Test Report issued under the responsibility of:

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

Report Reference No. ..... :	N40P0001
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Total number of pages ..... :	145
CB Testing Laboratory ..... :	SGS Germany GmbH, CRS Munich
Address ..... :	Hofmannstrasse 50, 81379 Munich, Germany
Applicant's name ..... :	**ADLINK Technology GmbH**
Address ..... :	Ulrichsberger Str. 17 94469 Deggendorf, Germany
Test specification:	
Standard..... :	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure ..... :	CB Scheme
Non-standard test method..... :	N/A
Test Report Form No. ..... :	IEC60601_1K
Test Report Form(s) Originator . :	UL(US)
Master TRF ..... :	2015-11

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:

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Digitally signed by Goncearuc Anatolie
Date: 2022.08.19 14:49:09 EEST
Reason: MoldSign Signature
Location: Moldova

Test item description .....:	Medical Panel Computer
Trade Mark ..... :	ADLINK Leading EDGE COMPUTING
Manufacturer ..... :	ADLINK Technology GmbH
Model/Type reference ..... :	MLC 8 series (MLC8-21, MLC8-23, MLC8-27)
Ratings ..... :	100 – 240 Vac; 1,5 A – 0,75 A; 50/60 Hz

Testing procedure and testing location:			
☒	**CB Testing Laboratory:**	SGS Germany GmbH, CRS Munich	
Testing location/ address..... :		Hofmannstrasse 50, 81379 Munich, Germany	
Tested by (name, function, signature) ..... :		Stefan Koschke Qualification Engineer	Stefan Koschke
Approved by (name, function, signature)..... :		Katja Blaesing Qualification Engineer	Blaesing
☐	**Testing procedure: CTF Stage 1:**		
Testing location/ address..... :			
Tested by (name, function, signature) ..... :			
Approved by (name, function, signature)..... :			
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address..... :			
Tested by (name, function, signature) ..... :			
Witnessed by (name, function, signature) ..... :			
Approved by (name, function, signature)..... :			
☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address..... :			
Tested by (name, function, signature) ..... :			
Witnessed by (name, function, signature) ..... :			
Approved by (name, function, signature)..... :			
Supervised by (name, function, signature) ..... :			

List of Attachments:

- IEC 60601-1-6 Test Report No.: N40P0002 of SGS Germany GmbH (kept in file)
- IEC 60601-1-2 Test Report No.: N40P0010 of SGS Germany GmbH (kept in file)
- IEC 60601-1-2 Test Report No.: N40P0014 of SGS Germany GmbH (kept in file)

Summary of testing:

Tests performed (name of test and test clause):

Clause	Tests
4.11	Power Input
5.7	Humidity Preconditioning treatment
7.1.2	Legibility of markings
7.1.3	Durability of Marking Test
8.4.3	ME equipment intended to be connected to a power source by a plug
8.6.4	Impedance and current-carrying capability of protective earth connections
8.7	Leakage currents and Patient auxiliary currents
8.7.4.7	Patient Leakage Current – measurements made under special test conditions
8.8.3	Dielectric Strength
8.9.4	Measurement of Creepage Distances and Air Clearances
11.1	Maximum temperature during normal use
11.6.3	Spillage test
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS
11.8	Interruption of the power supply / supply mains to ME equipment
13.2	Single fault conditions
15.3.2	Push test
15.3.3	Impact test
15.3.4	Drop test

Testing location:

SGS Germany GmbH, CRS Munich
Hofmannstrasse 50
81379 Munich
Germany

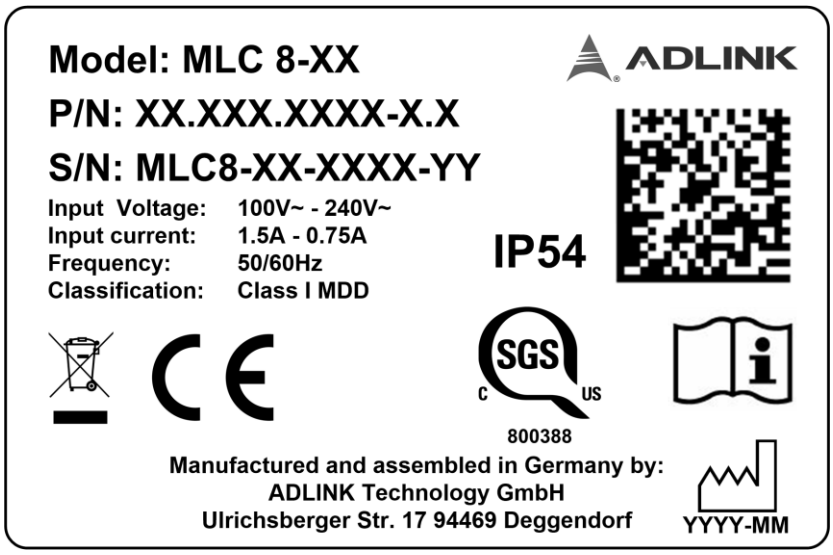
Summary of compliance with National Differences

☒ National Differences CA, US, CH, JP, KR

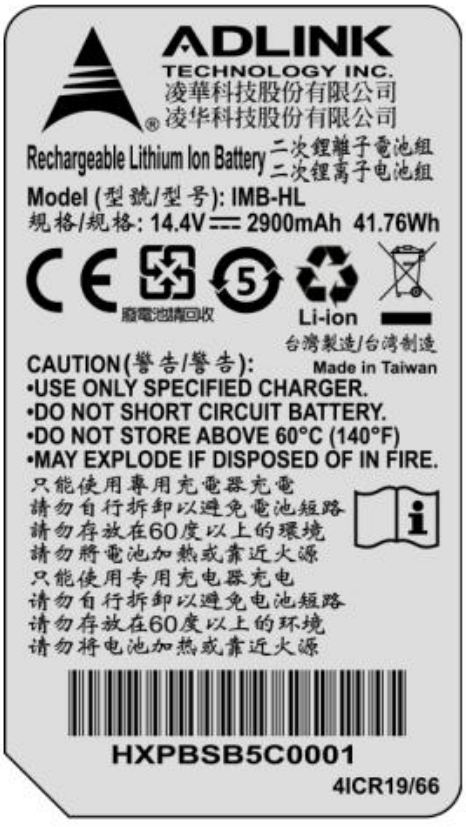
Explanation of Codes:
CA=Canada, CH=Switzerland, JP=Japan, KR=Korea, US=United States of America

Copy of marking plate

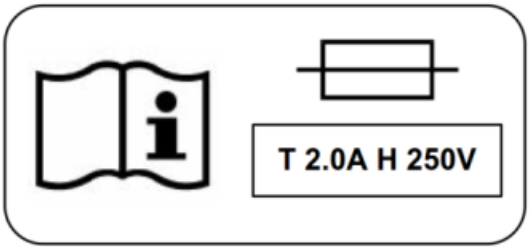
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



Product identification label



Battery pack label



Mains input fuse label

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	Stationary
Device type (component/sub-assembly/ equipment/ system) :	Equipment
Intended use (Including type of patient, application location) :	The All-in-One panel computers of the MLC 8 series are devices compliant to medical purpose and are intended to display, monitor and store data accumulating while processing medical and / or patient data in medical environments
Mode of operation ..... :	Continuous
Supply connection	Appliance coupler
Accessories and detachable parts included ..... :	None
Other options include ..... :	--
Testing ..... :	
Date of receipt of test item ..... :	Jul 08, 2019
Date(s) of performance of tests ..... :	Jul 08, 2019 to Nov 06, 2019
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) .....:	**Same as applicant**

General product information:

The product is an all-in-one medical panel computer system intended for use in medical environment (hospitals, medical centers, physician's facilities etc.).

It is and are intended to display, monitor and store data accumulating while processing medical and / or patient data in medical environments such as surgical OR theatres, intensive care units, emergency care units and further point-of-care sites in health care facilities like hospitals, out-patient care units and other medical care units.

The device provides medically relevant information to medical personnel. Patient and / or surgical and medical data are displayed, processed and stored locally or can be exported to external systems. The device is intended to be operated within the scope of the intended purpose by medical personnel working in health care facilities. Furthermore persons functioning as device administrators are intended to use the device and to maintain the device to the extent described in the according device manual.

The device is neither intended to be operated by, nor intended to be connected directly to patients (unless used as part of a medical system, configured by a third party).

The product is a Medical PC intended for stand-alone use or for usage in conjunction with (other) medical electrical equipment.

A dedicated type of patient is not specified and is depending on end medical use. The device is used inside patient environment, patients may come unintended in contact with parts of the device.

The maximum operating ambient temperature is +30 °C.

The device does not offer any essential performance itself. Essential performance depends on end user application.

The average service life-time of the device used within the limits of the intended purpose ranges from 3 to in max. 7 years.

The device is not intended to be used near high intensity emission equipment such as HF surgery devices or magnetic resonance imaging equipment in oxygen rich or flammable anesthetic environments

The device incorporates the LCD panel and computational elements in one enclosure. All operating controls are located on the lower front side. All connectors (I/O interfaces) are provided at the back-bottom side, underneath the cable cover. Depending from the product variation, the device is available with or without PCAP (projected capacitive) touch screen functionality.

Manufacturer and applicant of the product is ADLINK Technology GmbH, referenced as ATG. Trademark of the computer is provided on the device marking label.

The MLC 8 series devices can be identified via the assembled LCD panel size and power input. Sub variants are generated via different CPUs, optional interfaces and extensions such as WLAN/Bluetooth modules or various storage medium capacities. Sub variants are not reflected by key codes but tracked via serial number and device database entries.

All variants are available with incorporated PSU connected to mains

Tested Configuration:

Component	Type	Identification No	Iss.	Serial No	Comment
Medical Panel Computer	MLC 8-21	--	--	MLC8-21-0001-19	--
Medical Panel Computer	MLC 8-23	--	--	MLC8-23-0001-19	--
Medical Panel Computer	MLC 8-27	--	--	MLC8-27-0001-19	--

Conditions of Acceptability:

1. The system is to be installed, switched on and maintained only by suitably trained and qualified personnel in accordance with the installation instructions provided with the EUT.
2. The maximal acceptable operating temperature is +30 °C
3. The EUT is reliable connected to ground. For testing of clause 8.6.4 a detachable cord with 2 m length has been used (refer to table 8.10), different length shall be considered in end use application
4. Manual checked in English; for placing the product on other markets it should be in local language.
5. The device does not offer any essential performance itself. Essential performance must be evaluated in final end user application.
6. Any mechanical provisions to mount the displays are not part of this investigation and shall be considered in final end user application
7. All connected IT equipment must comply with appropriate standards and shall be considered in end use application
8. Performance of installed software and connection to an IT network (Chapter 14 of this standard) shall be considered in end use application

INSULATION DIAGRAM

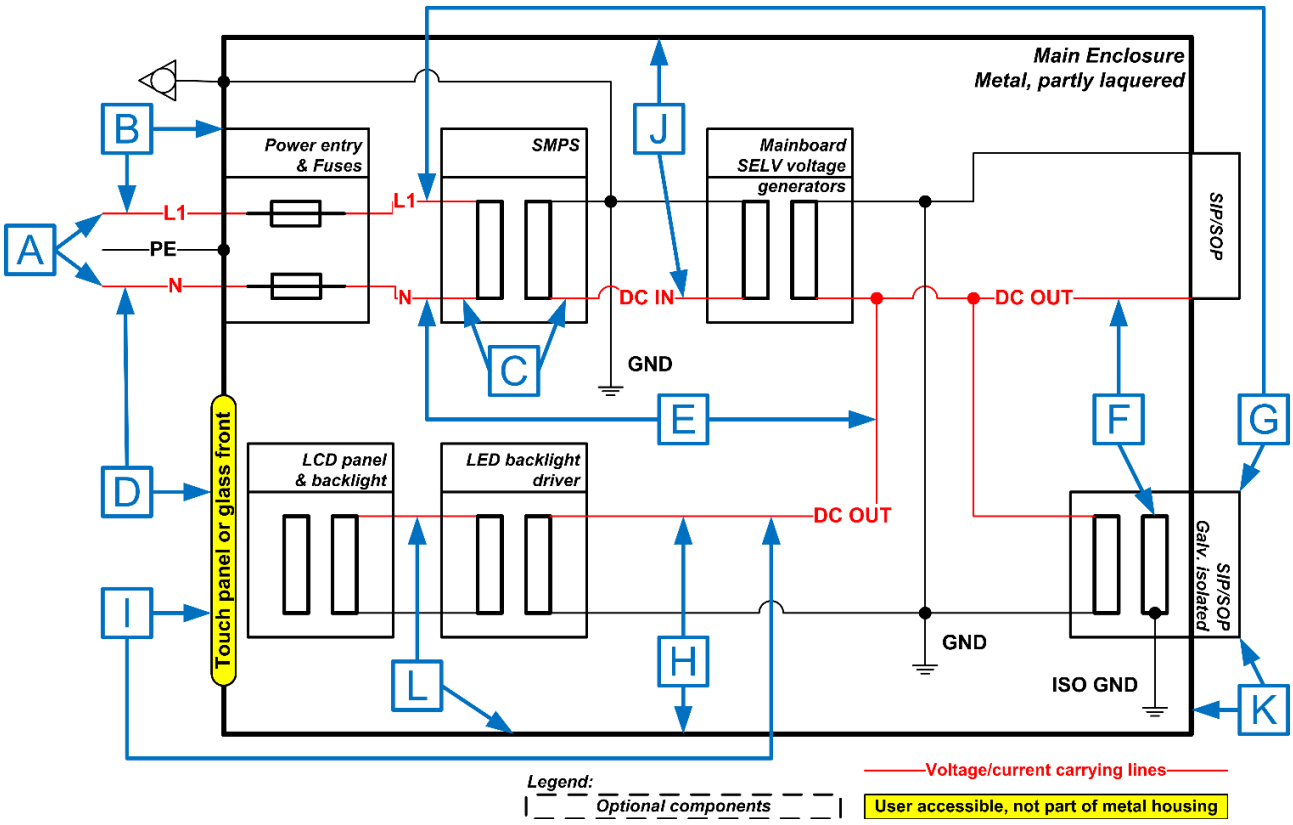


TABLE: INSULATION DIAGRAM		P
Pollution degree.....:	**2**	—
Overvoltage category.....:	**II**	—
Altitude.....:	**≤ 2000 m**	—
Additional details on parts considered as applied parts.....:	☒ **None** ☐ **Areas** _____ **(See Clause 4.6 for details)**	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			V_{rms}	V_{pk}					
A	1 MOOP	IIIb	240	340	2,5	2,0	Certified component, see table 8.10		Clause 8.9.1.1 Opposite polarity (mains side of fuse)
B	1 MOOP	IIIb	240	340	2,5	2,0	Certified component, see table 8.10		Mains to enclosure
C	2 MOOP	IIIb	240	340	5,0	4,0	Certified component, see table 8.10		Mains to SEC provided by PSU
D	2 MOOP	IIIb	240	340	5,0	4,0	> 6,5	> 5,2	Mains to touch panel, ensured by distance
E	2 MOOP	IIIb	240	340	5,0	4,0	> 6,5	> 5,2	Mains to SELV outside PSU
F	2 MOOP	IIIb	240	340	5,0	4,0	5,1	5,1	SIP/SOP to SEC measured at isolation PCB
G	2 MOOP	IIIb	240	340	5,0	4,0	> 6,5	> 5,2	SIP/SOP to Mains, ensured by distance
H	1 MOOP	IIIb	--	12	1,0	1,0	1,0	1,0	SELV to enclosure measured at PCB
I	2 MOOP	IIIb	--	12	2,0	2,0	> 2,6	< 2,6	SELV to touch panel ensured by distance
J	1 MOOP	IIIb	--	24	1,0	1,0	1,0	1,0	SEC to enclosure measured at PCB
K	1 MOOP	IIIb	240	340	2,5	2,0	2,5	2,5	SIP/SOP to enclosure measured at isolation PCB
L(1)	1 MOOP	IIIb	--	39	1,2	1,0	1,4	1,4	LED driver MLC 8-21 to enclosure measured at PCB
L(2)	1 MOOP	IIIb	--	62	1,4	1,0	1,4	1,4	LED driver MLC 8-23 to enclosure measured at PCB
L(3)	1 MOOP	IIIb	--	51	1,4	1,0	1,4	1,4	LED driver MLC 8-27 to enclosure measured at PCB

Supplementary Information:

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

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

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:
- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer
  windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

IEC 60601-1			
Clause	Requirement + Test	Result – Remark	Verdict
4	GENERAL REQUIREMENTS		P
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		P
4.2	RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS		P
4.2.2	General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007) ..... :	See Appended RM Results Table 4.2.2	P
4.2.3	Evaluating RISK		P
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level		P
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN ..... :	RISK MANAGEMENT PLAN DOCUMENT: Document name: risk management plan MLC 8; document No. ATGD-DMF-MLC8-006, checked Version 1.0; dated 2018-10-26	P
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		P
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		P
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.		P
4.3	Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.	To be considered in final end use application	N/A
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.		N/A
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		N/A
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE ..... :	The device does not offer any essential performance itself. Essential performance depends on end user application.	N/A
	- RISK CONTROL measures implemented		N/A
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		N/A
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE ..... :	ATGD-DMF-MLC8-008 Risk Analysis; chapter 4.2	P
4.5	Alternative RISK CONTROL methods utilized:		N/A

IEC 60601-1			
Clause	Requirement + Test	Result – Remark	Verdict
	RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Not used	N/A
	Alternative means based scientific data or clinical opinion or comparative studies ..... :		N/A
4.6	RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10 ..... :	Intended use excludes any patient contact during normal use, refer to risk cited below	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)	RMF Reference to specific RISKS: ATGD-DMF-MLC8-008 Risk Analysis; chapter 7.2.2 #45 and ATGD-DMF-MLC8-002 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.)	P
	Assessment identified the APPLIED PART TYPE requirements..... :	Device does not have Applied Parts	N/A
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2 ..... :	Me equipment remained single fault safe	P
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested.....: (ISO 14971 Cl. 4.2-4.4)	RISK ANALYSIS reference: ATGD-DMF-MLC8-008 Risk Analysis; chapter 7.2.2; (ISO 14971 Cl. 4.2-4.4)	P
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically ..... :	See appended Table 13.2 for simulated physical test	P
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified..... :	All components used within their rating	P
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS	No exceptions identified	N/A
	RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See above	N/A
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION .....:	See appended table 8.10	P
	Components determined to be acceptable where used as a MEANS OF PROTECTION.....:	See appended table 8.10	P

IEC 60601-1			
Clause	Requirement + Test	Result – Remark	Verdict
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following		P
	a) Applicable safety requirements of a relevant IEC or ISO standard	See appended table 8.10	P
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard	See appended table 8.10 for components “tested in appliance”	P
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately..... :	Not used	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)		N/A
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:		N/A
4.10	Power supply		P
4.10.1	ME EQUIPMENT is suitable for connection to indicated power source (select applicable) ..... :	Supply mains See IFU chapter “Backup battery module”: the device can continue operation with the optional battery for up to 10 minutes in case of supply mains failure but is not considered to be classified as internally powered.	P
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:		P
	- 250 V for HAND-HELD ME EQUIPMENT (V)..... :	Not hand-held	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) ..... :	240 V~	P
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS		N/A
4.11	Power input		P
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn’t exceed marked rating by more than 10%.... :	See appended Table 4.11	P

5	GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT		P
5.1	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods ..... :	All necessary tests performed	N/A

IEC 60601-1			
Clause	Requirement + Test	Result – Remark	Verdict
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. (ISO 14971 Cl. 4.2-4.4)	No such faults identified	N/A
5.3	Tests conducted within the environmental conditions specified in technical description		P
	Temperature (ºC), Relative Humidity (%) ..... :	0 °C…+30 °C 10 % ... 90 % (non-condensing)	—
	Atmospheric Pressure (kPa)..... :	700 hPa … 1060 hPa	—
5.5	a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V) ..... :	Rated: 100 – 240 V~ Tested: 90 – 264 V~	P
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz) ..... :	50/60 Hz	P
	c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current..... :	See above	P
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered ..... :		N/A
	e) ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions ..... :		N/A
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	No separate Power supply specified	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 ..... :	Setup completely	P
	ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +32°C for indicated time	T = 25 °C Time – 168 h	P
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		P
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS ..... :	No Applied Parts	N/A
5.9.2	ACCESSIBLE PARTS		P
5.9.2.1	Accessibility determined using standard test finger of Fig. 6	See Appended Table 5.9.2	P

IEC 60601-1			
Clause	Requirement + Test	Result – Remark	Verdict
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s		N/A
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS..... :	No such parts identified	N/A
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL.....:	No such parts identified	N/A
6	CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS		P
6.2	CLASS I ME EQUIPMENT, externally powered		P
	CLASS II ME EQUIPMENT, externally powered		N/A
	INTERNALLY POWERED ME EQUIPMENT		P
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements		P
	TYPE B APPLIED PART	No Applied Parts	N/A
	TYPE BF APPLIED PART		N/A
	TYPE CF APPLIED PART		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS		N/A
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529..... :	IP 54	P
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use ..... :	No sterilization	N/A
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2	Not for such use	N/A
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION ..... :	Continuous	P
7	ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS		P
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6 .....:	See Appended Table 7.1.2	P
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE	See appended Tables 7.1.3	P
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		P

IEC 60601-1			
Clause	Requirement + Test	Result – Remark	Verdict
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:	See IFU chapter “Markings and labels”	P
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT		N/A
	Single use item marked .....:	No single use item provided	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 provided,	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)		N/A
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and		N/A
	– a MODEL OR TYPE REFERENCE		N/A
	Software forming part of a PEMS identified with a unique identifier.....:	End use consideration	N/A
7.2.3	Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS	Used	P
	Safety sign 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	Not used	N/A
7.2.4	ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and.... :	Accessories inspected: Battery	P
	- with a MODEL or TYPE REFERENCE	See appended copy of marking plate	P
	– a serial number or lot or batch identifier	See appended copy of marking plate	P
	– the date of manufacture or use by date	See appended copy of marking plate	P

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Clause	Requirement + Test	Result – Remark	Verdict
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		N/A
7.2.5	ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following	No such equipment specified	N/A
	- the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or		N/A
	– Table D.2, safety sign No. 10 adjacent to the relevant connection point and listing of the required details in the instructions for use; or		N/A
	– Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use.		N/A
7.2.6	Connection to the Supply Mains		P
	Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point		P
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT	Not permanently installed	N/A
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V) ..... :	100 V~ – 240 V~	P
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V) ..... :		N/A
	– Nature of supply and type of current .....:	AC	P
	Symbols 1-5, Table D.1 (used for same parameters ..... :	~	P
	– RATED supply frequency or RATED frequency range in hertz..... :	50/60 Hz	P
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT..... :	Class I	N/A
7.2.7	RATED input in amps or volt-amps, (A, VA) .....:	1,5 A – 0,75 A	P
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) .....:	See above	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) :	See above	P
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W)..... :		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA)..... :		N/A
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W) ..... :		N/A
7.2.8	Output connectors		N/A
7.2.8.2	Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment	No such connectors	N/A
	Rated Voltage (V), Rated Current (A).....:		—
	Rated Power (W), Output Frequency (Hz).....:		—
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..... :	IP 54	P
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols ..... :	Device does not have Applied Parts	N/A
	TYPE B APPLIED PARTS with symbol 19 of Table D.1		N/A
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1:		N/A
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1:		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1..... :		N/A
	Proper symbol marked adjacent to or on connector for APPLIED PART..... :		N/A
	Safety sign 2 of Table D.2 placed near relevant outlet..... :		N/A
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use ..... :		N/A
7.2.11	ME EQUIPMENT suitable for CONTINUOUS OPERATION		P
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum “on” and “off” time..... :		N/A
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder		P
	Fuse type..... :	5x20 mm fusible cut-out	—
	Voltage (V) and Current (A) rating.....:	250 V; 2,0 A	—
	Operating speed (s) and Breaking capacity.....:	T 2,0 A H	—

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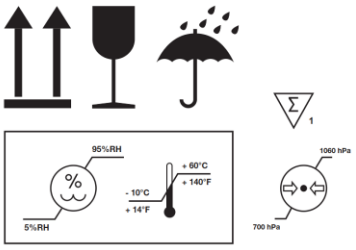
Clause	Requirement + Test	Result – Remark	Verdict
7.2.13	Physiological effects – safety sign and warning statements ..... :	No such effects	N/A
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.3)		N/A
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1	No such terminals	N/A
7.2.15	Requirements for cooling provisions marked ..... :	No cooling provisions	N/A
7.2.17	Packaging marked with special handling instructions for transport and/or storage.....:		P
	Permissible environmental conditions marked on outside of packaging .....:	-10 °C.+60 °C 5%..95% 700 hPa..1060 hPa	P
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK ..... :		N/A
	RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK...: (ISO 14971 Cl. 4.2-4.4, 5, 6.3-6.4)	Not identified as risk	N/A
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization	Not supplied sterile	N/A
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and .....:	No such pressure source	N/A
	- the RATED flow rate also marked		N/A
7.2.19	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL .....:	No such terminal provided	N/A
7.2.20	Removable protective means marked to indicate the necessity for replacement when the function is no longer needed ..... :	No such means used	N/A
7.2.21	MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms ..... :	Not mobile	N/A
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		P
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W) ..... :	No such parts	N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL		N/A
7.3.2	Symbol 24 of Table D.1, or safety sign No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts ..... :	No such parts	N/A
7.3.3	Type of battery and mode of insertion marked .....:	See IFU chapter “Backup battery (optional)” for details	P
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL ..... :		N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable		P
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an unacceptable RISK if replaced incorrectly.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	Only dedicated and provided battery can be inserted in coded slot, no further risk mitigation deemed necessary	N/A
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARD.....:		N/A
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified ..... :		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		P
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made	No such parts identified	N/A
7.3.6	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS	No used	N/A
7.3.7	Terminals for supply conductors marked adjacent to terminals ..... :	Appliance inlet used	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)		N/A
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3		N/A
	Marking for connection to a 3-phase supply, complies with IEC 60445		N/A
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		N/A
7.3.8	"For supply connections, use wiring materials suitable for at least X °C" or equivalent, marked at the point of supply connections		N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		N/A
7.4	Marking of controls and instruments		P
7.4.1	The "on" & "off" positions of switch to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 or	See IFU chapter "Device overview". No mains switch provided, disconnect by mains cable	N/A
	– indicated by an adjacent indicator light, or	Stand by switch is illuminated	P
	– indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, and	Not used	N/A
	– status indicated by adjacent indicator light		N/A
	– status indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or		N/A
	– status indicated by adjacent indicator light		N/A
	– status indicated by other unambiguous means		N/A
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means	Display	P
	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)	Provided device control settings of the monitor (e.g. display brightness) are unable to influence patient conditions.	N/A
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE .....:		N/A
	– or an indication of direction in which magnitude of the function changes		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009		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	Any readings shown during final application shall be considered by end user	N/A
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units		N/A
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3 .....:	See Appended Tables 7.1.2 and 7.1.3.	P
7.5	Safety signs		P
	Safety sign with established meaning used		P
	RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	RMF Reference to specific risk & Marking: ATGD-DMF-MLC8-008 Risk Analysis; chapter 7.2.2 # 38 Safety Sign Used: Table D.2 sign 2 (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	P
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT	All safety signs are described in IFU section “Specification”	P
	Specified colours in ISO 3864-1 used for safety signs .....:	Compliant	P
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)	Read IFU	P
	Safety signs including any supplementary text or symbols described in instructions for use	Not used	N/A
	- and in a language acceptable to the intended OPERATOR		P
7.6	Symbols		P
7.6.1	Meanings of symbols used for marking described in instructions for use .....:	See IFU chapter “Specifications”	P
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable		P
7.7	Colours of the insulation of conductors		P
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation		P
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations		P
7.7.3	Green and yellow insulation identify only following conductors:		P

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Clause	Requirement + Test	Result – Remark	Verdict
	– PROTECTIVE EARTH CONDUCTORS		P
	– conductors specified in 7.7.2		P
	– POTENTIAL EQUALIZATION CONDUCTORS		P
	– FUNCTIONAL EARTH CONDUCTORS		N/A
7.7.4	Neutral conductors of POWER SUPPLY CORDS are "light blue"	Power supply cord is certified component	P
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1	See above	P
7.8	Indicator lights and controls		P
7.8.1	Red indicator lights used only for Warning	Not used	N/A
	Yellow indicator lights used only for Caution	Not used	N/A
	Green indicator lights used only for Ready for use	Standy button illuminated	P
	Other colours: Meaning other than red, yellow, or green (colour, meaning).....:		N/A
7.8.2	Red used only for emergency control		N/A
7.9	ACCOMPANYING DOCUMENTS		P
7.9.1	ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description	Checked Instructions for Use (IFU) in English language: Manual_PENTA MLC8_rev 0.9_preliminary Dated: July 17, 2019 Technical description included in IFU	P
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		P
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to.....:	See IFU chapter "General Information" ADLINK Technology GmbH Ulrichsberger Straße 17 94469 Deggendorf, GERMANY Email: emea@adlinktech.com Internet: www.adlinktech.com www.penta.de	P
	– MODEL or TYPE REFERENCE .....:	See IFU cover page and chapter "User Information"	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	Provided as hardcopy	N/A
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	See IFU chapter "User Information", chapter "Administrator information" and chapter "Specifications	P

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Clause	Requirement + Test	Result – Remark	Verdict
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended		P
7.9.2	Instructions for use include the required information		P
7.9.2.1	– use of ME EQUIPMENT as intended by the MANUFACTURER:	See IFU chapter “Intended Purpose”	P
	– frequently used functions,	See IFU chapter “User Information” and chapter “Administrator information”	P
	– known contraindication(s) to use of ME EQUIPMENT	See IFU chapter “Specifications”	P
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient	See IFU chapter “Safety”	P
	– name or trademark and address of the MANUFACTURER	See IFU chapter “General Information” ADLINK Technology GmbH Ulrichsberger Straße 17 94469 Deggendorf, GERMANY Email: emea@adlinktech.com Internet: www.adlinktech.com www.penta.de	P
	– MODEL OR TYPE REFERENCE	See IFU cover page and chapter “User Information”	P
	Instruction for use included the following when the PATIENT is an intended OPERATOR:		N/A
	– the PATIENT is an intended OPERATOR	Patient is not intended operator	N/A
	– warning against servicing and maintenance while the ME EQUIPMENT is in use		N/A
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and		N/A
	–maintenance the PATIENT can perform		N/A
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	See IFU chapter “Specifications”	P
	Instructions for use are in a language acceptable to the intended operator	English version checked	P
7.9.2.2	Instructions for use include all warning and safety notices	See IFU chapter “Safety” and chapter “Specifications”	P
	Warning statement for CLASS I ME EQUIPMENT included	See IFU chapter “Safety and Warning Instructions”	P
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	See IFU chapter “Safety and Warning Instructions”	P

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Clause	Requirement + Test	Result – Remark	Verdict
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	See IFU chapter “EMC requirements”	P
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	No MSO provided	N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	See IFU chapter “Safety and Warning Instructions”	P
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions	No such power supply specified	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	See IFU chapter “Backup battery”	P
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	Specific RISKS: RA rev. 0.8 clause 60 (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	P
	Where the RISK is unacceptable, the IFU includes a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time.....:	See IFU chapter “Backup battery”	P
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided.....:	See IFU chapter “Backup battery”	P
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK .....:	See IFU chapter “Backup battery”	P
7.9.2.5	Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE	See IFU chapter “Intended Purpose”, chapter “User Information” and chapter “Administrator information”	P
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to	EUT is a Monitor, no ingredients used	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	See IFU chapter “User Information” and chapter “Administrator Information”	P
	APPLIED PARTS specified	EUT is a Monitor without 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	See IFU chapter “User Information” and chapter “Administrator Information”	P
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device	See IFU chapter “Safety Warnings and Instructions”	P

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Clause	Requirement + Test	Result – Remark	Verdict
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation	See IFU chapter “User Information” and chapter “Administrator Information”	P
7.9.2.9	Information provided to operate ME EQUIPMENT	See IFU chapter “User Information”, chapter “Administrator Information” and chapter “BIOS Configuration”	P
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	See IFU chapter “User Information” and chapter “Administrator Information”	P
7.9.2.10	A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message	See IFU chapter “Specification”	P
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	See IFU chapter “User Information” and chapter “Administrator Information”	P
7.9.2.12	Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified	See IFU chapter “Cleaning and Disinfection”	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 single use items	N/A
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	See IFU chapter “Maintenance and Service”	P
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	See IFU chapter “Maintenance and Service”	P
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	See IFU chapter “Maintenance and Service”	P
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	See IFU chapter “Maintenance and Service”	P
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	See IFU chapter “User Information” and chapter “Administrator Information”	P
	Other equipment providing power to ME SYSTEM sufficiently described	No such equipment specified	N/A
7.9.2.15	Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for use.....:	See IFU chapter “Specifications” and chapter “Replacing the battery pack”	P

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Clause	Requirement + Test	Result – Remark	Verdict
7.9.2.16	Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)	Technical description is included in IFU	P
7.9.2.17	Instruction for use for ME EQUIPMENT emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation	No such emission	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	Not supplied sterile	N/A
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization		N/A
7.9.2.19	The instructions for use contain a unique version identifier.....:	Version Revision:0.9 – PRELIMINARY Date: July 17, 2019	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		P
	Technical description separable from instructions for use contains required information, as follows		N/A
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT	Not separable, technical description is part of IFU	N/A
	– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and		N/A
	a unique version identifier.....:		N/A
	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		P
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT .....:	Not permanently installed	N/A
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and	Cord is detachable	N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	See IFU chapter "Safety"	P

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Clause	Requirement + Test	Result – Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment to determine if replacement of components results in any unacceptable RISKS .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risk identified	P
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component	See IFU chapter “Safety”	P
7.9.3.3	Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair	See IFU chapter “Safety”	P
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description	See IFU chapter “Safety” disconnecting from mains by cable	P

8	PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT		P
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS		P
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION .....: (ISO 14971 Cl. 4.3)	No such risk identified	N/A
8.2	Requirements related to power sources		P
8.2.1	Connection to a separate power source		N/A
	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM	No such power source specified	N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		N/A
8.2.2	Connection to an external d.c. power source		N/A
	No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source	No such power source specified	N/A
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset		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 does not have 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		N/A
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF		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 .:	EUT has no patient connections	N/A
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT .....:	See 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		N/A
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.) .....:		N/A
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J)		N/A
	d) Voltage and energy limits specified in c) above also applied to the following:		N/A
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	No such parts identified	N/A
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL	No such parts identified	N/A
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N		N/A
	Test repeated with a TOOL specified in instructions for use		N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE		N/A
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION		N/A
	A TOOL is required when it is possible to prevent the devices from operating		N/A
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one sec after disconnecting the plug of ME EQUIPMENT or its parts (V) .....:	See appended table 8.4.3	P
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC :	60 V not exceeded	N/A
8.4.4	Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC :		N/A
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description.....:		N/A
8.5	Separation of parts		P
8.5.1	MEANS OF PROTECTION (MOP)		P
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4		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	Such means disregarded	P
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		P
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)	Only MOOP used	N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test:		N/A
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6		N/A
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION .....:		N/A
	Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c.....:		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 $_{Total\ Working}$ (V) and C $_{Nominal}$ (μF).....:		—
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)		P
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		P
	– dielectric strength test .....:	Refer to table 8.8.3	P
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		P
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		P
	– limits of Tables 13 to 16 (inclusive); or		P
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		P
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6		P
	– or with requirements and tests of IEC 60950-1 for protective earthing .....:	See above	N/A
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION .....:	Not used outside certified component	N/A
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION .....:	Not used outside certified component	N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	Not used outside certified component	N/A
	Voltage $_{Total\ Working}$ (V) and C $_{Nominal}$ (μF).....:		—

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Clause	Requirement + Test	Result – Remark	Verdict
	Points and applied parts at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 were examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION	Considered	P
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION .....:		N/A
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION.....:	Refer to insulation table	P
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 does not have patient connections	N/A
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		N/A
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		N/A
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS ..... :		N/A
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4.....:		N/A
	Dielectric strength test conducted per 8.8.3 .....:		N/A
	CREEPAGE and CLEARANCES measured .....:		N/A
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s		N/A
8.5.2.2	PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED .....:		N/A
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and		N/A
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4.....:		N/A
	Dielectric strength test conducted per 8.8.3 .....:		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	Relevant CREEPAGE and CLEARANCES measured		N/A
	RISK MANAGEMENT FILE includes an assessment of the RISK of metal ACCESSIBLE PARTS contacting a source of voltage or LEAKAGE CURRENT above the limits.....: (ISO 14971 Cl. 4.2-4.4, 5)		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 does not have patient leads or cables	N/A
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter		N/A
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm		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		N/A
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,		N/A
	Test finger test (10 N) .....:		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)		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).....:	Rated: 100 – 240 VAC Tested: 90 – 264 VAC	P
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V).....:		N/A
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V) .....:	See Insulation Diagram and Insulation Table	P

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Clause	Requirement + Test	Result – Remark	Verdict
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth	EUT has 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).....:		N/A
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages		N/A
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V).....:	No such motors incorporated	N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	EUT does not have applied parts	N/A
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety		N/A
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		N/A
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator .....:		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 .....:		N/A
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load.....:		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		P
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8	No parts exempted	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 .....:	Detachable power supply cord used	P
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL	Appliance inlet used	N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside.....:		N/A
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		P
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		P
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part,	No such part	P
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See above	N/A
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop .....:	See appended Table 8.6.4 For information: detachable cord with 2 m length used, different length shall be considered in end use application	P
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits .....:	Impedance of protective earth connection not exceeded	N/A
8.6.5	Surface coatings		N/A
	Poorly conducting surface coatings on conductive elements removed at the point of contact	No such means used	N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		N/A
8.6.6	Plugs and sockets		P
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections		P
	- applied also where interchangeable parts are PROTECTIVELY EARTHED	No such parts	N/A
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR		P
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE	Terminal is located at bottom side close to all other connectors	P
	–accidental disconnection avoided in NORMAL USE		P

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Clause	Requirement + Test	Result – Remark	Verdict
	– Terminal allows conductor to be detached without a TOOL		P
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		P
	– Terminal marked with symbol 8 of Table D.1		P
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard	See IFU chapter “Safety”	P
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		P
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION	No functional earth terminal used	N/A
8.6.9	Class II ME EQUIPMENT		N/A
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen’s FUNCTIONAL EARTH TERMINAL, coloured green and yellow	Equipment is class I	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		P
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)	Impedance of protective earth connection not exceeded	N/A
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		P
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION	No such conditions	N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	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	EUT does not have Applied Parts	N/A
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 .....:	No applied Parts, no patient connections	N/A
	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}).....:	See appended Table 8.7	P
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710.....:	Not permanently installed	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 All measurements repeated with a non-frequency weighted device	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 FE	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)	No exemptions	N/A
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	All relevant insulations tested	N/A
8.8.2	Distance through solid insulation or use of thin sheet material		N/A
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:	Not used outside certified components	N/A

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

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Clause	Requirement + Test	Result – Remark	Verdict
8.8.3	Dielectric Strength		P
	Solid insulating materials with a safety function withstood dielectric strength test voltages .....:	See appended Table 8.8.3	P
8.8.4	Insulation other than wire insulation		P
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		P
	ME EQUIPMENT and design documentation examined.....:	See appended table 8.10	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)	RMF Reference to specific RISKS: ATGD-DMF-MLC8-008 Risk Analysis risk # 9; #18; #28 and chapter 7.1.8 (ISO 14971 Cl. Cl. 4.2-4.4, 5, 6.2-6.5)	P
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat.....:	See appended table 8.10	P
	Tests conducted in absence of satisfactory evidence for resistance to heat.....:		N/A
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus.....:	No such parts identified, metal enclosure and certified components used	N/A
	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).....:	No such parts outside certified components identified	N/A
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION		N/A
8.8.4.2	Resistance to environmental stress		P
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9	Virtue of design, no such risk reasonably foreseeable	P
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	Not used	N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	Not used	N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	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	Not used	N/A
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h		N/A
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		P
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive) :	Refer to Insulation Diagram	P
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1	No Applied Parts	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 .....:	Not used	N/A
8.9.3	Spaces filled by insulating compound		N/A
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound	No such spaces identified	N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests		N/A
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage).....:		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

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Clause	Requirement + Test	Result – Remark	Verdict
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage		N/A
8.9.4	Minimum spacing of grooves transvers to the CREEPAGE DISTANCES considered a MEANS OF OPERATOR PROTECTION adjusted based on pollution degree ……		N/A
	Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES		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.....:	Checked by inspection, all components mounted securely	P
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components.....: (ISO 14791 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: ATGD-DMF-MLC8-008 Risk Analysis; chapter 7.1.2 and 7.2.2, #24 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	P
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment .....:	Checked by inspection, all conductors and connectors mounted securely	P
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS	Not used	N/A
8.10.3	Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken ..:	Not used	N/A
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		N/A
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION	No such parts under evaluation. All connected control devices like keyboard, mouse shall be evaluated in end use application	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

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Clause	Requirement + Test	Result – Remark	Verdict
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges .....:	Checked by inspection	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	Not used	N/A
8.10.7	a) Insulating sleeve adequately secured.....:	See appended Table 8.10	P
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics		N/A
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C .....:	No such temperatures	N/A
8.11	MAINS PARTS, components and layout		P
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles.....:	See appended Table 8.10 detachable power supply cord used	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	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		N/A
	- the isolation device specified in the ACCOMPANYING DOCUMENTS		N/A
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description .....:	Detachable power supply cord used and described in IFU	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 .....:	No supply mains switch used	N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead		N/A
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		N/A
	f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH.....:	See appended Table 8.10	P
	g) A fuse or a semiconductor device not used as an isolating means	No such device used	P

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Clause	Requirement + Test	Result – Remark	Verdict
	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	No such device used	P
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering	No such parts identified	N/A
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage		N/A
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		N/A
	Standard test finger applied		N/A
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	No MSO provided	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 ..... :	Not used	N/A
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 .....:	See appended Table 8.10	P
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6 .....:	See appended Table 8.10	P
8.11.3.5	Cord anchorage		N/A
	a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage	Detachable cord used	N/A
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or		N/A

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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		N/A
	– metal provided with an insulating lining affixed to cord anchorage		N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components		N/A
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals		N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18.....:		N/A
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests		N/A
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position		N/A
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N/A
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged		N/A
8.11.3.6	POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment		N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N/A
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram attached to the free end of cord (g) .....:		N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		N/A
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D .....:		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
8.11.4	MAINS TERMINAL DEVICES		N/A
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection	Certified appliance inlet used	N/A
	Terminals alone are not used to keep conductors in position		N/A
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors		N/A
	Screws and nuts clamping external conductors do not serve to secure any other component		N/A
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N/A
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection		N/A
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		N/A
	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		N/A
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced after fastening and loosening a conductor of largest cross-sectional area 10 times		N/A
8.11.4.4	Terminals with clamping means for a rewireable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened		N/A
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewireable POWER SUPPLY CORD to allow for connection of conductors		N/A
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test		N/A
8.11.5	Mains fuses and OVER-CURRENT RELEASES		P
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection.....:	No FE provided	N/A
	- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT .....:	Class I	N/A
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	Not permanently installed	N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART	Fuses not omitted	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	No such device incorporated in PE conductor	P
	Justification for omission of fuses or OVER-CURRENT RELEASES documented :	Fuses not omitted	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..:	Certified appliance inlet with incorporated fuses used, see appended Table 8.10	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 for details	P
9	PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS		N/A
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 .....:	Device does not have 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)		N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and		N/A
	RISK CONTROLS implemented..... :		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	All RISKS associated with moving parts have been reduced to an acceptable level		N/A
9.2.2	TRAPPING ZONE		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:	No trapping zones	N/A
	– Gaps in Clause 9.2.2.2, or		N/A
	– Safe distances in Clause 9.2.2.3, or		N/A
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	– Continuous activation in Clause 9.2.2.5		N/A
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM		N/A
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20.....:		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 ..... :		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 such means	N/A
9.2.2.4.2	FIXED GUARDS held in place by systems that can only be dismantled with a TOOL		N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open		N/A
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,		N/A
	– absence or failure of one of their components prevents starting, and stops moving parts		N/A
	Movable GUARDS complied with any applicable tests		N/A
9.2.2.4.4	Other RISK CONTROL designed and incorporated into to the control system stops movement and		N/A
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or		N/A
	ME EQUIPMENT is SINGLE FAULT SAFE		N/A
9.2.2.5	Continuous activation		N/A
	Continuous activation used as a RISK CONTROL, complies with the following		N/A
	a) movement was in OPERATOR'S field of view		N/A
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR		N/A
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	- the continuous activation system is SINGLE FAULT SAFE		N/A
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement		N/A
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		N/A
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		N/A
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or		N/A
	- activation does not result in an unacceptable RISK		N/A
9.2.3.2	Over travel past range limits of the ME EQUIPMENT prevented .....:		N/A
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse.....:		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 such means	N/A
	a) Emergency stopping device reduced RISK to an acceptable level		N/A
	RISK MANAGEMENT FILE indicates the use of an emergency stopping device reduces the RISK to an acceptable level .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.6)		N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N/A
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N/A
	g) Means for stopping of movements operate as a result of one single action		N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or "STOP"		N/A
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed		N/A
	k) Emergency stopping device is suitable for its application		N/A
9.2.5	Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping ..... :	No such means	N/A
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		N/A
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented		N/A
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered.....:		N/A
9.4	Instability HAZARDS		N/A
9.4.1	ME EQUIPMENT and its parts, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE	All hazards related to instability must be evaluated in end use application with final mounting provisions	N/A
9.4.2	Instability – overbalance		N/A
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested.....:		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
9.4.2.2	Instability excluding transport		N/A
	ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE, ...:		N/A
	A warning provided when overbalance occurred during 10° inclined plane test		N/A
9.4.2.3	Instability from horizontal and vertical forces		N/A
	a) ME EQUIPMENT or its parts with a mass of 25kg or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it		N/A
	Surfaces of ME EQUIPMENT or its parts where a RISK of overbalancing exists from pushing, etc., permanently marked with a warning of the RISK		N/A
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)		N/A
	b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping		N/A
	ME EQUIPMENT or its parts, for use on the floor or on a table, where RISK of overbalancing exists, permanently marked with the RISK warning .....:		N/A
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b).....:		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	EUT is not mobile. If mounted to a cart or similar mobile provisions this shall be considered in end use application	N/A
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT did not exceed 200 N.....:		N/A
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold .....:		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		N/A
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements		N/A
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1		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 .....:		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test		N/A
9.4.4	Grips and other handling devices		N/A
	a) ME EQUIPMENT with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method	The EUT does not have such devices	N/A
	Handles, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS		N/A
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying		N/A
	c) Carrying handles and grips and their means of attachment withstood loading test.....:		N/A
9.5	Expelled parts HAZARD		N/A
9.5.1	Suitability of means of protecting against expelled parts determined by assessment and examination of RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)	No moving parts used, no such hazard foreseeable	N/A
	All identified RISKS associated with expelled parts mitigated to an acceptable level		N/A
9.5.2	Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965.....:	No such tubes used	N/A
9.6	Acoustic energy (including infra- and ultrasound) and vibration		N/A
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and	Device does not include any acoustic signals related to the intended purpose. Device does not produce vibration	N/A
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity.....:		N/A
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and (ISO 14971 Cl. 4.2-44, 5, 6.2-6.5)		N/A
	All identified RISKS mitigated to an acceptable level		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	See clause 9.6.1	N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	– 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)		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	Device does not produce such vibration	N/A
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2) ..... :		N/A
	– Accelerations for different times, inversely proportional to square root of time (m/s^2) ..... :		N/A
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N/A
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)	Device does not use such pressure	N/A
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		N/A
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		N/A
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		N/A
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply		N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N/A
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity		N/A
9.7.3	Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	a) RATED maximum supply pressure from an external source		N/A
	b) Pressure setting of a pressure-relief device provided as part of assembly		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		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 .....:		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 kPaI .....:		N/A
9.7.6	Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE .....:		N/A
9.7.7	Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests .....:		N/A
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair		N/A
	c) Could be adjusted or rendered inoperative without a TOOL		N/A
	d) With discharge opening located and directed as to not to release material towards any person		N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		N/A
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure		N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect		N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	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)		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 is not a support system	N/A
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		N/A
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		N/A
	– RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES		N/A
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials		N/A
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		N/A
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest		N/A
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing .....:		N/A
	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)		N/A
	All identified RISKS are mitigated to an acceptable level		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	When test were conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK .....:		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)		N/A
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		N/A
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints .....:	No such system	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)		N/A
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts		N/A
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER		N/A
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications		N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		N/A
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS		N/A
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance .....:		N/A
9.8.3.2	a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m^2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR .....:		N/A
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests .....:		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK		N/A
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test .....:		N/A
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE maintained BASIC SAFETY and ESSENTIAL PERFORMANCE confirmed test		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 such protective devices	N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		N/A
	– Designed based on TOTAL LOAD		N/A
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N/A
	– Activated before travel produced an unacceptable RISK		N/A
	– Takes into account Clauses 9.2.5 and 9.8.4.3		N/A
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests .....:		N/A
9.8.4.2	Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE		N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		N/A
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		N/A
	–use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE ..:		N/A
	– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal		N/A
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.		N/A
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE		N/A
	– Compliance confirmed by examination and following test .....:		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT		N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		N/A
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		N/A
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		N/A
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES .....:	No such system	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)		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 .....:	Device does not produce such radiation	N/A
	Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE		N/A
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or :		N/A
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		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)		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		N/A
	Microwave radiation is propagated intentionally		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
10.4	Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.		N/A
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ...: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		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)		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)		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		P
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION		P
	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)	Limits of table 23 not exceeded, no further mitigation deemed necessary	N/A
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.....:	Device does not have applied parts	N/A
	Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use		N/A
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in NORMAL CONDITION and SINGLE FAULT CONDITION ..:		N/A
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:		N/A
	Maximum Temperature.....:		—

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Clause	Requirement + Test	Result – Remark	Verdict
	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)		N/A
	APPLIED PARTS surface temperature of equal to or less than 41°C		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.....:		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)		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)	Device does not have applied parts	N/A
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		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)		N/A
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE .....:		N/A
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	No such guards	N/A
11.2	Fire prevention		P
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3		P
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		N/A
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of.....:	Not for such environment	N/A
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	1) when temperature of material raised to its ignition temperature		N/A
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature		N/A
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating		N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively.....:		N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three.....:		N/A
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3.....:		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 (%) .....:		N/A
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE .....:		N/A
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases .....:		N/A
11.2.2.2	RISK of ignition did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT		N/A
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks		N/A
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		N/A
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		N/A
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered		N/A
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2).....:		N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) .....:		N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a).....:		N/A
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a).....:		N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas.....:		N/A
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT		P
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2 .....:	Solid metal housing can be considered as fire enclosure	P
	Constructional requirements were met, or		P

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Clause	Requirement + Test	Result – Remark	Verdict
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: ATGD-DMF-MLC8-008 Risk Analysis; chapter 7.2.2, #10 & #11 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	P
	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		P
	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		P
	2) No openings on the sides within the area included within the inclined line C in Fig 39		P
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials.....:	See appended Table 8.10	P
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics		N/A
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G	Not for such use	N/A
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		N/A
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Not for such use	N/A
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT		P

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Clause	Requirement + Test	Result – Remark	Verdict
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT..... :	See Appended Table 11.6.1	P
11.6.2	Overflow in ME EQUIPMENT		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 used	N/A
	Maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.		N/A
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.		N/A
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM		P
	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)	See appended Tables 11.6.1; and RMF Reference to specific RISK: ATGD-DMF-MLC8-008 Risk Analysis; chapter 7.2.2, #36 and chapter 7.1. (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	P
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill .....:	Device is mounted in intended position (vertical with up to 45° deflection), 500ml of a conducting fluid is spilled over front, rear, top, left and right chassis part, either as splash (event duration <= 5s) or continuous event (duration > 5s).	P
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		P

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Clause	Requirement + Test	Result – Remark	Verdict
	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	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 ..... :	No excessive leakage current and no dielectric breakdown observed	P
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS		P
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use ..... :	See Appended Tables 11.6.1, and IFU chapter “Cleaning and Disinfection”	P
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER ..... :	ATGD-DMF-MLC8-008 Risk Analysis; chapter 7.1.10	P
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests..... :	Not intended to be sterilized	N/A
	RISK MANAGEMENT FILE includes an assessment of the RISKS associated with any deterioration following sterilization... ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		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)	No substances used	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	No such equipment	N/A
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	Devices start in standby mode after restoration of power and must be switched on again. (Devices with internal battery continue up to 10 minutes operation battery powered)	P

12	ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS		P
12.1	RISKS associated with accuracy of controls and instruments stated..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	To be considered in end use application depending on installed software	N/A

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Clause	Requirement + Test	Result – Remark	Verdict
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING .....:	See IEC 60601-1-6 Report N40P0002 for setup of monitor, any applications must be considered in end use application	P
12.3	MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8. .....:	No alarm system implemented	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)	Device itself does not produce any output	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)		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)		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)		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	Device does not produce such radiation	N/A
	Radiation safety ensured by compliance with requirements of appropriate standards		N/A
12.4.5.2	ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3.....:		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)		N/A
12.4.5.4	RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		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)		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

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Clause	Requirement + Test	Result – Remark	Verdict
	– 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.....:	No Applied Parts	N/A
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23.....:	No temperature rise beyond limits observed	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 such components	N/A
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed.....:	See appended Table 8.7	P
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS did not exceed .....:	See appended Table 8.7	P
13. 2	SINGLE FAULT CONDITIONS		P
13.2.1	During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination		P
	ME EQUIPMENT complied with 13.2.2 -13.2.12.....:	See appended Table 13.2	P
	RISK MANAGEMENT FILE includes and assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No liquids used	N/A
	RISK MANAGEMENT FILE defines the appropriate test conditions.....:		N/A
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of test environment temperature		N/A
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		N/A
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION, the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		N/A

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

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Clause	Requirement + Test	Result – Remark	Verdict
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable	No motors incorporated	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		N/A
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition		N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		N/A
	b) Motor met running overload protection test of this clause when:		N/A
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended		N/A
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C) .....:		N/A
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		N/A
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload		N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		N/A
	Test not conducted based on other justifications (justification) .....:		N/A
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10		N/A
13.2.13.4	ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION		N/A
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated	Continuous operation	N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	Motor winding temperatures did not exceed values in 13.2.10 .....:		N/A
	Insulation Class.....:		—
	Maximum temperature measured (°C) .....:		—
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)		N/A
14.1	Requirements in 14.2 to 14,12 not applied to PEMS when it provides no functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE, or	Any software and IT network requirements shall be considered in final end use application	N/A
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK.....:		N/A
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 4.2-4.4, 5)		N/A
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK		N/A
	When the requirements of 14.2 to 14.13 apply, the requirements of IEC 6204:2006 clause 4.3, 5, 7, 8 and 9 apply for the development or modification of software of each PESS		N/A
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304 .....:		N/A
	Software development process applied according to Clause 5 of IEC 62304.....:		N/A
	Software development process for Software risk management applied according to Clause 7 of IEC 62304 .....:		N/A
	Software development process Configuration Management applied according to Clause 8 of IEC 62304 .....:		N/A
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304 .....:		N/A
14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process.....:		N/A
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan		N/A
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented		N/A
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone		N/A
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules		N/A
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		N/A
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained		N/A
14.6	RISK MANAGEMENT PROCESS		N/A
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS .....:		N/A
	RISK MANAGEMENT FILE includes known or foreseeable HAZARDS associated with software, hardware, incorporation of the PEMS into an IT-NETWORK, components of 3rd party origin and legacy subsystems.....: (ISO 14971 Cl. 4.3)		N/A
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2 .....:		N/A
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure .....: (ISO 14971 Cl. 6.1)		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)		N/A
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems.....: (ISO 14971 Cl. 6.3)		N/A
14.9	Design is broken up into sub systems and descriptive data on design environment documented .....:		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
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)		N/A
	– milestone(s) when VERIFICATION is to be performed for each function		N/A
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		N/A
	– selection and utilization of VERIFICATION tools		N/A
	– coverage criteria for VERIFICATION		N/A
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented		N/A
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE .....:		N/A
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented		N/A
	The person with overall responsibility for PEMS VALIDATION is independent		N/A
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 6.3)		N/A
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE		N/A
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304 .....:		N/A
	Software Process for Software changes applied according to Clause 5 of IEC 62304 .....:		N/A
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304 .....:		N/A
	Configuration management of software changes applied per Clause 8 of IEC 62304 .....:		N/A
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304 .....:		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 .....:		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	a) Purpose of the PEMS connection to an IT-NETWORK		N/A
	b) required characteristics of the IT-NETWORK		N/A
	c) required configuration of the IT-NETWORK		N/A
	d) technical specifications of the network connection, including security specifications		N/A
	e) intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK		N/A
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the required characteristics (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)		N/A
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		N/A
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties		N/A
	– Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS		N/A
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis		N/A
	- Changes to the IT-NETWORK include: - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment		N/A
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 IEC 60601-1-6 report N40P0002	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	Solid metal enclosure, no such parts identified	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	Service only by authorized personnel	N/A
15.3	Mechanical strength		P

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Clause	Requirement + Test	Result – Remark	Verdict
15.3.1	Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		P
15.3.2	Push test conducted.....:	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.3	Impact test conducted.....:	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.4	Drop test		P
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested .....:	Not hand-held	N/A
	No unacceptable RISK resulted		N/A
15.3.4.2	Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test..... :	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		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.....:	No such equipment	N/A
	No damage resulting in an unacceptable RISK sustained		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	Metal enclosure	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.....:		N/A
	No damage resulting in an unacceptable RISK		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	Robust metal enclosure, no such hazards foreseeable	P

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Clause	Requirement + Test	Result – Remark	Verdict
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)	RMF Reference to specific RISKS: ATGD-DMF-MLC8-008 Risk Analysis; chapter 7.1.3 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	P
	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 connections	N/A
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection .....:	No such connections	N/A
15.4.2	Temperature and overload control devices		N/A
15.4.2.1	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION .....: (ISO 14971 Cl. 4.2-4.4, 5)	No such components incorporated	N/A
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT		N/A
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided .....: (ISO 14971 Cl. 4.2-4.4)		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)		N/A
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		N/A
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests:		N/A
	- Positive temperature coefficient devices complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17		N/A
	- ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13.....:		N/A
	- SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	- In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions operated 200 times		N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		N/A
	manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		N/A
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		N/A
	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		N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating .....: (ISO 14971 Cl. 4.2-4.4)		N/A
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS		N/A
15.4.3	Batteries		P
15.4.3.1	Battery housings provided with ventilation.....: (ISO 14971 Cl. 4.2-4.4)	Battery is inserted in slot which is not gastight, no further risk considerations deemed necessary	N/A
	Battery compartments designed to prevent accidental short circuiting	Connector used	P
15.4.3.2	Means provided to prevent incorrect connection of polarity.....:	Option Battery Backup: Battery pack with specific design contour only fitting into device housing opening; wrong insertion disabled by design	P
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries .....: (ISO 14971 Cl. 4.2-4.4)	Use of specifically designed battery pack prevents from incorrect connection and replacement by inappropriate batteries, no further risk considerations deemed necessary	N/A
15.4.3.3	Overcharging of battery prevented by virtue of design.....:	Device prepared for usage of battery backup includes corresponding charger board controlling and preventing overcharging of batteries by design	P

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Clause	Requirement + Test	Result – Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries..: (ISO 14971 Cl. 4.2-4.4)	Prevented by design, no further risk considerations deemed necessary	N/A
15.4.3.4	Primary lithium batteries comply with IEC 60086-4	No used	N/A
	Secondary lithium batteries comply with IEC 62133	See table 8.10	P
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire.....:	Certified component, see table 8.10	P
	Protective device has adequate breaking capacity		P
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented		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		N/A
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION	Certified component, see table 8.10	P
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for .....:	Illuminated stand-by button	P
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,	No such state	N/A
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational	No such parts incorporated	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)		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	Monitor does not produce any output itself	N/A
	Colours of indicator lights complied with 7.8.1		P
	Charging mode visibly indicated		N/A
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Device does not provide pre-set operational modes	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	N/A

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Clause	Requirement + Test	Result – Remark	Verdict
	b) Controls secured so that the indication of any scale always corresponds to the position of the control		N/A
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL		N/A
	When torque values per Table 30 applied knobs did not rotate .....:		N/A
	Tests conducted with no unacceptable RISK .....:		N/A
15.4.6.2	Stops on rotating/ movable parts of controls are of adequate mechanical strength .....:		N/A
	Torque values in Table 30 applied.....:		N/A
	No unexpected change of the controlled parameter when tested .....:		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 such devices	N/A
	b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage.....:		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 .....:		N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		N/A
15.4.7.3	a) Foot-operated control device is at least rated IPX1 ..... :		N/A
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6..... :		N/A
15.4.8	Aluminium wires less than 16 mm^2 in cross-sectional area are not used	No such wires used	P
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed	No oil containers incorporated	N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		N/A
	A pressure-release device operating during NORMAL USE is provided		N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		N/A

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Clause	Requirement + Test	Result – Remark	Verdict
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		N/A
15.5.1	Overheating		N/A
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating.....:	No transformers outside certified components	N/A
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		N/A
	Dielectric strength test conducted after short circuit and overload tests .....:		N/A
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved .....:		N/A
	Short circuit applied directly across output windings		N/A
15.5.1.3	Multiple overload tests conducted on windings ....:		N/A
15.5.2	Transformers operating at a frequency above 1kHz tested according to clause 8.8.3.....:		N/A
	Transformer windings provided with adequate insulation		N/A
	Dielectric strength tests were conducted.....:		N/A
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with .....:		N/A
	- Means provided to prevent displacement of end turns		N/A
	- protective earth screens with a single turn have insulated overlap		N/A
	- Exit of wires form internal windings of toroid transformers protected with double sleeving		N/A
	- insulation between primary and secondary windings complies with 8.8.2		N/A
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4		N/A

16	ME SYSTEMS		N/A
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK	Device is not considered to be a ME-System for this evaluation. Any system requirements must be considerations by end user in environment of final application	N/A

IEC 60601-1			
Clause	Requirement + Test	Result – Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with installation and modification of an ME SYSTEM ..... : (ISO 14971 Cl. 4.2-4.4, 5)		N/A
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered		N/A
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard		N/A
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards		N/A
	– tests performed in NORMAL CONDITION, except as specified		N/A
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM		N/A
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated		N/A
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR		N/A
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards		N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM		N/A
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM		N/A
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM		N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM		N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER		N/A
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER		N/A
	c) the required information is provided:		N/A
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM		N/A

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

IEC 60601-1			
Clause	Requirement + Test	Result – Remark	Verdict
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements		N/A
	Transient currents restricted to allowable levels for the specified IPS or UPS .....:		N/A
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified		N/A
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)		N/A
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed		N/A
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION		N/A
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V).....:		N/A
16.6	LEAKAGE CURRENTS		N/A
16.6.1	TOUCH CURRENT in NORMAL CONDITION did not exceed 100 µA ..... :		N/A
	TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR..... :		N/A
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA ..... :		N/A
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values ..... :		N/A
16.7	ME SYSTEM complied with applicable requirements of Clause 9 ..... :		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		N/A
16.9	ME SYSTEM connections and wiring		N/A
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result.....:		N/A

IEC 60601-1			
Clause	Requirement + Test	Result – Remark	Verdict
	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)		N/A
	– Plugs for connection of PATIENT leads or PATIENT cables could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no unacceptable RISK results		N/A
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable		N/A
16.9.2	MAINS PARTS, components and layout		N/A
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or		N/A
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		N/A
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		N/A
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 visible in NORMAL USE, and		N/A
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		N/A
	– marked to indicate the equipment or equipment parts it may safely be attached to		N/A
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT		N/A
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:		N/A
	– CREEPAGE and CLEARANCES complied with 8.9		N/A
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets		N/A
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:		N/A
	– ENCLOSURE complied with 8.4.2 d)		N/A
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable		N/A
	– RATINGS of components are not in conflict with conditions of use .....:		N/A

IEC 60601-1			
Clause	Requirement + Test	Result – Remark	Verdict
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL		N/A
	– POWER SUPPLY CORD complied with 8.11.3		N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:		N/A
	– Separating transformer complied with this standard or IEC 61558-2-1, ... :		N/A
	– Separating transformer is CLASS I		N/A
	– Degree of protection against ingress of water specified as in IEC 60529		N/A
	– Separating transformer assembly marked according to 7.2 and 7.3		N/A
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083		N/A
16.9.2.2	The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED did not exceed 200 mΩ		N/A
	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part		N/A
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL		N/A
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage		N/A

17	ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS		P
	RISKS associated confirmed by review.....:	See IFU chapter “Appendix”	P
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS .....:	See IFU chapter “Appendix”	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)	RMF Reference to specific RISKS: ATGD-DMF-MLC8-008 Risk Analysis; chapter 7.2.2, #29 to #34 (ISO 14971 Cl. 4.3; 4.4; 5.; 6.3; 6.4)	P

IEC 60601-1			
Clause	Requirement + Test	Result – Remark	Verdict
	– 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 Reports N40P0010 and N40P0014	P

ANNEX G	PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES	N/A
Not for such use		

ANNEX L	INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION	N/A
Not used		

4.2.2 RM RESULTS TABLE: General requirements for RISK MANAGEMENT

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	Document Ref. in RMF (Document No. paragraph/clause, version)		Result - Remarks	Verdict
	General process	Particular Medical Device		
3.1	Document PDG_Risk Management_2.0	—	Risk Management Process (excluding production and post-production)	P
3.2	Document PDG_Risk Management_2.0	—	Adequate Resources	P
3.2	PDG_Risk Management_2.0	—	Assignment of qualified personnel	P
3.2	Document PDG_Risk Management_2.0	—	Policy for determining criteria for risk acceptability	P
3.3	—	ATGD-DMF-MLC8-006_risk mgmt plan MLC8; chapter 5	Qualification of personnel	P
3.4a	—	ATGD-DMF-MLC8-006; chapter 6	Risk management plan (RMP) – life-cycle phases	P
3.4b	—	ditto; subchapters 6.1 to 6.4	RMP – Assignment of responsibilities and authorities	P
3.4c	—	ditto; chapter 7	RMP – requirements for review of risk management activities	P
3.4d	—	ATGD-DMF-MLC8-006; chapter 6 and ATGD-DMF-MLC8-008_RA MLC8; chapter 6.3.4	RMP – criteria for risk acceptability	P
3.4e	—	ATGD-DMF-MLC8-006; chapter 10 and ATGD-DMF-MLC8-008_RA MLC8; chapter 6.3.4	RMP – verification activities	P
3.5	—	ATGD-DMF-MLC8-008_RA MLC8; chapter 7	Risk management file	P
4.1	—	ATGD-DMF-MLC8-008_RA MLC8; chapter 5.2	Risk analysis process	P

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	Document Ref. in RMF (Document No. paragraph/clause, version)		Result - Remarks	Verdict
	General process	Particular Medical Device		
4.2	—	Intended use: ATGD-DMF-MLC8-008_RA MLC8; chapter 4.2 and document ATGD-DMF-MLC8-002_Intended Purpose Characteristics: ATGD-DMF-MLC8-008_RA MLC8; chapter 6.2	Intended use and identification of characteristics related to safety	P
4.3	—	ATGD-DMF-MLC8-008_RA MLC8; chapter 7.1 and RA table 7.2.2, left columns 2 to 6	Identification of hazards	P
4.4	—	ATGD-DMF-MLC8-008_RA MLC8, RA table 7.2.2, column 'Risk'	Estimation of risk(s)	P
5	—	ATGD-DMF-MLC8-008_RA MLC8, RA table 7.2.2, column 'possible damage'	Risk evaluation	P
6.2	—	ATGD-DMF-MLC8-008_RA MLC8, chapter 7.2.1	Risk control option analysis	P
6.3	—	ATGD-DMF-MLC8-008_RA MLC8, RA table 7.2.2, column 'risk minimising measure'	Implementation of risk control measure(s)	P
6.4	—	ATGD-DMF-MLC8-008_RA MLC8, RA table 7.2.2, last, most right column	Residual risk evaluation	P
6.5	—	ATGD-DMF-MLC8-008_RA MLC8, chapter 7.2.1	Risk/benefit analysis	P
6.6a	—	ATGD-DMF-MLC8-008_RA MLC8, chapter 7.2.1	Risks arising from risk control measures (introduction of new hazards or hazardous situations)	P
6.6b	—	ATGD-DMF-MLC8-008_RA MLC8, chapter 7.2.1	Estimated risks for previously identified hazardous situations not affected by introduction of risk control measures	P

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
6.7	—	ATGD-DMF-MLC8-008_RA MLC8, RA table 7.2.2, last line and ATGD-DMF-MLC8-013_risk management report, chapter 5.3	Completeness of risk control	**P**
7	—	ATGD-DMF-MLC8-013_risk management report, chapter 6	Evaluation of overall residual risk	**P**
8	—	ATGD-DMF-MLC8-013_risk management report	Risk management report	**P**

Supplementary Information:

Document name: Risk Management Process; document No. PDG_Risk Management_2.0; Rev 2.0; dated 2017-12-11

Document name: intended Purpose MLC 8; document No. ATGD-DMF-MLC8-002; checked Version 1.0; dated 2018-08-30

Document name: risk management plan MLC 8; document No. ATGD-DMF-MLC8-006, checked Version 1.0; dated 2018-10-26

Document name: product risk analysis MLC 8 series; document No. ATGD-DMF-MLC8-008; checked Version 0.7; dated 2019-02-01

Document name: Risk Management Report MLC 8; document No ATGD-DMF-MLC8-013_risk management report_1.0, checked version 1.0, dated 2019-01-31

Document Ref should be with regards to the policy/procedure documents and documents containing device specific output.

4.3 TABLE: ESSENTIAL PERFORMANCE

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

4.11	TABLE: Power Input MLC 8-23					P
Operating Conditions / Ratings		Voltage (V)	Frequency (Hz)	Current (A)	Power (W or VA)	Power factor (cos φ)
Operating		90	50	1,05	--	--
		100	50	0,92	--	--
		240	50	0,41	--	--
		264	50	0,38	--	--
		90	60	1,10	--	--
		100	60	1,01	--	--
		240	60	0,45	--	--
		264	60	0,41	--	--
Supplementary Information: current rating 1,5 A – 0,75 A						

4.11	TABLE: Power Input MLC 8-27					P
Operating Conditions / Ratings		Voltage (V)	Frequency (Hz)	Current (A)	Power (W or VA)	Power factor (cos φ)
Operating		90	50	1,08	--	--
		100	50	0,93	--	--
		240	50	0,41	--	--
		264	50	0,38	--	--
		90	60	1,03	--	--
		100	60	0,93	--	--
		240	60	0,42	--	--
		264	60	0,40	--	--
Supplementary Information: current rating 1,5 A – 0,75 A, representative for MLC 8-21						

5.9.2 TABLE: Determination of ACCESSIBLE parts

5.9.2	TABLE: Determination of ACCESSIBLE parts	P
Location	Determination method (NOTE1)	Comments
Enclosure	visual	No voltage accessible
Display	visual	No voltage accessible
Touch buttons	visual	No voltage accessible
Power supply cord	visual	No voltage accessible
Supplementary information: [1)] NOTE: The determination methods are: visual; rigid test finger; jointed test finger; test hook.		

7.1.2 TABLE: Legibility of Marking

7.1.2	TABLE: Legibility of Marking, for MLC 8-21; MLC 8-23 and MLC 8-27	P
Markings tested	Ambient Illuminance (lx)	Remarks
Outside Markings (Clause 7.2) ..... :	100/800/1500	Clearly readable
Inside Markings (Clause 7.3) ..... :	100/800/1500	Clearly readable
Controls & Instruments (Clause 7.4) ..... :	--	Display
Safety Signs (Clause 7.5) ..... :	100/800/1500	Clearly readable
Symbols (Clause 7.6) ..... :	100/800/1500	Clearly readable
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

7.1.3	TABLE: Durability of marking test for MLC 8-21; MLC 8-23 and MLC 8-27	P

Characteristics of the Marking Label tested:		Remarks
Material of Marking Label ..... :	Self-adhesive foil	
Ink/other printing material or process ..... :	thermal transfer printing	
Material (composition) of Warning Label ..... :	Self-adhesive foil	
Ink/other printing material or process ..... :	thermal transfer printing	
Other ..... :	Fuse label	
	Symbols at bottom printed at metal bar	

Marking Label Tested:	Remarks
Marking plate tested according specification, see below	Clearly readable, no curling edges
Warning label tested according specification, see below	Clearly readable, no curling edges
Fuse label tested according specification, see below	Clearly readable, no curling edges
Symbols at bottom tested according specification, see below	Clearly readable

Supplementary information:
Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96%, and then for 15 s with a cloth rag soaked with isopropyl alcohol.

8.4.2 TABLE: TABLE: Working Voltage / Power Measurement

8.4.2	TABLE: TABLE: Working Voltage / Power Measurement	N/A

Test supply voltage/frequency (V/Hz)[1)] ..... :

Location From/To	Measured values					Remarks
	Vrms	Vpk or Vdc	Peak-to-peak ripple[2)]	Power W/VA	Energy (J)	

Supplementary Information:

1) The input supply voltage to the ME EQUIPMENT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4.
2) If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2.2

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

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	0	0	0	0	0	0	0	0	0	0
Plug pin 1 and plug earth pin	0	0	0	0	0	0	0	0	0	0
Plug pin 2 and plug earth pin	0	0	0	0	0	0	0	0	0	0
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

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

Calculated stored charge (μc)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
Plug pins 1 and 2	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and enclosure	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and enclosure	--	--	--	--	--	--	--	--	--	--

Supplementary information:

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

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

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

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:

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

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

8.6.4	TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS tested with MLC 8-23 representative for MLC 8-21 and MLC 8-23	P

Type of ME EQUIPMENT & impedance measured between parts	Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)
PE at Appliance inlet at bottom plate (with SIP/SOP connectors) to opposite screw at bottom plate	40 / 120	--	34	100
PE at connector of mains plug at detachable cord above mentioned screw	40 / 120	--	107	200
PE at Appliance inlet to mounting screw at rear side	40 / 120	--	30	100
PE at connector of mains plug at detachable cord to screw at rear side	40 / 120	--	103	200

Supplementary information: detachable cord with 2 m length used, different length shall be considered in end use application

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

8.7 TABLE: leakage current

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 before/after humidity (µA)	Remarks	
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC	
ER; NC; S1=1; S5=N	264	60	201/223		
ER; NC; S1=1; S5=R	264	60	200/222		
ER; SFC; S1=0 (N Open); S5=N	264	60	382/428		
ER; SFC; S1=0 (N Open); S5=R	264	60	380/428		
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC	
TC, NC, S1=1, S5=N, S7=1	264	60	1,0/1,0	MD between enclosure and PE	
TC, NC, S1=1, S5 =R, S7=1	264	60	1,0/1,0		
TC, SFC, S1=0 (N open), S5=N, S7=1	264	60	1,0/1,0		
TC, SFC, S1=0 (N open), S5=R, S7=1	264	60	1,0/1,0		
TC, SFC, S1=1, S5=N, S7=0 (PE open)	264	60	199/222		
TC, SFC, S1=1, S5=R, S7=0 (PE open)	264	60	198/221		
TC, SFC; S5=N; S9=N (Mains on isolated SIP/SOP)	264	60	1,0/1,2		
TC, SFC; S5=N; S9=R (Mains on isolated SIP/SOP)	264	60	1,0/1,2		
TC, SFC; S5=R; S9=N (Mains on isolated SIP/SOP)	264	60	1,0/1,3		
TC, SFC; S5=R; S9=R (Mains on isolated SIP/SOP)	264	60	1,0/1,2		
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)	
				EUT has no Applied Part	
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	
				EUT has no Applied Part	
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)	
				EUT has no Applied Part	
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	
				EUT has no Applied Part	

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)
				EUT has no Applied Part
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)
				EUT has no Applied Part
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)
				EUT has no Applied Part
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
				EUT has no Applied Part
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
				EUT has no Applied Part
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
				No FECLC

Supplementary information: Cl. 8.7.3.e): measurement repeated with a non-frequency-weighted device: Leakage currents, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in normal or in single fault condition

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/N - Switch closed or set to normal polarity
0/R - Switch open or set to reversed polarity
NC - Normal condition
SFC - Single fault condition

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

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	1 MOOP	340	--	No test, certified component	
B	1 MOOP	340	--	1500	No/-/No/No
C	2 MOOP	340	--	No test, certified component	
D	2 MOOP	340	--	3000	No/-/No/No
E	2 MOOP	340	--	Covered by area C	
F	2 MOOP	340	--	3000	No/-/No/No
G	2 MOOP	340	--	3000	No/-/No/No
H	1 MOOP	--	12	No test required	
I	2 MOOP	--	12	No test required	
J	1 MOOP	--	24	No test required	
K	1 MOOP	340	--	1500	No/-/No/No
L	1 MOOP	--	62	661	No/-/No/No

Supplementary information: Variant MLC 8-27 representative for MLC 8-23 and MLC 8-21

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

8.8.4.1 TABLE: Resistance to heat - Ball pressure test of thermoplastic parts

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

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

Supplementary information:

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

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

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

Supplementary information:
1) Note : AC - AIR CLEARANCE CD - CREEPAGE DISTANCE

8.9.3.2 Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts

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.

8.9.3.3 Table: Thermal cycling tests on one sample of cemented joint with other insulating parts (see 8.9.3.3)

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

Supplementary information:

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

8.10 TABLE: List of critical components

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)]
Main Enclosure (INT)	Trust DCE	MLC 8-2x AC	**MLC 8-21 dimensions** (WxHxD): (551x342x86) mm **MLC 8-23 dimensions** (WxHxD): (602x371x86) mm **MLC 8-27 dimensions** (WxHxD): (673x412x86) mm Material: Aluminum die cast Thickness: (3-12) mm Mounting VESA100	IEC/UL 60601-1:2012	Tested in application
Main Processor Board – CPU	HANNSTAR Board CORP	MLC8 Standard (Coffe Lake-S) Type 4M PCB with electronics	Flammability V-0 130 °C	ANSI/UL 94 ANSI/UL 796 ANSI/UL 746A CAN/CSA-C22.2 No. 0.17	cURus E89382
Power entry module (INT) MLC 8-2x AC Type C14 appliance inlet with fuse holder and filter	Schaffner EMV AG Schaffner EMC Inc	FN9260B-2-06 Medical type	250 VAC; 50/60 Hz 2 A @ 40 °C (-25..+85) °C	UL 1283 CSA 22.2 No. 8 1986 (EMC) IEC/EN 60939 (EMC) UL/CAN/IEC/EN 60320-1 IEC/EN 60127-6	cURus E64388 (EMC) Reference no: SE-53672A1 (EMC) cURus E352674 Intertek reference no. 1608769
	TDK Electronics AG EPCOS AG	B84773M0004A000 Medical type	250 VAC; 50/60 Hz 4 A @ 40 °C (-25..+85) °C	ANSI/UL 1283 CSA 22.2 No. 8	cURus E70122
Mains Fuse (INT) MLC 8-2x AC	CONQUER ELECTRONICS CO LTD	VBS UDA 2A 250 V(PF) Time lag type	Current rating: 2 A Marking: T 250 V (High) breaking capacity: 1,5 kA Cylindrical	CSA 248 UL 248 IEC 60127	cURus E82636 VDE 40008022
	Littlefuse Inc.	0215002.MXP			cURus E10480

		Time lag type	dimension: (5 x 20) mm		
Switch Mode Power Supply (INT) MLC 8-2x AC	TDK-Lambda UK Ltd	CUS150M-24/U	Input: (100..240) VAC; 47..63 Hz Ambient temperature (derating): 50 °C / 100% Output: 24 VDC; 6,25 A	ANSI/AAMI ES 60601-1 +A1 CAN/CSA-C22.2 No. 60601-1 IEC 60601-1:2012	cURus E349607 CB report # E349607-D1003-1/A0/C0-ULCB
LED driver for MLC 8-21 (INT) Subassembly	CiVue PCB Material: ART PCB CORP	AIN-LED008-01-1 03V0	Input: (10,8 - 13,2) VDC; max 1430 mA Output: 55 VDC; max 360 mA; V-0; 130 °C	ANSI/UL 746A CAN/CSA-C22.2 No. 0.17	PCB material: cURus E171781
LED driver for MLC 8-23 (INT) Subassembly	CiVue PCB Material: ART PCB CORP	AIN-LED013-01-1 03V0	Input: 10,8 V~13,2 VDC; max 1700 mA Output: 72 VDC; max 295 mA V-0; 130 °C	ANSI/UL 746A CAN/CSA-C22.2 No. 0.17	PCB material: cURus E171781
LED driver for MLC 8-27 (INT) Subassembly	CiVue PCB Material: ART PCB CORP	AIN-LED021-01-1 03V0	Input: 10,8 V~13,2 VDC; max 2300 mA Output: 60 VDC; max 460 mA V-0; 130°C	ANSI/UL 746A CAN/CSA-C22.2 No. 0.17	PCB material: cURus E171781
LCD screen for MLC 8-21 (INT)	Innolux Corp	M215HJJ-L30	21,5” FullHD LCD panel with LED backlight; 40 °C; Input: 5,5 VDC; max 1500 mA Input LED bar: 42 V; max 90 mA	CAN/CSA C22.2 60950-1 UL 60950-1 IEC 6950-1	cURus E207943
LCD screen for MLC 8-23 (INT)	AU OPTRONICS CORP or Innolux CORP	M238HAN01.0 or M238HCJ-L31	23,8” FullHD LCD panel with LED backlight; 50 °C; Input: 5 VDC; max 880 mA Input LED bar: 61,2 VDC; max 77 mA	IEC / UL / CAN/CSA C22.2 60950-1 or IEC / ANSI/UL / CAN/CSA-C22.2 62368-1	cURus E204356 or cURus E207943
LCD screen for MLC 8-27 (INT)	AU OPTRONICS CORP	M270HVN02.0	27.0” FullHD LCD panel with LED backlight; 50 °C; Input: 5 VDC; max 1460 mA	UL 60950-1 CAN/CSA C22.2 # 60950-1 IEC60950-1	cURus E204356

			Input LED bar: 51,0 V; max 84 mA		
Touch controller (INT)	Dytos B.V. EETI	EXC80H5680S TCG USB touch controller PCB	Input: 3,5 V~5,5 VDC; max 200 mA Operating temperature range: -40..+85 °C	IEC/UL 60601-1:2012	Tested in application
Option: USB 2.0 isolation - power	DELTA	DM03S0505A 3W DC/DC converter	Dielectric strength: min. 4 kV Input: 4,5-75 VDC Output: 5-15 VDC / 0,4-0,066 A –40 °C to +85 °C	UL 1577 ANSI/AAMI ES60601-1 CSA60601-1:08 IEC60601-1:2005	cURus E354770
Option: USB 2.0 isolation - signal	Analog Devices	ADuM4160 5kV USB digital isolator	Dielectric strength: 4 kV 4,5 V to 5,5 V 105 °C	UL 1577 IEC 60601-1:2012 CSA 60950-1-07+A1+A2	cURus E214100 CSA 205078
Option: SSD M.2 (INT)	Transcend Information Inc.	TSxxxGMTS600 M.2 SSD, various types and capacities	Input: 3,3 VDC; Power consumption (active): 2500 mW Operating temperature range: (0..+70) °C	UL 60950-1 CAN/CSA C22.2 No. 60950-1	cURus E356634
Option: SSD (INT)	Phison Electronics Corp Branded for ADLINK	SSBxxxxGTTC7-SBA-4A 2.5” SATA SSD, various types and capacities	Input: 5 VDC Power consumption active (avg): 1960 mW Operating temperature range (case): (-40..+85) °C	UL 60950-1 CAN/CSA C22.2 No. 60950-1	cURus E337243
Option: HDD (INT)	HGST Japan Ltd	HTE5450xxA7E680 TT5SAEnnn Travelstar®Z5 K500 2.5” SATA HDD, various types and capacities	Input: 5 VDC; max 520 mA Ambient temperature range: (0..65) °C	UL 60950 CAN/CSA C22.2 No. 60950	cURus E182115
Option: PCI-Express x16 Riser Card (INT)	ZHUHAI FOUNDER TECHNOLOGY MULTILAYER PCB CO LTD	MLC-Riser Type 4M Right angled PCIe riser card	V-0; 130 °C	ANSI/UL 94 ANSI/UL 796 ANSI/UL 746A CAN/CSA-C22.2 No. 0.17	cURus E164671

RTC Battery (INT)	Maxell Ltd	CR2032 LiMnDioxide battery	3 VDC; 220 mAh Nominal discharge current: 0,2 mA Operating temp. range: (-20..+85) °C	UL 1642	cURus MH12568
RTC Battery protection (INT)	NXP B.V.	BAT54CW-7-F Schottky barrier diode	Reverse voltage (max): 30 V Forward voltage (max): 800 mV Reverse current (max): 0,002 mA Ambient temperature range: (-55..+150) °C	IEC/UL 60601-1	Tested in application
Option: M.2 module - WiFi (INT)	INTEL Corp	9260NGW M.2 2230 WLAN and Bluetooth adapter	Input supply voltage (typ): 3,3 VDC Operating temperature range (Shield): (0..+80) °C	UL 60950-1 CAN/CSA C22.2 No. 60950	cURus E178682
Option: mPCIe module - RFID (INT)	Maxsol GmbH	HF-mPCIe With antenna type KEU	Input: 3,3 V; 200 mA Frequency: 13,56 MHz Max. RFID output power: 100 mW Operating temperature (ambient): (-10..+85) °C	FCC Part 15 C RSS-210 issue 9	CSA Test Report T42153-00-00JP
				ETSI EN 300 330	CSA Test Report T42153-02-00JP
				EN 301 489-1 EN 301-489-3	CSA Test Report T42153-02-01JP
Network isolation (INT)	UDE	L21N001-M	Transformer for LAN applications Temperature range: 0..+70 °C Dielectric strength (min): 4 kVAC (tested with 3 kV)	IEC/UL 60601-1 IEC/UL 60950-1	Tested in application
RS232 Isolation – signal (INT)	On Semiconductor	HCPL0501 High speed transistor optocoupler	Isolation voltage (min): 2,5 kVAC rms Operating temperature (ambient): (-40..+85) °C	ANSI/UL 1577 VDE0884	cURus E90700 File# 136616
RS232 Isolation – power (INT)	Ancrona Murata	AL76253-55KV4Z 78253/55VC MAX253	Isolation voltage: 4 kVDC (tested with 3 kV) Operating	IEC/UL 60601-1	Tested in application

		Compatible Converter Transformer	temperature (ambient): (-40..+85) °C		
Type Label (INT)	3M WROCLAW SP Z O O	Type/Material 7872EC	Thermal transfer label (76x50) mm, polyester	ANSI/UL 969 CSA-C22.2 No. 0.15	cURus s MH18072
Option: Backup battery charger board (INT)	Hiper Enterprise CO LTD	MLC 8 Charging Board Charging board for MLC 8 backup battery P/N 55-A3035-000E	V-0; 130 °C	ANSI/UL 94 ANSI/UL 796 ANSI/UL 746A	cURus E224709
Option: Backup battery protection (included in battery pack)	Helix CO LTD	See backup battery documentation	See backup battery documentation	n/a	See following lines
Protection IC (U2) (INT)	Texas Instruments	TI BQ294700	Overvoltage protection voltage per cell: 4,350 V	IEC 62133:2012	See IEC 62133 test report #081-190222-000 issued by TÜV SÜD
Fuse (F1, F2) (INT)	Dexerials CORP	SFH-1412	# of serial cells: 4 Rated current: 12 A Rated voltage: 36 VDC Rated breaking capacity: 50 A Operating voltage: (10,5.. 19,6) V	ANSI/UL 248-1 ANSI/UL 248-14 CSA-C22.2 No. 248-1-00 CSA-C22.2 No. 248-14-00	cRUus E167588 TÜV certificate # J9650637
Option: Backup battery (INT)	Helix CO LTD	MD0401025002 (vendor P/N H454676-001)	Rechargeable LiIon battery pack Nom. Voltage: 14,4 V Capacity: 2900 mAh Type: 4ICR19/66	IEC/UL 62133:2012	See IEC 62133 test report #081-190222-000 issued by TÜV SÜD
Plastic frame for isolated SIP/SOP´s (INT)	Chi Mei CORP	Wonderloy PC-540	Thickness min. 0,8 mm V-2	UL 94 IEC 60601-1	cURus E56070
Cable Internal protection wires (INT)	HWA-LONG ELECTRONIC CO ., LTD.	HL0931508186 HL0931508187 HL0931508188	length max 50 (±5) mm length max 70 (±5) mm length max 70 (±5)	-	See following lines

			mm		
Wire (INT)	SUZHOU JENLY WIRES & CABLE CO LTD	Style 1015	min. AWG / AWM 14 105 °C; 600 V; FT1	UL 1581 / 758 CAN/CSA C22.2 No. 210.2	cURus E346938
Crimp connector (INT)	K.S. TERMINALS INC	RVS1-4	75 °C V-2	CAN/CSA-C22.2 No. 65 ANSI/UL 486A-486B	cURus E96029
Tubing for HL0931508186 and HL0931508188 (INT)	DAE CHANG ELECCOM CO LTD	DC-3	300 V 105 °C VW-1	ANSI/UL 224 CSA-C22.2 No. 198.1	cURus E120268
Tubing for HL0931508187 and HL0931508188 (INT)	SHENZHEN WOER HEAT SHRINKABLE MATERIAL CO LTD	RSFR-HPF	125 °C 600 V VW-1	ANSI/UL 224 CSA-C22.2 No 198.1	cURus E203950
Crimp connector for HL0931508187 and HL0931508188 (INT)	DONGGUAN JIAN HUI METAL & PLASTIC PARTS CO LT	J704	Metal 105 °C 300 V	ANSI/UL 310 CSA-C22.2 No 153	cURus E207921
Cable Power_Entry_Module-SMPS (INT) MLC 8-2x AC	REI HSING WIRE CO LTD	PVC Insulated Wire LF Style 1015	Length max. 200 (±10) mm min. AWG / AWM 18 105 °C; 600 V; VW-1 UL Style 1015	CSA No.127 / No.210 UL 758 IEC TS 60695-11-21	cURus E108485
Connector (P1) (INT)	JOWLE TECHNOLOGY CO LTD	A3963 series	-25 to +85 °C V-0; 250 V max. 10 A with AWG16	UL 1977 ANSI/UL 94 CSA-C22.2 No. 182.3	cURus E144544 CSA LR78619
Crimp-connector (P2/P3) (INT)	K S TERMINALS INC	KST FDFNYDX-250	max 600 V temp. 105 °C	ANSI/UL 310	cURus E128651
Tubing (internal mains wire) (INT)	HAMBURG INDUSTRIES CO LTD	H-2	Max voltage 600 V rms, Max. 125 °C	ANSI/UL 224 ANSI/UL 94 CSA-C22.2 No.	cURus E255394

			VW-1	198.1	
Cable SMPS-Mainboard (INT) MLC 8-2x AC	Shinintech Electronic CO LTD	ST-1805012	Style 1015 VW-1; 600 V 105 °C AWG20	ANSI/UL 758 CSA-C22.2 No.127 CSA-C22.2 No. 210	cURus E41396
Cable Chargerboard-Mainboard (INT)	Shinintech Electronic CO LTD	ST-1609008	Style 1015 VW-1; 600 V 105 °C AWG18	ANSI/UL 758 CSA-C22.2 No.127 CSA-C22.2 No. 210	cURus E41396
Cable RS232 isolation-DSUB9 (INT)	Shinintech Electronic CO LTD	ST-1601003	Style 2651 VW-1; 300 V 105 °C AWG28	ANSI/UL 758 CSA-C22.2 No.127 CSA-C22.2 No. 210	cURus E128076
Cable Mainboard-Isolation_PCB (INT)	HO-BASE TECHNOLOGY CO LTD	HL0931508179-A.1	Style 2725 FT1; 30 V 80 °C AWG28 & AWG24	ANSI/UL 758 CSA-C22.2 No.127 CSA-C22.2 No. 210	cURus E353532
Cable Mainboard-Front_key_PCB (INT)	Lian Yu CO LTD	Style 2651	VW-1 300 V 105 °C AWG28	ANSI/UL 758 CSA-C22.2 No.127 CSA-C22.2 No. 210	cURus E128076
Cable Mainboard-Touch_controller (INT)	Shinintech Electronic CO LTD	MD-5704256	Style 2725 VW-1; 30 V 80 °C AWG28	ANSI/UL 758 CSA-C22.2 No.127 CSA-C22.2 No. 210	cURus E238846
Cable Mainboard-LCD21 (INT)	Shinintech Electronic CO LTD	ST-1512007	Style 20276 VW-1; 30 V 80 °C AWG28	ANSI/UL 758 CSA-C22.2 No.127 CSA-C22.2 No. 210	cURus s E238846
Cable Mainboard-LCD23 (INT)	Shinintech Electronic CO LTD	ST-1512007	Style 20276 VW-1; 30 V 80 °C AWG28	ANSI/UL 758 CSA-C22.2 No.127 CSA-C22.2 No. 210	cURus E238846
Cable	Shinintech Electronic CO	ST-1512007	Style 20276	ANSI/UL 758	cURus

Mainboard-LCD27 (INT)	LTD		VW-1; 30 V 80 °C AWG28	CSA-C22.2 No.127 CSA-C22.2 No. 210	E238846
Cable Mainboard-LED27 (INT)	REI HSING WIRE CO LTD	Style 1061	VW-1 300 V 80 °C AWG32	ANSI/UL 758 CSA-C22.2 No.127 CSA-C22.2 No. 210	cURus E108485
Cable Mainboard-LED23 (INT)	Shinintech Electronic CO LTD	MD-5705097	Style 1007 VW-1; 300 V 80 °C AWG26	ANSI/UL 758 CSA-C22.2 No.127 CSA-C22.2 No. 210	cURus E238846
Cable Mainboard-LED21 (INT)	Shinintech Electronic CO LTD	MD-5705098	Style 1007 VW-1; 300 V 80 °C AWG28	ANSI/UL 758 CSA-C22.2 No.127 CSA-C22.2 No. 210	cURus E238846
Cable Mainboard-LED_PCB (INT)	Lian Yu CO LTD	Style 2651	VW-1 300 V 105 °C AWG28	ANSI/UL 758 CSA-C22.2 No.127 CSA-C22.2 No. 210	cURus E128076
Power_cord (INT)	Yung Li CO LTD	YP-22/YC-12 Countries addressed: EC	**Plug YP-22:** CEE (7/7) 16 A, 250 V	DIN VDE 0620-2-1	VDE 40003878 SGS Fimko FI 19608
			Connector YC-12: Type C13 10 A, 250 V	IEC 60320-1:2015 IEC 60320-3:2014	Certificate number(s) VDE 40029577
			Cord: H05VV-F 3G 0,75 mm²-1.0 m BLACK	EN 50525-2-11	Certificate number(s) VDE 40010145
	Yung Li CO LTD	YP-12/YC-12 Countries addressed: US, CA	**Plug YP-12:** NEMA 5-15 15 A, 125 V	IEC 60906-2:2011	E152635 LR76393
			Connector YC-12: Type C13 10 A, 125 V	IEC 60320-1:2015 IEC 60320-3:2014	E152635 LL76398
			Cord:	UL 62	E241374

			SVT 18/ 3C 105 °C	UL 1581	
	Yung Li CO LTD	YP-46/YC-12 Countries addressed: CH	**Plug YP-46:** CH-type 12 10 A, 250 V	IEC 60884-1(ed.3):02+A1:06 SEV 1011:09	+S File# 11-IK-0683
			Connector YC-12: Type C13 10 A, 250 V	DIN EN (VDE 0625-1):2008-05 EN 60320-1:2001 + A1:2007	VDE 40029577
			Cord: H05VV-F 3G 0,75 mm²	DIN VDE 0281-5:2002-09 HD 21.5 S3:1994 +A1:1999 + A2:2001	VDE 40010145
	Yung Li CO LTD	YP-22K/YC-12 Countries addressed: KR	**Plug YP-22K:** CEE 7/4 16 A, 250 V	K60884-1 KS C 8305	KTL SU04001-1003A
			Connector YC-12: Type C13 10 A, 250 V	K60320-1	SU04001-1002A
			Cord: H05VV-F 3G 0,75 mm²	IEC 60227	SU04001-1002A SU04001-1003A
	QUEEN PUO ELECTRIC CO., LTD	QP005+QP007 VCTF 3G 0.75mm² 6FT BLACK Countries addressed: JP	**Plug QP-005:** NEMA 5-15 7 A, 125 V	Jis 8303	PSE, JET JET2307-43001-1007
			Connector QP-007: Type C13 7 A, 125 V	Jis 8303	PSE, JET JET2307-43001-1007
			Cord: VCTF 3G 0,75 mm² 300 V	Jis 8303	PSE, JET JET2307-43004-1004

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

8.10 b TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS

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) 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

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

8.11.3.6 TABLE: Cord guard s

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

9.2.2.2 TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996)

9.2.2.2	TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996)				N/A
Part of body	Allowable adult gap[1)], mm	Measured adult gap, mm	Allowable children gap[1)], mm	Measured children gap, mm	
Body	> 500		> 500		
Head	> 300 or < 120		> 300 or < 60		
Leg	> 180		> 180		
Foot	> 120 or < 35		> 120 or < 25		
Toes	> 50		> 50		
Arm	> 120		> 120		
Hand, wrist, fist	> 100		> 100		
Finger	> 25 or < 8		> 25 or < 4		
Supplementary information: [1)] In general, gaps for adults used, except when the device is specifically designed for use with children, values for children applied.					

9.2.3.2 TABLE: Over-travel End Stop Test

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

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

9.4.2.2 TABLE: Instability—overbalance excluding transport position

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

9.4.2.3 TABLE: Instability—overbalance from horizontal and vertical forces

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

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

9.4.2.4.3	TABLE: Castors and wheels – Movement over a threshold	N/A

ME EQUIPMENT preparation	Test Condition (speed of movement)	Remarks

Supplementary information:

9.4.3.1 TABLE: Instability from unwanted lateral movement (including sliding) in transport position

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

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

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

9.7.5 TABLE: Pressure vessels

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

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

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

10.1.1 TABLE: Measurement of X - radiation

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			

11.1.1 TABLE: Excessive temperatures in ME EQUIPMENT

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT					**P**
Model No. ..... :		1	2			
Test ambient (°C) ..... :		24	27			
Test supply voltage/frequency (V/Hz)[4] ..... :		90/60	264/50			

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
1	1	Ambient	30	30,0	P
1	2	Ambient inside	70	62,7	P
1	3	PCB motherboard near PL3 power choke	105	80,1	P
1	4	PCB module at M.2 SSD	105	76,6	P
1	5	Battery enclosure	70	56,4	P
1	6	Rear side enclosure	56	52,1	P
1	7	Front side display	71	37,8	P
1	8	Front side touch panel	56	43,2	P
1	9	Top side enclosure	56	48,6	P
2	1	Ambient	30	30,0	P
2	2	Ambient inside	70	65,2	P
2	3	PCB motherboard near PL3 power choke	105	82,6	P
2	4	PCB module at M.2 SSD	105	78,6	P
2	5	Battery enclosure	70	59,4	P
2	6	Rear side enclosure	56	54,0	P
2	7	Front side display	71	38,9	P
2	8	Front side touch panel	56	44,0	P
2	9	Top side enclosure	56	51,4	P

Supplementary information:

Evaluated for MLC 8-23 considered to be representative for MLC 8-21 and MLC 8-27

Hot spots determined with IR camera

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

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

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

[4] Supply voltage:

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

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

Information from Risk Management, as applicable:

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

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

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:

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

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
11.6.3 spillage	Device is mounted in intended position (vertical with up to 45° deflection), 500ml of a conducting fluid is spilled over front, rear, top, left and right chassis part, either as splash (event duration <= 5s) or continuous event (duration > 5s).	EUT	Pass
11.6.5 ingress of water	IP 54 test according IEC 60529	EUT	Pass
11.6.6 cleaning	Cleaning according specification, see IFU chapter “Cleaning and Disinfection”	EUT	Pass
Supplementary information: Information from Risk Management, as applicable:			

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

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

13.2	TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive		P
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2	Electrical SINGLE FAULT CONDITIONS per Cl. 8.1:	—	—
	Leakage current with N open	See table 8.7	NO
	Leakage current with PE open	See table 8.7	NO
	Leakage current with mains on SIP/SOP open	See table 8.7	NO
	Short of PSU (represent any short in secondary circuits)	PSU shuts down	NO
13.2.3	Overheating of transformers per Clause 15.5:	—	—
		No transformers outside certified components	N/A
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:	—	—
		Not used	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:	—	—
		Not used	N/A
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—
		Not used	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	Not used	N/A
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls	Not used	N/A
	Simulated blocking of filters	Not used	N/A
	Flow of a cooling agent interrupted	Not used	N/A
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
		No such parts	N/A
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1)] – Also see 13.10	—	—
		Not used	N/A
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:	—	—

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)
	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
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	—	—
		Not for such environment	N/A
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	—	—
		No such hazards	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. Information from Risk Management, as applicable:			

15.3 TABLE: Mechanical Strength tests

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	Passed, no damage
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	Passed, minor damage of glass while impact at top side but no impairment of safety observed, function present
15.3.4.1	Drop Test (hand-held)	Free fall height (m) =	N/A
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5	Passed, no damage observed
15.3.5	Rough handling test	Travel speed (m/s) =	N/A
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) =	N/A
Supplementary information: 1)As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows or state N/A in Remarks field).			

15.4.6 TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests

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

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						N/A
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)[1)] .....:							—
RATED input frequency (Hz) .....:							—
Winding tested	Class of insulation (A, B, E, F, or H)	Type of protective device (fuse, circuit breaker) /Ratings	Protective device operated Yes/No	Time to THERMAL STABILITY (when protective device did not operate)(Min)	Maximum allowed temp from Table 31 (ºC)	Maximum winding temp measured (ºC)	Ambient (ºC)
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

15.5.1.3	TABLE: transformer overload test – conducted only when protective device under short-circuit test operated					N/A
Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1)] .....:						
RATED input frequency (Hz) .....:						
Test current just below minimum current that would activate protective device and 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)

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

15.5.2 TABLE: Transformer dielectric strength after humidity preconditioning of 5.7

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7				N/A
Transformer Model/Type/ Part No	Test voltage applied between	Test voltage, (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No

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

16.6.1 TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS

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

Supplementary information:

SP TABLE: Additional or special tests conducted

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

Supplementary information:

Photographs

Fig. 1 Model Overview MLC 8-21; MLC 8-23 and MLC 8-27

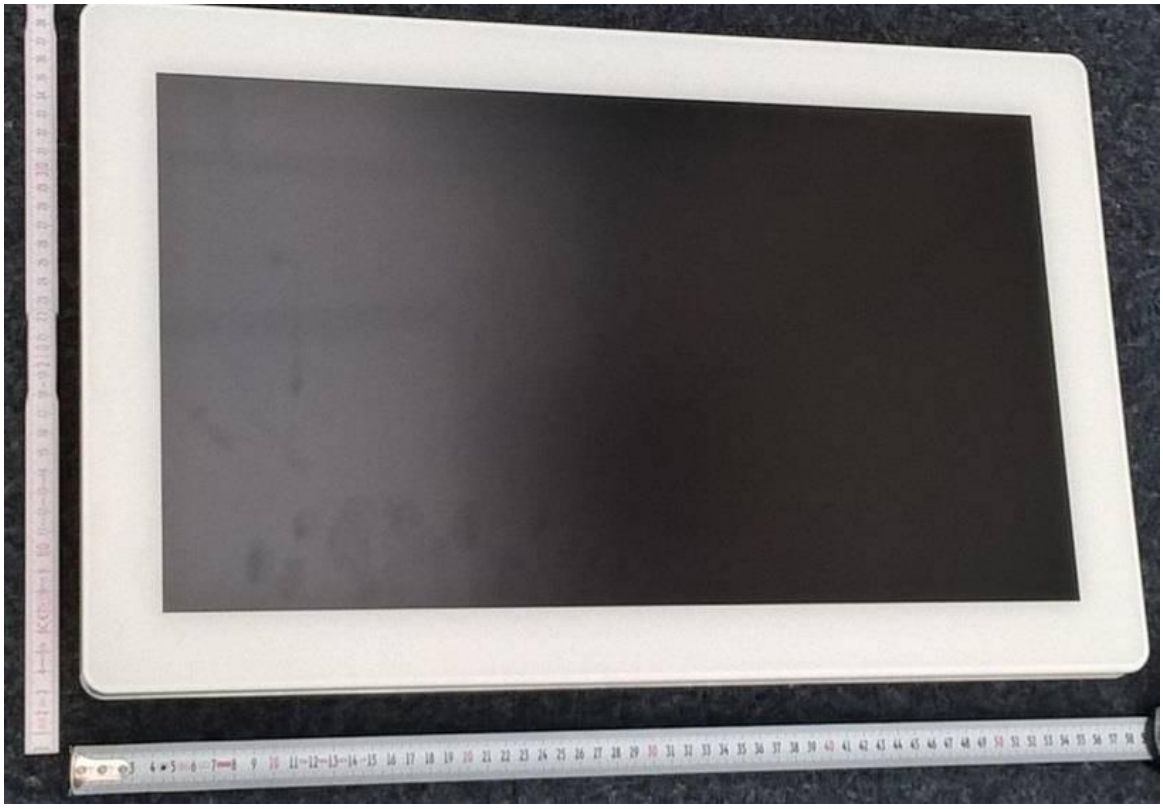

Fig. 2 Front view MLC 8-21 (representative for MLC 8-23 and MLC 8-27)

Fig. 3 Rear view of MLC 8-21 with hatch (representative for MLC 8-23 and MLC 8-27)

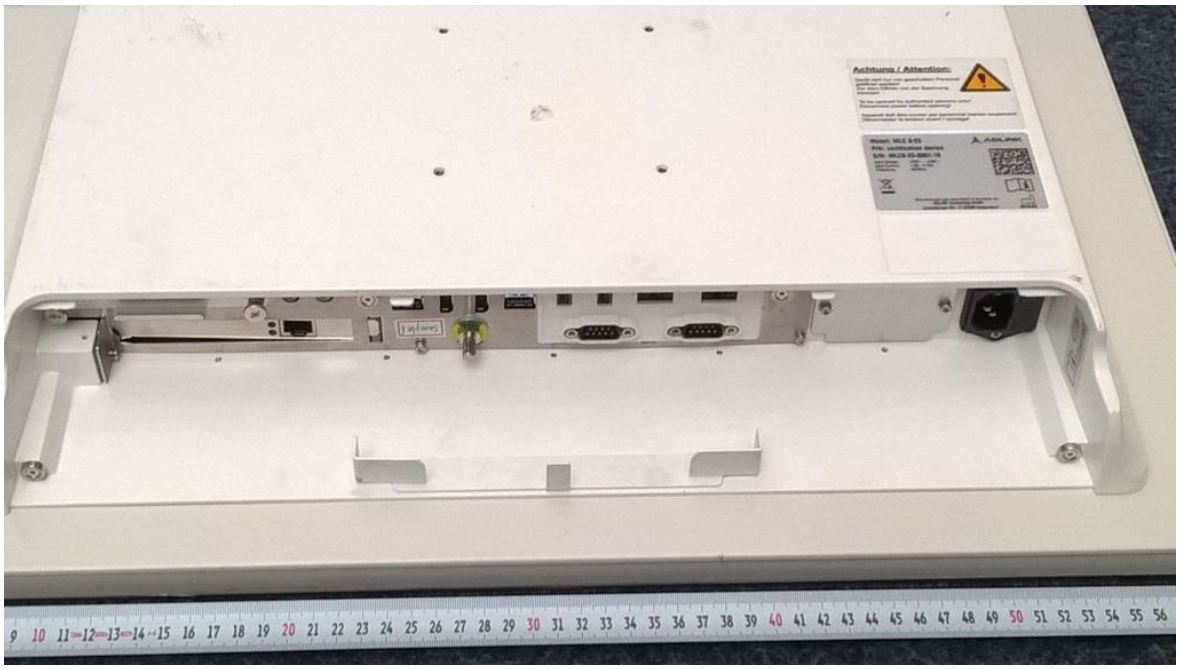

Fig. 4 Rear view of MLC 8-23 hatch removed (representative for MLC 8-21 and MLC 8-27)

Fig. 5 MLC 8-23 open, bottom part (representative for MLC 8-21 and MLC 8-27)

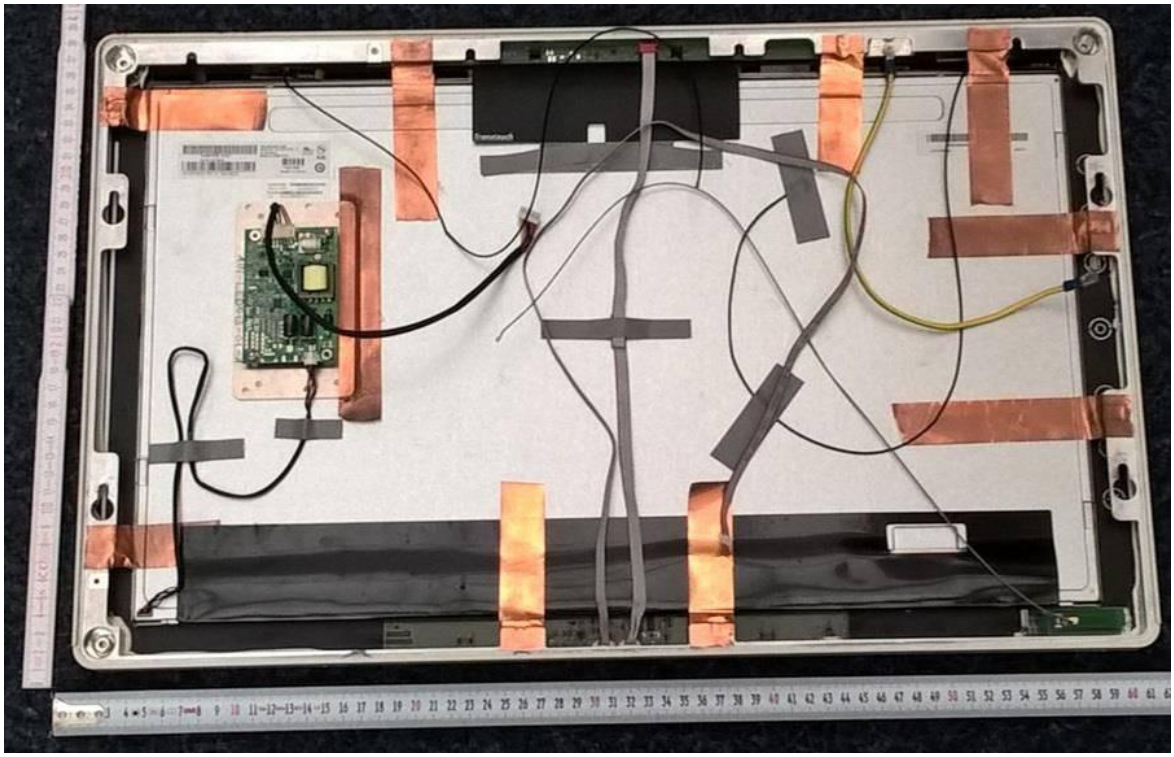

Fig. 6 MLC 8-23 open, front part with display (representative for MLC 8-21 and MLC 8-27)

Test equipment and additional test documentation

List of measuring equipment and test equipment used:

ID No.	Equipment	Type	Manufacturer	Specification	Cat	Last Cal.	Next Cal.
O1133	Data logger for pressure, humidity and temperature	testo 176 P1	testo AG	0...100%rF/ 0...100%rH; -20....+ 70°C/ -4... + 158°Ftd; 6000....1100mbar	chk	Jul 22, 2019	Jul 2020
O1235	Multimeter, digital; High Resolution TRMS System	METRAHIT ENERGY	GMC-Instruments	1µV...600V, 10nA....10A, 10mOhm...60MOhm, 10pF...600µF, 0.01Hz...300kHz, -250°C...1370°C; 10nW.....3.6 kW	cal	Apr 11, 2019	Apr 2020
O0774	Climatic Chamber	VC 4100	Vötsch	990 l; -40°C - +180°C; 10 % - 98 % rel. hum.	cal	Sep 07, 2018	Sep 2019
O1036	Steel rule	1500 mm, 2 Skalenteilungen	HAHN+KOLB Werkzeuge GmbH	1500 mm;	cal	Apr 05, 2019	Apr 2021
O0929	Luxmeter	Mavolux 5032C/B USB	Gossen	--	cal	May 25, 2018	May 2020
O0837	Clock Timer	2-Channel	Oregon Scientific	--	chk	Jun 03, 2019	Jun 2021
O1057	Ground Bond Tester	Hyamp III 1 to 60 AMp Ground Bond tester with graphic display	LXinstruments GmbH	Voltage: 115/230 VAC ± 10%, user selectable; Frequency: 50/60 Hz ± 5%	cal	Jun 04, 2019	Jun 2020
O1017	Leak Current Hitester	ST5540	HIOKI	--	cal	Feb 15, 2019	Feb 2020
O0822	High Voltage Tester	UX36-OPT12/16ADC-100	ETL Prüftechnik GmbH	12 kV AC, 16 kV DC, 1200 VA, m. Öltrafo	cal	Apr 05, 2018	Aug 2019
O1112	Caliper sliding, 150 mm, digital	CD-15CPX	Mitutoyo	0-150mm; Resolution 0,01mm; IP-67; depth rod: Ø 1,9 mm	cal	Feb 22, 2019	Feb 2021
O0968	Temperature Data Logger (Temperature Recorder)	MVAdvanced 1024	Yokogawa	24 channels, 125 ms/1s,	cal	May 14, 2019	May 2020
O1079	Force Meter (Handheld)	Modell 326, 0-1000 N (Version 02)	Test GmbH	0-1000 N (Version 02)	cal	Oct 30, 2018	Oct 2020
O0855	Oscilloscope (100 MHz/ 4-Channel)	TDS3014C	Tektronix	DPO, 4-Kanal; 100 MHz, 4 x 1.25 GS/s;	cal	Aug 13, 2018	Aug 2019

cal = Calibration, car = Calibration restricted use, chk = Check, chr = Check restricted use, cpu = Check prior to use, calchk = Calibration and check, ind = for indication only, cnn = Calibration not necessary, man = Maintenance

Attachments National Deviations

Canadian National Differences

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
Canadian National Differences - Differences according to Canadian National standard: CAN/CSA-C22.2 No. 60601-1:14			P
1	**Scope, object and related documents**		---
1.1	**Scope**		---
	This standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be installed in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1; CAN/CSA-C22.2 No. 0; and CAN/CSA-Z32.	Considered	P
	NOTE 1A: *In the IEC 60601 standards series adopted for use in Canada, the Canadian-particular standards may modify, replace, or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.*		---
1.3	**Collateral standards**		---
	Applicable Canadian collateral standards become normative at the date of their publication and apply together with this standard.	Considered	P
	NOTE 1: *When evaluating compliance with CAN/CSA-C22.2 No. 60601-1, it is permissible to assess independently compliance with the adopted Canadian collateral standards.*		---
1.4	**Particular standards**		---
	A requirement of a Canadian-particular safety standard takes precedence over this standard.	No such incidence	N/A
3	**Terminology and definitions**		---
3.41	**HIGH VOLTAGE**		---
	any voltage above 750 V, 1 050 V peak, as defined in the *Canadian Electrical Code (CEC), Part I*	No such voltages used	N/A
4	**General requirements**		---
4.8	**Components of ME EQUIPMENT**		---

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
	a) the applicable safety requirements of a relevant CSA, IEC, or ISO standard; or	Considered	P
	NOTE 1: *For the components, it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard.*		---
	b) where there is no relevant CSA, IEC, or ISO standard, the requirements of this standard have to be applied	Considered	P
	NOTE 2: *If there are neither requirements in this standard nor in a CSA, IEC, or ISO standard, any other applicable source (e.g., standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.*		---
4.10.2	**SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS**		----
	and shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1:	Considered	P
7	**ME EQUIPMENT identification, marking and documents**		---
7.7.1 to 7.7.5	and shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1	Considered	P
	A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION or insulation shall be identified by either green or green and yellow colour. Colours of neutral and POWER SUPPLY CORD conductors shall be in accordance with the *Canadian Electrical Code (CEC), Part I*, CSA C22.2 No. 21, and CSA C22.2 No. 49…….:	Considered, see table 8.10	P
8	**Protection against electrical HAZARDS from ME EQUIPMENT**		---
8.7.3	**Allowable values**		---
	Allowable values shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1.	Considered, see table 8.7	P
8.11.3	**POWER SUPPLY CORDS**		---
8.11.3.2	**Types**		---
	a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall be		---
	i) if molded-on type, hospital grade mains plug complying with CSA C22.2 No. 21;……..…:	Considered, see table 8.10	P

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
	ii) hospital grade disassembly attachment plug type complying with CSA C22.2 No. 42; or……..:	Certified cord set used	N/A
	iii) Class II equipment having fuses on the line side/sides and neutral and may use a non-polarized attachment plug or a polarized attachment plug — CSA configuration type 1-15P shall be required and shall meet all applicable requirements in CSA C22.2 No. 21 and CSA C22.2 No. 42. Where a polarized attachment plug is used, the POWER SUPPLY CORD shall be connected to the wiring of the EQUIPMENT on the ungrounded side of the line when any of the following devices are used in the primary circuit:…….:	Class I	N/A
	1- the centre contact of an Edison base lampholder;		N/A
	2- a single pole switch;		N/A
	3- an automatic control with a marked off position;		N/A
	4- a solitary fuse/fuse holder; or		N/A
	5- any other single pole overcurrent protective device		N/A
	b) Detachable POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) shall be of a type that		---
	i) can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety HAZARD to a PATIENT or OPERATOR;	Certified cord set and appliance inlet used, see table 8.10	P
	ii) can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety HAZARD to a PATIENT or OPERATOR; and	See table 8.6.3	P
	iii) has a terminal configuration or other constructional feature that will minimize the possibility of its replacement by a detachable POWER SUPPLY CORD which could create a HAZARDOUS SITUATION	Certified cord set and appliance inlet used, see table 8.10	P
	c) A detachable POWER SUPPLY CORD shall		---
	i) comply with the applicable requirements of CSA C22.2 No. 21; and……..:	Certified cord set used, see table 8.10	P
	ii) not be smaller than No. 18 AWG, and the mechanical serviceability shall be not less than….:		P
	1) Type SJ or equivalent for mobile or exposed to abuse ME EQUIPMENT;		N/A

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
	and…..:		
	2) Type SV or equivalent for ME EQUIPMENT not exposed to abuse (or Type HPN if required because of temperature)…..:	See table 8.10	P
	NOTE 1A: *See CSA C22.2 No. 49 for requirements on the cord types mentioned in Sub-item 2).*		---
	d) Power supply cords shall meet the requirements of the *Canadian Electrical Code, Part I*, as applicable……..:	Certified cord set used, see table 8.10	P
	Connecting cords between equipment parts shall meet the requirements of the *Canadian Electrical Code, Part I*, as applicable……..:	No connecting cords used	N/A
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		---
	Mains fuses and OVER-CURRENT RELEASES shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1……:	See table 8.10	P
9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**		---
9.7.5	**Pressure vessels**		---
	Pressure vessels shall comply with the requirements of CSA B51, as applicable…….:	No such parts incorporated	N/A
9.7.7	**Pressure-relief device**		---
	A pressure-relief device shall also comply as applicable to the requirements of ASME PTC 25 or equivalent Canadian requirements……:	No such parts incorporated	N/A
15	**Construction of ME EQUIPMENT**		---
15.4.1	**Construction of connectors**		---
	bA) The point of connection of gas cylinders to EQUIPMENT shall be gas specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on EQUIPMENT shall be		---
	i) gas specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1 380 kPa (200 psi); or…….:	No gas used	N/A
	ii) DISS type complying with CGA V-5 for pressures 1 380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA-		N/A

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
	Z5359……:		
	NOTE 1A: *Users of this standard should consult the CSA Z305 series of standards, CAN/CSA-Z9170-1, CAN/CSA-Z9170-2, CAN/CSA-Z10524, and CAN/CSA-Z15002 for further information regarding inlet connectors; ISO 407 for requirements addressing yoke-type valve connections; and ISO 32 for colour coding.*		---
15.4.8	**Internal wiring of ME EQUIPMENT**		---
	Internal wiring of ME EQUIPMENT shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1……:	See table 8.10	P
16	**ME SYSTEMS**		---
16.1	**General requirements for the ME SYSTEMS**		---
	An ME SYSTEM shall provide		---
	- within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and	Not a ME system	N/A
	- outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA, IEC, or ISO safety standards		N/A
	Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with CSA, IEC, or ISO safety standards that are relevant to that equipment.		N/A
16.9.2.1	**MULTIPLE SOCKET OUTLET**		---
	c) The MULTIPLE SOCKET-OUTLET shall comply with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and the following requirements……:		N/A
	- The separating transformer shall comply with the requirements of CAN/CSA-E61558-2-1 with a rated output not exceeding		---
	- 1 kVA for single-phase transformers; and		N/A
	- 5 kVA for polyphase transformers The separating transformer shall also have a degree of protection not exceeding IPX4.		N/A

Japan National Differences

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
Japan National Differences - Differences according to National standard: JIS T0601-1:2012			P
1.1	At the end, add the following: JIS T0601-1:1999 is applicable until 2017.05.31.	Considered	P
1.3	In NOTE 3, add the following: In Japan, to check the concerned JIS standard is required.	Considered	P
1.4	At the end of NOTE, add the following: In Japan, application of the concerned JIS standard(s) is required.	Considered	P
2	Except the part of the first paragraph, Attention and NOTE, replace the existing part listing standards with the following, and apply these properly in the following clauses if any: **JIS B7761-3**, Hand-transmitted vibration-Part 3: General requirements for measurement and evaluation NOTE: ISO 5349-1, Mechanical vibration - Measurement and evaluation of human exposure to hand-transmitted vibration - Part 1: General requirements (IDT) **JIS B9707**, Safety of machinery-Safety distances to prevent danger zones being reached by the upper limbs NOTE: ISO 13852, Safety of machinery - Safety distances to prevent danger zones being reached by the upper limbs (IDT) **JIS B9711**, Safety of machinery-Minimum gaps to avoid crushing of parts of the human body NOTE: ISO 13854, Safety of machinery - Minimum gaps to avoid crushing of parts of the human body (IDT) **JIS C0445**, Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system NOTE: IEC 60445, Basic and safety principles for man-machine interface, marking and identification - Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system (IDT) **JIS C0447**, Man-machine interface (MMI) - Actuating principles NOTE: IEC 60447, Basic and safety principles for man-machine interface, marking and identification - Actuating principles (IDT) **JIS C0920:2003**, Degrees of protection provided by enclosures (IP Code) NOTE: IEC 60529:2001, Degrees of protection provided by enclosures (IP Code) (IDT) **JIS C1509-1**, Electroacoustitcs - Sound level meters- Part 1: Specifications NOTE: IEC 61672-1, Electroacoustics - Sound level meters - Part 1: Specifications (IDT) **JIS C1509-2**, Electroacoustics -Sound level meters - Part 2: Pattern evaluation tests NOTE: IEC 61672-2, Electroacoustics - Sound level meters -	Considered	P

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NATIONAL DIFFERENCES
Medical electrical equipment, Part 1: General Requirements

Clause	Requirement + Test	Result - Remark	Verdict
	Part 2: Pattern evaluation tests (IDT) **JIS C2134**, Method for the determination of the proof and the comparative tracking indices of solid insulating materials NOTE: IEC 60112, Method for the determination of the proof and the comparative tracking indices of solid insulating materials (IDT) **JIS C3301:2000**, Rubber insulated flexible cords NOTE: IEC 60245-4:1994, Rubber insulated cables of rated voltages up to and including 450/750 V - Part 4: Cords and flexible cables, Amendment 1:1997 (NEQ) **JIS C3306:2000**, Polyvinyl chloride insulated flexible cords NOTE: IEC 60227-5:1997, Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V - Part 5: Flexible cables (cords) (NEQ) **JIS C4003**, Electrical insulation-Thermal evaluation and designation NITE: IEC 60085, Electrical insulation - Thermal evaluation and designation (MOD) **JIS C5101-14:2009**, Fixed capacitors for use in electronic equipment - Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains NOTE: IEC 60384-14:2005, Fixed capacitors for use in electronic equipment - Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains (IDT) **JIS C6065:2007**, Audio, video and similar electronic apparatus-Safety requirements NOTE: IEC 60065:2001, Audio, video and similar electronic apparatus - Safety requirements (MOD) **JIS C6802:2005**, Safety of laser products NOTE: IEC 60825-1:1993, Safety of laser products - Part 1: Equipment classification, requirements and user's guide, Amendment 1:1997 and Amendment 2 :2001 (IDT) **JIS C6965**, Mechanical safety of cathode ray tubes NOTE: IEC 61965, Mechanical safety of cathode ray tubes (IDT) **JIS C8282-1**, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements NOTE: IEC 60884-1, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements (MOD) **JIS C8303**, Plugs and receptacles for domestic and similar general use NOTE: No corresponding JIS exists. This standard has been listed as normative reference corresponding to IEC60083, Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC, which has been listed in IEC 60601-1:2005. Refer to JIS T1021, too. **JIS C60068-2-2:1995**, Environmental testing -Part 2-2:Tests -Test B: Dry heat NOTE: IEC 60068-2-2:1974, Environmental testing - Part 2: Tests. Tests B: Dry heat, Amendment 1:1993 and Amendment 2:1994 (IDT) **JIS C60079-0**, Explosive atmospheres-Part 0: Equipment-General requirements NOTE: IEC 60079-0, Electrical apparatus for explosive gas atmospheres - Part 0: General requirements (IDT) **JIS C60079-2**, Electrical apparatus for explosive gas atmospheres - Part 2: Pressurized enclosures "p" NOTE: IEC 60079-2, Electrical apparatus for explosive gas		

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
	atmospheres - Part 2: Pressurized enclosures “p” (IDT) **JIS C60079-6**, Electrical apparatus for explosive gas atmospheres - Part 6:Oil immersion "o" NOTE: IEC 60079-6, Electrical apparatus for explosive gas atmospheres - Part 6: Oil-immersion “o” (IDT) **JIS C60364-4-41**, Low-voltage electrical installations-Part 4-41: Protection for safety - Protection against electric shock NOTE: IEC 60364-4-41, Electrical installations of buildings - Part 4-41: Protection for safety - Protection against electric shock (IDT) **JIS C60664-1:2009**, Insulation coordination for equipment within low-voltage systems - Part 1:Principles, requirements and tests NOTE: IEC 60664-1:2007, Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests (IDT) **JIS C60695-11-10**, Fire hazard testing-Part11-10:Test flames-50W horizontal and vertical flame test methods NOTE: IEC 60695-11-10, Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods (IDT) **JIS T0307**, Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied NOTE: ISO 15223, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied (IDT) **JIS T0601-1-3**, Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment NOTE: IEC60601-1-3, Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment (IDT) **JIS T14971:2003**, Medical devices-Application of risk management to medical devices NOTE: ISO 14971:2000, Medical devices - Application of risk management to medical devices (IDT) **JIS Z8202** (all parts), Quantities and units NOTE: ISO 31 (all parts), Quantities and units (IDT) **JIS Z8203**, SI units and recommendations for the use of their multiples and of certain other units NOTE: ISO 1000, SI units and recommendations for the use of their multiples and of certain other units (IDT) **JIS Z8736-1**, Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1 : Measurement at discrete points NOTE: ISO 9614-1, Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1: Measurement at discrete points (IDT) **JIS Z9101:2005**, Safety colours and safety signs-Design principles for safety signs in workplaces and public areas NOTE: ISO 3864-1:2002, Graphical symbols - Safety colours and safety signs - Part 1: Design principles for safety signs in workplaces and public areas (IDT) **ISO 780**, Packaging - Pictorial marking for handling of goods NOTE: The corresponding JIS standard is JIS Z0150 Packaging-Pictorial marking for handling of goods (MOD) **ISO 1853**, Conducting and dissipative rubbers,		

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition
NATIONAL DIFFERENCES
Medical electrical equipment, Part 1: General Requirements

Clause	Requirement + Test	Result - Remark	Verdict
	vulcanized or thermoplastic—Measurement of resistivity NOTE: The corresponding JIS standard is JIS K6271 Rubber, vulcanized or thermoplastic-Determination of volume and surface resistivity (MOD) **ISO 2878**, Rubber - Antistatic and conductive products - Determination of electrical resistance **ISO 2882**, Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance Limits **ISO 3746**, Acoustics - Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane **ISO 7000-DB:2004**, Graphical symbols for use on equipment - Index and synopsis **ISO 7010:2003**, Graphical symbols - Safety colours and safety signs - Safety signs used in workplaces and public areas **ISO 10993** (all parts), Biological evaluation of medical devices NOTE: The corresponding JIS standard is JIS T0993-1 Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process (MOD). However, other Parts than Part 1 and Part 7 have still not been published as JIS. **ISO 11134**, Sterilization of health care products - Requirements for validation and routine control - Industrial moist heat sterilization NOTE: At present, as the corresponding JIS or international standards, the following exist: JIS T0816-1:2010 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices ISO 17665-1:2006, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (IDT) **ISO 11135**, Medical devices - Validation and routine control of ethylene oxide sterilization NOTE: At present, as the corresponding JIS or international standards, the following exist: JIS T0801-1:2010 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT) **ISO 11137**, Sterilization of health care products - Requirements for validation and routine control – Radiation Sterilization NOTE: At present, as the corresponding JIS or international standards, the following exist: JIS T0806-1:2010 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices ISO 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT) **ISO 23529**, Rubber - General procedures for preparing and conditioning test pieces for physical test methods NOTE: The corresponding JIS standard is JIS K6250 Rubber-		

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
	General procedures for preparing and conditioning test pieces for physical test methods (MOD) **IEC 60079-5**, Explosive gas atmospheres—Part 5: Equipment protection by powder filling "q" **IEC/TR 60083**, Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC **IEC 60086-4**, Primary batteries - Part 4: Safety of lithium batteries NOTE: The corresponding JIS standard is JIS C8513 Safety of primary lithium batteries (MOD) **IEC 60127-1**, Miniature fuses - Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links NOTE: The corresponding JIS standard is JIS C6575-1 Miniature fuses-Part 1: Definitions of miniature fuses and general requirements for miniature fuse-links (MOD) **IEC 60227-1:1993**, Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements, Amendment 1:1995 and Amendment 2:1998 NOTE: The corresponding JIS standard is JIS C3662-1:2009 Polyvinyl chloride insulated cables of rated voltages up to and including 450/750V - Part 1: General requirements (MOD) **IEC 60245-1:2003**, Rubber insulated cables - Rated voltages up to and including 450/750 V - Part 1: General requirements NOTE: The corresponding JIS standard is JIS C3663-1:2007 Rubber insulated cables-Rated voltages up to and including 450/750 V-Part 1: General requirements (MOD) **IEC 60252-1**, AC motor capacitors - Part 1: General - Performance, testing and rating - Safety requirements -Guide for installation and operation **IEC 60320-1**, Appliance couplers for household and similar general purposes - Part 1: General requirements NOTE: The corresponding JIS standard is JIS C8283-1 Appliance couplers for household and similar general purposes-Part 1: General requirements (MOD) **IEC 60335-1:2001**, Household and similar electrical appliances - Safety - Part 1: General requirements NOTE: The corresponding JIS standard is JIS C9335-1:2003 Household and similar electrical appliances - Safety - Part 1 : General requirements (MOD) **IEC 60417-DB:2002**, Graphical symbols for use on equipment **IEC 60601-1-2**, Medical electrical equipment - Part 1 - 2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests NOTE: The current "JIS T0601-1-2:2012 Medical electrical equipment - Part 1-2: General requirements for safety - Electromagnetic compatibility - Requirements and tests" corresponds to IEC 60601-1-2:2001 and Amendment 1:2004. **IEC 60601-1-6**, Medical electrical equipment - Part 1 - 6: General requirements for basic safety and essential performance - Collateral standard: Usability NOTE: As the corresponding international standard, IEC 62336 is applicable.		

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
	IEC 60601-1-8, Medical electrical equipment - Part 1 - 8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems NOTE: The corresponding JIS standard is now under drafting. **IEC 60730-1:1999**, Automatic electrical controls for household and similar use - Part 1: General requirements, Amendment 1:2003 and Amendment 2:2007 NOTE: The corresponding JIS standard is JIS C9730-1:2010 Automatic electrical controls for household and similar use-Part 1:General requirements (MOD) **IEC 60851-3:1996**, Winding wires - Test methods - Part 3: Mechanical properties, Amendment 1:1997 and Amendment 2:2003 **IEC 60851-5:1996**, Winding wires - Test methods - Part 5: Electrical properties, Amendment 1:1997 and Amendment 2:2004 **IEC 60851-6:1996**, Winding wires - Test methods - Part 6: Thermal properties and Amendment 1:1997 **IEC 60878:2003**, Graphical symbols for electrical equipment in medical practice **IEC 60884-1**, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements **IEC 60950-1:2001**, Information technology equipment – Safety - Part 1: General requirements NOTE: The corresponding JIS standard is JIS C 6950-1:2009 Information technology equipment - Safety - Part 1: General requirements (MOD) **IEC 61058-1:2000**, Switches for appliances - Part 1: General requirements and Amendment 1:2001 NOTE: The corresponding JIS standard is JIS C4526-1:2005 Switches for appliances - Part 1: General requirements (MOD) **IEC 61558-1:1997**, Safety of power transformers, power supply units and similar products - Part 1: General requirements and tests and Amendment 1:1998 NOTE: No corresponding JIS exists. However, as the standard corresponding to IEC 61558-1:2005, the following exists: JIS C 61558-1:2008 Safety of power transformers, power supplies, reactors and similar products - Part 1: General requirements and tests (MOD) **IEC 61558-2-1**, Safety of power transformers, power supplies, reactors and similar products - Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications NOTE: The corresponding JIS standard is JIS C61558-2-1 Safety of power transformers, power supplies, reactors and similar products-Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications (MOD)		
3.61	Add NOTE as follows: NOTE In this standard, MECHANICAL HAZARD is understandable suitably by replacing with mechanical HAZARD, mechanical HADARDOUS SITUATION, HARM or unacceptable RISK.	Considered	P

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
3.70	Replace the existing text with: condition in which all means provided for protection against HAZARDOUS SITUATION or HAZARDS are intact	Considered	P
4.2	Replace the existing NOTE 2 with the following: NOTE 2 Conditions or faults that can give rise to HAZARDOUS SITUATIONS are identified in the clauses of this standard. In these cases, it will often be necessary to carry out a RISK MANAGEMENT PROCESS to determine what the actual HAZARDOUS SITUATIONS are and the tests that need to be done to show that the identified HAZARDOUS SITUATIONS do not arise in the specified circumstances.	Considered	P
4.10.1	In the existing text, replace “a separate power supply” with “a separate power supply (e.g., a power supply of other equipment)”.	Considered	P
7.3.3	In the third paragraph, replace “could result in a HAZARD” with “could result in a HAZARDOUS SITUATION”.	Considered	P
7.4.3	Replace the existing first paragraph with the following: Numeric indications of parameters on ME EQUIPMENT shall be expressed in SI units according to JIS Z8202 (ISO 31 (IDT)) except the base quantities listed in Table 1 may be expressed in the indicated units, which are used in conjunction with the SI units system or as the approved combination. Replace the title of Table 1 with the following: Units which are used in conjunction with the SI units system or as the approved combination	Considered	P
7.7.4	Under the existing text, add the following: If polyvinyl chloride insulated flexible cord of JIS C3306 or rubber insulated flexible cord of JIS C3301 is used, the conductor may be coloured "white".	Not used	N/A
7.7.5	Under the existing text, add the following: If polyvinyl chloride insulated flexible cord of JIS C3306 or rubber insulated flexible cord of JIS C3301 is used, conductors may be of the colour specified in the said standards.	Not used	N/A
7.9.3.2	In the fourth dash, replace “the nature of the HAZARD” with “the HAZARDOUS SITUATION”.	Considered	P
8.4.2	For Item c), at the end of the paragraph of “For such parts, the voltage to earth or --,” replace “at a potential up to 2 V” with “at a potential of 2 V or more”. For Item c), replace the existing NOTE with NOTE 1, and add the following new NOTE 2: NOTE 2 – The corresponding international standard specifies as “not exceed 20 J at a potential up to 2	Considered	P

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
	V". However, 1.2.8.9 of IEC 60950-1, which was quoted by the said international standard, specifies as "2 V or more". Therefore, this JIS standard was harmonized to IEC 60950-1.		
8.8.2	For a), add the following NOTE: NOTE – Generally, "distance through insulation" means the thickness of insulation. However, for example, if a transformer installed into a metal case is insulated by filler, the thickness is always not uniformly. Therefore, such expression was used.	Considered	P
8.8.3	Between the third dash and the paragraph of "Initially, not more than --", add the following new paragraph. During the above-mentioned tests, the state of the power switch shall be kept with closed circuit.	Considered	P
8.9.1.2	At the end of the title of this sub-clause, add "(Apply to MOOP)".	Considered	P
8.9.1.3	At the end of the title of this sub-clause, add "(Apply to MOOP)".	Considered	P
8.9.1.4	At the end of the title of this sub-clause, add "(Apply to MOOP)".	Considered	P
8.9.1.5	At the end of the title of this sub-clause, add "(Apply to MOOP and MOPP)".	Considered	P
8.9.1.6	At the end of the title of this sub-clause, add "(Apply to MOOP and MOPP)".	Considered	P
8.9.1.7	At the end of the title of this sub-clause, add "(Apply to MOOP)".	Considered	P
8.9.1.8	At the end of the title of this sub-clause, add "(Apply to MOOP)".	Considered	P
8.9.1.9	At the end of the title of this sub-clause, add "(Apply to MOOP)".	Considered	P
8.9.1.10	At the end of the title of this sub-clause, add "(Apply to MOOP)".	Considered	P
8.9.1.11	At the end of the title of this sub-clause, add "(Apply to MOOP)".	Considered	P
8.9.1.12	At the end of the title of this sub-clause, add "(Apply to MOOP)".	Considered	P
8.9.1.13	At the end of the title of this sub-clause, add "(Apply to MOOP)".	Considered	P
8.9.1.14	At the end of the title of this sub-clause, add "(Apply to MOOP)".	Considered	P
8.11.3.2	Add the following between the first paragraph and the second paragraph: And, rubber insulated flexible cords of JIS C3301, polyvinyl chloride insulated flexible cords of JIS C3306 or cords of which the robustness is equal to or more than those are usable. Add the following between the second paragraph and the last paragraph:	Considered	P

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Clause	Requirement + Test	Result - Remark	Verdict
	And, in the case of cords of JIS C3306, shall not use; - for polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 60 °C, and; - for grade heat-resistant polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 75 °C.		
9.2.2.2	In the bottom column of Table 20, replace the existing text with the following: [a] The values in this table are taken from JIS B9711 (ISO 13854 (IDT)).		N/A
9.2.2.4.4	In the second dash, replace “no HAZARD or damage shall result” with “no HAZARDOUS SITUATION or unacceptable RISK shall result”.		N/A
9.2.4	In e), replace “no HAZARD or damage shall result” with “no HAZARDOUS SITUATION or unacceptable RISK shall result”.		N/A
9.4.4	In the first paragraph of a), replace “and no HAZARDS can develop” with “and no HAZARDOUS SITUATION can develop”.		N/A
9.7.5	In the last paragraph, delete “unmarked”.		N/A
9.8.4.1	Replace the existing NOTE with the following: NOTE The upper carriage of the human body test mass apparatus is formed of wood or a similar material. The bottom portion is foam. The resiliency or spring factor of the foam (ILD or IFD ratings) has not been specified. The foam is cylindrical, rather than spherical.		N/A
10.1.1	In the paragraph, replace “0,5 mR/h” with “0,5 mR/h ≈ 5 µGy/h”; and in NOTE 2, “0,1 mR/h” with “0,5 mR/h ≈ 1 µGy/h”.		N/A
11.1.1	To the existing text of a in the Table 22, add the following: (For example, the maximum temperature limit of a transformer with three insulating materials of Class A, Class B and Class E shall be 105 °C of Class A of the lowest limit.)		N/A
13.2.7	In the title of this sub-clause, replace “in a HAZARD” with “in a HAZARDOUS SITUATION”.		N/A
13.2.10	In Table 26, replace the existing NOTE with the following: NOTE The temperature limits in this table were derived from Table B.1 of IEC 60950-1:2001 (in the corresponding international standard, IEC 61010-1:2001 [22]).		N/A
15.4.2.1	In c), replace “could constitute a HAZARD” with “could constitute a HAZARDOUS SITUATION”.		N/A
15.4.3.4	In the first paragraph, replace “could become a HAZARD” with “could become a HAZARDOUS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	SITUATION".		
16.1	Replace the last two paragraphs with the following: Otherwise, non-medical equipment shall be those which are in compliance with relevant JIS standards or the Technical Requirements of the Electrical Appliance and Material Safety Act or which ensure safety equivalent to the said standards/technical requirements. Equipment in which protection against electric shock relies only on BASIC INSULATION shall not be used in an ME SYSTEM. For the measures for ensuring safety, e.g., the case combined with a separating transformer with DOUBLE INSULATION or RAINFORCED INSULATION, equipment only with BASIC INSULATION may be used. *Compliance is checked by inspection of appropriate documents or certificates.*		N/A
16.6.4.1	In NOTE, replace "no possibility of any HAZARD" with "no possibility of any HAZARDOUS SITUATION".		N/A
16.9.2.1	In the text of c), replace "IEC 60884-1" with "IEC 60884-1 or JIS C8282-1".		N/A
Annex D	In Table D.2, replace the sign of No. 10, which is shown as "IEC 60878 Safety 01 [b]", with the sign of "ISO 7010-M002 [b]". In the bottom column if Table D.2, replace the existing a and b with the following: [a] The description of this commonly used safety sign appeared in Annex B of ISO 3864:1984. [b] In accordance with the corrigendum of IEC 60601-1, Replaced "IEC 60878 Safety 01 " with "ISO 7010-M002	Considered	P
Annex I	In 1.1.3, replace the first dash with the following: - PATIENTS should only be connected to APPLIED PARTS of ME EQUIPMENT complying with this standard. Other equipment should comply with relevant IEC or ISO standards or comply with relevant JIS safety standards or the Technical Requirements of the Electrical Appliance and Material Safety Act, or ensure safety equivalent to the said standards/technical requirements. Replace the existing NOTE 2 with the following: NOTE 2 IEC 60601: MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601 (all parts) or JIS T0601 (all parts). Replace the existing NOTE 3 with the following: NOTE 3 IEC xxxxx: Non-medical equipment in compliance with relevant IEC safety standards.		N/A

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
	Include non-medical equipment in compliance with relevant JIS safety standards or the Technical Requirements of the Electrical Appliance and Material Safety Act, or non-medical equipment ensuring safety equivalent to the said standards/technical requirements.		
Annex L	In the first paragraph, replace “wound components” with “wound components (e.g., transformers, motors, etc.)”		N/A
Bibliography	Add the following at the end: [55] JIS T1021, "Hospital grade" outlet-sockets and plugs [56] JIS Q13485, Medical devices - Quality management systems - Requirements for regulatory purposes		N/A

Korea National Differences

ATTACHMENT TO TEST REPORT IEC 60601-1 NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
KR NATIONAL DIFFERENCES - Differences according to Republic of Korea KS C IEC 60601-1			P
	LIMITATIONS <Supply voltage rating> National supply voltages are 110,220V and 380V <Frequency> Only appliances having supply frequency of 60 Hz or a frequency range including 60 Hz are accepted. <Instruction> Instruction manuals and appliance markings related safety, including nameplate shall be in Korean or graphical symbols in accordance with IEC Publication 417. Plugs for connection of the equipment to the supply mains shall comply with the Korean Standard (KSC 8305 and 8300) More details are available from KTR on request.	Voltages and frequencies tested are within national range Manual shall be provided in Korean language Plug see table 8.10	P

Switzerland National Differences

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
Switzerland National Differences - Differences according to National standard: SN EN 60601-1:06			P
4	Ordinance on environmentally hazardous substances SR 814.081, Annex 1.7, Mercury - Annex 1.7 of SR 814.81 applies for mercury. Switches containing mercury such as thermostats, relays and level controllers are not allowed. Ordinance on chemical hazardous risk reduction SR 814.81, Annex 2.15 Batteries Annex 2.15 of SR 814.81 applies for batteries containing cadmium and mercury. Note: Ordinance relating to environmentally hazardous substances, SR 814.013 of 1986-06-09 is not longer in force and superseded by SR 814.81 of 2009-02-01 (ChemRRV).	Considered	P
4	Supply cords of portable electrical appliances having a rated current not exceeding 10 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1, SEV 1011 and one of the following dimension sheets: - SEV 6533-2:2009 Plug type 11, L + N, 250V 10A - SEV 6534-2:2009 Plug type 12, L + N + PE, 250V 10A - SEV 6532-2:2009 Plug type 15, 3L + N + PE, 250/400V 10A Supply cords of portable electrical appliances having a rated current not exceeding 16 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1, SEV 1011 and one of the following dimension sheets: - SEV 5933-2:2009 Plug type 21 L + N, 250 V, 16A - SEV 5934-2:2009 Plug type 23 L + N + PE, 250 V, 16A - SEV 5932-2:2009 Plug type 25 3L + N + PE, 250/400V 16A NOTE 16 A plugs are not often used in Swiss domestic installation system. See TRF template regulatory requirements Switzerland on IECEE Website R.R. TRF templates.	See table 8.10	P

USA - Differences

ATTACHMENT TO TEST REPORT IEC 60601-1 NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
US NATIONAL DIFFERENCES - Differences according to US National standard ANSI/AAMI ES60601-1:2005 + A1:2012 + C1:2009 and A2:2010			P
4.8 b	Replacement: where there was no relevant IEC/ISO standard, the relevant US ANSI standard applied	Considered	P
	- when no relevant US ANSI standard existed, the requirements of this standard applied	Considered	P
4.10.2	Replacement: Rated voltage not exceeding 250V dc or single phase ac. or 600V poly-phase ac for ME EQUIPMENT and ME SYSTEMS up to 4kVA	Considered	P
	Rated voltage not exceeding 600 V for all other ME EQUIPMENT and ME SYSTEMS	Considered	P
6.6	Addition: To comply with NFPA 70, X-Ray systems are classified as long time operation (> 5 min) or momentary operation (< 5 sec)	No X-Ray system	N/A
7.2.11	Addition: To comply with NFPA 70, X-Ray systems are marked as long time operation or momentary operation		N/A
7.2.21	New Sub-clause: **Colors of medical gas cylinders**		N/A
	To comply with NFPA 99: Cylinders containing medical gases and their connection points are colored in accordance with the requirements of NFPA 99	No such equipment	N/A
8.2	Addition: All FIXED ME EQUIPMENT & PERMANENTLY INSTALLED ME EQUIPMENT are CLASS I ME EQUIPMENT	Device is class I, installation depended on end use application	P
8.6.1	Addition: To comply with NFPA 99, the enclosure of X-ray ME EQUIPMENT operating over 600 Vac, 850Vdc MAINS VOLTAGE, or containing voltages up to 50 V peak and enclosed in protectively earthed enclosure as well as connections to X-ray tubes and other high voltage components that include high voltage shielded cables are PROTECTIVELY EARTHED.	No such equipment	N/A
	To comply with NFPA 99, non-current carrying conductive parts of X-Ray ME EQUIPMENT likely to become energized are PROTECTIVELY EARTHED		N/A
8.7.3 d	EARTH LEAKAGE CURRENT values are not higher than the stated values		P
	5 mA in NORMAL CONDITION	Considered	P
	10 mA in SINGLE FAULT CONDITION	Considered	P
8.11	Addition prior to the first paragraph: a) To comply with the NEC, add the following requirements to this clause:		P
	Addition: PERMANENTLY CONNECTED ME EQUIPMENT provided with field wiring provision in accordance with NEC	Detachable cord used	N/A

ATTACHMENT TO TEST REPORT IEC 60601-1 NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements			
Clause	Requirement + Test	Result - Remark	Verdict
	Installation of connecting cords between EQUIPMENT parts comply with NEC	No such cords used	N/A
	Cable used as external interconnection between units		N/A
	1) Exposed to abuse: Type SJT, SJTO, SJO, ST, SO, STO, or equivalent, or similar multiple-conductor appliance-wiring material,		N/A
	2) Not exposed to abuse: The cable was as in item 1) above, or		N/A
	i) Type SPT-2, SP-2, or SPE-2, or equivalent		N/A
	ii) Type SVr, SVRO, SVE, or equivalent or similar multiple-conductor appliance wiring material,		N/A
	iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more,		N/A
	- enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more		N/A
	Receptacles provided as part of ME EQUIPMENT and ME SYSTEMS for use in the patient care areas of pediatric wards, rooms, or areas are Listed tamper resistant		N/A
	- or employ a Listed tamper resistant cover in accordance with NEC		N/A
	Addition at the end of the clause: b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, 250 V/20 A “Hospital Grade” mains plug is provided and the POWER SUPPLY CORD is marked		N/A
8.11.3.2	Addition: The flexible cord is a type acceptable for the particular application,	See appended Table 8.10	P
	- and it is acceptable for use at a voltage not less than the rated voltage of the appliance		P
	- and has an ampacity as in NEC, not less than the current rating of the appliance		P
8.11.3.3	Addition: To comply with NFPA 99, for X-Ray ME EQUIPMENT with an attachment plug, the current rating on a hospital grade plug is 2X the maximum input current of the equipment	No x-Ray equipment	N/A

End of Test Report