**N/A**
15.4.3.3	**Overcharging of battery prevented by virtue of design ..... :**	No battery	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries..... : **(ISO 14971 Cl. 4.2-4.4)**	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
15.4.3.4	**Primary lithium batteries comply with IEC 80086-4**	No primary lithium batteries	**N/A**
	Secondary lithium batteries comply with IEC 62133	No secondary lithium batteries	**N/A**
15.4.3.5	**A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire ..... :**	No internal electrical power source	**N/A**
	Protective device has adequate breaking capacity	See above	**N/A**
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented	See above	**N/A**
	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	See above	**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	See above	**N/A**
15.4.4	**Indicator lights provided to indicate ME EQUIPMENT is ready for ..... :**	Indicator used	**Pass**
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,	Not exceeding 15 s	**N/A**
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational	No non-luminous heaters	**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. 4.2-4.4)**	No non-luminous heaters	**N/A**
	Requirement not applied to heated stylus-pens for recording purposes	No heated stylus-pens	**N/A**
	Indicator lights provided on ME EQUIPMENT to indicate an output exists	Indicator used	**Pass**
	Colours of indicator lights complied with 7.8.1	Complied with clause 7.8.1	**Pass**
	Charging mode visibly indicated	No charging mode	**N/A**
15.4.5	**RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No pre-set controls	**N/A**
15.4.6	**Actuating parts of controls of ME EQUIPMENT**		**Pass**
15.4.6.1	**a) Actuating parts cannot be pulled off or loosened during NORMAL USE**	Cannot be pulled off or loosened	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) Controls secured so that the indication of any scale always corresponds to the position of the control	No such parts	**N/A**
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL	No such parts	**N/A**
	When torque values per Table 30 applied knobs did not rotate ..... :	No rotating controls	**N/A**
	Tests conducted with no unacceptable RISK . :	See above	**N/A**
15.4.6.2	**Stops on rotating/ movable parts of controls are of adequate mechanical strength ..... :**	No such parts	**N/A**
	Torque values in Table 30 applied ..... :	See above	**N/A**
	No unexpected change of the controlled parameter when tested..... :	See above	**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 devices	**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	**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 hand-held and foot-operated control device	**N/A**
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position	See above	**N/A**
15.4.7.3	**a) Foot-operated control device is at least rated IPX1** ..... :	No foot-operated control device	**N/A**
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6.... :	No foot-operated control device	**N/A**
15.4.8	**Aluminium wires less than 16 mm^2 in cross-sectional area are not used**	No such parts	**N/A**
15.4.9	**a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed**	No oil container	**N/A**
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport	No mobile ME equipment	**N/A**
	A pressure-release device operating during NORMAL USE is provided	See above	**N/A**
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage	No such parts	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements	See above	**N/A**
15.5	**MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5**		**Pass**
15.5.1	**Overheating**		**Pass**
15.5.1.1	**Transformers of ME EQUIPMENT are protected against overheating..... :**	See appended Tables 15.5.1.2 and 15.5.1.3	**Pass**
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31	Windings did not open, no hazardous situation occurred, and maximum temperatures of windings did not exceed values in Table 31	**Pass**
	Dielectric strength test conducted after short circuit and overload tests ..... :	See appended Table 15.5.2	**Pass**
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	**Pass**
	Short circuit applied directly across output windings	Tested	**N/A**
15.5.1.3	**Multiple overload tests conducted on windings ..... :**	See appended Table 15.5.1.3	**Pass**
15.5.2	**Transformers operating at a frequency above 1kHz tested according to clause 8.8.3..... :**	No such transformers	**N/A**
	Transformer windings provided with adequate insulation		**Pass**
	Dielectric strength tests were conducted ..... :	See appended Table 15.5.2	**Pass**
15.5.3	**Transformers forming MEANS OF PROTECTION as required by 8.5 comply with ..... :**	Not used to forming means of protection	**N/A**
	- Means provided to prevent displacement of end turns	See above	**N/A**
	- protective earth screens with a single turn have insulated overlap	See above	**N/A**
	- Exit of wires form internal windings of toroid transformers protected with double sleeving	See above	**N/A**
	- insulation between primary and secondary windings complies with 8.8.2	See above	**N/A**
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4	See above	**N/A**
16	**ME SYSTEMS**		**N/A**
16.1	**After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK**	No ME systems	**N/A**

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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. 4.2-4.4, 5)	See above	N/A
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered	See above	N/A
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard	See above	N/A
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards	See above	N/A
	– tests performed in NORMAL CONDITION, except as specified	See above	N/A
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM	See above	N/A
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated	See above	N/A
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR	See above	N/A
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards	See above	N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM	See above	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	No ME systems	N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM	See above	N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER	See above	N/A
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER	See above	N/A
	c) the required information is provided:	See above	N/A
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM	See above	N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard	See above	**N/A**
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM	See above	**N/A**
	– additional safety measures to be applied during installation of ME SYSTEM	See above	**N/A**
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT	See above	**N/A**
	– additional measures to be applied during preventive maintenance	See above	**N/A**
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor	See above	**N/A**
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM	See above	**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	See above	**N/A**
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM	See above	**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	See above	**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	See above	**N/A**
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET	See above	**N/A**
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage	See above	**N/A**
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT	See above	**N/A**
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:	See above	**N/A**
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard	See above	**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**	No ME systems	**N/A**
	Transient currents restricted to allowable levels for the specified IPS or UPS ..... :	See above	**N/A**
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified	See above	**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)**	No ME systems	**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**	No ME systems	**N/A**
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION	See above	**N/A**
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V) ..... :	See above	**N/A**
16.6	**LEAKAGE CURRENTS**		**N/A**
16.6.1	**TOUCH CURRENT in NORMAL CONDITION did not exceed 100 µA.....:**	No ME systems	**N/A**
	TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR .....:	See above	**N/A**
16.6.2	**Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA....:**	No ME systems	**N/A**
16.6.3	**PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values .....:**	No ME systems	**N/A**
16.7	**ME SYSTEM complied with applicable requirements of Clause 9.....:**	No ME systems	**N/A**
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**	No ME systems	**N/A**
16.9	**ME SYSTEM connections and wiring**		**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
16.9.1	**Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result ..... :**	No ME systems	**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. 4.2-4.4, 5, 6.2-6.5)**	See above	**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	See above	**N/A**
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable	See above	**N/A**
16.9.2	**MAINS PARTS, components and layout**	No ME systems	**N/A**
16.9.2.1	**a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or**	No ME systems	**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	See above	**N/A**
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer	See above	**N/A**
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 visible in NORMAL USE, and	See above	**N/A**
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or	See above	**N/A**
	– marked to indicate the equipment or equipment parts it may safely be attached to	See above	**N/A**
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT	See above	**N/A**
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:	See above	**N/A**
	– CREEPAGE and CLEARANCES complied with 8.9	See above	**N/A**
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets	See above	**N/A**
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:	See above	**N/A**
	– ENCLOSURE complied with 8.4.2 d)	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable	See above	**N/A**
	– RATINGS of components are not in conflict with conditions of use .....:	See above	**N/A**
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL	See above	**N/A**
	– POWER SUPPLY CORD complied with 8.11.3	See above	**N/A**
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:	See above	**N/A**
	– Separating transformer complied with this standard or IEC 61558-2-1, ...:	See above	**N/A**
	– Separating transformer is CLASS I	See above	**N/A**
	– Degree of protection against ingress of water specified as in IEC 60529	See above	**N/A**
	– Separating transformer assembly marked according to 7.2 and 7.3	See above	**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	See above	**N/A**
16.9.2.2	**The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED did not exceed 200 mΩ**	No ME systems	**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	See above	**N/A**
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL	See above	**N/A**
16.9.2.3	**Conductors connecting different items within an ME SYSTEM protected against mechanical damage**	No ME systems	**N/A**

17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		**N/E**
	RISKS associated confirmed by review.....:		**N/E**
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS .....:		**N/E**

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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. 4.2-4.4, 5, 6.2-6.5)		N/E
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems		N/E
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		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.5 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)..... :		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)..... :		N/A
	Marking is as large as possible for the particular case		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	When above marking not possible, the 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.3.3	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 ..... :		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 ..... :		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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882 ..... :		N/A
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..... :		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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open		N/A
	– 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 .. :		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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing		N/A
	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 :		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		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:		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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 ..... :		N/A
	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 4.10		N/A
	– I_{max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 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..... :		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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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..... :		N/A
	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		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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
L.4.3	**Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1) .....:**		**N/A**
	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**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**Pass**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
3.1	Cl. 3.1 of Risk management report (RN-RMR-003, Rev.0)	—	Risk Management Process (excluding production and post-production)	**Pass**
3.2	Cl. 1.4.1 of Risk management plan (RN-RMP-003, Rev.0)	—	Adequate Resources	**Pass**
3.2	Cl. 1.4.2 of Risk management plan (RN-RMP-003, Rev.0)	—	Assignment of qualified personnel	**Pass**
3.2	Cl. 1.4.3 of Risk management plan (RN-RMP-003, Rev.0)	—	Policy for determining criteria for risk acceptability	**Pass**
3.3	—	Cl. 1.5 of Risk management plan (RN-RMP-003, Rev.0)	Qualification of personnel	**Pass**
3.4a	—	Cl. 2.2.2 of Risk management plan (RN-RMP-003, Rev.0)	Scope of risk management activities	**Pass**
3.4b	—	Cl. 3.8 of Risk management plan (RN-RMP-003, Rev.0)	Assignment of responsibilities and authorities	**Pass**
3.4c	—	Cl. 4 of Risk management plan (RN-RMP-003, Rev.0)	Requirements for review of activities	**Pass**
3.4d	—	Cl. 5 of Risk management plan (RN-RMP-003, Rev.0)	Evidence of risk acceptability criteria	**Pass**
3.4e	—	Cl. 6 of Risk management plan (RN-RMP-003, Rev.0)	Verification activities	**Pass**
3.5	—	Cl. 4, 5 & 6 of Risk management report (RN-RMR-003, Rev.0)	Criteria for the establishment of a risk management file providing traceability for each identified hazard	**Pass**
4.1	—	Cl. 4.1 of Risk management report (RN-RMR-003, Rev.0)	Procedure for risk analysis	**Pass**
4.2	—	Cl. 4.2 of Risk management report (RN-RMR-003, Rev.0)	Record of safety issue analysis	**Pass**

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

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**Pass**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
4.3	—	Cl. 4.3 of Risk management report (RN-RMR-003, Rev.0)	Record of hazard analysis	**Pass**
4.4	—	Cl. 4.4 of Risk management report (RN-RMR-003, Rev.0)	d. Definition of methods used for estimating risks e. Description of method(s) used. f. Result of risk estimation activities.	**Pass**
5	—	Cl. 5 of Risk management report (RN-RMR-003, Rev.0)	b. Result of risk evaluation activities	**Pass**
6.2	—	Cl. 6.2 of Risk management report (RN-RMR-003, Rev.0)	Record of risk control option analysis (including risk-benefit analysis, if appropriate).	**Pass**
6.3	—	Cl. 6.3 of Risk management report (RN-RMR-003, Rev.0)	Inputs from risk management activities	**Pass**
6.4	—	Cl. 6.4 of Risk management report (RN-RMR-003, Rev.0)	Final results of the residual risk evaluation and, if necessary, information necessary to explain the residual risk(s) in the appropriate accompanying documents	**Pass**
6.5	—	Cl. 6.5 of Risk management report (RN-RMR-003, Rev.0)	Evidence as necessary.	**Pass**
6.6a	—	Cl. 6.6 of Risk management report (RN-RMR-003, Rev.0)	Record of results of review of all risk controls for to identify if other hazards are introduced by any risk control measures and the associated risk(s) assessment(s)	**Pass**
6.6b	—	Cl. 6.6 of Risk management report (RN-RMR-003, Rev.0)	Record of results of review of all risk controls for to identify if other hazards are introduced by any risk control measures and the associated risk(s) assessment(s)	**Pass**
6.7	—	Cl. 6.7 of Risk management report (RN-RMR-003, Rev.0)	Record of assessment to assure that the risk(s) from all identified hazards have been evaluated	**Pass**
7	—	Cl. 7 of Risk management report (RN-RMR-003, Rev.0)	Records of related meetings, analysis, and overall results.	**Pass**
8	—	Cl. 8 of Risk management report (RN-RMR-003, Rev.0)	Documented review of risk management process prior to commercial distribution	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**Pass**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
Supplementary Information: **Document Ref should be with regards to the policy/procedure documents and documents containing device specific output.**				

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

4.3	**TABLE: ESSENTIAL PERFORMANCE**		**Pass**
List of ESSENTIAL PERFORMANCE functions	**MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)**	**Remarks**	
Accuracy of temperature output	**Clause 11.1 of Testing Data**	**Clause 201.11.1.2.1.101.1 of IEC 80601-2-35 Clause 201.13.1.2.101.2 of IEC 80601-2-35 Clause 201.12.4.101 of IEC 80601-2-35 Clause 201.12.4.102**	
Supplementary Information: Refer to the Documentum of 2783119 project ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.			

4.11	**TABLE: Power Input**				**Pass**
Operating Conditions / Ratings	**Voltage (V)**	**Frequency (Hz)**	**Current (A)**	**Power (W or VA)**	**Power factor (cos φ)**
Normal load condition / N/A	108	60	0.75	80.63	1.000
Normal load condition / 100 W	120	60	0.83	99.24	1.000
Normal load condition / N/A	132	60	0.93	122.58	0.999
Supplementary Information: Refer to the Documentum of 2783119 project					

5.9.2	**TABLE: Determination of ACCESSIBLE parts**	**Pass**
Location	**Determination method (NOTE1)**	**Comments**
All enclosure	**Visual and Rigid test finger**	**No hazard. No opening**
Supplementary information: Refer to the Documentum of 2783119 project NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.		

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

7.1.2	**TABLE: Legibility of Marking**		**Pass**
Markings tested		**Ambient Illuminance (lx)**	**Remarks**
Outside Markings (Clause 7.2) .....:		781	Legible
Inside Markings (Clause 7.3) .....:		781	Legible
Controls & Instruments (Clause 7.4) .....:		781	Legible
Safety Signs (Clause 7.5).....:		781	Legible
Symbols (Clause 7.6) .....:		781	Legible
Supplementary information: Refer to the Documentum of 2783119 project 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**	**Pass**
Characteristics of the Marking Label tested:		**Remarks**
Material of Marking Label ..... :	Ink or paint Type	No loose and curled
Ink/other printing material or process..... :		-
Material (composition) of Warning Label ..... :		-
Ink/other printing material or process..... :		-
Other..... :		-
Marking Label Tested:		**Remarks**
Time with distilled water: 15 s		No loose and curled
Time with methylated spirit: 15 s		No loose and curled
Time with isopropyl alcohol: 15 s		No loose and curled
Supplementary information: Refer to the Documentum of 2783119 project 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.		

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

8.4.2	TABLE: TABLE: Working Voltage / Power Measurement					N/A
Test supply voltage/frequency (V/Hz)[1] ..... :						
Location From/To	**Measured values**					**Remarks**
	Vrms	**Vpk or Vdc**	**Peak-to-peak ripple[2]**	**Power W/VA**	**Energy (J)**	
Main Transformer (T1) Primary winding wire / Secondary winding wire	132	187	-	-	-	-
Primary circuit to enclosure (control box)	132	187	-	-	-	-
Primary circuit to mat connector cable	132	187	-	-	-	-
Primary circuit to applied part (Mat)	132	187	-	-	-	-

Supplementary Information: Refer to the Documentum of 2783119 project

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 8.4.2.2

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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**	**Pass**

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	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	1 / 0	0 / 0	0 / 0	0 / 0	0 / 0
Plug pin 1 and plug earth pin	-	-	-	-	-	-	-	-	-	-
Plug pin 2 and plug earth pin	-	-	-	-	-	-	-	-	-	-
Plug pin 1 and enclosure	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0
Plug pin 2 and enclosure	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0	0 / 0

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	-	-	-	-	-	-	-	-	-	-

Supplementary information: Refer to the Documentum of 2783119 project

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

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	N/A

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)

Supplementary information:

PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 mΩME 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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

8.7	**TABLE: leakage current**				**Pass**
Type of leakage current and test condition (including single faults)	**Supply voltage (V)**	**Supply frequency (Hz)**	**Measured max. value (µA)**	**Remarks**	
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC	
N/A					
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC	
TC, NC, S1 = 1, S5 = N, S12 = 0	132	60	1.78 / 1.79	≤ 100 uA (MD2 between Top enclosure of control box (Plastic) and Bottom enclosure of control box (Plastic))	
TC, NC, S1 = 1, S5 = R, S12 = 0	132	60	0.49 / 3.26	≤ 100 uA, (See as above)	
TC, NC, S1 = 1, S5 = N, S12 = 1	132	60	2.05 / 2.78	≤ 100 uA, (See as above)	
TC, NC, S1 = 1, S5 = R, S12 = 1	132	60	0.57 / 2.69	≤ 100 uA, (See as above)	
TC, SFC (Neutral Open), S1 = 0, S5 = N, S12 = 0	132	60	0.66 / 1.77	≤ 500 uA, (See as above)	
TC, SFC (Neutral Open), S1 = 0, S5 = R, S12 = 0	132	60	0.39 / 2.28	≤ 500 uA, (See as above)	
TC, SFC (Neutral Open), S1 = 0, S5 = N, S12 = 1	132	60	0.48 / 0.59	≤ 500 uA, (See as above)	
TC, SFC (Neutral Open), S1 = 0, S5 = R, S12 = 1	132	60	0.37 / 1.36	≤ 500 uA, (See as above)	
-	-	-	After cleaning (uA)	–	
TC, NC, S1 = 1, S5 = N, S12 = 0	132	60	1.79	≤ 100 uA (MD2 between Top enclosure of control box (Plastic) and Bottom enclosure of control box (Plastic))	
TC, NC, S1 = 1, S5 = R, S12 = 0	132	60	1.70	≤ 100 uA, (See as above)	
TC, NC, S1 = 1, S5 = N, S12 = 1	132	60	2.25	≤ 100 uA, (See as above)	
TC, NC, S1 = 1, S5 = R, S12 = 1	132	60	1.27	≤ 100 uA, (See as above)	
TC, SFC (Neutral Open), S1 = 0, S5 = N, S12 = 0	132	60	1.16	≤ 500 uA, (See as above)	
TC, SFC (Neutral Open), S1 = 0, S5 = R, S12 = 0	132	60	1.09	≤ 500 uA, (See as above)	

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Clause	**Requirement + Test**			**Result - Remark**	**Verdict**

TC, SFC (Neutral Open), S1 = 0, S5 = N, S12 = 1	132	60	1.08	≤ 500 uA, (See as above)
TC, SFC (Neutral Open), S1 = 0, S5 = R, S12 = 1	132	60	1.02	≤ 500 uA, (See as above)
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)
P, NC, S1 = 1, S5 = N	132	60	15.63 / 20.03	≤100uA (Applied part)
P, NC, S1 = 1, S5 = R	132	60	13.28 / 15.89	≤ 100uA (See as above)
P, SFC (Neutral Open), S1 = 0, S5 = N	132	60	13.68 / 20.25	≤ 500uA (See as above)
P, SFC (Neutral Open), S1 = 0, S5 = R	132	60	12.79 / 20.58	≤ 500uA (See as above)
P, NC, S1 = 1, S5 = N, S13 = 0	132	60	14.81 / 15.88	≤100uA (Cable)
P, NC, S1 = 1, S5 = R, S13 = 0	132	60	15.44 / 17.47	≤ 100uA (See as above)
P, SFC (Neutral Open), S1 = 0, S5 = N, S13 = 0	132	60	14.38 / 20.42	≤ 500uA (See as above)
P, SFC (Neutral Open), S1 = 0, S5 = R, S13 = 0	132	60	12.59 / 20.56	≤ 500uA (See as above)
-	-	-	After cleaning (uA)	–
P, NC, S1 = 1, S5 = N	132	60	16.63	≤100uA (Applied part)
P, NC, S1 = 1, S5 = R	132	60	12.28	≤ 100uA (See as above)
P, SFC (Neutral Open), S1 = 0, S5 = N	132	60	14.28	≤ 500uA (See as above)
P, SFC (Neutral Open), S1 = 0, S5 = R	132	60	14.59	≤ 500uA (See as above)
P, NC, S1 = 1, S5 = N	132	60	14.90	≤100uA (Cable)
P, NC, S1 = 1, S5 = R	132	60	15.44	≤ 100uA (See as above)
P, SFC (Neutral Open), S1 = 0, S5 = N, S13 = 0	132	60	15.48	≤ 500uA (See as above)
P, SFC (Neutral Open), S1 = 0, S5 = R, S13 = 0	132	60	16.49	≤ 500uA (See as above)

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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
PM, SFC, S1 = 1, S5 = N, S7 = 1, S9 = N	264	60	31.1 / 32.5	≤ 5 000 µA
PM, SFC, S1 = 1, S5 = N, S7 = 1, S9 = R	264	60	51.3 / 54.5	≤ 5 000 µA
PM, SFC, S1 = 1, S5 = R, S7 = 1, S9 = N	264	60	32.7 / 33.8	≤ 5 000 µA
PM, SFC, S1 = 1, S5 = R, S7 = 1, S9 = R	264	60	52.4 / 54.7	≤ 5 000 µA
-	-	-	After cleaning (uA)	–
PM, SFC, S1 = 1, S5 = N, S7 = 1, S9 = N	264	60	33.7	≤ 5 000 µA
PM, SFC, S1 = 1, S5 = N, S7 = 1, S9 = R	264	60	54.1	≤ 5 000 µA
PM, SFC, S1 = 1, S5 = R, S7 = 1, S9 = N	264	60	33.9	≤ 5 000 µA
PM, SFC, S1 = 1, S5 = R, S7 = 1, S9 = R	264	60	54.2	≤ 5 000 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)
N/A				
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
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)
N/A				
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)
N/A				

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

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)
N/A				
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
N/A				
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
N/A				
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
N/A				

Supplementary information: Refer to the Documentum of 2783119 project

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).

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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

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

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.		
Primary circuit to enclosure (control box)	2 MOOP	187 Vpeak	-	2 000	No breakdown
Primary circuit to Applied part(Mat)	2 MOPP	187 Vpeak	-	3 000	No breakdown
Primary circuit to mat connector cable	2 MOPP	187 Vpeak	-	3 000	No breakdown

Supplementary information: Refer to the Documentum of 2783119 project

[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**		**Pass**
	Allowed impression diameter (mm) ..... :	**≤ 2 mm**	**—**
	Force (N) ..... :	**20**	**—**

Part/material	Test temperature (°C)	Impression diameter (mm)
Enclosure/External insulating parts		
Top plastic enclosure, 1h	75	1.2
Bottom plastic enclosure, 1h	75	1.3
Insulating material supporting un-insulated Mains Parts		
Transformer (T1) bobbin	125	1.0
Line Filter (LF2) bobbin	125	1.0
Supplementary information: Refer to the Documentum of 2783119 project		

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

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**		**Pass**
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**
Circuit areas of after main fuse(FS1)	CD	No	Main Fuse(FS1) opened, Test duration: 1 s
Supplementary information: Refer to the Documentum of 2783119 project Note 1: 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			
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.				

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

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.

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

8.10	**TABLE: List of critical components**				**Pass**
Component/ Part No.	**Manufacturer/ Trademark**	**Type No./model No./**	**Technical data**	**Standard No./, Edition**	**Mark(s) & Certificates of conformity [1]**
1: Main Enclosure of Controller	LG Chem Ltd.	AF312C	Type: Transportable Overall Dimensions: 170.5 x 105 x 35 mm by 2.5 mm thick Material: ABS (V-0) Color: Black, White Weight: 0.13 kg	CSA 0.17 UL 746C UL 94	UL (E67171)
2: Marking and labelling system	Avery Dennison Korea Ltd.	PET TC3	Material type: PET Dimensions:59 x 34 mm Color: Silver Impression type: Pressure-sensitive systems	CSA 0.15 UL 969	UR (MH26285)
3: Power Cord Set (INT)	Korea KDK Co., Ltd.	KKP-11W with SJT Flexible cord	- Power plug: 125 V~; 15 A - Power cord: Seize of wire: 18 AWG; 300 V; 60 ºC Type: SJT (Non-detachable type)	CSA 21 UL 817	UL (E58075)
4: Wire Connector (CN2 & CN3)	Yeon Ho Electronics Co., Ltd.	YWL500 YHL500	250 V; 5 A	CSA 182.3 UL 1977	UR (E108706)
5: Main Fuse (FS1)	Cooper Bussmann LLC	SS-5	250 V~; 3.15 A Interrupting rating: 35 A Type: T3.15AL Dimension: 8.6 x 4.3 x 8.4 mm	CSA 248-1 CSA 248-14 UL 248-1 UL 248-14	UR (E19180)
6: Surge protective device (TNR1)	Thinking Electronic Industrial Co., Ltd.	TVR10471	Varistor voltage: 470 V; Max. operating voltage: 300 V~; Max. surge current:	CSA 516 UL 1449	UR (E314979)

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

			2 500 A		
7: X2 Capacitor (C8 & C9)	Carli Electronics Co., Ltd.	MPX	0.01 µF; 275 V~; X2	CSA E60384-1 CSA E60384-14 UL 60384-14	UR (E120045)
8: Mains Transformer (TRANS)	Dongho Electronics	DH-2809-120	Primary: 120 V~; 60 Hz Secondary: 8 V~; 0.07 A; Class A; 105 ºC Protection	CSA 60601-1	Accepted
9: Optical Isolators / Couplers (PC1)	Fairchild Semiconductor Corp.	MOC3041	Isolation: 3 750 V~ Creepage: 7 mm	CSA Notice No. 5 UL 1577	UR (E90700)
10: PC-Board (Only material can be interchanged, due to layout and traces)	Shanghai Nanya Copper Clad Laminates Co., Ltd.	NY1140	Material: FR-4.0 Dimensions: 134 x 78.5 x 1.6 mm by 1.6 mm thick Inflammability rating: V-0; 130 ºC	UL 746E UL 796 IEC 60695-11-10	UR (E108706)
11: Front panel sheet	Mianyang Longhua Film Co., Ltd.	PC-1811A	Dimensions: 128 x 92 x 1 mm by 1.0 mm thick Inflammability rating: V-2; 80 ºC	UL 746 UL 94 CSA 0.17.92	UR (E254551)
12: Plastic of control switch	LG Chem Ltd.	AF312C	Inflammability rating: V-0; 80 ºC	UL 746 UL 94 CSA 0.17.92	UR (E67171)
13: Output Cord	Kwang Il Electric Wire Co., Ltd.	2464	18 AWG; 300 V; 80 ºC; VW-1 Type	CSA 127 UL 758	UR (150633)
14: Plastic enclosure of Output Connector (INT)	Samsung SDI Co., Ltd.	EN-1052(+)	Dimensions: 48 x 51.17 x 16.63 mm by 2.5 mm thick Inflammability rating: V-0; 130 ºC	UL 746 UL 94 CSA 0.17.92	UR (E115797)
Heating Mat					
1: Main Enclosure of Heating mat	R&L Co., Ltd.	MINI	Type: Transportable Overall Dimensions: 850 x 500 mm Weight: 3.6 kg	CSA 60601-1 ANSI 60601-1	Accepted

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

2: Plastic enclosure of Output Connector of Heating mat (INT)	Samsung SDI Co., Ltd.	EN-1052(+)	Dimensions: 66 x 77.13 x 32.49 mm by 2.5 mm thick Inflammability rating: V-0; 130 ºC	UL 746 UL 94 CSA 0.17.92	UR (E115797)
3: Output Terminal Block of Heating mat (INT)	Sunmoon Industrial Co.	103S	300 V; 6 A Heat resistance: 200 ºC Deflection temperature: 170 ºC	CSA 60601-1 ANSI 60601-1	Accepted
4: Heating Wire	Hyun Electronics Co.	-	120 V; 100 W	CSA 60601-1 ANSI 60601-1	Accepted
5: Temperature Sensor	International Sensor Co.	D203JCW-C2000M (Black)	10 kΩ	CSA 60601-1 ANSI 60601-1	Accepted
6: Thermostats	Seki Controls Co., Ltd.	ST-22	90 ºC	CSA 24 UL 873	UR (E162183)
7: Flame-resisting material (Thermal protection layer)	B & B	Thermal protection layer	Dimensions: 800 x 440 mm by 10 mm thick Inflammability rating: 200 ºC	CSA 60601-1 ANSI 60601-1	Accepted
8: Flame-resisting material (Thermal preservation layer)	Hyun Electronics Co.	Thermal preservation layer	Dimensions: 850 x 500 mm by 0.6 mm thick Inflammability rating: 210 ºC	CSA 60601-1 ANSI 60601-1	Accepted
9: Flame-resisting material (Aluminum insulation layer)	Hansung Hanalon Co., Ltd.	Aluminum insulation layer	Dimensions: 800 x 440 mm by 2 mm thick Inflammability rating: 90 ºC	CSA 60601-1 ANSI 60601-1	Accepted
10: Flame-resisting material (Fiber-grass layer)	GS	Fiber-grass layer	Dimensions: 800 x 440 mm by 0.3 mm thick Inflammability rating: 120 ºC	CSA 60601-1 ANSI 60601-1	Accepted

Supplementary information:
1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

8.10 b	TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS				N/A
Component/ Part No.	**Manufacturer/ Trademark**	**Type No./model No./**	**Technical data**	**Standard No./, Edition**	**Mark(s) & Certificates of conformity [1]**

Supplementary information:
1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

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

8.11.3.5	**TABLE: Cord anchorages**				**Pass**
Cord under test	**Mass of equipment (kg)**	**Pull (N)**	**Torque Nm)**	**Remarks**	
Power supply cord	3.96	60	0.25	No hazard	
Mat connector cable	3.40	60	0.25	No hazard	
Supplementary information: Refer to the Documentum of 2783119 project					

8.11.3.6	**TABLE: Cord guard**			**Pass**
Cord under test	**Test mass**	**Measured curvature**	**Remarks**	
Power supply cord	130 g	9.8	No hazard	
Mat connector cable	540 g	16.5	No hazard	
Supplementary information: Refer to the Documentum of 2783119 project				

9.2.2.2	**TABLE: Measurement of gap “a” according to Table 20 (ISO 13852: 1996)**				**N/A**
Part of body	**Allowable adult gap[1], mm**	**Measured adult gap, mm**	**Allowable children gap[1], 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**		
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:		

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

9.4.2.1	TABLE: Instability—overbalance in transport position		Pass
ME EQUIPMENT preparation	**Test Condition (transport position)**	**Remarks**	
Supplementary information: Refer to the Documentum of 2783119 project			

9.4.2.2	TABLE: Instability—overbalance excluding transport position		Pass
ME EQUIPMENT preparation	**Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)**	**Remarks**	
Supplementary information: Refer to the Documentum of 2783119 project			

9.4.2.3	TABLE: Instability—overbalance from horizontal and vertical forces		Pass
ME EQUIPMENT preparation	**Test Condition (force used, direction of force, weight of equipment, location of force)**	**Remarks**	
Supplementary information: Refer to the Documentum of 2783119 project			

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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

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:			

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

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
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:				

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

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 a distance of 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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT**					**Pass**
Model No. .....:		BIOMAT MINI	BIOMAT MINI			
Test ambient (°C) .....:		See below	See below			
Test supply voltage/frequency (V/Hz)...:		108 / 60	132 / 60			

Model No.	Thermo-couple No.	Thermocouple location3	Max allowable temperature1 from Table 22, 23 or 24 or RM file for AP (°C)	Max measured temperature2, (°C)	Remarks (Calculated temperature at 40 °C)
Normal condition (108 V, 60 Hz)	-	-	-	-	-
BIOMAT MINI	2	Power cable	-	22.7	40.6
BIOMAT MINI	3	Power cord bushing	-	22.6	40.5
BIOMAT MINI	4	AC connector (CN2)	-	26.4	44.3
BIOMAT MINI	5	AC connector (CN3)	-	25.6	43.5
BIOMAT MINI	6	Transformer Coil	95	41.3	59.2
BIOMAT MINI	7	Transformer core	95	41.9	59.8
BIOMAT MINI	8	PCB near BD1 (control board)	105	34.9	52.8
BIOMAT MINI	9	Top plastic enclosure	48 (1 min ≤ t)	25.7	43.6
BIOMAT MINI	10	Bottom plastic enclosure	48 (1 min ≤ t)	22.6	40.5
BIOMAT MINI	11	Temperature setting switch body	48 (1 min ≤ t)	23.8	41.7
BIOMAT MINI	12	Connector cable	41	23.0	40.9
BIOMAT MINI	14	Mat(Applied-TR)	-	66.0	-
BIOMAT MINI	15	Mat(Applied-T1)	-	64.9	-
BIOMAT MINI	16	Mat(Applied-T2)	-	67.4	-
BIOMAT MINI	17	Mat(Applied-T3)	-	59.8	-
BIOMAT MINI	18	Mat(Applied-T4)	-	62.4	-
BIOMAT MINI	20	Power on/off switch	48 (1 min ≤ t)	24.3	42.2
BIOMAT MINI	19	Ambient	-	22.1	-
Normal condition (132 V, 60 Hz)	-	-	-	-	-
BIOMAT MINI	2	Power cable	-	24.6	41.8
BIOMAT MINI	3	Power cord bushing	-	24.2	41.4

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

BIOMAT MINI	4	AC connector (CN2)	-	28.5	45.7
BIOMAT MINI	5	AC connector (CN3)	-	25.7	42.9
BIOMAT MINI	6	Transformer Coil	95	51.6	68.8
BIOMAT MINI	7	Transformer core	95	51.6	68.8
BIOMAT MINI	8	PCB near BD1 (control board)	105	40.3	57.5
BIOMAT MINI	9	Top plastic enclosure	48 (1 min ≤ t)	27.6	44.8
BIOMAT MINI	10	Bottom plastic enclosure	48 (1 min ≤ t)	24.2	41.4
BIOMAT MINI	11	Temperature setting switch body	48 (1 min ≤ t)	25.0	42.2
BIOMAT MINI	12	Connector cable	41	24.9	42.1
BIOMAT MINI	14	Mat(Applied-TR)	-	66.3	-
BIOMAT MINI	15	Mat(Applied-T1)	-	64.7	-
BIOMAT MINI	16	Mat(Applied-T2)	-	66.5	-
BIOMAT MINI	17	Mat(Applied-T3)	-	65.1	-
BIOMAT MINI	18	Mat(Applied-T4)	-	66.0	-
BIOMAT MINI	20	Power on/off switch	48 (1 min ≤ t)	25.1	42.3
BIOMAT MINI	19	Ambient	-	22.8	-

Supplementary information: Refer to the Documentum of 2783119 project

[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.

- Control box temperature setting: Max, Timer: Max

- Mat was Applied parts intended to supplied heat to a patient

- Applied part T1, T2, T3, T4 was reference only in accordance with IEC 80601-2-35

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

IEC 80601-2-35 Clause 201.11.1.2.1.101.1	**TABLE: Maximum CONTACT SURFACE TEMPERATURE in NORMAL CONDITION**						**Pass**
Model No. .....:	BIOMAT MINI (Figure 201.105 a)	BIOMAT MINI (Figure 201.105 b)	BIOMAT MINI (Figure 201.105 c)	BIOMAT MINI (Figure 201.105 d)	BIOMAT MINI (Figure 201.105 e)	BIOMAT MINI (Figure 201.105 f)	BIOMAT MINI (Figure 201.105 g)
Test ambient (°C) .....:	See below	See below	See below	See below	See below	See below	See below
Test supply voltage/frequency (V/Hz)...:	132 / 60	132 / 60	132 / 60	132 / 60	132 / 60	132 / 60	132 / 60

Model No.	**Thermo-couple No.**	**Thermocouple location**	**Max allowable temperature**	**Max measured temperature (°C)**	**Remarks (Calculated temperature at 40 °C)**
BIOMAT MINI (Figure 201.105 a)	-	-	-	-	-
BIOMAT MINI	2	Power cable	-	24.6	41.8
BIOMAT MINI	3	Power cord bushing	-	24.2	41.4
BIOMAT MINI	4	AC connector (CN2)	-	28.5	45.7
BIOMAT MINI	5	AC connector (CN3)	-	25.7	42.9
BIOMAT MINI	6	Transformer Coil	-	51.6	68.8
BIOMAT MINI	7	Transformer core	-	51.6	68.8
BIOMAT MINI	8	PCB near BD1 (control board)	-	40.3	57.5
BIOMAT MINI	9	Top plastic enclosure	-	27.6	44.8
BIOMAT MINI	10	Bottom plastic enclosure	-	24.2	41.4
BIOMAT MINI	11	Temperature setting switch body	-	25.0	42.2
BIOMAT MINI	12	Connector cable	-	24.9	42.1
BIOMAT MINI	14	Mat(Applied-TR)	-	66.3	-
BIOMAT MINI	15	Mat(Applied-T1)	-	64.7	-
BIOMAT MINI	16	Mat(Applied-T2)	-	66.5	-
BIOMAT MINI	17	Mat(Applied-T3)	-	65.1	-
BIOMAT MINI	18	Mat(Applied-T4)	-	66.0	-
BIOMAT MINI	20	Power on/off switch	-	25.1	42.3
BIOMAT MINI	19	Ambient	-	22.8	-
BIOMAT MINI (Figure 201.105 b)	-	-	-		
BIOMAT MINI	2	Power cable	-	23.8	41.1
BIOMAT MINI	3	Power cord bushing	-	23.9	41.2

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

BIOMAT MINI	4	AC connector (CN2)	-	28.5	45.8
BIOMAT MINI	5	AC connector (CN3)	-	26.3	43.6
BIOMAT MINI	6	Transformer Coil	-	51.4	68.7
BIOMAT MINI	7	Transformer core	-	51.8	69.1
BIOMAT MINI	8	PCB near BD1 (control board)	-	39.1	56.4
BIOMAT MINI	9	Top plastic enclosure	-	27.7	45.0
BIOMAT MINI	10	Bottom plastic enclosure	-	23.8	41.1
BIOMAT MINI	11	Temperature setting switch body	-	24.6	41.9
BIOMAT MINI	12	Connector cable	-	24.5	41.8
BIOMAT MINI	14	Mat(Applied-TR)	-	78.1	-
BIOMAT MINI	15	Mat(Applied-T1)	-	39.4	-
BIOMAT MINI	16	Mat(Applied-T2)	-	39.3	-
BIOMAT MINI	17	Mat(Applied-T3)	-	78.1	-
BIOMAT MINI	18	Mat(Applied-T4)	-	78.7	-
BIOMAT MINI	20	Power on/off switch	-	24.9	42.2
BIOMAT MINI	19	Ambient	-	22.7	-
BIOMAT MINI (Figure 201.105 c)	-	-	-	-	-
BIOMAT MINI	2	Power cable	-	24.6	41.3
BIOMAT MINI	3	Power cord bushing	-	24.6	41.3
BIOMAT MINI	4	AC connector (CN2)	-	28.8	45.5
BIOMAT MINI	5	AC connector (CN3)	-	26.7	43.4
BIOMAT MINI	6	Transformer Coil	-	52.1	68.8
BIOMAT MINI	7	Transformer core	-	52.8	69.5
BIOMAT MINI	8	PCB near BD1 (control board)	-	40.3	57.0
BIOMAT MINI	9	Top plastic enclosure	-	28.6	45.3
BIOMAT MINI	10	Bottom plastic enclosure	-	23.8	40.5
BIOMAT MINI	11	Temperature setting switch body	-	25.7	42.4
BIOMAT MINI	12	Connector cable	-	25.2	41.9
BIOMAT MINI	14	Mat(Applied-TR)	-	69.5	-
BIOMAT MINI	15	Mat(Applied-T1)	-	76.0	-
BIOMAT MINI	16	Mat(Applied-T2)	-	78.9	-
BIOMAT MINI	17	Mat(Applied-T3)	-	39.4	-

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

BIOMAT MINI	18	Mat(Applied-T4)	-	39.4	-
BIOMAT MINI	20	Power on/off switch	-	26.1	42.8
BIOMAT MINI	19	Ambient	-	23.3	-
BIOMAT MINI (Figure 201.105 d)	-	-	-	-	-
BIOMAT MINI	2	Power cable	-	22.3	40.8
BIOMAT MINI	3	Power cord bushing	-	22.3	40.8
BIOMAT MINI	4	AC connector (CN2)	-	28.3	46.8
BIOMAT MINI	5	AC connector (CN3)	-	26.2	44.7
BIOMAT MINI	6	Transformer Coil	-	52.4	70.9
BIOMAT MINI	7	Transformer core	-	52.7	71.2
BIOMAT MINI	8	PCB near BD1 (control board)	-	40.5	59.0
BIOMAT MINI	9	Top plastic enclosure	-	27.2	45.7
BIOMAT MINI	10	Bottom plastic enclosure	-	21.8	40.3
BIOMAT MINI	11	Temperature setting switch body	-	24.0	42.5
BIOMAT MINI	12	Connector cable	-	22.8	41.3
BIOMAT MINI	14	Mat(Applied-TR)	-	61.4	-
BIOMAT MINI	15	Mat(Applied-T1)	-	88.6	-
BIOMAT MINI	16	Mat(Applied-T2)	-	41.5	-
BIOMAT MINI	17	Mat(Applied-T3)	-	89.9	-
BIOMAT MINI	18	Mat(Applied-T4)	-	42.5	-
BIOMAT MINI	20	Power on/off switch	-	24.2	42.7
BIOMAT MINI	19	Ambient	-	21.5	-
BIOMAT MINI (Figure 201.105 e)	-	-	-	-	-
BIOMAT MINI	2	Power cable	-	22.3	40.8
BIOMAT MINI	3	Power cord bushing	-	22.0	40.5
BIOMAT MINI	4	AC connector (CN2)	-	28.0	46.5
BIOMAT MINI	5	AC connector (CN3)	-	25.5	44.0
BIOMAT MINI	6	Transformer Coil	-	51.3	69.8
BIOMAT MINI	7	Transformer core	-	51.9	70.4
BIOMAT MINI	8	PCB near BD1 (control board)	-	39.9	58.4
BIOMAT MINI	9	Top plastic enclosure	-	27.2	45.7
BIOMAT MINI	10	Bottom plastic enclosure	-	21.6	40.1

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

BIOMAT MINI	11	Temperature setting switch body	-	24.4	42.9
BIOMAT MINI	12	Connector cable	-	22.7	41.2
BIOMAT MINI	14	Mat(Applied-TR)	-	54.6	-
BIOMAT MINI	15	Mat(Applied-T1)	-	36.4	-
BIOMAT MINI	16	Mat(Applied-T2)	-	73.4	-
BIOMAT MINI	17	Mat(Applied-T3)	-	37.7	-
BIOMAT MINI	18	Mat(Applied-T4)	-	73.2	-
BIOMAT MINI	20	Power on/off switch	-	23.9	42.4
BIOMAT MINI	19	Ambient	-	21.5	-
BIOMAT MINI (Figure 201.105 f)	-	-	-	-	-
BIOMAT MINI	2	Power cable	-	23.0	40.9
BIOMAT MINI	3	Power cord bushing	-	22.8	40.7
BIOMAT MINI	4	AC connector (CN2)	-	28.1	46.0
BIOMAT MINI	5	AC connector (CN3)	-	25.8	43.7
BIOMAT MINI	6	Transformer Coil	-	51.8	69.7
BIOMAT MINI	7	Transformer core	-	52.4	70.3
BIOMAT MINI	8	PCB near BD1 (control board)	-	40.3	58.2
BIOMAT MINI	9	Top plastic enclosure	-	27.6	45.5
BIOMAT MINI	10	Bottom plastic enclosure	-	22.8	40.7
BIOMAT MINI	11	Temperature setting switch body	-	24.5	42.4
BIOMAT MINI	12	Connector cable	-	23.2	41.1
BIOMAT MINI	14	Mat(Applied-TR)	-	74.4	-
BIOMAT MINI	15	Mat(Applied-T1)	-	45.2	-
BIOMAT MINI	16	Mat(Applied-T2)	-	56.5	-
BIOMAT MINI	17	Mat(Applied-T3)	-	58.9	-
BIOMAT MINI	18	Mat(Applied-T4)	-	72.1	-
BIOMAT MINI	20	Power on/off switch	-	24.4	42.3
BIOMAT MINI	19	Ambient	-	22.1	-
BIOMAT MINI (Figure 201.105 g)	-	-	-	-	-
BIOMAT MINI	2	Power cable	-	22.6	40.6
BIOMAT MINI	3	Power cord bushing	-	23.1	41.1
BIOMAT MINI	4	AC connector (CN2)	-	29.3	47.3

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

BIOMAT MINI	5	AC connector (CN3)	-	27.4	45.4
BIOMAT MINI	6	Transformer Coil	-	52.5	70.5
BIOMAT MINI	7	Transformer core	-	53.4	71.4
BIOMAT MINI	8	PCB near BD1 (control board)	-	41.5	59.5
BIOMAT MINI	9	Top plastic enclosure	-	28.2	46.2
BIOMAT MINI	10	Bottom plastic enclosure	-	22.9	40.9
BIOMAT MINI	11	Temperature setting switch body	-	24.6	42.6
BIOMAT MINI	12	Connector cable	-	22.9	40.9
BIOMAT MINI	14	Mat(Applied-TR)	-	71.3	-
BIOMAT MINI	15	Mat(Applied-T1)	-	38.8	-
BIOMAT MINI	16	Mat(Applied-T2)	-	37.5	-
BIOMAT MINI	17	Mat(Applied-T3)	-	37.8	-
BIOMAT MINI	18	Mat(Applied-T4)	-	37.2	-
BIOMAT MINI	20	Power on/off switch	-	25.0	43.0
BIOMAT MINI	19	Ambient	-	22.0	-

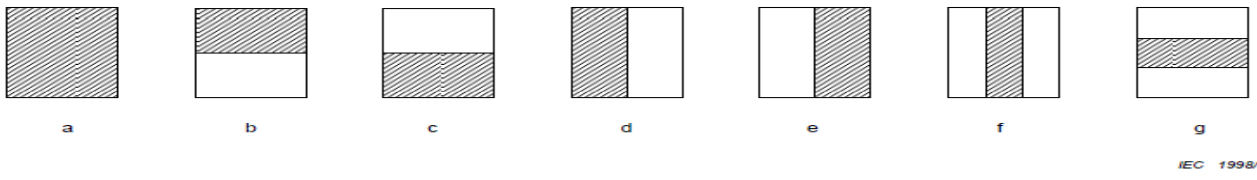
Supplementary information: Refer to the Documentum of 2783119 project

[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.

- Control box temperature setting: low temperature (35 °C)
- Copper plates used (65 mm × 65 mm × 0,5 mm)
- Applied part T1, T2, T3, T4 was reference only in accordance with IEC 80601-2-35
- IEC 80601-2-35 Clause 201.11.1.2.1.101.1 Figure 201.105



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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

IEC 80601-2-35 Clause 201.13.1.2.101.2	**TABLE: Excessive temperature TEST4**					**Pass**
Model No. .....:	BIOMAT MINI (Figure 201.107)	BIOMAT MINI (Figure 201.107)	BIOMAT MINI (Figure 201.107)	BIOMAT MINI (Figure 201.107)	BIOMAT MINI (Figure 201.107)	BIOMAT MINI (Figure 201.107)
Test ambient (°C) .....:	See below	See below	See below	See below	See below	See below
Test supply voltage/frequency (V/Hz)...:	132 / 60	132 / 60	132 / 60	132 / 60	132 / 60	132 / 60

Model No.	**Thermo-couple No.**	**Thermocouple location**	**Max allowable temperature**	**Max measured temperature, (°C)**	**Remarks (Calculated temperature at 40 °C)**
BIOMAT MINI (Figure 201.107, Abnormal condition-1)	-	-	-	-	-
BIOMAT MINI	2	Power cable	-	23.3	40.6
BIOMAT MINI	3	Power cord bushing	-	23.3	40.6
BIOMAT MINI	4	AC connector (CN2)	-	25.4	42.7
BIOMAT MINI	5	AC connector (CN3)	-	23.2	40.5
BIOMAT MINI	6	Transformer Coil	-	47.5	64.8
BIOMAT MINI	7	Transformer core	-	47.4	64.7
BIOMAT MINI	8	PCB near BD1 (control board)	-	33.1	50.4
BIOMAT MINI	9	Top plastic enclosure	-	24.9	42.2
BIOMAT MINI	10	Bottom plastic enclosure	-	24.6	41.9
BIOMAT MINI	11	Temperature setting switch body	-	24.9	42.2
BIOMAT MINI	12	Connector cable	-	23.4	40.7
BIOMAT MINI	14	Mat(Applied-TR)	-	50.0	-
BIOMAT MINI	15	Mat(Applied-T1)	-	43.8	-
BIOMAT MINI	16	Mat(Applied-T2)	-	47.9	-
BIOMAT MINI	17	Mat(Applied-T3)	-	45.5	-
BIOMAT MINI	18	Mat(Applied-T4)	-	49.6	-
BIOMAT MINI	20	Power on/off switch	-	25.0	42.3
BIOMAT MINI	19	Ambient	-	22.7	-
BIOMAT MINI (Figure 201.107, Abnormal condition-2)	-	-	-	-	-

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

BIOMAT MINI	2	Power cable	-	23.3	41.3
BIOMAT MINI	3	Power cord bushing	-	23.1	41.1
BIOMAT MINI	4	AC connector (CN2)	-	25.7	43.7
BIOMAT MINI	5	AC connector (CN3)	-	23.7	41.7
BIOMAT MINI	6	Transformer Coil	-	46.1	64.1
BIOMAT MINI	7	Transformer core	-	47.0	65.0
BIOMAT MINI	8	PCB near BD1 (control board)	-	34.3	52.3
BIOMAT MINI	9	Top plastic enclosure	-	22.2	40.2
BIOMAT MINI	10	Bottom plastic enclosure	-	22.5	40.5
BIOMAT MINI	11	Temperature setting switch body	-	22.3	40.3
BIOMAT MINI	12	Connector cable	-	23.5	41.5
BIOMAT MINI	14	Mat(Applied-TR)	-	50.3	-
BIOMAT MINI	15	Mat(Applied-T1)	-	46.1	-
BIOMAT MINI	16	Mat(Applied-T2)	-	50.1	-
BIOMAT MINI	17	Mat(Applied-T3)	-	45.2	-
BIOMAT MINI	18	Mat(Applied-T4)	-	49.0	-
BIOMAT MINI	20	Power on/off switch	-	22.5	40.5
BIOMAT MINI	19	Ambient	-	22.0	-
BIOMAT MINI (Figure 201.107, Abnormal condition-3)	-	-	-	-	-
BIOMAT MINI	2	Power cable	-	23.9	41.6
BIOMAT MINI	3	Power cord bushing	-	24.3	42.0
BIOMAT MINI	4	AC connector (CN2)	-	25.4	43.1
BIOMAT MINI	5	AC connector (CN3)	-	23.6	41.3
BIOMAT MINI	6	Transformer Coil	-	47.1	64.8
BIOMAT MINI	7	Transformer core	-	47.2	64.9
BIOMAT MINI	8	PCB near BD1 (control board)	-	33.9	51.6
BIOMAT MINI	9	Top plastic enclosure	-	23.1	40.8
BIOMAT MINI	10	Bottom plastic enclosure	-	23.4	41.1
BIOMAT MINI	11	Temperature setting switch body	-	23.3	41.0
BIOMAT MINI	12	Connector cable	-	24.3	42.0
BIOMAT MINI	14	Mat(Applied-TR)	-	42.0	-

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

BIOMAT MINI	15	Mat(Applied-T1)	-	35.0	-
BIOMAT MINI	16	Mat(Applied-T2)	-	36.1	-
BIOMAT MINI	17	Mat(Applied-T3)	-	47.6	-
BIOMAT MINI	18	Mat(Applied-T4)	-	49.5	-
BIOMAT MINI	20	Power on/off switch	-	23.3	41.0
BIOMAT MINI	19	Ambient	-	22.3	-
BIOMAT MINI (Figure 201.107, Abnormal condition-4)	-	-	-	-	-
BIOMAT MINI	2	Power cable	-	23.5	41.5
BIOMAT MINI	3	Power cord bushing	-	23.5	41.5
BIOMAT MINI	4	AC connector (CN2)	-	26.1	44.1
BIOMAT MINI	5	AC connector (CN3)	-	23.9	41.9
BIOMAT MINI	6	Transformer Coil	-	47.9	65.9
BIOMAT MINI	7	Transformer core	-	47.8	65.8
BIOMAT MINI	8	PCB near BD1 (control board)	-	34.2	52.2
BIOMAT MINI	9	Top plastic enclosure	-	22.5	40.5
BIOMAT MINI	10	Bottom plastic enclosure	-	22.8	40.8
BIOMAT MINI	11	Temperature setting switch body	-	22.4	40.4
BIOMAT MINI	12	Connector cable	-	23.8	41.8
BIOMAT MINI	14	Mat(Applied-TR)	-	31.9	-
BIOMAT MINI	15	Mat(Applied-T1)	-	29.9	-
BIOMAT MINI	16	Mat(Applied-T2)	-	30.8	-
BIOMAT MINI	17	Mat(Applied-T3)	-	34.5	-
BIOMAT MINI	18	Mat(Applied-T4)	-	35.9	-
BIOMAT MINI	20	Power on/off switch	-	22.5	40.5
BIOMAT MINI	19	Ambient	-	22.0	-
BIOMAT MINI (Figure 201.107, Abnormal condition-5)	-	-	-	-	-
BIOMAT MINI	2	Power cable	-	21.6	40.2
BIOMAT MINI	3	Power cord bushing	-	22.0	40.6
BIOMAT MINI	4	AC connector (CN2)	-	25.7	44.3
BIOMAT MINI	5	AC connector (CN3)	-	24.1	42.7

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

BIOMAT MINI	6	Transformer Coil	-	46.7	65.3
BIOMAT MINI	7	Transformer core	-	47.7	66.3
BIOMAT MINI	8	PCB near BD1 (control board)	-	34.4	53.0
BIOMAT MINI	9	Top plastic enclosure	-	23.5	42.1
BIOMAT MINI	10	Bottom plastic enclosure	-	22.8	41.4
BIOMAT MINI	11	Temperature setting switch body	-	23.6	42.2
BIOMAT MINI	12	Connector cable	-	22.0	40.6
BIOMAT MINI	14	Mat(Applied-TR)	-	31.3	-
BIOMAT MINI	15	Mat(Applied-T1)	-	30.3	-
BIOMAT MINI	16	Mat(Applied-T2)	-	30.8	-
BIOMAT MINI	17	Mat(Applied-T3)	-	30.0	-
BIOMAT MINI	18	Mat(Applied-T4)	-	31.1	-
BIOMAT MINI	20	Power on/off switch	-	23.8	42.4
BIOMAT MINI	19	Ambient	-	21.4	-
BIOMAT MINI (Figure 201.107, Abnormal condition-6)	-	-	-	-	-
BIOMAT MINI	2	Power cable	-	22.5	41.0
BIOMAT MINI	3	Power cord bushing	-	22.2	40.7
BIOMAT MINI	4	AC connector (CN2)	-	26.5	45.0
BIOMAT MINI	5	AC connector (CN3)	-	23.9	42.4
BIOMAT MINI	6	Transformer Coil	-	47.3	65.8
BIOMAT MINI	7	Transformer core	-	47.5	66.0
BIOMAT MINI	8	PCB near BD1 (control board)	-	35.2	53.7
BIOMAT MINI	9	Top plastic enclosure	-	21.6	40.1
BIOMAT MINI	10	Bottom plastic enclosure	-	21.9	40.4
BIOMAT MINI	11	Temperature setting switch body	-	21.9	40.4
BIOMAT MINI	12	Connector cable	-	22.9	41.4
BIOMAT MINI	14	Mat(Applied-TR)	-	30.2	-
BIOMAT MINI	15	Mat(Applied-T1)	-	29.8	-
BIOMAT MINI	16	Mat(Applied-T2)	-	30.1	-
BIOMAT MINI	17	Mat(Applied-T3)	-	31.7	-
BIOMAT MINI	18	Mat(Applied-T4)	-	29.8	-

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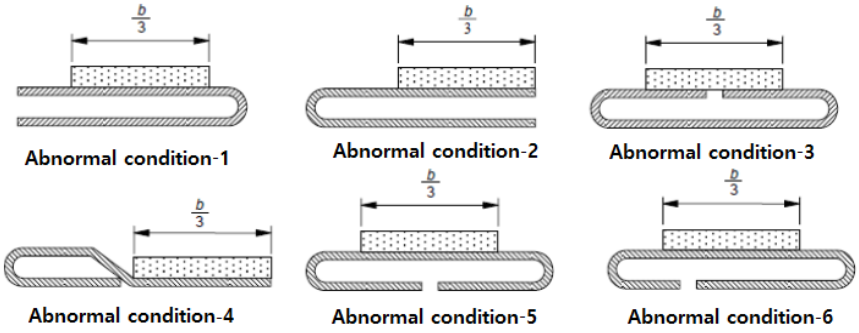
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

BIOMAT MINI	20	Power on/off switch	-	22.0	40.5
BIOMAT MINI	19	Ambient	-	21.5	-

Supplementary information: Refer to the Documentum of 2783119 project

- Control box temperature setting: low temperature (35 °C)
- Copper plates used (65 mm × 65 mm × 0,5 mm)
- Applied part T1, T2, T3, T4 was reference only in accordance with IEC 80601-2-35
- IEC 80601-2-35 Clause 201.11.1.2.1.101.1 Figure 201.107 Abnormal condition



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

IEC 80601-2-35 Clause 201.12.4.101	**TABLE: Variation of temperature across the contact surface**					**Pass**
Model No. .....:	BIOMAT MINI (after 10 min)	BIOMAT MINI (after 20 min)	BIOMAT MINI (after 30 min)	BIOMAT MINI (after 40 min)	BIOMAT MINI (after 50 min)	BIOMAT MINI (after 60 min)
Test ambient (°C) .....:	See below	See below	See below	See below	See below	See below
Test supply voltage/frequency (V/Hz)...:	132 / 60	132 / 60	132 / 60	132 / 60	132 / 60	132 / 60

Model No.	**Thermo-couple No.**	**Thermocouple location**	**Max allowable temperature (°C)**	**Measured temperature (max.temperature / min. tmeperature) (°C)**	**Remarks (Average temperature) (°C)**
BIOMAT MINI (after 10 min)	-	-	-	-	-
BIOMAT MINI	14	Mat(Applied-TR)	-	46.4 / 46.5	46.3
BIOMAT MINI	15	Mat(Applied-T1)	Average temperature of TR ± 1°C	46.5 / 46.5	46.5
BIOMAT MINI	16	Mat(Applied-T2)	Average temperature of TR ± 1°C	46.7 / 46.9	46.8
BIOMAT MINI	17	Mat(Applied-T3)	Average temperature of TR ± 1°C	46.8 / 46.9	46.9
BIOMAT MINI	18	Mat(Applied-T4)	Average temperature of TR ± 1°C	46.9 / 47.1	47.0
BIOMAT MINI	19	Ambient	23 ± 2°C	21.8 / 22.0	21.9
BIOMAT MINI (after 20 min)	-	-	-	-	-
BIOMAT MINI	14	Mat(Applied-TR)	-	46.3 / 46.5	46.4
BIOMAT MINI	15	Mat(Applied-T1)	Average temperature of TR ± 1°C	46.4 / 46.5	46.5
BIOMAT MINI	16	Mat(Applied-T2)	Average temperature of TR ± 1°C	46.7 / 46.9	46.8
BIOMAT MINI	17	Mat(Applied-T3)	Average temperature of TR ± 1°C	46.5 / 46.9	46.7
BIOMAT MINI	18	Mat(Applied-T4)	Average temperature of TR ± 1°C	46.6 / 47.1	46.9

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

BIOMAT MINI	19	Ambient	23 ± 2°C	21.8 / 22.1	22.0
BIOMAT MINI (after 30 min)	-	-	-	-	-
BIOMAT MINI	14	Mat(Applied-TR)	-	46.3 / 46.3	46.3
BIOMAT MINI	15	Mat(Applied-T1)	Average temperature of TR ± 1°C	46.3 / 46.4	46.4
BIOMAT MINI	16	Mat(Applied-T2)	Average temperature of TR ± 1°C	46.6 / 46.7	46.7
BIOMAT MINI	17	Mat(Applied-T3)	Average temperature of TR ± 1°C	46.5 / 46.5	46.5
BIOMAT MINI	18	Mat(Applied-T4)	Average temperature of TR ± 1°C	46.5 / 46.6	46.6
BIOMAT MINI	19	Ambient	23 ± 2°C	21.6 / 22.1	21.9
BIOMAT MINI (after 40 min)	-	-	-	-	-
BIOMAT MINI	14	Mat(Applied-TR)	-	46.1 / 46.3	46.2
BIOMAT MINI	15	Mat(Applied-T1)	Average temperature of TR ± 1°C	46.1 / 46.3	46.2
BIOMAT MINI	16	Mat(Applied-T2)	Average temperature of TR ± 1°C	46.4 / 46.6	46.5
BIOMAT MINI	17	Mat(Applied-T3)	Average temperature of TR ± 1°C	46.3 / 46.5	46.4
BIOMAT MINI	18	Mat(Applied-T4)	Average temperature of TR ± 1°C	46.4 / 46.5	46.5
BIOMAT MINI	19	Ambient	23 ± 2°C	21.6 / 22.1	21.9
BIOMAT MINI (after 50 min)	-	-	-	-	-
BIOMAT MINI	14	Mat(Applied-TR)	-	46.1 / 46.4	46.3
BIOMAT MINI	15	Mat(Applied-T1)	Average temperature of TR ± 1°C	46.1 / 46.5	46.3
BIOMAT MINI	16	Mat(Applied-T2)	Average temperature of TR ± 1°C	46.4 / 46.7	46.6
BIOMAT MINI	17	Mat(Applied-T3)	Average temperature of TR ± 1°C	46.3 / 46.7	46.5

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

BIOMAT MINI	18	Mat(Applied-T4)	Average temperature of TR ± 1°C	46.4 / 46.7	46.6
BIOMAT MINI	19	Ambient	23 ± 2°C	21.8 / 22.1	22.0
BIOMAT MINI (after 60 min)	-	-	-	-	-
BIOMAT MINI	14	Mat(Applied-TR)	-	46.1 / 46.4	46.3
BIOMAT MINI	15	Mat(Applied-T1)	Average temperature of TR ± 1°C	46.3 / 46.5	46.4
BIOMAT MINI	16	Mat(Applied-T2)	Average temperature of TR ± 1°C	46.4 / 46.7	46.6
BIOMAT MINI	17	Mat(Applied-T3)	Average temperature of TR ± 1°C	46.5 / 46.7	46.6
BIOMAT MINI	18	Mat(Applied-T4)	Average temperature of TR ± 1°C	46.5 / 46.7	46.6
BIOMAT MINI	19	Ambient	23 ± 2°C	21.8 / 22.1	22.0

Supplementary information: Refer to the Documentum of 2783119 project

- Applied part was HIGH HEAT TRANSFER HEATING DEVICES
- Control box temperature setting: low temperature (35 °C)
- Copper plates used (65 mm × 65 mm × 0,5 mm)
- Average Temperature: (Max. temperature + Min. temperature) / 2

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

IEC 80601-2-35 Clause 201.12.4.102	**TABLE: Variation of the CONTACT SURFACE TEMPERATURE**					**Pass**
Model No. .....:	BIOMAT MINI					
Test ambient (°C) .....:	See below					
Test supply voltage/frequency (V/Hz)...:	132 / 60					

Model No.	**Thermo-couple No.**	**Thermocouple location**	**Max allowable temperature (°C)**	**Measured temperature (initial temperature / after tmeperature) (°C)**	**Remarks (Variation temperature) (°C)**
BIOMAT MINI	9	Mat (Applied part - TR)	Initial temperature of TR± 0.5°C	46.3 / 46.4	0.1
BIOMAT MINI	14	Ambient	-	22.0 / 22.3	-

Supplementary information: Refer to the Documentum of 2783119 project

- Applied part was HIGH HEAT TRANSFER HEATING DEVICES
- Control box temperature setting: low temperature (35 °C)
- Copper plates used (65 mm × 65 mm × 0,5 mm)

11.1.3d	**TABLE: Temperature of windings by change-of-resistance method**						**Pass**
Temperature T of winding:	**t_1 (°C)**	**R_1 (Ω)**	**t_2 (°C)**	**R_2 (Ω)**	**T (°C)**	**Allowed T_{max} (°C)**	**Insulation class**
Normal condition (108 V, 60 Hz)							
Transformer(T1) primary coil	22.0	944	22.1	1 063	72.2	105	A
Transformer(T1) secondary coil	22.0	9.97	22.1	11.13	69.7	105	A
Normal condition (132 V, 60 Hz)							
Transformer(T1) primary coil	22.2	994	22.8	1 096	80.7	105	A
Transformer(T1) secondary coil	22.2	9.97	22.8	11.54	79.8	105	A
Supplementary information: Refer to the Documentum of 2783119 project							

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:

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

11.6.1	**TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances**	**Pass**

Clause / Test Name	Test Condition	Part under test	Remarks
11.6.6 / Cleaning	Wipe with soft cloth	Control box	No breakdown.
11.6.6 / Cleaning	Wipe with soft cloth	Mat	No breakdown.

Supplementary information: Refer to the Documentum of 2783119 project

Information from Risk Management, as applicable:

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:

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

13.2	**TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive**		**Pass**
Clause No.	**Description of SINGLE FAULT CONDITION**	**Results observed**	**HAZARDOUS SITUATION (Yes/No)**
13.2.2	**Electrical SINGLE FAULT CONDITIONS per Clause 8.1:**	**—**	**—**
	Transformer(T1) output short circuit pin(3,4)	Thermal fuse opened, (Transformer shot down temperature at T1 coil: 129.9 °C, T1 core: 126.3 °C, ambient: 22.6 °C duration time: 35 min final input current: 43.21 mA	NO
	BD1 pin(1,4) short circuit	Normal operation, Temperature stabilized at T1 coil: 86.3 °C, T1 core: 80.9 °C, ambient: 23.1 °C duration time: 1 h 40 min final input current: 0.8412 A	NO
	BD1 pin(2,3) short circuit	Normal operation, Temperature stabilized at T1 coil: 88.4 °C, T1 core: 82.6 °C, ambient: 21.9 °C duration time: 1 h 10 min final input current: 0.9105 A	NO
	Opto-coupler PC1 pin(4,6) short circuit	Normal operation, No components damaged, duration time: 5 min, final input current:0.8251 A	NO
	U3 pin(1,3) short circuit	No fuse(FS1) open, components damaged (R13, U3), Temperature stabilized at T1 coil: 43.1 °C, T1 core: 39.3 °C, ambient: 20.7 °C duration time: 1 h 20 min final input current: 16.33 mA	NO

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	U3 pin(1,2) short circuit	No fuse(FS1) open, components damaged (R13, U3), Temperature stabilized at T1 coil: 47.9 °C, T1 core: 45.6 °C, ambient: 21.2 °C duration time:1 h 10 min final input current: 13.50 mA	No
	Output connector CN2 pin(1,3) short circuit	Normal operation, No components damaged, duration time: 30 min, final input current:0.9021 A	No
13.2.3	**Overheating of transformers per Clause 15.5:**	—	—
	Transformer short circuit	See table 15.5.1.2	No
	Transformer overload	See table 15.5.1.3	No
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:**	—	—
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:**	—	—
	Mat Internally thermal sensor CN2 pin (2, 4) short circuit	Immediately alarm sound and flashing '104°F' temperature indicator, duration time: 10 min, final input current: 0.014 A, No components damaged	No
	Mat Internally Bi-metal short circuit	Normal operation, No components damaged, duration time: 30 min, final input current:0.9021 A	No
13.2.6	**Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)**	—	—
13.2.7	**Impairment of cooling that could result in a HAZARD using test method of 11.1:**	—	—
	Single ventilation fans locked consecutively		
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls		

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	Simulated blocking of filters		
	Flow of a cooling agent interrupted		
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**	**—**	**—**
		V measured =	
		V measured =	
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:		
	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		
	Temperatures measured as specified in 11.1.3 d)		
	Temperatures did not exceed limits of Table 26		
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):**	**—**	**—**
IEC 80601-2-35 clause 201.13.1.2 .101.2	Excessive temperature TEST4	See temperature test table: Excessive temperature TEST4	No

Supplementary information: Refer to the Documentum of 2783119 project

[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:

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

15.3	**TABLE: Mechanical Strength tests [1)]**			**Pass**
Clause	**Name of Test**	**Test conditions**	**Observed results/Remarks**	
15.3.2	**Push Test**	**Force = 250 N ± 10 N for 5 s**	No damage / No hazard	
15.3.3	**Impact Test**	**Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m**	No damage / No hazard	
15.3.4.1	**Drop Test (hand-held)**	**Free fall height (m) =**	-	
15.3.4.2	**Drop Test (portable)**	**Drop height (cm) = 5**	No damaged	
15.3.5	**Rough handling test**	**Travel speed (m/s) =**	-	
15.3.6	**Mould Stress Relief**	**7 h in oven at temperature (°C) = 70**	No damage, No hazard	
Supplementary information: [1)]As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows). Refer to the Documentum of 2783119 project				

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**
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**						**Pass**
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)[1] ....:						**132**	**—**
RATED input frequency (Hz).....:						**60**	**—**
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 (°C)**	**Maximum winding temp measured (°C)**	**Ambient (°C)**
Transformer (T1) Primary winding wire (12 V output)	A	Thermal fuse 105 / °C	Yes	30 min.	150	141.3	23.6
Transformer (T1) Secondary winding wire (12 V output)	A	-	-	30 min.	150	145.4	23.6
Supplementary information: Refer to the Documentum of 2783119 project [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.							

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

15.5.1.3	**TABLE: transformer overload test – conducted only when protective device under short-circuit test operated**	**Pass**

Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1]...:	**132**
RATED input frequency (Hz).....:	**60**
Test current just below minimum current that would activate protective device & achieve THERMAL STABILITY under method a) (A).....:	**0.43**
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A) .....:	

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 (°C)	Maximum winding temp measured (°C)	Ambient (°C)
Transformer (T1) Primary winding wire	A	Thermal fuse 105 °C	150	143.6	23.5
Transformer (T1) Secondary winding wire	A	-	150	146.8	23.5

Supplementary information: Refer to the Documentum of 2783119 project

[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.

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7	Pass

Transformer Model/Type/ Part No	Test voltage applied between	Test voltage, (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No
Liner / T1	Between Primary winding wire (120 V)	600	300	No	No
Liner / T1	Between Secondary winding wire (12 V)	60	300	No	No

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

Refer to the Documentum of 2783119 project

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

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		
	100		500		
	100		500		
	100		500		
	100		500		
Supplementary information:					

SP	TABLE: Additional or special tests conducted		N/A
Clause and Name of Test	Test type and condition	Observed results	
Supplementary information:			

End of IEC 60601-1 Checklist

Photo 1 – Overall View

Photo 2 – External View of Control box #1

Photo 3 – External View of Control box #2

Photo 4 – External View of Control box #3

Photo 5 – Internal View of Control box #1

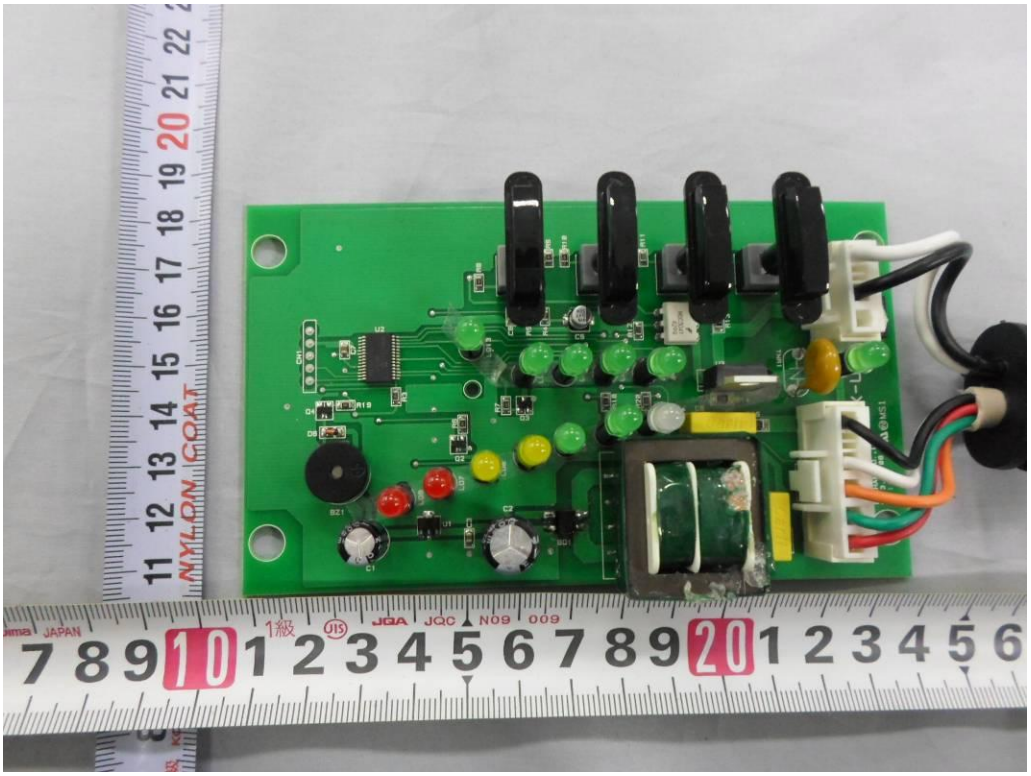

Photo 6 – Internal View of Control box #2

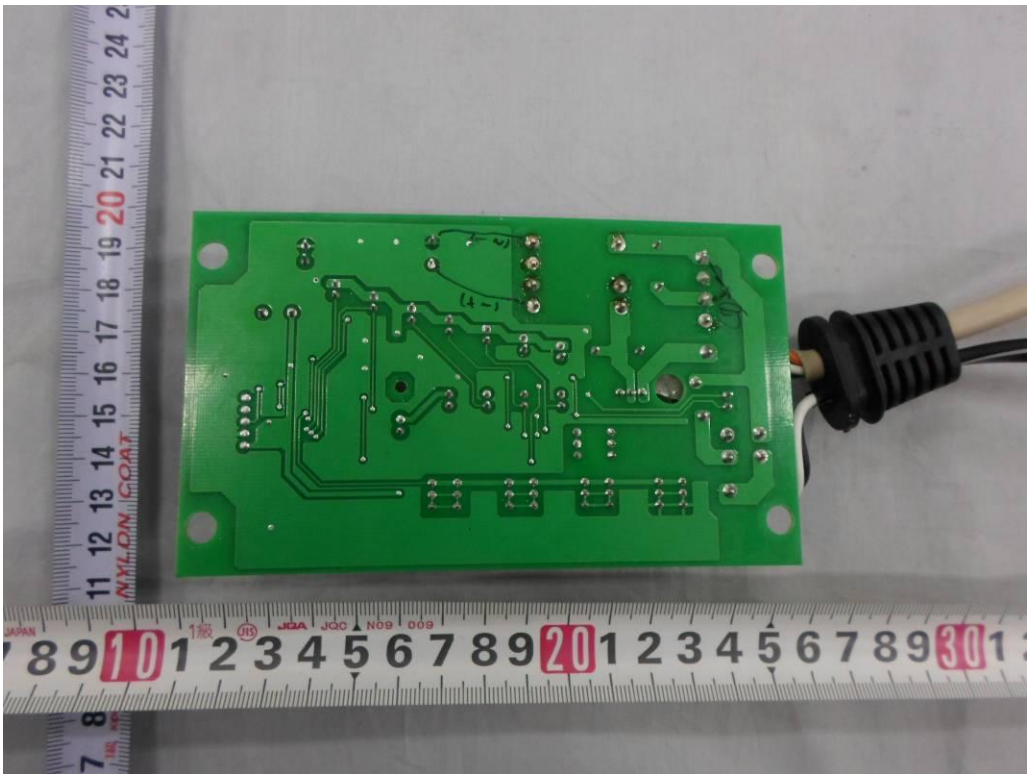

Photo 7 – Internal View of Control box #3

Photo 8 – Mat View

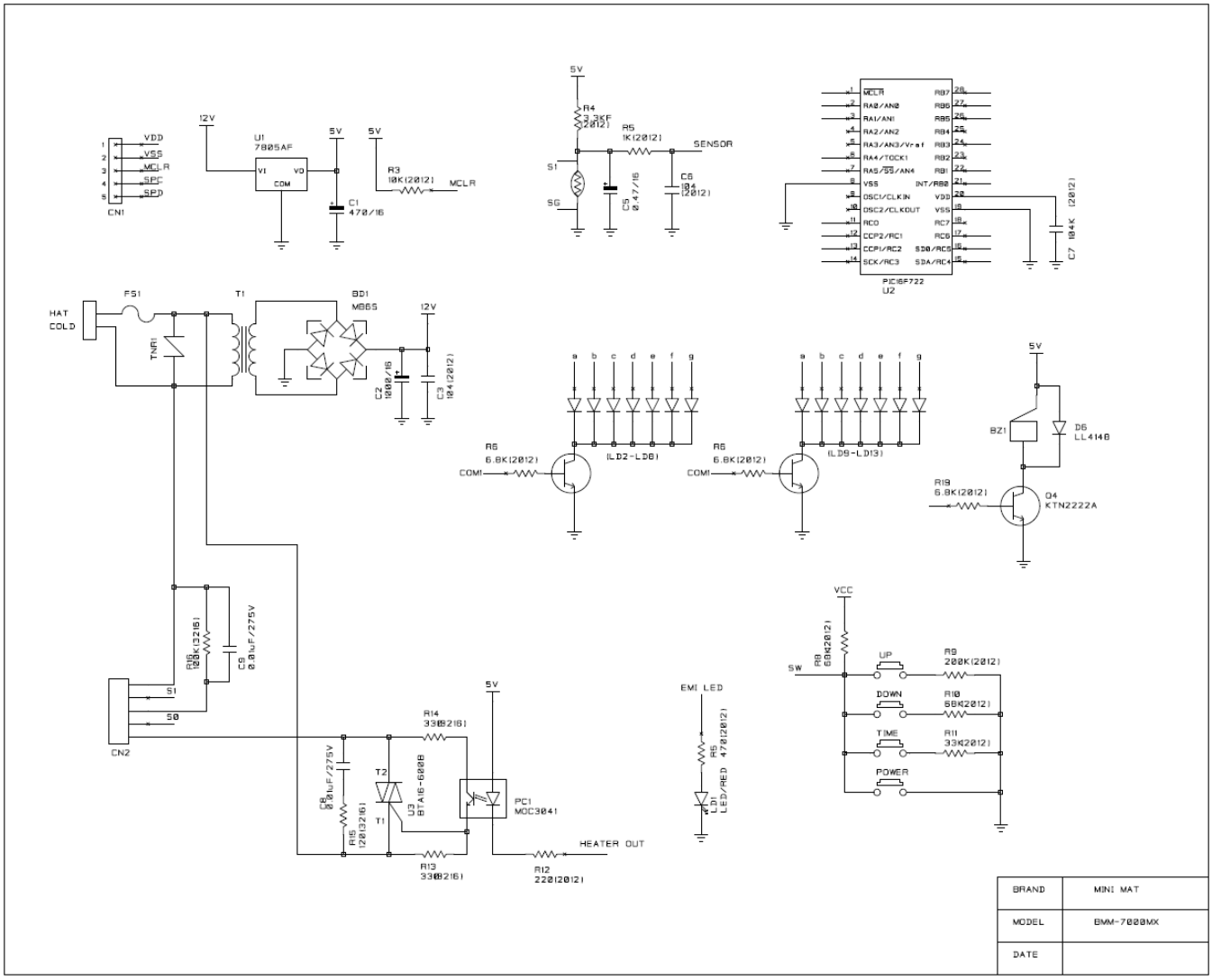

Illustration 1 – Schematic Diagram

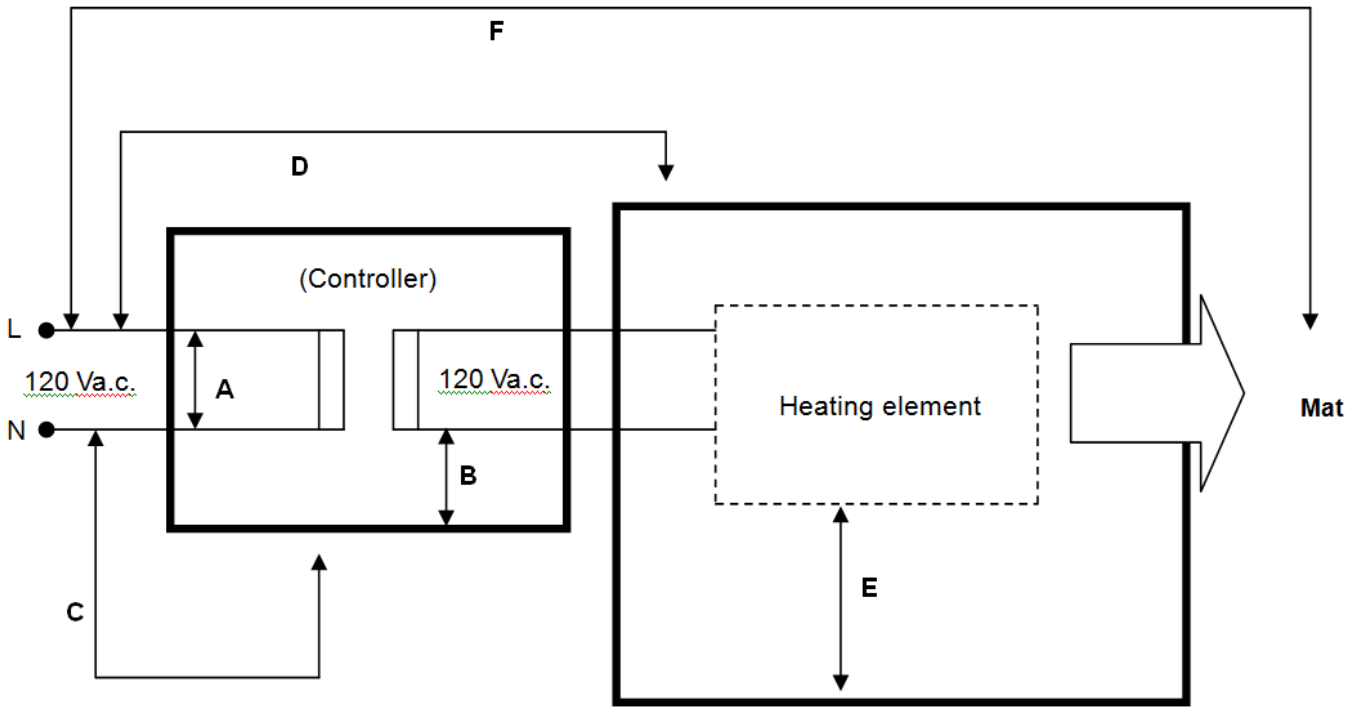

Illustration 2 – Block Diagram

Illustration 3 – Mat Label Drawing

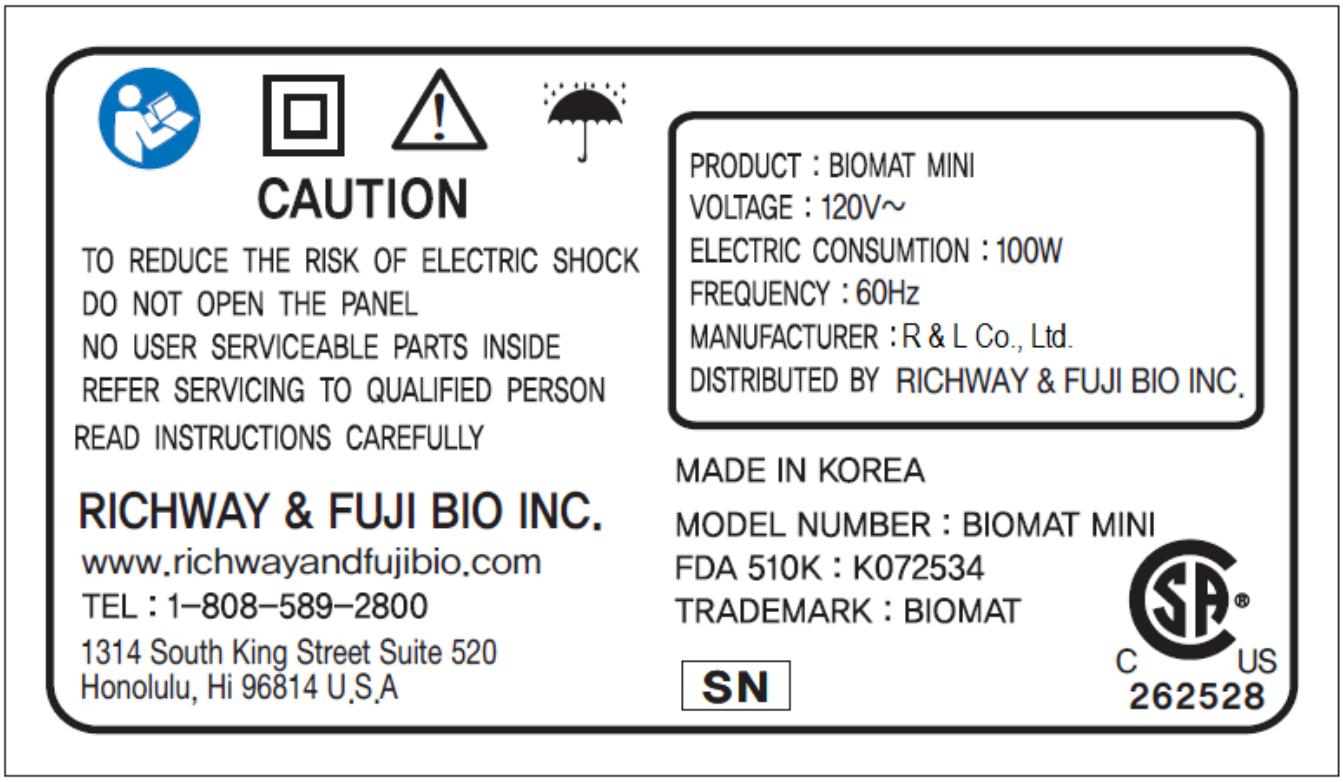

Illustration 4 – Controller Label Drawing

CANADIAN (CA) National deviations - IEC 60601-1 3rd edition ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition
CA - CANADIAN NATIONAL DIFFERENCES to
CAN/CSA-C22.2 No. 60601-1:08

Differences according to .....:	Canadian National standard: CAN/CSA-C22.2 No. 60601-1:08
Attachment Form No.....:	CA_ND_IEC60601_1G
Attachment Originator .....:	CSA International
Master Attachment.....:	2010-12

CA - Canadian National Differences as per CAN/CSA-C22.2 No. 60601-1:08			
1	**Scope, object and related documents**		---
1.1	**Scope**		---
	This standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be installed in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1; CAN/CSA-C22.2 No. 0; and CAN/CSA-Z32.	Accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1; CAN/CSA-C22.2 No. 0; and CAN/CSA-Z32.	**Pass**
	NOTE 1A: *In the IEC 60601 standards series adopted for use in Canada, the Canadian-particular standards may modify, replace, or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.*		---
1.3	**Collateral standards**		---
	Applicable Canadian collateral standards become normative at the date of their publication and apply together with this standard.		**Pass**
	NOTE 1: *When evaluating compliance with CAN/CSA-C22.2 No. 60601-1, it is permissible to assess independently compliance with the adopted Canadian collateral standards.*		---
1.4	**Particular standards**		---
	A requirement of a Canadian-particular safety standard takes precedence over this standard.		**N/A**
3	**Terminology and definitions**		---
3.41	**HIGH VOLTAGE**		---
	any voltage above 750 V, 1 050 V peak, as defined in the *Canadian Electrical Code (CEC), Part I*	120 V~	**N/A**

CANADIAN (CA) National deviations - IEC 60601-1 3rd edition ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
4	**General requirements**		---
4.8	**Components of ME EQUIPMENT**		---
	a) the applicable safety requirements of a relevant CSA, IEC, or ISO standard; or	See appended Table 8.10	**Pass**
	NOTE 1: *For the components, it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard.*		---
	b) where there is no relevant CSA, IEC, or ISO standard, the requirements of this standard have to be applied	See appended Table 8.10	**Pass**
	NOTE 2: *If there are neither requirements in this standard nor in a CSA, 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**		----
	and shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1:	Accordance with the CEC, Part 1, CSA C22.1	**Pass**
7	**ME EQUIPMENT identification, marking and documents**		---
7.7.1 to 7.7.5	and shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1	Accordance with the CEC, Part 1, CSA C22.1	**Pass**
	A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION or insulation shall be identified by either green or green and yellow colour. Colours of neutral and POWER SUPPLY CORD conductors shall be in accordance with the *Canadian Electrical Code (CEC), Part I*, CSA C22.2 No. 21, and CSA C22.2 No. 49…….:	Accordance with the CEC, Part 1, CSA C22.2 No. 21, and CSA C22.2 No. 49	**Pass**
8	**Protection against electrical HAZARDS from ME EQUIPMENT**		---
8.7.3	**Allowable values**		---
	Allowable values shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1.	Accordance with the CEC, Part 1, CSA C22.1	**Pass**
8.11.3	**POWER SUPPLY CORDS**		---
8.11.3.2	**Types**		---
	a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall be		---
	i) if molded-on type, hospital grade mains plug complying with CSA C22.2 No. 21;……..…:	Class II ME equipment	**N/A**
	ii) hospital grade disassembly attachment plug type complying with CSA C22.2 No. 42; or……..:	Class II ME equipment	**N/A**

CANADIAN (CA) National deviations - IEC 60601-1 3rd edition ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
	iii) Class II equipment having fuses on the line side/sides and neutral and may use a non-polarized attachment plug or a polarized attachment plug — CSA configuration type 1-15P shall be required and shall meet 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 shall be 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:	Polarized attachment plug used	**Pass**
	1- the centre contact of an Edison base lampholder;	No such parts	**N/A**
	2- a single pole switch;		**Pass**
	3- an automatic control with a marked off position;	No such parts	**N/A**
	4- a solitary fuse/fuse holder; or		**Pass**
	5- any other single pole overcurrent protective device	No such parts	**N/A**
	b) Detachable POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) shall be of a type that		---
	i) 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;	Non-detachable power supply cord	**N/A**
	ii) can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety HAZARD to a PATIENT or OPERATOR; and	See above	**N/A**
	iii) 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	See above	**N/A**
	c) A detachable POWER SUPPLY CORD shall		---
	i) comply with the applicable requirements of CSA C22.2 No. 21; and…….:	Non-detachable power supply cord	**N/A**
	ii) not be smaller than No. 18 AWG, and the mechanical serviceability shall be not less than…….:	See above	**N/A**
	1) Type SJ or equivalent for mobile or exposed to abuse ME EQUIPMENT; and…..:	See above	**N/A**
	2) Type SV or equivalent for ME EQUIPMENT not exposed to abuse (or Type HPN if required because of temperature)…..:	See above	**N/A**
	NOTE 1A: *See CSA C22.2 No. 49 for requirements on the cord types mentioned in Sub-item 2).*		---

CANADIAN (CA) National deviations - IEC 60601-1 3rd edition ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
	d) Power supply cords shall meet the requirements of the *Canadian Electrical Code, Part I*, as applicable……..:	Meet the requirements of the CEC, Part I	**Pass**
	Connecting cords between equipment parts shall meet the requirements of the *Canadian Electrical Code, Part I*, as applicable……..:	Meet the requirements of the CEC, Part I	**Pass**
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		---
	Mains fuses and OVER-CURRENT RELEASES shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1……..:	Accordance with the CEC, Part I, CSA C22.1	**Pass**
9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**		---
9.7.5	**Pressure vessels**		---
	Pressure vessels shall comply with the requirements of CSA B51, as applicable……..:	No pressure vessels	**N/A**
9.7.7	**Pressure-relief device**		---
	A pressure-relief device shall also comply as applicable to the requirements of ASME PTC 25 or equivalent Canadian requirements……:	No pressure-relief device	**N/A**
15	**Construction of ME EQUIPMENT**		---
15.4.1	**Construction of connectors**		---
	bA) The point of connection of gas cylinders to EQUIPMENT shall be gas specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on EQUIPMENT shall be		---
	i) gas specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1 380 kPa (200 psi); or……:	No gas cylinders	**N/A**
	ii) DISS type complying with CGA V-5 for pressures 1 380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA-Z5359……..:	See above	**N/A**
	NOTE 1A: *Users of this standard should consult the CSA Z305 series of standards, CAN/CSA-Z9170-1, CAN/CSA-Z9170-2, 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.*		---

CANADIAN (CA) National deviations - IEC 60601-1 3rd edition ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.8	**Internal wiring of ME EQUIPMENT**		---
	Internal wiring of ME EQUIPMENT shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1……:	Accordance with the CEC, Part I, CSA C22.1	**Pass**
16	**ME SYSTEMS**		---
16.1	**General requirements for the ME SYSTEMS**		---
	An ME SYSTEM shall provide		---
	- within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and	No ME system	**N/A**
	- outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA, IEC, or ISO safety standards	See above	**N/A**
	Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with CSA, IEC, or ISO safety standards that are relevant to that equipment.	See above	**N/A**
16.9.2.1	**MULTIPLE SOCKET OUTLET**		---
	c) The MULTIPLE SOCKET-OUTLET shall comply with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and the following requirements……:	No MSO	**N/A**
	- The separating transformer shall comply with the requirements of CAN/CSA-E61558-2-1 with a rated output not exceeding		---
	- 1 kVA for single-phase transformers; and	No MSO	**N/A**
	- 5 kVA for polyphase transformers The separating transformer shall also have a degree of protection not exceeding IPX4.	See above	**N/A**

IEC 60601_1G ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-1
US NATIONAL DIFFERENCES
Medical electrical equipment, Part 1: General Requirements

Differences according to.....:	US National standard ANSI/AAMI ES60601-1: 2005 / A2:2010
Attachment Form No.....:	US_ND_IEC60601_1G
Attachment Originator .....:	Underwriters Laboratories Inc.
Master Attachment.....:	2011-04

	US NATIONAL DIFFERENCES		
4.8 b	Replacement: where there was no relevant IEC/ISO standard, the relevant US ANSI standard applied	See appended Table 8.10	**Pass**
	- when no relevant US ANSI standard existed, the requirements of this standard applied	See appended Table 8.10	**Pass**
4.10.2	Replacement: Rated voltage not exceeding 250V dc or single phase ac. or 600V poly-phase ac for ME EQUIPMENT and ME SYSTEMS up to 4kVA	120 V~	**Pass**
	Rated voltage not exceeding 600 V for all other ME EQUIPMENT and ME SYSTEMS	See above	**N/A**
6.6	Addition: To comply with NFPA 70, X-Ray systems are classified as long time operation (> 5 min) or momentary operation (< 5 sec)	No X-ray system	**N/A**
7.2.11	Addition: To comply with NFPA 70, X-Ray systems are marked as long time operation or momentary operation	No X-ray system	**N/A**
7.2.21	New Sub-clause: **Colors of medical gas cylinders**		**N/A**
	To comply with NFPA 99: Cylinders containing medical gases and their connection points are colored in accordance with the requirements of NFPA 99	No medical gas cylinders	**N/A**
8.2	Addition: All FIXED ME EQUIPMENT & PERMANENTLY INSTALLED ME EQUIPMENT are CLASS I ME EQUIPMENT	Transportable ME equipment	**N/A**

IEC 60601_1G ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
8.6.1	Addition: To comply with NFPA 99, the enclosure of X-ray ME EQUIPMENT operating over 600 Vac, 850Vdc 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.	No X-ray system	**N/A**
	To comply with NFPA 99, non-current carrying conductive parts of X-Ray ME EQUIPMENT likely to become energized are PROTECTIVELY EARTHED	See above	**N/A**
8.7.3 d	EARTH LEAKAGE CURRENT values are not higher than the stated values	Class II ME equipment	**N/A**
	5 mA in NORMAL CONDITION	See above	**N/A**
	10 mA in SINGLE FAULT CONDITION	See above	**N/A**
8.11	Addition prior to the first paragraph: a) To comply with the NEC, add the following requirements to this clause:		
	Addition: PERMANENTLY CONNECTED ME EQUIPMENT provided with field wiring provision in accordance with NEC	Not permanently connected ME equipment	**N/A**
	Installation of connecting cords between EQUIPMENT parts comply with NEC		**Pass**
	Cable used as external interconnection between units		**Pass**
	1) Exposed to abuse: Type SJT, SJTO, SJO, ST, SO, STO, or equivalent, or similar multiple-conductor appliance-wiring material,	See appended Table 8.10	**Pass**
	2) Not exposed to abuse: The cable was as in item 1) above, or	See above	**N/A**
	i) Type SPT-2, SP-2, or SPE-2, or equivalent	See above	**N/A**
	ii) Type SVr, SVRO, SVE, or equivalent or similar multiple-conductor appliance wiring material,	See above	**N/A**
	iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more,	See above	**N/A**

IEC 60601_1G ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
	- enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more	See above	**N/A**
	Receptacles provided as part of ME EQUIPMENT and ME SYSTEMS for use in the patient care areas of pediatric wards, rooms, or areas are Listed tamper resistant	No such parts	**N/A**
	- or employ a Listed tamper resistant cover in accordance with NEC	See above	**N/A**
	Addition at the end of the clause: 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	No hospital grade power plug	**N/A**
8.11.3.2	Addition: The flexible cord is a type acceptable for the particular application,	See below	**Pass**
	- and it is acceptable for use at a voltage not less than the rated voltage of the appliance	Not less than the rated voltage	**Pass**
	- and has an ampacity as in NEC, not less than the current rating of the appliance	Not less than the current rating	**Pass**
8.11.3.3	Addition: To comply with NFPA 99, for X-Ray ME EQUIPMENT with an attachment plug, the current rating on a hospital grade plug is 2X the maximum input current of the equipment	No X-ray ME equipment	**N/A**

Test Report issued under the responsibility of:

CSA Group

TEST REPORT

IEC 60601-1-6

Medical electrical equipment

Part 1-6: General requirements for safety - Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices

Report Reference No..... :	**262528-70040865 (Project No.: 70040865, Ed.1)**
Date of issue ..... :	**July 31, 2015**
Total number of pages..... :	**5**
CB Testing Laboratory..... :	**N/A (Not CB project)**
Address ..... :	**N/A**
Applicant's name..... :	**R&L Co., Ltd.**
Address ..... :	**11th Floor, B-line, ACE Gwang Myeong Tower, #1365, Soha-Dong, Gwangmyeong-Si, Gyeonggi-Do, Korea**
Test specification:	
Standards..... :	IEC 60601-1-6:2010 (Third Edition) for use in conjunction with IEC 60601-1: 2005 (Third Edition)
Test procedure ..... :	CB Scheme
Non-standard test method……..:	N/A
Test Report Form No..... :	IEC60601_1_6E
Test Report Form Originator..... :	TÜV Rheinland North America
Master TRF..... :	Dated 2011-07

Test item description ..... :	Heating Mat
Trade Mark ..... :	R&L RICHWAY & LIFE CO.
Manufacturer..... :	R&L Co., Ltd.
Model/Type reference ..... :	BIOMAT MINI
Ratings ..... :	120 V~; 60 Hz; 100 W

Testing procedure and testing location: N/A
☐ **CB Testing Laboratory:** **Testing location/ address ..... :** ☐ **Associated CB Test Laboratory:** **Testing location/ address ..... :** **Tested by (name + signature) .... :** **Approved by (+ signature)..... :**
☐ **Testing procedure: TMP** **Tested by (name + signature) ... :** **Approved by (+ signature)..... :** **Testing location/ address ..... :**
☐ **Testing procedure: WMT** **Tested by (name + signature) .... :** **Witnessed by (+ signature) ..... :** **Approved by (+ signature)..... :** **Testing location/ address ..... :**
☐ **Testing procedure: SMT** **Tested by (name + signature) ....:** **Approved by (+ signature).....:** **Supervised by (+ signature) .....:** **Testing location/ address ..... :**

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

See IEC 60601-1 Test Report
See IEC 62366 Test Report

Summary of testing:

- Operating environment specification of The BIOMAT MINI is following:
  - Ambient temperature range: 5 to 40 ºC
  - Relative humidity: 15 to 93 %
  - Altitude: 700 to 1 060 hPa

Tests performed (name of test and test clause):	**Testing location:**
Refer to appended tables	**DT&C Co., Ltd.** **42, Yurim-ro 154 beon-gil, Cheoin-gu, Yougin-si, Gyeonggi-do, Korea 449-935**

Summary of compliance with National Differences:

List of countries addressed: N/A

☒ The product fulfils the requirements of IEC 60601-1-6.

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.

See IEC 60601-1 Test Report

Test item particulars ..... :	
Classification of installation and use ..... :	**See IEC 60601-1 Test Report**
Clinical application ..... :	**None**
Mode of operation ..... :	**Continuous operation**
Surface temperature of APPLIED PART ..... :	**Max. 70 ºC**
Possible test case verdicts:	
- test case does not apply to the test object..... :	**N/A (Not applicable)**
- test object does meet the requirement ..... :	**P (Pass)**
- test object does not meet the requirement..... :	**F (Fail)**
Testing:	
Date of receipt of test items..... :	**January 25, 2015**
Date(s) of performance of tests..... :	**January 25, 2015 – March 23, 2015**

Abbreviations used in the report:

- normal condition ..... : N.C. **- Single fault condition ..... : S.F.C.**
- means of Operator protection ..... : MOOP **- Means of Patient protection ..... : MOPP**

General remarks:

"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report a point is used as the decimal separator.
The tests 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 testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

This Test Report contains the general safety requirements as related to the usability of Medical Electrical Equipment. It can only be used together with IEC 62366 and IEC 60601-1 Test Reports.

The Risk Management Task Force reviewed the need for Risk Management tables in this TRF.

Name and address of factory (ies).....:	**See IEC 60601-1 Test Report**

General product information: See IEC 60601-1 Test Report

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
4.0	**General requirements**		**Pass**
4.2	**USABILITY ENGINEERING PROCESS complies with IEC 62366 including amended definitions**	**See attached IEC 62366 Test Report**	**Pass**
	Inspection of the USABILITY ENGINEERING FILE verified that the MANUFACTURER		**Pass**
	– established a USABILITY ENGINEERING PROCESS	**Established**	**Pass**
	– established acceptance criteria for USABILITY; and	**Established**	**Pass**
	– demonstrated that the acceptance criteria for USABILITY have been met.	**Demonstrated**	**Pass**

5	**Replacement of requirements given in IEC 62366**		**Pass**
	The instructions for use include a brief description of the ME EQUIPMENT, its physical operating principles and significant physical and performance characteristics relevant to its USABILITY	**Provided in User Manual (Document No.: RN-USM-003, Ver.: 2.3.0)**	**Pass**
	The same information is also included in the technical description, if this is provided as a separate document from instructions for use	**Provided in User Manual (Document No.: RN-USM-003, Ver.: 2.3.0)**	**Pass**
	The instructions for use contain a summary of the application specification	**Provided in User Manual (Document No.: RN-USM-003, Ver.: 2.3.0)**	**Pass**

	Test Report issued under the responsibility of: CSA Group

TEST REPORT
IEC 60601-1-11
MEDICAL ELECTRICAL EQUIPMENT – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Report Number..... :	**262528-70040865 (Project No.: 70040865, Ed.1)**
Date of issue.....:	**July 31, 2015**
Total number of pages.....:	**30**
Applicant's name ..... :	**R&L Co., Ltd.**
Address.....:	**11th Floor, B-line, ACE Gwang Myeong Tower, #1365, Soha-Dong, Gwangmyeong-Si, Gyeonggi-Do, Korea**
Test specification:	
Standard .....:	IEC 60601-1-11 (First Edition): 2010
Test procedure.....:	CB Scheme
Non-standard test method……..:	N/A
Test Report Form No. ..... :	IEC60601_1_11B
Test Report Form Originator.....:	Underwriters Laboratories Inc.
Master TRF.....:	2011-06

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description..... :	Heating Mat
Trade Mark .....:	R&L RICHWAY & LIFE CO.
Manufacturer.....:	R&L Co., Ltd.
Model/Type reference .....:	BIOMAT MINI
Ratings.....:	120 V~; 60 Hz; 100 W

Testing procedure and testing location: N/A			
☐	**CB Testing Laboratory:**		
Testing location/ address .....:			
☐	**Associated CB Laboratory:**		
Testing location/ address .....:			
	Tested by (name + signature) .....:		
	Approved by (name + signature) .....:		
☐	**Testing procedure: TMP**		
Testing location/ address .....:			
	Tested by (name + signature) .....:		
	Approved by (name + signature) .....:		
☐	**Testing procedure: WMT**		
Testing location/ address .....:			
	Tested by (name + signature) .....:		
	Witnessed by (name + signature) ....:		
	Approved by (name + signature) .....:		
☐	**Testing procedure: SMT**		
Testing location/ address .....:			
	Tested by (name + signature) .....:		
	Approved by (name + signature) .....:		
	Supervised by (name + signature) ...:		

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

See IEC 60601-1 Test Report

Summary of testing:

- Operating environment specification of The BIOMAT MINI is following:
  - Ambient temperature range: 5 to 40 ºC
  - Relative humidity: 15 to 93 %
  - Altitude: 700 to 1 060 hPa
- For heating test was conducted with clause 201.11.1.2.1.101 of IEC 80601-2-35.

Tests performed (name of test and test clause):	**Testing location:**
Refer to appended tables	**HCT Co., Ltd.** **74, Seoicheon-ro 578 beon-gil, Majang-myeon, Incheon-si, Gyeonggi-do, 467-811 Korea**

Summary of compliance with National Differences

List of countries addressed: US

☒ The product fulfils the requirements of IEC 60601-1-11.

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.

See IEC 60601-1 Test Report

Test item particulars.....:	
Classification of installation and use.....:	transportable / ~~portable~~ / ~~stationary~~ / ~~mobile~~ / ~~fixed~~ / ~~permanently installed~~ / ~~hand-held~~
Intended use (Including type of patient, application location) ..... :	
Mode of operation ..... :	Continuous / ~~non-continuous~~
Supply Connection .....:	~~internally powered~~ /~~permanently installed~~ / ~~appliance coupler~~ / non-detachable cord
Accessories and detachable parts included .....:	
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A (Not applicable)
- test object does meet the requirement..... :	P (Pass)
- test object does not meet the requirement..... :	F (Fail)
Testing.....:	
Date of receipt of test item ..... :	February 13, 2015
Date (s) of performance of tests ..... :	February 13, 2015 – March 5, 2015

- Normal condition..... : N.C.	- Single fault condition..... : S.F.C.
- Means of Operator protection ..... : MOOP	- Means of Patient protection ..... : MOPP

General remarks:

"(see Enclosure /Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.

This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

This Test Report Form is intended for the evaluation of medical electrical equipment and medical electrical systems used in the home healthcare environment in accordance with IEC 60601-1-11.
This Test Report Form can be used to complement the IEC 60601-1 Test Report.
The Risk Management Task Force reviewed and modified the Risk Management tables in this TRF.

Name and address of factory (ies) ..... :	**See IEC 60601-1 Test Report**
Same as manufacturer	

General product information: See IEC 60601-1 Test Report

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
4	**GENERAL REQUIREMENTS**		**Pass**
4.1	Characteristics of SUPPLY MAINS specified in 4.10.2 of Part 1 applied, except ME EQUIPMENT or ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT complied with the following:	See below	**Pass**
	– Voltage for non-LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEMS did not exceed 110 % or was not below 85 % of NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% V).....:	120 V~	—
	– Voltage for LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEMS did not exceed 110 % or was not below 80 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% V).....:	Non-life-supporting ME equipment	—
4.2.1	Permissible environmental conditions of transport and storage, after ME EQUIPMENT is removed from its protective packaging and subsequently between uses, indicated in instructions for use		**Pass**
	ME EQUIPMENT, except STATIONARY EQUIPMENT, after being removed from its protective packaging, and subsequently between uses, operated within its specified NORMAL USE after transport or storage in the following environmental temperature range,	See below	**Pass**
	-25 °C without relative humidity control	Operational in normal use	**Pass**
	+70 °C at a non-condensing relative humidity up to 93 %	Operational in normal use	**Pass**
	For more restricted range of environmental transport and storage conditions between uses, the environmental conditions are:	No more restricted range	**N/A**
	– Justified in the RISK MANAGEMENT FILE	See above	**N/A**
	– Marked on the ME EQUIPMENT	See above	**N/A**
	When not practicable, the more restricted range is disclosed in the instructions for use	See above	**N/A**
	– Marked on the carrying case when the instructions for use indicate the ME EQUIPMENT is intended to be transported or stored in a carrying case between uses	See above	**N/A**
	Environmental transport and storage test		**Pass**
	a) ME EQUIPMENT prepared for transportation or storage according to instructions for use (e.g., removal of batteries, emptying fluid reservoirs, etc.)	Prepared	**Pass**
	b) ME EQUIPMENT exposed to its lowest specified environmental transport and storage conditions (temperature -4^{0} °C) (°C).....:	-25 °C	**Pass**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– For at least 24 h or, ensure ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	24 h	**Pass**
	c) ME EQUIPMENT exposed to its highest specified environmental transport and storage conditions (temperature $^{+4}_{0}$ °C and relative humidity ± 3 %) (°C, ± %) .....:	+70 °C; 93 % R.H.	**Pass**
	– For at least 24 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	24 h	**Pass**
	Transition from low to high conditions made slowly enough to provide a non-condensing environment	See above	**N/A**
	d) At the end of this conditioning period, ME EQUIPMENT allowed to return and stabilize at the operating conditions of NORMAL USE	+5 °C to +40 °C; 15 % to 93 %, non-condensing; 700 hPa to 1 060 hPa	**Pass**
	e) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE	No damage. No hazards.	**Pass**
4.2.2	The permissible environmental operating conditions are indicated in the instructions for use		**Pass**
	ME EQUIPMENT complied with its specifications and all the requirements of this standard when operated in NORMAL USE under the following environmental operating conditions, except as indicated in the instructions for use:	See below	**Pass**
	– a temperature range of +5 °C to +40 °C (°C) .....:	+5 °C to +40 °C	**Pass**
	– a relative humidity range of 15 % to 93 %, non-condensing (% RH) .....:	15 % to 93 %, non-condensing	**Pass**
	– an atmospheric pressure range of 700 hPa to 1060 hPa (hPa).....:	700 hPa to 1 060 hPa	**Pass**
	When more restricted range of environmental operating conditions are stated in the instructions for use, they are justified or marked as follows:	No more restricted range	**N/A**
	– justified in the RISK MANAGEMENT FILE	See above	**N/A**
	– marked on the ME EQUIPMENT, except when not practicable	See above	**N/A**
	The more restricted range disclosed in the instructions for use; and	See above	**N/A**
	– marked on the carrying case when the instructions for use indicated the ME EQUIPMENT is intended to be operated in a carrying case	See above	**N/A**
	ME EQUIPMENT complied with its specifications and requirements of this standard when operated in NORMAL USE under the specified environmental operating conditions	Complied	**Pass**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	When a more restricted range stated in the instructions for use, the RISK MANAGEMENT FILE inspected	No more restricted range	**N/A**
	Environmental operating conditions test		**Pass**
	a) ME EQUIPMENT exposed to the ambient conditions	+5 °C to +40 °C; 15 % to 93 %, non-condensing; 700 hPa to 1 060 hPa	**Pass**
	– For at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h (h)	6 h	**Pass**
	b) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE	No damage. No hazards.	**Pass**
	c) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE while at the lowest specified atmospheric pressure	700 hPa	**Pass**
	d) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE while at the highest specified atmospheric pressure	1 060 hPa	**Pass**
	e) ME EQUIPMENT cooled to its lowest specified environmental operating conditions (temperature $^{0}_{-4}$ °C and relative humidity less than or equal to 15 %) (°C, RH %) .....:	+5 °C; 15 % R.H.	**Pass**
	f) ME EQUIPMENT held at its lowest specified environmental operating conditions for at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h (h)	6 h	**Pass**
	g) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE	No damage. No hazards.	**Pass**
	h) ME EQUIPMENT heated to its highest specified environmental operating conditions (temperature $^{+4}_{0}$ °C and relative humidity ± 3 %) (°C, RH %) .....:	+40 °C; 93 % R.H.	**Pass**
	i) ME EQUIPMENT held at its highest specified environmental operating conditions for at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h (h)	6 h	**Pass**
	j) ME EQUIPMENT evaluated to its specifications and ensured that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE	No damage. No hazards.	**Pass**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
4.2.3	TRANSIT-OPERABLE ME EQUIPMENT maintain BASIC SAFETY and ESSENTIAL PERFORMANCE in the presence of condensation and thermal shock when instructions for use state a wider range of environmental operating conditions than indicated in 4.2.2	No transit-operable ME equipment	**N/A**
	Environmental operating conditions test		**N/A**
	a) ME EQUIPMENT was set up for operation according to INTENDED USE	See above	**N/A**
	b) ME EQUIPMENT exposed to its lowest specified environmental operating conditions (temperature $^{0}_{-4}$ °C and relative humidity less than or equal to 15 %) (°C, RH %) .....:	See above	**N/A**
	c) ME EQUIPMENT held at its lowest specified environmental operating conditions for at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h (h)	See above	**N/A**
	d) ME EQUIPMENT exposed to its highest specified environmental operating conditions within 5 min (temperature $^{+4}_{0}$ °C and relative humidity ± 3 %) (°C, RH %) .....:	See above	**N/A**
	e) ME EQUIPMENT maintained at the environmental conditions of d) above	See above	**N/A**
	ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE until the ME EQUIPMENT reached THERMAL STABILITY, or for at least 2 h	See above	**N/A**
	LEAKAGE CURRENT and dielectric strength testing were not included in the evaluation of BASIC SAFETY due to pollution degree ratings required by Part 1	See above	**N/A**
	A separate test sample was, optionally, used for the following tests:		**N/A**
	f) ME EQUIPMENT was set up for operation according to INTENDED USE	See above	**N/A**
	g) ME EQUIPMENT exposed to its highest specified environmental operating conditions (temperature $^{+4}_{0}$ °C and relative humidity ± 3 %) (°C, RH %) .....:	See above	**N/A**
	h) ME EQUIPMENT held at its highest specified environmental operating conditions for at least 6 h or, ensured the ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	See above	**N/A**
	i) ME EQUIPMENT exposed to its lowest specified environmental operating conditions within 5 min (temperature $^{0}_{-4}$ °C and relative humidity ≤ 15 %) (°C, RH %) .....:	See above	**N/A**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	j) ME EQUIPMENT maintained at the environmental conditions in i) evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE until the ME EQUIPMENT reached THERMAL STABILITY, or for at least 2 h	See above	**N/A**
	Evaluation of BASIC SAFETY and ESSENTIAL PERFORMANCE repeated for two hours or until THERMAL STABILITY reached while ME EQUIPMENT was warming up or cooling down	See above	**N/A**
5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		**Pass**
	In addition to the requirements of 5.9.2.1 of with IEC 60601-1 standard, accessibility determined as indicated below:		**Pass**
	ACCESSIBLE parts of ME EQUIPMENT identified by inspection and, when necessary, by testing	Inspection and testing	**Pass**
	When in doubt, an ACCESSIBLE PART of ME EQUIPMENT determined by a test with the small finger probe of Fig 1, applied in a bent or straight position as follows:	See below	**Pass**
	– for all positions of the ME EQUIPMENT operating in NORMAL USE		**Pass**
	– after opening ACCESS COVERS and removal of parts, including lamps, fuses, and fuse holders when:	No such parts	**N/A**
	i) the ACCESS COVERS could be opened without the use of a TOOL, or	See above	**N/A**
	ii) the instructions for use instructed a LAY OPERATOR to open the relevant ACCESS COVER	See above	**N/A**
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		**Pass**
	ME EQUIPMENT intended for HOME HEALTHCARE ENVIRONMENT classified as follows, except for PERMANENTLY INSTALLED EQUIPMENT and as required by Part 1, Sub-clause 6.2:	See below	**Pass**
	– CLASS II or INTERNALLY POWERED .....:	Class II	**Pass**
	– Not provided with a FUNCTIONAL EARTH TERMINAL	Not provided	**Pass**
	– When equipped with APPLIED PARTS, they are TYPE BF or CF .....:	Type BF applied parts	**Pass**
7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		**Pass**
7.1	USABILITY of identification, marking, and ACCOMPANYING DOCUMENTS intended for LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION evaluated by an OPERATOR whose PROFILE included eight years of education	**Document Reference No. in USABILITY ENGINEERING FILE:** Cl. 5.2 of RN-USE-003 (Rev.0)	**Pass**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	ME EQUIPMENT and ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT are simple to use and do not require referencing complex ACCOMPANYING DOCUMENTS	Simple to use and do not require referencing complex user manual	**Pass**
	Results of USABILITY ENGINEERING PROCESS inspected	See USABILITY ENGINEERING FILE	**Pass**
7.2	The ENCLOSURE is marked with the IP classification required by 8.3.1 .....:	Ordinary ME equipment (IPX0)	**N/A**
	Degree of protection provided by the ENCLOSURE marked on ENCLOSURE and the degree of protection provided by carrying case marked on carrying case when some or all of the protection against ingress of water or particulate matter is provided by a carrying case	No such carrying case	**N/A**
	A carrying case not intended to provide protection against the ingress of water or particulate matter not marked	Not marked	**Pass**
	An ENCLOSURE, not providing the minimum required degree of protection against the ingress of water, is marked “keep dry”, or with symbol ISO 7000-0626 (2004-01) (Table C1, symbol 1):	Symbol (ISO 7000, 0626),  is used	**Pass**
	ENCLOSURE inspected, and tests and criteria of 7.1.2 and 7.1.3 of Part 1 applied .....:	See IEC 60601-1 Test report, Sub-clauses 7.1.2 and 7.1.3	**Pass**
7.3	ACCOMPANYING DOCUMENTS		**Pass**
7.3.1	ACCOMPANYING DOCUMENTS indicate the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION should contact the MANUFACTURER or MANUFACTURER'S representative on the following issues:	See below	**Pass**
	– Assistance in setting up, using, or maintaining the ME EQUIPMENT or ME SYSTEM when needed, or		**N/A**
	– To report unexpected operation or events	Provided in User manual	**Pass**
	ACCOMPANYING DOCUMENTS include a postal address and either a phone number or web address for the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION to contact the MANUFACTURER or MANUFACTURER'S representative	Provided in User manual	**Pass**
7.3.2	ACCOMPANYING DOCUMENTS include necessary details for healthcare professional to brief the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION on any known contraindication(s) to the use of ME EQUIPMENT or ME SYSTEM and any precautions to be taken including the following:	See below	**Pass**
	– Precautions to be taken in the event of changes in the performance of ME EQUIPMENT or ME SYSTEM	Provided in User manual	**Pass**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Precautions to be taken regarding the exposure of the ME EQUIPMENT or ME SYSTEM to reasonably foreseeable environmental conditions	Provided in User manual	**Pass**
	– Adequate information regarding medicinal substances that ME EQUIPMENT is designed to administer, including any limitations in the choice of substances to be delivered as indicated below:	No such parts	**N/A**
	– Information on any medicinal substances or human blood derivatives incorporated into the ME EQUIPMENT or ACCESSORIES as an integral part; and	No such parts	**N/A**
	– The degree of accuracy claimed for ME EQUIPMENT with a measuring FUNCTION	No measuring function	**N/A**
7.4	Instructions for use		**Pass**
7.4.1	Nature of the HAZARD, likely consequences that could occur if the advice is not followed, and precautions for reducing the RISK described in instructions for use corresponding to each warning and safety sign.....:	See RISK MANAGEMENT Table 7.4.1	**Pass**
	The instructions for use address the following issues, as applicable:		**Pass**
	– Strangulation due to cables and hoses, particularly due to excessive length	Provided in User manual	**Pass**
	– Inhalation or swallowing of small parts	No such component	**N/A**
	– Potential allergic reactions to accessible materials used in the ME EQUIPMENT	Provided in User manual	**Pass**
	– Contact injuries	Provided in User manual	**Pass**
	The instructions for use include warnings to the effect that the following actions could be unsafe as applicable:	See below	**Pass**
	– Use of ACCESSORIES, detachable parts, and materials not described in the instructions for use (see 7.9.2.14 of Part 1)	Provided in User manual	**Pass**
	– Interconnection of this equipment to other equipment not described in the instructions for use (see 16.2 c) indent 9) of Part 1)	No such parts	**N/A**
	– Modification of the equipment	Provided in User manual	**Pass**
	– Use of the ME EQUIPMENT outside its carrying case when some part of the protection required by this standard is provided by that carrying case (see 8.3.1 and 10.1)	No such parts	**N/A**
7.4.2	When BASIC SAFETY or ESSENTIAL PERFORMANCE dependents on the INTERNAL ELECTRICAL POWER SOURCE, the instructions for use describes the following:	No internal electrical power source	**N/A**
	– Typical operation time or number of procedures ....:	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Typical service life .....:	See above	**N/A**
	– Behaviour of ME EQUIPMENT while the rechargeable INTERNAL ELECTRICAL POWER SOURCE is charging .....:	See above	**N/A**
7.4.3	Instructions for use include easily understood diagrams, illustrations, or photographs of the fully assembled and ready-to-operate ME EQUIPMENT including all controls, visual INFORMATION SIGNALS, and indicators provided (see 7.1)	Provided in User manual	**Pass**
7.4.4	Instructions for use include:		**Pass**
	– Easily understood diagrams, illustrations, or photographs showing proper connection of the PATIENT to the ME EQUIPMENT, ACCESSORIES and other equipment (see 7.1)	Provided in User manual	**Pass**
	– the time from switching "ON" until the ME EQUIPMENT is ready for NORMAL USE, when it exceeds 15 s (see 15.4.4 of Part 1) (s).....:	No exceed 15 s	**N/A**
7.4.5	Instructions for use include a description of generally known conditions in the HOME HEALTHCARE ENVIRONMENT that can unacceptably affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT	Provided in User manual	**Pass**
	The steps that can be taken by the LAY OPERATOR to identify and resolve the above conditions	Provided in User manual	**Pass**
	At least the following issues are also included as applicable		**Pass**
	- The effects of lint, dust, light (including sunlight), etc	Provided in User manual	**Pass**
	- A list of known devices or other sources that can potentially cause interference problems	Provided in User manual	**Pass**
	- The effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems	Provided in User manual	**Pass**
	- The effects caused by pets, pests or children	Provided in User manual	**Pass**
	The instructions for use explain the meaning of the IP classification marked on the ME EQUIPMENT, and on any carrying case provided with the ME EQUIPMENT as applicable	See RISK MANAGEMENT Table 7. 4.5	**Pass**
7.4.6	Instructions for use include a troubleshooting guide for use when there are indications of a ME EQUIPMENT malfunction during start-up or operation	Provided in User manual	**Pass**
	Troubleshooting guide discloses the necessary steps in the event of an ALARM CONDITION	Provided in User manual	**Pass**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.4.7	Instructions for use for ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES for other than single use that can be contaminated by contact with PATIENT, body fluids, or expired gases, during INTENDED USE, indicate the following:	See below	**Pass**
	– Frequency of cleaning, cleaning and disinfection, or cleaning and sterilization, as appropriate, for ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES used on the same PATIENT including rinsing methods, drying, handling, and storage between uses (see 8.1 and 8.2); and	Provided in User manual	**Pass**
	– It is necessary to clean and disinfect, clean and sterilize the ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES for multiple PATIENT use between uses on different PATIENTS, including rinsing methods, drying, handling, and storage until re-use (see 8.1 and 8.2), or	Provided in User manual	**Pass**
	– ME EQUIPMENT, ME SYSTEMS and ACCESSORIES require professional hygienic maintenance prior to re-use and provide contact details for the source of these services (see 7.5.2)	No such parts	**N/A**
7.4.8	Instructions for use include:		**Pass**
	– EXPECTED SERVICE LIFE of the ME EQUIPMENT .....:	Provided in User manual	**Pass**
	– EXPECTED SERVICE LIFE of parts and ACCESSORIES shipped with the ME EQUIPMENT .....:	Provided in User manual	**Pass**
	– SHELF LIFE of parts and ACCESSORIES shipped with ME EQUIPMENT when SHELF LIFE is less than the EXPECTED SERVICE LIFE .....:	No such parts	**N/A**
7.4.9	Instructions for use include:		**Pass**
	– Information concerning the proper disposal of the ME EQUIPMENT, its parts and ACCESSORIES (see IEC 60601-1-9); and	Provided in User manual	**Pass**
	– A statement indicating the LAY RESPONSIBLE ORGANIZATION must contact its local authorities to determine the proper method of disposal of potentially bio hazardous parts and ACCESSORIES, as applicable	No such parts	**N/A**
7.4.10	Instructions for use includes the recommended placement of the remote parts of the DISTRIBUTED ALARM SYSTEM, when applicable, to ensure the OPERATOR can be notified at all times by an appropriate element of DISTRIBUTED ALARM SYSTEM within its specified range	No such parts	**N/A**
7.5	Technical description		**N/A**
7.5.1	The technical description for PERMANENTLY INSTALLED CLASS I ME EQUIPMENT includes:	Class II ME equipment	**N/A**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– A warning indicating the ME EQUIPMENT installation, including a correct PROTECTIVE EARTH CONNECTION, must only be carried out by qualified SERVICE PERSONNEL	See above	**N/A**
	– Specifications of the PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR	See above	**N/A**
	– A warning to verify the integrity of the external protective earthing system	See above	**N/A**
	– A warning to connect and verify that the PROTECTIVE EARTH TERMINAL of the PERMANENTLY INSTALLED ME EQUIPMENT is connected to the external protective earthing system	See above	**N/A**
7.5.2	Technical description includes methods for cleaning and disinfection or cleaning and sterilization for ME EQUIPMENT and ACCESSORIES requiring professional hygienic maintenance prior to reuse (see 7.4.7):	No such parts	**N/A**
	– Before and after any type of service PROCEDURE	See above	**N/A**
	– When the ME EQUIPMENT is transferred to another PATIENT	See above	**N/A**
8	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		**Pass**
8.1	A LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT can perform the cleaning or cleaning and disinfection PROCESSES when intended (see 7.4.7)	Can performed	**Pass**
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS	See USABILITY ENGINEERING FILE	**Pass**
8.2	A LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT can perform the cleaning and sterilization PROCESSES when intended (see 7.4.7)	No such parts	**N/A**
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS	See above	**N/A**
8.3	Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		**N/A**
8.3.1	TRANSIT-OPERABLE, HANDHELD, and BODY-WORN ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529:1989 for IP22	Ordinary ME equipment	**N/A**
	All other ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529:1989 for IP21	See above	**N/A**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	For PORTABLE ME EQUIPMENT intended to be used only with a carrying case, this requirement was, optionally, met with the ME EQUIPMENT in its the carrying case	See above	**N/A**
	PORTABLE ME EQUIPMENT with the carrying case was inspected, and the tests of IEC 60529:1989 applied	See above	**N/A**
	Maintenance of BASIC SAFETY and ESSENTIAL PERFORMANCE VERIFIED	See above	**N/A**
8.3.2	ENCLOSURES of the non-ME EQUIPMENT parts of the ME SYSTEMS provide the degree of protection against harmful ingress of water or particulate matter equivalent to equipment complying with their respective IEC or ISO safety standards	No ME system	**N/A**
	Tests of IEC 60529:1989 conducted with the equipment placed in the least favourable position of NORMAL USE and the ENCLOSURES inspected	See above	**N/A**
8.4	Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT and ME SYSTEM		**N/A**
	A LIFE SUPPORTING ME EQUIPMENT or ME SYSTEM maintained its ESSENTIAL PERFORMANCE for a sufficient time or for a sufficient number of PROCEDURES when loss or failure of SUPPLY MAINS or INTERNAL ELECTRICAL POWER SOURCE occurred	No life supporting ME equipment	**N/A**
	The time or number of PROCEDURES remaining allowed alternative life-supporting methods to be employed	See above	**N/A**
	Optionally, an INTERNAL ELECTRICAL POWER SOURCE was used to maintain ESSENTIAL PERFORMANCE .....:	See above	**N/A**
	Optionally, independent means were used to provide ESSENTIAL PERFORMANCE .....:	See above	**N/A**
	Instructions for use disclose the time or number of procedures available following a loss or failure of the electrical power supply	See above	**N/A**
	Instructions for use describes the alternative life-supporting methods to be employed	See above	**N/A**
	The technical description describes methods that can be employed for longer periods	See above	**N/A**
	LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM with no INTERNAL ELECTRICAL POWER SOURCE is equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY ALARM CONDITION indicating power failure ..:	See above	**N/A**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM with an INTERNAL ELECTRICAL POWER SOURCE is equipped with an automatic switchover to INTERNAL ELECTRICAL POWER SOURCE and an ALARM SYSTEM that includes at least a LOW PRIORITY ALARM CONDITION indicating switch-over to INTERNAL ELECTRICAL POWER SOURCE	See above	**N/A**
	LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM with an INTERNAL ELECTRICAL POWER SOURCE is equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION indicating the INTERNAL ELECTRICAL POWER SOURCE is nearing insufficient remaining power for operation	See above	**N/A**
	TECHNICAL ALARM CONDITION provides sufficient time or sufficient number of procedures for a LAY OPERATOR to act	See above	**N/A**
	A TECHNICAL ALARM CONDITION of at least LOW PRIORITY remained active until the INTERNAL ELECTRICAL POWER SOURCE returned to a level above the ALARM LIMIT or until depleted	See above	**N/A**
	It was not possible to inactivate the visual ALARM SIGNAL of this TECHNICAL ALARM CONDITION	See above	**N/A**
	Functional tests conducted, and the RISK MANAGEMENT FILE inspected .....:	See above	**N/A**
9	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		**Pass**
	The RISKS associated with USABILITY in the HOME HEALTHCARE ENVIRONMENT when performing the USABILITY ENGINEERING PROCESS include at least the following considerations:		**Pass**
	– changes of controls		**Pass**
	– unexpected movement	No such parts	**N/A**
	– potential for misconnection		**Pass**
	– potential for improper operation, or unsafe use		**Pass**
	– potential for confusion as to current operational mode		**Pass**
	– change in the transfer of energy or substance	No such parts	**N/A**
	– exposure to biological materials, and	No such parts	**N/A**
	– small parts being inhaled or swallowed	No such parts	**N/A**
	Particular emphasis is placed on the limited training of a LAY OPERATOR with respect to the ability to intervene and maintain BASIC SAFETY and ESSENTIAL PERFORMANCE		**Pass**
	USABILITY ENGINEERING FILE inspected	See USABILITY ENGINEERING FILE	**Pass**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
10	**CONSTRUCTION OF ME EQUIPMENT**		**Pass**
10.1	Additional requirements for mechanical strength		**Pass**
10.1.1	Table 28, Mechanical strength test applicability, replaced by Table 1, Mechanical strength test applicability, non-TRANSIT-OPERABLE, and Table 2, Mechanical strength test applicability, TRANSIT-OPERABLE	Replaced by Table 1 (Non-transit-operable)	**Pass**
10.1.2	ME EQUIPMENT, its parts, and mounting ACCESSORIES, intended for non-TRANSIT-OPERABLE use displayed adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, dropping and rough handling (not applicable to FIXED and STATIONARY ME EQUIPMENT)	Non-transit-operable ME equipment	**Pass**
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after mechanical tests		**Pass**
	OPERATOR-re-settable protective devices that can be reset without the use of a TOOL were, optionally, reset prior to the evaluation of BASIC SAFETY and ESSENTIAL PERFORMANCE	No protective devices	**N/A**
	a) Shock tests conducted in accordance with IEC 60068-2-27:2008	See Appended Table 10.1.2a	**Pass**
	b) Broad-band random vibration tests conducted in accordance with IEC 60068-2-64:2008, using the following conditions:	See Appended Table 10.1.2b	**Pass**
10.1.3	ME EQUIPMENT, parts, and mounting ACCESSORIES for TRANSIT-OPERABLE use displayed adequate mechanical strength when subjected to pushing, impact, dropping, rough handling, and rigorous conditions of PATIENT movement in NORMAL USE as well as transportation by trolleys, carts, road vehicles, trains, ships, and aircraft	Non-transit-operable ME equipment	**N/A**
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after the following tests:	See above	**N/A**
	a) Shock tests conducted on other than HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-27:2008	See above	**N/A**
	1) Test type: Type 1	See above	**N/A**
	2) Test type: Type 2	See above	**N/A**
	b) Shock tests conducted on HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-27:2008	See above	**N/A**
	1) Test type: Type 1	See above	**N/A**
	2) Test type: Type 2	See above	**N/A**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	c) Broad-band random vibration test conducted on ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-64:2008	See above	**N/A**
	d) Free fall tests conducted on PORTABLE and MOBILE ME EQUIPMENT, parts, and mounting ACCESSORIES per IEC 60068-2-31:2008, using PROCEDURE 1	See above	**N/A**
	BASIC SAFETY and ESSENTIAL PERFORMANCE were maintained	See above	**N/A**
10.2	ME EQUIPMENT equipped with a means for the OPERATOR to determine the state of INTERNAL ELECTRICAL POWER SOURCE when it is essential to maintain BASIC SAFETY, ESSENTIAL PERFORMANCE, or control the RISKS associated with the loss of ESSENTIAL PERFORMANCE	No internal electrical power source	**N/A**
	The state of the INTERNAL ELECTRICAL POWER SOURCE is, optionally, indicated as		**N/A**
	– a number of procedures remaining	See above	**N/A**
	– the remaining operating time	See above	**N/A**
	– the percentage of the remaining operating time or energy; or	See above	**N/A**
	– a "fuel" gauge	See above	**N/A**
	The state of the INTERNAL ELECTRICAL POWER SOURCE continuously indicated or by OPERATOR action	See above	**N/A**
	The instructions for use describe how to determine the state of the INTERNAL ELECTRICAL POWER SOURCE	See above	**N/A**
10.3	Controls of ME EQUIPMENT that can affect BASIC SAFETY or ESSENTIAL PERFORMANCE protected from accidental or unauthorized changes or adjustments	To be subjected to two-stage operation.	**Pass**
	OPERATOR-adjustable controls used for calibration include a means to prevent unintentional changes from the intended position	No such parts	**N/A**
11	**PROTECTION AGAINST STRANGULATION OR ASPHYXIATION**		**Pass**
	Means provided to control the RISK of strangulation and asphyxiation of the PATIENT and others to an acceptable level	Tubing used. No removable small parts	**Pass**
	EQUIPMENT and the RISK MANAGEMENT FILE inspected	See RISK MANAGEMENT Table 11	**Pass**
12	**ADDITIONAL REQUIREMENTS FOR ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		**N/E**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
13	**ADDITIONAL REQUIREMENTS FOR ALARM SYSTEMS OF ME EQUIPMENT AND ME SYSTEMS**		**N/A**
	IEC 60601-1-8:2006 applied except as follows:	No alarm systems	**N/A**
13.1	Each HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITION causes generation of auditory ALARM SIGNALS per IEC 60601-1-8:2006, except when equipment is connected to a DISTRIBUTED ALARM SYSTEM including the generation of auditory ALARM SIGNALS per IEC 60601-1-8:2006	No alarm systems	**N/A**
13.2	Reducing the auditory ALARM SIGNAL volume below audible levels resulted in the following:	No alarm systems	**N/A**
	- The indication of ALARM OFF or AUDIO OFF activated as specified in IEC 60601-1-8:2006	See above	**N/A**
	- For LIFE SUPPORTING ME EQUIPMENT and ME SYSTEM this action was not possible, except when the ALARM SYSTEM was connected to a DISTRIBUTED ALARM SYSTEM that included generation of auditory ALARM SIGNALS per IEC 60601-1-8:2006	See above	**N/A**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

4.2.1	RM RESULTS TABLE: Permissible environmental conditions of transport and storage		N/A
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2			
4.3			
4.4			

4.2.2	RM RESULTS TABLE: Permissible environmental conditions under normal use		N/A
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2			
4.3			
4.4			

7.4.1	RM RESULTS TABLE: Additional requirements for warning and safety notices		Pass
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2	Risk Management Report Cl. 4.2 of RN-RMR-003, Rev. 0	Detachable parts & Accessories: Mat	Pass
4.3	Risk Management Report Cl. 4.3 of RN-RMR-003, Rev. 0 FMEA Table	1. Strangulation resulting from baby or child entanglement in controller cable. 2. Potential allergic reactions to accessible materials used in the ME Equipment 3. Skin irritation due to prolonged exposure to applied parts or other parts 4. Use Accessories, detachable parts and materials not described 5. Modify the equipment The possible hazard of strangulation, tissue damage and electric shock to the operator or patient caused by the information hazard has been identified. (Hazard ID: H1-11-7.4.1)	Pass
4.4	Risk Management Report Cl. 4.4 of RN-RMR-003, Rev. 0 FMEA Table	The probability of occurrence of the harm has been estimated in “Occasional”. The severity of the harm has been estimated as “Critical”	Pass
5	Risk Management Report Cl. 5 of RN-RMR-003, Rev. 0 FMEA Table	The risk has been evaluated as “ALARP: To be reduced”	Pass
6.2	Risk Management Report Cl. 6.2 of RN-RMR-003, Rev. 0 FMEA Table	The measure that has been identified to control the risk is below. Information for safety	Pass

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

7.4.5	RM RESULTS TABLE: : Additional requirements for operating instructions		Pass
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.3	Risk Management Report Cl. 4.3 of RN-RMR-001, Rev. 0 FMEA Table	1. The effects of lint, dust & light 2. The effects caused by pets, pests or children The possible hazard of tissue damage and electric shock to the operator or patient caused by the information hazard has been identified. (Hazard ID: H1-11-7.4.5)	Pass
4.4	Risk Management Report Cl. 4.4 of RN-RMR-001, Rev. 0 FMEA Table	The probability of occurrence of the harm has been estimated in “Occasional”. The severity of the harm has been estimated as “Critical”	Pass
5	Risk Management Report Cl. 5 of RN-RMR-001, Rev. 0 FMEA Table	The risk has been evaluated as “ALARP: To be reduced”	Pass
6.2	Risk Management Report Cl. 6.2 of RN-RMR-001, Rev. 0 FMEA Table	The measure that has been identified to control the risk is below. Information for safety	Pass

8.4	RM RESULTS TABLE: Additional requirements for interruption of power supply / supply mains to ME Equipment and ME Systems		N/A
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2			
4.3			
5			
6.2			
6.3			
6.4			
6.5			
6.6			
6.7			

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

10.1.2a	**TABLE: Shock test (IEC 60068-2-27:2008), using the following conditions*:**		**Pass**
	Peak acceleration ..... :	150 m/s2 (15 g)	
	Duration ..... :	11 ms	
	Pulse shape ..... :	half-sine	
	Number of shocks ..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
Controller and Mat	X axis negative	Yes	3 shocks
Controller and Mat	X axis positive	Yes	3 shocks
Controller and Mat	Y axis negative	Yes	3 shocks
Controller and Mat	Y axis positive	Yes	3 shocks
Controller and Mat	Z axis negative	Yes	3 shocks
Controller and Mat	Z axis positive	Yes	3 shocks

Supplementary information:

*(NOTE 1 This represents Class 7M1 as described in IEC TR 60721-4-7:2001 [6])

Ambient Temperature (ºC)	23.4	Relative Humidity (rH%)	17.6	Atmospheric Pressure (hPA)	1005
TESTED BY:	Jae-Ho Jang 	DATE:	2015-02-15	TEST EQUIPMENT ASSET NUMBER:	HCT-S-163 HCT-S-231
WITNESSED BY:	Antonio Joo 	DATE:	2015-02-15		

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

10.1.2b	**TABLE: Broad-band random vibration test (IEC 60068-2-64:2008) using the following conditions*:**		**Pass**
1	Acceleration amplitude .....:	10 Hz to 100 Hz: 1,0 $(m/s^2)^2$/Hz	
2	Acceleration amplitude .....:	100 Hz to 200 Hz: – 3 db per octave	
3	Acceleration amplitude .....:	200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2$/Hz	
	Duration.....:	30 min per perpendicular axis (3 total)	

Perpendicular axis subjected to broad-band random vibration test	Acceleration amplitude	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
1	1	Yes	X Axis
2	1	Yes	X Axis
3	1	Yes	X Axis
1	2	Yes	Y Axis
2	2	Yes	Y Axis
3	2	Yes	Y Axis
1	3	Yes	Z Axis
2	3	Yes	Z Axis
3	3	Yes	Z Axis

Supplementary information:

* (NOTE 2 This represents Class 7M1 and 7M2 as described in IEC TR 60721-4-7:2001)

Ambient Temperature (ºC)	23.4	Relative Humidity (rH%)	17.6	Atmospheric Pressure (hPA)	1005
TESTED BY:	Jae-Ho Jang 	DATE:	2015-02-15	TEST EQUIPMENT ASSET NUMBER:	HCT-S-110 HCT-S-230
WITNESSED BY:	Antonio Joo 	DATE:	2015-02-15		

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

10.1.3a1	**TABLE: Shock test (IEC 60068-2-27:2008) for other than HAND-HELD EQUIPMENT, parts, and mounting ACCESSORIES under the following conditions (Test Type 1):**		**N/A**
	Peak acceleration..... :	150 m/s^2 (15 g)	
	Duration ..... :	11 ms	
	Pulse shape..... :	half-sine	
	Number of shocks ..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks

Supplementary information:

* (NOTE 3 This represents Class 7M2 as described in IEC/TR 60721-4-7:2001 [6])

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

10.1.3a2	**TABLE: Shock test (IEC 60068-2-27:2008) on other than HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES under the following conditions (Test Type 2):**		**N/A**
	Peak acceleration..... :	300 m/s^2 (15 g)	
	Duration ..... :	6 ms	
	Pulse shape..... :	half-sine	
	Number of shocks ..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
Supplementary information:			

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

10.1.3b1	**TABLE: Shock test (IEC 60068-2-27:2008) on HAND-HELD ME EQUIPMENT parts, and mounting ACCESSORIES using the following conditions (Test Type 1):**		**N/A**
	Peak acceleration ..... :	300 m/s^2 (30 g)	
	Duration ..... :	11 ms	
	Pulse shape ..... :	half-sine	
	Number of shocks ..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks

Supplementary information:

*(NOTE 4 This represents Class 7M3 as described in IEC/TR 60721-4-7:2001. (Test Type 1)

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

10.1.3b2	**TABLE: Shock test (IEC 60068-2-27:2008) on HAND-HELD ME EQUIPMENT parts, and mounting ACCESSORIES using the following conditions (Test Type 2):**		**N/A**
	Peak acceleration ..... :	1000 m/s^2 (100 g)	
	Duration ..... :	6 ms	
	Pulse shape ..... :	half-sine	
	Number of shocks ..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks

Supplementary information:

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

10.1.3c	**TABLE: Broad-band random vibration test (IEC 60068-2-64:2008) on ME EQUIPMENT, parts, and mounting ACCESSORIES using the following conditions*:**		**N/A**
1	Acceleration amplitude ..... :	10 Hz to 100 Hz: 1,0 $(m/s^2)^2$/Hz	
2	Acceleration amplitude ..... :	100 Hz to 200 Hz: - 3 db per octave	
3	Acceleration amplitude ..... :	200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2$/Hz	
	Duration ..... :	30 min per perpendicular axis (3 total)	

Perpendicular axis subjected to broad-band random vibration test	Acceleration amplitude	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
1	1		
2	1		
3	1		
1	2		
2	2		
3	2		
1	3		
2	3		
3	3		

Supplementary information:

*(NOTE 5 This represents Class 7M1 and 7M2 as described in IEC/TR 60721-4-7:2001)

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

10.1.3d	**TABLE: Free fall test (IEC 60068-2-31:2008), using PROCEDURE 1, on PORTABLE and MOBILE ME EQUIPMENT, parts, and mounting ACCESSORIES (with carrying case if intended), under the following conditions*:**		**N/A**
1	Fall height for mass ≤ 1 kg .....:	0,25 m	
2	Fall height for mass > 1 kg and ≤ 10 Kg .....:	0,1 m	
3	Fall height for mass > 10 kg and ≤ 50 Kg .....:	0,05 m	
4	Fall height for mass > 50 kg .....:	0,01 m	

Specified altitude (m)	Mass (Kg)	Fall No.	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
0,25	≤ 1	1		
0,25	≤ 1	2		
0,1	> 1 & ≤ 10	1		
0,1	> 1 & ≤ 10	2		
0,05	> 10 & ≤ 50	1		
0,05	> 10 & ≤ 50	2		
0,01	> 50	1		
0,01	> 50	2		

Supplementary information:

(*NOTE 6 This represents Class 7M2 as described in IEC/TR 60721-4-7:2001)

11.0	**RM RESULTS TABLE: PROTECTION AGAINST STRANGULATION AND ASPHYXIATION**		**Pass**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.3	**Risk Management Report Cl. 4.3 of RN-RMR-003, Rev. 0 FMEA Table**	**The possible hazard of strangulation to the operator or patient caused by the mechanical energy has been identified. (Hazard ID: H1-11-11)**	**Pass**
4.4	**Risk Management Report Cl. 4.4 of RN-RMR-003, Rev. 0 FMEA Table**	**IEC 60601-1 standard The probability of occurrence of the harm has been estimated in "Occasional". The severity of the harm has been estimated as "Critical".**	**Pass**
5	**Risk Management Report Cl. 5 of RN-RMR-003, Rev. 0 FMEA Table**	**The risk has been evaluated as "ALARP: To be reduced"**	**Pass**

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

11.0	RM RESULTS TABLE: PROTECTION AGAINST STRANGULATION AND ASPHYXIATION		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2	Risk Management Report Cl. 6.2 of RN-RMR-003, Rev. 0 FMEA Table	The measure that has been identified to control the risk is below. 1. Inherent safety by design 2. Information for safety	Pass
6.3	Risk Management Report Cl. 6.3 of RN-RMR-003, Rev. 0 FMEA Table	1. Cord bushing & tubing used 2. Description in User manual	Pass
6.4	Risk Management Report Cl. 6.4 of RN-RMR-003, Rev. 0 FMEA Table	IEC 60601-1 and IEC 60601-1-11 test reports are evidence for verification. The probability of occurrence of the harm has been reduced to “Improbable”. The residual risk has been evaluated as “Acceptable”	Pass
6.5		Not deemed necessary	N/A
6.6		Not deemed necessary	N/A

IEC60601_1_11B ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-1-11
US NATIONAL DIFFERENCES

Medical electrical equipment, Part 1-11: Collateral Standard:

Requirements for medical electrical equipment

and medical electrical systems used in the home healthcare environment

Differences according to.....:	ANSI/AAMI HA60601-1-11:2011
Attachment Form No.....:	US_ND_ IEC60601_1_11B
Attachment Originator .....:	UL(US)
Master Attachment.....:	2015-02

	US NATIONAL DIFFERENCES		
4.2.1	Instructions for use state a more restricted range of environmental transport and storage conditions between uses.....:	No more restricted range	N/A
	Environmental conditions are marked on the carrying case, or	See above	N/A
	- Need for discretion precludes such marking	See above	N/A
	Compliance checked by inspection of the USABILITY ENGINEERING FILE	See above	N/A
4.2.2	Instructions for use state a more restricted range of environmental operating conditions.....:	No more restricted range	N/A
	Environmental conditions are marked on the carrying case	See above	N/A
	Need for discretion precludes such marking	See above	N/A
	Compliance checked by inspection of the USABILITY ENGINEERING FILE	See above	N/A
7.1	ME EQUIPMENT or ME SYSTEM is designed in accordance with:	See below	Pass
	- 7.1.1 of the general standard	See IEC 60601-1 test report	Pass
	- USABILITY ENGINEERING PROCESS	See usability engineering file	Pass
	Reference to ACCOMPANYING DOCUMENTS are minimized	Minimized	Pass

IEC60601_1_11B ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
	Compliance checked by inspection of the USABILITY ENGINEERING FILE	See usability engineering file	Pass
7.3.1	ACCOMPANYING DOCUMENTS indicate that the LAY OPERATOR, LAY RESPONSIBLE ORGANIZATION or RESPONSIBLE ORGANIZATION should contact the MANUFACTURER or the MANUFACTURER'S representative:	See below	Pass
	– for assistance, if needed, in setting up, using or maintaining the ME EQUIPMENT or ME SYSTEM; or		N/A
	– to report unexpected operation or events.	Provided in User manual	Pass
7.3.2	ACCOMPANYING DOCUMENTS include:	See below	Pass
	- Precautions to be taken in the event of changes in the performance of the ME EQUIPMENT or ME SYSTEM	Provided in User manual	Pass
	- Precautions to be taken regarding the exposure of the ME EQUIPMENT or ME SYSTEM to reasonably foreseeable environmental conditions	Provided in User manual	Pass
	ME EQUIPMENT or ME SYSTEM utilize medicinal substances	No such parts	N/A
	– information regarding any medicinal substances that the ME EQUIPMENT is designed to administer	See above	N/A
	– information on any medicinal substances or human blood derivatives incorporated into the ME EQUIPMENT or ACCESSORIES as an integral part	See above	N/A
	ME EQUIPMENT incorporate a measuring FUNCTION	No measuring function	N/A
	- The degree of accuracy is claimed	See above	N/A
7.4.1	The instructions for use shall address at least the issues of:	See below	Pass
	– strangulation due to cables and hoses, particularly due to excessive length.	Provided in User manual	Pass
	– small parts being inhaled or swallowed.	No such component	N/A
	– potential allergic reactions to accessible materials used in the ME EQUIPMENT.	Provided in User manual	Pass
	– contact injuries.	Provided in User manual	Pass
7.4.3	Instructions for use include effective diagrams, illustrations, or photographs	Provided in User manual	Pass

IEC60601_1_11B ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
	Compliance checked by inspection of instructions for use and the USABILITY ENGINEERING FILE	See usability engineering file	Pass
7.4.4	Instructions for use include effective diagrams, illustrations, or photographs	Provided in User manual	Pass
	Compliance checked by inspection of instructions for use and the USABILITY ENGINEERING FILE	See usability engineering file	Pass
8.4	Compliance checked by inspection, inspection of the USABILITY ENGINEERING FILE, functional testing and inspection of the RISK MANAGEMENT FILE	No life supporting ME equipment	N/A
9	Particular emphasis is placed on the limited training and capabilities of a LAY OPERATOR with respect to the ability to intervene and maintain BASIC SAFETY and ESSENTIAL PERFORMANCE		Pass
10.2	Compliance checked by inspection and inspection of the USABILITY ENGINEERING FILE	No internal electrical power source	N/A
12.3	Compliance checked by inspection of instructions for use and inspection of the USABILITY ENGINEERING FILE.		N/E

Test Report issued under the responsibility of:

CSA Group

TEST REPORT
IEC 62366
Medical devices – Application of usability engineering to medical devices

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Address ..... :	**N/A**
Applicant's name ..... :	**R&L Co., Ltd.**
Address ..... :	**11th Floor, B-line, ACE Gwang Myeong Tower, #1365, Soha-Dong, Gwangmyeong-Si, Gyeonggi-Do, Korea**
Test specification:	
Standards ..... :	IEC 62366: 2007 (First Edition) for use in conjunction with IEC 60601-1-6: 2010
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC62366B
Test Report Form Originator ..... :	TÜV Rheinland North America
Master TRF ..... :	Dated 2011-07

Test item description ..... :	Heating Mat
Trade Mark ..... :	R&L RICHWAY & LIFE CO.
Manufacturer ..... :	R&L Co., Ltd.
Model/Type reference ..... :	BIOMAT MINI
Ratings ..... :	120 V~; 60 Hz; 100 W

Testing procedure and testing location: N/A
☐ **CB Testing Laboratory:** **Testing location/ address ..... :** ☐ **Associated CB Test Laboratory:** **Testing location/ address ..... :** **Tested by (name + signature) .... :** **Approved by (+ signature)..... :**
☐ **Testing procedure: TMP** **Tested by (name + signature) ... :** **Approved by (+ signature)..... :** **Testing location/ address ..... :**
☐ **Testing procedure: WMT** **Tested by (name + signature) .... :** **Witnessed by (+ signature) ..... :** **Approved by (+ signature)..... :** **Testing location/ address ..... :**
☐ **Testing procedure: SMT** **Tested by (name + signature) ....:** **Approved by (+ signature).....:** **Supervised by (+ signature) .....:** **Testing location/ address ..... :**

List of Attachments (including a total number of pages in each attachment): None

Summary of testing:

- Operating environment specification of The BIOMAT MINI is following:
  - Ambient temperature range: 5 to 40 ºC
  - Relative humidity: 15 to 93 %
  - Altitude: 700 to 1 060 hPa

Tests performed (name of test and test clause):	**Testing location:**
Refer to appended tables	**DT&C Co., Ltd.** **42, Yurim-ro 154 beon-gil, Cheoin-gu, Yougin-si, Gyeonggi-do, Korea 449-935**

Summary of compliance with National Differences

List of countries addressed: N/A

☒ The product fulfils the requirements of CAN/CSA-IEC 62366.

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.
See IEC 60601-1 Test Report

Test item particulars ..... :	
Classification of installation and use ..... :	**See IEC 60601-1 Test Report**
Clinical application ..... :	**None**
Mode of operation ..... :	**Continuous**
Surface temperature of APPLIED PART ..... :	**Max. 70 ºC**
Possible test case verdicts:	
- test case does not apply to the test object ..... :	**N/A (Not applicable)**
- test object does meet the requirement ..... :	**P (Pass)**
- test object does not meet the requirement ..... :	**F (Fail)**
Testing:	
Date of receipt of test items ..... :	**January 25, 2015**
Date(s) of performance of tests ..... :	**January 25, 2015 – March 23, 2015**
Abbreviations used in the report:	
- normal condition ..... : N.C.	**- Single fault condition ..... : S.F.C.**
- means of Operator protection ..... : MOOP	**- Means of Patient protection ..... : MOPP**

General remarks:

"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report a point is used as the decimal separator.
The tests 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 testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

This Test Report contains the general safety requirements as related to the usability of Medical Electrical Equipment. It can only be used together with IEC 60601-1 Test Report and IEC 60601-1-6 Test Report.

Name and address of factory (ies) ..... : See IEC 60601-1 Test Report

General product information: See IEC 60601-1 Test Report

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
4	**PRINCIPLES**		**Pass**
4.1.1	**The MANUFACTURER has established, documented and maintains a USABILITY ENGINEERING PROCESS addressing USER interactions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENT**	Had established, documented and maintains for Usability Engineering Process	**Pass**
4.1.2	**The USABILITY ENGINEERING PROCESS complies with this standard and the acceptance criteria in the USABILITY VALIDATION plan have been met**	Complied with this standard and the acceptance criteria in the Usability Validation plan	**Pass**
4.1.3	**Information for SAFETY used as a RISK CONTROL measure has been evaluated according to the USABILITY ENGINEERING PROCESS**	Evaluated according to the Usability Engineering Process	**Pass**
4.2	**The results of the USABILITY ENGINEERING PROCESS are recorded in the USABILITY ENGINEERING FILE ... :**	Recorded in the Usability Engineering file	**Pass**
4.3	**The USABILITY ENGINEERING PROCESS is scaled-up or scaled-down based on the significance of the modification as determined by the results of the RISK ANALYSIS .....:**	Determined by the results of the Risk Analysis	**Pass**
5	**USABILITY ENGINEERING PROCESS**		**Pass**
5.1	**The application of the MEDICAL DEVICE is specified in the USABILITY ENGINEERING FILE .....:**	**Document Reference No. in USABILITY ENGINEERING FILE:** Cl. 5.1 of RN-USE-003 (Rev.0)	**Pass**
	– intended medical indication	See clause 5.1.1 of Usability Engineering File	**Pass**
	– intended PATIENT population	See clause 5.1.2 of Usability Engineering File	**Pass**
	-- intended part of the body or type of tissue applied to or interacted with	See clause 5.1.3 of Usability Engineering File	**Pass**
	– intended USER PROFILE	See clause 5.1.4 of Usability Engineering File	**Pass**
	– intended conditions of use	See clause 5.1.5 of Usability Engineering File	**Pass**
	– operating principle	See clause 5.1.6 of Usability Engineering File	**Pass**
5.2	**The frequently used functions that involve USER interaction with the MEDICAL DEVICE are recorded in the USABILITY ENGINEERING FILE .....:**	**Document Reference No. in USABILITY ENGINEERING FILE:** Cl. 5.2 of RN-USE-003 (Rev.0)	**Pass**

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
5.3.1	**The MANUFACTURER identified characteristics related to SAFETY that focus on USABILITY**	**See Table 5.3.1**	**Pass**
5.3.2	**The MANUFACTURER identified known or foreseeable HAZARDS related to USABILITY**	**See Table 5.3.2**	**Pass**
	Reasonably foreseeable sequences or combinations of events involving the USER INTERFACE that can result in a HAZARDOUS SITUATION associated with the MEDICAL DEVICE are identified	Refer to "Identification of known or foreseeable Hazards and Hazardous Situations Table" of Usability Engineering File	**Pass**
	The SEVERITY of the resulting possible HARM was determined	Refer to "Identification of known or foreseeable Hazards and Hazardous Situations Table" of Usability Engineering File	**Pass**
5.4	**The MANUFACTURER determined the PRIMARY OPERATING FUNCTIONS and recorded them in the USABILITY FILE**	**Document Reference No. in USABILITY ENGINEERING FILE:** Cl. 5.4 of RN-USE-003 (Rev.0)	**Pass**
	The inputs to the PRIMARY OPERATING FUNCTIONS included frequently used functions and functions related to SAFETY of the MEDICAL DEVICE	Refer to "Identification of known or foreseeable Hazards and Hazardous Situations Table" of Usability Engineering File	**Pass**
5.5	**The MANUFACTURER developed the USABILITY SPECIFICATION**	**See Table 5.5**	**Pass**
5.6	**The MANUFACTURER prepared a USABILITY VALIDATION plan**	**See Table 5.6**	**Pass**
5.7	**The MANUFACTURER designed and implemented the USER INTERFACE as described in the USABILITY SPECIFICATION .....:**	**See 5.8 and 5.9**	—
5.8	**The MANUFACTURER verified the implementation of the MEDICAL DEVICE USER INTERFACE design against the requirements of the USABILITY SPECIFICATION**	**Document Reference No. in USABILITY ENGINEERING FILE:** Cl. 5.8 of RN-USE-003 (Rev.0) Also refer to "Result Table for Primary Operating Functions"	**Pass**
5.9	**The MANUFACTURER VALIDATED USABILITY of the MEDICAL DEVICE according to the USABILITY VALIDATION plan**	**Document Reference No. in USABILITY ENGINEERING FILE:** Cl. 5.9 of RN-USE-003 (Rev.0) Also refer to "Result Table for Primary Operating Functions"	**Pass**
	If the acceptance criteria are not met and no further improvements are practicable, the medical benefits outweigh the risk	No such parts	**N/A**

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
6	**ACCOMPANYING DOCUMENT**		**Pass**
	If provided, the ACCOMPANYING DOCUMENT includes a summary of the application specification	Provided in User manual (Document No.: RN-USM-003)	**Pass**
	If provided, the ACCOMPANYING DOCUMENT includes a concise description of the ME EQUIPMENT, its operating principles and significant physical and performance characteristics, and intended USER PROFILE	**Reference to instructions for use User Manual**	**Pass**
	If provided, the ACCOMPANYING DOCUMENT is written at a level consistent with the USER PROFILE.	Written at a level consistent with the User Profile	**Pass**
	If the ACCOMPANYING DOCUMENT is provided electronically, the USABILITY ENGINEERING PROCESS included consideration of which information also needs to be provided as hard copy or as markings on the MEDICAL DEVICE	Provided hard copy	**N/A**
7	**Training and materials for training**		**Pass**
	When training is required for the safe and effective use of PRIMARY OPERATING FUNCTIONS, the ACCOMPANYING DOCUMENT describes the available training options	Provided in User manual (Document No.: RN-USM-003)	**Pass**
	When training is required, the INTENDED USE and USER PROFILE(S) are the basis for training and training material	Provided in User manual (Document No.: RN-USM-003)	**Pass**

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.3.1	**USABILITY ENGINEERING FILE RESULTS TABLE: Characteristics related to SAFETY**		**Pass**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
An identification of characteristics related to SAFETY that focused on USABILITY was performed according to ISO 14971:2007, Clause 4.2	Cl. 5.3.1 of RN-USE-003 (Rev.0)	Refer to "5.1 Application specification" and "5.2 Frequently used functions" in UEF (Performed according to ISO 14971:2007, 4.2)	**Pass**
During the identification of characteristics related to SAFETY, the following was considered:			—
– application specification, including USER PROFILE(S)	Cl. 5.1 of RN-USE-003 (Rev.0)	Refer to "5.1 Application specification" in UEF	**Pass**
– frequently used functions	Cl. 5.2 of RN-USE-003 (Rev.0)	Refer to "5.2 Frequently used functions" in UEF	**Pass**

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.3.2	**USABILITY ENGINEERING FILE RESULTS TABLE: Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS**		**Pass**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
Identification of known or foreseeable HAZARDS related to USABILITY according to ISO 14971:2007, Cl. 4.3	Cl. 5.3.2 of RN-USE-003 (Rev.0)	Refer to "Identification of known or foreseeable Hazards and Hazardous Situations Table" (Performed according to ISO 14971:2007, 4.3)	**Pass**
The identification of HAZARDS considers HAZARDS to PATIENTS, USERS and other persons	Cl. 5.3.2 of RN-USE-003 (Rev.0)	Refer to "Identification of known or foreseeable Hazards and Hazardous Situations Table"	**Pass**
Reasonably foreseeable sequences or combinations of events involving the user interface that can result in a HAZARDOUS SITUATION associated with the MEDICAL DEVICE are identified	Cl. 5.3.2 of RN-USE-003 (Rev.0)	Refer to "Identification of known or foreseeable Hazards and Hazardous Situations Table"	**Pass**
The SEVERITY of the resulting possible HARM was determined	Cl. 5.3.2 of RN-USE-003 (Rev.0)	Refer to "Identification of known or foreseeable Hazards and Hazardous Situations Table"	**Pass**
During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered:			—
– application specification, including USER PROFILE(S)	Cl. 5.3.2.1 of RN-USE-003 (Rev.0)	Refer to "5.1 Application specification" in UEF	**Pass**
– task related requirements	Cl. 5.3.2.2 of RN-USE-003 (Rev.0)	Refer to "5.3.2.2 Task related requirements" in UEF	**Pass**
– context of use	Cl. 5.3.2.3 of RN-USE-003 (Rev.0)	Refer to "5.3.2.3 Context of use" in UEF	**Pass**
– information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available	Cl. 5.3.2.3 of RN-USE-003 (Rev.0)	Sources: Literature, Complaint file, Sales force & Risk analysis Refer to "5.3.2.3 Information on Hazards and Hazardous Situations known for existing User Interfaces of Medical Devices of a similar type, if available" in UEF	**Pass**

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.3.2	**USABILITY ENGINEERING FILE RESULTS TABLE: Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS**		**Pass**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
– preliminary USE SCENARIOS	Cl. 5.3.2.4 of RN-USE-003 (Rev.0)	Refer to "5.3.2.4 Preliminary Use Scenarios" in UEF	**Pass**
– possible USE ERRORS	Cl. 5.3.2.5 of RN-USE-003 (Rev.0)	Refer to "5.3.2.5 Possible Use Errors" in UEF	**Pass**
– if an incorrect mental model of the operation of the MEDICAL DEVICE can cause a USE ERROR resulting in a HAZARDOUS SITUATION	Cl. 5.3.2.6 of RN-USE-003 (Rev.0)	Refer to "5.3.2.6 Incorrect mental model of the operation of the Medical Device" in UEF	**Pass**
– results of the review of the USER INTERFACE	Cl. 5.3.2.7 of RN-USE-003 (Rev.0)	Refer to "5.3.2.7 Results of the review of the User Interface" in UEF	**Pass**

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.5	**USABILITY ENGINEERING FILE RESULTS TABLE: USABILITY SPECIFICATION**		**Pass**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
USABILITY SPECIFICATION	Cl. 5.5 of RN-USE-003 (Rev.0)	Refer to "5.1 Application specification", "5.2 Frequently used functions" & "5.3 Identification of Hazards and Hazardous Situations related to usability" of this document and "Identification of known or foreseeable Hazards and Hazardous Situations Table".	**Pass**
The USABILITY SPECIFICATION provides:			—
– testable requirements for USABILITY VERIFICATION	Cl. 5.5 of RN-USE-003 (Rev.0)	Refer to "Result Table for Primary Operating Functions"	**Pass**
– testable requirements for USABILITY of PRIMARY OPERATING FUNCTIONS including criteria for determining the adequacy of RISK CONTROL achieved by the USABILITY ENGINEERING PROCESS.	Cl. 5.5 of RN-USE-003 (Rev.0)	Refer to "Result Table for Primary Operating Functions"	**Pass**
Inputs to the USABILITY SPECIFICATION include the following:			—
– application specification	Cl. 5.1 of RN-USE-003 (Rev.0)	Refer to "5.1 Application specification"	**Pass**
– PRIMARY OPERATING FUNCTIONS	Cl. 5.4 of RN-USE-003 (Rev.0)	Refer to "5.4 Primary Operating Functions"	**Pass**
– HAZARDS and HAZARDOUS SITUATIONS related to USABILITY	Cl. 5.3.2 of RN-USE-003 (Rev.0)	Refer to "Identification of known or foreseeable Hazards and Hazardous Situations Table"	**Pass**

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.5	**USABILITY ENGINEERING FILE RESULTS TABLE: USABILITY SPECIFICATION**		**Pass**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
– known or foreseeable USE ERRORS associated with the MEDICAL DEVICE	Cl. 5.3.2.3 of RN-USE-003 (Rev.0)	Refer to "5.3.2.3 Information on Hazards and Hazardous Situations known for existing User Interfaces of Medical Devices of a similar type, if available"	**Pass**
The USABILITY SPECIFICATION describes:			—
– USE SCENARIOS related to the PRIMARY OPERATING FUNCTIONS	Cl. 5.5 of RN-USE-003 (Rev.0)	Refer to "Result Table for Primary Operating Functions"	**Pass**
– frequent USE SCENARIOS	Cl. 5.5 of RN-USE-003 (Rev.0)	Refer to "Result Table for Primary Operating Functions"	**Pass**
– reasonably foreseeable worst case USE SCENARIOS	Cl. 5.5 of RN-USE-003 (Rev.0)	Refer to "Result Table for Primary Operating Functions"	**Pass**
– USER INTERFACE requirements for the PRIMARY OPERATING FUNCTIONS, including those to mitigate RISK	Cl. 5.6.2.1 of RN-USE-003 (Rev.0)	Refer to "5.6.2.1 User Interface design requirements"	**Pass**
– requirements for determining whether PRIMARY OPERATING FUNCTIONS are easily recognizable by the USER.	Cl. 5.6.2.1 of RN-USE-003 (Rev.0)	Refer to "5.6.2.1 User Interface design requirements"	**Pass**

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.6	**USABILITY ENGINEERING FILE RESULTS TABLE: USABILITY VALIDATION plan**		**Pass**
	Document Ref. in USABILITY ENGINEERING FILE	**Result - Remarks**	**Verdict**
USABILITY VALIDATION plan	Cl. 5.6 of RN-USE-003 (Rev.0)	Refer to "5.6 Usability Validation plan"	**Pass**
The USABILITY VALIDATION plan specifies:			—
– any method used for VALIDATION of the USABILITY of PRIMARY OPERATING FUNCTIONS	Cl. 5.6.1 of RN-USE-003 (Rev.0)	Refer to "5.6.1 Usability of the Primary Operating Functions"	**Pass**
– the criteria for determining successful VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS based on the USABILITY SPECIFICATION	Cl. 5.6.2 of RN-USE-003 (Rev.0)	Refer to "5.6.2 The Criteria for determining successful Validation of the Usability of the Primary Operating Functions"	**Pass**
– the involvement of representative intended USERS	Cl. 5.6.3 of RN-USE-003 (Rev.0)	Refer to "5.6.3 Representative intended Users"	**Pass**
The USABILITY VALIDATION plan addresses:			—
– frequent USE SCENARIOS	Cl. 5.5 of RN-USE-003 (Rev.0)	Refer to "Result Table for Primary Operating Functions"	**Pass**
– reasonably foreseeable worst case USE SCENARIOS identified in the USABILITY SPECIFICATION	Cl. 5.5 of RN-USE-003 (Rev.0)	Refer to "Result Table for Primary Operating Functions"	**Pass**