Test Report issued under the responsibility of

Nemko

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

Report Reference No.	**253035**
Date of issue.....	**16.09.2014**
Total number of pages	**125**
CB Testing Laboratory	Nemko AS
Address.....	Gaustadalléen 30, N-0373 Oslo, Norway
Applicant's name	J.K. Medico Electronics
Address.....	Dam Enge 30, DK-3660 Stenløse, Denmark
Test specification:	
Standard.....	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure	CB Scheme
Non-standard test method……..:	N/A
Test Report Form No.	IEC60601_1I
Test Report Form Originator.....	UL
Master TRF.....	2014-03

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

General disclaimer:

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

Test item description.....	Battery charger for wheelchairs and scooters
Trade Mark.....	J.K. Medico Electronics
Manufacturer	J.K. Medico Aps Dam Enge 30, DK-3660 Stenløse, Denmark
Model/Type reference	CCC410S, CCC408S, CCC406S
Ratings	CCC410S: 460VA, 230Vac,50Hz, Output: 24Vdc 10A, IP54, Class II CCC408S: 365VA, 230Vac,50Hz, Output: 24Vdc 8A, IP54, Class II CCC406S: 275VA, 230Vac,50Hz, Output: 24Vdc 6A, IP54, Class II

Testing procedure and testing location:		
☒ **Testing Laboratory:**	Nemko AS	
Testing location/ address.....	Gaustadalléen 30, 0373, Oslo, Norway	
☐ **Associated Testing Laboratory:**		
Testing location/ address.....		
Tested by (name + signature)	Eirik Sollie	
Approved by (name + signature).....	Torgeir Hansen	
☐ **Testing procedure: Elsewhere**		
Testing location/ address.....		
Tested by (name + signature)		
Approved by (name + signature).....		

Calibration	All instruments used in the tests given in this test report are calibrated and traceable to national or international standards. Further information about traceability will be given on request.
Measurement uncertainty	Measurement uncertainties are calculated for all instruments and instrument set-ups given in this report. Calculations are based on the principles given in the standard EA-4/02 (Dec. 1999), IEC Guide 115:2007, Nemko routine L227 and other relevant internal Nemko-procedures. Further information about measurement uncertainties will be given on request.
Evaluation of results	If not explicitly stated otherwise in the standard, the test is passed if the measured value is equal to or below (above) the limit line, regardless of the measurement uncertainty. If the measured value is above (below) the limit line, the test is not passed - ref IEC Guide 115:2007, and Nemko routine L220. The instrumentation accuracy is within limits agreed by IECEE-CTL (ref. Nemko routine L227).

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

Attachment no.1 Nemko report no. 253035-1 Usability test report according to IEC 60601-1-6:2010 (5 pages)

Attachment no.2 Nemko report no. 253035-2 Usability test report according to IEC 62366:2007 (12 pages)

Attachment no.3 Nemko report no.253035-3 Home healthcare test report according to IEC 60601-1-11:2011 (25 pages)

Attachment no.4 Nemko report no.253035-4 Switzerland Deviation according to IEC 60601-1 (3ed.2005)+CORR.1(2006)+CORR(2007)) (1 page)

Attachment no. 5 Photos (6 pages)

Attachment no. 6 CCC4xxXX_Brugsanvisning_16092014-English (8 pages)

Attachment no. 7 Transformer specification (18 pages)

Attachment no. 8 TRF EMC test report according to IEC 60601-1-2 (32 pages)

Attachment no. 9 Electrical circuit diagrams (2 pages)

Summary of testing

Tests performed (name of test and test clause):	**Testing location:**
All tests according to this standard tested at:	Nemko A/S, Gaustadalléen 30, 0373, Oslo, Norway.

Clause	**Requirement**	**Comment**
4.2.2	General requirement for RISK MANAGEMENT	Risk management not evaluated because EUT is considered component battery charger and this has to be evaluated in end product.
4.6	ME Equipment or ME System parts that contact the patient	EUT is component battery charger and falls outside the definition applied parts. The enclosure and output plug is subjected to the same requirements as for applied part type B.
5.1	Type tests	This test report consists of 3 battery chargers (CCC410S, CCC408S and CCC406S). All test conducted on CCC410S because this charger is considered the worst case, regarding Safety and EMC.
8.5.1	Means of Protection	Due no Risk Management File evaluation of clause 4.6, all accessible parts of the battery charger is evaluated with separation requirements of MOPP. See figure A.12 of this standard.
8.8	Insulation	Some components (see insulation table) used in EUT needs cooling with a heatsink, mounted as part of chassis. For thermal connection between the components and the heatsink, holes have been cut out in the plastic chassis, right above the relevant components. To maintain 2xMOPP, one layer of Gap Pad (see table 8.10) and one layer of kapton tape (see table 8.10) is used between all the relevant components and the heatsink. It is important that the insulating materials are fitted correctly over the holes in chassis. If not done properly, distances may be compromised.
11.7	Biocompatibility	The manufacturer has declared that the equipment complies with requirements of ISO 10993-1. Compliance documented by the manufacturer.
11.1 and 13.1.2	Excessive temperatures in ME Equipment	Temperature limits from table 23 are considered applicable, even though battery charger considered as applied part.
17	Electromagnetic compatibility	The equipment has been tested by Nemko A/S according to IEC 60601-1-2:2007. See attachment no. 8.

Summary of compliance with National Differences

Complinance with Sweden, Austria, United Kingdom and Republic of Korea according to Online CB bulletin.

For national deviations for Switzerland according IEC60601-1:2005+Corr1+Corr2 (ed 3.0) refer attachment no.4.

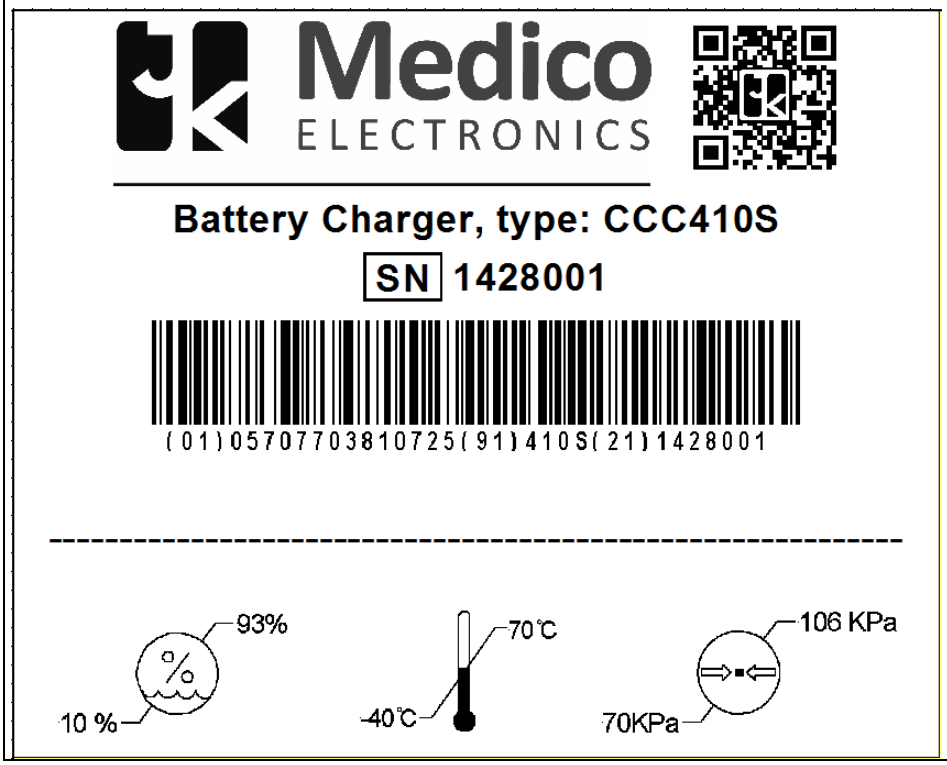
Copy of marking plate

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.

Marking label on EUT

....

Markings for transport and storage.



GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	Portable
Device type (component/sub-assembly/ equipment/ system) :	Component
Intended use (Including type of patient, application location) :	Charging of wheelchair or scooter batteries
Mode of operation ..... :	Continuous
Supply connection.....	Class II, Non-detachable cord
Accessories and detachable parts included ..... :	User manual.
Other options include ..... :	None.
Testing	
Date of receipt of test item(s)..... :	02.2014
Dates tests performed ..... :	02.2014 – 07.2014
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A
- test object does meet the requirement ..... :	Pass (P)
- test object was not evaluated for the requirement .....:	N/E (collateral standards only)
- test object does not meet the requirement ..... :	Fail (F)
Abbreviations used in the report:	
- normal condition ..... : N.C.	- single fault condition .....: S.F.C.
- means of Operator protection ..... : MOOP	- means of Patient protection ....: MOPP

General remarks:

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

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

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :

☐ **Yes**
☒ **Not applicable**

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies)..... :	J.K. Medico ApS Dam Enge 30 DK-3660 Stenløse Denmark

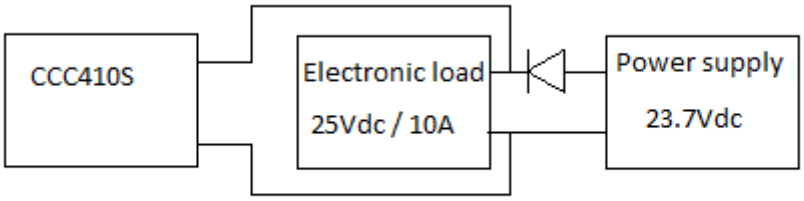
General product information:

The Equipment Under Test (EUT) is a switch-mode battery charger for wheelchairs and scooters not covered in this test report.

The EUT is Class II equipment with top and side enclosure made of insulating material. The bottom side is made from aluminium and is acting as heatsink material for internal components. The EUT provides 2xMOPP insulation from mains to secondary and accessible parts.

The EUT has an output connector for connection to a wheelchair battery, and thus is it evaluated as an applied part type B. The output connector has keyed polarity to prevent reverse polarity connection.

The EUT is intended only for charging lead-acid batteries of type Gel or AGM. During testing battery charger loaded with electroinic load in constant voltage mode set to 25Vdc with a power supply in parallel set to 23.7 Vdc / 0.1A and a diode to prevent current going back to power supply. (23.7Vdv – 0.7V= 23Vdc). This setup was recommended by manufacturer and considered representive. See diagram below:



Maximum recommended ambient (Tmra) = 40°C

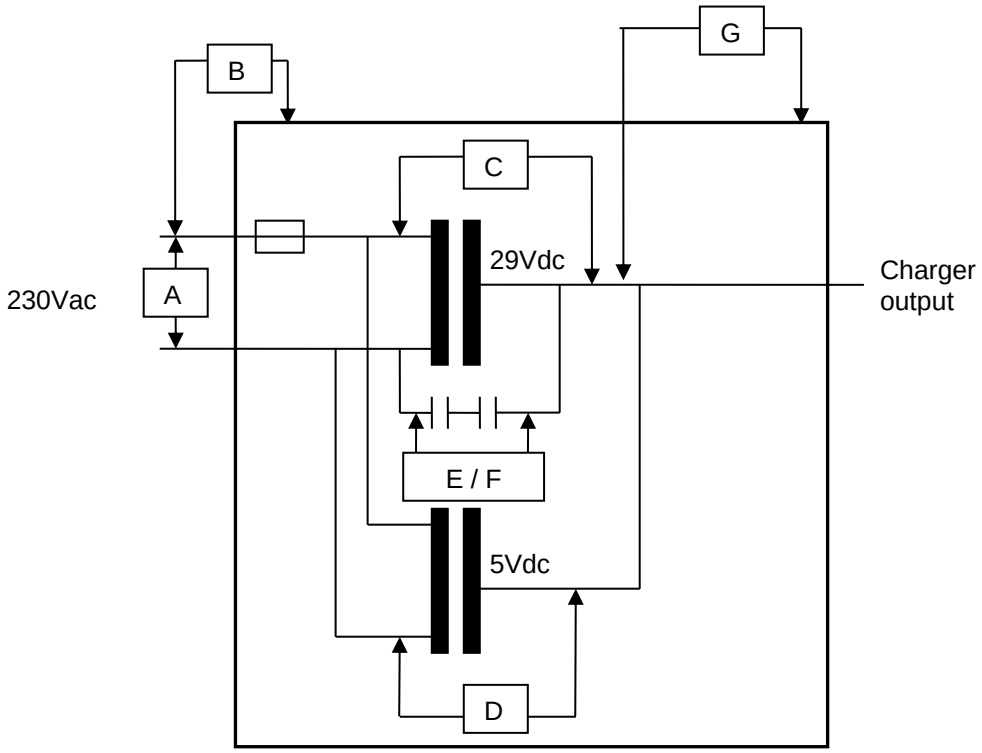
Battery charger series consists of three different chargers: CCC410S, CCC408S and CCC406S. Two last numbers is the charging capacity. 410=10A, 408= 8A and 406= 6A. No hardware difference between different models. Charging current limited by software.

All tests conducted on CCC410S since this the largest charging capacity model.

EUT is considered as component, risk management is not considered in this test report and has to be considered in the end product.

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

INSULATION DIAGRAM



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

TABLE: To insulation diagram		**P**
Pollution degree.....:	**2**	—
Overvoltage category.....:	**II**	—
Altitude.....:	**≤3000 meters**	—
Additional details on parts considered as applied parts.....:	☐ None ☒ Areas Enclosure (See Clause 4.6 for details)	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage Vrms	Working voltage Vpk	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A	1xMOOP	IIIb	230	324	2.5	2.3[2]	4.0	4.0	Across C50 / appliance inlet
B	2xMOPP	IIIb	230	324	8.0	5.0	12.0	12.0	Mains - accessible parts
C	2xMOPP	IIIb	252	380	8.5 *)	5.3 *)	10.7	9.7	T17
C	2xMOPP	IIIb	252	380	8.5 *)	5.3 *)	9.8	9.8	T1/T5 to heatsink
C	2xMOPP	IIIb	252	380	8.5 *)	5.3 *)	9.8	9.8	Below D204/T202 to heatsink
C	2xMOPP	IIIb	252	380	8.0	5.0	9.8	9.8	Below D21 to heatsink
C	2xMOPP	IIIb	230	324	8.0	5.0	8.0	8.0	Across optocouplers
D	2xMOPP	IIIb	230	348	8.0	5.0	8.0	8.0	TR2
E	2xMOPP	IIIb	230	324	8.0	5.0	8.5	8.5	From primary to secondary (C51 and C52)
F	2xMOPP	IIIb	230	324	8.0	5.0	8.5	8.5	From primary to secondary (C53 and C54)
G	2xMOPP	IIIb	-	29Vdc	4.0	2.0	1.1[1)]	1.1[1)]	DC plug - accessible part
G	2xMOPP	IIIb	-	29Vdc	4.0	2.0	4.8	4.8	D22 to heatsink

Supplementary information:

*) Linear interpolation used for calculating distance requirement.

[1)]Distance requirement not fufilled, distance short circuited; touch current and patient leakage current measured (7.4μAac/2.5μAdc).

[2)]Multiplication factor 1.14 due to 3000m altitude according to requirement of IEC 60601-1-11.

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**		**N/A**
4.2.2	**General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007) .....:**	RM is not considered for the component battery charger, the acceptability of risk of the battery charger is determined as part of the end product.	**N/A**
4.2.3	**Evaluating RISK**		**N/A**
4.2.3.1	**a) Compliance with the standard reduces residual risk to an acceptable level**	RM is not considered for the component battery charger, the acceptability of risk of the battery charger is determined as part of the end product.	**N/A**
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN .....:	See above	**N/A**
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.	See above	**N/A**
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.	See above	**N/A**
4.2.3.2	**MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.**	See above	**N/A**
4.3	**Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.**	RM is not considered for the component battery charger, the acceptability of risk of the battery charger is determined as part of the end product.	**N/A**
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.	See above	**N/A**
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated	See above	**N/A**
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE.....:	See above	**N/A**
	- RISK CONTROL measures implemented	See above	**N/A**
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented	See above	**N/A**
4.4	**EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE .....:**	RM is not considered for the component battery charger, the acceptability of risk of the battery charger is determined as part of the end product.	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
4.5	**Alternative RISK CONTROL methods utilized:**	RM is not considered no alternative means of addressing particular risks were considered	**N/A**
	RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
	Alternative means based scientific data or clinical opinion or comparative studies .....:	See above	**N/A**
4.6	**RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10.....:**	RM is not considered in the investigation of component battery charger. Enclosure and DC output plug is subjected to the same requirements as applied part type B. See summary of testing.	**N/A**
	MANUFACTURER assesses the risk of accessible parts coming into contact with the patient ....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
	Assessment identified the APPLIED PART TYPE requirements.....:	See above	**N/A**
4.7	**ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2.....:**	RM is not included; component battery charger remained Single Fault Safe, acceptability of risk to be determined as part of the end product.	**P**
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested.....: **(ISO 14971 Cl. 4.2-4.4)**	RM is not included; component battery charger remained Single Fault Safe, acceptability of risk to be determined as part of the end product.	**N/A**
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically .....:		**P**
4.8	**All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified ....:**	See table 8.10	**P**
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS	RM is not included; component battery charger remained Single Fault Safe, acceptability of risk to be determined as part of the end product.	**N/A**

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RISK MANAGEMENT PROCESS **assesses components to identify components where the failure results in a** HAZARDOUS SITUATION **for components used outside their ratings .....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
	MANUFACTURER **identified components where the failure results in a** HAZARDOUS SITUATION**...:**	No Components with high integrity characteristics	**N/A**
	Components determined to be acceptable where used as a MEANS OF PROTECTION **.....:**	RM is not included; component battery charger remained Single Fault Safe, acceptability of risk to be determined as part of the end product.	**N/A**
	Reliability of components used as MEANS OF PROTECTION **assessed for conditions of use in** ME EQUIPMENT**, and they complied with one of the following**	See table 8.10	**P**
	a) Applicable safety requirements of a relevant IEC or ISO standard	See table 8.10	**P**
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard	See table 8.10	**P**
4.9	**A** COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS **provided and selected appropriately.....:**	RM not included. No Components with high integrity characteristics.	**N/A**
	RISK MANAGEMENT FILE **includes an assessment to determine if the failure of components results in unacceptable** RISK **.....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC**:**	No Components with high integrity characteristics	**N/A**
4.10	**Power supply**		**P**
4.10.1	ME EQUIPMENT **is suitable for connection to indicated power source** (select applicable)**.....:**	Connected to mains with mains cord/plug	**P**
4.10.2	**Maximum rated voltage for** ME EQUIPMENT **intended to be connected to** SUPPLY MAINS**:**	CCC410S: 230VAC CCC408S: 230VAC CCC406S: 230VAC	**P**
	- 250 V for HAND-HELD ME EQUIPMENT **(V)..... :**		**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)..... :**		**P**
	– 500 V for all other ME EQUIPMENT **and** ME SYSTEMS		**N/A**
4.11	**Power input**		**P**

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%..... :	See appended Table 4.11	**P**
5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		**P**
5.1	**Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods .....:**	RM not provided: All test were conducted.	**N/A**
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. **(ISO 14971 Cl. 4.2-4.4)**	RM not included: End product Risk Management must determine the need for simultaneous fault tests.	**N/A**
5.3	**Tests conducted within the environmental conditions specified in technical description**		**P**
	Temperature (ºC), Relative Humidity (%) .....:	-10ºC - +40ºC, 93%	**—**
	Atmospheric Pressure (kPa) .....:	70-106kPa	**—**
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) .....:**	Refer to copy of marking plate and appended tables.	**P**
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)..... :	Refer to copy of marking plate and appended tables.	**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..... :	One rated voltage only	**N/A**
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered..... :	Not intended for dc supply connection.	**N/A**
	e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions..... :	None.	**N/A**
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	Equipment is a battery charger, connected to mains.	**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..... :**	Refer below:	**P**

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +32°C for indicated time	T = 24°C 168h / 95% RH	—
5.9	**Determination of APPLIED PARTS and ACCESSIBLE PARTS**		**P**
5.9.1	**APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS ..... :**	See clause 4.6 Remark	**N/A**
5.9.2	**ACCESSIBLE PARTS**		**P**
5.9.2.1	**Accessibility determined using standard test finger of Fig. 6**	See 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**	No openings.	**N/A**
5.9.2.3	**Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS ..... :**	No actuating mechanisms	**N/A**
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL.....:	See above	**N/A**
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		**P**
6.2	**CLASS I ME EQUIPMENT, externally powered**		**N/A**
	CLASS II ME EQUIPMENT, externally powered		**P**
	INTERNALLY POWERED ME EQUIPMENT		**N/A**
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements	The equipment is a battery charger, must be considered for the equipment the charger is connected to in end use.	**N/A**
	TYPE B APPLIED PART	Component battery charger, no applied part.	**N/A**
	TYPE BF APPLIED PART	Component battery charger, no applied part.	**N/A**
	TYPE CF APPLIED PART	Component battery charger, no applied part.	**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS	Component battery charger, no applied part.	**N/A**
6.3	**ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529 ..... :**	IP54	**P**

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
6.4	**ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use..... :**		**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**	Battery charger not investigated for oxygen rich environment	**N/A**
6.6	**CONTINUOUS or Non-CONTINUOUS OPERATION ..... :**	Continuous operation considered.	**P**
7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		**P**
7.1.2	**Legibility of Markings Test for Markings specified in Clause 7.2-7.6.....:**	See Appended Table 7.1.2	**P**
7.1.3	**Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE**	See appended Table 7.1.3	**P**
7.2	**Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**		**P**
7.2.1	**At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings .....:**	See attached copy of Marking Plate	**P**
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS .....:		**P**
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT	Markings on EUT	**N/A**
	Single use item marked.....:	Not for single use.	**N/A**
7.2.2	**ME EQUIPMENT marked with:**	See attached copy of marking plate	**P**
	– the name or trademark and contact information of the MANUFACTURER	See attached copy of marking plate	**P**
	– a MODEL OR TYPE REFERENCE	See attached copy of Marking Plate	**P**
	– a serial number or lot or batch identifier; and	See attached copy of marking plate	**P**
	– the date of manufacture or use by date	See attached copy of marking plate	**P**
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	No detachable components.	**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)**	No detachable components	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and	No detachable components.	**N/A**
	– a MODEL OR TYPE REFERENCE	No detachable components	**N/A**
	Software forming part of a PEMS identified with a unique identifier.....:	No PEMS.	**N/A**
7.2.3	**Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS**	Symbol 11 on table D.1 used	**P**
	Safety sign 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	Symbol 11 on table D.1 used	**N/A**
7.2.4	**ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and .....:**	No accessories provided.	**N/A**
	- with a MODEL or TYPE REFERENCE	No accessories provided.	**N/A**
	– a serial number or lot or batch identifier	No accessories provided.	**N/A**
	– the date of manufacture or use by date	No accessories provided.	**N/A**
	Markings applied to individual packaging when not practical to apply to ACCESSORIES	No accessories provided.	**N/A**
7.2.5	**ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following**	Component; final determination to be performed in the end-product	**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	Component; final determination to be performed in the end-product	**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	Component; final determination to be performed in the end-product	**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.	Component; final determination to be performed in the end-product	**N/A**
7.2.6	**Connection to the Supply Mains**		**P**
	Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point	Marking appearing outside on EUT an adjacent to the connection point.	**P**
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT	Not permanently installed ME Equipment	**N/A**
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V).....:	230V	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)...:	No multiple rated supply voltages or multiple rated voltages ranges,	**N/A**
	– Nature of supply and type of current.....:	Single phase equipment. 230V, 50Hz, Class II.	**P**
	Symbols 1-5, Table D.1 (used for same parameters.....:	Single phase equipment. Marked with 50Hz.	**P**
	– RATED supply frequency or RATED frequency range in hertz.....:	CCC410S/CCC408S/CCC406 S, marked 50Hz	**P**
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT .....:	Symbol 9 of table D.1 used.	**P**
7.2.7	**RATED input in amps or volt-amps, (A, VA) .....:**		**P**
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) .....:	Rated input in both volt-amps and watts.	**P**
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W).....:	Only rated for 230V, markings in and W/VA.	**P**
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W) .....:	Limits do not differ by more than 10% from mean value.	**P**
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA).....:		**N/A**
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W).....:	Must be evaluated in end product.	**N/A**
7.2.8	**Output connectors**		**P**
7.2.8.2	**Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment**	Marked with output rating. Refer below.	**P**
	Rated Voltage (V), Rated Current (A).....:	CCC410S: 24Vdc, 10A CCC408S: 24Vdc, 8A CCC406S: 24Vdc, 6A	**—**
	Rated Power (W), Output Frequency (Hz) .....:	DC Output	**—**
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....:**	EUT marked with IP54	**P**
7.2.10	**Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols .....:**	No Applied Parts in EUT. Charger subjected to same requirements as for applied part type B	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	TYPE B APPLIED PARTS with symbol 19 of Table D.1	See above	**N/A**
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 .....:	See above	**N/A**
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 .....:	See above	**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 .....:	See above	**N/A**
	Proper symbol marked adjacent to or on connector for APPLIED PART .....:	See above	**N/A**
	Safety sign 2 of Table D.2 placed near relevant outlet.....:	See above	**N/A**
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use .....:	See above	**N/A**
7.2.11	**ME EQUIPMENT suitable for CONTINUOUS OPERATION**	Continuous operation considered.	**P**
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time .....:	Continuous operation considered.	**N/A**
7.2.12	**Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder**	No operator accessible fuses.	**N/A**
	Fuse type.....:		**—**
	Voltage (V) and Current (A) rating .....:		**—**
	Operating speed (s) and Breaking capacity.....:		**—**
7.2.13	**Physiological effects – safety sign and warning statements .....:**	No physiological effects	**N/A**
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**	No physiological effects	**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**	None.	**N/A**
7.2.15	**Requirements for cooling provisions marked ...:**	No special cooling requirements.	**N/A**
7.2.17	**Packaging marked with special handling instructions for transport and/or storage.....:**	Refer to copy of marking plate.	**P**
	Permissible environmental conditions marked on outside of packaging .....:	Refer to copy of marking plate.	**P**
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK .....:	No safety risk when unpacking the battery charger.	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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 safety risk when unpacking the battery charger.	**N/A**
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization	No sterile parts or accessories.	**N/A**
7.2.18	**RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and .....:**	No connections to gas or liquid.	**N/A**
	- the RATED flow rate also marked	No connections to gas or liquid.	**N/A**
7.2.19	**Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL.....:**	No functional earth.	**N/A**
7.2.20	**Removable protective means marked to indicate the necessity for replacement when the function is no longer needed.....:**	No special protective means.	**N/A**
7.2.21	**MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms.....:**	No interlock provided.	**N/A**
7.3	**Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts**		**N/A**
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 lamps.	**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 lamps.	**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.....:**		**N/A**
7.3.3	**Type of battery and mode of insertion marked:**	No batteries provided.	**N/A**
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL .....:	No batteries provided.	**N/A**
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK.....:	No batteries or fuel cells provided.	**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an unacceptable RISK if replaced incorrectly .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**	No batteries or fuel cells provided.	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARD .....:	No batteries or fuel cells provided.	**N/A**
7.3.4	**Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified .....:**	No replaceable fuses or thermal cut-outs. Fuses soldered on to PCB.	**N/A**
	Voltage (V) and Current (A) rating .....:		**—**
	Operating speed(s), size & breaking capacity .:		**—**
7.3.5	**PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1**	Class II equipment.	**N/A**
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made	Class II equipment.	**N/A**
7.3.6	**Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS**	Class II equipment.	**N/A**
7.3.7	**Terminals for supply conductors marked adjacent to terminals.....:**	Class II equipment, No wiring terminals. No hazard if supply connections to the PBC inside equipment are swapped.	**N/A**
	Terminals for supply connections are not marked, the RISK MANAGEMENT FILE includes an assessment of the RISKS resulting from misconnections .....: (ISO 14971 Cl. 4.3)	Class II equipment, No wiring terminals. No hazard if supply connections to the PBC inside equipment are swapped.	**N/A**
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	Connections for supply connections on PCB marked with J1 and J2	**N/A**
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3	Not permanently installed equipment.	**N/A**
	Marking for connection to a 3-phase supply, complies with IEC 60445	Class II equipment. Single phase equipment.	**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	Connections for internal supply connections on PCB marked with J1 and J2	**N/A**
7.3.8	**"For supply connections, use wiring materials suitable for at least X °C" or equivalent, marked at the point of supply connections**	No terminal box or wiring compartment.	**N/A**
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made	No terminal box or wiring compartment.	**N/A**
7.4	**Marking of controls and instruments**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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 switches.	**N/A**
	– indicated by an adjacent indicator light, or	No switches.	**N/A**
	– indicated by other unambiguous means	No switches.	**N/A**
	The “on/off” positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, and	No switches.	**N/A**
	– status indicated by adjacent indicator light	No switches.	**N/A**
	– status indicated by other unambiguous means	No switches.	**N/A**
	The “on/off” positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or	No switches.	**N/A**
	– status indicated by adjacent indicator light	No switches.	**N/A**
	– status indicated by other unambiguous means	No switches.	**N/A**
7.4.2	**Different positions of control devices/switches indicated by figures, letters, or other visual means**	No switches.	**N/A**
	RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2, 6.3)**	No Switches.	**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 switches.	**N/A**
	– or an indication of direction in which magnitude of the function changes	No switches.	**N/A**
	Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009	No Switches.	**N/A**
7.4.3	**Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units**	No numeric indicators.	**N/A**
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units	No numeric indicators.	**N/A**
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3 .....:	No numeric indicators.	**N/A**
7.5	**Safety signs**		**N/A**
	Safety sign with established meaning used	No safety signs used	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**	No safety signs used	**N/A**
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT	No safety signs used	**N/A**
	Specified colours in ISO 3864-1 used for safety signs.....:	No safety signs used	**N/A**
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)	No safety signs used	**N/A**
	Safety signs including any supplementary text or symbols described in instructions for use	No safety signs used	**N/A**
	- and in a language acceptable to the intended OPERATOR	No safety signs used	**N/A**
7.6	**Symbols**		**P**
7.6.1	**Meanings of symbols used for marking described in instructions for use.....:**	Refer to 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**	Refer to user manual and copy of marking plate.	**P**
7.7	**Colours of the insulation of conductors**		**P**
7.7.1	**PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation**	Class II equipment.	**N/A**
7.7.2	**Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations**	Class II equipment.	**N/A**
7.7.3	**Green and yellow insulation identify only following conductors:**	Class II equipment.	**N/A**
	– PROTECTIVE EARTH CONDUCTORS	Class II equipment.	**N/A**
	– conductors specified in 7.7.2	Class II equipment.	**N/A**
	– POTENTIAL EQUALIZATION CONDUCTORS	Class II equipment.	**N/A**
	– FUNCTIONAL EARTH CONDUCTORS	Class II equipment.	**N/A**
7.7.4	**Neutral conductors of POWER SUPPLY CORDS are "light blue"**	See appended table 8.10	**P**
7.7.5	**Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1**	See appended table 8.10	**P**
7.8	**Indicator lights and controls**		**P**
7.8.1	**Red indicator lights used only for Warning**	Red LED used to indicate Error (Battery not connected)	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Yellow indicator lights used only for Caution	Yellow LED used to indicate Charging	**P**
	Green indicator lights used only for Ready for use	Green LED used to indicate Charging completed.	**P**
	Other colours: Meaning other than red, yellow, or green (colour, meaning) .....:	No other LEDs or lights.	**N/A**
7.8.2	**Red used only for emergency control**	No Controls.	**N/A**
7.9	**ACCOMPANYING DOCUMENTS**		**P**
7.9.1	**ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description**	User manual, attachment no. 6 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 .....:	Included in user manual	**P**
	– MODEL or TYPE REFERENCE .....:	Included in 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	Documents provided in paper and electronic format.	**P**
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	Specified in user manual.	**P**
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	Considered	**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:**	Included in user manual.	**P**
	– frequently used functions,	Battery charger. Only one used function.	**P**
	– known contraindication(s) to use of ME EQUIPMENT	No known contraindication.	**N/A**
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient	EUT is not to be serviced or maintained while in use with the patient.	**P**
	– name or trademark and address of the MANUFACTURER	Included in user manual.	**P**
	– MODEL OR TYPE REFERENCE	Included in user manual.	**P**
	Instruction for use included the following when the PATIENT is an intended OPERATOR:	Patient is an intended operator.	**P**
	– the PATIENT is an intended OPERATOR	Included	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– warning against servicing and maintenance while the ME EQUIPMENT is in use	Included	**P**
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and	Battery charger. Only one function.	**P**
	–maintenance the PATIENT can perform	None	**N/A**
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	Classifications as in Clause 6 included and all symbols/markings explained.	**P**
	Instructions for use are in a language acceptable to the intended operator	Instructions for use written in English inspected.	**P**
7.9.2.2	**Instructions for use include all warning and safety notices**		**P**
	Warning statement for CLASS I ME EQUIPMENT included	Class II	**N/A**
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments		**N/A**
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	Included in user manual	**P**
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	No multiple socket outlet	**N/A**
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	The battery charger is not used for specific investigations or treatments. No socket outlets.	**N/A**
7.9.2.3	**Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions**	Connection to mains only	**N/A**
7.9.2.4	**Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source**	No additional power source.	**N/A**
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**	No additional power source.	**N/A**
	Where the RISK is unacceptable, the IFU includes a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time..... :	No additional power source.	**N/A**
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided ..... :	No additional power source.	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK ..... :	No additional power source.	**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**	Included in user manual	**P**
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to	EUT is a battery charger, must be evaluated in end product.	**N/A**
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected	No SIP/SOP or Network/Data couplings	**N/A**
	APPLIED PARTS specified	No applied parts	**N/A**
7.9.2.6	**Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation**	Equipment is battery charger. No installation required.	**N/A**
7.9.2.7	**Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device**	Disconnecting device is power supply cord.	**N/A**
7.9.2.8	**Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation**	Included in user manual	**P**
7.9.2.9	**Information provided to operate ME EQUIPMENT**	Included in user manual	**P**
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	Included in user manual	**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**	Included in user manual	**P**
7.9.2.11	**Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT**	Included 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**	No cleaning, disinfection or sterilization methods. All applicable parameters included 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	No such parts	**N/A**
7.9.2.13	**Instructions provided on preventive inspection, calibration, maintenance and its frequency**	No required preventive inspection or maintenance.	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	See above	**N/A**
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	See above	**N/A**
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	See above	**N/A**
7.9.2.14	**A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided**	No detachable parts.	**N/A**
	Other equipment providing power to ME SYSTEM sufficiently described	No detachable parts.	**N/A**
7.9.2.15	**Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for use ..... :**	No waste products, residues etc.	**N/A**
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)**	Information in 7.9.3 is part of user 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**	EUT not emitting radiation for medical purposes.	**N/A**
7.9.2.18	**The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile indicate that they have been sterilized and the method of sterilization**	No sterilized accessories.	**N/A**
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization	No sterilized accessories.	**N/A**
7.9.2.19	**The instructions for use contain a unique version identifier..... :**	Version 16092014	**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**	Included in user manual	**P**
	Technical description separable from instructions for use contains required information, as follows		**P**
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT	Classifications in clause 6 included.	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and	Included in user manual	**P**
	a unique version identifier ..... :	Version 16092014	**P**
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description		**N/A**
7.9.3.2	**The technical description contains the following required information**		
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT ..... :	No external fuses.	**N/A**
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and	No serviceable parts.	**N/A**
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	No serviceable parts.	**N/A**
	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 serviceable parts.	**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	No serviceable parts.	**N/A**
7.9.3.3	**Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair**	No serviceable parts.	**N/A**
7.9.3.4	**Means used to comply with requirements of 8.11.1 clearly identified in technical description**	No serviceable parts.	**N/A**

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**	See table 8.7 and 13.1	**P**
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION ..... : **(ISO 14971 Cl. 4.3)**	Component battery charger not subjected to risk management analysis.	**N/A**
8.2	**Requirements related to power sources**		**N/A**
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	No separate power source.	**N/A**
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified	No separate power source.	**N/A**
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined	No 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	No connection to an external dc power source.	**N/A**
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE	No connection to an external dc power source.	**N/A**
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset	No connection to an external dc power source.	**N/A**
8.3	**Classification of APPLIED PARTS**		**N/A**
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	EUT is battery charger, no applied parts.	**N/A**
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART	EUT is battery charger, no applied parts.	**N/A**
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	EUT is battery charger, no applied parts.	**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 :	See appended Table 8.7	**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	See appended Table 8.7	**N/A**

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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) ..... :	Output from the battery charger is only on when connected to a battery, no output voltage or energy available when charger output is disconnected.	**P**
	d) Voltage and energy limits specified in c) above also applied to the following:		**N/A**
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	No openings in enclosure.	**N/A**
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL	No openings in enclosure.	**N/A**
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N	No openings in enclosure.	**N/A**
	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 openings in enclosure.	**N/A**
	Test repeated with a TOOL specified in instructions for use	No openings in enclosure.	**N/A**
	Test rod freely and vertically suspended through openings on top of ENCLOSURE	No openings in 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 openings in enclosure.	**N/A**
	A TOOL is required when it is possible to prevent the devices from operating	No openings in enclosure.	**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 .. :	See appended Table 8.4.3	**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 access covers	**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 access covers	**N/A**
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description.....:		**N/A**
8.5	**Separation of parts**		**P**
8.5.1	**MEANS OF PROTECTION (MOP)**		**P**
8.5.1.1	**Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4**	Two means of protection provided to prevent accessible parts from exceeding limits of 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	Considered	**P**
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10	See table 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.....:	See appended Table 8.8.3	**P**
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		**P**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6	Class II equipment	**NIA**
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION .....:	See appended Tables 8.8.3 and 8.10	**P**
	Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c. .....:	No single Y1 capacitors used for 2 x MOPP.	**N/A**
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		**P**
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (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:	See table to insulation diagram, area A	**P**
	– dielectric strength test .....:	See above	**P**
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION	See above	**P**
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:	See above	**P**
	– limits of Tables 13 to 16 (inclusive); or	See above	**P**
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION	See above	**P**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6	Class II equipment.	**N/A**
	– or with requirements and tests of IEC 60950-1 for protective earthing.....:	Class II equipment.	**N/A**
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION .....:		**N/A**
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION.....:		**N/A**
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		**N/A**
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) .....:		
	Points and applied parts at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 were examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION		**N/A**
	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.....:		**N/A**
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION.....:		**N/A**
8.5.2	**Separation of PATIENT CONNECTIONS**		**N/A**
8.5.2.1	**PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAX. MAINS VOLTAGE.....:**	EUT is components battery charger. No patient connections.	**N/A**
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART	See above	**N/A**

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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	See above	**N/A**
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS ..... :	See above	**N/A**
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	See above	**N/A**
	LEAKAGE CURRENT tests conducted per 8.7.4 .... :	See above	**N/A**
	Dielectric strength test conducted per 8.8.3 .... :	See above	**N/A**
	CREEPAGE and CLEARANCES measured ..... :	See above	**N/A**
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s	See above	**N/A**
8.5.2.2	**PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED .... :**	EUT is components battery charger. No patient connections.	**N/A**
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and	See above	**N/A**
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low	See above	**N/A**
	LEAKAGE CURRENT tests conducted per 8.7.4 .... :	See above	**N/A**
	Dielectric strength test conducted per 8.8.3 .... :	See above	**N/A**
	Relevant CREEPAGE and CLEARANCES measured	See above	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISK of metal ACCESSIBLE PARTS contacting a source of voltage or LEAKAGE CURRENT above the limits..... : **(ISO 14971 Cl. 4.2-4.4, 5)**	See above	**N/A**
8.5.2.3	**A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE**		**N/A**
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT..... :	EUT is components battery charger. No patient connections.	**N/A**
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm	See above	**N/A**
	– conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1	See above	**N/A**
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,	See above	**N/A**
	Test finger test (10 N) ..... :	See above	**N/A**
	Except when RISK MANAGEMENT PROCESS includes an assessment of RISKS resulting from contact with objects other than mains sockets or flat surfaces ..... : **(ISO 14971 Cl. 4.2-4.4, 5)**	See above	**N/A**
8.5.4	**WORKING VOLTAGE**		**P**
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V)..... :	230V	**P**
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V) ..... :		**N/A**
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V) ..... :	See Insulation Diagram and Insulation Table	**P**
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth	No patient connections	**N/A**
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V) ..... :	No patient connections of an F-type applied part.	**N/A**
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	No defibrillation proof applied parts.	**N/A**
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V) ..... :	No motors in equipment	**N/A**
8.5.5	**DEFIBRILLATION-PROOF APPLIED PARTS**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.5.5.1	**Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety**	No defibrillation proof applied parts.	**N/A**
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:	See above	**N/A**
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator .....:	See above	**N/A**
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS .....:	See above	**N/A**
8.5.5.2	**Means provided to limit energy delivered to a 100 Ω load.....:**	See above	**N/A**
8.6	**Protective and functional earthing and potential equalization of ME EQUIPMENT**		**P**
8.6.1	**Requirements of 8.6.2 to 8.6.8 applied**	Class II equipment	**N/A**
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8	IEC 60950-1 not considered.	**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.....:**	Class II equipment	**N/A**
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL	See above	**N/A**
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside.....:	See above	**N/A**
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL	See above	**N/A**
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing	See above	**N/A**
8.6.3	**PROTECTIVE EARTH CONNECTION not used for a moving part,**	Class II equipment	**N/A**
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.6.4	**a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop .....:**	Class II equipment	**N/A**
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits .....:	See above	**N/A**
8.6.5	**Surface coatings**		**N/A**
	Poorly conducting surface coatings on conductive elements removed at the point of contact	Class II equipment, no surface coatings.	**N/A**
	Coating not removed when requirements for impedance and current-carrying capacity met	See above	**N/A**
8.6.6	**Plugs and sockets**		**N/A**
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections	Class II equipment	**N/A**
	- applied also where interchangeable parts are PROTECTIVELY EARTHED	See above	**N/A**
8.6.7	**Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR**		**N/A**
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE	No terminal for connection of a potential equalization conductor.	**N/A**
	–accidental disconnection avoided in NORMAL USE	See above	**N/A**
	– Terminal allows conductor to be detached without a TOOL	See above	**N/A**
	– Terminal not used for a PROTECTIVE EARTH CONNECTION	See above	**N/A**
	– Terminal marked with symbol 8 of Table D.1	See above	**N/A**
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard	See above	**N/A**
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR	See above	**N/A**
8.6.8	**FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION**	Class II equipment	**N/A**
8.6.9	**Class II ME EQUIPMENT**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow		**N/A**
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.		**N/A**
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS		**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**	See appended Tables 8.7	**P**
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)	Class II equipment.	**N/A**
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time	Class II equipment.	**N/A**
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION	See appended tables.	**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	Considered.	**P**
8.7.3	**Allowable Values**		**P**
	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**

Revised page 2014.09.23, due to typo in verdict in clause 8.6.9. Eirik Sollie Eirik Sollie

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC}) .....:	See appended Table 8.7	**P**
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC}).....:	Class II equipment.	**N/A**
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 .....:	Class II 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 conductor.	**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)		**N/A**
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	IEC 60601-1 considered.	**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:		
	a) 0.4 mm, min, distance through insulation, or	Refer to appended tables 8.10 and 8.8.3	**P**
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		**P**
	– at least two layers of material, each passed the appropriate dielectric strength test .....:	Refer to appended table 8.10	**N/A**
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test .....:	Refer to appended table 8.10	**P**
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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		**P**
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		**N/A**
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L	Separately certified TIW used in T17 and TR2. Refer to appended table 8.10	**N/A**
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	Separately certified TIW used in T17 and TR2. Refer to appended table 8.10	**P**
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		**N/A**
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		**N/A**
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded	Separately certified TIW used in T17 and TR2. Refer to appended table 8.10	**P**
	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	Separately certified TIW used in T17 and TR2. Refer to appended table 8.10	**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 ..... :		**P**
	Finished component complied with routine dielectric strength tests of 8.8.3 ..... :		**N/A**
	Tests of Annex L not repeated since material data sheets confirm compliance ..... :	Separately certified TIW used in T17 and TR2. Refer to appended table 8.10	**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**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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)**	Component battery charger not subjected to risk management analysis	**N/A**
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat .....:	Refer below	**N/A**
	Tests conducted in absence of satisfactory evidence for resistance to heat .....:		**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) .....:	See appended Table 8.8.4.1	**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	Tested to IP54	**P**
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	None.	**N/A**
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	None.	**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		**N/A**
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h		**N/A**
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.9.1.1	**CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive) ..... :**	Refer to Insulation Diagram	**P**
8.9.1.15	**CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1**	No defibrillation proof parts	**N/A**
8.9.2	**a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION , min CREEPAGE and CLEARANCES not applied ..... :**	See appended Table 8.9.2	**P**
8.9.3	**Spaces filled by insulating compound**		**P**
8.9.3.1	**Only solid insulation requirements applied where distances between conductive parts filled with insulating compound**	Optocouplers are separately certified, refer to appended table 8.10	**P**
	Thermal cycling, humidity preconditioning, and dielectric strength tests		**N/A**
8.9.3.2	**For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage) ..... :**		**N/A**
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		**N/A**
8.9.3.3	**Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint**		**N/A**
	A winding of solvent-based enamelled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		**N/A**
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage ..... :		**N/A**
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage		**N/A**
8.10	**Components and wiring**		**P**
8.10.1	**Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely ..... :**		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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)**	Component battery charger not subjected to risk management analysis	**N/A**
8.10.2	**Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment .....:**	AC terminals soldered onto PCB. Fast on spade terminals and crimp female fast on.	**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 .....:**		**N/A**
8.10.4	**Cord-connected HAND-HELD parts and cord-connected foot-operated control devices**		**N/A**
8.10.4.1	**Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION**		**N/A**
8.10.4.2	**Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3**		**N/A**
	Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3		**N/A**
8.10.5	**Mechanical protection of wiring**		**P**
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges.....:		**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**		**N/A**
8.10.7	**a) Insulating sleeve adequately secured .....:**		**N/A**

Revised page 2014.09.23, due to typo in Result-Remark column in clause 8.10.2. Eirik Sollie Eirik Sollie

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics		**N/A**
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C .....:		**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.....:**	Plug on mains cord used. 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	See above	**N/A**
	- the isolation device specified in the ACCOMPANYING DOCUMENTS	See above	**N/A**
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description .....:	Plug on mains cord used. See appended Table 8.10	**P**
	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 .....:		**N/A**
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead		**P**
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		**N/A**
	f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH .....:		**P**
	g) A fuse or a semiconductor device not used as an isolating means	Plug on mains cord used. See appended Table 8.10	**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	Plug on mains cord used. See appended Table 8.10	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering		**N/A**
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage		**N/A**
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		**N/A**
	Standard test finger applied		**P**
8.11.2	**MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2**		**N/A**
8.11.3	**POWER SUPPLY CORDS**		**P**
8.11.3.1	**MAINS PLUG not fitted with more than one POWER SUPPLY CORD**		**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**
	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 ..... :		**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 ..... :**		**N/A**
8.11.3.5	**Cord anchorage**		**P**
	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		**P**
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or	Refer below:	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or	Cord anchorage and enclosure made of insulation materials; heat sink is made of aluminium, heat sink located on other side of equipment, away from cord anchorage.	**P**
	– metal provided with an insulating lining affixed to cord anchorage	2xMOPP, Class II equipment.	**N/A**
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation	No screws in cord anchorage.	**P**
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components		**N/A**
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals	Class II equipment.	**N/A**
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		**P**
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 .....:	See appended Table 8.11.3.5	**P**
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests	See appended Table 8.11.3.5	**P**
	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	See appended Table 8.11.3.5	**P**
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		**P**
	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		**P**
8.11.3.6	**POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment**		**P**
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		**N/A**
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram attached to the free end of cord (g).....:	See appended Table 8.11.3.6	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		**N/A**
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D .....:	See appended Table 8.11.3.6	**P**
8.11.4	**MAINS TERMINAL DEVICES**		**P**
8.11.4.1	**PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection**	6.3mm insulated terminals.	**P**
	Terminals alone are not used to keep conductors in position	Insulation of terminal clamps cable insulation.	**P**
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors	Not used.	**N/A**
	Screws and nuts clamping external conductors do not serve to secure any other component		**N/A**
8.11.4.2	**Arrangement of MAINS TERMINAL DEVICES**		**P**
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection	Class II.	**N/A**
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		**P**
	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	6.3mm insulated terminals crimped on mains cord conductors (Live and Neutral). See appended table 8.10	**P**
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**		**P**
8.11.4.4	**Terminals with clamping means for a rewireable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened**	Quick plug terminals used.	**P**
8.11.4.5	**Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewireable POWER SUPPLY CORD to allow for connection of conductors**		**P**
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test		**N/A**
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection . :	One fuse provided class II equipment.	**P**
	- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT ..... :	One fuse provided class II equipment.	**P**
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	Not permanently installed equipment.	**N/A**
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART		**N/A**
	Protective devices have adequate breaking capacity 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	Class II equipment.	**N/A**
	Justification for omission of fuses or OVER-CURRENT RELEASES documented ..... :		**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.	**P**
	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)	See above	**N/A**
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and	See above	**N/A**
	RISK CONTROLS implemented ..... :	See above	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	All RISKS associated with moving parts have been reduced to an acceptable level	See above	**N/A**
9.2.2	**TRAPPING ZONE**		**N/A**
9.2.2.1	**ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:**	No trapping zones.	**N/A**
	– Gaps in Clause 9.2.2.2, or	See above	**N/A**
	– Safe distances in Clause 9.2.2.3, or	See above	**N/A**
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or	See above	**N/A**
	– Continuous activation in Clause 9.2.2.5	See above	**N/A**
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM	See above	**N/A**
9.2.2.2	**A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20 ..... :**	No trapping zones.	**N/A**
9.2.2.3	**A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008 .....:**	No trapping zones.	**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 zones.	**N/A**
9.2.2.4.2	**FIXED GUARDS held in place by systems that can only be dismantled with a TOOL**	No trapping zones.	**N/A**
9.2.2.4.3	**Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open**	No trapping zones.	**N/A**
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,	See above	**N/A**
	– absence or failure of one of their components prevents starting, and stops moving parts	See above	**N/A**
	Movable GUARDS complied with any applicable tests	See above	**N/A**
9.2.2.4.4	**Other RISK CONTROL designed and incorporated into to the control system stops movement and**	Component battery charger not subjected to risk management.	**N/A**
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or	See above	**N/A**
	ME EQUIPMENT is SINGLE FAULT SAFE	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.2.2.5	**Continuous activation**		**N/A**
	Continuous activation used as a RISK CONTROL, complies with the following	Component battery charger not subjected to risk management analysis.	**N/A**
	a) movement was in OPERATOR'S field of view	See above	**N/A**
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR	See above	**N/A**
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or	See above	**N/A**
	- the continuous activation system is SINGLE FAULT SAFE	See above	**N/A**
9.2.2.6	**Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement**	No moving parts	**N/A**
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK	See above	**N/A**
9.2.3	**Other MECHANICAL HAZARDS associated with moving parts**		**N/A**
9.2.3.1	**Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated**	No moving parts	**N/A**
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or	See above	**N/A**
	- activation does not result in an unacceptable RISK	See above	**N/A**
9.2.3.2	**Over travel past range limits of the ME EQUIPMENT prevented ..... :**	No moving parts	**N/A**
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse ... :	See above	**N/A**
9.2.4	**Emergency stopping devices**		**N/A**
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power..... :	No emergency stopping device.	**N/A**
	a) Emergency stopping device reduced RISK to an acceptable level	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RISK MANAGEMENT FILE indicates the use of an emergency stopping device reduces the RISK to an acceptable level..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.6)**	See above	**N/A**
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM	See above	**N/A**
	c) Emergency stopping device actuator was readily accessible to OPERATOR	See above	**N/A**
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT	See above	**N/A**
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD	See above	**N/A**
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like	See above	**N/A**
	g) Means for stopping of movements operate as a result of one single action	See above	**N/A**
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls	See above	**N/A**
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or "STOP"	See above	**N/A**
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed	See above	**N/A**
	k) Emergency stopping device is suitable for its application	See above	**N/A**
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 means of releasing patient. Equipment is component battery charger.	**N/A**
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented	See above	**N/A**
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented	See above	**N/A**
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See above	N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered..... :		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	Refer below:	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
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		N/A
9.4.2.3	Instability from horizontal and vertical forces		N/A
	a) ME EQUIPMENT or its parts with a mass of 25kg or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it	Mass of battery charger not 25kg or more.	N/A
	Surfaces of ME EQUIPMENT or its parts where a RISK of overbalancing exists from pushing, etc., permanently marked with a warning of the RISK	See above	N/A
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)	See above	N/A
	b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping	See above	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.... :	See above	N/A
	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		N/A
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE	No castors or wheels	N/A
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT did not exceed 200 N..... :	No castors or wheels	N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.4.2.4.3	**MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold ..... :**	No castors or wheels	**N/A**
9.4.3	**Instability from unwanted lateral movement (including sliding)**		**N/A**
9.4.3.1	**a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control**	EUT not power driven Mobile Me Equipment.	**N/A**
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements	See above	**N/A**
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1	See above	**N/A**
9.4.3.2	**Instability excluding transport**		**N/A**
	a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test ..... :	EUT not Mobile Me Equipment provided with wheel locks or breaking system.	**N/A**
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test	See above	**N/A**
9.4.4	**Grips and other handling devices**		**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	Mass of battery charger not 20kg or more.	**N/A**
	Handles, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS	See above	**N/A**
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying	See above	**N/A**
	c) Carrying handles and grips and their means of attachment withstood loading test..... :	See 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)**	Component battery charger not subjected to risk management analysis. No expelled parts.	**N/A**
	All identified RISKS associated with expelled parts mitigated to an acceptable level	See above.	**N/A**
9.5.2	**Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965..... :**	No cathode ray tubes.	**N/A**
9.6	**Acoustic energy (including infra- and ultrasound) and vibration**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.6.1	**Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and**	No acoustic energy or vibration.	**N/A**
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity ..... :	See above	**N/A**
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and **(ISO 14971 Cl. 4.2-44, 5, 6.2-6.5)**	Component battery charger not subjected to risk management analysis. No acoustic energy	**N/A**
	All identified RISKS mitigated to an acceptable level	See above	**N/A**
9.6.2	**Acoustic energy**		**N/A**
9.6.2.1	**PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE**	No acoustic energy or	**N/A**
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA) ..... :		**—**
	- 83 dBA (when halving the cumulative exposure time) (dBA) ..... :		**—**
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB) ..... :		**—**
9.6.2.2	**RISK MANAGEMENT FILE examined ..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	Component battery charger not subjected to risk management. No acoustic 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) ..... :	See above	**N/A**
	– Accelerations for different times, inversely proportional to square root of time (m/s^2) ..... :	See above	**N/A**
9.7	**Pressure vessels and parts subject to pneumatic and hydraulic pressure**		**N/A**
9.7.2	**Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE ..... :** **(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**	Component battery charger not subjected to risk management analysis. No pressure vessels and parts subject to pneumatic and hydraulic pressure.	**N/A**
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum	No pressure vessels and parts subject to pneumatic and hydraulic pressure.	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure	See above	**N/A**
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects	See above	**N/A**
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply	See above	**N/A**
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible	See above	**N/A**
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity	See above	**N/A**
9.7.3	**Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:**	No pressure vessels and parts subject to pneumatic and hydraulic pressure.	**N/A**
	a) RATED maximum supply pressure from an external source	See above	**N/A**
	b) Pressure setting of a pressure-relief device provided as part of assembly	See above	**N/A**
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device	See above	**N/A**
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 pressure vessels and parts subject to pneumatic and hydraulic 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 pressure vessels and parts subject to pneumatic and hydraulic pressure.	**N/A**
9.7.6	**Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE . :**	No pressure vessels and parts subject to pneumatic and hydraulic pressure.	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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 pressure vessels and parts subject to pneumatic and hydraulic pressure.	**N/A**
	a) Connected as close as possible to pressure vessel or parts of system it is to protect	See above	**N/A**
	b) Installed to be readily accessible for inspection, maintenance, and repair	See above	**N/A**
	c) Could be adjusted or rendered inoperative without a TOOL	See above	**N/A**
	d) With discharge opening located and directed as to not to release material towards any person	See above	**N/A**
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK	See above	**N/A**
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure	See above	**N/A**
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect	See above	**N/A**
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)	See above	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the risks associated with the discharge opening of the pressure relief device..... : **(ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)**	Component battery charger not subjected to risk management analysis No pressure vessels and parts subject to pneumatic and hydraulic pressure.	**N/A**

9.8	**HAZARDS associated with support systems**		**N/A**
9.8.1	**ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK .. :**	EUT not designed to support loads to provide actuating forces.	**N/A**
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD	See above	**N/A**
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– 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)**	Component battery charger not subjected to risk management analysis EUT not designed to support loads to provide actuating forces.	**N/A**
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES	See above	**N/A**
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials	See above	**N/A**
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to	See above	**N/A**
9.8.2	**Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest**	Component battery charger not subjected to risk management analysis EUT not designed to support loads to provide actuating forces.	**N/A**
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing.. :	See above	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the structural integrity of support system.. : **(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**	See above	**N/A**
	All identified RISKS are mitigated to an acceptable level	See above	**N/A**
	When test were conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK ..... :	See above	**N/A**
	Where the equipment is not at equilibrium after 1 min, the RISK MANAGEMENT FILE includes an assessment of the test results..... : **(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**	See above	**N/A**
9.8.3	**Strength of PATIENT or OPERATOR support or suspension systems**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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 patient or operator support or suspension systems	**N/A**
	RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	Component battery charger not subjected to risk management analysis EUT not designed to support loads to provide actuating forces.	**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 patient or operator support or suspension 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	See above	**N/A**
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications	See above	**N/A**
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS	See above	**N/A**
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS	See above	**N/A**
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance ..... :	See above	**N/A**
9.8.3.2	**a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m^2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR ..... :**	No patient or operator support or suspension systems	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests..... :	See above	**N/A**
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK	See above	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test ..... :	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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 patient or operator support or suspension systems	**N/A**
9.8.4	**Systems with MECHANICAL PROTECTIVE DEVICES**		**N/A**
9.8.4.1	**a) A MECHANICAL PROTECTIVE DEVICE provided for the support system**	No patient or operator support or suspension systems	**N/A**
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:	See above	**N/A**
	– Designed based on TOTAL LOAD	See above	**N/A**
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7	See above	**N/A**
	– Activated before travel produced an unacceptable RISK	See above	**N/A**
	– Takes into account Clauses 9.2.5 and 9.8.4.3	See above	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests ..... :	See above	**N/A**
9.8.4.2	**Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE**	No patient or operator support or suspension systems.	**N/A**
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced	See above	**N/A**
9.8.4.3	**MECHANICAL PROTECTIVE DEVICE intended to function once**		**N/A**
	–use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE :	See above	**N/A**
	– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal	See above	**N/A**
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.	See above	**N/A**
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE	See above	**N/A**
	– Compliance confirmed by examination and following test ..... :	See above	**N/A**
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR	See above	**N/A**
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function	See above	**N/A**
9.8.5	**Systems without MECHANICAL PROTECTIVE DEVICES**		
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES..... :	No patient or operator support or suspension systems	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system ..... : **(ISO 14971 Cl. 4.3,4.4,5,6.2-6.5)**	Component battery charger not subjected to risk management analysis No patient or operator support or suspension systems	**N/A**
10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		**N/A**
10.1	**X-Radiation**		**N/A**
10.1.1	**The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT.....:**	EUT does not produce any 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	See above	**N/A**
10.1.2	**RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or .....:**	EUT does not produce any 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)**	Component battery charger not subjected to risk management analysis EUT does not produce any X-Radiation	**N/A**
10.2	**RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE .....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	Component battery charger not subjected to risk management analysis EUT does not produce any alpha, beta, gamma neutron or other particle radiation.	**N/A**
10.3	**The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2**	EUT does not produce any microwave radiation.	**N/A**
	Microwave radiation is propagated intentionally	See above	**N/A**
10.4	**Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.**	No lasers on EUT.	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
10.5	**RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	Component battery charger not subjected to risk management analysis EUT does not produce any visible electromagnetic radiation.	**N/A**
10.6	**RISK associated with infrared radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	Component battery charger not subjected to risk management analysis EUT does not produce any infrared radiation.	**N/A**
10.7	**RISK associated with ultraviolet radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	Component battery charger not subjected to risk management analysis EUT does not produce any ultraviolet radiation.	**N/A**

11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		**P**
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	See appended Table 11.1.1	**P**
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	No thermal cut outs, see table 8.10	**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)**	Component battery charger not subjected to risk management analysis This is component PSU, duration shall be evaluated in end product but testing here is according to manufacture specification	P
11.1.2	**Temperature of APPLIED PARTS**		**N/A**
11.1.2.1	**APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply .....:**	No applied parts	**N/A**
	Clinical effects determined and documented in the RISK MANAGEMENT FILE **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	Component battery charger not subjected to risk management analysis No applied parts	**N/A**
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use	No applied 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. :**	No applied parts	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:	See above	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)	Component battery charger not subjected to risk management analysis No applied parts	N/A
	APPLIED PARTS surface temperature of equal to or less than 41°C	No applied parts	N/A
	Analysis documented in the RISK MANAGEMENT FILE show that APPLIED PART temperatures are not affected by operation of the ME EQUIPMENT including SINGLE FAULT CONDITIONS. Measurement of APPLIED PART temperature according to 11.1.3 is not conducted ..... :	Component battery charger not subjected to risk management analysis No applied parts	N/A
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Component battery charger not subjected to risk management analysis No applied parts	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)	Component battery charger not subjected to risk management analysis	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)	Component battery charger not subjected to risk management analysis	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)	Component battery charger not subjected to risk management analysis	N/A
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE..... :	Component battery charger not subjected to risk management analysis	N/A
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL		P
11.2	Fire prevention		P

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
11.2.1	**ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3**	See appended tables 15.3.3 and 15.3.4.2	**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 ..... :**	EUT not be used in Oxygen Rich Environment	**N/A**
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions	See above	**N/A**
	1) when temperature of material raised to its ignition temperature	See above	**N/A**
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature	See above	**N/A**
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating	See above	**N/A**
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton	See above	**N/A**
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton	See above	**N/A**
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively ..... :	See above	**N/A**
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three..... :	See above	**N/A**
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See above	**N/A**

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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2) ..... :	EUT not be used in Oxygen Rich Environment	**N/A**
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) ..... :	See above	**N/A**
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) ..... :	See above	**N/A**
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a) ..... :	See above	**N/A**
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas ..... :	See above	**N/A**
11.3	**Constructional requirements for fire ENCLOSURES of ME EQUIPMENT**		**P**
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2 ..... :	Fire enclosure provided.	**P**
	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)**	Component battery charger not subjected to risk management analysis	**N/A**
	Justification, when requirement not met ..... :		**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 ..... :	See appended Table 8.10	**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		**N/A**
	b) Fire ENCLOSURE met following:		**P**
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm	No openings in enclosure, tested for IP54	**P**
	2) No openings on the sides within the area included within the inclined line C in Fig 39	See above	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials ..... :	See above	**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	EUT 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)**	Component battery charger not subjected to risk management analysis EUT not intended for use 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**
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 No opening in enclosure, tested for IP54	**P**
11.6.2	**Overflow in ME EQUIPMENT**		**N/A**
	ME EQUIPMENT incorporates a reservoir or liquid storage that did not wet any MEANS OF PROTECTION, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE ..... :	No liquid reservoir or storage.	**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 liquid reservoir or storage.	**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 liquid reservoir or storage.	**N/A**
11.6.3	**Spillage on ME EQUIPMENT and ME SYSTEM**	EUT tested for IP54	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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)**	Component battery charger not subjected to risk management analysis EUT tested for IP54	**P**
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill ..... :	See above	**P**
11.6.5	**Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**		**P**
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)..... :	See Appended Table 11.6.1 IP54 test according to IEC 60529 conducted	**P**
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION.. :	See appended Tables 8.7 8.8.3	**P**
11.6.6	**Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS**		**N/A**
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use ..... :	No intended cleaning and disinfection	**N/A**
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER ..... :	No intended cleaning and disinfection	**N/A**
11.6.7	**Sterilization of ME EQUIPMENT and ME SYSTEMS**		**N/A**
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests..... :	EUT 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)**	Component battery charger not subjected to risk management analysis. EUT 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)**	Component battery charger not subjected to risk management analysis. EUT not intended to be sterilized	**N/A**
11.7	**ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented**	EUT is component battery charger. No direct or indirect contact with biological tissues.	**N/A**
11.8	**Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**	EUT is component battery charger. Interruption of power supply only results in not fully charged battery.	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		**N/A**
12.1	**RISKS associated with accuracy of controls and instruments stated..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	Component battery charger not subjected to risk management analysis. EUT has no controls and no instruments.	**N/A**
12.2	**RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING..... :**		**P**
12.3	**MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8. ..... :**	No alarm systems.	**N/A**
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)**	Component battery charger not subjected to risk management analysis	**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)**	Component battery charger not subjected to risk management analysis	**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)**	Component battery charger not subjected to risk management analysis	**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)**	Component battery charger not subjected to risk management analysis	**N/A**
12.4.5	**Diagnostic or therapeutic radiation**		**N/A**
12.4.5.1	**Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation**	No diagnostic or therapeutic radiation.	**N/A**
	Radiation safety ensured by compliance with requirements of appropriate standards	See above	**N/A**
12.4.5.2	**ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3..... :**	Component battery charger not subjected to risk management analysis No diagnostic or therapeutic 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)**	Component battery charger not subjected to risk management analysis No diagnostic or therapeutic radiation.	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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)**	Component battery charger not subjected to risk management analysis No diagnostic or therapeutic radiation.	**N/A**
12.4.6	**RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	Component battery charger not subjected to risk management analysis No diagnostic or therapeutic radiation.	**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**
	– 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..... :	See summary of testing.	**N/A**
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23..... :	See appended Table 11.1.1	**P**
	–Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 °C were not exceeded		**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	No adjustable safety components.	**N/A**
13.1.3	**– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed..... :**	Leakage current measured also after Single Fault Conditions and values does not differ from original measurement.	**P**
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS did not exceed..... :	Leakage current measured also after Single Fault Conditions and values does not differ from original measurement.	**P**
13. 2	**SINGLE FAULT CONDITIONS**		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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**	Considered	**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)**	Component battery charger not subjected to risk management analysis	**N/A**
	RISK MANAGEMENT FILE defines the appropriate test conditions.....:	See above.	**N/A**
13.2.13	**ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of the temperature in the test environment**		**P**
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted	No motors in equipment.	**N/A**
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION, the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		**N/A**
13.2.13.2	**ME EQUIPMENT with heating elements**		**N/A**
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	EUT has no heating elements	**N/A**
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests	See above	**N/A**
	a 3) other ME EQUIPMENT with heating elements met test	See above	**N/A**
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively	See above	**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	See above	**N/A**
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself	See above	**N/A**
	b) ME EQUIPMENT with heating elements without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V) ..... :	See above	**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	See above	**N/A**
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted	See above	**N/A**
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION	See above	**N/A**
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and	See above	**N/A**
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS	See above	**N/A**
	2) When more than one control provided, they were disabled in turn	See above	**N/A**
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time	See above	**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	EUT has 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	See above	**N/A**
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition	See above	**N/A**
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT	See above	**N/A**
	b) Motor met running overload protection test of this clause when:	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or	See above	**N/A**
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended	See above	**N/A**
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C)..... :	See above	**N/A**
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps	See above	**N/A**
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload	See above	**N/A**
	Test not conducted where electronic drive circuits maintained a substantially constant drive current	See above	**N/A**
	Test not conducted based on other justifications (justification)..... :	See above	**N/A**
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10	See above	**N/A**
13.2.13.4	**ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION**		**N/A**
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated	EUT rated for continuous operation.	**N/A**
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle	See above	**N/A**
	Motor winding temperatures did not exceed values in 13.2.10 ..... :	See above	**N/A**
	Insulation Class ..... :	See above	**—**
	Maximum temperature measured (°C)..... :	See above	**—**

14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		**N/A**
14.1	**Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE, or**	EUT has no PEMS	**N/A**
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK ..... :	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 4.2-4.4, 5)	Component battery charger not subjected to risk management analysis EUT has no PEMS	**N/A**
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK	EUT has no PEMS	**N/A**
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304..... :	See above	**N/A**
	Software development process applied according to Clause 5 of IEC 62304..... :	See above	**N/A**
	Software development process for Software risk management applied according to Clause 7 of IEC 62304 ..... :	See above	**N/A**
	Software development process Configuration Management applied according to Clause 8 of IEC 62304..... :	See above	**N/A**
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304..... :	See above	**N/A**
14.2	**Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process ..... :**	EUT has no PEMS	**N/A**
14.3	**RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan**	EUT has no PEMS	**N/A**
14.4	**A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented**	EUT has no PEMS	**N/A**
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	See above	**N/A**
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	See above	**N/A**
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules	See above	**N/A**
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	See above	**N/A**
14.5	**A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained**	EUT has no PEMS	**N/A**
14.6	**RISK MANAGEMENT PROCESS**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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..... :**	Component battery charger not subjected to risk management analysis EUT has no PEMS	**N/A**
	RISK MANAGEMENT FILE includes known or foreseeable HAZARDS associated with software, hardware, incorporation of the PEMS into an IT-NETWORK, components of 3rd party origin and legacy subsystems.....: **(ISO 14971 Cl. 4.3)**	See above	**N/A**
14.6.2	**Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2 :**	Component battery charger not subjected to risk management analysis EUT has no PEMS	**N/A**
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure.....: **(ISO 14971 Cl. 6.1)**	See above	**N/A**
14.7	**A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem ..... :** **(ISO 14971 Cl. 6.3)**	Component battery charger not subjected to risk management analysis EUT has no PEMS	**N/A**
14.8	**An architecture satisfying the requirement is specified for PEMS and each of subsystems .... :** **(ISO 14971 Cl. 6.3)**	Component battery charger not subjected to risk management analysis EUT has no PEMS	**N/A**
14.9	**Design is broken up into sub systems and descriptive data on design environment documented ..... :**	EUT has no PEMS	**N/A**
14.10	**A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures..... :** **(ISO 14971 Cl. 6.3)**	Component battery charger not subjected to risk management analysis EUT has no PEMS	**N/A**
	– milestone(s) when VERIFICATION is to be performed for each function	See above	**N/A**
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION	See above	**N/A**
	– selection and utilization of VERIFICATION tools	See above	**N/A**
	– coverage criteria for VERIFICATION	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
14.11	**A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE ..... :**	EUT has no PEMS	**N/A**
	Methods used for PEMS VALIDATION documented	See above	**N/A**
	The person with overall responsibility for PEMS VALIDATION is independent	See above	**N/A**
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE **(ISO 14971 Cl. 6.3)**	Component battery charger not subjected to risk management analysis EUT has no PEMS See above	**N/A**
14.12	**Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE**	EUT has no PEMS	**N/A**
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304 ..... :	See above	**N/A**
	Software Process for Software changes applied according to Clause 5 of IEC 62304..... :	See above	**N/A**
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304..... :	See above	**N/A**
	Configuration management of software changes applied per Clause 8 of IEC 62304 .... :	See above	**N/A**
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304 .... :	See above	**N/A**
14.13	**For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following ..... :**	See above	**N/A**
	a) Purpose of the PEMS connection to an IT-NETWORK	See above	**N/A**
	b) required characteristics of the IT-NETWORK	See above	**N/A**
	c) required configuration of the IT-NETWORK	See above	**N/A**
	d) technical specifications of the network connection, including security specifications	See above	**N/A**
	e) intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK	See above	**N/A**
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the characteristics required **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)**	Component battery charger not subjected to risk management analysis EUT has no PEMS	**N/A**
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties	EUT has no PEMS	**N/A**
	– Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS	See above	**N/A**
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis	See above	**N/A**
	- Changes to the IT-NETWORK include: - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment	See above	**N/A**
15	**CONSTRUCTION OF ME EQUIPMENT**		**P**
15.1	**RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS..... :**	See Attached IEC 60601-1-6 report. See attachment no.1	**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**	No such parts	**N/A**
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring	Only for service at manufacturer's premises/location, service done by qualified personnel.	**N/A**
15.3	**Mechanical strength**		**P**
15.3.1	**Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**		**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 ..... :**	EUT not hand-held equipment.	**N/A**
	No unacceptable RISK resulted	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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 ..... :**	EUT not mobile ME Equipment	**N/A**
	No damage resulting in an unacceptable RISK sustained	See above	**N/A**
15.3.6	**Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK**	No moulded materials	**N/A**
	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 ..... :	See above	**N/A**
	No damage resulting in an unacceptable RISK	See above	**N/A**
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**	Considered	**P**
	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	Considered	**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)**	Component battery charger not subjected to risk management analysis	**N/A**
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions, ... :	No patient leads or cables.	**N/A**
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection ..... :	No medical gas connections.	**N/A**
15.4.2	**Temperature and overload control devices**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
15.4.2.1	**a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION ..... :** **(ISO 14971 Cl. 4.2-4.4, 5)**	Component battery charger not subjected to risk management analysis No such device.	**N/A**
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT	No such device.	**N/A**
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided ..... : **(ISO 14971 Cl. 4.2-4.4)**	Component battery charger not subjected to risk management analysis No such device.	**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)**	Component battery charger not subjected to risk management analysis No such device.	**N/A**
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS	No such device.	**N/A**
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests:	No such device.	**N/A**
	- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17	See above	**N/A**
	- ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13 ..... :	See above	**N/A**
	- SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards.....	See above	**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	See above	**N/A**
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards	See above	**N/A**
	manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times	See above	**N/A**
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating	No such device.	**N/A**
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating. : **(ISO 14971 Cl. 4.2-4.4)**	Component battery charger not subjected to risk management analysis No such device.	**N/A**
15.4.2.2	**Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS**	No thermostats in EUT	**N/A**
15.4.3	**Batteries**		**N/A**
15.4.3.1	**Battery housings provided with ventilation.... :** **(ISO 14971 Cl. 4.2-4.4)**	Component battery charger not subjected to risk management analysis No batteries in EUT	**N/A**
	Battery compartments designed to prevent accidental short circuiting	No batteries in EUT	**N/A**
15.4.3.2	**Means provided to prevent incorrect connection of polarity ..... :**	No batteries in EUT	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries ..... : **(ISO 14971 Cl. 4.2-4.4)**	Component battery charger not subjected to risk management analysis No batteries in EUT	**N/A**
15.4.3.3	**Overcharging of battery prevented by virtue of design ..... :**	No batteries in EUT	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries ..... : **(ISO 14971 Cl. 4.2-4.4)**	Component battery charger not subjected to risk management analysis No batteries in EUT	**N/A**
15.4.3.4	**Primary lithium batteries comply with IEC 80086-4**	No batteries in EUT	**N/A**
	Secondary lithium batteries comply with IEC 62133	See above.	**N/A**
15.4.3.5	**A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire ..... :**	No batteries in EUT	**N/A**
	Protective device has adequate breaking capacity	See above.	**N/A**
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented	See above.	**N/A**
	Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPS provided, or	See above.	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION	See above.	**N/A**
15.4.4	**Indicator lights provided to indicate ME EQUIPMENT is ready for ..... :**	Green: Fully charged battery Yellow: Charging Red: Battery not connected	**P**
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,	No	**N/A**
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational	No non-luminous heater in EUT.	**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)**	Component battery charger not subjected to risk management analysis No non-luminous heater in EUT.	**N/A**
	Requirement not applied to heated stylus-pens for recording purposes		**N/A**
	Indicator lights provided on ME EQUIPMENT to indicate an output exists		**N/A**
	Colours of indicator lights complied with 7.8.1		**P**
	Charging mode visibly indicated	Yellow light indicates charging	**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)**	Component battery charger not subjected to risk management analysis	**N/A**
15.4.6	**Actuating parts of controls of ME EQUIPMENT**		**N/A**
15.4.6.1	**a) Actuating parts cannot be pulled off or loosened during NORMAL USE**	No actuating parts of controls.	**N/A**
	b) Controls secured so that the indication of any scale always corresponds to the position of the control	See above	**N/A**
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL	See above	**N/A**
	When torque values per Table 30 applied knobs did not rotate ..... :	See above	**N/A**
	Tests conducted with no unacceptable RISK . :	See above	**N/A**
15.4.6.2	**Stops on rotating/ movable parts of controls are of adequate mechanical strength ..... :**	No actuating parts of controls.	**N/A**
	Torque values in Table 30 applied ..... :	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	No unexpected change of the controlled parameter when tested..... :	See above	**N/A**
15.4.7	**Cord-connected HAND-HELD and foot-operated control devices**		**N/A**
15.4.7.1	**a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1**	No cord Hand Held and foot-operated control device.	**N/A**
	b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage ..... :	See above	**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 cord Hand Held and foot-operated control device.	**N/A**
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position	See above	**N/A**
15.4.7.3	**a) Foot-operated control device is at least rated IPX1** ..... :	No cord Hand Held and foot-operated control device.	**N/A**
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6.... :	See above	**N/A**
15.4.8	**Aluminium wires less than 16 mm^2 in cross-sectional area are not used**	No aluminium wires.	**N/A**
15.4.9	**a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed**	No oil containers.	**N/A**
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport	See above	**N/A**
	A pressure-release device operating during NORMAL USE is provided	See above	**N/A**
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage	See above	**N/A**
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements	See above	**N/A**
15.5	**MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5**		**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 ..... :	See appended Table 15.5.2	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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 ..... :**	Electronic current limitation.	**P**
15.5.2	**Transformers operating at a frequency above 1kHz tested according to clause 8.8.3..... :**	Switch mode power supply, transformer operating at frequency above 1kHz	**N/A**
	Transformer windings provided with adequate insulation	See above	**N/A**
	Dielectric strength tests were conducted ..... :	See above	**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		**P**
	- protective earth screens with a single turn have insulated overlap		**P**
	- Exit of wires form internal windings of toroid transformers protected with double sleeving		**P**
	- insulation between primary and secondary windings complies with 8.8.2		**P**
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4		**P**

16	**ME SYSTEMS**		**N/A**
16.1	**After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK**	EUT is component battery charger. No ME system.	**N/A**
	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)**	Component battery charger not subjected to risk management analysis EUT is component battery charger. No ME system.	**N/A**
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered	EUT is component battery charger. No ME system.	**N/A**
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard	See above	**N/A**
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards	See above	**N/A**
	– tests performed in NORMAL CONDITION, except as specified	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM	See above	**N/A**
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated	See above	**N/A**
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR	See above	**N/A**
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards	See above	**N/A**
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM	See above	**N/A**
16.2	**ACCOMPANYING DOCUMENTS of an ME SYSTEM**		**N/A**
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM	EUT is component battery charger. No ME system.	**N/A**
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM	See above	**N/A**
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER	See above	**N/A**
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER	See above	**N/A**
	c) the required information is provided:	See above	**N/A**
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM	See above	**N/A**
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard	See above	**N/A**
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM	See above	**N/A**
	– additional safety measures to be applied during installation of ME SYSTEM	See above	**N/A**
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT	See above	**N/A**
	– additional measures to be applied during preventive maintenance	See above	**N/A**
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM	See above	**N/A**
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM	See above	**N/A**
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM	See above	**N/A**
	– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM	See above	**N/A**
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer	See above	**N/A**
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET	See above	**N/A**
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage	See above	**N/A**
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT	See above	**N/A**
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:	See above	**N/A**
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES	See above	**N/A**
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard	See above	**N/A**
16.3	**Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements**	EUT is component battery charger. No ME system.	**N/A**
	Transient currents restricted to allowable levels for the specified IPS or UPS ..... :	See above	**N/A**
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified	See above	**N/A**
16.4	**Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)**	EUT is component battery charger. No ME system.	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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**	EUT is component battery charger. No ME system.	**N/A**
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION	See above	**N/A**
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V)..... :	See above	**N/A**
16.6	**LEAKAGE CURRENTS**		**N/A**
16.6.1	**TOUCH CURRENT in NORMAL CONDITION did not exceed 100 µA.....:**	EUT is component battery charger. No ME system.	**N/A**
	TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR.....:	See above	**N/A**
16.6.2	**Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA....:**	EUT is component battery charger. No ME system.	**N/A**
16.6.3	**PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values .....:**	EUT is component battery charger. No ME system.	**N/A**
16.7	**ME SYSTEM complied with applicable requirements of Clause 9.....:**	EUT is component battery charger. No ME system.	**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**	EUT is component battery charger. No ME system.	**N/A**
16.9	**ME SYSTEM connections and wiring**		**N/A**
16.9.1	**Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result ..... :**	EUT is component battery charger. No ME system.	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with plugs for connection of PATIENT leads or cables likely to be located in the PATIENT ENVIRONMENT ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	Component battery charger not subjected to risk management analysis EUT is component battery charger. No ME system.	**N/A**
	– Plugs for connection of PATIENT leads or PATIENT cables could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no unacceptable RISK results	EUT is component battery charger. No ME system.	**N/A**
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable	EUT is component battery charger. No ME system.	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
16.9.2	**MAINS PARTS, components and layout**	EUT is component battery charger. No ME system.	**N/A**
16.9.2.1	**a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or**	EUT is component battery charger. No ME system.	**N/A**
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or	See above	**N/A**
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer	See above	**N/A**
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 visible in NORMAL USE, and	See above	**N/A**
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or	See above	**N/A**
	– marked to indicate the equipment or equipment parts it may safely be attached to	See above	**N/A**
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT	See above	**N/A**
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:	See above	**N/A**
	– CREEPAGE and CLEARANCES complied with 8.9	See above	**N/A**
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets	See above	**N/A**
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:	See above	**N/A**
	– ENCLOSURE complied with 8.4.2 d)	See above	**N/A**
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable	See above	**N/A**
	– RATINGS of components are not in conflict with conditions of use ..... :	See above	**N/A**
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL	See above	**N/A**
	– POWER SUPPLY CORD complied with 8.11.3	See above	**N/A**
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:	See above	**N/A**
	– Separating transformer complied with this standard or IEC 61558-2-1, ... :	See above	**N/A**
	– Separating transformer is CLASS I	See above	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Degree of protection against ingress of water specified as in IEC 60529		
	– Separating transformer assembly marked according to 7.2 and 7.3	See above	**N/A**
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083	See above	**N/A**
16.9.2.2	**The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED did not exceed 200 mΩ**	EUT is component battery charger. No ME system.	**N/A**
	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part	See above	**N/A**
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL	See above	**N/A**
16.9.2.3	**Conductors connecting different items within an ME SYSTEM protected against mechanical damage**	EUT is component battery charger. No ME system.	**N/A**
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		**P**
	RISKS associated confirmed by review..... :		**P**
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS ..... :	Included 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)**	Component battery charger not subjected to risk management analysis	**N/A**
	– 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 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**		**N/A**
G.2.2	**FLAMMABLE AESTHETIC MIXTURE WITH**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
G.2.3	A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE		N/A
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5		N/A
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE comply with G.4 and G.6		N/A
	ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7		N/A
G.3	Marking, ACCOMPANYING DOCUMENTS		N/A
G.3.1	CATEGORY APG ME EQUIPMENT prominently marked "APG" (symbol 23 in Table D.1)..... :		N/A
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case		N/A
	When above marking not possible, relevant information included in instructions for use ... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.2	CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle "AP" (symbol 22 in Table D.1)..... :		N/A
	Marking is as large as possible for the particular case		N/A
	When above marking not possible, the relevant information included in instructions for use ... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.3	The marking placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts		N/A
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts		N/A
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG		N/A
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT		N/A
G.4.1	a) CREEPAGE and CLEARANCES are according to Table 12 for one MEANS OF PATIENT PROTECTION		N/A
	b) Connections protected against accidental disconnection		N/A
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD,		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
G.4.2	Construction details		N/A
	a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL		N/A
	b) ENCLOSURE complies with ..... :		N/A
	– no openings on top covers of ENCLOSURE,		N/A
	– openings in side-covers prevented penetration of a solid cylindrical test rod		N/A
	– openings in base plates prevented penetration of a solid cylindrical test		N/A
	c) Short circuiting conductor(s) to a conductive part (when no explosive gasses) did not result in loss of integrity of the part, an unacceptable temperature, or any HAZARDOUS SITUATION		N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures		N/A
	– Use of antistatic materials with a limited electrical resistance ..... :		N/A
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor		N/A
	b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882 ..... :		N/A
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5		N/A
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components		N/A
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5		N/A
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5 ..... :		N/A
G.5.2	Temperature limits..... :		N/A
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:		

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1..... :		N/A
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 ..... :		N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3 ..... :		N/A
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1		N/A
	No extrapolation made for voltages above 42 V		N/A
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2		N/A
	No extrapolation made for voltages above 242V		N/A
	U_{max} determined using actual resistance R		N/A
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3		N/A
	No extrapolation made for inductances larger than 900 mH		N/A
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open		N/A
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed		N/A
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks		N/A
	– Peak value considered when a.c. supplied		N/A
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit... :		N/A
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max} , and C_{max} determined with application of Figs G.1-G.3 .. :		N/A
	Alternatively, compliance was verified by examination of design data .....:		N/A
G.5.4	External ventilation with internal overpressure		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR t removed by ventilation before EQUIPMENT energized,		N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa)..... :		N/A
	Overpressure maintained at the site of potential ignition		N/A
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE		N/A
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present		N/A
	c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa) ..... :		N/A
	d) External surface of ENCLOSURE did not exceed 150 °C in 25 °C ..... :		N/A
G.5.5	ENCLOSURES with restricted breathing		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:		N/A
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing		N/A
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h :		N/A
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained		N/A
	Cords are fitted with adequate anchorages to limit stresses as determined by test		N/A
	Overpressure not reduced below 200 Pa		N/A
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		N/A
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C) ..... :		N/A
	Steady state operating temperature of ENCLOSURE also measured (°C) ..... :		N/A
G.6	CATEGORY APG ME EQUIPMENT, parts and components thereof		N/A
G.6.1	ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test		N/A
G.6.2	Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION..... :		N/A
G.6.3	Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS..... :		N/A
	a) no sparks produced and temperatures did not exceed 90 °C, or		N/A
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U_{max} and I_{max} occurring in their circuits complied with requirements, taking C_{max} and L_{max} into consideration:		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 ..... :		N/A
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 ..... :		N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 ..... :		N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated		N/A
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10		N/A
	– I_{max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10		N/A
	– C_{max} and L_{max} are values occurring in relevant circuit		N/A
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω		N/A
	– Peak value considered when a.c. supplied		N/A
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components		**N/A**
	- requirement not applied to transformers complying with this standard		**N/A**
	- requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture		**N/A**
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or		**N/A**
	Temperature measurements made in accordance with 11.1..... :		**N/A**
	- or U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6 ..... :		**N/A**
	Alternatively, compliance verified by comparison with design data .....:		**N/A**
G.6.4	**ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1..... :**		**N/A**
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE		**N/A**
G.7	**Test apparatus for flammable mixtures according to this Clause and Fig G.7**		**N/A**

ANNEX L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**		**P**
L.1	**BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex**	Separately approved TIW wire used, refer to appended table 8.10	**P**
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	Separately approved TIW wire used, refer to appended table 8.10	**N/A**
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap	See above	**N/A**
L.3	**Type Test**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified	Separately approved TIW wire used, refer to appended table 8.10	**N/A**
	Temperature (°C)..... :		**—**
	Humidity (%)..... :		**—**
L.3.1	**Dielectric strength**		**N/A**
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted with no breakdown:	Separately approved TIW wire used, refer to appended table 8.10	**N/A**
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	See above	**N/A**
	– 6000 V for REINFORCED INSULATION (V) ..... :	See above	**N/A**
L.3.2	**Flexibility and adherence**		**N/A**
	Sample subjected to flexibility and adherence	Separately approved TIW wire used, refer to appended table 8.10	**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	See above	**N/A**
	Test voltage was at least the voltage in Tables 6 and 7 but not less than the following:	See above	**N/A**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	See above	**N/A**
	– 3000 V for REINFORCED INSULATION (V) ..... :	See above	**N/A**
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa ..... :	See above	**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	Separately approved TIW wire used, refer to appended table 8.10	**N/A**
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	See above	**N/A**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	See above	**N/A**
	– 3000 V for REINFORCED INSULATION (V) ..... :	See above	**N/A**
	Oven temperature based on Table L.2 (°C)..... :		**—**
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm^2)..... :	See above	**N/A**
	Dielectric strength test conducted at room temperature after removal from the oven	See above	**N/A**
L.3.4	**Retention of electric strength after bending**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests	Separately approved TIW wire used, refer to appended table 8.10	**N/A**
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	See above	**N/A**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	See above	**N/A**
	– 3000 V for REINFORCED INSULATION (V) ..... :	See above	**N/A**
	Test voltage applied between the shot and conductor	See above	**N/A**
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm^2) ..... :	See above	**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 .....:**	Separately approved TIW wire used, refer to appended table 8.10	**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:**	See above	**N/A**
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V).....:	See above	**N/A**
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V) .....:	See above	**N/A**
L.4.3	**Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1) .....:**	Separately approved TIW wire used, refer to appended table 8.10	**N/A**
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:	See above	**N/A**
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION..... :	See above	**N/A**
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION ..... :	See above	**N/A**

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

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			N/A
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
3.1		—	Component battery charger not subjected to risk management analysis	N/A
3.2		—		N/A
3.2		—		N/A
3.2		—		N/A
3.3	—			N/A
3.4a	—			N/A
3.4b	—			N/A
3.4c	—			N/A
3.4d	—			N/A
3.4e	—			N/A
3.5	—			N/A
4.1	—			N/A
4.2	—			N/A
4.3	—			N/A
4.4	—			N/A
5	—			N/A
6.2	—			N/A
6.3	—			N/A
6.4	—			N/A
6.5	—			N/A
6.6a	—			N/A
6.6b	—			N/A
6.7	—			N/A
7	—			N/A
8	—			N/A

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

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 or VA)**	**Power factor (cos φ)**
CCC410S Loaded at 24V/10A		196V	50Hz	2.26A	293W / 443VA	0.66
CCC410S Loaded at 24V/10A		207V	50Hz	2.21A	297W / 457VA	0.65
CCC410S Loaded at 24V/10A		230V	50Hz	2.06A	298W / 474VA	0.63
CCC410S Loaded at 24V/10A		253V	50Hz	1.87A	294W / 474VA	0.62

Supplementary Information: Measured at 85% of rated voltage due to IEC 60601-1-11 requirement.

5.9.2	TABLE: Determination of ACCESSIBLE parts		P
Location	**Determination method (NOTE1)**	**Comments**	
Enclosure	Visual	Heatsink are accessible, complies with applied part type B leakage limits in normal and single fault condition.	
Output connector	Rigid test finger	No charging voltage/energy present when not connected to a battery.	

Supplementary information:

NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.

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

7.1.2	**TABLE: Legibility of Marking**		**P**
Markings tested		**Ambient Illuminance (lx)**	**Remarks**
Outside Markings (Clause 7.2) .....:		100	Pass
Inside Markings (Clause 7.3) .....:			No such markings
Controls & Instruments (Clause 7.4) .....:			No such markings
Safety Signs (Clause 7.5).....:			No such markings
Symbols (Clause 7.6) .....:		100	Pass
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 ..... :	Metalized Polyester	**Pass**
Ink/other printing material or process..... :	Thermal Transfer printing	**Pass**
Material (composition) of Warning Label ..... :	Metalized Polyester	**Pass**
Ink/other printing material or process..... :	Thermal Transfer printing	**Pass**
Other..... :	Laminated with a pressure sensitive acrylic adhesive and a white glassine liner.	**Pass**
Marking Label Tested:		**Remarks**
Marking label		**Pass**
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		

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

8.4.2	**TABLE: TABLE: Working Voltage / Power Measurement**					**P *)**
Test supply voltage/frequency (V/Hz)[1] ..... :						**230V/50Hz**
Location From/To	**Measured values**					**Remarks**
	Vrms	**Vpk or Vdc**	**Peak-to-peak ripple[2]**	**Power W/VA**	**Energy (J)**	
Output from charger	28.4	33.6	-	-	-	Normal condition (without batteries connected)
Output from charger	9.0	12.0	-	-	-	Single fault condition, D22 Anode-Cathode S-c

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

*) measurements of output voltage from the charger in normal and single fault condition conducted. (voltage across secondary winding of T17 is 70Vrms/150Vpk, Diode D22 is the limiting component between secondary output winding of T17 and charger output.

8.4.3	**TABLE: ME EQUIPMENT for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply**									**P**
Maximum allowable voltage (V) ..... :										**60**
Voltage measured (V)										
Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2	52	60	60	56	56	60	56	56	56	60
Plug pin 1 and enclosure	0	0	0	0	0	0	0	0	0	0
Plug pin 2 and enclosure	0	0	0	0	0	0	0	0	0	0
Supplementary information:										
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**
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Supplementary information:										

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

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

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

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

Supplementary information:

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

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

Supplementary information:

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

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

Supplementary information:

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

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

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

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

8.6.4	**TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS**	N/A

Type of ME EQUIPMENT & impedance measured between parts	Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)

Supplementary information:

PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 mΩME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part - Limit 100 mΩ
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a PROTECTIVELY EARTHED part - Limit 200 mΩ
ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part - Limit 200 mΩ

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

8.7	TABLE: leakage current				P
Type of leakage current and test condition (including single faults)	**Supply voltage (V)**	**Supply frequency (Hz)**	**Measured max. value (µA)**	**Remarks**	
CCC4xxS					
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC	
Class II equipment					
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC	
MD, B, NC, S1= 1, S5 = 1	253V	50Hz	20.5µA		
MD, B, NC, S1= 1, S5 = 0	253V	50Hz	19.6µA		
MD, B, SFC, S1= 0, S5 = 1	253V	50Hz	35.0µA		
MD, B, SFC, S1= 0, S5 = 0	253V	50Hz	35.1µA		
MD, A, NC, S1= 1, S5 = 1	253V	50Hz	20.6µA		
MD, A, NC, S1= 1, S5 = 0	253V	50Hz	19.7µA		
MD, A, SFC, S1= 0, S5 = 1	253V	50Hz	35.1µA		
MD, A, SFC, S1= 0, S5 = 0	253V	50Hz	35.1µA		
				Maximum allowed values: 10mA r.m.s	
NFWD, B, NC, S1= 1, S5 = 1	253V	50Hz	30.6µA		
NFWD, B, NC, S1= 1, S5 = 0	253V	50Hz	29.1µA		
NFWD, B, SFC, S1= 0, S5 = 1	253V	50Hz	39.1µA		
NFWD, B, SFC, S1= 0, S5 = 0	253V	50Hz	39.6µA		
NFWD, A, NC, S1= 1, S5 = 1	253V	50Hz	31.2µA		
NFWD, A, NC, S1= 1, S5 = 0	253V	50Hz	29.4µA		
NFWD, A, SFC, S1= 0, S5 = 1	253V	50Hz	42.3µA		
NFWD, A, SFC, S1= 0, S5 = 0	253V	50Hz	41.5µA		
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)	
MD, B, NC, S1= 1, S5 = 1	253V	50Hz	20.5 µA / 0.2µA		
MD, B, NC, S1= 1, S5 = 0	253V	50Hz	19.6 µA / 0.2µA		
MD, B, SFC, S1= 0, S5 = 1	253V	50Hz	35.1 µA / 0.2µA		
MD, B, SFC, S1= 0, S5 = 0	253V	50Hz	35.0 µA / 0.2µA		

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

MD, A, NC, S1= 1, S5 = 1	253V	50Hz	20.6µA / 0.0µA	
MD, A, NC, S1= 1, S5 = 0	253V	50Hz	19.7 µA / 0.0µA	
MD, A, SFC, S1= 0, S5 = 1	253V	50Hz	35.1 µA / 0.1µA	
MD, A, SFC, S1= 0, S5 = 0	253V	50Hz	35.1 µA / 0.1µA	
				Maximum allowed values: 10mA r.m.s
NFWD, B, NC, S1= 1, S5 = 1	253V	50Hz	30.6 µA / 0.3µA	
NFWD, B, NC, S1= 1, S5 = 0	253V	50Hz	29.1 µA / 0.2µA	
NFWD, B, SFC, S1= 0, S5 = 1	253V	50Hz	39.1 µA / 0.3µA	
NFWD, B, SFC, S1= 0, S5 = 0	253V	50Hz	39.6 µA / 0.1µA	
NFWD, A, NC, S1= 1, S5 = 1	253V	50Hz	31.2 µA / 0.7µA	
NFWD, A, NC, S1= 1, S5 = 0	253V	50Hz	29.4 µA / 0.6µA	
NFWD, A, SFC, S1= 0, S5 = 1	253V	50Hz	42.3 µA / 0.5µA	
NFWD, A, SFC, S1= 0, S5 = 0	253V	50Hz	41.5 µA / 0.5µA	
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 µA Type CF AP: 50 µA
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 µA Type CF: N/A
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current)

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

Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC;1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000 µA Type CF: 100 µA
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 µA Type CF: N/A
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC

Supplementary information:

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

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

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

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

A - After humidity conditioning
B - Before humidity conditioning
1 - Switch closed or set to normal polarity
0 - Switch open or set to reversed polarity
NC - Normal condition
SFC - Single fault condition

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

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

Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1]	Dielectric breakdown after 1 minute Yes/No[2]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
A	1XMOOP	324		1500	No
B	2xMOPP	324	-	4000	No
C	2xMOPP	380	-	4075	No
D	2xMOPP	348	-	4000	No
E	1xMOPP	324	-	1500	No
F	1xMOPP	324	-	1500	No
*)	*)	380	-	4075	No
**)	**)	380	-	4075	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).

*) Dielectric strength test conducted on Gap Pad for 2 x MOPP. Test conducted on Brady, type: Tsoft3ST 60. Test repeated after humidity pre-conditioning for 168h due requirements of clause 5.7.

**) Dielectric strength test conducted on Polymid isolation tape for 2 x MOPP. Test conducted on 3M, type: Type 92. Test repeated after humidity pre-conditioning for 168h due requirements of clause 5.7.

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		
Plastic enclosure	75°C	0.8mm
Insulating material supporting un-insulated Mains Parts		
Transformer Bobbin, T17	125°C	1.1mm
Supplementary information:		

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

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

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
G: DC plug - accessible part	AC and CD	NO, LEAKAGE CURRENT MEASURED	Pass

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**

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 ± 2 °C = ___°C[1]		
		2 - 1 h at 25 °C ± 2 °C		
		3 - 2 h at 0 °C ± 2 °C		
		4 - 1 or more h at 25 °C ± 2 °C		
	2	Humidity Conditioning per 5.7		
	3	Humidity Conditioning per 5.7		

Supplementary information:

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

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

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]
Plug primary	Shee Line	SL-10	16A, 250Vac	IEC 60884-1, sheet 7	N, S, D, Fi, VDE, Kema, ÖVE
Alternative	Yun Hao	YH-022	16A, 250V,	IEC 60884-1, sheet 7	N, S, D, Fi, VDE, Kema, ÖVE
Supply Cord	Yun Hao	H05VV-F	2x0.75mm^2, 2meters, PVC, 70°C	HD 21.5	VDE
Internal terminal connectors on mains supply cord	AMP	2-520407-2	6.3mm, metal	UL1977	UL, E115497
Strain relief	J.K Medico	DWG 82000-037	2x0.75mm^2	IEC 60601-1 (3.1 ed)	Tested in equipment
Strain relief material (primary cord)	Asia Int'l Enterprise (Hong Kong) Ltd	5010F, 50G5F/50G6F	PA6, V-0 for min 1.5mm, measured = 2.0mm	IEC 60695-11-10	UL E252275
Enclosure material	Asia Int'l Enterprise (Hong Kong) Ltd	2010BF	ABS, V-0, min. thickness 1.5mm, measured=2.1mm, 88°C	IEC 60695-11-10	UL E252275
Heatsink	Sapa	S/SW	Aluminum, min. thickness 2.6mm	IEC 60601-1 (3.1ed)	Tested in equipment.
PCB	J.K Medico	P/N: 4 0500-005	FR-4-1.6, V-0, 130°C	UL 94	UR
Primary gap pads (between primary/secondary and polyamid insulation tape on heatsink	Brady	Tsoft3ST 60	V-0 for min 0.25mm, measured =1,45mm, 150°C	IEC 60695-11-10	UL E316839
Alternative 1	Bergquist CO	GAP PAD 2000S40	V-0 for min 0.35mm, measured= 1,45, 150°C	IEC 60695-11-10	UL E59150

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

Polymid isolation tape	3M	Tape 92	180°C, 0.05mm thickness, 40mm width	UL 510	UL E17385
J1, J2	Keystone Electronics Corp	PC Quick-Fit terminal	14.02 x 7.92mm	IEC 60601-1 (3.1 ed)	Tested in equipment
Discharge resistors, R88, R89, R97	YAGEO	RC0850FR-07270KL	270kΩ,1%, 0.1W, SMD, 0805R	IEC 60601-1 (3.1ed)	Tested in equipment
Alternative 1	Various	Various	270kΩ,1%, 0.1W, SMD, 0805R	IEC 60601-1 (3.1ed)	Tested in equipment
C50	Murata	Type KY	1nF, 250VAC, 125°C, Y2	UL1414 IEC60384-14 2.ed EN60065 EN132400 IEC60384-14 2.ed	UL E37921 CSA LR44559 BSI 2277935 N, D, FI, VDE, S, SEV, BSI SAA 6824/2
Alternative 1	Murata	Type KH	1nF, 250VAC, 125°C, Y2	UL1414 E384-14 EN60065 EN132400 IEC60384-14 2.ed	UL E37921 CSA LR44559 BSI 2277936 N, D, FI, VDE, S, SEV, BSI SAA 6529/5
Alternative 2	Panasonic	Type TS	1nF, 440VAC, 125°C, Y2	UL1414 CSA C22.2 No.1 K60384-14 IEC60384-14 2.ed	UL E62674 CSA LR58064 SU03012-3002 N, D, FI, VDE, S, SEV, BSI
L1	Murata	PLH10	2x70µH, 105°C, Flame class: V-0	IEC 60601-1 (3.1ed)	Tested in equipment
Alternative 1	Motocraft	MTC	2x70µH, 105°C, Flame class: V-0	IEC 60601-1 (3.1ed)	Tested in equipment

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

C7	Murata	Type KY	1nF, 250VAC, 125°C, Y2	UL1414 IEC60384-14 2.ed EN60065 EN132400 IEC60384-14 2.ed	UL E37921 CSA LR44559 BSI 2277935 N, D, FI, VDE, S, SEV, BSI SAA 6824/2
Alternative 1	Murata	Type KH	1nF, 250VAC, 125°C , Y2	UL1414 E384-14 EN60065 EN132400 IEC60384-14 2.ed	UL E37921 CSA LR44559 BSI 2277936 N, D, FI, VDE, S, SEV, BSI SAA 6529/5
Alternative 2	Panasonic	Type TS	1nF, 440VAC, 125°C, Y2	UL1414 CSA C22.2 No.1 K60384-14 IEC60384-14 2.ed	UL E62674 CSA LR58064 SU03012-3002 N, D, FI, VDE, S, SEV, BSI
VDR2	AVX	VE17M02750KEB	275V	UL1414 UL1449 IEC61051-1 IEC61051-2	UL, VDE
Alternative 1	Epcos	S20K275E3	275V	UL1414 UL1449 IEC61051-1 IEC61051-2	UL, VDE
Alternative 2	Littelfuse	TMOV14RP275E	275V	UL1414 UL1449 IEC61051-1 IEC61051-2	UL, VDE
C53, C54	Vishay	VY1471M31Y5UQ6*V0	470pF, 250VAC, 125C	IEC60384-14 2ed	VDE, ENEC
Primary Fuse F2	Schurter	001.2510.xx	T4AH, 250VAC	IEC60127-2-5	IEC,UL,CSA
Alternative	Littelfuse	02150004SP	T4AH, 250VAC	IEC60127-2-5	IEC,UL,CSA
C49	Vishay	BFC233620334	330nF, 275V, 110°C, X2	IEC60384-14 2ed	VDE

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

L2	Epcos	B82734	2x10mH, 130°C, Flame class: V-0	EN 60983-2 UL 1283	VDE UL E70122
Alternative 1	Motocraft	MTC	2x10mH, 130°C, Flame class: V-0	IEC 60601-1	Tested in equipment.
C48	Vishay	BFC233620334	330nF, 275V, 110°C, X2	IEC60384-14 2ed	VDE
C51, C52	Vishay	VY1471M31Y5UQ6*V0	470pF, 250VAC, 125C	IEC60384-14 2ed	VDE, ENEC
Alternative 1	Murata	DE1E3KX471MN5A01	470pF, 250VAC, 125C	IEC60384-14 2ed	N,D,S, FI,VDE, SEV, BSI
Alternative 2	TDK	CD85-B2GA471KYoKA	470pF, 400VAC, 125C	IEC60384-14 2ed	N, D, S, FI, VDE, SEV
Alternative 3	TDK	CD95-B2GA471KY□S	470p, 250VAC, 105C	IEC60384-14 2ed	N, D, S, FI, VDE, SEV, BSI
L5	Epcos	B82734	2x10mH, 130°C, Flame class: V-0	EN 60983-2 UL 1283	VDE UR E70122
Alternative 1	Motocraft	MTC	2x10mH, 130°C, Flame class: V-0	IEC 60601-1	Tested in equipment.
C2	Vishay	BFC233620334	330nF, 275V, 110°C, X2	IEC 60384-14 2ed	VDE
R79	Epcos	B57238S100M000	10R/5A, NTC, S70x160	IEC 60601-1 (3.1ed)	Tested in equipment
Alternative 1	Various	Various	10R/5A, NTC, S70x160		Tested in equipment
D21	Vishay	GBU4K-E3/45	4A/800V	IEC 60601-1 (3.1ed)	Tested in equipment
Alternative 1	Various	Various	4A/800V		
C46	Nichicon	LGU2G331MELC	330µF, 400V, 105°C	IEC 60601-1 (3.1ed)	Tested in equipment.
L201	Dantrafo	DT 15724-3	2mH/2.8A	IEC 60601-1 (3.1ed)	Tested in equipment.
Winding wire	IRCE-SPA	Salflex 1550	IEC Class F 155°C, 0.5mnm	UL 1446	UL E60641
Alternative 1	Isodraht GMBH	Isoflex	IEC Class F 155°C, 0.5mm	UL 1446	UL E106565
Alternative 2	Dahrentrad AB	Dasol	IEC Class F 155°C, 0.5mm	UL 1446	UL E101843
Bobbin	El Dupont De Nemours & CO INC	Rynite FR530L	IEC Class N (UL:200°C), 0.75mm	UL 94	UL E41938
Potting Compound	Casco Nobel	Polyester 2099/1821	IEC Class F 155°C)	UL 1446	UL E190275, UL E114913
Case Material	El Dupont De Nemours & CO INC	Rynite FR530L	IEC Class N (UL: 200°C)	UL 94	UL E34739

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

Alternative L201	Transelectro	PMS 82000-055	2mH/2.8A	IEC 60601-1 (3.1ed)	Tested in equipment.
Winding wire	IRCE-SPA	Salflex 1550	IEC Class F 155°C, 0.5mm	UL 1446	UL E60641
Alternative 1	Isodraht GMBH	Isoflex	IEC Class F 155°C, 0.5mm	UL 1446	UL E106565
Alternative 2	Dahrentrad AB	Dasol	IEC Class F 155°C, 0.5mm	UL 1446	UL E101843
Bobbin	El Dupont De Nemours & CO INC	Rynite FR530L	IEC Class N (UL:200°C), 0.75mm	UL 94	UL E41938
Potting Compound	Casco Nobel	Polyester 2099/1821	IEC Class F 155°C, 0.5mm	UL 1446	UL E190275 UL E114913
Case Material	El Dupont De Nemours & CO INC	Rynite FR530L	IEC Class N (UL: 200°C)	UL 94	UL E34739
C73	Kernet	R60MN41005040 J	1µF, 400V	IEC 60601-1 (3.1ed)	Tested in equipment
Alternative 1	Various	Various	1µF, 400V	IEC 60601-1 (3.1ed)	Tested in equipment
C22, C72	Vishay	BFC237347105	1µF, 250V	IEC 60601-1 (3.1ed)	Tested in equipment
Alternative 1	Various	Various	1µF, 250V	IEC 60601-1 (3.1ed)	Tested in equipment
L3	Murata	PLH10	2x70µH, 105°C, V-0	IEC 60601-1	Tested in equipment.
Alternative 1	Motocraft	MTC	2x70µH,105°C, V-0	IEC 60601-1	Tested in equipment.
T17	Transelectro	PMS82000-059D	Class B 130°C, Insulation system CZ130N	IEC 60601-1 (3.1ed)	Tested in equipment. UL E69939
Bobbin	Ferroxcube	CPH-E42/20-1S-12PD-Z	UL: 130°C	UL 94	UL E41938
TIW	Furukawa E	TEX-E	UL: 130°C	UL 2353, IEC 60950-1	UL E206440
Insulation tape	Dupont Tejin Films	Mylar A, Isolation system CZ130N	50µm thickness, UL:130°C	UL 94 IEC 60085	UL E 93687 UL E69939
Alternative 1	Garware Polyester	ER/ERE, Isolation system CZ130N	50µm thickness, UL:130°C	UL 94 IEC 60085	UL E110983 UL E69939
Alternative 2	Mitsubishi Polyester Film	Hostaphan, Isolation system CZ130N	50µm thickness, UL:130°C	UL 94 IEC 60085	UL E53895 UL E69939
Tube	Synflex	Sleeving H	Class H (180°C)	IEC 60684-123/124	Tested in equipment

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

Alternative, T17	Motocraft	PMS82000-059D	Class B130°C	IEC 60601-1 (3.1ed)	Tested in equipment.
Bobbin	NANJIDA ELECTRONICS PRODUCTS FACTORY	EE4220	UL:130°C	UL94	E130155
TIW	YOUNG CHING SILICOME CO.,LTD	STW-B	0.60mm 3 layers isolation wire, UL: 130C	UL2353, IEC 60950-1	UL E242198
Insulation tape	HUIZHOU YAHUA STICKING TAPE CO.,LTD.		130°C	UL 510 UL 510	UL E165111 UL E 324093
Tube teflon	DONGGUAN CITY CHANGJIE METALS & PLASTIC PRODUCTS CO LTD	(1) #24T ,Thickness: 0.25mm (2) #18L Thickness: 0.15mm , Two Teflon tube total Thickness: 0.40mm	UL: 200°C Temprature:200° C Class : H	UL 224	UL E338209
Silicon tube	SHENZHEN WOER HEAT-SHRINKABLE MATERIAL CO LTD	#T2.0 Wall Thickness: 0.50mm	Temprature:200° C Class : H	UL 224	E203950
Nomex	E I DUPONT DE NEMOURS & CO INC	T410	UL: 220°C	UL 94	UL E34739
C26, C27	Vishay	VY1102M35Y5UQ6*V0	1nF, 250VAC, 125C	IEC60384-14 2ed	VDE, ENEC
Alternative 1	TDK	CD70ZU2GA102MYoKA	1nF, 440VAC, 125C	IEC60384-14 2ed	ENEC, N
Alternative 2	TDK	CD85-E2GA102MY□S	1nF, 400VAC, 125C	IEC60384-14 2ed	VDE
U5, U6	Vishay	SFH617A- 2X016	8mm	EN60747-5-5	VDE 40033345

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

TR2	Li Tone Electronics	PMS82000-048 P/N: 40301013	Class A	IEC 60601-1	Tested in equipment.
Bobbin material	Chang Chun Plastics	T375J	Phenolic, Flame class: V-0	UL 94	UL E59481
Tape	3M Company	1350F-1	130°C	UL 510	UL E17385
TIW	Furukawa	TEX-E	UL: 130C	UL 2353, IEC 60950-1	UL E206440
U10, U12	Vishay	SFH617A- 2X016	8mm	EN60747-5-5	VDE 40033345
Secondary Fuse F1	Littelfuse	SMD/451015	F15AL, 65V, 125C	UL 248-14, CSA C22.2	UL E10480, CSA
Alternative 1	Tyco	1206SFH150F/24-2	T15AL, 65V,125C	UL 248-14, CSA C22.2	UL, CSA
Alternative 2	Schurter	3413.0330.xx	T15AL, 63V, 90C	UL 248-14, CSA C22.2	UL E41599, CSA
Strain relief	J.K Medico	DWG 82000-037	2x0.75mm^2	IEC 60601-1 (3.1 ed)	Tested in equipment
Strain relief material (secondary cord)	Asia Int'l Enterprise (Hong Kong) Ltd	5010F, 50G5F/50G6F	PA6, V-0 for min 1.5mm, measured = 2.0mm	IEC 60695-11-10	UL E252275
DC output cord	Kenic	H05VV-F	2x1.5mm^2, 300V, PVC, 2 meters,	HD 21.5	N, S, D, Fi, VDE, Kema, ÖVE, CCC
1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.					

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

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

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

8.11.3.5	TABLE: Cord anchorages			P
Cord under test	**Mass of equipment (kg)**	**Pull (N)**	**Torque Nm)**	**Remarks**
Mains cord	2.2Kg	60	0.25	Pass
Outlet cord	2.2Kg	60	0.25	Pass

Supplementary information:
Measured d: 6.53mm

8.11.3.6	TABLE: Cord guard			P
Cord under test	**Test mass**	**Measured curvature**	**Remarks**	
Mains cord	423g	11.5mm	Required: 9.8mm	
Outlet cord	423g	11.5mm	Required: 9.8mm	

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	
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.

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

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
In standing position	10 degree tilt	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
In standing position	10 degree tilt	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:		

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

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

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Clause	Requirement + Test	Result - Remark	Verdict

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

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

9.4.4	TABLE: Grips and other handling devices	P
Clause and Name of Test	Test Condition	Remarks
9.4.4 c)	Loaded with 4x weight=9kg	Pass
Supplementary information:		

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

9.8.3.2	TABLE: PATIENT support/suspension system - Static forces			N/A
ME EQUIPMENT part or area	Position	Load	Area	Remarks
Supplementary Information:				

9.8.3.3	TABLE: Support/Suspension System – Dynamic forces due to loading from persons			N/A
ME EQUIPMENT part or area	Position	Safe Working Load	Area	Remarks
Supplementary Information:				

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

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

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

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

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT**					**P**
Model No. ..... :	**CCC410S**					
Test ambient (°C) ..... :	**24 (40)[5]**					
Test supply voltage/frequency (V/Hz)[4] .. :	**196V/50Hz**					

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP(°C)	Max measured temperature[2], (°C)	Remarks
CCC410 S		C50	125	77	T marking
CCC410 S		L1	95	85	Class A Table 22
CCC410 S		C49	110	90	T marking
CCC410 S		L2	120	120	Class B Table 22
CCC410 S		C46	105	91	T marking
CCC410 S		L4	120	111	Class B Table 22
CCC410 S		T17	120	113	Class B Table 22
CCC410 S		TR2	120	99	Class B Table 22
CCC410 S		F2	125	97	T marking
CCC410 S		Primary wiring	70	67	T marking
CCC410 S		Secondary wiring	70	67	T marking
CCC410 S		Plastic handle	60	49	Table 23 10s ≤ t 1min
CCC410 S		Enclosure plastic	71	68	Table 23 1s ≤ t ≤ 10s
CCC410 S		Enclosure metal	74	72	Table 23 t < 1s
CCC410 S		C2	110	110	T marking

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] Temperatures recalculated to ambient temperature 40°C.

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

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT**					**P**
Model No. ..... :	**CCC410S**					
Test ambient (°C) ..... :	**24 (40)[5]**					
Test supply voltage/frequency (V/Hz)[4] .. :	**253V/50Hz**					

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP (°C)	Max measured temperature[2], (°C)	Remarks
CCC410 S		C50	125	78	T marking
CCC410 S		L1	95	84	Class A Table 22
CCC410 S		C49	110	90	T marking
CCC410 S		L2	120	110	T marking
CCC410 S		C46	105	91	T marking
CCC410 S		L4	120	106	Class B Table 22
CCC410 S		T17	120	119	Class B Table 22
CCC410 S		TR2	120	99	Class B Table 22
CCC410 S		F2	125	98	T marking
CCC410 S		Primary wiring	70	68	T marking
CCC410 S		Secondary wiring	70	68	T marking
CCC410 S		Plastic handle	60	51	Table 23 10s ≤ t 1min
CCC410 S		Enclosure plastic	71	67	Table 23 1s ≤ t ≤ 10s
CCC410 S		Enclosure metal	74	73	Table 23 t < 1s
CCC410 S		C2	110	103	T marking

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] Temperatures recalculated to ambient temperature 40°C.

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

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**
1.		
2.		
3.		
4.		
5.		
6.		
Test parameters selected representing worst case conditions for ME EQUIPMENT:		**Remarks**
Oxygen concentration (%).....:		
Fuel .....:		
Current (A) .....:		
Voltage (V) .....:		
Capacitance (µF).....:		
Inductance or resistance (h or Ω).....:		
No. of trials (300 Min) .....:		
Sparks resulted in ignition (Yes/No) :		
Supplementary information: Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur. **Information from Risk Management, as applicable:**		

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

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
11.6.5	IP54	Battery Charger	No ingress of water
Supplementary information:			

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

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

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

13.2	**TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive**	**P**

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2	**Electrical SINGLE FAULT CONDITIONS per Clause 8.1:**	**—**	**—**
	S-C L1	F2 blows. Test time: 5 min Final input: 230V / 0A.	No
	S-C L2	F2 blows. Test time: 5 min Final input: 230V / 0A.	No
	S-C R47	Normal operation.	No
	O-C R47	Output voltage 32V, shutdown after 1s.	No
	S-C R53	Normal operation	No
	O-C R53	Output current 14A, shutdown after 1s	No
	S-C C36	Shutdown 1s.Test time: 5 min Final input: 230V / 0A.	No
	O-C C36	Normal operation.	No
	S-C D21	F2 blows. Test time: 5 min Final input: 230V / 0A.	No
	S-C C46	F2 blows. Test time: 5 min Final input: 230V / 0A.	No

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	Reverse polarity connection of battery to 24dc o/p	Output does not activate. Test time: 5min. Final input: 230V / 0A.	No
	S-c, U5 pin 1-2	Output shutdown. Test time: 5min. Final input: 230V / 0A.	No
	S-c, U5 pin 3-4	Normal operation. Test time: 5min. Final input: 230V / 1.85A.	No
	S-c, U6 pin 3-4	Output shutdown. Test time: 5min. Final input: 230V / 0A.	No
	S-c, U6 pin 1-2	Output increased to 10.4A/28.8V. Test time: 3 hrs. Final input: 230V / 2.21A. Ambient: 25°C, T17 L1 winding: 80°C, T17 L2 winding: 82°C, T17 T1 winding: 81°C, TR2 winding: 68°C.	No
13.2.3	**Overheating of transformers per Clause 15.5:**	**—**	**—**
	Transformer short circuit. See table 15.5	See table 15.5	No
	Output overload see table 13.2.3	Output overloaded at 10A/29V. Equipment loaded until temperatures are stable.	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:**	**—**	**—**
	—	**N/A**	**—**
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:**	**—**	**—**
	—	**N/A**	**—**
13.2.6	**Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)**	**—**	**—**
	—	**N/A**	**—**
13.2.7	**Impairment of cooling that could result in a HAZARD using test method of 11.1:**	**—**	**—**
	Single ventilation fans locked consecutively	**N/A**	

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls	N/A	
	Simulated blocking of filters	N/A	—
	Flow of a cooling agent interrupted	N/A	—
	—	N/A	—
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
	—	N/A	
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	—	—
	—	N/A	—
	—	N/A	—
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:	—	—
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or upper limit of RATED voltage range for specified time:	N/A	—
	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	N/A	—
	Temperatures measured as specified in 11.1.3 d)	N/A	—
	Temperatures did not exceed limits of Table 26	N/A	—
	—	N/A	—
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	—	—
	—	N/A	—
	—	N/A	—
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	—	—
	—	N/A	—
	—	N/A	—
	—	N/A	—

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.

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

13.2.3	**TABLE: Overheating of transformers, Output overload[6]**					**P**
Model No. ..... :	**CCC410S**					
Test ambient (°C) ..... :	**24[7]**					
Test supply voltage/frequency (V/Hz)[4] .. :	**253V/50Hz**					

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP(°C)	Max measured temperature[2], (°C)	Remarks
CCC410 S		C50	175	64	(T x 1.5) – 12.5°C
CCC410 S		L1	140	71	Class A Table 31
CCC410 S		C49	153	76	(T x 1.5) – 12.5°C
CCC410 S		L2	165	102	Class B Table 31
CCC410 S		C46	145	90	(T x 1.5) – 12.5°C
CCC410 S		L4	165	95	Class B Table 31
CCC410 S		T17	165	98	Class B Table 31
CCC410 S		TR2	165	89	Class B Table 31
CCC410 S		F2	175	86	(T x 1.5) – 12.5°C
CCC410 S		Primary wiring	118	53	(T x 1.5) – 12.5°C
CCC410 S		Secondary wiring	118	53	(T x 1.5) – 12.5°C
CCC410 S		Plastic handle	60	35	Table 23 10s ≤ t 1min
CCC410 S		Enclosure plastic	71	52	Table 23 1s ≤ t ≤ 10s
CCC410 S		Enclosure metal	74	58	Table 23 t < 1s
CCC410 S		C2	153	94	(T x 1.5) – 12.5°C
CCC410 S		Ambient	-	24	Informational only

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

Supplementary information:

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

[2] Max temperature determined in accordance with 11.1.3e)

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

[4] Supply voltage:

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

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

[6] Overload at 10A/29V

[7] Ambient temperature in single fault condition not recalculated to 40C ambient.

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	Pass
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	Pass
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5cm	Pass
15.3.6	Mould stress relief test	7h, 81°C	Pass
Supplementary information: [1)] As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows).			

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] .... :							**253V**	**—**
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 (ºC)**	**Maximum winding temp measured (ºC)**	**Ambient (ºC)**	
TR2: pin 6 - 7	B	Fuse F2	No	30 min	150	38	23	
T17 pin 8,9-10,11	B	Fuse F2	Yes	Fuse opens immediately.	165	24	24	

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

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.

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] ..:		**253V**
RATED input frequency (Hz).....:		**50Hz**
Test current just below minimum current that would activate protective device & achieve THERMAL STABILITY under method a) (A).....:		-
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A) .....:		-

Winding tested	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (ºC)	Maximum winding temp measured (ºC)	Ambient (ºC)
Secondary winding overload[2]	B	Electronic	175	T17: 123 TR2: 105	24

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.
[2] overloaded at 10A/29V

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: SMPSU with a transformer frequency above 1khz, test not applicable.					

16.6.1	**TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS**	**N/A**

Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	Allowable TOUCH CURRENT in NORMAL CONDITION (µA)	Measured TOUCH CURRENT in NORMAL CONDITION (µA)	Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)	Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)
Supplementary information:				

SP	**TABLE: Additional or special tests conducted**	**N/A**

Clause and Name of Test	Test type and condition	Observed results
Supplementary information:		