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文件名称(Document Name) : IEC60601-1(3rd edition) test report of SE-12 series

文件编号(Number) : ST-2086C-D0003

版本(Version) : 1.3

产品型号(Product Model) : SE-12 Express;SE-1200 Express;SE-1200;SE-12

项目编码(Project Code) : 2086C000

签批信息(Signature):

作者(Originator) : 明 镭 (minglei) 2021-04-15 17:53:19

审核人(Reviewers) : 兰 小燕 (lanxiaoyan) 2021-04-16 09:28:22

审核人(Reviewers) : 肖 文聪 (xiaowencong) 2021-04-16 09:00:48

批准人(Approvers) : 程 亮 (chengliang) 2021-04-16 09:39:04

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**IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 +
AM1:2012**

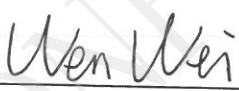

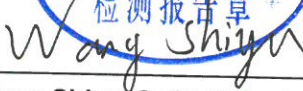
Report No. : TR2103090402

Product: ELECTROCARDIOGRAPH

Model: SE-12, SE-12 Express, SE-1200, SE-1200 Express

Prepared For: Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen P.R.China

Prepared By : Delta Technology Service (Shenzhen) Co., Ltd.
1-01, Building 1& 1-01 A-01, Building 3, No.15 Jinhui Rd., Kengzi Subdistrict, Pingshan District, Shenzhen, 518122, P.R.China

Operator: (+ signature)		2021.4.15
	Wen Wei, Engineer	
Reviewer: (+ signature)		2021.4.15
	Wang Shiyu, Sr.Staff Engineer	
Approver: (+ signature)		2021.4.15
	Wang Shiyu, Sr.Staff Engineer	

Comments

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TEST REPORT IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No.	TR2103090402
Total number of pages	147 pages
Testing Laboratory	Delta Technology Service (Shenzhen) Co., Ltd.
Address	1-01, Building 1& 1-01 A-01, Building 3, No.15 Jinhui Rd., Kengzi Subdistrict, Pingshan District, Shenzhen, 518122, P.R.China
Applicant's name	Edan Instruments, Inc.
Address	#15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, 518122 Shenzhen P.R.China
Manufacturer's name	Same as applicant
Address	Same as applicant
Factory's name	Same as applicant
Address	Same as applicant
Test specification:	
Standard	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure	N/A
Non-standard test method	None
Test Report Form Original No.	IEC60601_1J
Test Report Form(s) Originator	UL(US)
Master TRF	2014-07
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Test item description	ELECTROCARDIOGRAPH
Trade Mark	EDAN
Manufacturer	Same as applicant
Model/Type reference	SE-12, SE-12 Express, SE-1200, SE-1200 Express
Ratings	Input: 100-240V~, 50Hz/60Hz, 0.9A-0.4A

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

Attachment 1: Photos (14 pages)
Attachment 2: Accessories (2 pages)

Summary of testing

Tests performed (name of test and test clause):

Test report TR2103090402:
Clause 11.1 Excessive temperatures in ME EQUIPMENT

It is applicable for all tests but except situations as below:
Subclause 11.7 Biocompatibility, refer to ISO 10993,
Subclause 12.2 and 15.1 Usability, refer to IEC 60601-1-6
or IEC 62366;
Clause 17 EMC, refer to IEC 60601-1-2

Testing location:

1-01, Building 1& 1-01 A-01, Building 3, No.15
Jinhui Rd., Kengzi Subdistrict, Pingshan District,
Shenzhen, 518122, P.R.China

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.

EDAN ELECTROCARDIOGRAPH

Model: **SE-12 Express** YYYY-MM-DD

SN CCCC

Anti-electro-shock Type: **Class I**
100V-240V~ 50Hz/60Hz 0.9A-0.4A

EC REP Shanghai International Holding Corp. GmbH.
Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175 E-mail: shholding@hotmail.com

Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District,
Pingshan District, 518122 Shenzhen, P.R.China
Tel: +86-755-26898326 Fax: +86-755-26898330
[http:// www.edan.com.cn](http://www.edan.com.cn)

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(11)YYMMDD

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EDAN ELECTROCARDIOGRAPH

Model: **SE-1200 Express** YYYY-MM-DD

SN CCCC

Anti-electro-shock Type: **Class I**
100V-240V~ 50Hz/60Hz 0.9A-0.4A

EC REP Shanghai International Holding Corp. GmbH.
Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175 E-mail: shholding@hotmail.com

Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District,
Pingshan District, 518122 Shenzhen, P.R.China
Tel: +86-755-26898326 Fax: +86-755-26898330
[http:// www.edan.com.cn](http://www.edan.com.cn)

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Rx Only

EDAN ELECTROCARDIOGRAPH

Model: SE-1200

YYYY-MM-DD

SN



CCCC

Anti-electro-shock Type: Class I

100V-240V~ 50Hz/60Hz 0.9A-0.4A

EC REP

Shanghai International Holding Corp. GmbH.

Eiffestrasse 80, 20537 Hamburg, Germany

Tel: +49-40-2513175 E-mail: shholding@hotmail.com



Edan Instruments, Inc.

#15 Jinhui Road, Jinsha Community, Kengzi Sub-District,

Pingshan District, 518122 Shenzhen, P.R.China

Tel: +86-755-26898326 Fax: +86-755-26898330

http:// www.edan.com.cn



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EDAN ELECTROCARDIOGRAPH

Model: SE-12

YYYY-MM-DD

SN



CCCC

Anti-electro-shock Type: Class I

100V-240V~ 50Hz/60Hz 0.9A-0.4A

EC REP

Shanghai International Holding Corp. GmbH.

Eiffestrasse 80, 20537 Hamburg, Germany

Tel: +49-40-2513175 E-mail: shholding@hotmail.com



Edan Instruments, Inc.

#15 Jinhui Road, Jinsha Community, Kengzi Sub-District,

Pingshan District, 518122 Shenzhen, P.R.China

Tel: +86-755-26898326 Fax: +86-755-26898330

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GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use	Portable/Mobile
Device type (component/sub-assembly/ equipment/ system):	Equipment/System
Intended use (Including type of patient, application location) :	See section 1.1 in user manual (82-01.54.032423-3.2)
Mode of operation	Continuous
Supply connection	Mains supply/Internally powered
Accessories and detachable parts included.....	See attachment 2 in this report
Other options include	None
Testing	
Date of receipt of test item(s)	2021-03-09
Dates tests performed	2021-03-09 to 2021-04-06
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.
- means of Operator protection	MOOP
- single fault condition.....	S.F.C.
- 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.

General product information:

1. Intended use: See section 1.1 in user manual (82-01.54.032423-3.2).
2. The electrocardiograph has four models: SE-12, SE-12 Express, SE-1200 and SE-1200 Express. They have the same power module, main-board, ECG-board, bottom enclosure and the internal structure except screen. Specifically, SE-12 adopts 5.7 inch single colour, non-touch and turnover LCD screen; SE-12 Express adopts 12.1 inch multicolour, touch and turnover LCD screen, and with optional Wi-Fi module; SE-1200 adopts 5.7 inch single colour, non-touch and non-turnover LCD screen; SE-1200 Express adopts 8.0 inch multicolour, touch and non-turnover LCD screen, and with optional Wi-Fi module. Therefore, we choose the SE-12 Express to test.
3. This equipment can be supplied by mains and also can be internally powered with internal rechargeable li-ion battery.
4. SIP/SOP metal housing is supplied by SELV. Per manufacturer's declaration accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards.
5. Protection against electric shock of the applied part is classified as Type CF and defibrillation-proof applied parts.
6. The user manual mentioned in this report is 82-01.54.032423-3.2 SE-12 Series Electrocardiograph User Manual.
7. Accessories see attachment 2.

Test report TR2103090402:

Based on test report TR1603010201, this report have some updates as follow:

- a) Change part of the resistance on the power board;
- b) Refer to the latest Risk Management Report and user manual.

After the evaluation, additional testing was conducted as reported under Summary of testing. All clauses related to the user manual and management files were re-examined.

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

INSULATION DIAGRAM

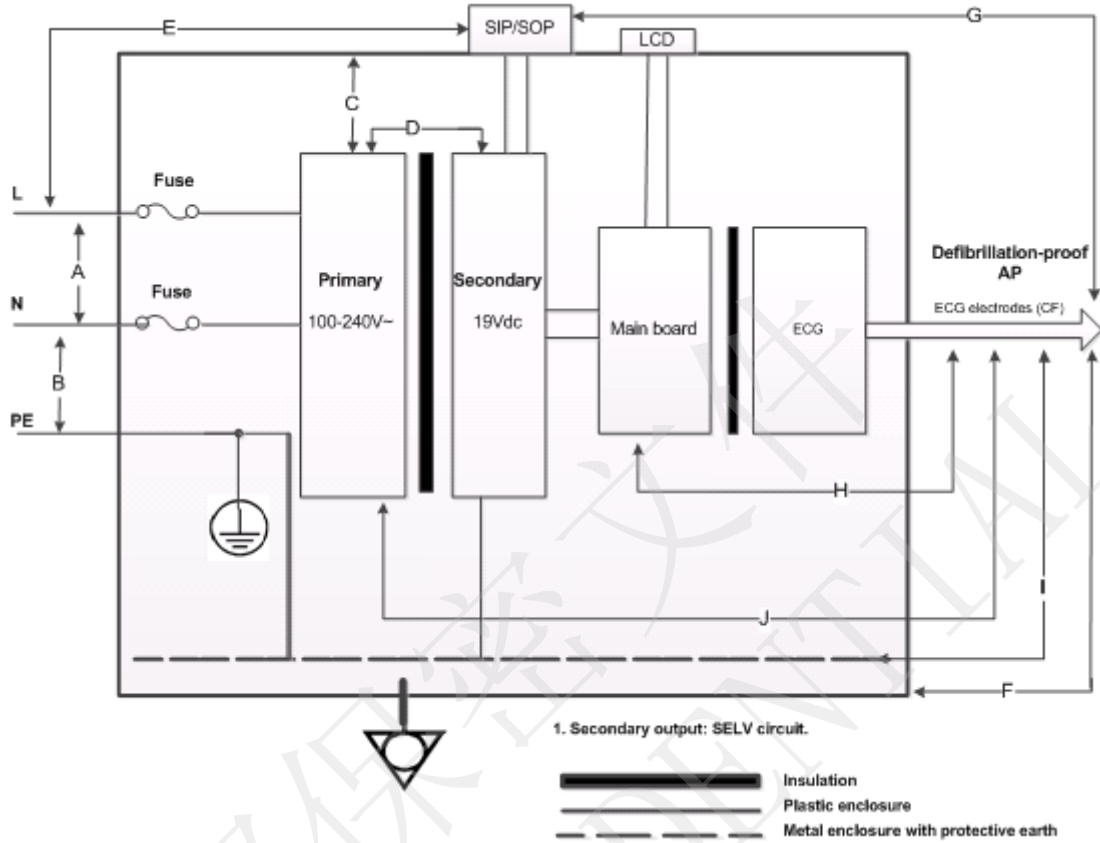


TABLE: INSULATION DIAGRAM									P
Pollution degree					2				—
Overvoltage category					II				—
Altitude.....					≤2000m				—
Additional details on parts considered as applied parts					<input type="checkbox"/> None <input checked="" type="checkbox"/> Areas _____ (See Clause 4.6 for details)				—
Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			V _{rms}	V _{pk}					
A	1MOOP	IIIb	240	340	2.4	2.0	11.50	11.50	Between L-N before fuse
B	1MOOP	IIIb	240	340	2.4	2.0	4.00	4.00	Mains part to PE
C	2MOOP	IIIb	240	340	4.8	4.0	8.00	7.40	Mains part to plastic enclosure
D	2MOOP	IIIb	392.9	513	7.9	4.4	8.00	8.00	Primary to secondary(via XL2,Y-cap and optocoupler)

IEC 60601-1									
Clause	Requirement + Test				Result - Remark				Verdict
E	2MOOP	IIIb	392.9	513	7.9	4.4	8.00	8.00	Mains part to SIP/SOP)
F	2MOPP	IIIb	19Vdc	--	4.0	4.0	5.12	5.12	AP to plastic enclosure
	1MOPP		240	340					
G	2MOPP	IIIb	19Vdc	--	4.0	4.0	5.70	5.70	AP to SIP/SOP
	1MOPP		240	340					
H	2MOPP	IIIb	19Vdc	--	4.0	4.0	5.70	5.70	AP to secondary
	1MOPP		240	340					
I	2MOPP	IIIb	19Vdc	--	4.0	4.0	5.70	5.70	AP to metal enclosure with PE
	1MOPP		240	340					
J	2MOPP	IIIb	240	340	8.0	5.0	Covered by area D+H		AP to mains part
Supplementary Information:									

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

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

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

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



IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4	GENERAL REQUIREMENTS		P
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		P
4.2	RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS		P
4.2.2	General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007)	See Appended RM Results Table 4.2.2.	P
4.2.3	Evaluating RISK		P
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level		P
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN	RISK MANAGEMENT PLAN Document: SE-12 Series Risk Management Plan-2.9 (JG-2082C-2-D0005).	P
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		P
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		P
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.		P
4.3	Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.		P
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.		P
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		P
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE.....	See Appended Table 4.3	P
	- RISK CONTROL measures implemented		P
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		P
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE	10 years.	P
4.5	Alternative RISK CONTROL methods utilized:	No alternative methods utilized.	N/A



IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No alternative methods utilized.	N/A
	Alternative means based scientific data or clinical opinion or comparative studies	No alternative methods utilized.	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..... :	Section 1.3 in SE-12 Series Risk Management Report-3.3	P
	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)	Section 1.3 and C.2.3 in section 3.1 of SE-12 Series Risk Management Report-3.3 (ISO 14971 Cl. 4.2) 1.3 in SE-12 Series Risk Analysis Table-3.3(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)	P
	Assessment identified the APPLIED PART TYPE requirements..... :	Type CF.	P
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2..... :	See below risk analysis reference.	P
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested..... : (ISO 14971 Cl. 4.2-4.4)	1.1.1 and 1.1.5 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4)	P
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically	See appended Table 13.2 for simulated physical test.	P
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified :	See appended table 8.10	P
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS	No exception.	N/A
	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)	No such risk.	N/A
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION... :		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Components determined to be acceptable where used as a MEANS OF PROTECTION		P
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following		P
	a) Applicable safety requirements of a relevant IEC or ISO standard		P
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		P
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately.....	See appended Table 8.10 b.	P
	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)	1.1.1 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	P
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:		P
4.10	Power supply		P
4.10.1	ME EQUIPMENT is suitable for connection to indicated power source (select applicable).....	Main supply and internal battery.	P
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:		P
	- 250 V for HAND-HELD ME EQUIPMENT (V).....	Not hand-held equipment.	N/A
	- 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V).....	100-240V~	P
	- 500 V for all other ME EQUIPMENT and ME SYSTEMS	See above.	N/A
4.11	Power input		P
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%.....	See appended Table 4.11	P
5	GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT		P
5.1	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods	No such case.	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 case.	N/A
5.3	Tests conducted within the environmental conditions specified in technical description		P
	Temperature (°C), Relative Humidity (%)	5°C to 40°C, 25%RH~80%RH	—
	Atmospheric Pressure (kPa)	86kPa~106kPa	—
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)	At the most unfavourable condition.	P
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz).....	Both 50Hz and 60Hz.	P
	c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current.....	At the most unfavourable condition.	P
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered.....	Not connected to d.c. supply.	N/A
	e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions.....	At the most unfavourable condition.	P
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	Not connected to a separate power supply.	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.....	Power cord and accessories detached.	P
	ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +32°C for indicated time	25°C, 95%RH, 48hrs	—
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		P
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS	Type CF.	P
5.9.2	ACCESSIBLE PARTS		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.9.2.1	Accessibility determined using standard test finger of Fig. 6	See Appended Table 5.9.2.	P
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s		P
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS :	No actuating mechanisms.	N/A
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL.....:	No actuating mechanisms.	N/A




6	CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS		P
6.2	CLASS I ME EQUIPMENT, externally powered		P
	CLASS II ME EQUIPMENT, externally powered	Not Class II equipment.	N/A
	INTERNALLY POWERED ME EQUIPMENT		P
	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	Class I equipment and internally powered equipment.	P
	TYPE B APPLIED PART	No such applied part.	N/A
	TYPE BF APPLIED PART	No such applied part.	N/A
	TYPE CF APPLIED PART		P
	DEFIBRILLATION-PROOF APPLIED PARTS		P
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529 :	Ordinary equipment.	P
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.	P
7	ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6..... :	See Appended Table 7.1.2	P
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE	See appended Tables 7.1.3 and 8.10	P
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		P
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings	See marking plate.	P
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS	See section 1.3 in user manual.	P
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT		P
	Single use item marked..... :	Disposable Electrodes.	P
7.2.2	ME EQUIPMENT marked with:		P
	– the name or trademark and contact information of the MANUFACTURER	See marking plate.	P
	– a MODEL OR TYPE REFERENCE	See marking plate.	P
	– a serial number or lot or batch identifier; and	See marking plate.	P
	– the date of manufacture or use by date	See marking plate.	P
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	Marked.	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)	Marked.	N/A
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and	Power cord and accessories inspection.	P
	– a MODEL OR TYPE REFERENCE		P
	Software forming part of a PEMS identified with a unique identifier..... :		P
7.2.3	Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS		P
	Safety sign 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted		P


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Clause	Requirement + Test	Result - Remark	Verdict
7.2.4	ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and	All accessories inspection.	P
	- with a MODEL or TYPE REFERENCE		P
	- a serial number or lot or batch identifier		P
	- the date of manufacture or use by date		P
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		P
7.2.5	ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following	Not intended to receive power from other equipment.	N/A
	- the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or	Not intended to receive power from other equipment.	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	Not intended to receive power from other equipment.	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.	Not intended to receive power from other equipment.	N/A
7.2.6	Connection to the Supply Mains		P
	Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point	100-240V~	P
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT	Not permanently installed equipment.	N/A
	- RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V).....:	100-240V~	P
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)....:	Single.	N/A
	- Nature of supply and type of current.....:	Single.	N/A
	Symbols 1-5, Table D.1 (used for same parameters.....:	~	P
	- RATED supply frequency or RATED frequency range in hertz.....:	50/60Hz	P
	- Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT	Class I equipment.	N/A
7.2.7	RATED input in amps or volt-amps, (A, VA)	0.9A-0.4A	P
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W)	Power factor not exceed 0.9.	N/A

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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).....:		P
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W)	More than 10%.	N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA).....:	No such parts.	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 part.	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	No such parts.	N/A
	Rated Voltage (V), Rated Current (A).....:	No such parts.	—
	Rated Power (W), Output Frequency (Hz)	No such parts.	—
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.....:	Ordinary equipment.	P
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols	See below.	P
	TYPE B APPLIED PARTS with symbol 19 of Table D.1	No such applied part.	N/A
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1	No such applied part.	N/A
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1		P
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1		P
	Proper symbol marked adjacent to or on connector for APPLIED PART	Adjacent to connector.	P
	Safety sign 2 of Table D.2 placed near relevant outlet.....:		P
	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 section 1.3 in user manual.	P

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Clause	Requirement + Test	Result - Remark	Verdict
7.2.11	ME EQUIPMENT suitable for CONTINUOUS OPERATION	Continuous operation.	P
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum “on” and “off” time	Continuous operation.	N/A
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder		P
	Fuse type.....	T3.15AH250V	—
	Voltage (V) and Current (A) rating	3.15A, 250V	—
	Operating speed (s) and Breaking capacity.....	T, H	—
7.2.13	Physiological effects – safety sign and warning statements	No such 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)	No such risk.	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 such parts.	N/A
7.2.15	Requirements for cooling provisions marked ...	No such requirements.	N/A
7.2.17	Packaging marked with special handling instructions for transport and/or storage.....		P
	Permissible environmental conditions marked on outside of packaging	-20°C to +55°C, 25%RH~93%RH, 70kPa~106kPa	P
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK		P
	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)	No such risk.	N/A
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization	No need sterilization.	N/A
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and	No such parts.	N/A
	- the RATED flow rate also marked	No such parts.	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 such protective means.	N/A
7.2.21	MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms.....:	29.8kg for MT-201 52.5Kg for MT-801	P
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		P
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W)	No heating elements or lamp-holders.	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	No heating elements or lamp-holders.	N/A
7.3.2	Symbol 24 of Table D.1, or safety sign No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts.....:	 on SMPS.	P
7.3.3	Type of battery and mode of insertion marked:		P
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL	 , on battery cover.	P
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK.....:	See section 1.2 in user manual.	P
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an unacceptable RISK if replaced incorrectly	1.1.4 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	P
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARD	See section 1.2 in user manual.	P
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified	Specification adjacent to component.	P
	Voltage (V) and Current (A) rating	T3.15AH250V	—
	Operating speed(s), size & breaking capacity .:	T, H	—
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made	Adjacent to protective earth terminal.	P
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.....:		P
	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)	Marked adjacent to terminals.	N/A
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	No such terminal.	N/A
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3	Not permanently installed.	N/A
	Marking for connection to a 3-phase supply, complies with IEC 60445	Not for connection to a 3-phase supply.	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		P
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 permanently installed.	N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made	Not permanently installed.	N/A
7.4	Marking of controls and instruments		P
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 such switch used.	N/A
	– indicated by an adjacent indicator light, or		P
	– indicated by other unambiguous means	No such switch used.	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 switch used.	N/A
	– status indicated by adjacent indicator light	No such switch used.	N/A
	– status indicated by other unambiguous means	No such switch used.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	The “on/off” positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or	No such switch used.	N/A
	– status indicated by adjacent indicator light	No such switch used.	N/A
	– status indicated by other unambiguous means	No such switch used.	N/A
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means		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)	No such risk.	N/A
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE :	No such part.	N/A
	– or an indication of direction in which magnitude of the function changes	No such part.	N/A
	Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009		P
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		P
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units		P
	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.	P
7.5	Safety signs		P
	Safety sign with established meaning used		P
	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)	1.2 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	P
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT		P
	Specified colours in ISO 3864-1 used for safety signs..... :		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		P
	Safety signs including any supplementary text or symbols described in instructions for use	See section 1.3 in user manual.	P
	- and in a language acceptable to the intended OPERATOR		P
7.6	Symbols		P
7.6.1	Meanings of symbols used for marking described in instructions for use	See section 1.3 in user manual.	P
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable		P
7.7	Colours of the insulation of conductors		P
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation	Green and yellow	P
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations	Green and yellow	P
7.7.3	Green and yellow insulation identify only following conductors:		P
	– PROTECTIVE EARTH CONDUCTORS		P
	– conductors specified in 7.7.2		P
	– POTENTIAL EQUALIZATION CONDUCTORS		P
	– FUNCTIONAL EARTH CONDUCTORS	No functional earth conductor.	N/A
7.7.4	Neutral conductors of POWER SUPPLY CORDS are “light blue”		P
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1		P
7.8	Indicator lights and controls		P
7.8.1	Red indicator lights used only for Warning	No red indicator lights used.	N/A
	Yellow indicator lights used only for Caution	No yellow indicator lights used.	N/A
	Green indicator lights used only for Ready for use	Indicates the power status only.	P
	Other colours: Meaning other than red, yellow, or green (colour, meaning)		P
7.8.2	Red used only for emergency control	No emergency control.	N/A
7.9	ACCOMPANYING DOCUMENTS		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.1	ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description		P
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		P
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to..... :	See last page in user manual.	P
	– MODEL or TYPE REFERENCE :	See first page of user manual.	P
	When ACCOMPANYING DOCUMENTS provided electronically, USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT	No provided electronically.	N/A
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	See section 1.1 in user manual.	P
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended		P
7.9.2	Instructions for use include the required information		P
7.9.2.1	– use of ME EQUIPMENT as intended by the MANUFACTURER:	See section 1.1 in user manual.	P
	– frequently used functions,	See chapter 4 in user manual.	P
	– known contraindication(s) to use of ME EQUIPMENT	See section 1.2.6 in user manual.	P
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient	See section 1.2 in user manual.	P
	– name or trademark and address of the MANUFACTURER	See last page in user manual.	P
	– MODEL OR TYPE REFERENCE		P
	Instruction for use included the following when the PATIENT is an intended OPERATOR:	Patient not as operator.	N/A
	– the PATIENT is an intended OPERATOR	Patient not as operator.	N/A
	– warning against servicing and maintenance while the ME EQUIPMENT is in use	Patient not as operator.	N/A
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and	Patient not as operator.	N/A
	–maintenance the PATIENT can perform	Patient not as operator.	N/A
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	See section 1.3 in user manual.	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Instructions for use are in a language acceptable to the intended operator		P
7.9.2.2	Instructions for use include all warning and safety notices	See section 1.2 in user manual.	P
	Warning statement for CLASS I ME EQUIPMENT included	See section 1.2 in user manual.	P
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	No such case.	N/A
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	See section 1.2 in user manual.	P
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	No such parts.	N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	No such parts.	N/A
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions	Not connection to a separate power supply.	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		P
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	1.1.4 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	P
	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..... :	See section 1.2 in user manual.	P
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided :	See section A1.4 in user manual.	P
	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 risk.	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	See chapter 3 in user manual.	P
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to		P

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Clause	Requirement + Test	Result - Remark	Verdict
	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	See section 1.2 in user manual.	P
	APPLIED PARTS specified	See chapter 3 in user manual.	P
7.9.2.6	Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation	See chapter 3 in user manual.	N/A
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device	See section 1.2 in user manual.	P
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation	See section 3.5 in user manual.	P
7.9.2.9	Information provided to operate ME EQUIPMENT	See chapter 4 in user manual.	P
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use		P
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	See chapter 12 in user manual.	P
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	See section 3.5 in user manual.	P
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	See chapter 14 in user manual.	P
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	See chapter 14 in user manual.	P
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	See chapter 14 in user manual.	P
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	See chapter 14 in user manual.	P
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	See chapter 14 in user manual.	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	See chapter 14 in user manual.	P
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	See chapter 15 in user manual.	P
	Other equipment providing power to ME SYSTEM sufficiently described	No such part.	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	See section 1.2 in user manual.	P
7.9.2.16	Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)		P
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 radiation.	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 need to be sterilized.	N/A
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization		N/A
7.9.2.19	The instructions for use contain a unique version identifier	Version 3.2.	P
7.9.3	Technical description		P
7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use	See chapter Appendix 1 in user manual.	P
	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	Technical description not separable from instructions.	N/A
	– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and	Technical description not separable from instructions.	N/A
	a unique version identifier	Technical description not separable from instructions.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description	Technical description not separable from instructions.	N/A
7.9.3.2	The technical description contains the following required information		P
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT..... :	Not permanently installed.	N/A
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and	Detachable power supply cord used.	N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	See chapter 14 in user manual.	P
	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)	No such risk.	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 section 1.2 in user manual.	P
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		P
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description		P
8	PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT		P
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL OR SINGLE FAULT CONDITIONS		P
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION : (ISO 14971 Cl. 4.3)	No such risk.	N/A
8.2	Requirements related to power sources		P
8.2.1	Connection to a separate power source		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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	Not connected to a separate power source.	N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified	Not connected to a separate power source.	N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined	Not connected to a separate power source.	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	Not connected to external d.c. power source.	N/A
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE	Not connected to external d.c. power source.	N/A
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset	Not connected to external d.c. power source.	N/A
8.3	Classification of APPLIED PARTS		P
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	Not designed for intracardiac use or direct cardiac application.	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	Type CF	P
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	See above.	N/A
8.4	Limitation of voltage, current or energy		P
8.4.2	ACCESSIBLE PARTS and APPLIED PARTS		P
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT :		P
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT..... :	See appended Table 8.7	P
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.) :	See appended Table 8.4.2	P
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J) :	See appended Table 8.4.2	P
	d) Voltage and energy limits specified in c) above also applied to the following:		P
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and		P
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL	No such opening.	N/A
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		P
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N	No pre-set control.	N/A
	Test repeated with a TOOL specified in instructions for use	No such tool specified in instruction for use.	N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE	No openings on top of enclosure.	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	No such parts.	N/A
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one sec after disconnecting the plug of ME EQUIPMENT or its parts (V)..... :	See appended Table 8.4.3	P
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC.. :	Not exceeded 60V	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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 parts.	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	No such parts.	N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description	No such parts.	N/A
8.5	Separation of parts		P
8.5.1	MEANS OF PROTECTION (MOP)		P
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4		P
	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		P
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		P
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		P
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test..... :	Complied.	P
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12	Complied.	P
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6	No such connections.	N/A
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION	As MOOP.	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. :	As MOOP.	N/A
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	Only one, as MOOP.	N/A
	Voltage_{Total Working} (V) and C_{Nominal} (μF)		—
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		P
	– dielectric strength test	See appended Table 8.8.3	P
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION	Complied with this standard.	N/A
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		P
	– limits of Tables 13 to 16 (inclusive); or		P
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION	Complied with this standard.	N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6		P
	– or with requirements and tests of IEC 60950-1 for protective earthing.....	Complied with this standard.	N/A
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION	Y1	N/A
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION	Complied.	P
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		P
	Voltage_{Total Working} (V) and C_{Nominal} (μF)	250Vac, 1000pF	—
	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		P
	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.....		P
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION		P
8.5.2	Separation of PATIENT CONNECTIONS		P
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		P
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		P

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Clause	Requirement + Test	Result - Remark	Verdict
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		P
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS :		P
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	Type CF and defibrillation-proof applied.	P
	LEAKAGE CURRENT tests conducted per 8.7.4 :	See appended Table 8.7	P
	Dielectric strength test conducted per 8.8.3.... :	See appended Table 8.8.3	P
	CREEPAGE and CLEARANCES measured :	Refer to insulation diagram.	P
	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		P
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 CF applied part.	N/A
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and	Type CF applied part.	N/A
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low	Type CF applied part.	N/A
	LEAKAGE CURRENT tests conducted per 8.7.4 :	Type CF applied part.	N/A
	Dielectric strength test conducted per 8.8.3.... :	Type CF applied part.	N/A
	Relevant CREEPAGE and CLEARANCES measured	Type CF applied part.	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)	Type CF applied part.	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		P
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT :		P

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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		P
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm	>0.5mm	P
	– 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		P
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,		P
	Test finger test (10 N) :	See appended Table 5.9.2	P
	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)	No such risk.	N/A
8.5.4	WORKING VOLTAGE		P
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V) :	240V~	P
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V)..... :	See Insulation Diagram and Insulation Table.	P
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V)..... :	See Insulation Diagram and Insulation Table.	P
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth		P
	– 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)..... :		P
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages		P

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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		P
8.5.5.1	Classification “DEFIBRILLATION-PROOF APPLIED PART” applied to one APPLIED PART in its entirety		P
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		P
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator :	See appended Table 8.5.5.1a	P
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS :	See appended Table 8.5.5.1b	P
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load..... :	See appended Table 8.5.5.2	P
8.6	Protective and functional earthing and potential equalization of ME EQUIPMENT		P
8.6.1	Requirements of 8.6.2 to 8.6.8 applied		P
	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	Complied with this standard.	N/A
8.6.2	PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR..... :	Appliance coupler	P
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL		P
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside..... :	No screws used.	N/A
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		P
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		P

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Clause	Requirement + Test	Result - Remark	Verdict
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part,	No such connections.	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)	No such connections.	N/A
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop..... :	See appended Table 8.6.4	P
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits :	Not exceeded values in 8.6.4 a).	N/A
8.6.5	Surface coatings		N/A
	Poorly conducting surface coatings on conductive elements removed at the point of contact	No such surface coatings.	N/A
	Coating not removed when requirements for impedance and current-carrying capacity met	No such surface coatings.	N/A
8.6.6	Plugs and sockets		P
	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		P
	- applied also where interchangeable parts are PROTECTIVELY EARTHED	No such parts.	N/A
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR		P
	- Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE		P
	-accidental disconnection avoided in NORMAL USE		P
	- Terminal allows conductor to be detached without a TOOL		P
	- Terminal not used for a PROTECTIVE EARTH CONNECTION		P
	- Terminal marked with symbol 8 of Table D.1		P
	- Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		P

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Clause	Requirement + Test	Result - Remark	Verdict
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		P
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION	No functional earth terminal.	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	Class I equipment.	N/A
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.	Class I equipment.	N/A
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS	Class I equipment.	N/A
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		P
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3..... :	See appended Tables 8.7	P
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7..... :	See appended Tables 8.7	P
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		P
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		P
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		P
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		P
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		P
8.7.3	Allowable Values		P

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Clause	Requirement + Test	Result - Remark	Verdict
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b. :	See appended Table 8.7	P
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz :	See appended Table 8.7	P
	c) TOUCH CURRENT did not exceed 100 μ A in NORMAL CONDITION and 500 μ A in SINGLE FAULT CONDITION (I_{TNC} , I_{TSFC})..... :	See appended Table 8.7	P
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC} , I_{ESFC}) :	See appended Table 8.7	P
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 :	Not permanently installed equipment.	N/A
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device :	See appended Table 8.7	P
	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 terminal.	N/A
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements :	See appended Table 8.7	P
8.8	Insulation		P
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing		P
	Insulation exempted from test (complies with clause 4.8)	Testing.	N/A
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	Complied with this standard.	N/A
8.8.2	Distance through solid insulation or use of thin sheet material		P
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		P
	a) 0.4 mm, min, distance through insulation, or		P

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Clause	Requirement + Test	Result - Remark	Verdict
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		P
	– at least two layers of material, each passed the appropriate dielectric strength test..... :	Three layers.	N/A
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test..... :	Three layers.	P
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION	See below.	N/A
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		P
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when	Complying with b) above.	P
	c) Wire with solid insulation, other than solvent based enamel, complying with a)	No such parts.	N/A
	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	No such parts.	N/A
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded	No such parts.	N/A
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded	No such parts.	N/A
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values	No such parts.	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..... :	By Teflon tube.	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Finished component complied with routine dielectric strength tests of 8.8.3..... :	See appended Table 8.8.3	P
	Tests of Annex L not repeated since material data sheets confirm compliance..... :	No need to test.	N/A
8.8.3	Dielectric Strength		P
	Solid insulating materials with a safety function withstood dielectric strength test voltages :	See appended Table 8.8.3	P
8.8.4	Insulation other than wire insulation		P
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE OF ME EQUIPMENT		P
	ME EQUIPMENT and design documentation examined..... :		P
	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)	No such risk.	N/A
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat..... :	No such part.	N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat..... :	Test conducted, see below	P
	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	P
	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)..... :		P
	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		P
8.8.4.2	Resistance to environmental stress		P
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9		P

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Clause	Requirement + Test	Result - Remark	Verdict
	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	No such parts.	N/A
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples	No such parts.	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	No such parts.	N/A
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		P
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive)	Complied.	P
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1		P
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 13.2	P
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 insulating compound used.	N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests	No such insulating compound used.	N/A
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage)	No such insulating compound used.	N/A
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur	No such insulating compound used.	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 insulating compound used.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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:	No such insulating compound used.	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 :	No such insulating compound used.	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	No such insulating compound used.	N/A
8.9.4	Minimum spacing of grooves transverses to the CREEPAGE DISTANCES considered a MEANS OF OPERATOR PROTECTION adjusted based on pollution degree	2	P
	Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES		P
8.10	Components and wiring		P
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely :		P
	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)	1.1.5 in SE-12 Series Risk Analysis Table -3.3 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	P
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment :	Insulating sleeving used.	P
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS		P
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 :		P
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		N/A
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION	No such control devices used.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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 such control devices used.	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	No such control devices used.	N/A
8.10.5	Mechanical protection of wiring		P
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges :	Internally wire, adequately protected.	P
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS		P
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..... :		P
	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 such parts.	N/A
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C :	Not exceed 70°C.	N/A
8.11	MAINS PARTS, components and layout		P
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles..... :	Mains plug See appended Table 8.10	P
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	Not permanently installed 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	Not permanently installed equipment.	N/A
	- the isolation device specified in the ACCOMPANYING DOCUMENTS	Not permanently installed equipment.	N/A
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description :	Mains plug See appended Table 8.10	P

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Clause	Requirement + Test	Result - Remark	Verdict
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV :	No supply mains switch used.	N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	No supply mains switch used.	N/A
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447	No supply mains switch used.	N/A
	f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH :	Appliance coupler used. See appended Table 8.10	P
	g) A fuse or a semiconductor device not used as an isolating means		P
	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		P
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering	No such parts.	N/A
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage	No such parts.	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	No such parts.	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 used.	N/A
8.11.3	POWER SUPPLY CORDS		P
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD	Only one.	P
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design 53)... :	See appended Table 8.10	P

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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 :	Not exceed 75°C.	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..... :	See appended Table 8.10	P
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6..... :	See appended Table 8.10	P
8.11.3.5	Cord anchorage		N/A
	a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage	No cord anchorage used.	N/A
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or	No cord anchorage used.	N/A
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or	No cord anchorage used.	N/A
	– metal provided with an insulating lining affixed to cord anchorage	No cord anchorage used.	N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation	No cord anchorage used.	N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components	No such parts.	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 such parts.	N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR	No cord anchorage used.	N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 :	No cord anchorage used. No testing required.	N/A
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests	No cord anchorage used. No testing required.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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	No cord anchorage used. No testing required.	N/A
	CREEPAGE and CLEARANCES not reduced below limits in 8.9	No cord anchorage used. No testing required.	N/A
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged	No cord anchorage used. No testing required.	N/A
8.11.3.6	POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment	No such parts used.	N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or	No testing required.	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 D² gram attached to the free end of cord (g) :	No testing required.	N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance	No testing required.	N/A
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D..... :	No testing required.	N/A
8.11.4	MAINS TERMINAL DEVICES		N/A
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection	Not permanently installed equipment.	N/A
	Terminals alone are not used to keep conductors in position	No such terminals.	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	No such terminals.	N/A
	Screws and nuts clamping external conductors do not serve to secure any other component	No such screws and nuts.	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	No such terminals.	N/A
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL	No such terminals.	N/A



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Clause	Requirement + Test	Result - Remark	Verdict
	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	No such terminals.	N/A
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced after fastening and loosening a conductor of largest cross-sectional area 10 times	No such terminals.	N/A
8.11.4.4	Terminals with clamping means for a rewirable 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 terminals.	N/A
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewirable POWER SUPPLY CORD to allow for connection of conductors	No such part.	N/A
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test	No such part.	N/A
8.11.5	Mains fuses and OVER-CURRENT RELEASES		P
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection . . :	Fuse provided in each supply lead. See appended Table 8.10	P
	- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT :	Class I equipment.	N/A
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	Not permanently installed equipment.	N/A
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART	Fuses used.	N/A
	Protective devices have adequate breaking capacity to interrupt the max. fault current :	See appended Table 8.10	P
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		P
	Justification for omission of fuses or OVER-CURRENT RELEASES documented :	Fuses used.	N/A
8.11.6	Internal wiring of the MAINS PART		P
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable :	See appended Table 8.10	P

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient..... :	See appended Table 8.10	P
9	PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS		P
9.2	HAZARDS associated with moving parts		N/A
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level	No moving parts.	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)	No moving parts.	N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and	No moving parts.	N/A
	RISK CONTROLS implemented	No moving parts.	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)	No moving parts.	N/A
	All RISKS associated with moving parts have been reduced to an acceptable level	No moving parts.	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 trapping zone.	N/A
	– Gaps in Clause 9.2.2.2, or	No trapping zone.	N/A
	– Safe distances in Clause 9.2.2.3, or	No trapping zone.	N/A
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or	No trapping zone.	N/A
	– Continuous activation in Clause 9.2.2.5	No trapping zone.	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	No trapping zone.	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 trapping zone.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008 :	No trapping zone.	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 trapping zone.	N/A
9.2.2.4.2	FIXED GUARDS held in place by systems that can only be dismantled with a TOOL	No such parts.	N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open	No such 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,	No such parts.	N/A
	– absence or failure of one of their components prevents starting, and stops moving parts	No such parts.	N/A
	Movable GUARDS complied with any applicable tests	No such parts.	N/A
9.2.2.4.4	Other RISK CONTROL designed and incorporated into to the control system stops movement and	No such parts.	N/A
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or	No such parts.	N/A
	ME EQUIPMENT is SINGLE FAULT SAFE	No such parts.	N/A
9.2.2.5	Continuous activation		N/A
	Continuous activation used as a RISK CONTROL, complies with the following	No such parts.	N/A
	a) movement was in OPERATOR'S field of view	No such parts.	N/A
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR	No such parts.	N/A
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or	No such parts.	N/A
	- the continuous activation system is SINGLE FAULT SAFE	No such parts.	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 such parts.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK	No such parts.	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 such parts.	N/A
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or	No such parts.	N/A
	- activation does not result in an unacceptable RISK	No such parts.	N/A
9.2.3.2	Over travel past range limits of the ME EQUIPMENT prevented	No such parts.	N/A
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse.....	No such parts.	N/A
9.2.4	Emergency stopping devices		N/A
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power	No emergency stopping devices.	N/A
	a) Emergency stopping device reduced RISK to an acceptable level	No emergency stopping devices.	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)	No emergency stopping devices.	N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM	No emergency stopping devices.	N/A
	c) Emergency stopping device actuator was readily accessible to OPERATOR	No emergency stopping devices.	N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT	No emergency stopping devices.	N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD	No emergency stopping devices.	N/A
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like	No emergency stopping devices.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	g) Means for stopping of movements operate as a result of one single action	No emergency stopping devices.	N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls	No emergency stopping devices.	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"	No emergency stopping devices.	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	No emergency stopping devices.	N/A
	k) Emergency stopping device is suitable for its application	No emergency stopping devices.	N/A
9.2.5	Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping	No such parts.	N/A
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented	No such parts.	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	No such parts.	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	No such parts.	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)	No such risk.	N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered	No rough surface, sharp corners and edges.	P
9.4	Instability HAZARDS		P
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		P
9.4.2	Instability – overbalance		P
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	P

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Clause	Requirement + Test	Result - Remark	Verdict
9.4.2.2	Instability excluding transport		P
	ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE, ...:	See appended Table 9.4.2.2	P
	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		P
	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	See below.	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	The symbol'  " on the trolley	P
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)	See above.	N/A
	b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping	See below.	N/A
	ME EQUIPMENT or its parts, for use on the floor or on a table, where RISK of overbalancing exists, permanently marked with the RISK warning.....:		P
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b).....:	See above.	N/A
9.4.2.4	Castors and wheels		P
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		P
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT did not exceed 200 N	See appended Table 9.4.2.4.2	P
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold	See appended Table 9.4.2.4.3	P
9.4.3	Instability from unwanted lateral movement (including sliding)		P
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 power-driven mobile equipment.	N/A
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements		P
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1	See appended Table 9.4.3.1	P
9.4.3.2	Instability excluding transport		P

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Clause	Requirement + Test	Result - Remark	Verdict
	a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test	See appended Table 9.4.3.2	P
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test	See appended Table 9.4.3.2	P
9.4.4	Grips and other handling devices		P
	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	Not exceed 20kg.	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	PORTABLE ME EQUIPMENT.	N/A
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying	Not exceed 20kg.	N/A
	c) Carrying handles and grips and their means of attachment withstood loading test	See appended Table 9.4.4	P
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 such risk.	N/A
	All identified RISKS associated with expelled parts mitigated to an acceptable level	No such risk.	N/A
9.5.2	Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965	No cathode ray tube used.	N/A
9.6	Acoustic energy (including infra- and ultrasound) and vibration		P
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and		P
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity	No such risk.	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)	No such risk.	N/A
	All identified RISKS mitigated to an acceptable level	No such risk.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.6.2	Acoustic energy		P
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE		P
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA).....:	68.8dBA	—
	- 83 dBA (when halving the cumulative exposure time) (dBA).....:	--	—
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB).....:	70.6dBC	—
9.6.2.2	RISK MANAGEMENT FILE examined.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No infrasound and ultrasound energy.	N/A
9.6.3	Hand-transmitted vibration		N/A
	Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values	No hand-transmitted vibration.	N/A
	– 2.5 m/s ² for a cumulative time of 8 h during a 24 h period (m/s ²)	No hand-transmitted vibration.	N/A
	– Accelerations for different times, inversely proportional to square root of time (m/s ²).....:	No hand-transmitted vibration.	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 such risk.	N/A
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum	No such risk.	N/A
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure	No such risk.	N/A
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects	No such risk.	N/A
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply	No such risk.	N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible	No such means.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity	No such parts.	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 part with pressure.	N/A
	a) RATED maximum supply pressure from an external source	No part with pressure.	N/A
	b) Pressure setting of a pressure-relief device provided as part of assembly	No part with pressure.	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	No part with pressure.	N/A
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 part with pressure.	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 such 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 such part.	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 part.	N/A
	a) Connected as close as possible to pressure vessel or parts of system it is to protect	No such part.	N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair	No such part.	N/A
	c) Could be adjusted or rendered inoperative without a TOOL	No such part.	N/A
	d) With discharge opening located and directed as to not to release material towards any person	No such part.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK	No such part.	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	No such part.	N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect	No such part.	N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)	No such part.	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)	No such risk.	N/A
9.8	HAZARDS associated with support systems		P
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK ...:		P
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		P
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		P
	– 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)	1.2.1 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	P
	– 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		P
	– 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		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		P
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		P
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing...:		P
	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)	1.2.1 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	P
	All identified RISKS are mitigated to an acceptable level		P
	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.....:	In equilibrium.	P
	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 such support 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)	No such support systems.	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	No such support systems.	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	No such support systems.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications	No such support systems.	N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS	No such support systems.	N/A
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS	No such support systems.	N/A
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance	No such support systems.	N/A
9.8.3.2	a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m² on a foot rest temporarily supporting a standing PATIENT or OPERATOR	No such support systems.	N/A
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests	No such support systems.	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 support systems.	N/A
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test	No such support systems.	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 such support 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	No MECHANICAL PROTECTIVE DEVICES.	N/A
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7	No MECHANICAL PROTECTIVE DEVICES.	N/A
	– Activated before travel produced an unacceptable RISK	No MECHANICAL PROTECTIVE DEVICES.	N/A
	– Takes into account Clauses 9.2.5 and 9.8.4.3	No MECHANICAL PROTECTIVE DEVICES.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests	No MECHANICAL PROTECTIVE DEVICES.	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	No MECHANICAL PROTECTIVE DEVICES.	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	No MECHANICAL PROTECTIVE DEVICES.	N/A
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.	No MECHANICAL PROTECTIVE DEVICES.	N/A
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE	No MECHANICAL PROTECTIVE DEVICES.	N/A
	– Compliance confirmed by examination and following test	No MECHANICAL PROTECTIVE DEVICES.	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	No MECHANICAL PROTECTIVE DEVICES.	N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR	No MECHANICAL PROTECTIVE DEVICES.	N/A
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function	No MECHANICAL PROTECTIVE DEVICES.	N/A
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		P
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES	Row 1, B.	P
	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)	No such support systems.	N/A
10	PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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 X-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	Not has permanent proximity to patient.	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	Not producing X-radiation.	N/A
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE..... (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risk.	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	No such risk.	N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		
10.3	The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m ²	No microwave radiation.	N/A
	Microwave radiation is propagated intentionally	No microwave radiation.	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.		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	No such risk.	N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		
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	No such risk.	N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		
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	No such risk.	N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		
11	PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS		P

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

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Clause	Requirement + Test	Result - Remark	Verdict
	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)	No such risk.	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)	Conducted test.	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)	No such risk.	N/A
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risk.	N/A
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE..... :	No thermal regulatory devices.	N/A
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	No such parts.	N/A
11.2	Fire prevention		P
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3		P
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		N/A
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of :	Not used in conjunction with oxygen rich environments.	N/A
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions	Not used in conjunction with oxygen rich environments.	N/A
	1) when temperature of material raised to its ignition temperature	Not used in conjunction with oxygen rich environments.	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	Not used in conjunction with oxygen rich environments.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating	Not used in conjunction with oxygen rich environments.	N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton	Not used in conjunction with oxygen rich environments.	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	Not used in conjunction with oxygen rich environments.	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)	Not used in conjunction with oxygen rich environments.	N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively :	Not used in conjunction with oxygen rich environments.	N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three..... :	Not used in conjunction with oxygen rich environments.	N/A
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Not used in conjunction with oxygen rich environments.	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..... :	Not used in conjunction with oxygen rich environments.	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 (%)..... :	Not used in conjunction with oxygen rich environments.	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	Not used in conjunction with oxygen rich environments.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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..... :	Not used in conjunction with oxygen rich environments.	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 :	Not used in conjunction with oxygen rich environments.	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 conjunction with oxygen rich environments.	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 conjunction with oxygen rich environments.	N/A
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques	Not used in conjunction with oxygen rich environments.	N/A
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means	Not used in conjunction with oxygen rich environments.	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 conjunction with oxygen rich environments.	N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3)..... :	Not used in conjunction with oxygen rich environments.	N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) :	Not used in conjunction with oxygen rich environments.	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) :	Not used in conjunction with oxygen rich environments.	N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas..... :	Not used in conjunction with oxygen rich environments.	N/A
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT		P
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2..... :		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Constructional requirements were met, or		P
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risk.	N/A
	Justification, when requirement not met :	Meet.	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	P
	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 :		P
	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:		P
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh $\leq 2 \times 2$ mm centre to centre and wire diameter of at least 0.45 mm	No openings.	P
	2) No openings on the sides within the area included within the inclined line C in Fig 39	No openings.	P
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials :		P
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics		N/A
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G	Not 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		P

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Clause	Requirement + Test	Result - Remark	Verdict
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	P
11.6.2	Overflow in ME EQUIPMENT	No reservoir or liquid storage used.	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 reservoir or liquid storage used.	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.	No reservoir or liquid storage used.	N/A
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.	No reservoir or liquid storage used.	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 need handling liquids.	N/A
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill :	No need handling liquids.	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.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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.. :	Ordinary equipment.	N/A
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS		P
	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	P
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER :		P
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)	Not intended to be sterilized.	N/A
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)	1.3.2 in SE-12 Series Risk Analysis Table-3.3(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	P
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented		P
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		P
12	ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS		P
12.1	RISKS associated with accuracy of controls and instruments stated.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	1.4 in SE-12 Series Risk Analysis Table-3.3(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	P
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING.....:	Refer to IEC 60601-1-6 or IEC 62366 test reports.	P
12.3	MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8.:	No alarm system.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
12.4	Protection against hazardous output		N/A
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such part.	N/A
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)	No such risk.	N/A
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risk.	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)	1.4 in SE-12 Series Risk Analysis Table-3.3(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	P
12.4.5	Diagnostic or therapeutic radiation		N/A
12.4.5.1	Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation	Not such equipment.	N/A
	Radiation safety ensured by compliance with requirements of appropriate standards	Not such equipment.	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 produce X-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 risk.	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 risk.	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 risk.	N/A
13	HAZARDOUS SITUATIONS AND FAULT CONDITIONS		P
13.1	Specific HAZARDOUS SITUATIONS		P
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature		P
	- Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		P

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Clause	Requirement + Test	Result - Remark	Verdict
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		P
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24..... :		P
	– 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.	P
	–Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C were not exceeded	See appended Table 11.1.1.	P
	Limits for windings in Tables 26, 27, and 31 not exceeded		P
	Table 22 not exceeded in all other cases		P
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		P
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed..... :	See appended Table 8.7	P
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS did not exceed..... :	See appended Table 8.7	P
13.2	SINGLE FAULT CONDITIONS		P
13.2.1	During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination		P
	ME EQUIPMENT complied with 13.2.2 -13.2.12 :	See appended Table 13.2	P
	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 risk.	N/A
	RISK MANAGEMENT FILE defines the appropriate test conditions..... :	See above.	P
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		P
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		P

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Clause	Requirement + Test	Result - Remark	Verdict
	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).		P
13.2.13.2	ME EQUIPMENT with heating elements		N/A
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	No heating elements.	N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests	No heating elements.	N/A
	a 3) other ME EQUIPMENT with heating elements met test	No heating elements.	N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively	No heating elements.	N/A
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration	No heating elements.	N/A
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part	No heating elements.	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	No heating elements.	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)	No heating elements.	N/A
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY	No heating elements.	N/A
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted	No heating elements.	N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION	No heating elements.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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	No heating elements.	N/A
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS	No heating elements.	N/A
	2) When more than one control provided, they were disabled in turn	No heating elements.	N/A
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time	No heating elements.	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 motor.	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	No such part.	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	No heating elements.	N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT	No motor.	N/A
	b) Motor met running overload protection test of this clause when:	No such motors.	N/A
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or	No such motors.	N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended	No such motors.	N/A
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C)..... :	No such motors.	N/A
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps	No such motors.	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	No such motors.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Test not conducted where electronic drive circuits maintained a substantially constant drive current	No such motors.	N/A
	Test not conducted based on other justifications (justification)..... :	No such motors.	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 such 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 operating.	N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle	Continuous operating.	N/A
	Motor winding temperatures did not exceed values in 13.2.10 :	Continuous operating.	N/A
	Insulation Class :	Continuous operating.	—
	Maximum temperature measured (°C)..... :	Continuous operating.	—
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)		P
14.1	Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE, or		P
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK..... :	See below.	P
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 4.2-4.4, 5)	1.4 in SE-12 Series Risk Analysis Table-3.3(ISO 14971 Cl. 4.2-4.4, 5)	P
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK		P
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304..... :	Class B	P
	Software development process applied according to Clause 5 of IEC 62304..... :	Refer to JG-2082C-D0192 (1.0) SE Series Project WBS Schedule.	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Software development process for Software risk management applied according to Clause 7 of IEC 62304 :	Refer to JG-2082C-D0018 (3.3) SE-12 Risk Management Report, JG-2082-0-2-SWE-SP024 (1.1) SE-12 Software Architecture Design Chart, parts of "OTS Software" in chapter 15.	P
	Software development process Configuration Management applied according to Clause 8 of IEC 62304 :	The product is managed by Edan's WIKF25-software configuration management procedure and WIKF28-VSS software configuration management procedure. Refer to 2082C (SE-12) VSS Configuration Library Information Table of SE-12. Refer to SVN Catalog and Limits of Authority Set-up Table of SE-12.	P
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304..... :	Refer to chapter 11 "Unresolved Anomalies" in <JG-2406C-D0044(2.1)SE Series Software Validation Report>	P
14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process :	JG-2082C-D0018(3.3) SE-12 Risk Management Report	P
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan	Refer to chapter 11 "Unresolved Anomalies" in <SE-12 Software Validation Report>	P
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented		P
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	Refer to JG-2082-0-5-SC223 (1.0) SE-12 9G45 Project WBS Schedule.	P
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	Refer to JG-2082-0-1-SP014 (1.0) Software Requirements Specification of SE-12.	P
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules	Refer to JG-2082-0-5-SC223 (1.0) SE-12 9G45 Project WBS Schedule.	P
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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	Refer to JG-2082-0-1-SP014 (1.0) Software Requirements Specification of SE-12.	P
14.6	RISK MANAGEMENT PROCESS		P
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..... :		P
	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)	1.4 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.3)	P
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 :		P
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure.....: (ISO 14971 Cl. 6.1)	1.4 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 6.1)	P
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)	1.4 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 6.3)	P
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems : (ISO 14971 Cl. 6.3)	1.4 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 6.3)	P
14.9	Design is broken up into sub systems and descriptive data on design environment documented :		P
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)	1.4 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 6.3)	P
	- milestone(s) when VERIFICATION is to be performed for each function		P

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Clause	Requirement + Test	Result - Remark	Verdict
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		P
	– selection and utilization of VERIFICATION tools		P
	– coverage criteria for VERIFICATION		P
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented		P
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE		P
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented	Refer to JG-2082-0-2-SWE-SP024 (1.1) Software Architecture Design Chart of SE-12.	P
	The person with overall responsibility for PEMS VALIDATION is independent	Refer to JG-2082C-D0018 (3.3) SE-12 Risk Management Report	P
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 6.3)	1.4 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 6.3)	P
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE		P
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304		P
	Software Process for Software changes applied according to Clause 5 of IEC 62304.....		P
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304.....		P
	Configuration management of software changes applied per Clause 8 of IEC 62304		P
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304		P
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		P
	a) Purpose of the PEMS connection to an IT-NETWORK		P
	b) required characteristics of the IT-NETWORK		P

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Clause	Requirement + Test	Result - Remark	Verdict
	c) required configuration of the IT-NETWORK		P
	d) technical specifications of the network connection, including security specifications		P
	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		P
	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)	1.4 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)	P
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		P
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties		P
	– Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS		P
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis		P
	- Changes to the IT-NETWORK include: <ul style="list-style-type: none"> - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment 		P
15	CONSTRUCTION OF ME EQUIPMENT		P
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS..... :	Refer to IEC 60601-1-6 or IEC 62366 test reports.	P
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		P
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		P
15.3	Mechanical strength		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.3.1	Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		P
15.3.2	Push test conducted :	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.3	Impact test conducted..... :	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.4	Drop test		P
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested :	See Appended Table 15.3	P
	No unacceptable RISK resulted		P
15.3.4.2	Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test..... :	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.5	MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests..... :	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P
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		P
	Mould-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C :		P
	No damage resulting in an unacceptable RISK		P
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT		P

IEC 60601-1			
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		P
15.4	ME EQUIPMENT components and general assembly		P
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists,..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	1.5.1 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)	P
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions,..... :	Can't connect to outlets on the same equipment.	P
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection :	No such connections.	N/A
15.4.2	Temperature and overload control devices		N/A
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)	No thermal cut-outs and over-current releases with automatic resetting used.	N/A
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT	No thermal cur-outs with a safety function used.	N/A
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided : (ISO 14971 Cl. 4.2-4.4)	No such risk.	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)	No such risk.	N/A
	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:	No such parts.	N/A
	- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17	No such parts.	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	- ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13	No such parts.	N/A
	- SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards.....	No such parts.	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	No such parts.	N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards	No such parts.	N/A
	manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times	No such parts.	N/A
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted	No such parts.	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 such parts.	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		P
15.4.3.1	Battery housings provided with ventilation.... : (ISO 14971 Cl. 4.2-4.4)	1.1.4 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4)	P
	Battery compartments designed to prevent accidental short circuiting	The battery socket is different from others, so wrong plugging is avoided.	P
15.4.3.2	Means provided to prevent incorrect connection of polarity	See below	P
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries..... : (ISO 14971 Cl. 4.2-4.4)	1.1.4 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4)	P

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Clause	Requirement + Test	Result - Remark	Verdict
15.4.3.3	Overcharging of battery prevented by virtue of design	See below	P
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries (ISO 14971 Cl. 4.2-4.4)	1.1.4 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4)	P
15.4.3.4	Primary lithium batteries comply with IEC 80086-4		N/A
	Secondary lithium batteries comply with IEC 62133	See appended Table 8.10.	P
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire	Protective device used.	P
	Protective device has adequate breaking capacity		P
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented	Protective device used.	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		P
	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	Battery protected when short circuit.	P
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for		P
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,	Not exceed 15s.	N/A
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational	No 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 such risk.	N/A
	Requirement not applied to heated stylus-pens for recording purposes	No such parts.	N/A
	Indicator lights provided on ME EQUIPMENT to indicate an output exists	No such parts.	N/A
	Colours of indicator lights complied with 7.8.1		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Charging mode visibly indicated		P
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		N/A
15.4.6.1	a) Actuating parts cannot be pulled off or loosened during NORMAL USE	No such parts.	N/A
	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 such parts.	N/A
	Tests conducted with no unacceptable RISK . :	No such parts.	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	No such parts.	N/A
	No unexpected change of the controlled parameter when tested..... :	No such parts.	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 such control devices.	N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position	No such control devices.	N/A
15.4.7.3	a) Foot-operated control device is at least rated IPX1	No such control devices.	N/A
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6.... :	No such control devices.	N/A
15.4.8	Aluminium wires less than 16 mm² in cross-sectional area are not used		P
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed	No oil container.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport	No oil container.	N/A
	A pressure-release device operating during NORMAL USE is provided	No oil container.	N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage	No oil container.	N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements	No oil container.	N/A
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		P
15.5.1	Overheating		P
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating..... :	See appended Tables 15.5.1.2 and 15.5.1.3	P
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		P
	Dielectric strength test conducted after short circuit and overload tests :		P
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved :	See appended Table 15.5.1.2	P
	Short circuit applied directly across output windings		P
15.5.1.3	Multiple overload tests conducted on windings :	See appended Table 15.5.1.3	P
15.5.2	Transformers operating at a frequency above 1kHz tested according to clause 8.8.3..... :		P
	Transformer windings provided with adequate insulation	Not such transformer.	N/A
	Dielectric strength tests were conducted :	No such transformer.	N/A
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with :	See appended Table 8.10	P
	- Means provided to prevent displacement of end turns	4 mm wide margin tape and Teflon is provided. see transformer spec.	P
	- protective earth screens with a single turn have insulated overlap	No protective earthed screen.	N/A
	- Exit of wires form internal windings of toroid transformers protected with double sleeving	No toroidal transformer.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- insulation between primary and secondary windings complies with 8.8.2	Recognized insulation tape suitable for double/reinforced insulation. See 8.8.2 in this report.	P
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4		P

16	ME SYSTEMS		P
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK		P
	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)	1.1.1 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4)	P
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered		P
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard		P
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards		P
	– tests performed in NORMAL CONDITION, except as specified		P
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM		P
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated		P
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR		P
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards	External printer complied with IEC 60950-1.	P
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM		P
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM		P
	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		P

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Clause	Requirement + Test	Result - Remark	Verdict
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM		P
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER		P
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER		P
	c) the required information is provided:		P
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM		P
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard		P
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM		P
	– additional safety measures to be applied during installation of ME SYSTEM	Not ME systems.	P
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT	Not ME systems.	P
	– additional measures to be applied during preventive maintenance	Not ME systems.	P
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor	Not ME systems.	P
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM	Not ME systems.	P
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM	Not ME systems.	P
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(s) used with ME SYSTEM	No MSO provided by manufacture.	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	No MSO provided by manufacture.	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		P

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Clause	Requirement + Test	Result - Remark	Verdict
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET		P
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage		P
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT		P
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:		P
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES		P
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard		P
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	Intended to receive its power from mains supply.	N/A
	Transient currents restricted to allowable levels for the specified IPS or UPS	No IPS or UPS used.	N/A
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified	No IPS or UPS used.	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)	There is no non-ME equipment in patient environment.	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 such part.	N/A
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION	No such part.	N/A
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V).....	No such part.	N/A
16.6	LEAKAGE CURRENTS		P
16.6.1	TOUCH CURRENT in NORMAL CONDITION did not exceed 100 μA.....	See appended Table 16.6.1	P

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Clause	Requirement + Test	Result - Remark	Verdict
	TOUCH CURRENT did not exceed 500 μA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR :	See appended Table 16.6.1	P
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA :	No MSO provided.	N/A
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values :	See appended Tables 8.7 8.7.4.7 and 16.6.1	P
16.7	ME SYSTEM complied with applicable requirements of Clause 9..... :	External printer complied with IEC60950-1.	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		P
16.9	ME SYSTEM connections and wiring		P
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result :		P
	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)	1.1.1 in SE-12 Series Risk Analysis Table-3.3 (ISO 14971 Cl. 4.2-4.4)	P
	– 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	Patient cables connector has an only electrical construction, so no such hazards.	P
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable	No gas connections.	N/A
16.9.2	MAINS PARTS, components and layout		P
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or	No MSO used.	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	No MSO used.	N/A
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer	No MSO used.	N/A
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 visible in NORMAL USE, and	No MSO used.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or	No MSO used.	N/A
	– marked to indicate the equipment or equipment parts it may safely be attached to	No MSO used.	N/A
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT	No MSO used.	N/A
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:	No MSO used.	N/A
	– CREEPAGE and CLEARANCES complied with 8.9	No MSO used.	N/A
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets	No MSO used.	N/A
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:	No MSO used.	N/A
	– ENCLOSURE complied with 8.4.2 d)	No MSO used.	N/A
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable	No MSO used.	N/A
	– RATINGS of components are not in conflict with conditions of use	No MSO used.	N/A
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL	No MSO used.	N/A
	– POWER SUPPLY CORD complied with 8.11.3	No MSO used.	N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:	No MSO used.	N/A
	– Separating transformer complied with this standard or IEC 61558-2-1,	No MSO used.	N/A
	– Separating transformer is CLASS I	No MSO used.	N/A
	– Degree of protection against ingress of water specified as in IEC 60529	No MSO used.	N/A
	– Separating transformer assembly marked according to 7.2 and 7.3	No MSO used.	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	No MSO used.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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	Not share mains connection.	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		P
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL	No additional protective earth conductors provided.	N/A
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage		P

17	ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS		P
	RISKS associated confirmed by review	See below remark.	P
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS	See Appendix 2 in user manual.	P
	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)	1.1.2 in SE-12 Series Risk Analysis Table-3.3(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)	P
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems	See IEC 60601-1-2 test report.	P

ANNEX G	PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES		N/A
G.2	Locations and basic requirements		N/A
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5	Not such equipment.	N/A
G.2.2	FLAMMABLE AESTHETIC MIXTURE WITH	Not use with such gas.	N/A
G.2.3	A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE	Not use with such gas.	N/A
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5	Not use with such gas.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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	Not use with such gas.	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	Not use with such gas.	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)..... :	Not such equipment.	N/A
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case	Not such equipment.	N/A
	When above marking not possible, relevant information included in instructions for use ... :	Not such equipment.	N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3	Not such equipment.	N/A
G.3.2	CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle "AP" (symbol 22 in Table D.1)..... :	Not such equipment.	N/A
	Marking is as large as possible for the particular case	Not such equipment.	N/A
	When above marking not possible, the relevant information included in instructions for use ... :	Not such equipment.	N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3	Not such equipment.	N/A
G.3.3	The marking placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts	Not such equipment.	N/A
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts	Not such equipment.	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	Not such equipment.	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	Not such equipment.	N/A
	b) Connections protected against accidental disconnection	Not such equipment.	N/A
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD,	Not such equipment.	N/A
G.4.2	Construction details		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL	Not such equipment.	N/A
	b) ENCLOSURE complies with :	Not such equipment.	N/A
	– no openings on top covers of ENCLOSURE,	Not such equipment.	N/A
	– openings in side-covers prevented penetration of a solid cylindrical test rod	Not such equipment.	N/A
	– openings in base plates prevented penetration of a solid cylindrical test	Not such equipment.	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	Not such equipment.	N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures	Not such equipment.	N/A
	– Use of antistatic materials with a limited electrical resistance :	Not such equipment.	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	Not such equipment.	N/A
	b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882 :	Not such equipment.	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	Not such equipment.	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	Not such equipment.	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 :	Not such equipment.	N/A
G.5.2	Temperature limits..... :	Not such equipment.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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:	Not such equipment.	N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1..... :	Not such equipment.	N/A
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ... :	Not such equipment.	N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 :	Not such equipment.	N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24 V$ as in Fig G.3 :	Not such equipment.	N/A
	– Combinations of currents and corresponding voltages within the limitations $I_{zR} \cdot U_{zR} \leq 50 W$ extrapolated from Fig G.1	Not such equipment.	N/A
	No extrapolation made for voltages above 42 V	Not such equipment.	N/A
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2 mJ$ extrapolated from Fig G.2	Not such equipment.	N/A
	No extrapolation made for voltages above 242V	Not such equipment.	N/A
	U_{max} determined using actual resistance R	Not such equipment.	N/A
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3 mJ$ extrapolated from Fig G.3	Not such equipment.	N/A
	No extrapolation made for inductances larger than 900 mH	Not such equipment.	N/A
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open	Not such equipment.	N/A
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed	Not such equipment.	N/A
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks	Not such equipment.	N/A
	– Peak value considered when a.c. supplied	Not such equipment.	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... :	Not such equipment.	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 .. :	Not such equipment.	N/A
	Alternatively, compliance was verified by examination of design data:	Not such equipment.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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:	Not such equipment.	N/A
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR removed by ventilation before EQUIPMENT energized,	Not such equipment.	N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa)..... :	Not such equipment.	N/A
	Overpressure maintained at the site of potential ignition	Not such equipment.	N/A
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE	Not such equipment.	N/A
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present	Not such equipment.	N/A
	c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa)	Not such equipment.	N/A
	d) External surface of ENCLOSURE did not exceed 150 °C in 25 °C	Not such equipment.	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:	Not such equipment.	N/A
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing	Not such equipment.	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 :	Not such equipment.	N/A
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained	Not such equipment.	N/A
	Cords are fitted with adequate anchorages to limit stresses as determined by test	Not such equipment.	N/A
	Overpressure not reduced below 200 Pa	Not such equipment.	N/A
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)	Not such equipment.	N/A
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C)	Not such equipment.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Steady state operating temperature of ENCLOSURE also measured (°C) :	Not such equipment.	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	Not such equipment.	N/A
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test	Not such equipment.	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..... :	Not such equipment.	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..... :	Not such equipment.	N/A
	a) no sparks produced and temperatures did not exceed 90 °C, or	Not such equipment.	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:	Not such equipment.	N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 :	Not such equipment.	N/A
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5... :	Not such equipment.	N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 :	Not such equipment.	N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24 V$ as in Fig G.6 :	Not such equipment.	N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated	Not such equipment.	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	Not such equipment.	N/A
	– I_{max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10	Not such equipment.	N/A
	– C_{max} and L_{max} are values occurring in relevant circuit	Not such equipment.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω	Not such equipment.	N/A
	– Peak value considered when a.c. supplied	Not such equipment.	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	Not such equipment.	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	Not such equipment.	N/A
	- requirement not applied to transformers complying with this standard	Not such equipment.	N/A
	- requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture	Not such equipment.	N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or	Not such equipment.	N/A
	Temperature measurements made in accordance with 11.1..... :	Not such equipment.	N/A
	- or U_{max} , I_{max} , R, L_{max} and C_{max} determined together with application of Figs G.4-G.6	Not such equipment.	N/A
	Alternatively, compliance verified by comparison with design data	Not such equipment.	N/A
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1..... :	Not such equipment.	N/A
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE	Not such equipment.	N/A
G.7	Test apparatus for flammable mixtures according to this Clause and Fig G.7	Not such equipment.	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	No need to test.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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	No need to test.	N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap	No need to test.	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	No need to test.	N/A
	Temperature (°C)..... :	No need to test.	—
	Humidity (%)..... :	No need to test.	—
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:	No need to test.	N/A
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	No need to test.	N/A
	– 6000 V for REINFORCED INSULATION (V) :	No need to test.	N/A
L.3.2	Flexibility and adherence		N/A
	Sample subjected to flexibility and adherence	No need to test.	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	No need to test.	N/A
	Test voltage was at least the voltage in Tables 6 and 7 but not less than the following:	No need to test.	N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	No need to test.	N/A
	– 3000 V for REINFORCED INSULATION (V) :	No need to test.	N/A
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa :	No need to test.	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	No need to test.	N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	No need to test.	N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	No need to test.	N/A
	– 3000 V for REINFORCED INSULATION (V) :	No need to test.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Oven temperature based on Table L.2 (°C)..... :	No need to test.	—
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm²)..... :	No need to test.	N/A
	Dielectric strength test conducted at room temperature after removal from the oven	No need to test.	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	No need to test.	N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	No need to test.	N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	No need to test.	N/A
	– 3000 V for REINFORCED INSULATION (V)..... :	No need to test.	N/A
	Test voltage applied between the shot and conductor	No need to test.	N/A
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm²)..... :	No need to test.	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..... :	No need to test.	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:	No need to test.	N/A
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V)..... :	No need to test.	N/A
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V)..... :	No need to test.	N/A
L.4.3	Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1)..... :	No need to test.	N/A
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:	No need to test.	N/A
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION..... :	No need to test.	N/A
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION..... :	No need to test.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT		P	
Clause of ISO 14971	Document Ref. in RMF (Document No. paragraph/clause, version)		Result - Remarks	Verdict
	General process	Particular Medical Device		
3.1	SE-12 Series Risk Management Plan-2.9(JG-2082C-2-D0005), chapter 3	—	Risk management process	P
3.2	SE-12 Series Risk Management Plan-2.9(JG-2082C-2-D0005), chapter 2	—	Allocation of responsibility	P
3.2	SE-12 Series Risk Management Plan-2.9(JG-2082C-2-D0005), chapter 4.1	—	Assignment of qualified personnel	P
3.2	SE-12 Series Risk Management Plan-2.9 (JG-2082C-2-D0005), chapter 5	—	Criteria for Risk Acceptability	P
3.3	—	SE-12 Series Risk Management Plan-2.9(JG-2082C-2-D0005), chapter 4.1	Qualification of personnel	P
3.4a	—	SE-12 Series Risk Management Plan-2.9(JG-2082C-2-D0005), chapter 1	Scope	P
3.4b	—	SE-12 Series Risk Management Plan-2.9(JG-2082C-2-D0005), chapter 2	Assignment of responsibilities and authorities	P
3.4c	—	SE-12 Series Risk Management Plan-2.9(JG-2082C-2-D0005), chapter 4.2	Requirements for Reviewing Risk Management Activities	P
3.4d	—	SE-12 Series Risk Management Plan-2.9(JG-2082C-2-D0005), chapter 5	Criteria for Risk Acceptability	P
3.4e	—	SE-12 Series Risk Management Plan-2.9(JG-2082C-2-D0005), chapter 7	Verification	P
3.5	—	SE-12 Series Risk Management Plan-2.9(JG-2082C-2-D0005), chapter 3	Established and maintain a risk management file	P

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Clause	Requirement + Test	Result - Remark	Verdict	
4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT		P	
Clause of ISO 14971	Document Ref. in RMF (Document No. paragraph/clause, version)		Result - Remarks	Verdict
	General process	Particular Medical Device		
4.1	—	SE-12 Series Risk Management Report-3.3 (JG-2082C-D0018), chapter 1, 2 and 3	Risk analysis process	P
4.2	—	SE-12 Series Risk Management Report-3.3(JG-2082C-D0018), chapter 1.4 and 3.1	Intended use and Hazard Identification	P
4.3	—	SE-12 Series Risk Analysis Table-3.3	Identification of hazards	P
4.4	—	SE-12 Series Risk Analysis Table-3.3	Estimation of the risk for each hazardous situation	P
5	—	SE-12 Series Risk Analysis Table-3.3	Risk evaluation	P
6.2	—	SE-12 Series Risk Analysis Table-3.3	Risk control option analysis	P
6.3	—	SE-12 Series Risk Analysis Table-3.3	Implementation of risk control measure	P
6.4	—	SE-12 Series Risk Analysis Table-3.3	Residual risk evaluation	P
6.5	—	N/A	N/A	N/A
6.6a	—	--	No news hazards or hazards situations introduced	P
6.6b	—	--	None are affected by the introduction of the risk control measures	P
6.7	—	SE-12 Series Risk Management Report-3.3 (JG-2082C-D0018), chapter 3	All identified hazardous situations have been considered and keep on file	P
7	—	SE-12 Series Risk Management Report-3.3(JG-2082C-D0018), chapter 4	Acceptance criteria for overall residual risk	P
8	—	SE-12 Series Risk Management Report-3.3 (JG-2082C-D0018) SE-12 Series Risk Management Plan-2.9 (JG-2082C-2-D0005)	Risk management plan and risk management report are kept on file	P
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		P
List of ESSENTIAL PERFORMANCE functions	MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)	Remarks	
Section 1.5	SE-12 Series Risk Management Report-3.3 (JG-2082C-D0018)	P	
Supplementary Information:			
ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.			

4.11	TABLE: Power Input					P
Operating Conditions / Ratings	Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Power factor (cos φ)	
USB load to 0.5A, beat volume and luminance set to the max. ECG: 180bpm, 1mv. Gain:10mm/mV, Printing speed:25mm/s Printing and empty battery charging.	90	50	0.830	46.7	--	
	90	60	0.807	45.8	--	
	100	50	0.708	44.5	--	
	100	60	0.706	44.4	--	
	240	50	0.358	45.3	--	
	240	60	0.349	45.6	--	
	264	50	0.322	44.8	--	
	264	60	0.315	44.1	--	
Supplementary Information:						

5.9.2	TABLE: Determination of ACCESSIBLE parts		P
Location	Determination method (NOTE1)	Comments	
Enclosure	Visual inspection	Evaluated in clause 8 of this standard.	
Screen	Visual inspection	Ditto	
All openings in side and bottom	Visual; rigid test finger; jointed test finger; test hook.	Ditto	
Supplementary information:			
NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.			

7.1.2	TABLE: Legibility of Marking		P
Markings tested	Ambient Illuminance (lx)	Remarks	
Outside Markings (Clause 7.2)	240	Clearly legibility	
Inside Markings (Clause 7.3)	240	Clearly legibility	
Controls & Instruments (Clause 7.4)	240	Clearly legibility	
Safety Signs (Clause 7.5).....	240	Clearly legibility	

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Clause	Requirement + Test	Result - Remark	Verdict

7.1.2	TABLE: Legibility of Marking		P
Symbols (Clause 7.6)		240	Clearly legibility
Supplementary information:			
Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR or if not defined at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.			

7.1.3	TABLE: Durability of marking test		P
Characteristics of the Marking Label tested:			Remarks
Material of Marking Label	Polyester label	Clearly legibility	
Ink/other printing material or process	Ink	Clearly legibility	
Material (composition) of Warning Label	Ink	Clearly legibility	
Ink/other printing material or process	Ink	Clearly legibility	
Other	--	--	
Marking Label Tested:			Remarks
Identification & Rating markings: Label, trademark, model, silk print(key, applied part connector, SIP/SOP, equipotential grounding, fuse-holder, appliance inlet)			Clearly legibility
Markings of applied part: marking plate			Clearly legibility
Marking of battery: marking plate			Clearly legibility
Markings of trolley: safety signs and warning statement			Clearly legibility
Supplementary information:			
Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96%, and then for 15 s with a cloth rag soaked with isopropyl alcohol.			

8.4.2	TABLE: TABLE: Working Voltage / Power Measurement		P			
Test supply voltage/frequency (V/Hz)¹			240/50			
Location From/To	Measured values					Remarks
	Vrms	Vpk or Vdc	Peak-to-peak ripple²	Power W/VA	Energy (J)	
19V output	--	19.41Vdc	0.13%(25mV)	--	--	No loading
19V output	--	18.95Vdc	0.69%(130mV)	103.5W (Max.)	--	Normal
19V output	--	0	--	--	--	U2 Pin1-Pin2 SC
19V output	--	18.98Vdc	0.74%(114mV)	103.4W (Max.)	--	U1 Pin1-Pin 2 SC
19V output	--	19.13Vdc	0.13%	--	--	No loading ,U1 Pin1-Pin 2 SC
12V output	--	--	--	96.681W (Max.)	--	Normal
12V output	--	--	--	94.513W (Max.)	--	R3 SC
5V output	--	--	--	27.748W (Max.)	--	Normal

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Clause	Requirement + Test	Result - Remark	Verdict

8.4.2	TABLE: TABLE: Working Voltage / Power Measurement	P
Supplementary Information:		
1, The input supply voltage to the ME EQUIPMENT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value, See clause 8,5,4,		
2, If the d,c peak-to-peak ripple >10%, waveform considered as a,c, See clause 8,4,2,2		

8.4.3	TABLE: ME EQUIPMENT for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply	P								
Maximum allowable voltage (V)		60 V								
Voltage measured (V)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
Plug pins 1 and 2	12.5	10	11.25	22.5	23.75	11.25	22.5	12.5	21.25	22.5
Plug pin 1 and plug earth pin	11.5	12.5	6.25	0	11.25	7.5	10	20	10	22.5
Plug pin 2 and plug earth pin	0	0	0	0	0	0	0	0	0	0
Plug pin 1 and enclosure	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and enclosure	--	--	--	--	--	--	--	--	--	--
Maximum allowable stored charge when measured voltage exceeded 60 v (μc)		45								
Calculated stored charge (μc)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
Plug pins 1 and 2	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and enclosure	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and enclosure	--	--	--	--	--	--	--	--	--	--
Supplementary information:										

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

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Clause	Requirement + Test	Result - Remark	Verdict

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Supplementary information:

8.5.5.1a	TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies					P
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
				Mains supply	Battery	
Figs. 9	Enclosure	ECG	+/-	10/10	20/10	--
	Metal board	ECG	+/-	10/20	10/10	
	SIP/SOP(include applied parts)	ECG	+/-	10/10	10/10	
Figs. 10	Enclosure	R to others electrodes	+/-	10/10	10/10	--
	Metal board	R to others electrodes	+/-	20/10	20/20	
	SIP/SOP(include applied parts)	R to others electrodes	+/-	20/20	10/20	
	Enclosure	L to others electrodes	+/-	10/0	10/10	
	Metal board	L to others electrodes	+/-	10/20	10/10	
	SIP/SOP(include applied parts)	L to others electrodes	+/-	0/10	10/10	
	Enclosure	F to others electrodes	+/-	10/10	10/20	
	Metal board	F to others electrodes	+/-	20/10	20/10	
	SIP/SOP(include applied parts)	F to others electrodes	+/-	10/20	20/20	
	Enclosure	N to others electrodes	+/-	0/0	20/20	
	Metal board	N to others electrodes	+/-	10/10	20/0	
	SIP/SOP(include applied parts)	N to others electrodes	+/-	10/10	10/10	
	Enclosure	C1 to others electrodes	+/-	10/10	10/10	
	Metal board	C1 to others electrodes	+/-	10/0	10/10	
	SIP/SOP(include applied parts)	C1 to others electrodes	+/-	10/10	10/0	
	Enclosure	C2 to others electrodes	+/-	20/20	10/10	
	Metal board	C2 to others electrodes	+/-	10/10	10/10	
	SIP/SOP(include applied parts)	C2 to others electrodes	+/-	10/20	20/20	
Enclosure	C3 to others electrodes	+/-	10/20	30/10		
Metal board	C3 to others electrodes	+/-	10/10	10/10		

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Clause	Requirement + Test			Result - Remark		Verdict
	SIP/SOP(include applied parts)	C3 to others electrodes	+/-	20/20	10/0	
	Enclosure	C4 to others electrodes	+/-	20/10	10/10	
	Metal board	C4 to others electrodes	+/-	0/10	10/10	
	SIP/SOP(include applied parts)	C4 to others electrodes	+/-	10/10	10/10	
	Enclosure	C5 to others electrodes	+/-	10/10	10/10	
	Metal board	C5 to others electrodes	+/-	20/0	10/10	
	SIP/SOP(include applied parts)	C5 to others electrodes	+/-	10/10	10/10	
	Enclosure	C6 to others electrodes	+/-	10/10	10/10	
	Metal board	C6 to others electrodes	+/-	10/10	20/20	
	SIP/SOP(include applied parts)	C6 to others electrodes	+/-	20/20	10/10	
Supplementary information:						

8.5.5.1b	TABLE: defibrillation-proof applied parts – verification of recovery time				P
Applied part with test voltage	Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)		Remarks
			Mains supply	Battery	
All applied parts	+/-	5	0/0	0/0	--
R-others	+/-	5	2.60/2.59	2.61/2.60	--
L-others	+/-	5	2.61/2.61	2.61/2.60	--
N-others	+/-	5	0/0.02	0/0.02	--
F-others	+/-	5	2.51/2.59	2.59/2.60	--
V1-others	+/-	5	2.61/2.61	2.52/2.60	--
V2-others	+/-	5	2.52/2.71	2.71/2.60	--
V3-others	+/-	5	2.50/2.60	2.52/2.60	--
V4-others	+/-	5	2.69/2.60	2.69/2.70	--
V5-others	+/-	5	2.70/2.50	2.61/2.61	--
V6-others	+/-	5	2.70/2.60	2.60/2.53	--
Supplementary information:					

8.5.5.2	TABLE: DEFIBRILLATION-PROOF APPLIED PARTS OR PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load			P
Test Voltage applied to	Measured Energy E1 (J)	Measured Energy E2 (J)	Energy E1 as % of E2	

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Clause	Requirement + Test	Result - Remark	Verdict
L- All Others (+/-)	371.55/398.18	378.67/406.69	98.12/97.90
R- All Others (+/-)	368.28/397.05	378.67/406.69	97.25/97.62
F- All Others (+/-)	368.28/395.36	378.67/406.69	97.25/97.21
N- All Others (+/-)	369.37/397.62	378.67/406.69	97.54/97.76
V1- All Others (+/-)	267.21/395.92	378.67/406.69	96.97/97.35
V2- All Others (+/-)	369.37/394.81	378.67/406.69	97.54/97.07
V3- All Others (+/-)	366.12/395.37	378.67/406.69	96.68/97.22
V4- All Others (+/-)	368.83/397.05	378.67/406.69	97.40/97.63
V5- All Others (+/-)	367.75/398.18	378.67/406.69	97.11/97.90
V6- All Others (+/-)	371.55/397.62	378.67/406.69	97.11/97.76

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

8.6.4	TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS				P
Type of ME EQUIPMENT & impedance measured between parts	Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (m Ω)	Maximum allowable impedance (m Ω)	
Impedance between earth pin in the appliance inlet and a protectively earthed part	25/5	0.32	13	100	
Impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a protectively earthed part	25/5	1.92	77	200	

Supplementary information:
 PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 m Ω
 ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part - Limit 100 m Ω
 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 m Ω
 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 m Ω

8.7	TABLE: leakage current				P
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μ A)	Remarks	
Fig. 13 - Earth Leakage (ER)	—	—	B/A	Maximum allowed values: 5 mA NC; 10 mA SFC	
ER, NC, S1 = 1, S5 = N, S12 = 0	264	60	96/105	--	
ER, NC, S1 = 1, S5 = R, S12 = 0	264	60	96/107	--	

IEC 60601-1					
Clause	Requirement + Test	Result - Remark		Verdict	
	ER, NC, S1 = 1, S5 = N, S12 = 1	264	60	96/106	--
	ER, NC, S1 = 1, S5 = R, S12 = 1	264	60	97/107	--
	ER, SFC (Neutral Open), S1 = 0, S5 = N, S12 = 0	264	60	186/205	--
	ER, SFC (Neutral Open), S1 = 0, S5 = R, S12 = 0	264	60	186/203	--
	ER, SFC (Neutral Open), S1 = 0, S5 = N, S12 = 1	264	60	187/206	--
	ER, SFC (Neutral Open), S1 = 0, S5 = R, S12 = 1	264	60	186/202	--
	Fig. 14 - Touch Current (TC)	—	—	B/A	Maximum allowed values: 100 µA NC; 500 µA SFC
MD between enclosure to earth					
	TC, NC, S1 = 1, S5 = N, S7 = 1, S12 = 0	264	60	0/0	--
	TC, NC, S1 = 1, S5 = R, S7 = 1, S12 = 0	264	60	0/0	--
	TC, NC, S1 = 1, S5 = N, S7 = 1, S12 = 1	264	60	0/0	--
	TC, NC, S1 = 1, S5 = R, S7 = 1, S12 = 1	264	60	0/0	--
	TC, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1, S12 = 0	264	60	0/0	--
	TC, SFC (Neutral Open), S1 = 0, S5 = R, S7 = 1, S12 = 0	264	60	0/0	--
	TC, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1, S12 = 1	264	60	0/0	--
	TC, SFC (Neutral Open), S1 = 0, S5 = R, S7 = 1, S12 = 1	264	60	0/0	--
	TC, SFC (Ground Open), S1 = 1, S5 = N, S7 = 0, S12 = 0	264	60	97/104	--
	TC, SFC (Ground Open), S1 = 1, S5 = R, S7 = 0, S12 = 0	264	60	95/107	--
	TC, SFC (Ground Open), S1 = 1, S5 = N, S7 = 0, S12 = 1	264	60	96/105	--
	TC, SFC (Ground Open), S1 = 1, S5 = R, S7 = 0, S12 = 1	264	60	97/107	--
MD between different enclosure parts.					
	TC, NC, S1 = 1, S5 = N, S7 = 1, S12 = 0	264	60	0/0	--
	TC, NC, S1 = 1, S5 = R, S7 = 1, S12 = 0	264	60	0/0	--
	TC, NC, S1 = 1, S5 = N, S7 = 1, S12 = 1	264	60	0/0	--
	TC, NC, S1 = 1, S5 = R, S7 = 1, S12 = 1	264	60	0/0	--
	TC, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1, S12 = 0	264	60	0/0	--
	TC, SFC (Neutral Open), S1 = 0, S5 = R, S7 = 1, S12 = 0	264	60	0/0	--
	TC, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1, S12 = 1	264	60	0/0	--
	TC, SFC (Neutral Open), S1 = 0, S5 = R, S7 = 1, S12 = 1	264	60	0/0	--
	TC, SFC (Ground Open), S1 = 1, S5 = N, S7 = 0, S12 = 0	264	60	2/2	--
	TC, SFC (Ground Open), S1 = 1, S5 = R, S7 = 0, S12 = 0	264	60	2/2	--

IEC 60601-1				
Clause	Requirement + Test	Result - Remark		Verdict
TC, SFC (Ground Open), S1 = 1, S5 = N, S7 = 0, S12 = 1	264	60	2/2	--
TC, SFC (Ground Open), S1 = 1, S5 = R, S7 = 0, S12 = 1	264	60	2/2	--
TC, Internally power supply	14.8dc	--	0/0	
Fig. 15 - Patient Leakage Current (P) All probes have been considered.	—	—	B/A	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,S7=1,S13=0,S15=0	264	60	0/0	a.c.
			0/0	d.c.
P,NC, S1=1,S5=R,S7=1,S13=0,S15=0	264	60	0/0	a.c.
			0/0	d.c.
P,NC, S1=1,S5=N,S7=1,S13=1,S15=0	264	60	0/0	a.c.
			0/0	d.c.
P,NC, S1=1,S5=R,S7=1,S13=1,S15=0	264	60	0/0	a.c.
			0/0	d.c.
P,NC, S1=1,S5=N,S7=1,S13=0,S15=1	264	60	0/0	a.c.
			0/0	d.c.
P,NC, S1=1,S5=R,S7=1,S13=0,S15=1	264	60	0/0	a.c.
			0/0	d.c.
P,NC, S1=1,S5=N,S7=1,S13=1,S15=1	264	60	0/0	a.c.
			0/0	d.c.
P,NC, S1=1,S5=R,S7=1,S13=1,S15=1	264	60	0/0	a.c.
			0/0	d.c.
P,SFC (Neutral Open), S1=0,S5=N,S7=1,S13=0,S15=0	264	60	2/0	a.c.
			0/0	d.c.
P,SFC (Neutral Open), S1=0,S5=R,S7=1,S13=0,S15=0	264	60	2/0	a.c.
			0/0	d.c.
P,SFC (Neutral Open), S1=0,S5=N,S7=1,S13=1,S15=0	264	60	1/0	a.c.
			0/0	d.c.
P,SFC (Neutral Open), S1=0,S5=R,S7=1,S13=1,S15=0	264	60	1/0	a.c.
			0/0	d.c.

IEC 60601-1				
Clause	Requirement + Test	Result - Remark		Verdict
P,SFC (Neutral Open), S1=0,S5=N,S7=1,S13=0,S15=1	264	60	1/0	a.c.
			0/0	d.c.
P,SFC (Neutral Open), S1=0,S5=R,S7=1,S13=0,S15=1	264	60	1/0	a.c.
			0/0	d.c.
P,SFC (Neutral Open), S1=0,S5=N,S7=1,S13=1,S15=1	264	60	1/0	a.c.
			0/0	d.c.
P,SFC (Neutral Open), S1=0,S5=R,S7=1,S13=1,S15=1	264	60	1/0	a.c.
			0/0	d.c.
P,SFC (Ground Open), S1=1,S5=N,S7=0,S13=0,S15=0	264	60	3/4	a.c.
			0/0	d.c.
P,SFC (Ground Open), S1=1,S5=R,S7=0,S13=0,S15=0	264	60	4/4	a.c.
			0/0	d.c.
P,SFC (Ground Open), S1=1,S5=N,S7=0,S13=1,S15=0	264	60	4/4	a.c.
			0/0	d.c.
P,SFC (Ground Open), S1=1,S5=R,S7=0,S13=1,S15=0	264	60	4/4	a.c.
			0/0	d.c.
P,SFC (Ground Open), S1=1,S5=N,S7=0,S13=0,S15=1	264	60	4/4	a.c.
			0/0	d.c.
P,SFC (Ground Open), S1=1,S5=R,S7=0,S13=0,S15=1	264	60	4/4	a.c.
			0/0	d.c.
P,SFC (Ground Open), S1=1,S5=N,S7=0,S13=1,S15=1	264	60	4/4	a.c.
			0/0	d.c.
P,SFC (Ground Open), S1=1,S5=R,S7=0,S13=1,S15=1	264	60	4/4	a.c.
			0/0	d.c.
P,NC ,Internally power supply	14.8Vdc	--	0/0	a.c.
			0/0	d.c.
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	B/A	Maximum allowed values: Type B: N/A Type BF AP: 5000 μ A Type CF AP: 50 μ A
PM, SFC, S1 = 1, S5 = N, S7 = 1, S9 = N, S13 = 1	264	60	23/27	--
PM, SFC, S1 = 1, S5 = R, S7 = 1, S9 = N, S13 = 1	264	60	24/28	--
PM, SFC, S1 = 1, S5 = N, S7 = 1, S9 = R, S13 = 1	264	60	24/29	--

IEC 60601-1				
Clause	Requirement + Test	Result - Remark		Verdict
PM, SFC, S1 = 1, S5 = R, S7 = 1, S9 = R, S13 = 1	264	60	23/29	--
PM, SFC, S1 = 1, S5 = N, S7 = 1, S9 = N, S13 = 0	264	60	22/28	--
PM, SFC, S1 = 1, S5 = R, S7 = 1, S9 = N, S13 = 0	264	60	24/24	--
PM, SFC, S1 = 1, S5 = N, S7 = 1, S9 = R, S13 = 0	264	60	24/29	--
PM, SFC, S1 = 1, S5 = R, S7 = 1, S9 = R, S13 = 0	264	60	22/23	--
PM, SFC, Internally power supply	14.8 dc	--	23/26	--
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	B/A	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)
--	--	--	--	SIP/SOP is no external voltage.
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	B/A	Maximum allowed values: Type B or BF AP: 500 µA Type CF: N/A
--	--	--	--	--
Fig. 19 – Patient Auxiliary Current	—	—	B/A	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)
PA, NC, S1 = 1, S5 = N, S7 = 1	264	60	0/0	--
			0/0	--
PA, NC, S1 = 1, S5 = R, S7 = 1	264	60	0/0	--
			0/0	--
PA, SFC, S1 = 0, S5 = N, S7 = 1	264	60	0/0	--
			0/0	--
PA, SFC, S1 = 0, S5 = R, S7 = 1	264	60	0/0	--
			0/0	--
PA, SFC, S1 = 1, S5 = N, S7 = 0	264	60	0/0	--
			0/0	--
PA, SFC, S1 = 1, S5 = R, S7 = 0	264	60	0/0	--

IEC 60601-1				
Clause	Requirement + Test	Result - Remark		Verdict
			0/0	--
			0/0	--
		14.8 dc	--	0/0
				--
	Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	B/A
				Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
--		--	--	--
	Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	B/A
				Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
--		--	--	--
	Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	B/A
				Maximum allowed values: Type B: NA Type BF: 5000 µA Type CF: 100 µA
--		--	--	--
	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	—	—	B/A
				Maximum allowed values: Type B & BF: 1000 µA Type CF: N/A
--		--	--	--
	Function Earth Conductor Leakage Current (FECLC)	—	—	B/A
				Maximum allowed values: 5 mA NC; 10 mA SFC
--		--	--	--
Supplementary information:				
Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5; Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6; Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7 Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values. Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).				
ER - Earth leakage current			A - After humidity conditioning	

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

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	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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8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)	P
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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.		
B	1MOOP	339	--	1500	No
C	2MOOP	339	--	3000	No
D	2MOOP	513	--	3000	No
E	2MOOP	513	--	3000	No
F	2MOPP	--	19	1000	No
F	1MOPP	339	--	1500	No
G	2MOPP	--	19	1000	No
G	1MOPP	339	--	1500	No
H	2MOPP	--	19	1000	No
H	1MOPP	339	--	1500	No
I	2MOPP	--	19	1000	No
I	1MOPP	339	--	1500	No
J	2MOPP	339	--	4000	No

Supplementary information:

¹ Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.

² A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

8.8.4.1	TABLE: Resistance to heat - Ball pressure test of thermoplastic parts		P
	Allowed impression diameter (mm)	≤ 2 mm	—
	Force (N)	20	—
Part/material		Test temperature (°C)	Impression diameter (mm)
Enclosure/External insulating parts: 945(GG)		75	0.87
Insulating material supporting un-insulated Mains Parts: input		125	1.22

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

connector(P2)

Supplementary information: --

8.9.2	TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4	N/A
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Specific areas of circuits short-circuited and test conditions	Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE ¹	HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No	Remarks
--	--	--	--

Supplementary information:
 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
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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.

IEC 60601-1				
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 $T1 \pm 2 \text{ }^\circ\text{C} = \text{ }^\circ\text{C}^1$		
		2 - 1 h at $25 \text{ }^\circ\text{C} \pm 2 \text{ }^\circ\text{C}$		
		3 - 2 h at $0 \text{ }^\circ\text{C} \pm 2 \text{ }^\circ\text{C}$		
	4 - 1 or more h at $25 \text{ }^\circ\text{C} \pm 2 \text{ }^\circ\text{C}$			
2	Humidity Conditioning per 5.7	--	--	
3	Humidity Conditioning per 5.7	--	--	
Supplementary information:				
¹ T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.				

8.10	TABLE: List of critical components				P
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity ¹⁾
Enclosure					
-Handle	SABIC INNOVATIVE PLASTICS US L L C	945(GG)	V-0, min. thickness 1.6 mm, 120 degree C, Overall 168.4 mm by 58 mm by 16 mm, secured by screws.	UL94	UL E121562
-Top enclosure of printer	SABIC INNOVATIVE PLASTICS US L L C	945(GG)	V-0, min. thickness 1.6 mm, 120 degree C, overall size 330 mm by 108 mm by 35 mm, secured by screws and physical fit.	UL94	UL E121562
-Top enclosure of display and keyboard	SABIC INNOVATIVE PLASTICS US L L C	945(GG)	V-0, min. thickness 1.6 mm, 120 degree C, overall size 290 mm by 285 mm by 20.5 mm, secured by screws and physical fit.	UL94	UL E121562

IEC 60601-1					
Clause	Requirement + Test	Result - Remark	Verdict		
-Bottom enclosure	SABIC INNOVATIVE PLASTICS US L L C	945(GG)	V-0, min. thickness 1.6 mm, 120 degree C, overall size 415 mm by 330 mm by 51 mm, secured by screws and physical fit.	UL94	UL E121562
-Battery gate	SABIC INNOVATIVE PLASTICS US L L C	945(GG)	V-0, min. thickness 1.6 mm, 120 degree C, Overall 153.6 mm by 74.6 mm by 6 mm, secured at the bottom by screw.	UL94	UL E121562
Printed Wiring Board	Various	Various	Min. V-1, 130 degree C.	UL94	UL
Power supply cord	Various	Various	Hospital grade, 125V, 10A with NEMA 5-15P or 250 V, 10 A, with NEMA 6-15P, type SJT, VW-1, min. 18AWG x 3C, 105 degree C. Other end with cord-connected body, grounding type, suitable for cord size, rating not less than that of attachment plug.	IEC 60227-1	UL
Appliance Inlet	Rong Feng Industrial Co., Ltd	SS-120	Rated 250V, 10A,	IEC 60127-6	UL E102641
Appliance Inlet (alternate)	Pronic Electronics (shenzhen) Co., Ltd	PST-101	Rated 250V, 10A,	IEC 60127-6	UL E188311
Fuse (F1, F2)	LITTELFUSE INC	618	Rated T1A, 250Vac.	UL248-1, UL248-14	UL E10480
Fuse holder (for F1, F2)	Stelvio Kontek SPA	PTF/50	250V, 6.3 A	UL248-1, UL248-14	UL E157417
Connector (AP3, P2)	JAPAN SOLDERLESS TERMINAL MFG CO LTD	VH	250V, 10A	UL94,UL197 7	UL E60389
Primary wire connecting terminals AP3 and P2	Various	Various	FEP, PTFE, PVC, TFE, neoprene, polyamide or marked VW-1; 300 V, min. 105 degree C, min. 18 AWG	UL758	UL

IEC 60601-1					
Clause	Requirement + Test		Result - Remark	Verdict	
Internal PE wire	Various	Various	FEP, PTFE, PVC, TFE, neoprene, polyamide or marked VW-1; min 300V, 105 degree C, 18 AWG. Colored with green/yellow.	UL758	UL
PE Quick Connector	JIAN HUI METAL PLASTIC PART FACTORY	F250183	Suitable for 18AWG stranded wire	--	UL E207921
Secondary Connectors and receptacles	Various	Various	Min V-2	UL 758	UL
Wiring, internal secondary ELV/SELV circuit	Various	Various	Min. V-2, FEP, PTFE, PVC, TFE, neoprene, polyamide or marked VW-1; min. 60 V, 22AWG, 80 degree C.	UL 758	UL
PE Quick Connector (alternate)	Shun Sheng Terminal MFG LTD	752-BS, 7522-BS	Suitable for 18AWG stranded wire	--	UL E177315
Printer DC motor	DONG GUAN SHINANO MOTOR CO. LTD	STP-42D1072	Step motor, 10.5VDC, 350mA/phase	-	--
Lithium battery pack	LEUNG'S COMMUNICATION & ELECTRIC PRODUCTS (GUANGZHOU) LTD	Lithium battery pack	14.8V, 2500mAh, black PVC, 1x4	UL2054, IEC62133	UL,CE
Lithium battery pack (For SE-12E/SE-1200E)	LEUNG'S COMMUNICATION & ELECTRIC PRODUCTS (GUANGZHOU) LTD	Product:TWSL B-004 Battery Core:HL-18650Q	14.8V, 5000mAh, VHR-3P, 2x4	UL2054, IEC62133	UL,CE
Shrinkage tube	Various	Various	Min. V-2, min. 130 degree C.	UL94	UL
Power board	Edan Instruments Inc	PS900D	Unlisted medical open frame power supply, I/P: 100-240Vac, 0.9-0.4A	IEC60601-1	UL E330156
ECG board Transformer (T1)	SHENZHEN CEC PANDA STRONG ELECTRONICS CO., LTD	EFD15-034	Class A, see enclosure for details	Test with appliance	--
- Core	--	--		--	--

IEC 60601-1					
Clause	Requirement + Test	Result - Remark			Verdict
- Coil	PACIFIC ELECTRIC WIRE & CABLE CO., LTD	Φ0.18mm, Φ0.16mm	2UEW	--	UL
- Coil (optional)	TAI-I ELECTRIC WIRE & CABLE CO., LTD	Φ0.18mm, Φ0.16mm	2UEW	--	UL
-Coil	FURUKAWA ELECTRIC CO., LTD.	Φ0.20mm	TEX-E	--	UL
- Bobbin	SUMITOMO CHEMICAL CO., LTD.	PM9820	PHENOLIC	UL94	UL
- Margin Tape	3M COMPANY ELECTRICAL MARKETS DIV(EMD)	t=1L t=2L	#44	UL510	UL
- Margin Tape (optional)	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	t=0.15mm t=0.25mm	WF	UL510	UL
- Insulating Tape	3M COMPANY ELECTRICAL MARKETS DIV(EMD)	t=0.025mm	CT	UL510	UL
- Insulating Tape (optional)	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	t=0.025mm	#1318-1	UL510	UL
Optical Isolator (U27, U28)	Vishay Semiconductor GMBH	6N-137	2500Vac isolation	UL1557	UL E76222
Resistor (R95)	--	--	100M ohm	--	--
LCD display module	--	--	--	--	--
LCD panel (For model SE-12 Express)	AU OPTRONICS CORP	G121SN01	12.1inch TFT LCD module, 3.3Vdc, max. 325mA	--	UL E204356
LCD panel (For model SE-12/SE-1200)	SHENZHEN TOPWAY TECHNOLOGY	LM32019TGW	5.7inch STN LCD module, 5Vdc, max. 200mA	--	--

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Clause	Requirement + Test	Result - Remark	Verdict		
LCD panel (For model SE-1200 Express)	AU OPTRONICS CORP	G084SN03	8.4 inch TFT LCD module, 3.3Vdc, PCFL 2.3W (typ).	--	UL E204356
Speaker	Various	Various	Max. 1W, one provided near the lower right bottom.	--	--
Mylar Film	AGC POLYCARBONATE CO LTD	8B35	Minimum thickness 0.25 mm, VTM-2, 80 degree C	UL94	UL E141248
Supplementary information: 1) Indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.					

8.10 b	TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS					P
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity ¹	
Y capacitor (C1, C2, C3, C4)	JYH CHUNG ELECTRONICS CO LTD	JD	250V, max. 1000pF, class Y1.	UL60384-14	UL E187963	
Supplementary information: 1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.						

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

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

9.2.2.2	TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996)				N/A
Part of body	Allowable adult 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	--	

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Clause	Requirement + Test		Result - Remark	Verdict
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:			

9.4.2.1	TABLE: Instability—overbalance in transport position		P
ME EQUIPMENT preparation	Test Condition (transport position)	Remarks	
Main unit with all accessories(including battery, power supply and ECG lead wire)	10° incline	No overbalance	
Main unit on MT-201 with safety loading	10° incline	No overbalance	
Main unit on MT-801 with safety loading	10° incline	No overbalance	
Supplementary information:			

9.4.2.2	TABLE: Instability—overbalance excluding transport position		P
ME EQUIPMENT preparation	Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)	Remarks	
Main unit with all accessories(including battery, power supply and ECG lead wire)	10° incline	No overbalance	
Main unit on MT-201 with safety loading	10° incline	No overbalance	
Main unit on MT-801 with safety loading	10° incline	No overbalance	
Supplementary information:			

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

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Clause	Requirement + Test	Result - Remark	Verdict

9.4.2.4.2	TABLE: Castors and wheels – Force for propulsion		P
ME EQUIPMENT preparation	Test Condition (force location and height)	Remarks	
Main unit on MT-201 with safety loading	Pushing trolley attaining 0.4m/s speed at the 77cm height	Applied force is 40N, not exceeding 200N.	
Main unit on MT-801 with safety loading	Pushing trolley attaining 0.4m/s speed at the 98cm height	Applied force is 40N, not exceeding 200N.	
Supplementary information:			

9.4.2.4.3	TABLE: Castors and wheels – Movement over a threshold		P
ME EQUIPMENT preparation	Test Condition (speed of movement)	Remarks	
Main unit on MT-801 with safety loading	0.8m/s	Passing over a 10 mm threshold and no overbalance.	
Supplementary information:			

9.4.3.1	TABLE: Instability from unwanted lateral movement (including sliding) in transport position		P
ME EQUIPMENT Preparation	Test Condition (transport position, working load, locking device(s), caster position)	Remarks	
Main unit on MT-201 with safety loading	10 ° incline with caster locked	No unwanted movement.	
Main unit on MT-801 with safety loading	10 ° incline with caster locked	No unwanted movement.	
Supplementary information:			

9.4.3.2	TABLE: Instability from unwanted lateral movement (including sliding) excluding transport position		P
ME EQUIPMENT Preparation	Test Condition (working load, locking device(s), caster position, force, force location, force direction)	Remarks	
Main unit on MT-201 with safety loading	5 ° incline with caster locked	No unwanted movement.	
Main unit on MT-801 with safety loading	5 ° incline with caster locked	No unwanted movement.	
Main unit on MT-201 with safety loading	150N force applied to any position	No unwanted movement	
Main unit on MT-801 with safety loading	150N force applied to any position	No unwanted movement	
Supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

9.4.4	TABLE: Grips and other handling devices		P
Clause and Name of Test		Test Condition	Remarks
9.4.4 c) handle loading test		Apply 33.8kg loading on handle for 1 min	No crack or break loose on handle
Supplementary information: Only the style which with handle but no thermal printer.			

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:					

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./ Description¹		Measured Radiation, pA/kg (μSv/h) (mR/h)	Remarks
1/ /		--	--
2/ /		--	--
3/ /		--	--
4/ /		--	--
5/ /		--	--
6/ /		--	--
7/ /		--	--
8/ /		--	--

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Clause	Requirement + Test	Result - Remark	Verdict
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			

11.1.1 TABLE: Excessive temperatures in ME EQUIPMENT					P	
Model No.....		SE-12 Express	--	--	-	--
Test ambient (°C)		See below	--	--	--	--
Test supply voltage/frequency (V/Hz) ⁴ ..		90/60	--	--	--	--
Model No.	Thermo-couple No.	Thermocouple location ³	Max allowable temperature ¹ from Table 22, 23 or 24 or RM file for AP ⁵ (°C)	Max measured temperature ² , (°C) (Corrected to 40°C)	Remarks	
SE-12 Express	Main unit					
	305	Handle	60	51.687	33.105	
	306	LCD panel(outside)	71	47.195	28.613	
	307	LCD monitor top enclosure(inside)	80	49.888	31.306	
	308	Top enclosure near power board(inside)	80	64.847	46.265	
	309	Bottom enclosure near power board(inside)	80	70.179	51.597	
	310	Bottom enclosure near power board(outside)	71	65.833	47.251	
	311	Keyboard	71	49.973	31.391	
	312	DC motor	Ref.	55.456	36.874	
	313	AC inlet	65	53.303	34.721	
	314	BT2 on ECG board	95	56.904	38.322	
	315	LCD inverter transformer	95	66.698	48.098	
	316	Li-ion battery	60	50.416	31.934	
	317	R electrode	41	40.219	21.528	
	Power supply module					
	317	XL1 wingding	95	82.455	63.813	
	318	XL1 core	95	78.479	59.897	
	319	L5 coil	120	75.269	56.687	

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Clause	Requirement + Test	Result - Remark		Verdict
320	L7 coil	120	68.404	49.822
304	Bulk capacitance	105	68.322	49.740
217	ambient	--	40.000	21.418

Supplementary information:

¹ Maximum allowable temperature on surfaces of test corner is 90 °C
² Max temperature determined in accordance with 11.1.3e)
³ When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
⁴ Supply voltage:
 - ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
 - Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
 - Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.
⁵ APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

Information from Risk Management, as applicable: N/A

11.1.1		TABLE: Excessive temperatures in ME EQUIPMENT (Test report TR2103090402)				P
Model No.....	SE-12 Express	SE-12 Express	--	-	--	
Test ambient (°C)	See below	See below	--	--	--	
Test supply voltage/frequency (V/Hz) ⁴ ..	264/50	90/60	--	--	--	
Model No.	Thermo-couple No.	Thermocouple location ³	Max allowable temperature ¹ from Table 22, 23 or 24 or RM file for AP ⁵ (°C)	Max measured temperature ² , (°C) (Corrected to 40°C)	Remarks	
SE-12 Express	Main unit					
	101	U4	105	52.5	36.4	
	102	Q4	130	61.7	45.6	
	103	U29	105	58.4	42.3	
	104	U30	105	56.7	40.6	
	105	SL1	105	52.4	36.3	
	106	U12	105	59.1	43.0	
	107	T1	105	49.1	33.0	
	108	U21	105	52.2	36.1	
	109	Display screen	66	44.1	28.0	
	110	Plastic enclosure	71	50.7	34.6	
	111	Key	71	43.2	27.1	
	112	R electrode	41	40.3	24.2	
Power supply module						

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Clause	Requirement + Test	Result - Remark		Verdict	
113	XL2 wingding	105	83.2	67.1	
114	XL1 winding	105	55.1	39.0	
115	C1	90	57.2	41.1	
116	D10	130	60.0	43.9	
117	XL4	105	52.8	36.7	
118	Q3	130	91.3	75.2	
119	D3	130	77.2	61.1	
120	C14	90	57.6	41.5	
201	U1	105	66.3	50.2	
202	PCB-XL2	130	58.2	42.1	
203	PCB-Q3	130	47.0	30.9	
204	C5	130	54.4	38.3	
205	C17	90	71.1	55.0	
206	Ambient	--	40.0	23.9	
SE-12 Express	Main unit				
	101	U4	105	57.9	42.3
	102	Q4	130	57.9	42.3
	103	U29	105	56.3	40.7
	104	U30	105	55.9	40.3
	105	SL1	105	58.6	43.0
	106	U12	105	49.1	33.5
	107	T1	105	52.1	36.5
	108	U21	105	43.9	28.3
	109	Display screen	66	42.9	27.3
	110	Plastic enclosure	71	42.3	26.7
	111	Key	71	57.9	42.3
	112	R electrode	41	40.2	24.6
	Power supply module				
	113	XL2 wingding	105	71.2	55.6
114	XL1 winding	105	62.3	46.7	
115	C1	90	63.9	48.3	
116	D10	130	69.1	53.5	
117	XL4	105	59.7	44.1	

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
118	Q3		130	68.3	52.7
119	D3		130	68.5	52.9
120	C14		90	61.2	45.6
201	U1		105	60.6	45.0
202	PCB-XL2		130	53.1	37.5
203	PCB-Q3		130	44.7	29.1
204	C5		130	50.3	34.7
205	C17		90	64.8	49.2
206	Ambient		--	40.0	24.4

Supplementary information:

¹ Maximum allowable temperature on surfaces of test corner is 90 °C

² Max temperature determined in accordance with 11.1.3e)

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

⁴ Supply voltage:

- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

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

Information from Risk Management, as applicable: N/A

11.1.3d	TABLE: Temperature of windings by change-of-resistance method						N/A	
Temperature T of winding:	t ₁ (°C)	R ₁ (Ω)	t ₂ (°C)	R ₂ (Ω)	T (°C)	Allowed T _{max} (°C)	Insulation class	
--	--	--	--	--	--	--	--	

Supplementary information:

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		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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) :		--	
<p>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.</p> <p>Information from Risk Management, as applicable:</p>			

11.6.1	TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances		P
Clause / Test Name	Test Condition	Part under test	Remarks
11.6.6/Cleaning	Test process according to user manual.	Whole device including all the accessories	No damage, and pass dielectric strength test.
11.6.6/ Disinfection	Test process according to user manual.	Whole device including all the accessories	No damage, and pass dielectric strength test.
<p>Supplementary information:</p> <p>Information from Risk Management, as applicable:</p>			

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	

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Clause	Requirement + Test	Result - Remark	Verdict

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

Supplementary information: See table 8.4.2 of this report.

13.2	TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive	P
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Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2	Electrical SINGLE FAULT CONDITIONS per Cl. 8.1:	—	—
	D8 short	Fuse F1 open	No
	C15 short	Fuse F1 open	No
	XL1 pin6-pin 8 short	Shut down at once Final input current: 0.18A	No
	XL1 pin 7-pin 10 short	Shut down at once Final input current: 0.4A	No
	U5 pin1-pin 2 short	Shut down at once Final input current: 0.15A	No
	U5 pin 3 open	Shut down at once Final input current: 0-1.17 Test duration: 2hrs. No high temperature	No
	U6 pin1-pin 2 short	Shut down at once. Final input current 0.16A	No
	U6 pin4-pin7 short	Fuse F1 open. Final input current 0 A	No
	Output P1.1-P1.4 short	Working normally. Final input current 0.37 A	No
	Output P1.2-P1.4 short	Shut down at once except P1.3. Final input current: 0.14A	No
	Output Pin 1.3-Pin 1.4 short	Working normally. Final input current: 0.41A	No
	Output overload P1.1_+12V,1.5A	Ambient: 25°C XL1 core: 85.5°C XL1 coil: 85.1°C	No
	Output overload P1.2_+5V,1.8A	Ambient:25°C XL1 core:86.2°C XL1 coil:86.2°C	No
	Output overload P1.3_+12V,7W	Ambient:25°C XL1 core:88.2°C XL1 coil:88°C	No

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Clause	Requirement + Test	Result - Remark	Verdict
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	Short D18 pin1-pin 3 on ECG board	Patient current: 0uA ac, 0uA dc Patient auxiliary current: 20uA ac, 20uA dc	No
	Short D18 pin2-pin 3 on ECG board	Patient current: 0uA ac, 0uA dc Patient auxiliary current: 20uA ac, 20uA dc	No
	Short R80 on ECG board	Patient current: 0uA ac, 0uA dc Patient auxiliary current: 0uA ac, 0uA dc	No
	Short C106 on ECG board	Patient current: 5uA ac, 0uA dc Patient auxiliary current: 0uA ac, 0uA dc	No
	Short D15 pin2-pin 3 on ECG board	Patient current: 0uA ac, 0uA dc Patient auxiliary current: 0uA ac, 0uA dc	No
	Short R36 on ECG board	Patient current: 0uA ac, 0uA dc Patient auxiliary current: 0uA ac, 0uA dc	No
	Short R95 on ECG board	Patient current: 0uA ac, 0uA dc Patient auxiliary current: 5uA ac, 35uA dc	No
13.2.3	Overheating of transformers per Clause 15.5:	—	—
	See table 15.5.1.2&15.5.1.3	See table 15.5.1.2&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:	—	—
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:	—	—

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Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	Single ventilation fans locked consecutively	No fans	N/A
	Ventilation openings on top and sides impaired by covering openings on top of enclosure or positioning of me equipment against walls	Transformer: T1 Coil:64.224°C T1 Core:60.439°C Ambient:24.353°C Supply: 90V/60Hz	No
	Simulated blocking of filters	No filters	N/A
	Flow of a cooling agent interrupted	No cooling agent	N/A
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 started 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):	—	—

Supplementary information:

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

Information from Risk Management, as applicable:

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

15.3	TABLE: Mechanical Strength tests ¹⁾			P
Clause	Name of Test	Test conditions	Observed results/Remarks	
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	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) = 1.0	No damage, No hazard.	
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5.0	No damage, No hazard.	
15.3.5	Rough handling test	Travel speed (m/s) = N/A	No damage, No hazard.	
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 or state N/A in Remarks field).

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

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

15.5.1.2	TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION						P
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)¹ :				264	—		
RATED input frequency (Hz)..... :				50	—		
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)
XL1 pin 1- Pin4	A	IC protective circuit	Yes	--	140	--	24.0

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

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				P
Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)¹:					264
RATED input frequency (Hz).....:					50
Test current just below minimum current that would activate protective device & achieve THERMAL STABILITY under method a) (A).....:					3.2
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A).....:					N/A
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)
XL1 pin 1-pin 4 after D3	A	IC protective circuit	140	109.1	25.0
Supplementary information:					
¹ Loads on other windings between no load and their NORMAL USE load. Time durations: - IEC 60127-1 fuse: 30 min at current from Table 32. Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved. - Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a). This portion concluded at specified time or when a second protective device opened.					

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7				N/A
Transformer Model/Type/ Part No	Test voltage applied between	Test voltage, (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No
--	--	--	--	--	--
Supplementary information: Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details					

16.6.1	TABLE: leakage currents in me system _ touch current measurements				P
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)	Remark
SIP/SOP metal shell of SE-12 Express to earth(1)	100	0	500	0	--
SIP/SOP metal shell of SE-12 Express to earth(2)	100	0	500	0	--
SIP/SOP metal shell of	100	0	500	0	--

IEC 60601-1				
Clause	Requirement + Test	Result - Remark	Verdict	
SE-12 Express to earth(3)				
<p>Supplementary information:</p> <p>(1) SE-601C with external printer HP Laserjet M401, but external printer is outside patient environment and use 2c) of table I.1</p> <p>(2) SE-601C with external printer HP Laserjet P2015,, but external printer is outside patient environment and use 2c) of table I.1</p> <p>(3) SE-601C with external printer HP Laserjet P2035,, but external printer is outside patient environment and use 2c) of table I.1</p>				

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Attachment 1, photo documentation

Details of: SE-12

View:

- general
- front
- rear
- right
- left
- top
- bottom



Details of: SE-12

View:

- general
- front
- rear
- right
- left
- top
- bottom



Attachment 1, photo documentation

Details of: SE-12

View:

- general
- front
- rear
- right
- left
- top
- bottom



Details of: SE-12

View:

- general
- front
- rear
- right
- left
- top
- bottom



Attachment 1, photo documentation

Details of: SE-12 Express

View:

- general
- front
- rear
- right
- left
- top
- bottom



Details of: SE-12 Express

View:

- general
- front
- rear
- right
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- top
- bottom



Attachment 1, photo documentation

Details of: SE-12 Express

View:

- general
- front
- rear
- right
- left
- top
- bottom



Details of: SE-12 Express

View:

- general
- front
- rear
- right
- left
- top
- bottom



Attachment 1, photo documentation

Details of: SE-1200

View:

- general
- front
- rear
- right
- left
- top
- bottom



Details of: SE-1200

View:

- general
- front
- rear
- right
- left
- top
- bottom



Attachment 1, photo documentation

Details of: SE-1200

View:

- general
- front
- rear
- right
- left
- top
- bottom



Details of: SE-1200

View:

- general
- front
- rear
- right
- left
- top
- bottom



Attachment 1, photo documentation

Details of: SE-1200 Express



Details of: SE-1200 Express



Attachment 1, photo documentation

Details of: SE-1200 Express

View:

- general
- front
- rear
- right
- left
- top
- bottom



Details of: SE-1200 Express

View:

- general
- front
- rear
- right
- left
- top
- bottom



Attachment 1, photo documentation

Details of: Internal circuit(SE-12 Express)

View:

- general
- front
- rear
- right
- left
- top
- bottom



Details of: Main board

View:

- general
- front
- rear
- right
- left
- top
- bottom

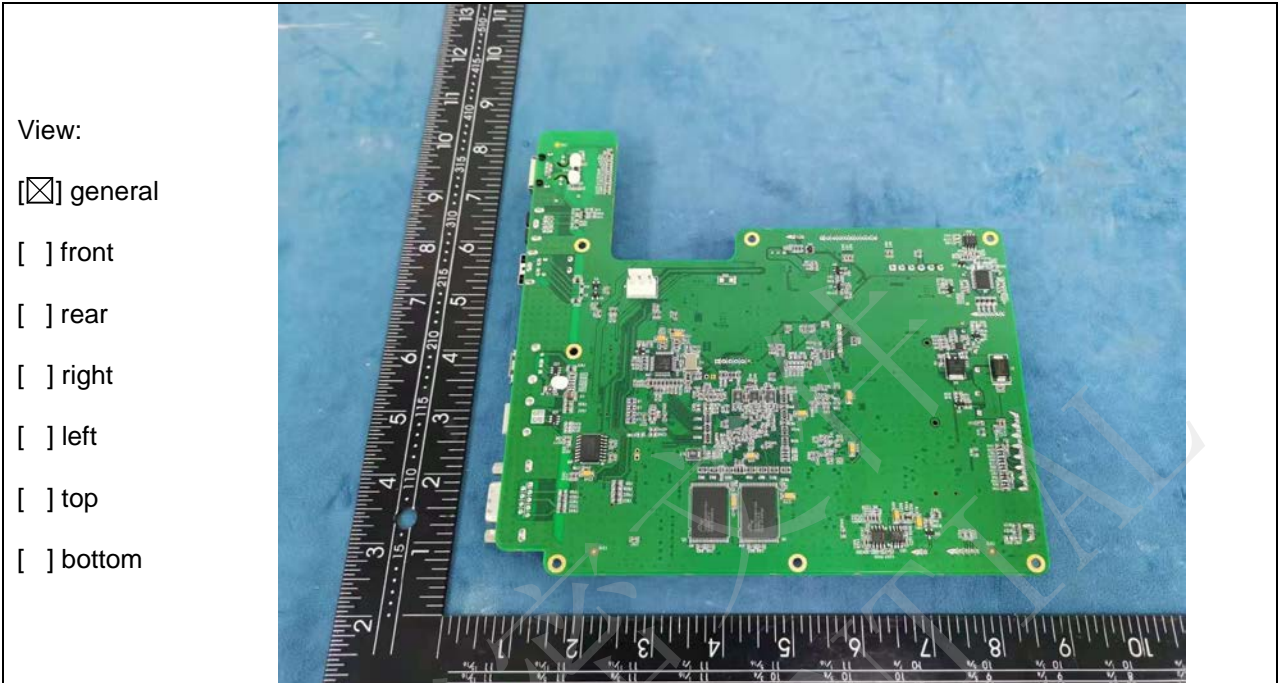


Attachment 1, photo documentation

Details of: Main board

View:

- general
- front
- rear
- right
- left
- top
- bottom



Details of: ECG board

View:

- general
- front
- rear
- right
- left
- top
- bottom

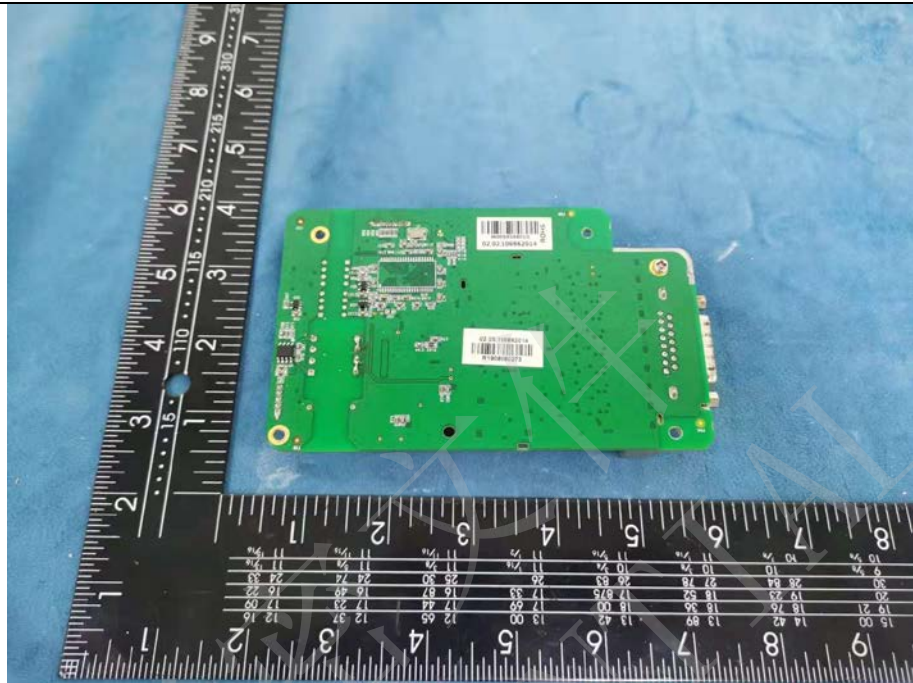


Attachment 1, photo documentation

Details of: ECG board

View:

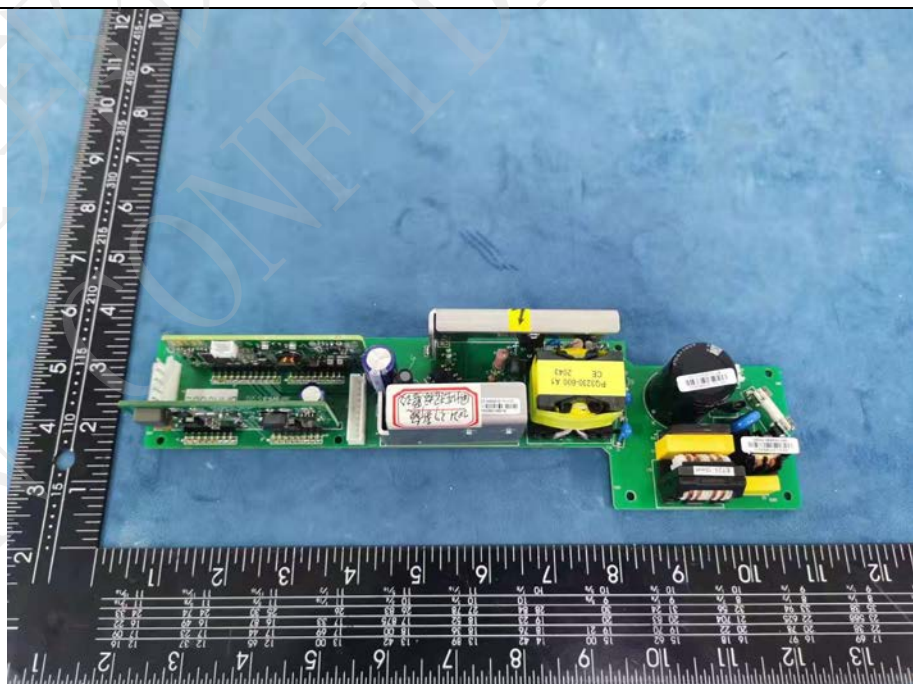
- general
- front
- rear
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- left
- top
- bottom



Details of: Power module

View:

- general
- front
- rear
- right
- left
- top
- bottom

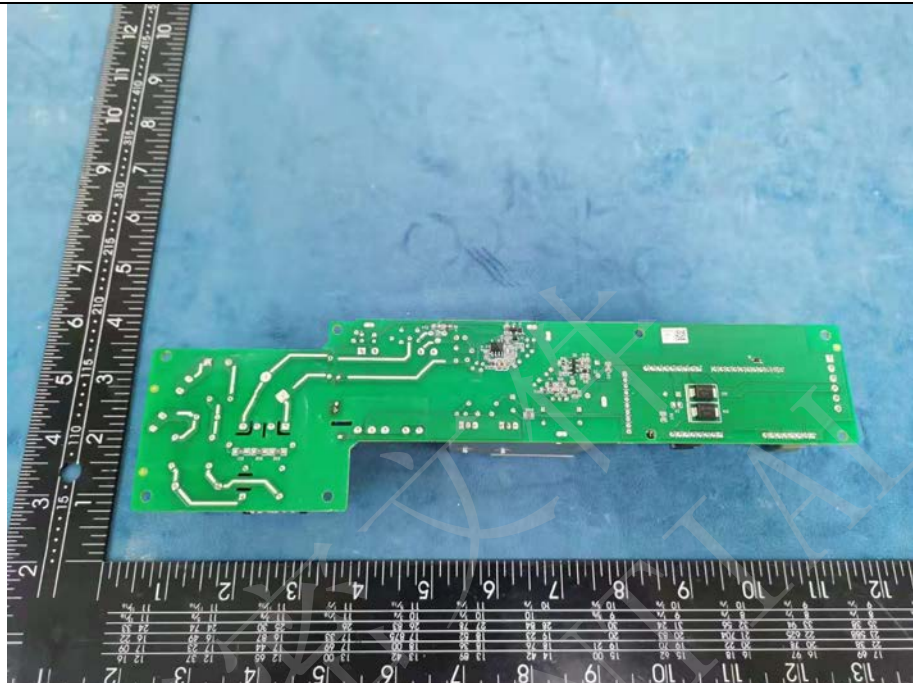


Attachment 1, photo documentation

Details of: Power module

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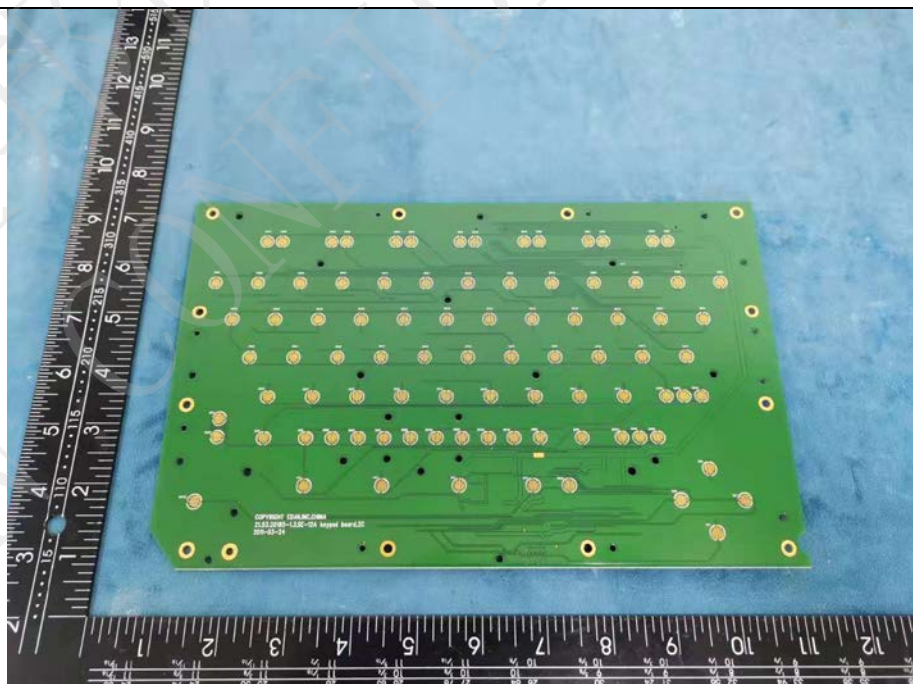
- general
- front
- rear
- right
- left
- top
- bottom



Details of: Key board

View:

- general
- front
- rear
- right
- left
- top
- bottom

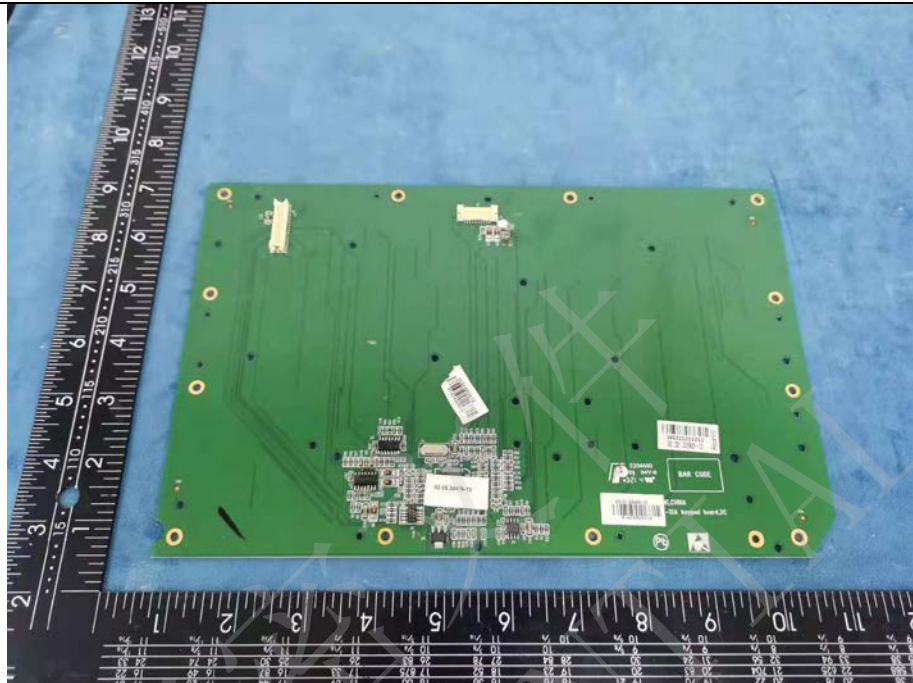


Attachment 1, photo documentation

Details of: Key board

View:

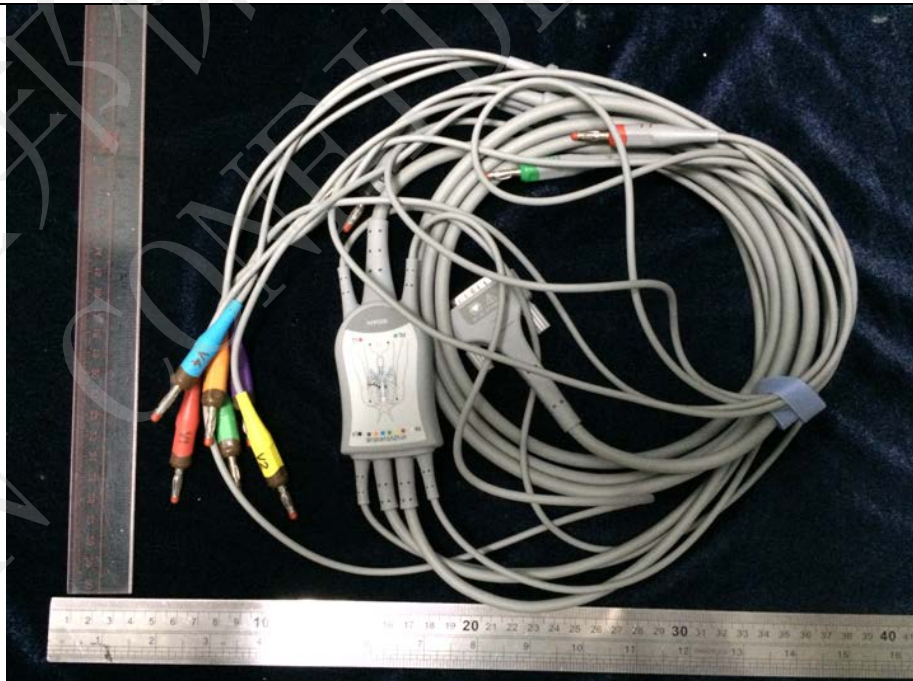
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- top
- bottom



Details of: ECG cable

View:

- general
- front
- rear
- right
- left
- top
- bottom



Attachment 1, photo documentation

Details of: MT-801

View:

- general
- front
- rear
- right
- left
- top
- bottom



Details of: MT-201

View:

- general
- front
- rear
- right
- left
- top
- bottom



Attachment 2 Accessories

Part Number	Accessories
Standard accessory list	
Power cord (European)	01.13.036638
Power cord(American)	01.13.037122
ECG Cable, Patient Cable (European)	01.57.471500*
ECG Cable, Patient Cable (American)	01.57.471499*
Adult Chest electrodes	01.57.040163
Adult Limb electrodes	01.57.040162
Thermal Recorder Paper	01.57.107371
Rechargeable Li-ion Battery (SE-12), TWSLB-005	21.21.064149
Rechargeable Li-ion Battery (SE-12 Express), TWSLB-004	21.21.064146
Fuse	21.21.64073
	21.21.064172
Configurable Accessories	
ECG Cable, Patient Cable (European)	01.57.107581 (Snap Style)
	01.57.107583 (Grabber Style)
ECG Cable, Patient Cable (American)	01.57.107582 (Snap Style)
	01.57.107584 (Grabber Style)
ECG Cable (Patient Cable) for Exercise ECG, European Standard	01.57.109850
ECG Cable (Patient Cable) for Exercise ECG, American Standard	01.57.109851
Grounding Wire	01.13.114214
Pediatric Chest Electrodes	01.57.040168
Pediatric Limb Electrodes	01.57.040169
Adult Disposable Adhesive Electrodes	01.57.471858
	01.57.471862
Pediatric Disposable Adhesive Electrodes	01.57.471859
Disposable Resting electrodes	01.57.471863
Disposable Exercise electrodes	01.57.471860
Snap/Banana Socket Adapters	01.57.471864
Clip/Snap/Banana Socket Adapter	01.57.040172
Thermal Recorder Paper (Rolled, 210mm×30m)	01.57.32461
Thermal Recorder Paper (Folded, 215mm×280mm×100P)	01.57.107451
BP Monitor	83.61.328019
ECG Bag	01.56.465625
MT-201 Trolley	83.61.111847
MT-801 Trolley	83.63.5600232
Belt for Exercise Test	01.57.106750
U Disk	01.18.052245
CA-100 Lead wire bracket	02.04.111902

Attachment 2 Accessories

	02.04.242639*
	02.04.242640*
Bar Code Reader (One-Dimension)	01.23.068023
Bar Code Reader (Two-Dimension)	21.18.052311

NOTE:

- 1 * Currently not available in the U.S.
- 2 The chest electrodes, limb electrodes, pediatric chest electrodes and pediatric limb electrodes are not available in the U.S.
- 3 The part name may vary depending on context, but the part number is constant.

-- End of Report --