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Test Report issued under the responsibility of:

Korea Testing Laboratory

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

Report Reference No. ..... :	13-041142-01-1
Date of issue ..... :	2014-04-29
Total number of pages ..... :	174
CB Testing Laboratory ..... :	Korea Testing Laboratory(KTL)
Address ..... :	87, Digital-ro 26-gil, Guro-gu, Seoul 152-718 KOREA, REPUBLIC OF
Applicant's name..... :	Charmcare Co., Ltd.
Address ..... :	(Gasan-Dong , Woolim Lions 2-cha), 714, 2, Gasandigital1-ro, Geumcheon-Gu, Seoul, Korea
Test specification:	
Standard ..... :	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1: 2012
Test procedure..... :	CB Scheme
Non-standard test method..... :	N/A
	IEC60601_1H
Test Report Form Originator ..... :	UL(US)
Master TRF ..... :	Dated 2012-12

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

Test item description ..... :	Pulse Oximeter
Trade Mark..... :	**Charmcare Co., Ltd**
Manufacturer ..... :	Charmcare Co., Ltd.
Model/Type reference ..... :	CX130
Ratings ..... :	External 9Vdc, 1.7 A power adaptor 3.7Vdc Li-ion Battery or 4 x AA Type 1.5 Vdc (6Vdc,)

Testing procedure and testing location:

☒ CB Testing Laboratory:	Korea Testing Laboratory(KTL)
Testing location/ address ....:	87, Digital-ro 26-gil, Guro-gu, Seoul 152-718 KOREA, REPUBLIC OF
☐ Associated CB Test Laboratory:	
Testing location/ address ....:	
Tested by (name + signature) .....:	Park Ho Joon
Approved by (+ signature)...........:	Lee Ho Sung
☐ Testing procedure: TMP	
Tested by (name + signature) .....:	
Approved by (+ signature)............:	
Testing location/ address ....:	
☐ Testing procedure: WMT	
Tested by (name + signature) .....:	
Witnessed by (+ signature) ....:	
Approved by (+ signature)...........:	
Testing location/ address ....:	
☐ Testing procedure: SMT	
Tested by (name + signature) .....:	
Approved by (+ signature)...........:	
Supervised by (+ signature) ....:	
Testing location/ address ....:	

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

1. Photos : 7 pages
2. Test report of IEC 60601-1-6 : 5 pages
3. Test report of IEC 62366 : 11 pages
4. Test report of ISO 80601-2-61 : 41 pages

Summary of testing

Tests performed (name of test and test clause):	Testing location:
	See Page 2.

Summary of compliance with National Differences

List of countries addressed:

☐ The product fulfils the requirements of

IEC 60601-1:2012,

IEC 60601-1-6:2010,

ISO 80601-2-61:2007

(insert standard number and edition and delete the text in parenthesis or delete the whole sentence if not applicable)

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.

TRF No. IEC60601_1H

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	**transportable** / portable / stationary / mobile / fixed / permanently installed / **hand-held**
Device type (component/sub-assembly/ equipment/ system) . :	equipment
Intended use (Including type of patient, application location) .. :	CX130 is intended to measure pulse waveform and heart rate in the finger by lighting a fingertip with combination of infrared LED and photodiode
Mode of operation ..... :	**Continuous** / non-continuous
Supply connection ..... :	**internally powered** /permanently installed / appliance coupler / non-detachable cord
Accessories and detachable parts included ..... :	
Other options include ..... :	
Testing	
Date of receipt of test item(s) ..... :	2013-09-17
Dates tests performed ..... :	2013-09-17 ~ 2014-04-29
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A(N)
- 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:

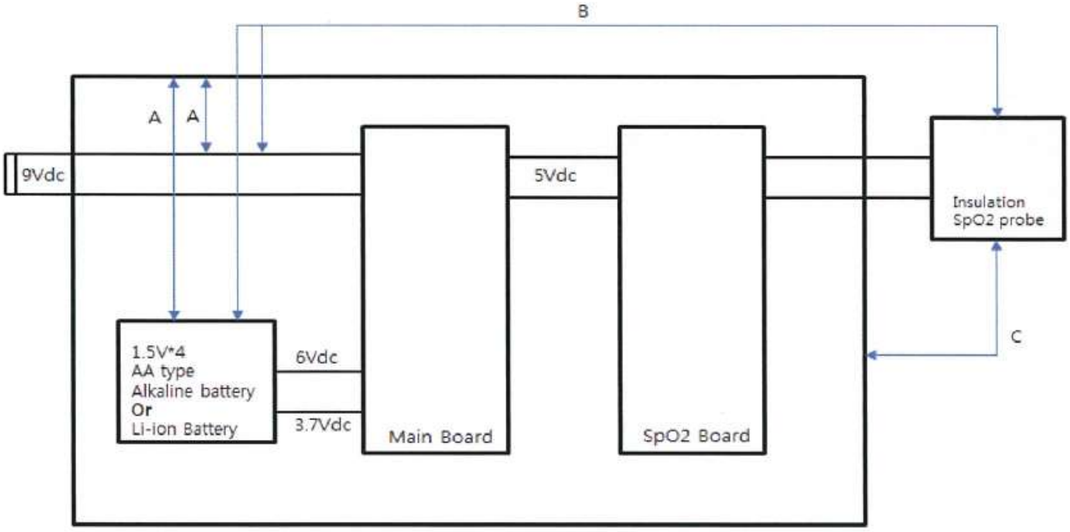
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :

☐ Yes
☒ Not applicable

When differences exist; they shall be identified in the General product information section.
Name and address of factory (ies)............................:   Charmcare Co., Ltd (Gasan-Dong , Woolim Lions 2-cha), 714, 2, Gasandigital1-ro, Geumcheon-Gu, Seoul, Korea
General product information: - Weight : Main 273g - Dimensions : 72(H) x 154(W) x 26(D) mm - Pulse Rate : 30 to 250bpm - % SpO2 : 0 to 100% - External 9Vdc 1.7A power adaptor 3.7Vdc Li-ion Battery or 4 x AA Type 1.5 Vdc (6Vdc,)

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

INSULATION DIAGRAM



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

TABLE: To insulation diagram									P
Pollution degree .... :		2							—
Overvoltage category .... :		2							—
Altitude .... :		< 2,000 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 (IIIb, unless is known)	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			Vrms	Vpk					
A	2 MOOP	IIIb		9	1.0	2.0	>>2.0	>>2.0	
				6	1.0	1.4	>>2.0	>>2.0	
B	2 MOPP	IIIb		9	3.4	1.6	>>3.4	>>1.6	
C	2 MOPP	IIIb		5	3.4	1.6	>>4.0	>>2.5	
	1MOPP		250		4.0	2.5	>>4.0	>>2.5	

<u>INSULATION DIAGRAM CONVENTIONS and GUIDANCE:</u>

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.

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: RM report	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.	The performance of clinical functions has been identified in risk analysis process. - Refer to appended table 4.3	P
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.	refer to clause 201.4.101 of ISO 80601-2-61	P
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated	refer to clause 201.4.101 of ISO 80601-2-61	P
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE.......................................:	See Appended Table 4.3	P
	- RISK CONTROL measures implemented	The risk control measure for essential performance has been implemented in risk control process.	P
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented	The methods to verify the effectiveness of the risk control measures has been implemented in risk control process.	P

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Clause	Requirement + Test	Result - Remark	Verdict
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE...:	5 years Refer to RM report (Document No. : RA05-02)	P
4.5	Alternative means of addressing particular RISKS considered acceptable based on MANUFACTURER'S justification that RESIDUAL RISKS resulting from application of alternative means are comparable to the RESIDUAL RISKS resulting from requirements of this standard...:	See Appended RM Results Table 4.5 No alternative means used	N
	Alternative means based scientific data or clinical opinion or comparative studies..............................:		N
4.6	RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10...............:	See Appended Insulation Diagram Table and RM Results Table 4.6	N
	Assessment identified the APPLIED PART TYPE requirements ....:	No parts that can come into contact with PATIENT but not defined as APPLIED PARTS	N
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2...:	See Appended RM Results Table 4.7	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
	RISK associated with failure of component during EXPECTED SERVICE LIFE of ME EQUIPMENT taken into account to evaluate if a component should be subjected to failure simulation		P
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified...............:		P
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS	See Appended RM Results Table 4.8	N
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following		P
	a) Applicable safety requirements of a relevant IEC or ISO standard		P
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		P

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Clause	Requirement + Test	Result - Remark	Verdict
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK ...:	See appended Table 8.10 & RM Results Table 4.9	N
	COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS selected and evaluated consistent with their conditions of use and reasonable foreseeable misuse during EXPECTED SERVICE LIFE of ME EQUIPMENT by reviewing RISK MANAGEMENT FILE ...:	See Appended RM Results Table 4.9	N
4.10	Power supply		
4.10.1	ME EQUIPMENT is suitable for connection to a SUPPLY MAINS, specified to be connected to a separate power supply, can be powered by an INTERNAL ELECTRICAL POWER SOURCE, or a combination of the three ...:	Certified external 9Vdc power adaptor or 3.7Vdc Li-ion Battery / 4 x AA Type 1.5 Vdc (6Vdc,)	P
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:	Transportable ME equipment	N
	- 250 V for HAND-HELD ME EQUIPMENT (V) ...:		N
	– 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) ...:		N
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS		N
4.11	Power input		P
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10% ...:	See appended Table 4.11	P
	– Measurements on ME EQUIPMENT or a ME SYSTEM marked with one or more RATED voltage ranges made at both upper and lower limits of the range.:	See appended Table 4.11	P
	Measurements made at a voltage equal to the mean value of the range when each marking of RATED input was related to the mean value of relevant voltage range		P
	Power input, expressed in volt-amperes, measured with a volt-ampere meter or calculated as the product of steady state current (measured as described above) and supply voltage ...:	See appended Table 4.11	P

5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		**P**
5.1	TYPE TESTS determined in consideration of Clause 4, in particular 4.2		N

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Clause	Requirement + Test	Result - Remark	Verdict
	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods ....:	See Appended RM Results Table 5.1	N
	RISK MANAGEMENT FILE identified combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION.		N
	- Testing determined BASIC SAFETY and ESSENTIAL PERFORMANCE were maintained.		P
5.2	TYPE TESTS conducted on one representative sample under investigation; multiple samples used simultaneously when validity of results was not significantly affected...:	One sample used for the test	P
5.3	a) Tests conducted within the environmental conditions specified in technical description		P
	Temperature (°C), Relative Humidity (%) ....:	5-35 °C, 5-95 %	—
	Atmospheric Pressure (kPa).................................:	80-106 kPa	—
	b) ME EQUIPMENT shielded from other influences that might affect the validity of tests		P
	c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained ....:	Temperature result is compensated with ambient Temp. for use in IFU.	P
5.4	a) ME EQUIPMENT tested under least favourable working conditions specified in instructions for use ....:		P
	b) ME EQUIPMENT with adjustable or controlled operating values by anyone other than SERVICE PERSONNEL adjusted to values least favourable for the relevant test per instructions for use		P
	c) When test results influenced by inlet pressure and flow or chemical composition of a cooling liquid, tests performed within the limits in technical description ....:	No cooling liquid used	N
	d) Potable water used for cooling		N
5.5	a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V) ....:		P
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)...:		N
	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 .... :	Certified external 9Vdc power adaptor or 3.7Vdc Li-ion Battery / 4 x AA Type 1.5 Vdc (6Vdc,)	P

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Clause	Requirement + Test	Result - Remark	Verdict
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered .... :		P
	e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions .... :		P
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use		N
5.6	When failure occurred or probability of future failure detected during sequence of tests, per agreement with manufacturer, all tests affecting results conducted on a new sample		P
	Alternatively, upon repair and modification of the sample, only the relevant tests conducted		P
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 .... :		P
	Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS were opened and detached		P
	ME EQUIPMENT heated to a temperature between T and T + 4℃ for at least 4 h and placed in a humidity chamber (relative humidity 93%±3%) and an ambient within 2 ℃ of T in the range of + 20 ℃ to + 30 ℃ for 48 h for units rated IPX0	T = 25℃	P
	- For units rated higher than IPX0 test time extended to 168 h. .... :	IPX1	P
5.8	Unless stated otherwise, tests in this standard sequenced as in Annex B to prevent influencing results of any subsequent test		P
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		P
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS .... :	See clause 4.6 Remark Applied parts : Type BF - SpO2 sensor - SpO2 cable	P
5.9.2	ACCESSIBLE PARTS		P
5.9.2.1	Accessibility, when necessary, determined using standard test finger of Fig 6 applied in a bent or straight position	See Appended Table 5.9.2 Enclosure of equipment	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Openings preventing entry of test finger of Fig. 6 mechanically tested with a straight un-jointed test finger of the same dimensions with a force of 30 N		P
	When the straight un-jointed test finger entered, test with the standard test finger (Fig 6) was repeated, if necessary, by pushing the finger through the opening		N
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s		P
	All additional parts that became accessible checked using standard test finger and by inspection		P
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS .... :		N
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, etc. required use of a TOOL ..... :		N

6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		**P**
6.2	CLASS I ME EQUIPMENT, externally powered		N
	CLASS II ME EQUIPMENT, externally powered		P
	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		N
	TYPE BF APPLIED PART		P
	TYPE CF APPLIED PART		N
	DEFIBRILLATION-PROOF APPLIED PARTS		N
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter (IPN_1N_2) as per IEC 60529 .... :	IP_ See RM Results Table 11.6.5. IPX1	P
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use .... :	No parts intended to be sterilized	N
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		N
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION .... :	Continuous operation	P

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Clause	Requirement + Test	Result - Remark	Verdict
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		P
	a) After tests, adhesive labels didn't loosen up or curl up at edges and markings complied with requirements in Clause 7.1.2 ....:	See appended Tables 7.1.3 and 8.10	P
	b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after marking durability test ....:	See appended Tables 7.1.3 and 8.10	P
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		P
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 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 ....:	All marking are described in Instructions for use	P
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT		P
	A material, component, ACCESSORY, or ME EQUIPMENT intended for a single use, or its packaging marked "Single Use Only", "Do Not Reuse" or with symbol 28 of Table D.1 (ISO 7000-1051, DB:2004-01) ....:	No disposable MEE	N
7.2.2	ME EQUIPMENT marked with:		P
	– the name or trademark and contact information of the MANUFACTURER	Charmcare Co., Ltd	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		N
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	See Appended RM Results Table 7.2.2	P
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and	Charmcare	P
	– a MODEL OR TYPE REFERENCE	RapidSense ™	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Software forming part of a PEMS identified with a unique identifier, such as revision level or date of release/issue, and identification are available to designated persons ....:	Version is displayed on a screen.	P
7.2.3	Symbol 11 on Table D.1 (ISO 7000-1641, DB: 2004-01) used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS		N
	Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted		P
7.2.4	ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and ....:	Accessories : SpO2 sensor & cable	P
	- with a MODEL or TYPE REFERENCE	RapidSense ™	P
	– a serial number or lot or batch identifier	serial number	P
	– the date of manufacture or use by date		N
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		P
7.2.5	ME EQUIPMENT intended to receive power from other electrical equipment in an ME SYSTEM and compliance with the requirements of this standard is dependent on that other equipment, one of the following is provided:		P
	- the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or		N
	–safety sign ISO 7010-M002 (see Table D.2, safety sign 10) adjacent to the relevant connection point and listing of the required details in the instructions for use; or		P
	– Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use.		N
7.2.6	Connection to the Supply Mains		P
	Except for PERMANENTLY INSTALLED ME EQUIPMENT, marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point	Certified external 9Vdc power adaptor or 3.7Vdc Li-ion Battery / 4 x AA Type 1.5 Vdc (6Vdc,)	N
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT, preferably, adjacent to SUPPLY MAINS connection	Not permanently installed equipment	N
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V) ....:	9Vdc	P
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V) ....:		N

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Clause	Requirement + Test	Result - Remark	Verdict
	– Nature of supply (e.g., No. of phases, except single-phase) and type of current...........................:		N
	Symbols 1-5, Table D.1 (symbols of IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033, all 2002-10) used, optionally, for same parameters ....:		N
	– RATED supply frequency or RATED frequency range in hertz...:	DC	P
	– Symbol 9 of Table D.1 (symbol IEC 60417-5172, 2003-02) used for CLASS II ME EQUIPMENT................:		P
7.2.7	RATED input in amps or volt-amps, (A, VA)...........:	9Vdc, 1.7A	P
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W)....................:		N
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W) ....:		P
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W) ....:		N
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA) ....:		N
	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
7.2.8	Output connectors		N
7.2.8.1	See 16.9.2.1 b) for MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT		N
7.2.8.2	Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment		N
	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........:	IPX1	P
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols as follows (not applied to parts identified according to 4.6) ....:	BF type applied part	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	TYPE B APPLIED PARTS with symbol 19 of Table D.1 (IEC 60417-5840, 2002-10), not applied in such a way as to give the impression of being inscribed within a square in order to distinguish it from symbol IEC 60417-5333 ....:		N
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 (IEC 60417-5333, 2002-10)....................................:		P
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 (IEC 60417-5335, 2002-10).....................................:	BF type applied part	N
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 (IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336, all 2002-10) ....:	No defibrillation-proof applied part	N
	Proper symbol marked adjacent to or on connector for APPLIED PART, except marked on APPLIED PART when there is no connector, or connector used for more than one APPLIED PART and different APPLIED PARTS with different classifications...........................:	See above	P
	Safety sign 2 of Table D.2 (ISO 7010-W001) placed near relevant outlet when protection against effect of discharge of a cardiac defibrillator is partly in the PATIENT cable ....:	See above	N
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use ....:	See above	N
7.2.11	ME EQUIPMENT not marked to the contrary assumed to be 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
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder		N
	Fuse type...:		—
	Voltage (V) and Current (A) rating ....:		—
	Operating speed (s) and Breaking capacity..........:		—
7.2.13	A safety sign CLEARLY LEGIBLE and visible after INSTALLATION in NORMAL USE applied to a prominent location of EQUIPMENT that produce physiological effects capable of causing HARM to PATIENT or OPERATOR not obvious to OPERATOR ....:		P
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use ....:	See Appended RM Results Table 7.2.13	P

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Clause	Requirement + Test	Result - Remark	Verdict
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1 (symbol IEC 60417-5036, 2002-10)	No high voltage terminal used	N
7.2.15	Requirements for cooling provisions marked (e.g., supply of water or air) ....:	No such a part used	N
7.2.16	ME EQUIPMENT with limited mechanical stability		N
7.2.17	Packaging marked with special handling instructions for transport and/or storage ....:		P
	Permissible environmental conditions for transport and storage marked on outside of packaging........:	Temperature : -20℃ ~ +70℃ Humidity : 10% ~ 100%	P
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK.......................:	No such a safety sign used	N
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization	No sterile equipment	N
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and ....:	No such a part used	N
	- where required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE, the RATED flow rate also marked		N
7.2.19	Symbol 7 of Table D.1 (IEC 60417-5017, 2002-10) marked on FUNCTIONAL EARTH TERMINAL..................:	No functional earth terminal used	N
7.2.20	Protective means, required to be removed to use a particular function of ME EQUIPMENT with alternate applications, marked to indicate the necessity for replacement when the function is no longer needed ....:	No such means used	N
	No marking applied when an interlock provided		N
7.2.21	MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms..........:	Transportable MEE	N
	- The marking is obvious that it applies to the whole of the MOBILE ME EQUIPMENT when loaded with its SAFE WORKING LOAD and		N
	- is separate and distinct from any markings related to maximum bin, shelf or drawer loading requirements.		N
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		P
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W) ....:	No heating elements and lamp used	N

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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
7.3.2	Symbol 24 of Table D.1 (symbol IEC 60417-5036, 2002-10), or safety sign 3 of Table D.2 used to mark presence of HIGH VOLTAGE parts ....:	No high voltage parts used	N
7.3.3	Type of battery and mode of insertion when applicable is marked ....:	4 x AA Alkaline batteries, 3.7Vdc Li-ion Rechargeable battery	P
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL..:	4 x AA Alkaline batteries are changeable by operator and Li-ion rechargeable battery is only replaceable by a manufacturer.	N
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement by inadequately trained personnel would result in an unacceptable RISK (e.g., excessive temperatures, fire or explosion)...:	CX130 User Manual, 1.3.6 Battery Replacement	P
	An identifying marking also provided referring to instructions in ACCOMPANYING DOCUMENTS ....:	See Appended RM Results Table 7.3.3	P
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL		P
	Identified by specification adjacent to the component, or		P
	by reference to ACCOMPANYING DOCUMENTS		P
	Voltage (V) and Current (A) rating ....:	5A x 2	—
	Operating speed(s), size & breaking capacity ......:		—
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1 (IEC 60417-5019, 2002-10), except for the PROTECTIVE EARTH TERMINAL in an APPLIANCE INLET according to IEC 60320-1		N
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		N
7.3.6	Symbol 7 of Table D.1 (IEC 60417-5017, 2002 -10) marked on FUNCTIONAL EARTH TERMINALS	No functional earth terminal used	N
7.3.7	Terminals for supply conductors marked adjacent to terminals, except when no unacceptable RISK would result when interchanging connections ....:		N
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings		N

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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 (Code in IEC 60445)		N
	Marking for connection to a 3-phase supply, if necessary, complies with IEC 60445		N
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		N
7.3.8	"For supply connections, use wiring materials suitable for at least X ℃" (where X > than max temperature measured in terminal box or wiring compartment under NORMAL USE), or equivalent, marked at the point of supply connections		N
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		N
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 (IEC 60417-5007, 2002-10, and IEC 60417-5008, 2002-10), or		P
	– indicated by an adjacent indicator light, or		P
	– indicated by other unambiguous means		P
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1 (IEC 60417-5010 2002-10), and		N
	– status indicated by adjacent indicator light		N
	– status indicated by other unambiguous means		N
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 (symbol 60417-5011 2002-10), or		N
	– status indicated by adjacent indicator light		N
	– status indicated by other unambiguous means		N
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means		N
	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 ....:	See Appended RM Results Table 7.4.2 Only on/off function switch is provided.	N
	– or an indication of direction in which magnitude of the function changes	Only on/off function is provided.	N

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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 (2002-10) (Table D.1, Symbol 29).		P
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units	%, bpm, min	P
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units		P
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3 ....:	See Appended Tables 7.1.2 and 7.1.3.	P
7.5	Safety signs		P
	Safety sign with established meaning used.		P
	Markings used to convey a warning, prohibition or mandatory action mitigating a RISK not obvious to OPERATOR are safety signs from ISO 7010 ....:	See Appended RM Results Table 7.5	P
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT	see attached marking plate	P
	Specified colours in ISO 3864-1 used for safety signs ....:	warning sign (yellow used) mandatory sign (blue used)	P
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)	user manual 1.3.11 Description of product & Label symbols - Refer to instruction manual	P
	Safety signs including any supplementary text or symbols described in instructions for use	user manual 1.3.11 Description of product & Label symbols	P
	- and in a language acceptable to the intended OPERATOR	English	P
7.6	Symbols		P
7.6.1	Meanings of symbols used for marking described in instructions for use ....:	See Appended Instruction for Use.	P
7.6.2	Symbols required by this standard conform to IEC or ISO publication referenced		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		N
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation		N

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Clause	Requirement + Test	Result - Remark	Verdict
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations		N
7.7.3	Green and yellow insulation identify only following conductors:		N
	– PROTECTIVE EARTH CONDUCTORS		N
	– conductors specified in 7.7.2		N
	– POTENTIAL EQUALIZATION CONDUCTORS		N
	– FUNCTIONAL EARTH CONDUCTORS		N
7.7.4	Neutral conductors of POWER SUPPLY CORDS are "light blue" specified in IEC 60227-1 or IEC 60245-1		N
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1		N
7.8	Indicator lights and controls		P
7.8.1	Red indicator lights mean: Warning (i.e., immediate response by OPERATOR required)	Refer to alarm specification in IFU	P
	Yellow indicator lights mean: Caution (i.e., prompt response by OPERATOR required)		P
	Green indicator lights mean: Ready for use		P
	Other colours, if used: Meaning other than red, yellow, or green (colour, meaning)........................:		N
7.8.2	Red used only for emergency control	High priority alarm	P
7.9	ACCOMPANYING DOCUMENTS		P
7.9.1	ME EQUIPMENT accompanied by documents containing at least instructions for use, and a technical description		P
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		P
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to ....:	Charmcare Co., Ltd	P
	– MODEL or TYPE REFERENCE ....:	CX130	P
	When ACCOMPANYING DOCUMENTS provided electronically (e.g., on CD ROM), USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT (for emergency operation)		N
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use		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:	Refer to IFU 2.1	P
	– frequently used functions,	Refer to IFU 2.1	P
	– known contraindication(s) to use of ME EQUIPMENT		P
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient		N
	– name or trademark and address of the MANUFACTURER	Charmcare Co., Ltd	P
	– MODEL OR TYPE REFERENCE	CX130	P
	Instruction for use included the following when the PATIENT is an intended OPERATOR:	Patient is not an intended operator	N
	– the PATIENT is an intended OPERATOR		N
	– warning against servicing and maintenance while the ME EQUIPMENT is in use		N
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and		N
	–maintenance the PATIENT can perform		P
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	1.3.11 Description of product & Label symbols	P
	Instructions for use are in a language acceptable to the intended operator	English	P
7.9.2.2	Instructions for use include all warning and safety notices		P
	Warning statement for CLASS I ME EQUIPMENT indicating: "WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth"	Certified external 9Vdc power adaptor or 3.7Vdc Li-ion Battery / 4 x AA Type 1.5 Vdc (6Vdc,)	N
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	User Manual part 5 measuring the SpO2 - measuring SpO2 on a patient undergoing an MRI may result in severe buns for the patient	N

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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	- The measured values of the monitoring system can be affected by patient conditions, excessive patient movement, sensors, and nearby electromagnetic external conditions - Anyone who connects equipment to the data interface is configuring a medical system and, therefore, is responsible for ensuring the system complies with the requirements for medical electrical system IEC/EN standard 60601-1 and the electromagnetic compatibility IEC/EN standard 60601-1-2:2007	P
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET indicating, "connecting electrical equipment to MSO effectively leads to creating an ME SYSTEM, and can result in a reduced level of safety"	Not provided an integral multiple socket-outlet	N
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS		P
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply indicating "power supply is specified as a part of ME EQUIPMENT or combination is specified as a ME SYSTEM"		N
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	User manual part 4 how to use product - power usage The battery usage warranty period is six months. Following this period, battery life can diminish significantly	P
	Warning to remove primary batteries when ME EQUIPMENT is not likely to be used for some time when leakage from battery would result in an unacceptable RISK ....:	See Appended RM Results Table 7.9.2.4 User Manual 1.3.6 battery replacement	N
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided ....:	User Manual part 10 product specifications - power	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 Appended RM Results Table 7.9.2.4	N

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Clause	Requirement + Test	Result - Remark	Verdict
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	- User Manual 2.1 product description, 3 how to use product, part 10 product specifications	P
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to when such exposure can constitute an unacceptable RISK	No hazardous materials and ingredients exposed to patient or operator.	N
	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		N
	APPLIED PARTS specified	SpO2 probe and cable	P
7.9.2.6	Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation		N
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device when an APPLIANCE COUPLER or MAINS PLUG or other separable plug is used as isolation means to meet 8.11.1 a)	User manual 1.3.8 Electrical safety	P
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation including initial control settings, and connection to or positioning of PATIENT prior to use of ME EQUIPMENT, its parts, or ACCESSORIES	User manual 1.3.8 electrical safety, part 5 measuring the SpO2 - attaching the SpO2 probe	P
7.9.2.9	Information provided to operate ME EQUIPMENT including explanation of controls, displays and signals, sequence of operation, connection of detachable parts or ACCESSORIES, replacement of material consumed during operation	User Manual part 4 how to use product - the screen, button usage (shortcut button usage), part 5 measuring the SpO2	P
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	User Manual 1.3.11 Description of product & Label symbols	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	User Manual part 9 basic troubleshooting	P
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	power button	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	User manual 1.3.9 maintenance and cleaning	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	No such components	N
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	User manual 1.3.9 maintenance and cleaning	P
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	User manual 1.3.8 electrical safety, part 3 how to use product - post-use storage and management	P
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	User manual 1.3.9 maintenance and cleaning	P
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	User Manual 1.3.6 battery replacement	P
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	User Manual 2.2 list of parts	P
	Other equipment providing power to ME SYSTEM sufficiently described (e.g. part number, RATED VOLTAGE, max or min power, protection class, intermittent or continuous duty)		N
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 ....:	 & user manual 1.3.6 battery replacement	P
7.9.2.16	Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)	Refer to 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 emitting radiation	N
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		N
	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
7.9.2.19	The instructions for use contain a unique version identifier .... :	Refer to IFU	P
7.9.3	Technical description		P

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Clause	Requirement + Test	Result - Remark	Verdict
7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use including the following:	CX130 User Manual	P
	– information as in clause 7.2		P
	– permissible environmental conditions of use including conditions for transport and storage	user manual part 10 product specification - environment	P
	– all characteristics of ME EQUIPMENT including range(s), accuracy, and precision of displayed values or where they can be found	user manual part 10 product specification	P
	– special installation requirements such as maximum permissible apparent impedance of SUPPLY MAINS		N
	– permissible range of values of inlet pressure and flow, and chemical composition of cooling liquid used for cooling		N
	– a description of means of isolating ME EQUIPMENT from SUPPLY MAINS, when such means not in ME EQUIPMENT		N
	– a description of means for checking oil level in partially sealed oil filled ME EQUIPMENT or its parts when applicable		N
	– a warning statement addressing HAZARDS that can result from unauthorized modification of ME EQUIPMENT according to following examples	User manual 1.3.2 Warning	P
	"WARNING: No modification of this equipment is allowed"		P
	"WARNING: Do not modify this equipment without authorization of the manufacturer"		N
	"WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment"		N
	- information pertaining to ESSENTIAL PERFORMANCE and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency		P
	Technical description separable from instructions for use contains required information, as follows		N
	– information as in clause 7.2		N
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT		N

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Clause	Requirement + Test	Result - Remark	Verdict
	– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and		N
	a unique version identifier ....:		N
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description		N
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, when type and rating of fuses are not apparent from information on RATED current and mode of operation of ME EQUIPMENT ....:		N
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and if so, instructions for correct connection and anchoring to ensure compliance with 8.11.3		N
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	Only manufacturer is available.	N
	– 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		P
7.9.3.3	Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair		P
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description		N

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
	NORMAL CONDITION considered as simultaneous occurrence of situations identified in 8.1a)		P
	SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b) ....:	See Appended RM Results Tables 8.1b	P
	ACCESSIBLE PARTS determined according to 5.9		P
	LEAKAGE CURRENTS measured according to 8.7		P
8.2	Requirements related to power sources		P

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Clause	Requirement + Test	Result - Remark	Verdict
8.2.1	Connection to a separate power source		N
	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		N
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		N
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		N
8.2.2	Connection to an external d.c. power source		P
	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	9Vdc	P
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE		P
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset		P
8.3	Classification of APPLIED PARTS		P
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF		N
	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
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	BF type applied part	P
8.4	Limitation of voltage, current or energy		P
8.4.1	PATIENT CONNECTIONS intended to deliver Current		N
	Limits in 8.4.2 not applied to currents intended to flow through body of PATIENT to produce a physiological effect during NORMAL USE		N
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 and PATIENT AUXILIARY CURRENT per Tables 3 and 4 when measured according to Clause 8.7.4 ....:	See appended Table 8.7	P

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Clause	Requirement + Test	Result - Remark	Verdict
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT in Cl. 8.7.3 c) when measured per Clause 8.7.4 (mA)...:	See appended Table 8.7	P
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed		P
	– accessible contacts of connectors		P
	– contacts of fuseholders accessible during replacement of fuse		N
	– contacts of lampholders accessible after removal of lamp		N
	– parts inside an ACCESS COVER that can be opened without a TOOL, or where a TOOL is needed but the instructions for use instruct an OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER	Battery compartment	P
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.) ....:	See appended Table 8.4.2	P
	Limit of 60 V d.c. applied with no more than 10% peak-to-peak ripple, and when ripple larger than specified value, 42.4 V peak limit applied (V d.c.):	See appended Table 8.4.2	P
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J)........................:	See appended Table 8.4.2	N
	LEAKAGE CURRENT limits referred to in 8.4.2 b) applied when voltages higher than limits in 8.4.2 c) were present (mA)..:	See appended Table 8.4.2	N
	d) Voltage and energy limits specified in c) above also applied to the following:		N
	– internal parts, other than contacts of plugs, connectors and socket-outlets, touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	No access internal parts touchable by test pin inserted through an opening in an ENCLOSURE	N
	– 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 the RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL	No internal parts touchable by a metal test rod inserted through any opening on top of ENCLOSURE	N
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		N

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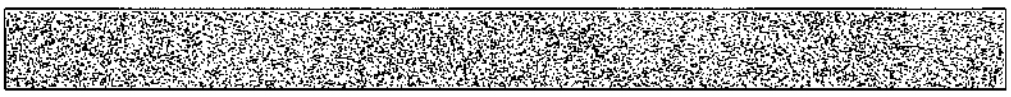
Clause	Requirement + Test	Result - Remark	Verdict
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N		N
	Test repeated with a TOOL specified in instructions for use		N
	Test rod freely and vertically suspended through openings on top of ENCLOSURE		N
	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 TOOL is required when it is possible to prevent the devices from operating		N
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	N
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC .....:	See appended Table 8.4.3	N
8.4.4	Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC .....:	See appended Table 8.4.4	N
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		N
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 (IEC 60417-5036, 2002-10), and manual discharging device specified in technical description.....:		N
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
	Each MEANS OF PROTECTION categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking into account Clause 4.6, and flow chart in Fig A.12		P



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Clause	Requirement + Test	Result - Remark	Verdict
	Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION		P
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		P
	Insulation, CREEPAGE, CLEARANCES, components or earth connections not complying with 8.5.1.2 and 8.5.1.3 not considered as MEANS OF PROTECTION, and failure of these parts regarded as NORMAL CONDITION		P
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		P
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of Clause 8.8 at test voltage of Table 6		P
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		P
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6		N
	A Y (Y1 or Y2) capacitor complying with IEC 60384-14 considered one MEANS OF PATIENT PROTECTION .... :	See Appended Tables 8.8.3 and 8.10	N
	Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c. .... :	See Appended Tables 8.8.3 and 8.10	N
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (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 of 8.8 at test voltage of Table 6; or		P
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N
	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		N
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6		N

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Clause	Requirement + Test	Result - Remark	Verdict
	– or with requirements and tests of IEC 60950-1 for protective earthing .....:	See Attachment #	N
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION .....:	See Appended Tables 8.8.3 and 8.10	N
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION .....:	See Appended Tables 8.8.3 and 8.10	N
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (μF).....:		—
	Points at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION		N
	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 MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION.....:		N
8.5.2	Separation of PATIENT CONNECTIONS		P
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to maximum MAINS VOLTAGE and complied with limit for PATIENT LEAKAGE CURRENT at 110 % of max. MAINS VOLTAGE .....:	See appended Table 8.7.	P
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		P
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		N
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS .....:		N
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART		P
	LEAKAGE CURRENT tests conducted per 8.7.4 .....:	See appended Table 8.7	P
	Dielectric strength test conducted per 8.8.3.....:	See appended Table 8.8.3	P
	CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		P

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Clause	Requirement + Test	Result - Remark	Verdict
	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
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 ......:	See Appended RM Results Table 8.5.2.2 BF Applied part	N
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and		N
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low		N
	LEAKAGE CURRENT tests conducted per 8.7.4 ....:	See appended Table 8.7	N
	Dielectric strength test conducted per 8.8.3..........:	See appended Table 8.8.3	N
	Relevant CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable		N
	The RISK MANAGEMENT FILE reviewed		N
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
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT ....:	See Appended RM Results Table 8.5.2.3	N
	– 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
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm		N
	– 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
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N, except when RISK MANAGEMENT PROCESS indicated no unacceptable RISK existed from contact with objects other than a mains socket or a flat surface:	See Appended RM Results Table 8.5.2.3	N
8.5.3	MAXIMUM MAINS VOLTAGE		P

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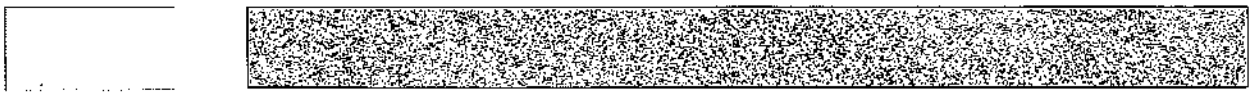
Clause	Requirement + Test	Result - Remark	Verdict
	– MAXIMUM MAINS VOLTAGE determined to be the highest RATED supply voltage for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT, as well as INTERNALLY POWERED ME EQUIPMENT with a means of connection to a SUPPLY MAINS (V) .....:	external 9Vdc power adaptor or 3.7Vdc Li-ion Battery / 4 x AA Type 1.5 Vdc (6Vdc,)	P
	When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V		P
	– MAXIMUM MAINS VOLTAGE was the highest RATED phase to neutral supply voltage for poly-phase ME EQUIPMENT (V).....:		N
	– for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V	4xAA1.5V or 3.7Vdc	P
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) .....:	external 9Vdc power adaptor or 3.7Vdc Li-ion Battery / 4 x AA Type 1.5 Vdc (6Vdc,)	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
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V).....:	See Insulation Diagram and Insulation Table	P
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth		P
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V).....:		P
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages		N
	– 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).....:		N
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS		N
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety, but not separate functions of same APPLIED PART	Type BF applied part	N



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Clause	Requirement + Test	Result - Remark	Verdict
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		N
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ....:	See Appended Table 8.5.5.1a	N
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS.............:	See Appended Table 8.5.5.1b	N
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load to at least 90% of energy delivered to this load with ME EQUIPMENT disconnected ....:	See Appended Table 8.5.5.2	N
8.6	Protective and functional earthing and potential equalization of ME EQUIPMENT		N
8.6.1	Requirements of 8.6.2 to 8.6.8 applied		N
	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		N
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 ....:		N
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL		N
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside ....:		N
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		N
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		N
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part, except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE :	See Appended RM Results Table 8.6.3	N
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop ....:	See appended Table 8.6.4	N

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits ..... :	See appended Table 8.6.4 & Clause 8.7	N
8.6.5	Surface coatings		P
	Poorly conducting surface coatings on conductive elements removed at the point of contact		P
	Coating not removed when requirements for impedance and current-carrying capacity met		N
8.6.6	Plugs and sockets		N
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections		N
	- applied also where interchangeable parts are PROTECTIVELY EARTHED		N
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR		N
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE	Not use potential equalization conductor	N
	–accidental disconnection avoided in NORMAL USE		N
	– Terminal allows conductor to be detached without a TOOL		N
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		N
	– Terminal marked with symbol 8 of Table D.1		N
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		N
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		N
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION		N
8.6.9	Class II ME EQUIPMENT		P
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow		N

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Clause	Requirement + Test	Result - Remark	Verdict
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.		N
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS		P
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		P
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3.....:	See appended Tables 8.7	P
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7 ....:	See appended Tables 8.7	P
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		P
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		N
	– 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		N
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		P
8.7.3	Allowable Values		P
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b.......................:	See appended Table 8.7	P
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz..............................:	See appended Table 8.7	P
	c) TOUCH CURRENT did not exceed 100 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	N

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Clause	Requirement + Test	Result - Remark	Verdict
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 ....:	See appended Table 8.7	N
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device ....:	See appended Table 8.7	N
	f) LEAKAGE CURRENTS that can flow in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION .:	See appended Table 8.7	N
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements...:	See appended Table 8.7	P
8.8	Insulation		P
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing		P
	Insulation exempted from test (complies with clause 4.8)		N
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		N
8.8.2	Distance through solid insulation or use of thin sheet material		P
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		P
	a) 0.4 mm, min, distance through insulation, or		N
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		P
	– at least two layers of material, each passed the appropriate dielectric strength test........................ :	See appended Table 8.8.3	N
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test........................ :	See appended Table 8.8.3	P
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		P
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		P

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Clause	Requirement + Test	Result - Remark	Verdict
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		P
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		N
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		N
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L		N
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		N
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		N
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		N
	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
	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
	Finished component complied with routine dielectric strength tests of 8.8.3 ....:	See appended Table 8.8.3	N
	Tests of Annex L not repeated since material data sheets confirm compliance...................................:	See Table 8.10 and Material Information Attachment	N
8.8.3	Dielectric Strength		P
	Solid insulating materials with a safety function withstood dielectric strength test voltages ....:	See appended Table 8.8.3	P
8.8.4	Insulation other than wire insulation		P
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		P
	ME EQUIPMENT and design documentation examined...:		P
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests ....:	See Appended RM Results Table 8.8.4.1	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat ....:	See Attachment table 8.10	N
	Tests conducted in absence of satisfactory evidence for resistance to heat ....:		N
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus ....:	See Table 8.8.4.1	P
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 ℃ ± 2 °C or ambient indicated in technical description ±2℃ plus temperature rise determined during test of 11.1 of relevant part, if higher (℃) ....:	See Table 8.8.4.1	N
	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
8.8.4.2	Resistance to environmental stress		P
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9		P
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION		N
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION		N
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples		N
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 ℃ ± 2 ℃ for 96h, and afterwards, left at room temperature for at least 16h		N
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		P
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are ≥ to values in Tables 12 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15		P

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Clause	Requirement + Test	Result - Remark	Verdict
	- Insulation between parts of opposite polarity of the MAINS PART on the supply mains side of any mains fuse or OVER-CURRENT RELEASE, one MEANS OF OPERATOR PROTECTION are ≥ to values in Table 13, Table 14 and Table 16		P
8.9.1.2	Tables 12 to 16 (inclusive) not applied to CREEPAGE and CLEARANCES forming MEANS OF OPERATOR PROTECTION per IEC 60950-1 for INSULATION CO-ORDINATION and used under conditions compliance was tested		N
8.9.1.3	Specified min CLEARANCE applied as min CREEPAGE for CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics		N
8.9.1.4	When min CREEPAGE derived from Tables 12 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE		N
8.9.1.5	ME EQUIPMENT RATED to operate at an altitude of 2000 m		P
	ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m) ....:	< 2,000 m	P
	Operating altitude corresponding to actual air pressure for ME EQUIPMENT intended for pressurized environments (e.g., aircraft) used to determine multiplication factor from Table 8, and AIR CLEARANCE was multiplied by this factor		N
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE		N
8.9.1.6	When WORKING VOLTAGE was between those in Tables 12 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows:		N
	– CREEPAGE DISTANCES determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ....:	See Insulation Diagram and Table	N
	– CLEARANCES for PEAK WORKING VOLTAGES above 2800 V peak or d.c. determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ....:	See Insulation Diagram and Table	N
	– for AIR CLEARANCES corresponding to PEAK WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied		N
8.9.1.7	Material groups classified in accordance with Table 9 (Material Group) ....:	See Insulation Diagram/Table.	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112.......................................:	See attached test data	N
	Material of unknown group considered IIIb	IIIb	P
8.9.1.8	– Pollution degree 1: Micro-environment sealed to exclude dust and moisture		N
	– Pollution degree 2: Micro-environment with non-conductive pollution, except occasional conductivity caused by condensation		P
	– Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation		N
	– Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions		N
	Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION		N
	Where insulation between MAINS PART and earth might be compromised, measures such as maintenance ensure that micro-environment is mitigated to a lower pollution degree		N
	Means employed according to Annex M to reduce the pollution degree.............................:		N
8.9.1.9	Overvoltage category classification; value of MAINS TRANSIENT VOLTAGE determined from overvoltage category per IEC60664-1 and NOMINAL a.c. MAINS VOLTAGE using Table 10		N
	V_{MT} Peak (V) ....:		—
	V_{MN} r.m.s (V) ....:		—
8.9.1.10	AIR CLEARANCE for MAINS PARTS (operating on RATED MAINS VOLTAGES up to 300 V) were values for r.m.s. or d.c. RATED MAINS VOLTAGE in Table 13 plus additional CLEARANCE in Table 14 for PEAK WORKING VOLTAGE		N
8.9.1.11	SUPPLY MAINS overvoltage category II applied according to IEC 60664-1		P
	For ME EQUIPMENT intended for overvoltage category III, Tables 13 to 15 (inclusive) not used for clearance, instead values in the next MAINS TRANSIENT VOLTAGE column upwards used		N
	When PATIENT protection (Table 12) is required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, guidance provided on values required in the rationale for Cl. 8.9 used		N

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.1.12	A SECONDARY CIRCUIT derived from a SUPPLY MAINS, normally, considered to be overvoltage category I according to IEC 60664-1 when the MAINS PART is overvoltage category II (Table 15)		P
	Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT		N
	Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS		P
	Table 15 applied when SECONDARY CIRCUIT was separated from MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in SECONDARY CIRCUIT were below the levels expected for overvoltage category I		P
	Table 15 column for circuits not subject to transient over-voltages applied to:		N
	– d.c. SECONDARY CIRCUITS reliably connected to earth and have capacitive filtering limiting peak-to-peak ripple to 10 % of d.c. voltage, and		N
	– circuits in INTERNALLY POWERED ME EQUIPMENT		N
8.9.1.13	For PEAK WORKING VOLTAGES above 1400 V peak or d.c. Table 15 not applied since all the following conditions were met:		N
	– CLEARANCE was at least 5 mm		N
	– insulation complied with dielectric strength test of 8.8.3 using an a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, or		N
	– a d.c. test voltage equal to peak value of a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, and		N
	– CLEARANCE path was partly or entirely through air or along the surface of an insulating material of material group I		N
	Dielectric strength test conducted only across part(s) of the path that are through air when CLEARANCE path was also partly along surface of a non- group I material		N
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION obtained by doubling values in Table 16 for one MEANS OF OPERATOR PROTECTION		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		N

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION described in 13.1 for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied...:	See appended Table 8.9.2	N
	b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths		P
	c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION is such that the relevant parts are rigid and located by moulding, or there is no reduction of a distance below specified value by deformation or movement of parts		P
	Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE		N
8.9.3	Spaces filled by insulating compound		N
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound were such that CLEARANCES and CREEPAGE DISTANCES don't exist		N
	Thermal cycling, humidity preconditioning, and dielectric strength tests in 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4 conducted		N
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 (clause 8.8.3), test voltage multiplied by 1.6 ....:	See appended Table 8.9.3.2	N
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		N
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint		N
	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
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling, it was subjected to dielectric strength test of 8.8.3 except at 1.6 times the test voltage ....:	See appended Table 8.9.3.4	N
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of 8.8.3 at 1.6 times the test voltage		N

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.3.4	One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times ....:	See appended Table 8.9.3.4	N
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 as indicated in RISK MANAGEMENT FILE.....:	See Appended RM Results Table 8.10.1	N
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION :		P
	Conductors and connectors of ME EQUIPMENT when breaking free at their joint are not capable of touching circuit points resulting in a HAZARDOUS SITUATION described in 13.1		P
	Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION		P
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS described in 13.1 due to poor contact		N
8.10.3	Flexible cords detachable without a TOOL used to interconnect different parts of ME EQUIPMENT provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS of 8.4 when a connection is loosened or broken as shown by measurement or test finger ....:	See Appended Table 5.9.2	N
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		N
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 a part used	N
	d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple		N
	42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit		N
8.10.4.2	Connection and anchorage at both ends of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT at both ends of cable to control device complied with 8.11.3 when breaking free or shorting between conductors could result in a HAZARDOUS SITUATION described in 13.1		N
	This requirement applied to other HAND-HELD parts when disturbance or breaking of one or more of connections could result in a HAZARDOUS SITUATION described in 13.1		N

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Clause	Requirement + Test	Result - Remark	Verdict
8.10.5	Mechanical protection of wiring		P
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION described in 13.1 ....:		P
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION described in 13.1		P
8.10.6	Guiding rollers of insulated conductors prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead concerned in NORMAL USE		N
8.10.7	a) Insulating sleeve that can only be removed by breaking or cutting, or secured at both ends, is used on internal wiring of when needed ....:	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		P
	c) Insulated conductors subject to temperatures > 70 ℃ in NORMAL USE provided with insulation of heat-resistant material when compliance is likely to be impaired due to deterioration of insulation ....:	See appended Table 8.10	N
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 Certified external 9Vdc power adaptor or 3.7Vdc Li-ion Battery / 4 x AA Type 1.5 Vdc (6Vdc,)	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)		N
	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 if reconnection would result in a HAZARDOUS SITUATION or		N
	– any OPERATOR including SERVICE PERSONNEL is unable to view the means of isolation from their intended position		N
	The locking mechanism by the RESPONSIBLE ORGANIZATION, and		N

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Clause	Requirement + Test	Result - Remark	Verdict
	- the isolation device specified in the ACCOMPANYING DOCUMENTS		N
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description ....:	See appended Table 8.10	N
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE and CLEARANCES in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV ....:	See appended Table 8.10	N
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	See appended Table 8.10	N
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		N
	f) A suitable plug device such as an APPLIANCE COUPLER or a flexible cord with a MAINS PLUG used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS switch to isolate it from SUPPLY MAINS considered to comply with 8.11.1 a) ....:	See appended Table 8.10	N
	g) A fuse or a semiconductor device not used as an isolating means		N
	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		N
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering		N
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage (symbol 10 of Table D.1 is insufficient)		N
	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
	Standard test finger of Fig 6 applied		N
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2		N
8.11.3	POWER SUPPLY CORDS		P
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD		P

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Clause	Requirement + Test	Result - Remark	Verdict
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design. 53) ....:	See appended Table 8.10	N
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE ....:	See appended Table 8.10	N
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 (mm^2 Cu) ....:		N
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6 ....:	See appended Table 8.10	N
8.11.3.5	Cord anchorage (for APPLIANCE COUPLERS not complying with IEC 60320-1)		N
	a) Conductors of POWER SUPPLY CORD provided with strain relieve and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage		N
	b) Cord anchorage of POWER SUPPLY CORD is made of and arranged as follows when a total insulation failure of POWER SUPPLY CORD caused conductive non-PROTECTIVELY EARTHED ACCESSIBLE PARTS to exceed limits of 8.4:		N
	– insulating material, or		N
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		N
	– metal provided with an insulating lining affixed to cord anchorage, except when it is a flexible bushing forming part of the cord guard in 8.11.3.6, and complying with the requirements for one MEANS OF PROTECTION		N
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage		N
	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 when cord anchorage fails		N

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Clause	Requirement + Test	Result - Remark	Verdict
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 ....:	See appended Table 8.11.3.5	N
	Cord subjected to a torque in Table 18 for 1 min immediately after pull tests		N
	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
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N
	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
8.11.3.6	POWER SUPPLY CORDS other than for STATIONARY ME EQUIPMENT protected against excessive bending at inlet opening of equipment or of MAINS CONNECTOR by means of an insulating cord guard or by means of an appropriately shaped opening		N
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram attached to the free end of cord (g).......................................:	See appended Table 8.11.3.6	N
	Cord guard of temperature-sensitive material tested at 23 ℃ ± 2 ℃, and flat cords bent in the plane of least resistance		N
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D ....:	See appended Table 8.11.3.6	N
8.11.4	MAINS TERMINAL DEVICES		N
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD replaceable by SERVICE PERSONNEL provided with MAINS TERMINAL DEVICES ensuring reliable connection		N
	Terminals alone are not used to keep conductors in position, except when barriers are provided such that CREEPAGE and CLEARANCES cannot be reduced below 8.9 if any conductor breaks away		N

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Clause	Requirement + Test	Result - Remark	Verdict
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked according to 7.3.7 used as terminals intended for external conductors		N
	Screws and nuts clamping external conductors do not serve to secure any other component, except they also clamp internal conductors when unlikely to be displaced when fitting the supply conductors		N
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N
	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
	b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6		N
	c) Marking of MAINS TERMINAL DEVICES complied with 7.3		N
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		N
	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
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced below 8.9 after fastening and loosening a conductor of largest cross-sectional area 10 times		N
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 as verified by test of 8.11.3.4		N
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, and covers fitted without damage to conductors or their insulation		N
	Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation test		N
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 per clause 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT ....:	See appended Table 8.10	N

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Clause	Requirement + Test	Result - Remark	Verdict
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT		N
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts of opposite polarity within MAINS PART, and between all parts of MAINS PART and earth, and such provisions continued within all components		N
	Effect of short-circuit fault conditions in other circuits VERIFIED before eliminating fuses or OVER-CURRENT RELEASES		N
	Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit ....:	See appended Table 8.10	N
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		N
	Fuses complying with IEC 60127 have high breaking capacity (1 500 A) and prospective short-circuit current > 35 A or 10 times current rating of the fuse, whichever is greater		N
	Justification for omission of fuses or OVER-CURRENT RELEASES documented		N
8.11.6	Internal wiring of the MAINS PART		N
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices is not less than minimum required for POWER SUPPLY CORD as in clause 8.11.3.3 (mm^2 Cu)....................................:		N
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits sufficient to prevent fire in case of fault currents...:	See appended Table 8.10	N
	When necessary, ME EQUIPMENT connected to a SUPPLY MAINS with max available short-circuit fault, and subsequent simulation of a fault in a single insulation in MAINS PART did not result in any of the HAZARDOUS SITUATIONS in 13.1.2		N

9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		**P**
9.1	ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3)		P
9.2	HAZARDS associated with moving parts		N
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 ....:	See Appended RM Results Table 9.2.1 No moving part used	N

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Clause	Requirement + Test	Result - Remark	Verdict
	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
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and		N
	RISK CONTROLS implemented ....:		N
9.2.2	TRAPPING ZONE		N
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:	No trapping zone used	N
	– Gaps in Clause 9.2.2.2, or		N
	– Safe distances in Clause 9.2.2.3, or		N
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or		N
	– Continuous activation in Clause 9.2.2.5		N
	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
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20 ....:	See appended Table 9.2.2.2	N
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008 ....:	See appended Table 9.2.2.2	N
	Distances measured from expected positions of OPERATOR, PATIENT, and others near EQUIPMENT in NORMAL USE or under foreseeable misuse		N
9.2.2.4	GUARDS and other RISK CONTROL measures		N
9.2.2.4.1	A TRAPPING ZONE considered 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 based on results of applicable tests in 15.3 for ENCLOSURES ....:	See Appended Table 15.3	N
9.2.2.4.2	FIXED GUARDS held in place by systems that can only be dismantled with a TOOL		N
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open		N

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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
	– absence or failure of one of their components prevents starting, and stops moving parts		N
	Movable GUARDS complied with any applicable tests		N
9.2.2.4.4	Other RISK CONTROL designed and incorporated into to the control system stops movement if a TRAPPING ZONE is reached and motion has started, and		N
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or		N
	ME EQUIPMENT is SINGLE FAULT SAFE		N
9.2.2.5	Continuous activation		N
	Continuous activation used as a RISK CONTROL, where impractical to make the TRAPPING ZONE inaccessible, complies with the following		N
	a) movement was in OPERATOR'S field of view		N
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR as long as OPERATOR response to deactivate device relied upon to prevent HARM		N
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or		N
	- the continuous activation system is SINGLE FAULT SAFE		N
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT, when contact with ME EQUIPMENT could result in a unacceptable RISK, limited to allow OPERATOR control of the movement		N
	Over travel (stopping distance) of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		N
9.2.3	Other MECHANICAL HAZARDS associated with moving parts		N
9.2.3.1	Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated		N
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or		N
	- activation does not result in an unacceptable RISK		N

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Clause	Requirement + Test	Result - Remark	Verdict
9.2.3.2	Over travel past range limits of the ME EQUIPMENT prevented .... :		N
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse .... :	See Table 9.2.3.2	N
9.2.4	Emergency stopping devices		N
	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................ :	See Appended RM Results Table 9.2.4	N
	a) Emergency stopping device reduced RISK to an acceptable level		N
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD		N
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N
	g) Means for stopping of movements operate as a result of one single action		N
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 (symbol IEC 60417-5638, 2002-10) or "STOP"		N
	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
	k) Emergency stopping device is suitable for its application		N
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..........:	See Appended RM Results Table 9.2.5	N

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Clause	Requirement + Test	Result - Remark	Verdict
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		N
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented		N
	– 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
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered ....:		P
9.4	Instability HAZARDS		P
9.4.1	ME EQUIPMENT, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE		P
9.4.2	Instability – overbalance		P
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when not specified, as in 9.4.2.2, and placed on a 10° inclined plane from horizontal consisting of a hard and flat surface (e.g., concrete floor covered with 2 to 4 mm thick vinyl material).......................:	See Appended Table 9.4.2.1	P
9.4.2.2	Instability excluding transport		P
	ME EQUIPMENT or its parts prepared based on a) to g), inclusive, did not overbalance when placed in different positions of NORMAL USE, except transport positions, on a 5° inclined plane from horizontal (hard and flat surface)...:	See Appended Table 9.4.2.2	P
	A warning provided, stating “Transport only under conditions described in instructions for use or marked on ME EQUIPMENT with an indication of RESIDUAL RISK if ME EQUIPMENT or its parts overbalances” when overbalance occurred during 10° inclined plane test		N
9.4.2.3	Instability from horizontal and vertical forces		P
	a) ME EQUIPMENT or its parts with a mass of 25kg or more, other than FIXED ME EQUIPMENT for use on floor, did not overbalance due to pushing or resting	Small equipment Weight : 273g Dimensions : 72(H) x 154(W) x 26(D) mm	N

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Clause	Requirement + Test	Result - Remark	Verdict
	Surfaces of ME EQUIPMENT or its parts where a RISK of overbalancing exists from pushing, leaning, resting etc., permanently marked with a CLEARLY LEGIBLE warning of the RISK (e.g., safety sign 5 of Table D.2, safety sign ISO 7010-P017) and visible during NORMAL USE		N
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a force of 15% of its weight, but not more than 150 N, applied in different directions, except a direction with an upward component		N
	b) ME EQUIPMENT or its parts, other than FIXED ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping		P
	ME EQUIPMENT or its parts, other than FIXED ME EQUIPMENT, for use on the floor or on a table, where a RISK of overbalancing exists due to sitting or stepping permanently marked with a CLEARLY LEGIBLE warning of the RISK (e.g., safety signs 6 and 7 of Table D.2, safety signs ISO 7010-P018, or ISO 7010-P019 as appropriate) and visible during NORMAL USE ..... :		N
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a constant force of 800 N applied at the point of maximum moment to working surfaces, offering an foothold or sitting surface of a min 20 x 20 cm area, and at a height ≤ 1 m from the floor ..... :	See Appended Table 9.4.2.3	P
9.4.2.4	Castors and wheels		N
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT (e.g., castors or wheels) did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE	No such a part used	N
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT along a hard and flat horizontal surface did not exceed 200 N applied at a height of 1 m above floor or highest point on ME EQUIPMENT when < 1 m high, except when instructions indicated more than one person needed (N) ..... :	See Appended Table 9.4.2.4.2	N
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg configured with a SAFE WORKING LOAD, moved 10 times in forward direction over a solid vertical plane obstruction with wheels impacting the obstruction at a speed of 0.8 m/s ± 0.1 m/s for manual or with max speed for motor driven MOBILE ME EQUIPMENT :	See Appended Table 9.4.2.4.3	N
	ME EQUIPMENT went up the obstruction without overbalancing		N
	BASIC SAFETY and ESSENTIAL PERFORMANCE was maintained ..... :		N

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Clause	Requirement + Test	Result - Remark	Verdict
9.4.3	Instability from unwanted lateral movement (including sliding)		N
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
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements of ME EQUIPMENT or its parts in transport position		N
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position or worst case NORMAL USE position with SAFE WORKING LOAD, and locking device activated, on a 10° inclined hard flat surface with castors in worst-case position		N
	Following initial elastic movement, creepage, and pivoting of castors, no further movement of MOBILE ME EQUIPMENT > 50 mm (in relation to inclined plane) occurred (mm) .... :	See Appended Table 9.4.3.1	N
	RISK due to any initial movement assessed taking into consideration NORMAL USE of ME EQUIPMENT		N
9.4.3.2	Instability excluding transport		N
	a) Further movement of ME EQUIPMENT (after initial elastic movement) was less than 50 mm when MOBILE ME EQUIPMENT with a SAFE WORKING LOAD positioned on a 5° inclined hard flat surface with wheel locked or braking system activated (mm) . :	See Appended Table 9.4.3.2	N
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT		N
	b) MOBILE ME EQUIPMENT with a SAFE WORKING LOAD prepared as in 9.4.2.2 and placed on a horizontal plane with locking device activated and castors, when supplied, in their worst case position		N
	Further movement of ME EQUIPMENT (after initial elastic movement), was no more than 50 mm when a force of 15 % of weight of unit, but less than 150 N, applied in different directions, except a direction with an upwards component, at highest point of ME EQUIPMENT but ≤ 1.5 m from floor......................... :	See Appended Table 9.4.3.2	N
9.4.4	Grips and other handling devices		N
	a) ME EQUIPMENT other than PORTABLE EQUIPMENT or its part 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, except when handling is obvious and causing unacceptable RISK		N

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Clause	Requirement + Test	Result - Remark	Verdict
	Handles, when supplied, 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
	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
	c) Carrying handles and grips and their means of attachment withstood loading test .... :	See Appended Table 9.4.4	N
9.5	Expelled parts HAZARD		N
9.5.1	Suitability of means of protecting against unacceptable RISK of expelled parts determined by assessment and examination of RISK MANAGEMENT FILE .... :	See Appended RM Results Table 9.5.1 No expelled part used	N
9.5.2	Cathode ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965 .... :	See appended Table 8.10	N
9.6	Acoustic energy (including infra- and ultrasound) and vibration		N
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK based on the tests of 9.6.2 and 9.6.3, and		N
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity .... :	See Appended RM Results Table 9.6.1	N
9.6.2	Acoustic energy		P
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE, except for auditory ALARM SIGNALS		P
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA).. :	Less than 40 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 for RISKS associated with infrasound or ultrasound addressed in RISK MANAGEMENT PROCESS .... :	See Appended RM Results Table 9.6.2.2	N
9.6.3	Hand-transmitted vibration		N
	Means provided, except for INTENDED USE vibrations, to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values measured at points of hand contact with PATIENT or OPERATOR		N

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Clause	Requirement + Test	Result - Remark	Verdict
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2) ....:		N
	– Accelerations for different times, inversely proportional to square root of time (m/s^2) ....:		N
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N
9.7.1	Requirements of this clause applied to vessels and parts of ME EQUIPMENT subject to pressure resulting in rupture and unacceptable RISK		N
	Parts of a pneumatic or hydraulic system used as a support system, comply with 9.8		N
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE ....:	See Appended RM Results Table 9.7.2	N
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		N
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		N
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		N
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply		N
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N
	– 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
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) RATED maximum supply pressure from an external source		N
	b) Pressure setting of a pressure-relief device provided as part of assembly		N
	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

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Clause	Requirement + Test	Result - Remark	Verdict
9.7.4	Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests......................:		N
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was > 50 kPa, and product of pressure and volume was more than 200 kPal...:	See Appended Table 9.7.5	N
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
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 ....:	See Appended RM Results Table 9.7.7	N
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		N
	b) Installed to be readily accessible for inspection, maintenance, and repair		N
	c) Could be adjusted or rendered inoperative without a TOOL		N
	d) With discharge opening located and directed as to not to release material towards any person		N
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		N
	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
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect		N
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N
9.8	HAZARDS associated with support systems		N
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK ....:	See appended Table 8.10 and Appended RM Results Table 9.8.1 No support systems used	N

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Clause	Requirement + Test	Result - Remark	Verdict
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		N
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		N
	– 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		N
	– 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
	– 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
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		N
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
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing........:	See Appended RM Results Table 9.8.2	N
	When test were conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK..:	See appended Table 8.10	N
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		N
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints :	See Appended RM Results Table 9.8.3.1	N
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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
	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
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		N
	Max allowable PATIENT mass > 135 kg stated in ACCOMPANYING DOCUMENTS		N
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance ....:	See copy of Marking Label	N
9.8.3.2	Part of SAFE WORKING LOAD representing mass of PATIENTS or OPERATORS is distributed on support/suspension surface representing human body as in Fig A.19		N
	Part of SAFE WORKING LOAD representing mass of ACCESSORIES deployed as in NORMAL USE and, when not defined, at worst case position permitted by configuration or ACCESSORIES attachment on support/suspension parts		N
	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
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests ....:	See appended Table 8.10	N
	PATIENT support/suspension system positioned horizontally in most disadvantageous position in NORMAL USE, and a mass 2 x 135 kg or twice intended person's load (the greater used), applied to foot rest over an area of 0.1 m^2 for 1 min (Kg) :	See appended Table 9.8.3.2	N
	Damage or deflection greater than 5° from normal did not occur		N
	BASIC SAFETY and ESSENTIAL PERFORMANCE was maintained		N
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test.....................................:	See appended Table 8.10	N
	PATIENT support/suspension system set in most unfavourable NORMAL USE position, and a mass of 60 % of part of SAFE WORKING LOAD simulating PATIENT or OPERATOR, or a min 80 kg, placed on support or suspension system with centre of load 60 mm from outer edge of support or suspension system for at least 1 min (Kg)..............................:	See appended Table 9.8.3.2	N
	Deflection of support/suspension from normal greater than 5°did not occur, and		N
	- BASIC SAFETY and ESSENTIAL PERFORMANCE was maintained		N
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 by following test		N
	PATIENT support/suspension system set in most unfavourable NORMAL USE position, and a mass equal to SAFE WORKING LOAD simulating PATIENT or OPERATOR dropped from 150 mm above seat area on an area of support/ suspension a PATIENT or OPERATOR can sit ....:	See appended Table 9.8.3.3	N
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES		N
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided when a support system or its parts impaired by wear have a TENSILE SAFETY FACTOR ≥ to values in Table 21, rows 5 and 6, but less than 3 and 4 ....:	No support parts used	N
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		N
	– Designed based on TOTAL LOAD, and includes effects of SAFE WORKING LOAD when applicable		N
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N
	– Activated before travel (movement) produced an unacceptable RISK		N
	– Takes into account Clauses 9.2.5 and 9.8.4.3		N
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests ....:	See appended Table 8.10	N
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 (e.g., a secondary cable)		N

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Clause	Requirement + Test	Result - Remark	Verdict
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		N
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		N
	– Further use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE .:		N
	– ACCOMPANYING DOCUMENTS instruct once MECHANICAL PROTECTIVE DEVICE is activated, SERVICE PERSONNEL shall be called, and MECHANICAL PROTECTIVE DEVICE must be replaced before ME EQUIPMENT can be used		N
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.2 (i.e., safety sign ISO 7010-W001)		N
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE or its location relative to MECHANICAL PROTECTIVE DEVICE is obvious to service personnel		N
	– Compliance confirmed by examination of ME EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and following test ....:	See appended Table 8.10	N
	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
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		N
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		N
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		N
	Support system parts have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 1 and 2, and are not impaired by wear ....:	See Appended RM Results Table 9.8.5 No support parts used	N
	Support system parts impaired by wear, however, they have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 3 and 4		N
	Examination of ME EQUIPMENT, design documentation and RISK MANAGEMENT FILE confirmed compliance		N

10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**	**N**
10.1	X-Radiation	N

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Clause	Requirement + Test	Result - Remark	Verdict
10.1.1	The air kerma did not exceed 5 μGy/hat 5 cm from surface of ME EQUIPMENT including background radiation for ME EQUIPMENT not producing therapeutic/diagnostic X-radiation but producing ionizing radiation .... :	See Table 10.1.1	N
	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
	Amount of radiation measured by means of an ionizing chamber radiation monitor with an effective area of 10 cm^2 or by other instruments producing equal results		N
	ME EQUIPMENT operated as in NORMAL USE at most unfavourable RATED MAINS VOLTAGE and controls adjusted to emit maximum radiation		N
	Internal pre-set controls not intended for adjustment during EXPECTED SERVICE LIFE of ME EQUIPMENT not taken into consideration		N
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
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE...:	See Appended RM Results Table 10.1.2	N
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE...................................... :	See Appended RM Results Table 10.2 None provided	N
10.3	The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2 at any point 50 mm away from a surface of the ME EQUIPMENT under reference test conditions		N
	Microwave radiation is propagated intentionally for example, at waveguide output ports		N
10.4	Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.	No lasers provided	N
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 .. :	See Appended RM Results Table 10.5	N
10.6	RISK associated with infrared radiation other than emitted by lasers and LEDS, as applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .... :	See Appended RM Results Table 10.6 SpO_2 Sensor	P

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Clause	Requirement + Test	Result - Remark	Verdict
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS, as applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .... :	See Appended RM Results Table 10.7	N

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 23 operating in worst-case NORMAL USE at maximum rated ambient operating temperature T......................................:	See appended Table 11.1.1 and appended RM Results Table 11.1.1	N
	Surfaces of test corner did not exceed 90 ℃		N
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION		P
11.1.2	Temperature of APPLIED PARTS		P
11.1.2.1	APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply..:		N
	Clinical effects determined and documented in the RISK MANAGEMENT FILE	See RM Results Table 11.1.2.1	N
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use		N
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in NORMAL CONDITION and SINGLE FAULT CONDITION ..:		P
	APPLIED PARTS surface temperature exceeds 41℃ disclosed in the instruction manual:		N
	Maximum Temperature ....:		—
	Conditions for safe contact, e.g. duration or condition of the PATIENT ....:		—
	Clinical effects with respect to characteristics taken or surface pressure documented in the RISK MANAGEMENT FILE	See RM Results Table 11.1.2.2	N
	APPLIED PARTS surface temperature of equal to or less than 41℃		N
	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
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS..:		N

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Clause	Requirement + Test	Result - Remark	Verdict
11.1.2.2	APPLIED PARTS not supplying heat to a PATIENT met Table 24 with max surface temperatures > 41 °C disclosed in instructions for use, and clinical effects regarding maturity of PATIENTS, body surface, surface pressure, medications taken, as shown in RISK MANAGEMENT FILE ....:	See appended Table 11.1.2.2 40 °C	N
	Surfaces of APPLIED PARTS cooled below ambient temperatures that can also result in HAZARD evaluated as part of RISK MANAGEMENT PROCESS		N
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 ....:	See appended Table 11.1.3 and RM Results Table 11.1.3	N
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE		P
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE	Contact time : AP : 10min ≤ t	P
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL		N
11.2	Fire prevention		P
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire caused by reasonably foreseeable misuse 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
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of fire under NORMAL or SINGLE FAULT CONDITIONS when source of ignition in contact with ignitable material ....:	See appended Table 8.10 Equipment is not used in oxygen rich environment.	N
	Requirements of 13.1.1 applied to oxygen concentrations up to 25 % at one atmosphere or partial pressures up to 27.5 kPa for higher atmospheric pressures		N
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT in NORMAL and SINGLE FAULT CONDITIONS under any of the following conditions		N
	1) when temperature of material raised to its ignition temperature		N
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300℃ or sparks due to overheating		N
	4) when temperatures of parts or components exceeded 300℃, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N
	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
	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 ....:	See Appended RM Results Table 11.2.2.1	N
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively ....:	See appended Table 11.2.2.1	N
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three ....:		N
	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 ....:	See Appended RM Results Table 11.2.2.1	N
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3.........:	See appended Tables 4.11, 11.1.1 to 11.1.2.2, inclusive; and Table 13.2	N
	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
	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
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE ....:	See Attachment #	N

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Clause	Requirement + Test	Result - Remark	Verdict
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases ....:	See Attachment #	N
11.2.2.2	RISK of ignition under least favourable conditions 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 when electrical components mounted outside of ME EQUIPMENT or ME SYSTEM		N
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks due to loosening or breaking, except when limited in power and energy to values in 11.2.2.1 a) 5)		N
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		N
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		N
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered		N
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2)..............................:	Equipment is not used in oxygen rich environment.	N
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) ....:		N
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a)..........................:		N
	– 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
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas ....:		N
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 ....:	See Appended RM Results Table 11.3	N
	Constructional requirements were met, or		N
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE ....:	See Appended RM Results Table 11.3	N

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Clause	Requirement + Test	Result - Remark	Verdict
	Justification, when requirement not met ....:		P
	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	N
	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	N
	If no FV Certification, FV tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings		N
	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, except constructions based on Table 25 and a mesh; FV-2 or better for TRANSPORTABLE ME EQUIPMENT, FV-1 or better for fixed EQUIPMENT, or STATIONARY EQUIPMENT per IEC 60695-11-10, determined by ENCLOSURE examination or flammability classification based on 11.3a) ....:	See appended Table 8.10	P
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics		N
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable anaesthetics (CATEGORY AP) or anaesthetics with oxidants (CATEGORY APG) comply with Annex G	No AP/APG equipment	N
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		N
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE ....:	See Appended RM Results Table 11.5 No flammable agents used	N
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
	ME EQUIPMENT incorporates a reservoir or liquid storage that is liable to be overfilled or to overflow in NORMAL USE, liquid overflowing from the reservoir or chamber did not wet any MEANS OF PROTECTION that is liable to be adversely affected by such a liquid, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.......................:	See Appended Table 11.6 No liquid part used	N
	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
	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
11.6. 3	Spillage on ME EQUIPMENT and ME SYSTEM		N
	ME EQUIPMENT and ME SYSTEMS handling liquids in NORMAL USE positioned as in 5.4 a) and liquid with composition, volume, duration of spill and point of contact based on the RISK ANALYSIS and test conditions based on RISK MANAGEMENT PROCESS poured steadily on a point on top of ME EQUIPMENT ....:	See Appended RM Results Table 11.6.3 and Table 11.6 No liquid part used	N
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and un-insulated electrical parts or electrical insulation of parts that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION were not wet ....:	See appended Tables 8.7 8.8.3	N
11.6.4	Leakage	See 13.2.6	N
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 RM Results Table 11.6.5 IPX1 equipment	P
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION ....:	See appended Tables 8.7 8.8.3	P
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS		P
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected once using methods specified in instructions for use including any cooling or drying period ....:	See Appended Table 11.6	P
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests, with no deterioration resulting in an unacceptable RISK present ....:	See appended Tables 8.7 8.8.3	P
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER and assurance that the processes did not cause a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE ....:	See the Operation Manual.	P
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		N
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented according to ISO 11135-1, ISO 11137-1, or ISO 17665-1 as appropriate ....:	See Appended RM Results Table 11.6.7	N
	After the test, ME EQUIPMENT complied with the appropriate dielectric strength and LEAKAGE CURRENT tests and there was no deterioration resulting in an unacceptable RISK.........................:	See appended Tables 8.7 8.8.3, and 11.6	N
	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE..................	See Appended RM Results Table 11.6.8	N
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented per ISO 10993		N
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		P

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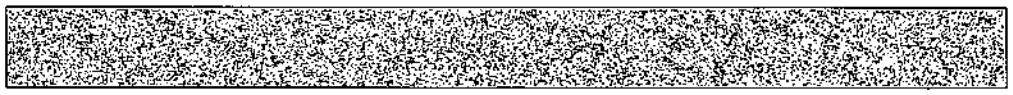
Clause	Requirement + Test	Result - Remark	Verdict

12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		**P**
12.1	RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review .....:	See Appended RM Results Table 12.1	P
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING PROCESS complying with IEC 60601-1-6 .....:	See Report based on IEC 60601-1-6	P
12.3	MANUFACTURER implemented an ALARM SYSTEM that complies with IEC 60601-1-8. .....:	See Report based on IEC 60601-1-8 Refer to the Managing Alarm and Alarm Limits in user manaual	N/E
12.4	Protection against hazardous output		N
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE .....:	See Appended RM Results Table 12.4.1 No an intentional exceeding safety limit used	N
12.4.2	When applicable, need for indication of parameters associated with hazardous output addressed in RISK MANAGEMENT PROCESS .....:	See Appended RM Results Table 12.4.2	P
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit designed to provide low and high-intensity outputs for different treatments addressed in RISK MANAGEMENT PROCESS, confirmed in RISK MANAGEMENT FILE .....:	See Appended RM Results Table 12.4.3	N
12.4.4	When applicable, RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE .....:	See Appended RM Results Table 12.4.4	N
12.4.5	Diagnostic or therapeutic radiation		N
12.4.5.1	Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation emitted by ME EQUIPMENT designed to produce radiation for diagnostic/therapeutic purposes		N
	Radiation safety ensured by compliance with requirements of appropriate standards		N
12.4.5.2	ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3 .....:	See IEC 60601-1-3 No X-ray	N
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE .....:	See Appended RM Results Table 12.4.5.3 No a radiotherapy equipment	N



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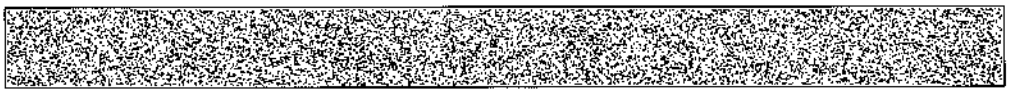
Clause	Requirement + Test	Result - Remark	Verdict
12.4.5.4	RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE.....:	See Appended RM Results Table 12.4.5.4	N
12.4.6	When applicable, RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE.....:	See Appended RM Results Table 12.4.6	N
13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		**P**
13.1	Specific HAZARDOUS SITUATIONS		P
13.1.1	None of HAZARDOUS SITUATIONS in 13.1.2-13.1.4, inclusive, occurred when SINGLE FAULT CONDITIONS applied, one at a time, as in 4.7 and 13.2		P
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature		N
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		N
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		N
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 when measured as in 11.1.3 .....:	See appended Tables 11.1.1, 11.1.2.1, and 11.1.2.2	N
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 when measured and adjusted as in 11.1.3.....:	See appended Tables 11.1.1, 11.1.2.1, and 11.1.2.2	N
	–Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 ℃ were not exceeded		N
	Limits for windings in Tables 26, 27, and 31 not exceeded		N
	Table 22 not exceeded in all other cases		N
	Temperatures measured according to 11.1.3		N
	SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where:		N
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit in SINGLE FAULT CONDITION .....:	See appended Table 13.1.2	N
	- or secondary circuits mounted on materials with a minimum flame rating of FV1, and		N
	- Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and		N



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Clause	Requirement + Test	Result - Remark	Verdict
	- Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and		N
	- Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide		N
	- or components in the circuit have HIGH INTEGRITY CHARACTERISTICS ....:	See appended Table 4.9	N
	– or parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation		N
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		N
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed ....:	See appended Table 8.7	P
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed...................:	See appended Table 8.7	P
13.1.4	ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS		P
13. 2	SINGLE FAULT CONDITIONS		P
13.2.1	During application of SINGLE FAULT CONDITIONS in 13.2.2 -13.2.13, inclusive, NORMAL CONDITIONS in 8.1 a) applied in least favourable combination......:	See appended Table 13.2	P
13.2.2 – 13.2.12	ME EQUIPMENT complied with 13.2.2 -13.2.12 ....:	See appended Table 13.2 and RM Results Table 13.2.6	P
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to within 3 °C of the temperature in the test environment		N
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		N
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION (see 8.8), 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
13.2.13.2	ME EQUIPMENT with heating elements		N
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, or for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests of 13.2.13.2 b) & 13.2.13.2 c)	No heater used	N
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests of 13.2.13.2 b) and 13.2.13.2 c)		N

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Clause	Requirement + Test	Result - Remark	Verdict
	a 3) other ME EQUIPMENT with heating elements met test of 13.2.13.2 b)		N
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		N
	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
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		N
	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
	b) ME EQUIPMENT with heating elements tested per clause 11.1without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V)..... :		N
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY		N
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		N
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION		N
	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
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS		N
	2) When more than one control provided, they were disabled in turn		N
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		N
13.2.13.3	ME EQUIPMENT with motors		N
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable	No motor used	N

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Clause	Requirement + Test	Result - Remark	Verdict
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		N
	a 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 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		N
	b) Motor met running overload protection test of this clause when:		N
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended		N
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C)..................................:		N
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		N
	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
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		N
	Test not conducted based on other justifications (justification) ....:		N
	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
13.2.13.4	ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION		N
	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 ℃ in one hour, or a protective device operated	Continuous operation equipment	N
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle		N
	Motor winding temperatures did not exceed values in 13.2.10...:		N

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Clause	Requirement + Test	Result - Remark	Verdict
	Insulation Class ...:		—
	Maximum temperature measured (°C)...:		—

14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		**P**
14.1	Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE, or		N
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK...:	See Appended RM Results Table 14.1	N
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK	Do not use the IT-network	P
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304 ...:	Software Class: B See Section 4 and 7 in Appended PEMS SOFTWARE REQUIREMENT SPECIFICATION (Doc#. SRS05)	P
	Software development process applied according to Clause 5 of IEC 62304 ...:	See Appended PEMS Software Validation Plan (Doc#. SVP05), PEMS SOFTWARE REQUIREMENT SPECIFICATION (Doc#. SRS05), PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05), PEMS SOFTWARE TEST REPORT (Doc#. VVT05), PEMS Software Risk Management (Doc#. SRM05), and PEMS Software Validation Report (Doc#. SVR05)	P
	Software development process for Software risk management applied according to Clause 7 of IEC 62304 ...:	See Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05) and PEMS Software Risk Management (Doc#. SRM05)	P
	Software development process Configuration Management applied according to Clause 8 of IEC 62304 ...:	See Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. HC-SDS-01) and PEMS Software Validation Report (Doc#. HC-SVR-01)	P
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304 ...:	See Section 10 in Appended PEMS Software Validation Plan (Doc#. HC-SVP-01)	P

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Clause	Requirement + Test	Result - Remark	Verdict
14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process .... :	The Reports related PEMS Software Validation are managed by document management procedures	P
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan	See Section 17 in Appended PEMS Software Validation Plan (Doc#. SVP05)	P
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented	See Section 8 and 10 in Appended PEMS Software Validation Plan (Doc#. SVP05)	P
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	See Appended PEMS SOFTWARE TEST REPORT (Doc#. VVT05)	P
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	See Appended PEMS Software Risk Management (Doc#. SRM05)	P
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules	See Section 8 in Appended PEMS Software Validation Plan (Doc#. SVP05)	P
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	The Reports related PEMS Software Validation are documented by requirements of documentation	P
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 where appropriate	See Section 11 in Appended PEMS Software Validation Plan (Doc#. SVP05)	P
	Problem resolution system meets prescribed criteria depending on type of product:		P
	– it is documented as a part of PEMS DEVELOPMENT LIFE-CYCLE	An activity is performed to resolve the possible problems in the reports related PEMS Software Validation	P
	– it allows reporting of potential or existing problems affecting BASIC SAFETY or ESSENTIAL PERFORMANCE	See Section 5, 6 and 7 in Appended PEMS Software Risk Management (Doc#. SRM05)	P
	– it includes an assessment of each problem for associated RISKS	See Section 7 in Appended PEMS Software Risk Management (Doc#. SRM05)	P
	– it identifies criteria that must be met for the issue to be closed	See Section 4 in Appended PEMS Software Risk Management (Doc#. SRM05)	P
	– it identifies the action to be taken to resolve each problem	See Section 9 in Appended PEMS Software Risk Management (Doc#. SRM05)	P
14.6	RISK MANAGEMENT PROCESS		P

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Clause	Requirement + Test	Result - Remark	Verdict
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS ....:	See Section 5 in Appended PEMS Software Risk Management (Doc#. SRM05)	P
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2 ....:	See Section 9 in Appended PEMS Software Risk Management (Doc#. SRM05)	P
14.7	A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem ....:	See Appended PEMS SOFTWARE REQUIREMENT SPECIFICATION (Doc#. SRS05)	P
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems..........:	See Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05)	P
	The architecture specification makes use of considers the specified items to reduce RISK to an acceptable level, where appropriate:		P
	a) COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS		N
	b) fail-safe functions	See Section 9 in Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05)	P
	c) redundancy	See Section 9 in Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05)	P
	d) diversity;	See Section 9 in Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05)	P
	e) partitioning of functionality	See Section 9 in Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05)	P
	f) defensive design potentially limiting hazardous effects by restricting available output power or by introducing means to limit travel of actuators	See Section 9 in Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05)	P
	g) allocation of RISK CONTROL measures to subsystems and components of PEMS	See Section 9 in Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05)	P
	h) failure modes of components and their effects;	See Section 9 in Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05)	P

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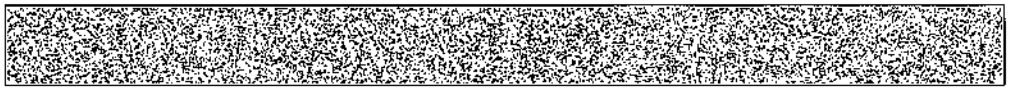
Clause	Requirement + Test	Result - Remark	Verdict
	i) common cause failures	See Section 9 in Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05)	P
	j) systematic failures	See Section 9 in Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05)	P
	k) test interval duration and diagnostic coverage	See Section 9 in Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05)	P
	l) maintainability	See Section 9 in Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05)	P
	m) protection from reasonably foreseeable misuse	See Section 9 in Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05)	P
	n) IT-NETWORK specification, when applicable	Do not use the IT-network	N
14.9	Design is broken up into subsystems, each with a design and test specification where appropriate, and descriptive data on design environment documented.....:	See Section 6 and 9 in Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05), and PEMS SOFTWARE TEST REPORT(Doc#. VVT05)	P
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures .....:	See Appended RM Results Table 14.10 See Section 3 in Appended PEMS SOFTWARE TEST REPORT (Doc#. VVT05)	P
	– milestone(s) when VERIFICATION is to be performed for each function	See Section 3, 5 and 6 in Appended PEMS SOFTWARE TEST REPORT (Doc#. VVT05)	P
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION	See Section 6 in Appended PEMS Software Validation Plan (Doc#. SVP05)	P
	– selection and utilization of VERIFICATION tools	See Section 7 in Appended PEMS Software Validation Plan (Doc#. SVP05), and PEMS SOFTWARE TEST REPORT (Doc#. VVT05)	P
	– coverage criteria for VERIFICATION	See Appended PEMS SOFTWARE TEST REPORT (Doc#. VVT05)	P



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Clause	Requirement + Test	Result - Remark	Verdict
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE ....:	See Appended PEMS SOFTWARE REQUIREMENT SPECIFICATION (Doc#. SRS05) and PEMS SOFTWARE TEST REPORT (Doc#. VVT05)	P
	Methods used for PEMS VALIDATION documented	See Appended PEMS SOFTWARE TEST REPORT (Doc#. VVT05)	P
	The person with overall responsibility for PEMS VALIDATION is independent of design team, and no member of a design team is responsible for PEMS VALIDATION of their own design	See Section 6 in Appended PEMS Software Validation Plan (Doc#. SVP05) and PEMS SOFTWARE TEST REPORT (Doc#. VVT05)	P
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE	See Section 6 in Appended PEMS Software Validation Plan (Doc#. SVP05)	P
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE	The Reports related PEMS Software Validation are evaluated by document management procedures	P
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304 ....:	Software Class: B See Section 4 and 7 in Appended PEMS SOFTWARE REQUIREMENT SPECIFICATION (Doc#. SRS05)	P
	Software Process for Software changes applied according to Clause 5 of IEC 62304 ....:	See Appended PEMS Software Validation Plan (Doc#. SVP05), PEMS SOFTWARE REQUIREMENT SPECIFICATION (Doc#. SRS05), PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05), PEMS SOFTWARE TEST REPORT (Doc#. VVT05), PEMS Software Risk Management (Doc#. SRM05), and PEMS Software Validation Report (Doc#. SVR05)	P
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304 ....:	See Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05) and PEMS Software Risk Management (Doc#. SRM05)	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Configuration management of software changes applied per Clause 8 of IEC 62304 ....:	See Appended PEMS SOFTWARE DESIGN SPECIFICATION (Doc#. SDS05) and PEMS Software Validation Report (Doc#. SVR05)	P
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304 ....:	See Section 11 in Appended PEMS Software Validation Plan (Doc#. SVP05)	P
14.13	For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following ....:	Do not use the IT-network	N
	a) Purpose of the PEMS connection to an IT-NETWORK		N
	b) required characteristics of the IT-NETWORK		N
	c) required configuration of the IT-NETWORK		N
	d) technical specifications of the network connection, including security specifications		N
	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
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the characteristics required		N
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		N
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties		N
	– Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS		N
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis		N
	- Changes to the IT-NETWORK include: - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment		N

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Clause	Requirement + Test	Result - Remark	Verdict
15	**CONSTRUCTION OF ME EQUIPMENT**		**P**
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS in accordance with IEC 60601-1-6, when applicable:	See Report based on IEC 60601-1-6	P
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance		P
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		P
15.3	Mechanical strength		P
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 by subjecting external parts of ENCLOSURE to a steady force of 250 N ± 10 N for 5 s applied to a circular (30mm) plane surface, except bottom of ENCLOSURE of an ME EQUIPMENT >18 kg, using a suitable test tool .....:	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.3	Impact test conducted by subjecting a complete ENCLOSURE or its largest non-reinforced area, except for HAND-HELD ME EQUIPMENT and parts, to a free falling 500 g ± 25 g solid smooth steel ball, approx. 50 mm in diameter from a height of 1.3 m .....:	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 allowed to fall freely once from each of 3 different positions as in NORMAL USE from height specified in ACCOMPANYING DOCUMENTS, or from 1 m onto a 50 mm ± 5 mm thick hardwood board lying flat on a concrete or rigid base.....:	See Appended Table 15.3	P
	No unacceptable RISK resulted		P

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Clause	Requirement + Test	Result - Remark	Verdict
15.3.4.2	Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD lifted to a height as in Table 29 above a 50 ± 5 mm thick hardwood board lying flat on a concrete floor or rigid base, dropped 3 times from each orientation in NORMAL USE (cm) ....:	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.5	Each sample of MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests...:	See Appended Table 15.3 No mobile equipment	N
	a) Ascending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0. 8m/s ± 0.1 m/s against an ascending hardwood step obstruction without the sample going over the obstruction		N
	b) Descending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0.8m/s ± 0.1 m/s in order to fall over a vertical step affixed flat on a rigid base with direction of movement perpendicular to face of the step until full descent achieved		N
	c) Door frame shock test conducted on the sample by moving it 3 times in its normal direction of travel at 0.8 m/s ± 0.1 m/s, or for motor driven EQUIPMENT, at maximum possible speed against a hardwood vertical obstacle higher than EQUIPMENT contact point(s)		N
	No damage resulting in an unacceptable RISK sustained		N
15.3.6	Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK		P
	Mould-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10℃ over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 ℃..:	Equipment functions normally. No any damage observed	P
	No damage resulting in an unacceptable RISK		P
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK		P
15.4	ME EQUIPMENT components and general assembly		P
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular ....:	See Appended RM Results Table 15.4.1	P
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions, except when no unacceptable RISK could result ...:	See attachment #	P
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection ....:	See attachment #	N
15.4.2	Temperature and overload control devices		N
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 described in 13.1by resetting action as verified by review of the design documentation and RISK MANAGEMENT FILE ....:	See Appended RM Results Table 15.4.2.1 a) No temperature limit device used	N
	b) THERMAL CUT-OUTS with a safety function that are reset by a soldering not fitted in ME EQUIPMENT		N
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided where a failure of a THERMOSTAT could in a HAZARDOUS SITUATION described in 13.1; the temperature of operation of the additional device is outside that attainable at the extreme setting of the normal control device, but within the temperature limit for the ME EQUIPMENT ....:	See Appended RM Results Table 15.4.2.1 c)	N
	d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION described in 13.1 or the loss of ESSENTIAL PERFORMANCE ....:	See Appended RM Results Table 15.4.2.1 d)	N
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		N
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety of ME EQUIPMENT as verified by following tests:		N
	Positive temperature coefficient devices (PTC's) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17 as applicable		N

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13 ....:	See appended Table 13.2	N
	SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) Certified according to appropriate standards		N
	In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) operated 200 times		N
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		N
	When certification based on IEC standards, or data from MANUFACTURER demonstrating reliability of component to perform its safety-related function is not available, manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		N
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		N
	g) Protective device, provided on ME EQUIPMENT 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
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating in both leads where a conductive connection to earth could result in overheating as verified by review of design and RISK MANAGEMENT FILE ....:	See Appended RM Results Table 15.4.2.1 h)	N
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS		N
15.4.3	Batteries		P
15.4.3.1	Battery housings from which gases can escape during charging or discharging are ventilated to prevent unacceptable RISK from accumulation of gasses and possible ignition ....:	See Appended RM Results Table 15.4.3.1	P
	Battery compartments designed to prevent accidental short circuiting of battery when this could result in a HAZARDOUS SITUATION as described in clause 13.1		P
15.4.3.2	Means provided to prevent incorrect connection of polarity when a HAZARDOUS SITUATION may develop by incorrect connection or replacement of a battery ....:	See Appended RM Results Table 15.4.3.2	P

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Clause	Requirement + Test	Result - Remark	Verdict
15.4.3.3	Overcharging of battery prevented by virtue of design when it could result in an unacceptable RISK as verified by review of design ....:	See Appended RM Results Table 15.4.3.3	P
15.4.3.4	Primary lithium batteries comply with IEC 60086-4		N
	Secondary lithium batteries comply with IEC 62133	Certified Li-ion batteries used	P
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire caused by excessive currents when (in case of a short circuit) layout of internal wiring, cross-sectional area, rating of connected components can result in a fire ....:		P
	Protective device has adequate breaking capacity to interrupt the maximum fault current		P
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented		N
	Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPs provided, or		P
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION described in clause 13.1		P
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for NORMAL USE, except when apparent to OPERATOR from normal operating position, and marking of 7.4.1 are insufficient for this purpose ..:	See Appended RM Results Table 15.4.4	N
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s, except when apparent to OPERATOR from normal operating position		N
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational when a HAZARDOUS SITUATION could exist, except when apparent to OPERATOR from normal operating position		N
	Requirement not applied to heated stylus-pens for recording purposes		N
	Indicator lights provided on ME EQUIPMENT to indicate an output exists where an accidental or prolonged operation of output circuit could constitute a HAZARDOUS SITUATION		N
	Colours of indicator lights complied with 7.8.1		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE		N
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS when applicable as verified by review of RISK MANAGEMENT FILE ....:	See Appended RM Results Table 15.4.5	N
15.4.6	Actuating parts of controls of ME EQUIPMENT		N
15.4.6.1	a) Actuating parts cannot be pulled off or loosened up during NORMAL USE		N
	b) Controls secured so that the indication of any scale always corresponds to the position of the control		N
	c) Incorrect connection of indicating device to relevant component prevented by adequate construction when it could be separated without use of a TOOL		N
	When torque values per Table 30 applied between control knob and shaft of rotating controls for not less than 2 s, 10 times in each direction, knobs did not rotate ....:	See appended Table 15.4.6	N
	Tests conducted by applying an axial force of 60 N for electrical components and 100 N for other components for 1 min when an axial pull was required in NORMAL USE with no unacceptable RISK ....:	See appended Table 15.4.6	N
15.4.6.2	Stops of adequate mechanical strength provided on rotating/ movable parts of controls of ME EQUIPMENT where necessary to prevent an unexpected change from max to min, or vice-versa, of the controlled parameter ....:	See appended Table 15.4.6	N
	Torque values in Table 30 applied 10 times in each direction to rotating controls for 2 sec ....:	See appended Table 15.4.6	N
	No unexpected change of the controlled parameter resulted from the application of an axial force of 60 N for electrical components and 100 N for other components to rotating or movable parts of controls for 1 min when an axial pull was likely to be applied..........:	See appended Table 15.4.6	N
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		N
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1	No such a controller used	N
	b) Foot-operated control device supported an actuating force of 1350 N for 1 min applied over an area of 30 mm diameter in its position of NORMAL USE with no damage to device causing an unacceptable RISK ....:		N

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Clause	Requirement + Test	Result - Remark	Verdict
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
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		N
15.4.7.3	a) Foot-operated control device is at least IPX1 & complies with tests of IEC 60529 (IP Code) ....:	See appended Table 11.6 IP Code = ____	N
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6 and complies with IEC 60529 if in NORMAL USE liquids are likely to be found (IP Code)..............................:	See appended Table 11.6 IP Code = ____	N
15.4.8	Aluminium wires less than 16 mm^2 in cross-sectional area are not used	No aluminium wire used	N
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed to prevent loss of oil in any position	No oil container used	N
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		N
	A pressure-release device operating during NORMAL USE is, optionally, provided		N
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		N
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		N
15.5.1	Overheating		N
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating in the event of short circuit or overload of output windings and comply with this Clause and tests of 15.5.1.2 – 3 ....:	See appended Tables 15.5.1.2 and 15.5.1.3	N
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		N
	Dielectric strength test of 8.8.3 conducted on transformer after short circuit and overload tests .:	See appended Table 15.5.2	N
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved ....:	See appended Table 15.5.1.2 See above	N
	Short circuit applied directly across output windings for transformers not tested according to 5X frequency and 5X voltage test of 15.5.2 a) or 2x frequency and 2x voltage test of 15.5.2 b)		N

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Clause	Requirement + Test	Result - Remark	Verdict
15.5.1.3	Multiple overload tests conducted on windings with more than one protective device to evaluate worst-case NORMAL USE loading and protection .....:	See appended Table 15.5.1.3	N
15.5.2	Transformers operating at a frequency above 1 kHz tested in accordance with clause 8.8.3.....:		N
	Transformer windings provided with adequate insulation to prevent internal short-circuits that could cause overheating which could result in a HAZARDOUS SITUATION		N
	Dielectric strength tests were conducted in accordance with requirements of this clause with no breakdown of insulation system and no detectable deterioration of transformer .....:	See appended Table 15.5.2	N
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with .....:	See appended Table 8.10	N
	- Means provided to prevent displacement of end turns beyond the inter-winding insulation		N
	- protective earth screens with a single turn have insulated overlap not less than 3mm and the width of the screen is at least equal to the axial winding length of the primary side		N
	- Exit of wires form internal windings of toroid transformers protected with double sleeving providing 2 MOPs and a total wall thickness of 0.3mm extending 20mm from the windings		N
	- insulation between primary and secondary windings complies with 8.8.2		N
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4 and the exceptions of this sub-clause		N
16	**ME SYSTEMS**		**N**
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK	See Appended RM Results Table 16.1 No ME systems	N
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered		N
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard		N
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards		N
	– tests performed in NORMAL CONDITION, except as specified		N

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Clause	Requirement + Test	Result - Remark	Verdict
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM		N
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated		N
	RISK MANAGEMENT methods, optionally, used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR to determine configurations with highest RISKS and measures to ensure any configuration of ME SYSTEM will not present unacceptable RISKS		N
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards		N
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM		N
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM		N
	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
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM		N
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER		N
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER		N
	c) the required information is provided:		N
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM		N
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard		N
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM		N
	– additional safety measures to be applied during installation of ME SYSTEM		N
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT		N
	– additional measures to be applied during preventive maintenance		N

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Clause	Requirement + Test	Result - Remark	Verdict
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor		
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM		N
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM		N
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM		N
	– 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
	– 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
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET		N
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage		N
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT		N
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:		N
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES		N
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard		N
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
	Transient currents restricted to allowable levels for the specified IPS or UPS where the ME SYSTEM is intended to receive power from an IPS or UPS and the ME SYSTEM can draw large transient currents when being switched on/off when operating.....:		N
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified		N

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Clause	Requirement + Test	Result - Remark	Verdict
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors, etc., without use of a TOOL operated at a voltage ≤ voltage in 8.4.2 c) supplied from a source separated from SUPPLY MAINS by two MEANS OF OPERATOR PROTECTION		N
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
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION appropriate for highest voltage occurring across SEPARATION DEVICE during a fault condition		N
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V).................:		N
16.6	LEAKAGE CURRENTS		N
16.6.1	TOUCH CURRENT in NORMAL CONDITION, from or between parts of ME SYSTEM within the PATIENT ENVIRONMENT, did not exceed 100 µA...................:	See appended Table 16.6.1	N
	TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, from or between parts of ME SYSTEM within PATIENT ENVIRONMENT ..:	See appended Table 16.6.1	N
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET did not exceed 5 mA .....:		N
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values specified for ME EQUIPMENT in Tables 3 and 4 ....:	See appended Tables 8.7 8.7.4.7 and 16.6.1	N
	Measurements made using a device as in clause 8.7.4.4		N
16.7	ME SYSTEM complied with applicable requirements of Clause 9 when a MECHANICAL HAZARD existed ..:	See applicable appended Tables in section 9	N
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
16.9	ME SYSTEM connections and wiring		N
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result...............................:	See Appended RM Results Table 16.9.1	N

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable		N
16.9.2	MAINS PARTS, components and layout		N
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or		N
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		N
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		N
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 (i.e., safety sign ISO 7010-W001) visible in NORMAL USE, and		N
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		N
	– marked to indicate the equipment or equipment parts it may safely be attached to		N
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT		N
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:		N
	– CREEPAGE and CLEARANCES complied with 8.9		N
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets		N
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:		N
	– ENCLOSURE complied with 8.4.2 d)		N
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable		N
	– RATINGS of components are not in conflict with conditions of use ....:	See appended Table 8.10	N
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL		N
	– POWER SUPPLY CORD complied with 8.11.3		N

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Clause	Requirement + Test	Result - Remark	Verdict
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:		N
	– Separating transformer complied with this standard or IEC 61558-2-1, except requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 were not applied..........:	See appended Table 8.10	N
	– Separating transformer is CLASS I		N
	– Degree of protection against ingress of water specified as in IEC 60529		N
	– Separating transformer assembly marked according to 7.2 and 7.3		N
	– 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
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 for each part of the ME SYSTEM that shares a MAINS CONNECTION when tested per 8.6.4		N
	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
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL		N
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage		N

17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		**P**
	RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review.....:	See Appended RM Results Table 17	P
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS ....:		P
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems		P

ANNEX G	**PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**	**N**
G.2	Locations and basic requirements	N

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Clause	Requirement + Test	Result - Remark	Verdict
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5	No AP/APG equipment	N
G.2.2	FLAMMABLE AESTHETIC MIXTURE WITH AIR occurring due to a leakage or discharge of a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE from an ENCLOSURE considered 5 to 25 cm from point of occurrence		N
G.2.3	A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE contained in a completely / partly enclosed ME EQUIPMENT part and in PATIENT'S respiratory tract 5 cm from an ENCLOSURE part where leakage or discharge occurs		N
G.2.4	ME EQUIPMENT or parts thereof specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR (in a location as in G.2.2) are CATEGORY AP or APG ME EQUIPMENT and complied with G.4 and G.5		N
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (location per G.2.2) are CATEGORY APG ME EQUIPMENT and comply with G.4 and G.6		N
	ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7		N
G.3	Marking, ACCOMPANYING DOCUMENTS		N
G.3.1	CATEGORY APG ME EQUIPMENT prominently marked, with a green-coloured band ≥ 2 cm wide with letters "APG" according to symbol 23 in Table D.1 :	See copies of Marking Labels	N
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case		N
	When above marking not possible, relevant information included in instructions for use ....:		N
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N
G.3.2	CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle ≥ 2 cm in diameter, with characters "AP" according to symbol 22 in Table D.1 ....:	See copies of Marking Labels	N
	Marking is as large as possible for the particular case		N
	When above marking not possible, the relevant information included in instructions for use ....:		N
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N

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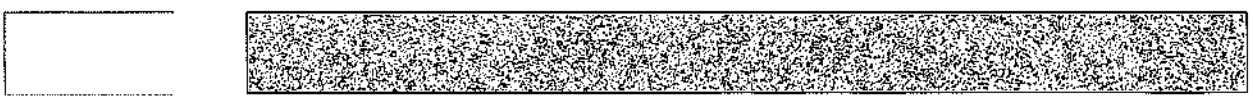
Clause	Requirement + Test	Result - Remark	Verdict
G.3.3	The marking according to G.3.1 and G.3.2 placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts, and not repeated on detachable parts that can only be used with the marked EQUIPMENT		N
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts		N
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG		N
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT		N
G.4.1	a) CREEPAGE and CLEARANCES between points of POWER SUPPLY CORD connection are according to Table 12 for one MEANS OF PATIENT PROTECTION		N
	b) Connections, except those in circuits described in G.5.3 and G.6.3, protected against accidental disconnection in NORMAL USE or connection and disconnection can be performed only with a TOOL		N
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD, except when circuit complied with G.5.3 and G.6.3		N
G.4.2	Construction details		N
	a) Opening of an ENCLOSURE providing protection against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL		N
	b) ENCLOSURE complies with requirements to minimize arcing and sparking due to penetration of foreign objects.....:	See appended Table 8.10	N
	– no openings on top covers of ENCLOSURE, except for openings for controls covered by control knobs		N
	– openings in side-covers prevented penetration of a solid cylindrical test rod of 4 mm in diameter applied in all possible directions without appreciable force		N
	– openings in base plates prevented penetration of a solid cylindrical test rod of 12 mm in diameter applied in all directions without appreciable force		N
	c) Short circuiting conductor(s) to a conductive part without presence of explosive gasses where insulation may contact a part containing a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE, ignitable gases alone, or oxygen, did not result in loss of integrity of the part, an unacceptable temperature, or any HAZARDOUS SITUATION other HAZARD		N



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Clause	Requirement + Test	Result - Remark	Verdict
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures		N
	– Use of antistatic materials with a limited electrical resistance as specified in G.4.3 b) ....:	See appended Table 8.10	N
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor of medical room		N
	b) Electrical resistance limits of aesthetic tubing, mattresses and pads, castor tires, and other antistatic material complied with ISO 2882 based on measurements according to ISO 1853, ISO 2878 and ISO 23529 ....:		N
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5		N
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components		N
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5 (inclusive)		N
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5..................:		N
G.5.2	ME EQUIPMENT, its parts, and components in contact with gas mixtures in NORMAL USE and CONDITIONS not producing sparks and not resulting in surface temperatures above 150 ℃ in case of restricted or 200 ℃ in case of unrestricted vertic al air circulation measured at 25 ℃ comply with G.5.1 ....:	See appended Tables 11.1.1, 11.1.2.1, 11.1.2.2, & 11.2.2.1	N
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:		N
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1 ....:	U_{max} = ____V U_{zR} = ____ V I_{zR} = ____A	N
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ....:	U_{max} = ____V U_c = ____V C_{max} = ____μF	N

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Clause	Requirement + Test	Result - Remark	Verdict
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 .....:	I_{max} = ____A I_{zR} = ____A U_{zR} = ____V	N
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3.....:	I_{max} = ____A I_{zL} = ____A L_{max} = ____mH	N
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1		N
	No extrapolation made for voltages above 42 V		N
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2		N
	No extrapolation made for voltages above 242V		N
	U_{max}, additionally, determined using actual resistance R when the equivalent resistance R was less than 8000 Ω		N
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3		N
	No extrapolation made for inductances larger than 900 mH		N
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open, taking into consideration MAINS VOLTAGE variations in 4.10		N
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed, taking into consideration MAINS VOLTAGE variations required in 4.10		N
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks		N
	– Peak value considered when a.c. supplied		N
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit.....:		N
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max} , and C_{max} determined with application of Figs G.1-G.3 .....:	See appended Tables 11.1.1, 11.1.2.1, & 11.1.2.2	N
	Alternatively, compliance was verified by examination of design data .....:		N
G.5.4	External ventilation with internal overpressure		N

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:		N
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR that might have penetrated into ENCLOSURE of ME EQUIPMENT or part removed by ventilation before EQUIPMENT energized, and penetration of such mixtures during operation was prevented by maintenance of overpressure by means of air without flammable gases, or by physiologically acceptable inert gas (e.g., nitrogen)		N
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa).....:		N
	Overpressure maintained at the site of potential ignition even when air or inert gas could escape through openings in ENCLOSURE necessary for normal operation of ME EQUIPMENT or its parts		N
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE so that the displaced volume of air or inert gas was at least five times the volume of ENCLOSURE		N
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present		N
	c) Ignition sources de-energized automatically by means used where G.4 does not apply, or complied with G.5 when during operation overpressure dropped below 50 Pa (Pa) .....:		N
	d) External surface of ENCLOSURE in which internal overpressure was maintained did not exceed 150 ℃ in 25 ℃ ambient under NORMAL USE and CONDITION (℃) .....:		N
G.5.5	ENCLOSURES with restricted breathing		N
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:		N
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing when it was surrounded by a FLAMMABLE AESTHETIC MIXTURE WITH AIR of a high concentration for at least 30 min without any pressure difference inside ENCLOSURE		N
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 ℃ ± 2 ℃ and 96 h ..:	See appended Table 8.10	N

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained when the cords were stressed by bending or pulling		N
	Cords are fitted with adequate anchorages to limit stresses		N
	After the test in G.5.4 b), an internal overpressure of 400 Pa was created and 30 pulls of the value in Table G.1 applied to each flexible cord in axial direction of cord inlet and in the least favourable direction for 1 s		N
	Overpressure not reduced below 200 Pa		N
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		N
	Operating temperature of external surface of ENCLOSURE was ≤ 150 ℃ in 25 ℃ (℃)................:		N
	Steady state operating temperature of ENCLOSURE also measured (℃) ....:		N
G.6	CATEGORY APG ME EQUIPMENT, parts and components thereof		N
G.6.1	ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION		N
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test after attaining thermal steady state (max. 3 h) over a period of 10 min in a 12.2 % ± 0.4 ether by volume/oxygen mixture		N
G.6.2	Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION...:		N
G.6.3	Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS..................:		N
	a) no sparks produced and temperatures did not exceed 90 ℃, or	See Tables 11.1.1, 11.1.2.1, 11.1.2.2, 11.2.2.1, and 13.2	N
	b) a temperature limit of 90 ℃ not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U_{max} and I_{max} occurring in their circuits complied with requirements, taking C_{max} and L_{max} into consideration:	See Tables 11.1.1, 11.1.2.1, 11.1.2.2, and 13.2	N

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Clause	Requirement + Test	Result - Remark	Verdict
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 ....:	U_{max} = ____V U_{zR} = ____ V I_{zR} = ____A	N
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5 ......:	U_{max} = ____V U_c = ____V C_{max} = ____μF	N
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 ....:	I_{max} = ____A I_{zR} = ____A U_{zR} = ____V	N
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 ....:	I_{max} = ___A I_{zL} = ___A L_{max} = ___mH	N
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated		N
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10		N
	– I_{max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10		N
	– C_{max} and L_{max} are values occurring in relevant circuit		N
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω		N
	– Peak value taken into consideration when a.c. supplied		N
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ....:		N
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components		N
	Above requirement not applied to transformers complying with this standard		N
	Above requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture		N
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or		N
	Temperature measurements made in accordance with 11.1 ....:	See Tables 11.1.1, 11.1.2.1, and 11.1.2.2	N

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Clause	Requirement + Test	Result - Remark	Verdict
	- or U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6............:	U_{max} = ____V I_{max} = ____A R = ___Ω L_{max} = ____mH C_{max} = ____μF	N
	Alternatively, compliance verified by comparison with design data ....:		N
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1........:	See appended Table 8.10	N
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE		N
G.7	Test apparatus for flammable mixtures		N
	Test apparatus used was in accordance with this Clause and Fig G.7		N

ANNEX L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**		**N**
L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex covering round winding wires between 0.05 mm and 5.00 mm diameters	No such a wire used	N
L.2	Wire construction		N
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component		N
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		N
L.3	Type Test		N
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified		N
	Temperature (℃) ....:		—
	Humidity (%)...:		—
L.3.1	Dielectric strength		N
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted by preparing the sample according to IEC 60851-5:1996, Clause 4.4.1 for a twisted pair with test voltages at least twice Tables 6 & 7, but not less than below with no breakdown:		N

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Clause	Requirement + Test	Result - Remark	Verdict
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V)...:		N
	– 6000 V for REINFORCED INSULATION (V)..............:		N
L.3.2	Flexibility and adherence		N
	Sample subjected to flexibility and adherence test 8 of IEC 60851-3:1996, clause 5.1.1, using mandrel diameters of Table L.1		N
	Sample examined according to IEC 60851-3: 1997, clause 5.1.1.4, followed by dielectric test of clause 8.8.3, except test voltage applied between wire and mandrel with no breakdown		N
	Test voltage was at least the voltage in Tables 6 and 7but not less than the following:		N
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)...:		N
	– 3000 V for REINFORCED INSULATION (V)..............:		N
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa ....:		N
L.3.3	Heat Shock		N
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3, except test voltage applied between the wire and mandrel		N
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)...:		N
	– 3000 V for REINFORCED INSULATION (V)..............:		N
	Oven temperature based on Table L.2 (°C).........:		—
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm^2)..:		N
	Dielectric strength test conducted at room temperature after removal from the oven		N
L.3.4	Retention of electric strength after bending		N
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests		N
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)...:		N
	– 3000 V for REINFORCED INSULATION (V)..............:		N

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Clause	Requirement + Test	Result - Remark	Verdict
	Test voltage applied between the shot and conductor.		N
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm^2).. :		N
L.4	Tests during manufacture		N
L.4.1	Production line dielectric strength tests conducted by the manufacture according to L.4.2 and L.4.3. :	See attached manufacturer's routine testing verification	N
L.4.2	Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:		N
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V) .... :	See manufacturer's routine testing verification	N
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V) .... :	See manufacturer's routine testing verification	N
L.4.3	Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1).......... :	See manufacturer's routine testing verification	N
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:		N
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION.................................. :	See manufacturer's routine testing verification	N
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION .... :	See manufacturer's routine testing verification	N

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
3.2	See document QP- 405 Rev.3 Refer to clause 4.1	Adequate Resources in RM Procedure Documented as the following: - Top management should provide ensuring the provision of adequate resources for the risk management	P
3.2	See document QP- 405 Rev.3 Refer to clause 4.2	Assignment of qualified personnel in RM Procedure Documented as the following: - Top management should provide ensuring the assignment of qualified personnel for the risk management	P
3.2	See document QP- 405 Rev.3 Refer to clause 5.5 and 5.7	Policy for determining criteria for risk acceptability in RM Procedure Documented as the following: - Top management should define the policy for determining criteria for risk acceptability - The policy for criteria are based upon applicable national or regional regulations and relevant International Standards, and take into account available information such as the generally accepted state of the art and known stakeholder concerns	P
3.3	See document RA05-00 Rev.2 Refer to clause 8.2	Qualification of personnel in RM Plan Documented as the following: - Qualification of personnel : • Persons performing risk management tasks shall have the knowledge and experience appropriate to the tasks assigned to them • These include, where appropriate, knowledge and experience of the particular medical device (or similar medical devices) and its use, the technologies involved or risk management techniques. • Appropriate qualification records have been maintained.	P

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
3.4a	See document RA05-00 Rev.2 Refer to clause 2	Scope of the planned risk management activities in RM Plan Identified the medical device and the life-cycle phases for which each element of the plan is applicable, and described the activities for each life-cycle phases Recorded as the following: - Product : Pulse Oximeter - Model : CX130	P
3.4b	See document RA05-00 Rev.2 Refer to clause 8.4	Assignment of responsibilities and authorities in RM Plan Assigned responsibilities and authorities for each life-cycle phases.	P
3.4c	See document RA05-00 Rev.2 Refer to clause 9	Requirements for review of risk management activities in RM Plan Identified the requirements for review of risk management activities for each life-cycle phases.	P
3.4d	See document RA05-00 Rev.2 Refer to clause 11	Criteria for risk acceptability in RM Plan Identified and described as the following: - 5 levels of probabilities - 5 levels of severities - Criteria for risk acceptability : • Broadly acceptable region (A1) : Low risk, Do risk control as far as possible • Acceptable region (A2) : Moderate risk, Do risk control as far as possible • Unacceptable region (UA) : Unacceptable risk, Project cancellation or device redesign	P
3.4e	See document RA05-00 Rev.2 Refer to clause 10	Verification activities in RM Plan Identified and described the verification activities for each life-cycle phases.	P
3.5	See document RA05 Rev.2	Risk management file Provided traceability for each identified hazard to: - the risk analysis; - the risk evaluation; - the implementation and verification of the risk control measures; - the assessment of the acceptability of any residual risk(s).	P

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.1	See document RA05-01 Rev. 2 Refer to clause 6	RA Process according to ISO 14971 in RM Report Performed, recorded and additionally included as the following : - Intended use : The intended use of CX130 is detecting and measurement as below parameters to provide and help doctors for making figure out the patient's vital condition - Product : Pulse oximeter - Model : CX130 - Performed by : chamcare	P
4.2	See document RA05-01 Rev. 2 Refer to clause 7.1	Intended use and identification of characteristics related to the safety of medical device in RM Report Identified by questions from : - EN ISO 14971:2012, Annex C - IEC 60601-1:2012 - IEC 60601-1-6:2010 - ISO 80601-2-61:2007	P
4.3	See document RA05-01 Rev. 2 Refer to clause 7.2	Identification of hazards in RM Report Recorded the known or foreseeable hazards in both normal and fault condition.	P
4.4	See document RA05-01 Rev. 2 Refer to clause 7.3	Estimation of the risk for each hazardous situation in RM Report Methods used for estimating risks : FMEA Recorded as the following criteria : - 5 levels of probabilities - 5 levels of severities	P
5	See document RA05-01 Rev. 2 Refer to clause 8	Risk evaluation in RM Report - Risk : probability x Severity - Criteria for risk acceptability : • Broadly acceptable region (A1) • Acceptable region (A2) • Unacceptable region (UA)	P
6.1	See document RA05-01 Rev. 2 Refer to clause 9	Risk reduction in RM Report RM process contains: - Risk Control Option Analysis - Implementation of Risk Control Measures - Residual Risk Evaluation - Risk Benefit Analysis - Risks arising from risk control measures - Completeness of risk control	P

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2	See document RMR-130620 Rev. 0 Refer to clause 6.2	Risk control option analysis in RM Report Considered the following risk control options: - Inherent safety by design - Protective measures in the medical device itself or in the manufacturing process - Information for safety	P
6.3	See document RA05-01 Rev. 2 Refer to clause 9	Implementation of risk control measure(s) in RM Report Recorded the risk management activities each risk control measures.	P
6.4	See document RA05-01 Rev. 2 Refer to clause 9	Residual risk evaluation in RM Report Recorded the result of residual risk evaluation for each risk. Each residual risk judged to meet the criteria.	P
6.5	See document RA05-01 Rev. 2 Refer to clause 9	Risk/benefit analysis in RM Report No unacceptable risks judged to remain.	P
6.6a	See document RA05-01 Rev. 2 Refer to clause 9	Risks arising from risk control measures in RM Report No other hazards identified.	P
6.6b	See document RA05-01 Rev. 2 Refer to clause 9	Risks arising from risk control measures in RM Report No affected risks by the introduction of the risk control measures identified.	P
6.7	See document RA05-01 Rev. 2 Refer to clause 9	Completeness of risk control in RM Report Recorded the completeness of risk control as assuring of all identified hazards have been evaluated.	P
7	See document RA05-01 Rev. 2 Refer to clause 10	Evaluation of overall residual risk acceptability in RM Report Recorded as the overall residual risk judged acceptable.	P

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
8	See document RA05-01 Rev. 2 Refer to clause 11	Risk management report in RM Report Risk management report for a review of the risk management process contains: - the risk management plan has been appropriately implemented - the overall residual risk is acceptable - appropriate methods are in place to obtain relevant production and post-production information. The results of this review recorded as the risk management report and included in the risk management file. The responsibility for review assigned in the risk management plan to persons having the appropriate authority.	P
Supplementary Information: - RM Procedure : QP-405 Rev.3 - RM Plan : RA05-00 Rev.2 - RM Report : RA05-01 Rev.2			

4.3	TABLE: ESSENTIAL PERFORMANCE		P
List of ESSENTIAL PERFORMANCE functions	MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)	Remarks	
SpO2 accuracy	clause 201.4.101 of ISO 80601-2-61		
Heart rate accuracy	clause 201.4.101 of ISO 80601-2-61		
Alarm Limit	clause 201.4.101 of ISO 80601-2-61		
Battery condition alarm	clause 201.4.101 of ISO 80601-2-61		
Supplementary Information: ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.			

4.5	RM RESULTS TABLE: Equivalent Safety for ME Equipment of ME System		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No alternative means.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary Information:			

4.6	RM RESULTS TABLE: ME Equipment or system parts contacting the patient		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No such a part identified	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary Information:			

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Clause	Requirement + Test	Result - Remark	Verdict

4.7	RM RESULTS TABLE: Single Fault Condition for ME Equipment		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	1. Checks the battery operating Vdc and maximum current(Adc) both maximum control settings and component failure in output circuits including the maximum fault currents. (60601-1, 13.1) 2. Battery (+/-) polarity short circuit 3. EMC (EMI & EMS)	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard has been identified. Recorded as the following : - Emissions, deformation of enclosure or exceeding maximum temperature, - Exceeding leakage current or voltage limits - Degradation of essential performances	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following: - Severity : 4 - Probability : 2	P
Supplementary Information:			

4.8	RM RESULTS TABLE: Components of ME Equipment		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		All components, including wiring, the failure of which could result in a HAZARDOUS SITUATION is in accordance with their specified ratings. No components and wiring exception in the standard or by RISK MANAGEMENT PROCESS.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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Clause	Requirement + Test	Result - Remark	Verdict

4.8	RM RESULTS TABLE: Components of ME Equipment		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
Supplementary Information:			

4.9	RM RESULTS TABLE: Use of components with high-integrity characteristics		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	.	No components with high-integrity characteristics	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary Information:			

4.11	TABLE: Power Input				P
Operating Conditions / Ratings	Voltage (V)	Frequency (Hz)	Current (A)	Power (W or VA)	Power factor (cos φ)
Medium Alarm	8.1Vdc	-	0.20		
Medium Alarm	9.0Vdc	-	0.22		
Medium Alarm	9.9Vdc	-	0.23		
Supplementary Information:					

5.1	RM RESULTS TABLE: Type Tests		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No test according to other tests or methods.	
4.3			
4.4			
Supplementary Information:			

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Clause	Requirement + Test	Result - Remark	Verdict

5.9.2	TABLE: Determination of ACCESSIBLE parts		P
Location		Determination method (NOTE1)	Comments
MEE enclosure		Jointed test finger with a force of 30 N	No access through the opening of enclosure of MEE to hazardous circuit

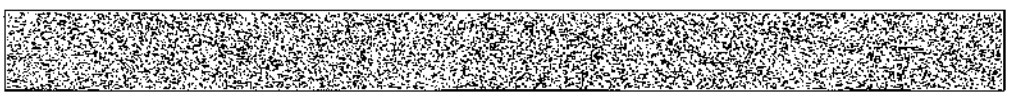
Supplementary information:
NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.

7.1.2	TABLE: Legibility of Marking		P
Markings tested		Ambient Illuminance (lx)	Remarks
Outside Markings (Clause 7.2) ..... :		110	Clearly legible
Inside Markings (Clause 7.3) ..... :		100	Clearly legible
Controls & Instruments (Clause 7.4)..... :		110	Clearly legible
Safety Signs (Clause 7.5) ..... :		110	Clearly legible
Symbols (Clause 7.6)..... :		110	Clearly legible

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

7.1.3	TABLE: Durability of marking test		P
Characteristics of the Marking Label tested:			Remarks
Material of Marking Label ..... :		Polycarbonate with adhesive	
Ink/other printing material or process ..... :		Ink	
Material (composition) of Warning Label ..... :		Polycarbonate with adhesive	
Ink/other printing material or process ..... :		Ink	
Other ..... :			

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



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Clause	Requirement + Test	Result - Remark	Verdict

7.2.2	RM RESULTS TABLE: Identification		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	Complies and addressed in "Risk management report"	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	Complies and addressed in "Risk management report"	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	Complies and addressed in "Risk management report"	P
5	See document RA05-02 Refer to clause 5 and appended table	Complies and addressed in "Risk management report"	P
6.4	See document RA05-02 Refer to clause 6.4 and appended table	Complies and addressed in "Risk management report"	P
Supplementary information:			

7.2.13	RM RESULTS TABLE: Physiological effects (safety signs and warning)		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	The part has been identified. SpO2 probe contains the silicone	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard of the physiological effects has been identified. Recorded as the following : - Biological hazard	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following : - Severity : 3 - Probability : 2	P
5	See document RA05-02 Refer to clause 5 and appended table	The risk has been evaluated. Recorded as the following : - Risk : A2 (acceptable)	P

7.2.13	RM RESULTS TABLE: Physiological effects (safety signs and warning)		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	See document RA05-02 Refer to clause 6.3 and appended table	The risk control measure(s) has been implemented. Recorded as the following : 1. ISO 10993-5 and 10993-10 certified probe is implemented with CX-130 2. "QP-803" inspection and test procedure "QP-709" Identification and traceability control procedure "QP-705" material and product control procedure	P
Supplementary information:			

7.2.17	RM RESULTS TABLE: Protective packaging		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No special handling for unpacking.	
4.3			
4.4			
5			
6.3			
6.4			
Supplementary information:			

7.3.3	RM RESULTS TABLE: Batteries		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	The part has been identified. Recorded as the following : Li-ion rechargeable battery and general AA type primary batteries are used.	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard of the physiological effects has been identified. Recorded as the following : - Incorrect connection	P

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Clause	Requirement + Test	Result - Remark	Verdict

7.3.3	RM RESULTS TABLE: Batteries		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following : - Severity : 3 - Probability : 2	P
5	See document RA05-02 Refer to clause 5 and appended table	The risk has been evaluated. Recorded as the following : - Risk : A2 (acceptable)	P
6.3	See document RA05-02 Refer to clause 6.3 and appended table	The risk control measure(s) has been implemented. Recorded as the following : - Special style connector is implemented on a rechargeable battery. And the polarity of the general AA type alkaline battery is marked on the battery compartment. - Warning statement that the battery doesn't replaceable by the operator is described in the instructions for use.	P
Supplementary information:			

7.3.7	RM RESULTS TABLE: Supply terminals		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		Battery and/or specified 9Vdc power adaptor cable is used for device operation.	N
Supplementary information:			

7.4.2	RM RESULTS TABLE: Control devices		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	The safety sign has been identified. Recorded as the following : - It has an operator changeable alarm limits setting.	P

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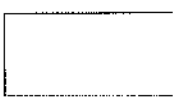
Clause	Requirement + Test	Result - Remark	Verdict

7.4.2	RM RESULTS TABLE: Control devices		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard has been identified. Recorded as the following : - use errors	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following: - Severity : 2 - Probability : 2	P
5	See document RA05-02 Refer to clause 5 and appended table	The risk has been evaluated. Recorded as the following : - Risk : A1 (Acceptable)	P
6.2	See document RA05-02 Refer to clause 6.2 and appended table	The risk control measure has been identified. Recorded as the following : - alarm limits are needed to be displayed continuously for the user's recognition. - alarm signal is needed to be provided in a device. - related information should be described in the instructions for use.	P
6.3	See document RA05-02 Refer to clause 6.3 and appended table	The risk control measure(s) has been implemented. Recorded as the following : - Alarm limits are implemented to be displayed continuously on a display with a relevant physiological parameter. - Physiological and technical alarm signal are provided by a device. - Related information is described in the instructions for use.	P
Supplementary information:			



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Clause	Requirement + Test	Result - Remark	Verdict

7.5	RM RESULTS TABLE: Safety signs		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	The safety sign has been identified. Recorded as the following : refer to ISO 60601-2-61, clause 201.7.2.3 : Consult accompanying document : mandatory action(follow instructions for use, ISO 7010-M002)	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard of safety signs has been identified. Recorded as the following : Incomplete labelling	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following: - Severity : 2 - Probability : 2	P
5	See document RA05-02 Refer to clause 5 and appended table	The risk has been evaluated. Recorded as the following : - Risk : A1 (Acceptable)	P
6.3	See document RA05-02 Refer to clause 6.3 and appended table	The risk control measure(s) has been implemented. Recorded as the following : - ISO 201.7.2.3 requirement is implemented in the labelling design - ISO 7010-M002 safety sign is implemented on labelling	P
Supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

7.9.2.4	RM RESULTS TABLE: Electrical power source		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	Rechargeable Lithium Ion Cell and general primary AA type alkaline batteries are used. Intended use : Charmcare Pulse Oximeter CX130 is portable device indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients via finger in hospitals, medical facilities, and sub-acute environments. CX130 is intended for spot-checking and / or continuous monitoring of patients, the sensor of device is reusable	N
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard of safety signs has been identified. Recorded as the following : leakage of battery	N
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following: - Severity : 3 - Probability : 2	N
5	See document RA05-02 Refer to clause 5 and appended table	The risk has been evaluated. Recorded as the following : - Risk : A2 (Acceptable)	N
6.3	See document RA05-02 Refer to clause 6.3 and appended table	The risk control measure(s) has been implemented. Recorded as the following : - Li-Ion rechargeable battery that pass the requirements of the European council directive 2006/66/EC is used in the device - Medium alarm priority auditory alarm signal is provided to indicate the "low battery status. - Warning statement to remove the battery if the MEE is not likely to be used for some time is described in the instructions for use.	N
Supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

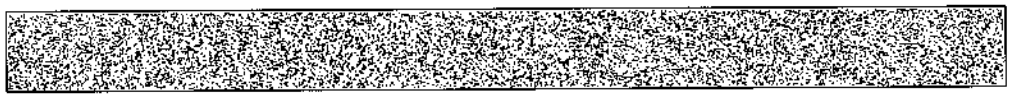
7.9.3.2	RM RESULTS TABLE: Replacement of fuses, power supply cords, other parts		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		Only the trained service personnel of the manufacturer will carry out the repair service.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

8.1 b	RM RESULTS TABLE: Fundamental rule of protection against electric shock - accidental detachment of conductors and connectors		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	See document RA05-02 Refer to clause 4.3 and appended table	Rechargeable battery is connected on a PCB with (red/black) wires and connector.	P
Supplementary information:			

8.4.2	TABLE: TABLE: Working Voltage / Power Measurement					P
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)	
Battery Component		3.7dc	-	11.1W		P
External adaptor		9Vdc	-	13.5W		P

Supplementary Information:

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



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Clause	Requirement + Test	Result - Remark	Verdict

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

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

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Clause	Requirement + Test	Result - Remark	Verdict

8.5.2.2	RM RESULTS TABLE: Type B applied parts		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		BF type applied part	
4.3			
4.4			
5			
Supplementary information:			

8.5.2.3	RM RESULTS TABLE: PATIENT Leads		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		It has only one SpO2 probe with insulating material covered on lighting parts. There is no conductive part to contact the patient.	
4.3			
4.4			
5			
Supplementary information:			

8.5.5.1a	TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies				N
Test Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
Supplementary information:					

8.5.5.1b	TABLE: defibrillation-proof applied parts – verification of recovery time			N
Applied part with test voltage	Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks
Supplementary information:				

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Clause	Requirement + Test	Result - Remark	Verdict

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

8.6.3	RM RESULTS TABLE: Protective earthing of moving parts		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving parts used in the device.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

8.6.4	TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS				N
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)

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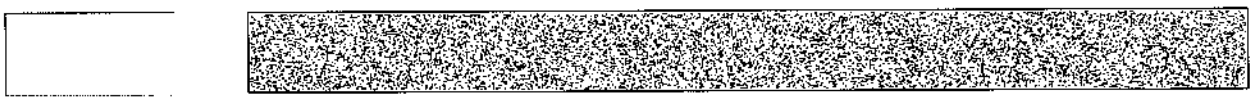
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 mΩME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part - Limit 100 mΩ

ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a PROTECTIVELY EARTHED part - Limit 200 mΩ

ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part - Limit 200 mΩ



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Clause	Requirement + Test	Result - Remark	Verdict

8.7	TABLE: leakage current				P
Type of leakage current and test condition (including single faults)		Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks
Fig. 13 - Earth Leakage (ER)		—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
Fig. 14 - Touch Current (TC)		—	—	—	Maximum allowed values: 100 μA NC; 500 μA SFC
NC; S1=1; S5=1;		9 Vdc		0/0	
NC; S1=1; S5=0;		9 Vdc		0/0	
SFC; S1=0; S5=1;		9 Vdc		0/0	
SFC; S1=0; S5=0;		9 Vdc		0/0	
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)
NC; S1=1; S5=1;		9 Vdc		0/0	
NC; S1=1; S5=0;		9 Vdc		0/0	
SFC; S1=0; S5=1;		9 Vdc		0/0	
SFC; S1=0; S5=0;		9 Vdc		0/0	
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
SFC;S5=1;S9=1		9 Vdc		0/0	
SFC;S5=1;S9=0		9 Vdc		0/0	
SFC;S5=0;S9=1		9 Vdc		0/0	
SFC;S5=0;S9=0		9 Vdc		0/0	
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)

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Clause	Requirement + Test	Result - Remark	Verdict

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

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Clause	Requirement + Test	Result - Remark	Verdict

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

Supplementary information:

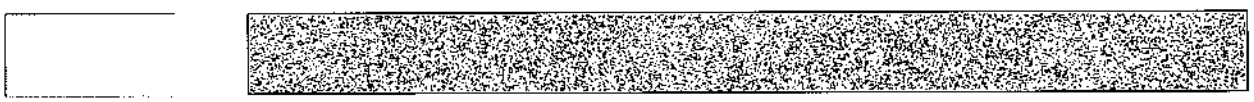
Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

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

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

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

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



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

8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				P
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1]	Dielectric breakdown after 1 minute Yes/No[2]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
A	2 MOOP	-	9	2000	No
			9	-	-
B	2 MOPP	-	9	1000	No
C	2 MOPP		5	1000	No
	1MOPP	250		1500	No

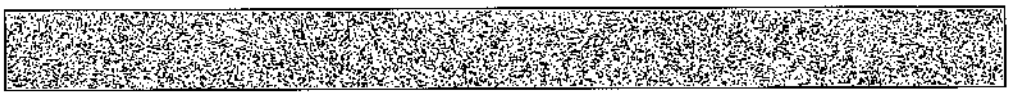
Supplementary information:

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

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

Part/material	Test temperature (°C)	Impression diameter (mm)
Enclosure/External insulating parts	75	1.1
Insulating material supporting un-insulated Mains Parts		

Supplementary information:



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

8.8.4.1	RM RESULTS TABLE: Mechanical strength and resistance to heat		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	The safety sign has been identified. Recorded as the following : - plastic enclosure is used as 2 MOOP to limit the leakage currents.	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard has been identified. Recorded as the following : - Leakage current. - High temperature	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following: - Severity : 2 - Probability : 2	P
5	See document RA05-02 Refer to clause 5 and appended table	The risk has been evaluated. Recorded as the following : - Risk : A1 (Acceptable)	P
6.2	See document RA05-02 Refer to clause 6.2 and appended table	The risk control measure has been identified. Recorded as the following : - Enclosure thermal specification have to be considered the internal working temperature	P
6.3	See document RA05-02 Refer to clause 6.3 and appended table	The risk control measure(s) has been implemented. Recorded as the following : - Certified enclosure material is implemented in the design	P
6.4	See document RA05-02 Refer to clause 6.4 and appended table	The residual risk has been evaluated. Recorded as the following : - Severity : 2 - Probability : 1 - Risk: A1(Broadly acceptable)	P
6.5		Not deemed necessary.	N
Supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

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

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

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

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Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.2	Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts			N
Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No	
1	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			
2	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			
3	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			
4	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 releva nt part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature mea sured by an embedded thermocouple. Used gradual transition from one temperature to another.

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Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.4	Table: Thermal cycling tests on one sample of cemented joint (see 8.9.3.3)			N
Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No	
1	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			
2	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			
3	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			
4	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 releva nt part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature mea sured by an embedded thermocouple. Used gradual transition from one temperature to another.

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

8.10	TABLE: List of critical components				P
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity [1]
Battery Pack (Rechargeable - Li-ion battery)	LG Chem	ICP523450D2	Rated 3.7 V, approximately 2360 mAh	IEC62133 UL 1642	UL
Connector	Molex incorporate ted	53398	Rated 125 V, 1.0 A Rated minimum V-0 flame rating.	UL 94	UL
Enclosure (Polymeric)	Cheil industries inc chemical div	VH-0810(+)	2.0 mm thick. Rated minimum V-1 flame rating.	IEC 60695-11-10 ANSI/UL 94	UL
PCB(PWB)	Ha do electronics	Type 2, 3	Rated minimum V-0 flame rating.	UL 796 IEC 60603-2 UL 94	UL
SpO2 Probe (Silicon)	Mednis co.ltd	LD-AS250T	Dielectric strength : 4000 Vrms	IEC 60601-1	Tested in equipment
Chip Fuses,	COOPER BUSSMANN INC	BA100-5 (3216FF)	Rated 32V, 5A Fast acting	UL248	UL

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

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

8.10.1	RM RESULTS TABLE: Fixing of components		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		The component legs that hand-soldered to the PCB match those are soldered by dedicated equipment to automatically by cutting the legs so those legs doesn't likely to be shorted on other electrical part.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

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

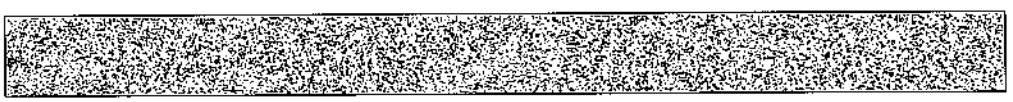
8.11.3.6	TABLE: Cord guard		N
Cord under test	Test mass	Measured curvature	Remarks
Supplementary information:			

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

9.2.1	RM RESULTS TABLE: HAZARDS associated with moving parts - General		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No moving part used	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

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

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



9.2.4	RM RESULTS TABLE: Emergency stopping devices		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No emergency stopping devices used	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
6.6			

9.2.5	RM RESULTS TABLE: Release of patient		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No part relevant restraint to patient	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

9.4.2.1	TABLE: Instability—overbalance in transport position	P
ME EQUIPMENT preparation	Test Condition (transport position)	Remarks
Transport Position	10°from the normal position / each direction	No overbalance
Supplementary information:		

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

9.4.2.2	TABLE: Instability—overbalance excluding transport position		P
ME EQUIPMENT preparation	Test Condition (excluding transport position) Test either 5 °incline and verify Warning marking or 10 °incline)	Remarks	
Excluding Transport Position	5°from the normal pos ition / each direction	No overbalance	
Supplementary information:			

9.4.2.3	TABLE: Instability—overbalance from horizontal and vertical forces		P
ME EQUIPMENT preparation	Test Condition (force used, direction of force, weight of equipment, location of force	Remarks	
Horizontal Forces	800N, Horizontal, 0.27Kg, MEE	No overbalance	
Vertical Force	800N, Horizontal, 0.27Kg, MEE	No overbalance	
Supplementary information:			

9.4.2.4.2	TABLE: Castors and wheels – Force for propulsion		N
ME EQUIPMENT preparation	Test Condition (force location and height)	Remarks	
	Not mobile equipment		
Supplementary information:			

9.4.2.4.3	TABLE: Castors and wheels – Movement over a threshold		N
ME EQUIPMENT preparation	Test Condition (speed of movement)	Remarks	
	Not mobile equipment		
Supplementary information:			

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

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

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

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

9.5.1	RM RESULTS TABLE: Protective means		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No expelled parts used	
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

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

9.6.1	RM RESULTS TABLE: Acoustic energy - General		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No acoustic energy emitting device	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

9.6.2.2	RM RESULTS TABLE: Infrasound and ultrasound energy		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No infrasound or ultrasound energy.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

9.7.2	RM RESULTS TABLE: Pneumatic and hydraulic parts		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No pneumatic and hydraulic parts used	
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

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

9.7.7	RM RESULTS TABLE: Pressure-relief device		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No parts associated with a pressure	
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

9.8.1	RM RESULTS TABLE: Hazards associated with support systems - General		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

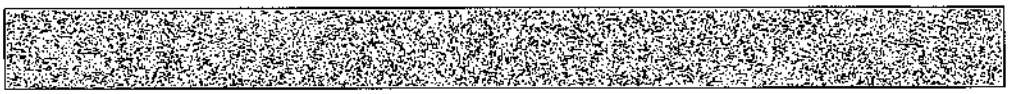
IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.8.2	RM RESULTS TABLE: Tensile safety factor		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No parts associated with support systems	
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

9.8.3.1	RM RESULTS TABLE: Strength of patient or operator support or suspension systems - General		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No parts associated with support systems	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

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

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



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Clause	Requirement + Test	Result - Remark	Verdict

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

9.8.5	RM RESULTS TABLE: Systems without mechanical protective devices		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3		No parts associated with support systems	
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

10.1.1	TABLE: Measurement of X - radiation		N
Maximum allowable radiation pA/kg (µSv/h) (mR/h)		36 (5 µSv/h) (0.5 mR/h)	
Surface area under test Surface no./ Description[1]		Measured Radiation, pA/kg (µSv/h) (mR/h)	Remarks
1/ /			
2/ /			
3/ /			
4/ /			
5/ /			
6/ /			
7/ /			
8/ /			
9/ /			
10/ /			
Supplementary information: [1] Measurements made at a distance of 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access			

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Clause	Requirement + Test	Result - Remark	Verdict

10.1.2	RM RESULTS TABLE: ME equipment intended to produce diagnostic or therapeutic X-radiation		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No parts associated with X-radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

10.2	RM RESULTS TABLE: Alpha, beta, gamma, neutron & other particle radiation		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No part associated with alpha, beta, gamma, neutron or other particle radiation.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

10.5	RM RESULTS TABLE: Other visible electromagnetic radiation		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		SpO2 sensor uses light emitting diode (LED).	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

10.6	RM RESULTS TABLE: RISK associated with infrared radiation other than emitted by lasers and LEDS		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		SpO2 sensor uses light emitting diode (LED).	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

10.7	RM RESULTS TABLE: RISK associated with ultraviolet radiation other than emitted by lasers and LEDS		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No part associated with ultraviolet radiation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

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

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				P
Model No. ...:		CX-130			
Test ambient (°C) ...:		23.3			
Test supply voltage/frequency (V/Hz)[4] ...:		9.9Vdc			
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
CX-130	CH1	Main IC	105	50.2	P
CX-130	CH2	Main Board	105	50.4	P
CX-130	CH3	SpO2 Board	105	45.9	P
CX-130	CH4	Battery	48	39.4	P
CX-130	CH5	Display	48	41.2	P
CX-130	CH6	Applied Part	48	35.3	P
CX-130	CH7	Enclosure	48	38.7	P
CX-130	CH8	Swtich	48	37.8	P

Supplementary information:
[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

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

11.1.1	RM RESULTS TABLE: Maximum temperature during normal use (Table 23 or 24)		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No part that can contact more than 10% of the surface area operator or patient's body or 10% of the surface area of the patient's or operator's head.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			

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Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	RM RESULTS TABLE: Maximum temperature during normal use (Table 23 or 24)		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.5			
Supplementary information:			

11.1.2.1	RM RESULTS TABLE: Applied parts intended to supply heat to patient		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		SpO2 is not intended to supply heat to a patient	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

11.1.2.2	RM RESULTS TABLE: Applied parts not intended to supply heat to patient		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No applied parts that exceed 41℃ or cool below ambient temperature.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

11.1.3	TABLE: Temperature of windings by change-of-resistance method						N
Temperature T of winding:	t_1 (℃)	R_1 (Ω)	t_2 (℃)	R_2 (Ω)	T (°C)	Allowed T_{max} (°C)	Insulation class
Supplementary information:							

11.1.3	RM RESULTS TABLE: Measurements		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		- The probability of occurrence of contact: every measurement need to be contact the patient. - Duration of contact: 8 hour. - Refer to ISO 80601-2-61, clause 201.11 Test method of measuring the skin temperature described in the technical description : - Temperature sensor: near 0.5mm dimension characteristics (e.g. the bead of a thermocouple welded from 0.25mm wire) or smaller than 0.5mm. - Measurement errors : ±0.3℃ - Measurement duration : 8 hours - Measurement point: a midway point on the probe between the two LED chips.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

11.2.2.1	RM RESULTS TABLE: Risk of fire in an oxygen rich environment		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No MEE used in an oxygen rich environment.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

11.2.2.1	TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source		N
Areas where sparking might cause ignition:			Remarks
1.			
2.			
3.			
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) ....:			

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Clause	Requirement + Test	Result - Remark	Verdict

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.		

11.3	RM RESULTS TABLE: Constructional requirements for fire enclosures of ME equipment		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		The supply circuit cannot supply 15 W so the circuit is considered to limit power dissipation to less than 15W. see below test data : - Battery charging : 9.0Vdc, 0.5A - Component failure in the device : - LCD component(FPCB cable short) : 9.0Vdc, 0.4A - Li-ion Battery(3.7Vdc_2360mAh) cable short : 9.0Vdc, 0.2A - Coin battery holder short : 9.0Vdc, 0.46A	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

11.5	RM RESULTS TABLE: ME equipment and ME systems intended for use in conjunction with flammable agents		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No MEE used in conjunction with flammable agents.	
4.3			
4.4			
5			

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Clause	Requirement + Test	Result - Remark	Verdict

11.5	RM RESULTS TABLE: ME equipment and ME systems intended for use in conjunction with flammable agents		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

11.6.1	TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances		N
Clause / Test Name	Test Condition	Part under test	Remarks
Supplementary information:			

11.6.3	RM RESULTS TABLE: Spillage on ME equipment and ME system		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		It requires IPX1 requirement in ISO 80601-2-61 clause 201.11.6.5.101. refer to also 11.6.5	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

11.6.5	RM RESULTS TABLE: Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	The part has been identified. Recorded as the following : ISO 80601-2-61, clause 201.11.6.5.101 requires IPX1 requirement not intended for use during professional transport of a patient outside a professional healthcare facility.	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard has been identified. Recorded as the following : - ingress of water	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following : - Severity : 3 - Probability : 2	P
5	See document RA05-02 Refer to clause 5 and appended table	The risk has been evaluated. Recorded as the following : - Risk : A2 (Acceptable)	P
Supplementary information:			

11.6.7	RM RESULTS TABLE: Sterilization of ME equipment and ME systems		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

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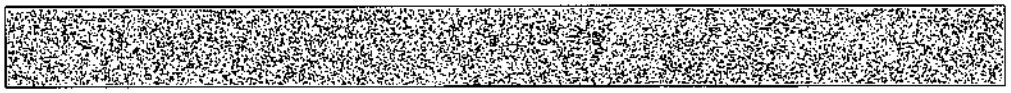
Clause	Requirement + Test	Result - Remark	Verdict

11.6.8	RM RESULTS TABLE: Compatibility with substances used		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No substances used with the MEE.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

12.1	RM RESULTS TABLE: Accuracy of controls and equipment		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	The part has been identified. Recorded as the following : ISO 80601-2-61, clause 201.12.1 requires specific SpO2 accuracy and pulse rate accuracy of pulse oximeter equipment.	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard has been identified. Recorded as the following : - incorrect funcitonality	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following : - Severity : 3 - Probability : 3	P
5	See document RA05-02 Refer to clause 5 and appended table	The risk has been evaluated. Recorded as the following : - Risk : A2 (acceptable)	P

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

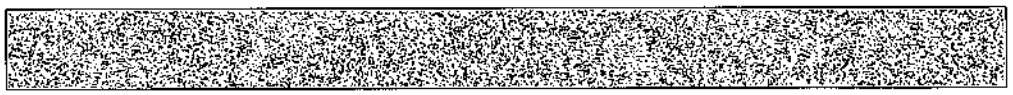
12.1	RM RESULTS TABLE: Accuracy of controls and equipment		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2	See document RA05-02 Refer to clause 6.2 and appended table	The risk control measure has been identified. Recorded as the following : - SpO2 values are needed to be compared with the values of the calibrated simulator - Hear rate values are needed to be compared with the values of the calibrated simulator Alarm limit algorism have to include the SpO2, heart rate and battery conditions in a software requirements. It is needed to compare the result values between the SpO2 meter and Hemoximeter through the clinical trials.	P
6.3	See document RA05-02 Refer to clause 6.3 and appended table	The risk control measure(s) has been implemented. Recorded as the following : - SpO2 algorism is corrected after comparison with the result data from the calibrated SpO2 simulator. - Heat rate of the device is corrected after comparison with the result data from the calibrated SpO2 simulator. - Alarm Limit algorism is implemented in software requirements to be activated at a limit values of the SpO2 and heart rate.	P
6.4	See document RA05-02 Refer to clause 6.4 and appended table	The residual risk has been evaluated. Recorded as the following : - Severity : 2 - Probability : 2 - Risk: A1 (Broadly acceptable)	P
6.5		Not deemed necessary.	N
Supplementary information:			



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

12.4.1	RM RESULTS TABLE: Intentional exceeding of safety limits		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		It doesn't have functions to provide the energy intentionally exceeding of the safety limits for the intended clinical purpose	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

12.4.2	RM RESULTS TABLE: Indication of parameters relevant to safety		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	The part has been identified. Recorded as the following : ISO 80601-2-61, clause 201.12.4.101, "data update period" and 201.12.4.102 "signal inadequacy" is need to be considered	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard has been identified. Recorded as the following : - Incorrect display	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following : - Severity : 3 - Probability : 3	P
5	See document RA05-02 Refer to clause 5 and appended table	The risk has been evaluated. Recorded as the following : - Risk : A2 (acceptable)	P



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

12.4.2	RM RESULTS TABLE: Indication of parameters relevant to safety		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2	See document RA05-02 Refer to clause 6.2 and appended table	The risk control measure has been identified. Recorded as the following : - Data update period : 10s Device provide alarm signal as below: - Unable to determine pulse rate or SpO2, Communication Error and Clock settings lost.	P
6.3	See document RA05-02 Refer to clause 6.3 and appended table	The risk control measure(s) has been implemented. Recorded as the following : - Data update period : 10s Device provide alarm signal as below: - Unable to determine pulse rate or SpO2 : Low auditory alarm and visual signal "Check Probe" - Communication Error : high auditory alarm and visual signal "SpO2 fault" - Clock settings lost : Low auditory alarm and visual signal "CLOCK" - related information is described in the instructions for use	P
6.4	See document RA05-02 Refer to clause 6.4 and appended table	The residual risk has been evaluated. Recorded as the following : - Severity : 2 - Probability : 2 - Risk: A1 (Broadly acceptable)	P
6.5		Not deemed necessary.	N
Supplementary information:			

12.4.3	RM RESULTS TABLE: Accidental selection of excessive output values		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		It doesn't provide any output features for therapeutic purpose.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			

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Clause	Requirement + Test	Result - Remark	Verdict

12.4.3	RM RESULTS TABLE: Accidental selection of excessive output values		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.5			
Supplementary information:			

12.4.4	RM RESULTS TABLE: Incorrect output		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		It has only monitoring purpose features such as SpO2 saturation and pulse rate of the patient.	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

12.4.5.3	RM RESULTS TABLE: Radiotherapy equipment		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		It doesn't intended for radiotherapy purpose	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

12.4.5.4	RM RESULTS TABLE: Other ME equipment producing diagnostic or therapeutic radiation		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		It has only monitoring purpose features such as SpO2 saturation and pulse rate of the patient.	
4.3			
4.4			
5			
6.2			

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Clause	Requirement + Test	Result - Remark	Verdict

12.4.5.4	RM RESULTS TABLE: Other ME equipment producing diagnostic or therapeutic radiation		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3			
6.4			
6.5			
Supplementary information:			

12.4.6	RM RESULTS TABLE: Diagnostic or therapeutic acoustic pressure		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		It doesn't have acoustic pressure output	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

13.1.2	TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances			N
Power dissipated less than (W) ....:	15			
Energy dissipated less than (J) ....:	900			
Part or component tested	Measured power dissipated (W)	Calculated energy dissipated (J)	SINGLE FAULT CONDITIONS waived (Yes/No)	Remarks
Supplementary information:				

13.2	TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive		P
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2	Electrical SINGLE FAULT CONDITIONS per Clause 8.1:	—	—
	DC power line open	Operated by internally power	No
13.2.3	Overheating of transformers per Clause 15.5:	—	—
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—
13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	—	—
	Single ventilation fans locked consecutively		
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls		
	Simulated blocking of filters		
	Flow of a cooling agent interrupted		
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—

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Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	—	—
		V measured =	
		V measured =	
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:	—	—
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or upper limit of RATED voltage range for specified time:		
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices		
	Temperatures measured as specified in 11.1.3 d)		
	Temperatures did not exceed limits of Table 26		
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	—	—
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	—	—
	Clause 9 and 15.3	No hazardous situation observed	No

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

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Clause	Requirement + Test	Result - Remark	Verdict

13.2.6	RM RESULTS TABLE: Leakage of liquid		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		It doesn't have any liquid in the device for normal operation	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

14.1	RM RESULTS TABLE: Programmable electrical medical systems - General		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
Supplementary information:			

14.6.1	RM RESULTS TABLE: Identification of known and foreseeable hazards		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	PEMS Software Risk Management (Doc#. SRM05)	Section 6 and 14	P
Supplementary information:			

14.6.2	RM RESULTS TABLE: Risk control		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.1	PEMS Software Risk Management (Doc#. SRM05)	Section 9	P
Supplementary information:			

14.7	RM RESULTS TABLE: Requirement specification		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	PEMS Software Risk Management (Doc#. SRM05)	Section 9	P
Supplementary information:			

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

14.8	RM RESULTS TABLE: Architecture		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	PEMS Software Risk Management (Doc#. SRM05)	Section 9	P
Supplementary information:			

14.10	RM RESULTS TABLE: Verification		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	PEMS Software Risk Management (Doc#. SRM05)	Section 9	P
Supplementary information:			

14.11	RM RESULTS TABLE: PEMS validation		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3	PEMS Software Risk Management (Doc#. SRM05)	Section 9	P
Supplementary information:			

14.13	RM RESULTS TABLE: PEMS intended to be incorporated into an IT-NETWORK		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
Supplementary information:			

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

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

15.4.1	RM RESULTS TABLE: Construction of connectors		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	The part has been identified. Recorded as the following : SpO2 probe cable is used	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard has been identified. Recorded as the following : - leakage current	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following : - Severity : 2 - Probability : 2	P
5	See document RA05-02 Refer to clause 5 and appended table	The risk has been evaluated. Recorded as the following : - Risk : A1 (broadly acceptable)	P

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

15.4.1	RM RESULTS TABLE: Construction of connectors		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2	See document RA05-02 Refer to clause 6.2 and appended table	The risk control measure has been identified. Recorded as the following : - Special type of connector is needed for SpO2 connector - type BF applied part symbol is needed to be marked adjacent to the connector	P
6.3	See document RA05-02 Refer to clause 6.3 and appended table	The risk control measure(s) has been implemented. Recorded as the following : - special type connector is implemented into the device. - Type BF applied part symbol is marked adjacent to the connector.	P
6.4	See document RA05-02 Refer to clause 6.4 and appended table	The residual risk has been evaluated. Recorded as the following : - Severity : 1 - Probability : 2 - Risk: A1 (Broadly acceptable)	P
6.5			
Supplementary information:			

15.4.2.1 a	RM RESULTS TABLE: THERMAL CUT-OUTS and OVER-CURRENT RELEASES		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No automatic resetting components used	
4.3			
4.4			
5			
Supplementary information:			

15.4.2.1 c	RM RESULTS TABLE: Independent non-SELF-RESETTING THERMAL CUT-OUT		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No thermostat used in the device	
4.3			
4.4			
Supplementary information:			

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

15.4.2.1 d	RM RESULTS TABLE: Loss of function of ME EQUIPMENT		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No thermal cut-out is used	
4.3			
4.4			
Supplementary information:			

15.4.2.1 h	RM RESULTS TABLE: ME EQUIPMENT with tubular heating elements		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No tubular heating elements	
4.3			
4.4			
Supplementary information:			

15.4.3.1	RM RESULTS TABLE: Housing		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	The part has been identified. Recorded as the following : Rechargeable Li-ion battery is used. - 3.7Vdcc, 2360 mAh - capacity : 8 hours, - charging time : 6 hours	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard has been identified. Recorded as the following : - hazardous gases	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following : - Severity : 3 - Probability : 4	P
Supplementary information:			

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

15.4.3.2	RM RESULTS TABLE: Connection		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	The part has been identified. Recorded as the following : Model A : AA type battery *4ea are used Model B : Li-ion 3.7Vdc 2360 mAh battery pack is used	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard has been identified. Recorded as the following : - battery wrong connection	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following : - Severity : 3 - Probability : 4	P
Supplementary information:			

15.4.3.3	RM RESULTS TABLE: Protection against overcharging		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	The part has been identified. Recorded as the following : Li-ion 3.7Vdc 2360mAh battery pack is used	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard has been identified. Recorded as the following : - over charging	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following : - Severity : 3 - Probability : 4	P
Supplementary information:			

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

15.4.4	RM RESULTS TABLE: Indicators		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No non-luminous heaters and output where an accidental or prolonged operation of the output circuit could constitute a hazardous situation are used.	
4.3			
4.4			
Supplementary information:			

15.4.5	RM RESULTS TABLE: Pre-set controls		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2		No pre-set controls used in the device	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

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

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

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
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 (°C)	Maximum winding temp measured (°C)	Ambient (°C)

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	N
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 & 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 (°C)	Maximum winding temp measured (°C)	Ambient (°C)

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.

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

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

16.1	RM RESULTS TABLE: General requirements for ME Systems		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
Supplementary information:			

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

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

16.9.1	RM RESULTS TABLE: Connection terminals and connectors		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

17	RM RESULTS TABLE: Electromagnetic compatibility of ME equipment and ME systems		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	See document RA05-02 Refer to clause 4.2 and appended table	The part has been identified. Recorded as the following : - IEC 60601-1-2, general requirements and ISO 60601-2-61, particular EMC requirements are applicable	P
4.3	See document RA05-02 Refer to clause 4.3 and appended table	The possible hazard has been identified. Recorded as the following : - Electric fields - Magnetic fields	P
4.4	See document RA05-02 Refer to clause 4.4 and appended table	The probability of occurrence of the harm has been estimated and the severity of the harm has been estimated. Recorded as the following : - Severity : 2 - Probability : 3	P
5	See document RA05-02 Refer to clause 5 and appended table	The risk has been evaluated. Recorded as the following : - Risk : A2 (Acceptable)	P

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

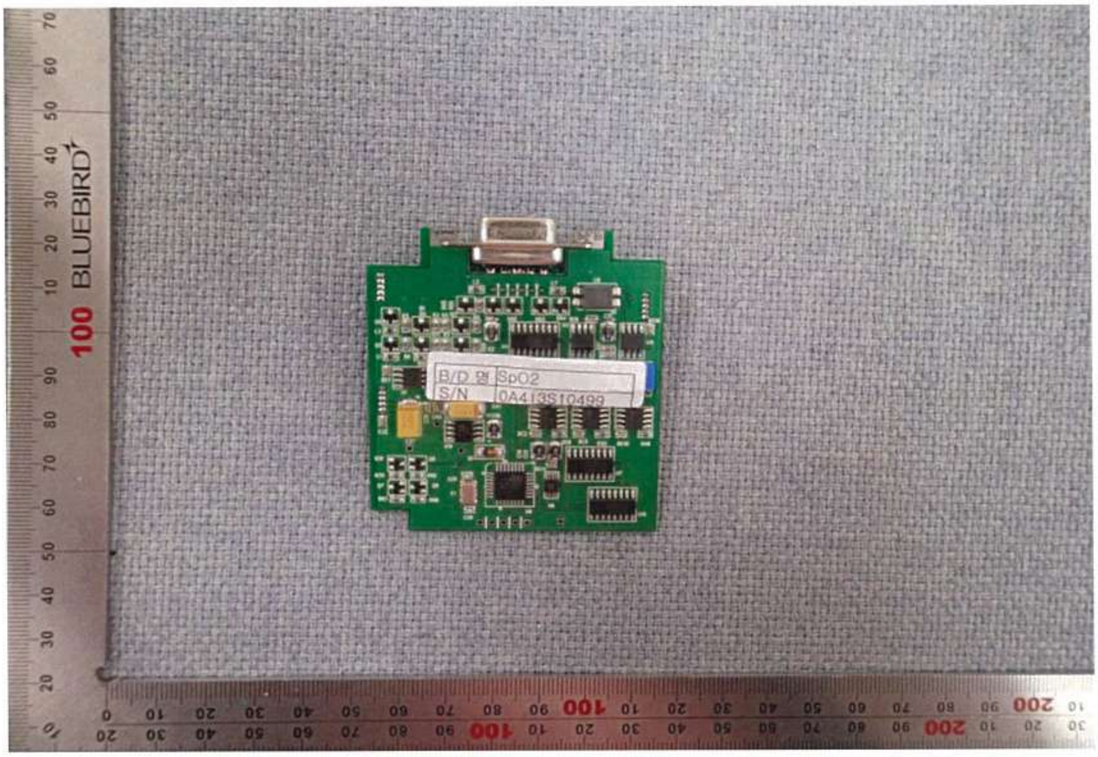
17	RM RESULTS TABLE: Electromagnetic compatibility of ME equipment and ME systems		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2	See document RA05-02 Refer to clause 6.2 and appended table	The risk control measure has been identified. Recorded as the following : - Bead is needed to reduce the EMC noise. - Related information is needed to be described in the instructions for use.	P
6.3	See document RA05-02 Refer to clause 6.3 and appended table	The risk control measure(s) has been implemented. Recorded as the following : - Bead is implemented in the mains PCB part to reduce the external EMC effect. - Related information is described in the instructions for use. - refer to part 10, Product specification, "Electromagnetic Emissions"	P
6.4	See document RA05-02 Refer to clause 6.4 and appended table	The residual risk has been evaluated. Recorded as the following : - Severity : 2 - Probability : 1 - Risk: A1 (Broadly acceptable)	P
6.5		Not deemed necessary.	N
Supplementary information:			

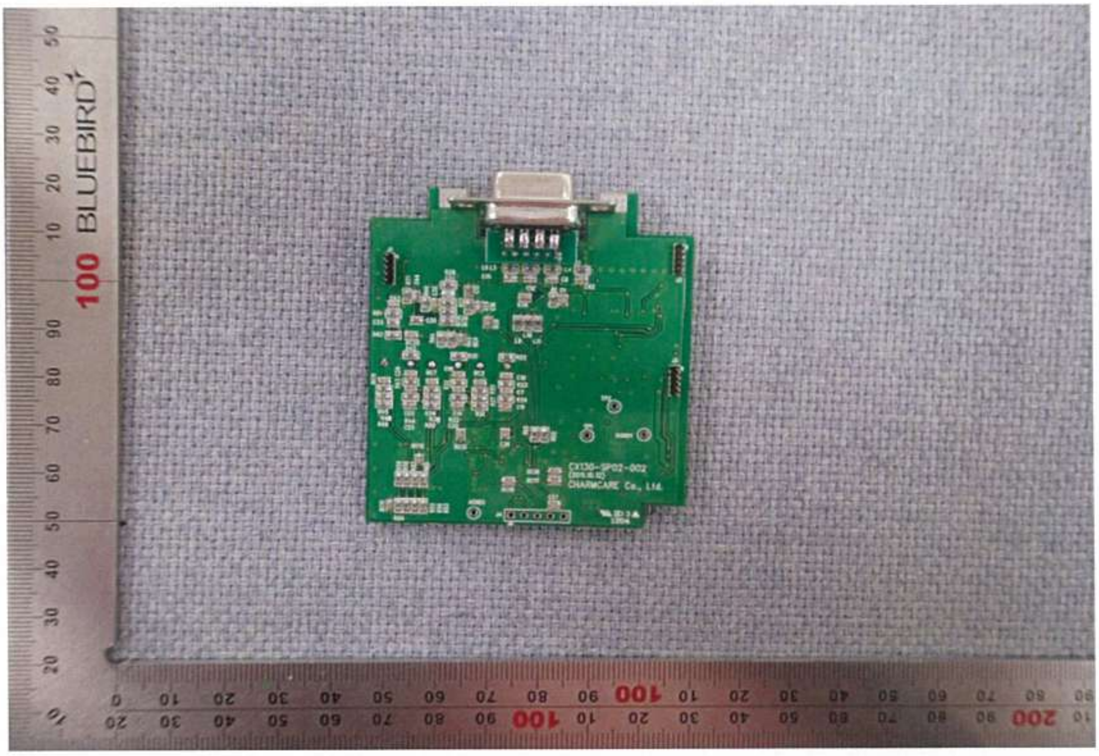
SP	TABLE: Additional or special tests conducted		N
Clause and Name of Test	Test type and condition	Observed results	
Supplementary information:			

Front View

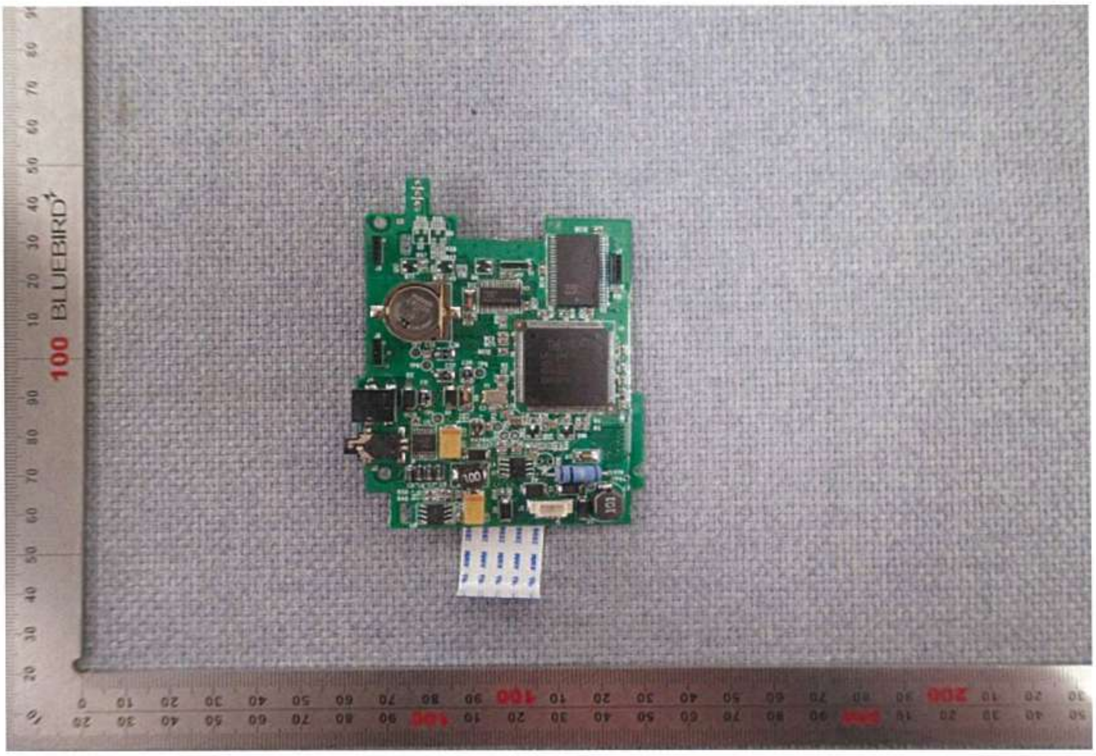
Rear View

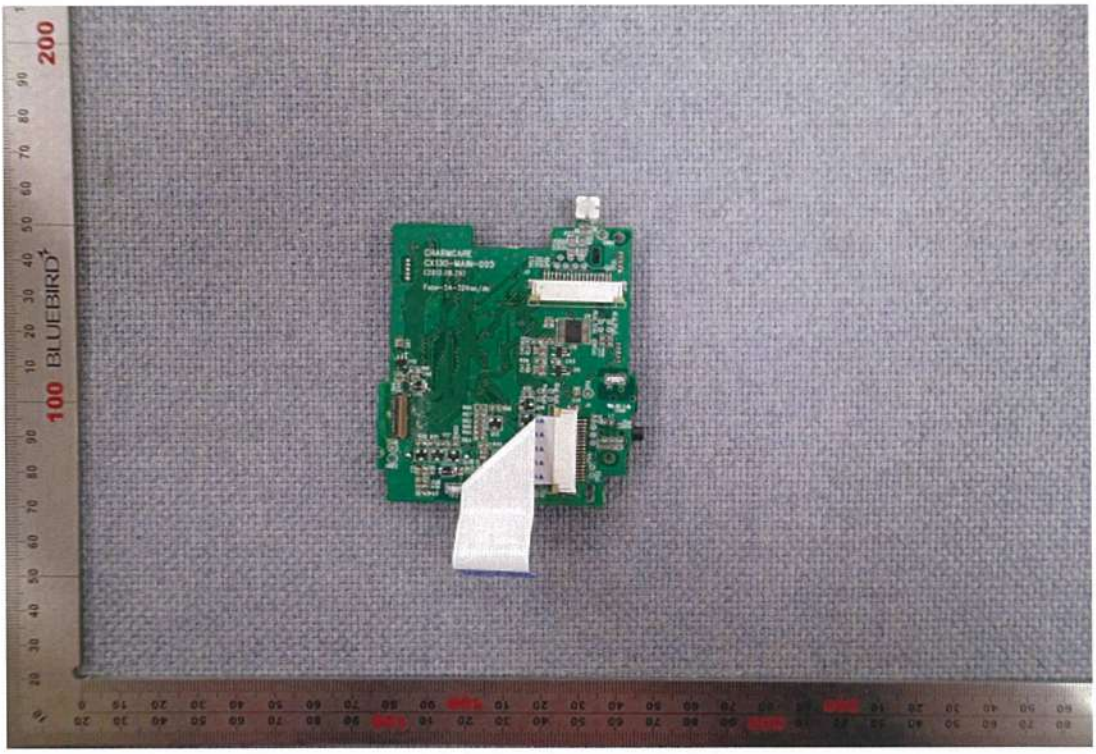
Side View



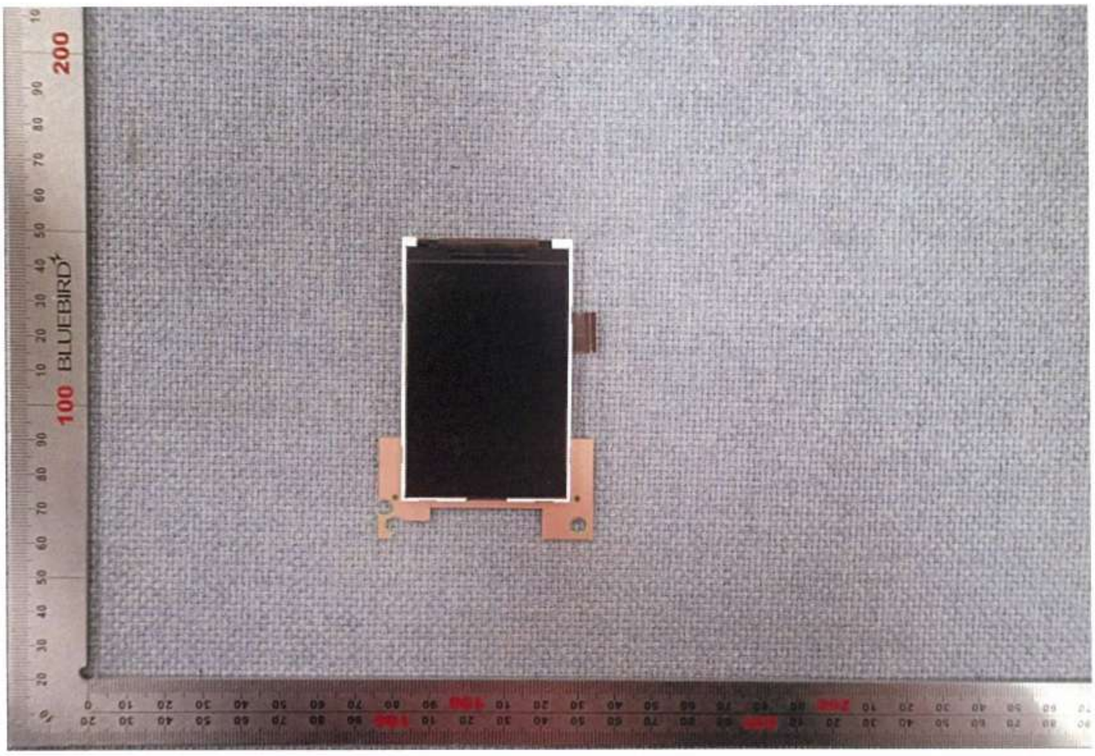


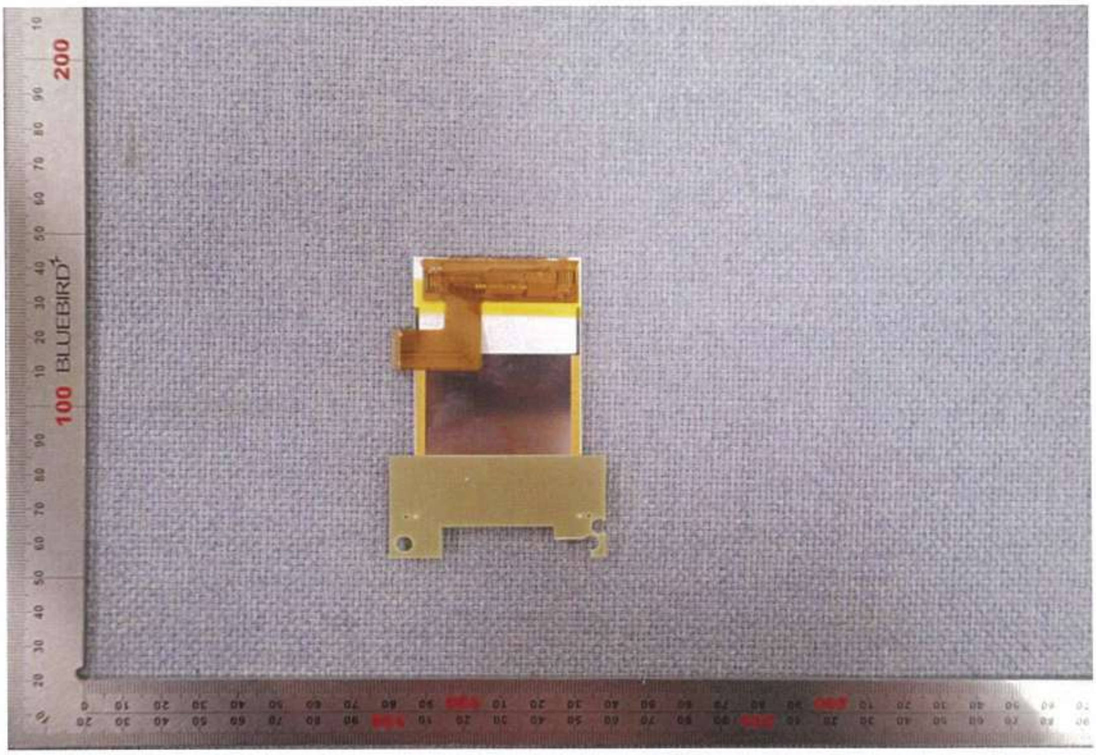
SpO2 Board



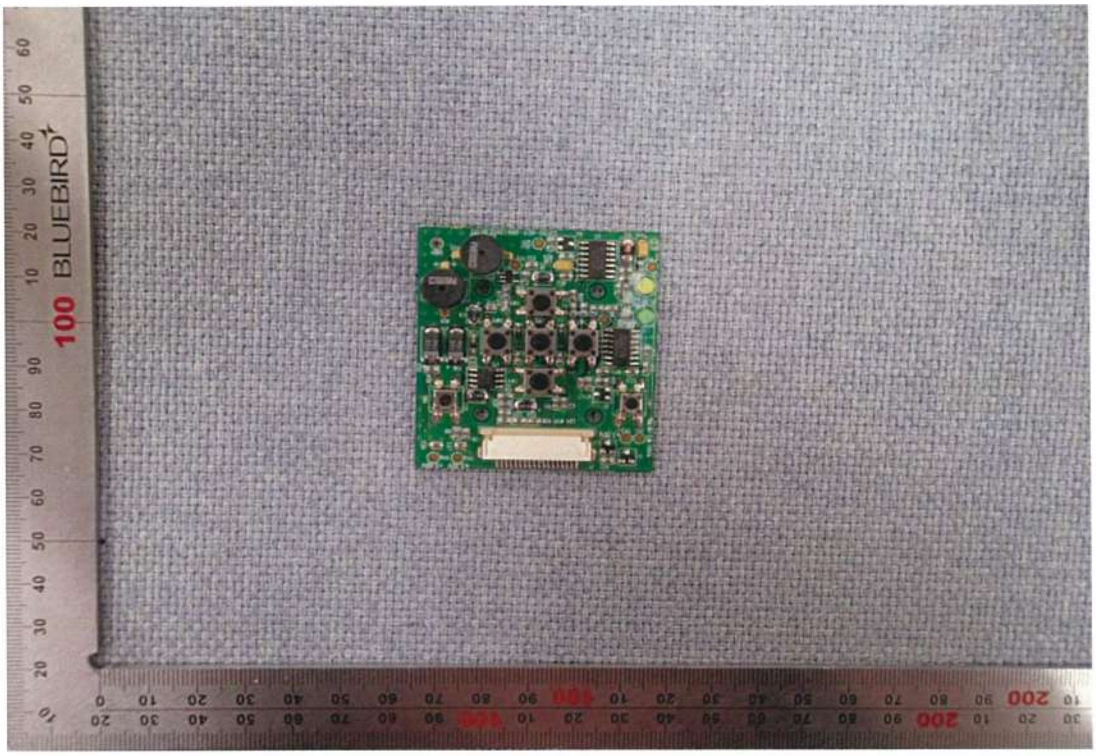


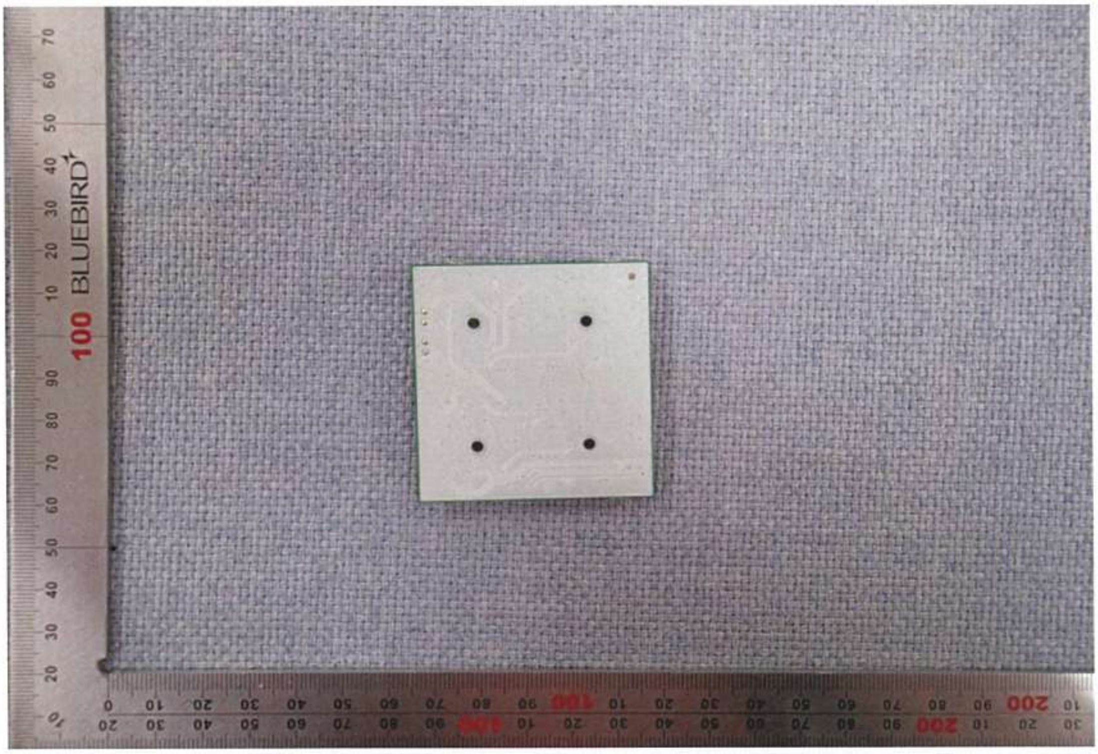
Main Board





LCD Display





Control Board

Battery Pack

SpO2 Probe

Test Report issued under the responsibility of:

Korea Testing Laboratory

TEST REPORT
IEC 60601-1-6
Medical electrical equipment
Part 1-6: General requirements for safety - Collateral Standard: Usability including IEC 62366: Application of usability engineering to medical devices

Report Reference No.	13-041142-01-1
Date of issue	2014-04-29
Total number of pages	5
CB Testing Laboratory	Korea Testing Laboratory(KTL)
Address	87, Digital-ro 26-gil, Guro-gu, Seoul 152-718 KOREA, REPUBLIC OF
Applicant's name	Charmcare Co., Ltd.
Address	(Gasan-Dong , Woolim Lions 2-cha), 714, 2, Gasandigital1-ro, Geumcheon-Gu, Seoul, Korea
Test specification:	
Standards	IEC 60601-1-6:2010 (Third Edition) for use in conjunction with IEC 60601-1: 2005 (Third Edition)
Test procedure	CB Scheme
Non-standard test method	N/A
Test Report Form No.	IEC60601_1_6E
Test Report Form Originator	TÜV Rheinland North America
Master TRF	Dated 2011-07

Test item description	Pulse Oximeter
Trade Mark	**Charmcare Co., Ltd.**
Manufacturer	Charmcare Co., Ltd.
Model/Type reference	CX130
Ratings	External 9Vdc 1.7A power adaptor 3.7Vdc Li-ion Battery or 4 x AA Type 1.5 Vdc (6Vdc,)

Testing procedure and testing location:

☒ CB Testing Laboratory: Korea Testing Laboratory(KTL)

Testing location/ address .... : 87, Digital-ro 26-gil, Guro-gu, Seoul 152-718 KOREA, REPUBLIC OF

☐ Associated CB Test Laboratory:

Testing location/ address .... :

Tested by (name + signature)........ : Park Ho Joon

Approved by (+ signature).............. : Lee Ho Sung

☐ Testing procedure: TMP

Tested by (name + signature).......:

Approved by (+ signature).............:

Testing location/ address .... :

☐ Testing procedure: WMT

Tested by (name + signature)........ :

Witnessed by (+ signature) .... :

Approved by (+ signature).............. :

Testing location/ address .... :

☐ Testing procedure: SMT

Tested by (name + signature)....... :

Approved by (+ signature).............:

Supervised by (+ signature) .... :

Testing location/ address .... :

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

See IEC 60601-1 Test Report

Summary of testing

Tests performed (name of test and test clause):

Testing location:

Korea Testing Laboratory(KTL)

Summary of compliance with National Differences

List of countries addressed:

☐ The product fulfils the requirements of _____ (insert standard number and edition and delete the text in parenthesis or delete the whole sentence if not applicable)

Copy of marking plate

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

See IEC 60601-1 Test Report

Test item particulars ....:	
Classification of installation and use.................................:	See IEC 60601-1 Test Report
Clinical application ....:	
Mode of operation...:	
Surface temperature of APPLIED PART ....:	
Possible test case verdicts:	
- test case does not apply to the test object....................:	N/A(N)
- test object does meet the requirement ....:	Pass (P)
- test object does not meet the requirement ....:	Fail (F)
Testing:	
Date of receipt of test items..:	2013-09-17
Date(s) of performance of tests..:	2013-09-17 ~ 2014-04-29

Abbreviations used in the report:

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

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

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

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

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

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

General product information:

See IEC 60601-1 Test Report

IEC 60601-1-6			
Clause	Requirement + Test	Result - Remark	Verdict
4.0	**General requirements**		**P**
4.2	USABILITY ENGINEERING PROCESS complies with IEC 62366 including amended definitions	See attached IEC 62366 Test Report	P
	Inspection of the USABILITY ENGINEERING FILE verified that the MANUFACTURER		P
	– established a USABILITY ENGINEERING PROCESS	Refer to report for usability engineering file "CX130"	P
	– established acceptance criteria for USABILITY; and		P
	– demonstrated that the acceptance criteria for USABILITY have been met.		P
5	**Replacement of requirements given in IEC 62366**		**P**
	The instructions for use include a brief description of the ME EQUIPMENT, its physical operating principles and significant physical and performance characteristics relevant to its USABILITY	See attached IEC 62366 Test Report	P
	The same information is also included in the technical description, if this is provided as a separate document from instructions for use		P
	The instructions for use contain a summary of the application specification	Refer to IFU	P

Test Report issued under the responsibility of:

Korea Testing Laboratory

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

Report Reference No.	:	13-041142-01-1
Date of issue	:	2014-04-29
Total number of pages	:	11
CB Testing Laboratory	:	Korea Testing Laboratory(KTL)
Address	:	87, Digital-ro 26-gil, Guro-gu, Seoul 152-718 KOREA, REPUBLIC OF
Applicant's name	:	Charmcare Co., Ltd.
Address	:	(Gasan-Dong , Woolim Lions 2-cha), 714, 2, Gasandigital1-ro, Geumcheon-Gu, Seoul, Korea
Test specification:		
Standards	:	IEC 62366: 2007 (First Edition) for use in conjunction with IEC 60601-1-6: 2010
Test procedure	:	CB Scheme
Non-standard test method	:	N/A
Test Report Form No.	:	IEC62366B
Test Report Form Originator	:	TÜV Rheinland North America
Master TRF	:	Dated 2011-07

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

Test item description	:	Pulse Oximeter
Trade Mark	:	**Charmcare Co., Ltd.**
Manufacturer	:	Charmcare Co., Ltd.
Model/Type reference	:	CX130
Ratings	:	External 9Vdc 1.7A power adaptor 3.7Vdc Li-ion Battery or 4 x AA Type 1.5 Vdc (6Vdc,)

Testing procedure and testing location:

☒ CB Testing Laboratory: Korea Testing Laboratory(KTL)

Testing location/ address ....: 87, Digital-ro 26-gil, Guro-gu, Seoul 152-718 KOREA, REPUBLIC OF

☐ Associated CB Test Laboratory:

Testing location/ address ....:

Tested by (name + signature)........: Park Ho Joon

Approved by (+ signature)..............: Lee Ho Sung

☐ Testing procedure: TMP

Tested by (name + signature).......:

Approved by (+ signature).............:

Testing location/ address ....:

☐ Testing procedure: WMT

Tested by (name + signature)........:

Witnessed by (+ signature) ....:

Approved by (+ signature)..............:

Testing location/ address ....:

☐ Testing procedure: SMT

Tested by (name + signature).......:

Approved by (+ signature).............:

Supervised by (+ signature) ....:

Testing location/ address ....:

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

Summary of testing

Tests performed (name of test and test clause):	Testing location:
	See Page 2.

Summary of compliance with National Differences

List of countries addressed:

☐ The product fulfils the requirements of __________ (insert standard number and edition and delete the text in parenthesis or delete the whole sentence if not applicable)

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.
See IEC 60601-1 Test Report

Test item particulars ....:	
Classification of installation and use.................................:	See IEC 60601-1 Test Report
Clinical application ....:	
Mode of operation ....:	
Surface temperature of APPLIED PART ....:	
Possible test case verdicts:	
- test case does not apply to the test object.....................:	N/A(N)
- test object does meet the requirement ....:	Pass (P)
- test object does not meet the requirement ....:	Fail (F)
Testing:	
Date of receipt of test items..:	2013-09-17
Date(s) of performance of tests.......................................:	2013-09-17 ~ 2014-04-29

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

Name and address of factory (ies)............................ : See Part 1 Report

General product information:
See IEC 60601-1 Test Report

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
4	**PRINCIPLES**		P
4.1.1	The MANUFACTURER has established, documented and maintains a USABILITY ENGINEERING PROCESS addressing USER interactions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENT		P
4.1.2	The USABILITY ENGINEERING PROCESS complies with this standard and the acceptance criteria in the USABILITY VALIDATION plan have been met		P
4.1.3	Information for SAFETY used as a RISK CONTROL measure has been evaluated according to the USABILITY ENGINEERING PROCESS		P
4.2	The results of the USABILITY ENGINEERING PROCESS are recorded in the USABILITY ENGINEERING FILE.....:		P
4.3	The USABILITY ENGINEERING PROCESS is scaled-up or scaled-down based on the significance of the modification as determined by the results of the RISK ANALYSIS .....:	The MEE is subject to legacy d evices where the USER INTER FACE design is of unknown pr ovenance (UOUP) and is perfo rming USABILITY ENGINEERI NG PROCESS accordingly.	P
5	**USABILITY ENGINEERING PROCESS**		P
5.1	The application of the MEDICAL DEVICE is specified in the USABILITY ENGINEERING FILE .....:	Document Reference No. in U SABILITY ENGINEERING FILE: UEF Document No. : UF05	P
	– intended medical indication		P
	– intended PATIENT population		P
	-- intended part of the body or type of tissue applied to or interacted with		P
	– intended USER PROFILE		P
	– intended conditions of use		P
	– operating principle		P
5.2	The frequently used functions that involve USER interaction with the MEDICAL DEVICE are recorded in the USABILITY ENGINEERING FILE .....:	Document Reference No. in U SABILITY ENGINEERING FILE: UEF Document No. : UF05	P
5.3.1	The MANUFACTURER identified characteristics related to SAFETY that focus on USABILITY	See Table 5.3.1	P
5.3.2	The MANUFACTURER identified known or foreseeable HAZARDS related to USABILITY	See Table 5.3.2	P

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
	Reasonably foreseeable sequences or combinations of events involving the USER INTERFACE that can result in a HAZARDOUS SITUATION associated with the MEDICAL DEVICE are identified		P
	The SEVERITY of the resulting possible HARM was determined		P
5.4	The MANUFACTURER determined the PRIMARY OPERATING FUNCTIONS and recorded them in the USABILITY FILE	Document Reference No. in USABILITY ENGINEERING FILE:	P
	The inputs to the PRIMARY OPERATING FUNCTIONS included frequently used functions and functions related to SAFETY of the MEDICAL DEVICE		P
5.5	The MANUFACTURER developed the USABILITY SPECIFICATION	See Table 5.5 User interface of unknown prov enance. Excluded from manufa cturer's request	N
5.6	The MANUFACTURER prepared a USABILITY VALIDATION plan	See Table 5.6 User interface of unknown prov enance. Excluded from manufa cturer's request	N
5.7	The MANUFACTURER designed and implemented the USER INTERFACE as described in the USABILITY SPECIFICATION ....:	See 5.8 and 5.9	—
5.8	The MANUFACTURER verified the implementation of the MEDICAL DEVICE USER INTERFACE design against the requirements of the USABILITY SPECIFICATION	Document Reference No. in USABILITY ENGINEERING FILE:	N
5.9	The MANUFACTURER VALIDATED USABILITY of the MEDICAL DEVICE according to the USABILITY VALIDATION plan	Document Reference No. in USABILITY ENGINEERING FILE:	N
	If the acceptance criteria are not met and no further improvements are practicable, the medical benefits outweigh the risk	Document Reference No. in USABILITY ENGINEERING FILE:	N

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict
6	**ACCOMPANYING DOCUMENT**		P
	If provided, the ACCOMPANYING DOCUMENT includes a summary of the application specification		P
	If provided, the ACCOMPANYING DOCUMENT includes a concise description of the ME EQUIPMENT, its operating principles and significant physical and performance characteristics, and intended USER PROFILE	Reference to instructions for us e 23 / page 55	P
	If provided, the ACCOMPANYING DOCUMENT is written at a level consistent with the USER PROFILE.		P
	If the ACCOMPANYING DOCUMENT is provided electronically, the USABILITY ENGINEERING PROCESS included consideration of which information also needs to be provided as hard copy or as markings on the MEDICAL DEVICE		P
7	Training and materials for training		P
	When training is required for the safe and effective use of PRIMARY OPERATING FUNCTIONS, the ACCOMPANYING DOCUMENT describes the available training options		P
	When training is required, the INTENDED USE and USER PROFILE(S) are the basis for training and training material		P

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.3.1	USABILITY ENGINEERING FILE RESULTS TABLE: Characteristics related to SAFETY		P
	Document Ref. in USABILITY ENGINEERING FILE	Result - Remarks	Verdict
An identification of characteristics related to SAFETY that focused on USABILITY was performed according to ISO 14971:2007, Clause 4.2	UEF Document No. : UF05 Refer to clause 8	Identified characteristics related to SAFETY that focus on USABILITY.	P
During the identification of characteristics related to SAFETY, the following was considered:			—
– application specification, including USER PROFILE(S)	UEF Document No. : UF05	Refer to clause 6	P
– frequently used functions	UEF Document No. : UF05	Refer to clause 7	P

IEC 62366			
Clause	Requirement + Test	Result - Remark	Verdict

Table 5.3.2	USABILITY ENGINEERING FILE RESULTS TABLE: Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS		P
	Document Ref. in USABILITY ENGINEERING FILE	Result - Remarks	Verdict
Identification of known or foreseeable HAZARDS related to USABILITY according to ISO 14971:2007, Cl. 4.3	UEF Document No. : UF05 Refer to clause 9	Identified all known or foreseeable HAZARDS and HAZARDOUS SITUATIONS related to USABILITY (or poor USABILITY)	P
The identification of HAZARDS considers HAZARDS to PATIENTS, USERS and other persons	UEF Document No. : UF05	Refer to clause 9.1	P
Reasonably foreseeable sequences or combinations of events involving the user interface that can result in a HAZARDOUS SITUATION associated with the MEDICAL DEVICE are identified	UEF Document No. : UF05	Refer to clause 9.2	P
The SEVERITY of the resulting possible HARM was determined	UEF Document No. : UF05	Refer to clause 9.3	P
During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered:			—
– application specification, including USER PROFILE(S)	UEF Document No. : UF05	Refer to clause 9.1.1	P
– task related requirements	UEF Document No. : UF05	Refer to clause 9.1.2	P
– context of use	UEF Document No. : UF05	Refer to clause 9.1.3	P
– information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available	UEF Document No. : UF05	Refer to clause 9.1.4	P
– preliminary USE SCENARIOS	UEF Document No. : UF05	Refer to clause 9.1.5	P
– possible USE ERRORS	UEF Document No. : UF05	Refer to clause 9.1.6	P
– if an incorrect mental model of the operation of the MEDICAL DEVICE can cause a USE ERROR resulting in a HAZARDOUS SITUATION			N
– results of the review of the USER INTERFACE	UEF Document No. : UF05	Refer to clause 9.1.7	P

TRF No: IEC62366B

Table 5.5	USABILITY ENGINEERING FILE RESULTS TABLE: USABILITY SPECIFICATION		N
	Document Ref. in USABILITY ENGINEERING FILE	Result - Remarks	Verdict
USABILITY SPECIFICATION			N
The USABILITY SPECIFICATION provides:			—
– testable requirements for USABILITY VERIFICATION			N
– testable requirements for USABILITY of PRIMARY OPERATING FUNCTIONS including criteria for determining the adequacy of RISK CONTROL achieved by the USABILITY ENGINEERING PROCESS.			N
Inputs to the USABILITY SPECIFICATION include the following:			—
– application specification			N
– PRIMARY OPERATING FUNCTIONS			N
– HAZARDS and HAZARDOUS SITUATIONS related to USABILITY			N
– known or foreseeable USE ERRORS associated with the MEDICAL DEVICE			N
The USABILITY SPECIFICATION describes:			—
– USE SCENARIOS related to the PRIMARY OPERATING FUNCTIONS			N
– frequent USE SCENARIOS			N
– reasonably foreseeable worst case USE SCENARIOS			N
– USER INTERFACE requirements for the PRIMARY OPERATING FUNCTIONS, including those to mitigate RISK			N
– requirements for determining whether PRIMARY OPERATING FUNCTIONS are easily recognizable by the USER.			N

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Clause	Requirement + Test	Result - Remark	Verdict

Table 5.6	USABILITY ENGINEERING FILE RESULTS TABLE: USABILITY VALIDATION plan		N
	Document Ref. in USABILITY ENGINEERING FILE	Result - Remarks	Verdict
USABILITY VALIDATION plan			N
The USABILITY VALIDATION plan specifies:			—
– any method used for VALIDATION of the USABILITY of PRIMARY OPERATING FUNCTIONS			N
– the criteria for determining successful VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS based on the USABILITY SPECIFICATION			N
– the involvement of representative intended USERS			N
The USABILITY VALIDATION plan addresses:			—
– frequent USE SCENARIOS			N
– reasonably foreseeable worst case USE SCENARIOS identified in the USABILITY SPECIFICATION			N

Test Report issued under the responsibility of:

Korea Testing Laboratory

TEST REPORT
ISO 80601-2-61
Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Report Number. ..... :	13-041142-01-1
Date of issue ..... :	2014-04-29
Total number of pages	41
CB Testing Laboratory ..... :	Korea Testing Laboratory(KTL)
Address	87, Digital-ro 26-gil, Guro-gu, Seoul 152-718 KOREA, REPUBLIC OF
Applicant's name ..... :	Charmcare Co., Ltd.
Address ..... :	(Gasan-Dong , Woolim Lions 2-cha), 714, 2, Gasandigital1-ro, Geumcheon-Gu, Seoul, Korea
Test specification:	
Standard ..... :	ISO 80601-2-61:2011 (First Edition) for use with IEC 60601-1: 2005 (Third Edition) + CORR.1 (2005) + CORR. 2 (2007)
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	N/A
Test Report Form No ..... :	ISO80601_2_61A
Test Report Form(s) Originator ..... :	CSA International
Master TRF ..... :	2012-12

Test item description ..... :	Pulse Oximeter
Trade Mark ..... :	**Charmcare Co., Ltd.**
Manufacturer ..... :	Charmcare Co., Ltd.
Model/Type reference ..... :	CX130
Ratings ..... :	External 9Vdc, 1.7A power adaptor 3.7Vdc Li-ion Battery or 4 x AA Type 1.5 Vdc (6Vdc,)

Testing procedure and testing location:

☒ CB Testing Laboratory: Korea Testing Laboratory(KTL)

Testing location/ address............................: 87, Digital-ro 26-gil, Guro-gu, Seoul 152-718 KOREA, REPUBLIC OF

☐ Associated CB Test Laboratory:

Testing location/ address......................:

Tested by (name + signature) ....: Park Ho Joon

Approved by (name + signature).........: Lee Ho Sung

☐ Testing procedure: TMP

Testing location/ address............................:

Tested by (name + signature) ....:

Approved by (name + signature).........:

☐ Testing procedure: WMT

Testing location/ address............................:

Tested by (name + signature) ....:

Witnessed by (name + signature) ....:

Approved by (name + signature).........:

☐ Testing procedure: SMT

Testing location/ address............................:

Tested by (name + signature) ....:

Approved by (name + signature).........:

Supervised by (name + signature) ......:

List of Attachments (including a total number of pages in each attachment):
See IEC 60601-1 Test Report

Summary of testing:

Tests performed (name of test and test clause):	Testing location: See Page 2.

Summary of compliance with National Differences
List of countries addressed:

☐ The product fulfils the requirements of _________ (insert standard number and edition and delete the text in parenthesis or delete the whole sentence if not applicable)

Copy of marking plate

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

See IEC 60601-1 Test Report

Test item particulars ....:	
Classification of installation and use ....:	**Transportable**/portable/stationary/mobile/fixed/ permanently installed/**hand-held**
Device type (component/sub-assembly/ equipment/ system ....:	equipment
Intended use (Including type of patient, application location) ....:	CX130 is intended to measure pulse waveform and heart rate in the finger by lighting a fingertip with combination of infrared LED and photodiode
Mode of operation ....:	**Continuous** / non-continuous
Supply Connection ....:	**Internally powered** /permanently installed / appliance coupler / non-detachable cord
Accessories and detachable parts included ....:	
Other options included ....:	
Possible test case verdicts:	
- test case does not apply to the test object ....:	N/A(N)
- test object does meet the requirement ....:	Pass (P)
- test object does not meet the requirement ....:	Fail (F)
Testing ....:	
Date of receipt of test item ....:	2013-09-17
Date (s) of performance of tests ....:	2013-09-17 ~ 2014-04-29

General remarks:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.
"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.

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

This Test Report Form is intended for the investigation of the basic safety and essential performance of pulse oximeter medical devices in accordance with ISO 80601-2-61. It can only be used together with the IEC 60601-1 (3rd edition) Test Report Form (TRF).

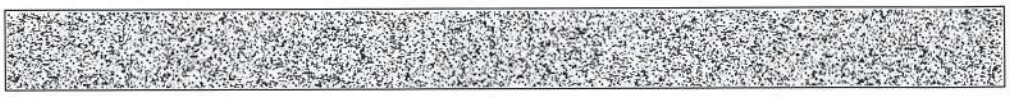
Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ....:	☐ Yes ☒ Not applicable

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

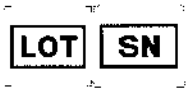
Name and address of factory (ies) ....:	Charmcare Co., Ltd. (Gasan-Dong , Woolim Lions 2-cha), 714, 2, Gasandigital1-ro, Geumcheon-Gu, Seoul, Korea
General product information: See IEC 60601-1 Test Report	

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

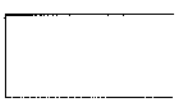
201.4	**General requirements**		**P**
201.4.101	Additional requirements for ESSENTIAL PERFORMANCE		P
	Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101 of this standard	See appended Table 201.4.101	P
201.4.102	Additional requirements for acceptance criteria		P
	When the MANUFACTURER specifies in the ACCOMPANYING DOCUMENT performance levels better than those specified within this International Standard, these MANUFACTURER-specified levels become the acceptance levels.....:		P
201.4.103	Additional requirements for Pulse Oximeter Equipment, parts and Accessories		P
	The PULSE OXIMETER EQUIPMENT, as well as all individual parts and ACCESSORIES specified for use with a PULSE OXIMETER MONITOR, shall comply with all requirements specified in this International Standard. This includes all combinations of parts or ACCESSORIES that are specified by a MANUFACTURER for use in PULSE OXIMETER EQUIPMENT.....:		P
	All specified combinations of PULSE OXIMETER EQUIPMENT, as well as all individual parts and ACCESSORIES specified for use with a PULSE OXIMETER MONITOR, shall be disclosed in the instructions for use. Additional information is found in 201.7.9.2.1 g) and 201.7.9.2.14.101 a) and b).....:		P
201.7	ME EQUIPMENT identification, marking and documents		P
201.7.2.3	Consult Accompanying Documents		P
	The PULSE OXIMETER EQUIPMENT shall be marked with the safety sign for the mandatory action: 'follow instructions for use', ISO 7010-M002. (Additional information is found in IEC 60601-1:2005+TC1, Table D.2, Number 10).....:		P



ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
201.7.2.9	IP Classification		P
	Notwithstanding the requirements of IEC 60601-1:2005, 7.2.9, the ENCLOSURE of ME EQUIPMENT shall be marked with the IP classification required by 201.11.6.5.101. If some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then the degree of protection provided by the ENCLOSURE shall be marked on the ENCLOSURE and the degree of protection provided by the carrying case shall be marked on the carrying case....:	See IEC 60601-1 Test report, Sub-clauses 7.1.2 and 7.1.3 IPX1 Equipment	P
	An ENCLOSURE or a carrying case that is classified IPX0 need not be marked as such. If an ENCLOSURE does not provide the minimum required degree of protection against the ingress of water, it shall be marked 'keep dry' or with ISO 15223-1:2007, Symbol 5.8 (see Table 201.D.2, Symbol 1)		P
201.7.2.101	Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		P
	ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLY marked as follows:		---
	a) Any particular storage and handling instructions...:	Appropriate documentation provided as part of the Operator Manual	P
	b) A serial number or ISO 15223-1:2007, Symbol 5.16 (see Table D.2.101, Symbol 5) or lot identifying number or batch identifying number or ISO 15223-1:2007, Symbol 5.14 (see Table D.2.101, Symbol 3)	SN LOT Refer to previous comment	P
	c) The PULSE OXIMETER MONITOR, its parts and ACCESSORIES with regard to proper disposal, as appropriate..................:	Appropriate documentation provided as part of the Operator Manual and documentation which accompanies the individual accessories.	P
	d) If a PULSE OXIMETER MONITOR is not provided with a low *Sp*O2 ALARM CONDITION, a statement to the effect "No *Sp*O2 Alarms" or Symbol IEC 60417-5319 (DB-2002-10) (see IEC 60601-1-8:2006, Table C.1, Symbol 3)	 Low SpO2 ALARM is provided	N
	If applicable, ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLY marked as follows:		---

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	e) With an indication of the date, after which it should not be used, expressed as the year and month. ISO 15223-1:2007, Symbol 5.12 (see Table D.2.101, Symbol 2) may be used	 Refer to previous comment	N
	f) For a detachable PULSE OXIMETER PROBE, with a lot identifying number or batch identifying number or ISO 15223-1:2007, Symbol 5.14 (see Table D.2.101, Symbol 3) or serial number ISO 15223-1:2007, Symbol 5.16 (see Table D.2.101, Symbol 5) on it or on the packaging, as appropriate	 Refer to previous comment	P
	g) For a PULSE OXIMETER PROBE for single-PATIENT use, the package or the PULSE OXIMETER PROBE itself marked with an indication that the PULSE OXIMETER PROBE is for single-PATIENT use	 Refer to previous comment	N
	h) For a PULSE OXIMETER PROBE for single-use, the package or the PULSE OXIMETER PROBE itself marked with an indication that the PULSE OXIMETER PROBE is for single-use. ISO 15223-1:2007, Symbol 5.2 (see IEC 60601-1:2005, Table D.1, Symbol 28) may be used. For a specific MODEL OR TYPE REFERENCE, the indication of single-use shall be consistent	 Refer to previous comment	N
	i) For a REPROCESSED PULSE OXIMETER PROBE, marked as such.....:	Refer to previous comment	N
201.7.2.4.101	Addition requirements for ACCESSORIES		P
	ACCESSORIES shall be marked with:		P
	a) where appropriate, an indication of the date after which the ACCESSORY should not be used expressed as the year and month. ISO 15223-1:2007, Symbol 5.12 (see Table D.2.101, Symbol 2) may be used	 Refer to previously commented clause 207.7.2.101	N
	b) any particular storage or handling instructions.....:	Refer to previously commented clause 207.7.2.101	N
201.7.2.13.101	Additional requirements for physiological effects		N
	All latex-containing ACCESSORIES shall be CLEARLY LEGIBLY marked as containing latex. Symbol ISO 7000-2725 (DB2004-01) (see Table D.2.101, Symbol 11) may be used. All latex-containing components shall be disclosed as such in the instructions for use..:	 Silicon is used	N
201.7.2.17.101	Additional requirements for protective packaging		P
	Packages of ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLY marked:		---

TRF No. ISO80601_2_61A



ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	a) with the following:		---
	– a description of the contents		P
	– an identification reference to the batch, type or serial number or ISO 15223-1:2007, Symbols 5.14, 5.15, 5.16 (see Table D.2.101, Symbols 3, 4, 5).	LOT REF SN	P
	– for packages containing latex, the word 'LATEX', or Symbol ISO 7000-2725 (see Table D.2.101,Symbol 11).	 Silicon is used	N
	– if applicable, the word "STERILE," or one of ISO 15223-1:2007, Symbols 5.20 to 5.24 (see Table D.2.101, Symbol 7 to 10). Packaging of sterile ME EQUIPMENT, parts or ACCESSORIES shall ensure sterile conditions until opened or damaged or until its expiration date is reached	STERILE, STERILE A, STERILE EO, STERILE R, STERILE No sterilized Accessories	N
	b) for those containing parts intended for single-use, with the words "SINGLE USE", "DO NOT REUSE", "NOT FOR REUSE", Symbol ISO 7000-1051 or Symbol ISO 15223-1:2007, 5.2 (see IEC 60601-1:2005, Table D.1, Symbol 28). For a specific MODEL OR TYPE REFERENCE, the indication of single-use shall be consistent.	 Not for Single-use	N
	Consideration should be given to the disposal of packaging waste...................................:		N
201.7.4.3	Unit of measure		P
	FUNCTIONAL OXYGEN SATURATION shall be expressed in units of per cent *Sp*O2 and shall be marked as % *Sp*O2 or *Sp*O2...........:	SpO2(%)	P
	Pulse rate shall be expressed in units of reciprocal minutes (1/min).	bpm	P
201.7.9.1	Additional general requirements		
	– Name or trade name and address of..........:	Charmcare Co., Ltd si the legal manufacturer	P
	– the MANUFACTURER...........................:		P
	– where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale...................:	CHARMCARE Co., Ltd. Rm.918, Woolim Lions2-cha, 680 Kasan-Dong, Geumcheon-Gu, Seoul, Korea 153-787	N
	to which the RESPONSIBLE ORGANIZATION can refer.........................:		P
201.7.9.2.1.101	Additional general requirements		P

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	The instructions for use shall indicate the following:		---
	a) for each PULSE OXIMETER EQUIPMENT and PULSE OXIMETER PROBE, the specified use of the PULSE OXIMETER EQUIPMENT and PULSE OXIMETER PROBE regarding:		P
	– PATIENT population.............................:	User manual part 2.1 intended use	P
	– part of the body or type of tissue applied to.:	User manual part 2.1 intended use	P
	– application...:	User manual part 2.1 intended use	P
	b) that the PULSE OXIMETER EQUIPMENT is calibrated to display FUNCTIONAL OXYGEN SATURATION..........................:	User manual part 7 display menu usage changing measurement screen	P
	c) the range of the peak wavelengths and maximum optical output power of the light emitted by the PULSE OXIMETER PROBE and a statement to the effect that information about wavelength range can be especially useful to clinicians....................................:	User manual part 10.11 SpO2 sensor light source	P
	d) a description of the effect on displayed and transmitted *Sp*O2 and pulse rate data values by:		P
	– data averaging and other signal processing,		P
	– the DATA UPDATE PERIOD,		P
	– the ALARM CONDITION DELAY, and	Refer to part 6 of User Manual	P
	– ALARM SIGNAL GENERATION DELAY	Refer to part 6 of User Manual	P
	including the effects of any selectable operating mode that affects these properties;	No selectable mode for SpO2	N
	e) the DISPLAYED RANGES of *Sp*O2 and pulse rate;	Refer to part 10 of User Manual	P
	f) if no ALARM SYSTEM that includes the capability to detect an *Sp*O2 or pulse rate PHYSIOLOGICAL ALARM CONDITION is provided, a statement to that effect............:	Alarm System is provided	N
	g) for PULSE OXIMETER MONITORS, the PULSE OXIMETER PROBE(S) and PROBE CABLE EXTENDERS with which the PULSE OXIMETER MONITOR has been VALIDATED and tested for compliance with this International Standard (additional information is found in 201.4.103). The list may be made available by electronic means.....................:	Provided as part of System user manual, labels and combination with accessories.	P

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict
	h) if the PULSE OXIMETER EQUIPMENT or its parts are intended for single-use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the PULSE OXIMETER EQUIPMENT or its parts would be re-used.............................:	Not for Single-use	N
	i) date of issue or the revision of the instructions for use.................................:		P
201.7.9.2.2.101	Additional requirements for warnings and safety notices		P
	The instructions for use shall include:		---
	a) for each PULSE OXIMETER PROBE and PROBE CABLE EXTENDER, a warning to the effect that probes and cables are designed for use with specific monitors.........................:	User Manual Part 5 Measuring the SpO2 - SpO2 sensor port Use only approved sensors and interface cables when connecting to the sensor port. Connecting any other cable or sensor influences the accuracy of sensor data, which may lead to adverse results	P
	b) a warning to the effect that the responsible organization and/or operator needs to verify the compatibility of the monitor, probe, and cable before use, otherwise patient injury can result...:	User Manual Part 5 Measuring the SpO2 SpO2 sensor port	P
	c) a warning to the effect that misapplication of a PULSE OXIMETER PROBE with excessive pressure for prolonged periods can induce pressure injury.............................:	User Manual Part 5 Measuring the SpO2 SpO2 sensor port	P
201.7.9.2.8.101	Additional requirements for start-up PROCEDURE		P
	If an ALARM SYSTEM that includes the capability to detect PHYSIOLOGICAL ALARM CONDITIONS is provided and automatic self-test of ALARM SIGNAL generation is not provided, the instructions for use shall include a method for OPERATOR-initiated testing of ALARM SIGNAL generation	Provided as part of the User manual.	P
201.7.9.2.9.101	Additional requirements for operating instructions		P
	The instructions for use shall indicate the following:	Noted	---

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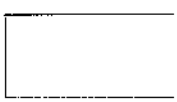
Clause	Requirement + Test	Result - Remark	Verdict
	a) a description of the signal inadequacy indicator and its function. If there is a waveform, a statement as to whether or not it is NORMALIZED shall be provided.....:		P
	b) if the PULSE OXIMETER EQUIPMENT is provided with adjustable ALARM LIMITS, the range of adjustment of the ALARM LIMITS....:	User Manual part 5 how to use menu - basic alarm settings and ranges	P
	c) the recommended maximum application time for each type of PULSE OXIMETER PROBE at a single site.....:	User manual part 5 measuring the SpO2 attaching the SpO2 Probe	P
	d) the IP classification of the PULSE OXIMETER EQUIPMENT ENCLOSURE and, if applicable, on any carrying case provided with the PULSE OXIMETER EQUIPMENT along with a brief description of that classification's meaning.....:	Degree of protection against harmful ingress of water : IPX1	P
	e) if the PULSE OXIMETER EQUIPMENT is provided with temperature capability such that the PULSE OXIMETER PROBE can operate at greater than 41 ℃, specific instructions emphasizing the importance of proper PULSE OXIMETER PROBE application, without excessive pressure. In addition, specific instructions for any changes in recommended maximum application time when using temperatures greater than 41 ℃.....:		N
201.7.9.2.14.101	Additional requirements for ACCESSORIES, supplementary equipment, used material		P
	The instructions for use shall include the following:		—
	a) for PULSE OXIMETER PROBES, the PULSE OXIMETER MONITOR(S) and PROBE CABLE EXTENDERS with which the PULSE OXIMETER PROBES have been VALIDATED and tested for compliance with this International Standard (additional information is found in 201.4.103). The list may be made available by electronic means..:	Provided as part of System user manual, labels and combination with accessories. User Manual 2.2 list of part	P
	b) for PROBE CABLE EXTENDERS, the PULSE OXIMETER MONITOR(S) and PULSE OXIMETER PROBES with which the PROBE CABLE EXTENDERS have been VALIDATED and tested for compliance with this International Standard (additional information is found in 201.4.103). The list may be made available by electronic means..:	Provided as part of System user manual, labels and combination with accessories. User Manual 2.2 list of part	P



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Clause	Requirement + Test	Result - Remark	Verdict
	c) information regarding toxicity or the effect on tissues of materials with which the PATIENT or any other person can come into contact and information on residual RISKS for children, pregnant or nursing women and, if applicable, any appropriate precautionary measures...:	See appended Risk Management Table 201.7.9.2.14.101	P
	d) if a PULSE OXIMETER PROBE is delivered in sterile packaging, a description of how to re-sterilize it, if permissible, in the event of damage to the sterile packaging......:	Not delivered in sterile packaging	N
201.7.9.3.1.101	Additional general requirements		P
	The technical description shall include a statement to the effect that a FUNCTIONAL TESTER cannot be used to assess the ACCURACY of a PULSE OXIMETER PROBE or a PULSE OXIMETER MONITOR.............: (additional information is found in Annex FF)	User Manual 1.3 Safety Information, Warning, Caution and Note Because the pulse oximeter does all critical computations in the software and there are no critical parts to drift, no recalibration is required during the life of the device.	P
	The technical description should provide descriptions on how the RESPONSIBLE ORGANIZATION can VERIFY operation of the PULSE OXIMETER EQUIPMENT. If the use of a FUNCTIONAL TESTER is specified, the technical description should indicate the MODEL OR TYPE REFERENCE and its software unique identifier of at least one FUNCTIONAL TESTER that is compatible with the basic functions of the PULSE OXIMETER EQUIPMENT..........................:	See previous comment+	P
201.8	Protection against electrical HAZARDS from ME EQUIPMENT		P
201.8.3.101	Additional requirements for classification of APPLIED PARTS		P
	APPLIED PARTS of PULSE OXIMETER EQUIPMENT shall be TYPE BF or TYPE CF APPLIED PARTS......................................:	BF APPLIED PART	P
201.10	Protection against unwanted and excessive radiation HAZARDS		N/E
	Depending on the light source used in a PULSE OXIMETER PROBE, the relevant requirements of IEC 60825-1:2007 or IEC 62471:2006 shall apply to a PULSE OXIMETER PROBE...............................:	See attached IEC 60825-1:2007 or IEC 62471:2006 Test report	N/E
	In the case of laser fibre optics, the requirements of IEC 60825-2:2004+A1:2006 shall apply.	See attached IEC 60825-2:2004+A1:2006 Test Report	N/E

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Clause	Requirement + Test	Result - Remark	Verdict
201.11	Protection against excessive temperatures and other hazards		N/E
	The PULSE OXIMETER PROBE-tissue interface shall be evaluated when the skin temperature is initially at 35 ℃ for each PULSE OXIMETER MONITOR and PULSE OXIMETER PROBE with which it is intended to be used.	See appended Table 201.11	N/E
	If the surface temperature of the PULSE OXIMETER PROBE at the tissue interface is capable of exceeding 41 ℃, then................:		N/E
	a) the PULSE OXIMETER EQUIPMENT shall have an OPERATOR-adjustable control for activating any elevated temperature mode that exceeds 41 ℃. A deliberate sequence of OPERATOR actions shall be required to activate this mode. The instructions for use shall describe this sequence of OPERATOR actions..:		N/E
	b) the PULSE OXIMETER EQUIPMENT shall provide a means to limit the duration of an elevated temperature mode in excess of 41 ℃. The duration of the elevated temperature mode shall not exceed 4 h at 43 ℃ or 8 h at 42 ℃...:		N/E
	c) the instructions for use shall include a statement to the effect that the use of temperature settings greater than 41 ℃ requires special attention in PATIENTS with susceptible skin, such as neonates, geriatric PATIENTS, burn victims..........................:		N/E
	d) the PULSE OXIMETER EQUIPMENT shall indicate when it is in the elevated temperature mode...:		N/E
	e) the technical description shall describe the test method used to measure the maximum temperature at the PULSE OXIMETER PROBE-tissue interface. When performing the temperature measurements for the PULSE OXIMETER PROBE-tissue interface, as specified in IEC 60601-1:2005, 11.1.3, the test method disclosed in the technical description may be utilized........................:		N/E
201.11.6.5.101	Additional requirements for ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEM		N

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Clause	Requirement + Test	Result - Remark	Verdict
	The ENCLOSURE of a PULSE OXIMETER EQUIPMENT shall provide a degree of protection to the harmful ingress of water of:		---
	– at least an IPX2 for PULSE OXIMETER EQUIPMENT intended for use during professional transport of a PATIENT outside a professional healthcare facility; and	User Manual 2.1 Intended use Used in the hospital only	N
	– at least an IPX1 for PULSE OXIMETER EQUIPMENT not intended for use during professional transport of a PATIENT outside a professional healthcare facility	User Manual 2.1 Intended use Used in the hospital only	N
	For PORTABLE ME EQUIPMENT that is only intended to be used within a protective case, this requirement may be met while the ME EQUIPMENT is inside the case		N
201.11.8.101.1	Supply failure TECHNICAL ALARM CONDITION		P
	If PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM that detects a PHYSIOLOGICAL ALARM CONDITION the ALARM SYSTEM shall provide at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION to indicate when the power supply falls outside the values specified for normal operation	See appended Table 201.11.8.101.1 a)	P
	If the function of the PULSE OXIMETER EQUIPMENT is maintained by the switchover to an INTERNAL ELECTRICAL POWER SOURCE, the supply failure MEDIUM PRIORITY TECHNICAL ALARM CONDITION shall not be activated. Any such switchover to an INTERNAL ELECTRICAL POWER SOURCE shall be indicated by an INFORMATION SIGNAL or a LOW PRIORITY TECHNICAL ALARM CONDITION	See appended Table 201.11.8.101.1 b)	P
201.11.8.101.2	Settings and data storage following short interruptions or automatic switchover		P
	When the SUPPLY MAINS to the PULSE OXIMETER EQUIPMENT is interrupted for less than 30 s or automatic switchover to an INTERNAL ELECTRICAL POWER SOURCE occurs, all settings and all stored PATIENT data shall be preserved unchanged	See appended Table 201.11.8.101.2	P
201.11.8.101.3	Operation following long interruptions		P
	The instructions for use shall disclose the operation of the PULSE OXIMETER EQUIPMENT after the SUPPLY MAINS has been interrupted when the "on-off" switch remains in the "on" position and is restored after a period of time that is longer than 30 s..:		P

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Clause	Requirement + Test	Result - Remark	Verdict
201.12	ACCURACY of controls and instruments and protection against hazardous outputs		N/E
201.12.1.101.1	SpO_2 ACCURACY of the pulse oximeter equipment – Specification		N/E
	The *Sp*O2 ACCURACY of PULSE OXIMETER EQUIPMENT shall be a root-mean-square difference of less than or equal to 4,0 % *Sp*O2 over the range of 70 % to 100 % *Sa*O2. The *Sp*O2 shall be indicated as FUNCTIONAL OXYGEN SATURATION and shall not be indicated as FRACTIONAL OXYHAEMOGLOBIN.............................. .:		N/E
	The DECLARED RANGES of *Sp*O2 and *Sp*O2 ACCURACY over those ranges shall be disclosed in the instructions for use. The *Sp*O2 ACCURACY shall be stated over the range 70 % to 100 % (additional information is found in 50.101.2.1). *Sp*O2 ACCURACY information shall be accompanied by a note reminding the reader that, because PULSE OXIMETER EQUIPMENT measurements are statistically distributed, only about two-thirds of PULSE OXIMETER EQUIPMENT measurements can be expected to fall within ±*A*rms of the value measured by a CO-OXIMETER. When a PULSE OXIMETER MONITOR is suitable for use with a variety of PULSE OXIMETER PROBES, *Sp*O2 ACCURACY information shall be made available for each type of PULSE OXIMETER PROBE... .:		N/E
	Additional *Sp*O2 ACCURACY specifications over other ranges may also be provided.		---
	If *Sp*O2 ACCURACY claims below 65 % *Sa*O2 are made, *Sp*O2 ACCURACY shall be stated in an additional range over a span of saturation not to exceed 20 % *Sa*O2...........:	SpO2 ACCURACY range 70 % to 100 %	N/E
	Span of Saturation *Sa*O2 (%)......................:		---
201.12.1.101.2.1	Determination of SpO_2 ACCURACY – Data collection		N/E
	The claims of *Sp*O2 ACCURACY shall be supported by CONTROLLED DESATURATION STUDY measurements taken over the full range of *Sa*O2 values +3 % of the lower value and −3 % of the upper value for which *Sp*O2 ACCURACY is claimed	Reference attached document - controlled desaturation study conducted according to ISO 14155:2011	N/E

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Clause	Requirement + Test	Result - Remark	Verdict
	The CONTROLLED DESATURATION STUDY shall comply with the requirements of ISO 14155:2011		N/E
	Data points should be recorded with comparable density over the full range claimed..:		N/E
	Any types of interference known to influence or affect the *Sp*O2 ACCURACY need not be stated as part of the *Sp*O2 ACCURACY specification, but shall be disclosed in the instructions for use..................................:		N/E
	A summary of the test methods used to establish the *Sp*O2 ACCURACY claims shall be disclosed in the technical description		N/E
	FUNCTIONAL TESTERS or PATIENT simulators shall not be used to VALIDATE the *Sp*O2 ACCURACY of PULSE OXIMETER EQUIPMENT		N/E
201.12.1.101.2.2	Data analysis		N/E
	For each range specified, *Sp*O2 ACCURACY of the PULSE OXIMETER EQUIPMENT shall be stated in terms of the root-mean-square (rms) difference between measured values (*Sp*O2*i*) and reference values (*Sri*), as given by Equation (1). $A_{rms} = \sqrt{\frac{\sum_{i=1}^{n}(SpO_{2i} - S_{Ri})^2}{n}}$		N/E
	The standard reference for the *Sp*O2 ACCURACY as read by PULSE OXIMETER EQUIPMENT shall be traceable to *Sa*O2 values obtained from CO-OXIMETER analysis of simultaneously drawn arterial blood. The CO-OXIMETER should have a specified *Sa*O2 performance of 1 % (1 standard deviation) or better over the range for which the MANUFACTURER makes *Sp*O2 ACCURACY claims. Quality assurance, including maintenance and calibration, PROCEDURES for assessing CO-OXIMETER performance that are required in laboratories reporting clinical data shall be utilized for the CO-OXIMETER. Particular attention shall be given to the range for which the MANUFACTURER makes *Sp*O2 ACCURACY claims..................................:		N/E
201.12.1.101.2.3	Characteristics of the clinical study population		N/E

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Clause	Requirement + Test	Result - Remark	Verdict
	The summary of the clinical study report used to assess *Sp*O2 ACCURACY shall state whether the test subjects were sick or healthy and shall describe their skin colour, age and gender. This information shall be disclosed in the ACCOMPANYING DOCUMENT............:		N/E
201.12.1.102	Accuracy under conditions of motion		N/E
	If a MANUFACTURER claims that the PULSE OXIMETER EQUIPMENT is accurate during motion, ACCURACY specifications during motion shall be disclosed in the instructions for use..:		N/E
	A summary of the test methods used to establish the ACCURACY claims during motion shall be disclosed in the technical description. The summary should include the average percentage modulation (of the infrared signal as an indicator of pulsatile signal strength) in quiescent and motion periods during the test.................................:		N/E
201.12.1.103	ACCURACY under conditions of low perfusion		N/E
	If a MANUFACTURER claims that the PULSE OXIMETER EQUIPMENT is accurate under conditions of low perfusion, ACCURACY specifications under these conditions shall be disclosed in the instructions for use.............:		N/E
	A summary of the test methods used to establish the ACCURACY claims under conditions of low perfusion shall be disclosed in the technical description. The summary should include percentage modulation of the infrared signal as an indicator of pulsatile signal strength...:		N/E
201.12.1.104	Pulse rate ACCURACY		N/E

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Clause	Requirement + Test	Result - Remark	Verdict
	Pulse rate ACCURACY shall be stated as the root-mean-square (rms) difference between paired pulse rate data recorded with the PULSE OXIMETER EQUIPMENT and with a reference method. Pulse rate ACCURACY shall be stated either over the full claimed range of the PULSE OXIMETER EQUIPMENT or as separate pulse rate ACCURACY specifications over segments of that range. The reference method for the computation of pulse rate ACCURACY may be an electronic pulse simulator, ECG heart rate, palpated pulse, thoracic auscultation or a second PULSE OXIMETER EQUIPMENT which has been qualified by comparison to one of these references. The reference method for the determination of pulse rate ACCURACY shall be disclosed in the technical description.................................:		N/E
201.12.4.101	Protection against hazardous output – DATA UPDATE PERIOD		P
	There shall be an indication that *Sp*O2 or pulse rate data is not current when the DATA UPDATE PERIOD is greater than 30 s. The DATA UPDATE PERIOD time may be shorter than 30 s. A maximum DATA UPDATE PERIOD for saturation and pulse rate shorter than 30 s is recommended for continuous neonatal monitoring and diagnostic applications...:	User Manual Part 8 TREND Manu Usage Data update period – 6 to 7 seconds and the response time is 2 to 4 seconds in Fast seconds	P
	If the PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM that detects any PHYSIOLOGICAL ALARM CONDITIONS, the ALARM SYSTEM shall provide at least a LOW PRIORITY ALARM CONDITION to indicate when the DATA UPDATE PERIOD exceeds 30 s................:		P
	PULSE OXIMETER EQUIPMENT that is not equipped with an ALARM SYSTEM that detects any PHYSIOLOGICAL ALARM CONDITION shall indicate when the DATA UPDATE PERIOD exceeds 30 s. The indication shall be described in the instructions for use...................................:		N
201.12.4.102	Signal inadequacy		P

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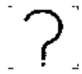
Clause	Requirement + Test	Result - Remark	Verdict
	An indicator of signal inadequacy shall be provided to the OPERATOR when the displayed *Sp*O2 or pulse rate value is potentially incorrect. Symbol ISO 7000-0435 (see Table D.2.101, Symbol 12) may be used for this indication. A description of the indicator and its function shall be provided in the ACCOMPANYING DOCUMENT............:	 There are "- - -" or "MOVING" provided on the display as an indicator of signal inadequacy Appropriate documentation provided in the user manual.	P
201.13	HAZARDOUS SITUATIONS and fault conditions		P
201.13.101	Detection of PULSE OXIMETER PROBE faults and PROBE CABLE EXTENDER faults		P
	If the PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM to detect any PHYSIOLOGICAL ALARM CONDITIONS, the ALARM SYSTEM shall provide a TECHNICAL ALARM CONDITION to indicate when any wire in the PULSE OXIMETER PROBE cable or PROBE CABLE EXTENDER is opened or shorted to any other wire in the PULSE OXIMETER PROBE cable or PROBE CABLE EXTENDER that causes other than normal operation	See appended Table 201.13.101	P
	PULSE OXIMETER EQUIPMENT that is not equipped with an ALARM SYSTEM that detects any PHYSIOLOGICAL ALARM CONDITIONS shall visually indicate the presence of PULSE OXIMETER PROBE FAULTS. The indication shall be described in the instructions for use	See appended Table 201.13.101	
201.15	Construction of ME EQUIPMENT		N
201.15.3.5.101.1	Additional requirements for rough handling – Shock and Vibration		N
	PULSE OXIMETER EQUIPMENT or its parts not intended for use during professional transport of a PATIENT outside a professional healthcare facility shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping and rough handling. STATIONARY EQUIPMENT is exempt from the requirements of this sub-clause	See appended Table 201.15.3.5.101.1 a) and b) Used in the hospital only	N
	After the specified tests, the PULSE OXIMETER EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE	See appended Table 201.15.3.5.101.1 a) and b)	N
201.15.3.5.101.2	Shock and vibration for professional transport		N

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Clause	Requirement + Test	Result - Remark	Verdict
	PULSE OXIMETER EQUIPMENT or its parts, intended for use during professional transport of a PATIENT outside a professional healthcare facility, shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping and rough handling	See appended Table 201.15.3.5.101.2 a), b and c) Used in the hospital only	N
	After the specified tests, the PULSE OXIMETER EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE	See appended Table 201.15.3.5.101.2 a), b and c)	N
201.15.101	Mode of operation		P
	PULSE OXIMETER EQUIPMENT shall be suitable for CONTINUOUS OPERATION......:	Equipment is suitable for Continuous operation	P
201.101.1	Pulse oximeter probes and probe cable extenders – General		N/E
	All PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS shall comply with the requirements of this International Standard, whether they are produced by the MANUFACTURER of the PULSE OXIMETER MONITOR, by another entity ("third party manufacturer" or healthcare provider) or are REPROCESSED......................................:		N/E
	MANUFACTURERS of REPROCESSED PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS shall perform testing to ensure that all PULSE OXIMETER EQUIPMENT specifications are met with each model of PULSE OXIMETER MONITOR with which the PULSE OXIMETER PROBE or PROBE CABLE EXTENDER is intended to be used. The ACCOMPANYING DOCUMENT of REPROCESSED PULSE OXIMETER PROBES and PROBE CABLE EXTENDERS shall list all PULSE OXIMETER MONITORS with which compatibility is claimed...............:		N/E
	It is the responsibility of the MANUFACTURER to VALIDATE their PROCESSES to ensure that any new or REPROCESSED product complies with the requirements of this International Standard		N/E
201.101.2	Labelling		P

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Clause	Requirement + Test	Result - Remark	Verdict
	The MODEL OR TYPE REFERENCE of at least one PULSE OXIMETER MONITOR shall be included in the ACCOMPANYING DOCUMENT provided with each PULSE OXIMETER PROBE, compliant with 201.101.1.....:	The model serial numbers for SpO2 sensors are identified on the sensors.	P
	Statements shall be included in the ACCOMPANYING DOCUMENT of each PULSE OXIMETER PROBE or PROBE CABLE EXTENDER to the effect that:		P
	a) probes are designed for use with specific monitors.....:	Refer to the user manual	P
	b) the operator is responsible for checking the compatibility of the monitor, probe and cable before use.....:	Refer to the user manual	P
	c) incompatible components can result in degraded performance.....:	Refer to the user manual	P
201.102	Saturation of pulse INFORMATION SIGNAL		P
	If a variable-pitch auditory INFORMATION SIGNAL is provided to indicate the detection of a pulse and the relative *Sp*O2 level, the pitch change shall follow the *Sp*O2 reading, e.g. the pitch decreases as the *Sp*O2 reading decreases.....:	Appropriate construction.	P

201.103.1	SIGNAL INPUT/OUTPUT PART – General		N
	BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained during failure of equipment connected to or the disruptions of connections to SIGNAL INPUT/OUTPUT PARTS of PULSE OXIMETER EQUIPMENT	See appended Risk Management Table 201.103.1 See appended Table 201.103.1 No signal input/output part	N
201.103.2	Connection to electronic health record		N
	PULSE OXIMETER EQUIPMENT should be equipped with a SIGNAL INPUT/OUTPUT PART that permits data transmission from the PULSE OXIMETER EQUIPMENT to an electronic health record. The data transmitted should include:	See appended Table 201.103.2 No signal input/output part	N
	a) PULSE OXIMETER EQUIPMENT identification		---
	– This may be provided by MODEL OR TYPE REFERENCE, serial number and the software unique identifier of the PULSE OXIMETER EQUIPMENT.....:		N

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Clause	Requirement + Test	Result - Remark	Verdict
	– This may be provided by a unique device identifier (UDI)..:		N
	b) the *Sp*O2 reading..:		N
	c) if provided, the pulse rate..............................:		N
	d) if PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM that detects any ALARM CONDITIONS, the ALARM SYSTEM status including:		N
	– the ALARM LIMITS..:		N
	– the presence of any ALARM CONDITIONS.:		N
	– the occurrence of any ALARM SIGNAL inactivation..:		N
	The data transmission should be capable of being provided with a NETWORK/DATA COUPLING in accordance with ASTM F2761-09..:		N
201.103.3	Connection to a distributed alarm system		N
	For PULSE OXIMETER EQUIPMENT that is equipped with an ALARM SYSTEM that detects a PHYSIOLOGICAL ALARM CONDITION, the ALARM SYSTEM should be equipped with a SIGNAL INPUT/OUTPUT PART that permits connection to a DISTRIBUTED ALARM SYSTEM. The data transmission should be capable of being provided with a NETWORK/DATA COUPLING in accordance with ASTM F-2761-09..:	Not for connection to a distributed alarm system	N
201.103.4	Connection for remote control		N
	PULSE OXIMETER EQUIPMENT may be equipped with a SIGNAL INPUT/OUTPUT PART for connection for external control of the PULSE OXIMETER EQUIPMENT. The data transmission should be capable of being provided with a NETWORK/DATA COUPLING in accordance with ASTM F-2761-09..:	Not to other electronic health record system	N
202	**Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests**		**P**
202.6.2.1.7	Patient simulation		P
	For ME EQUIPMENT and ME SYSTEMS without a manual sensitivity adjustment	See attached IEC 60601-1-2 EMC Test Report	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– During immunity testing, the PULSE OXIMETER EQUIPMENT shall be tested at an *Sp*O2 reading within the calibrated range that is at least 5 % different from that of a noise-induced value and less than (100 % minus the *Sp*O2 ACCURACY of the PULSE OXIMETER EQUIPMENT)..........................:		P
	– The pulse rate shall be different from that of the noise-induced signal frequency and within the specified range of the pulse rate display		P
	– The *Sp*O2 and pulse rate signal may be derived from a PATIENT simulator for these tests...:		P
202.6.2.1.10	Requirements		P
	Under the IMMUNITY TEST LEVELS specified in IEC 60601-1-2:2007, 6.2, PULSE OXIMETER EQUIPMENT shall be able to provide BASIC SAFETY and ESSENTIAL PERFORMANCE	See attached IEC 60601-1-2 EMC Test Report	P
	The following conditions associated with BASIC SAFETY and ESSENTIAL PERFORMANCE shall apply:		---
	a) No permanent degradation or loss of function which is not recoverable, due to damage of ME EQUIPMENT (components) or software, or loss of data shall be observed at any IMMUNITY TEST LEVEL specified in IEC 60601-1-2:2007, 6.2 and 202.6.2.3 aa)		P
	b) Operation within specified *Sp*O2 ACCURACY limits and pulse rate ACCURACY limits or generation of either a TECHNICAL ALARM CONDITION or an indication of abnormal operation		P
	c) Any temporary degradation of performance or interruption of an intended operation at immunity testing according to IEC 60601-1-2:2007, 6.2.2, 6.2.4, 6.2.5 and 6.2.7 shall recover from any disruption within 30 s without OPERATOR intervention		P
	d) No change of operating mode		P
	e) No inappropriate delivery of energy to the PATIENT shall occur at any IMMUNITY TEST LEVEL specified in IEC 60601-1-2:2007, 6.2 and 202.6.2.3 aa).		P
202.6.2.3	Radiated RF electromagnetic fields		P

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Clause	Requirement + Test	Result - Remark	Verdict
	In addition to these requirements, PULSE OXIMETER EQUIPMENT intended for use during professional transport of a PATIENT outside the professional healthcare facility shall comply with 202.6.2.1.10 at the IMMUNITY TEST LEVEL of 20 V/m (80 % amplitude-modulated at 1 000 Hz) over the range of 80 MHz to 2,5 GHz (additional information is found in IEC 60601-1-2:2007, Table 9).	See attached IEC 60601-1-2 EMC Test Report	P
208	**Medical electrical equipment — Part 1-8: General requirements for safety — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems**		P
208.6.1.2.101	Additional requirements for ALARM CONDITION priority		P
	If the PULSE OXIMETER EQUIPMENT is equipped with an ALARM SYSTEM that detects a PHYSIOLOGICAL ALARM CONDITION, the ALARM SYSTEM shall provide at least a MEDIUM PRIORITY ALARM CONDITION for low *Sp*O2 level	See appended Table 208.6.1.2.101	P
208.6.5.4.101	Additional requirements for DEFAULT ALARM PRESET		P
	If the PULSE OXIMETER MONITOR is equipped with an ALARM SYSTEM to detect a low *Sp*O2 level PHYSIOLOGICAL ALARM CONDITION, the ALARM LIMIT in the MANUFACTURER-configured ALARM PRESET for the *Sp*O2 level PHYSIOLOGICAL ALARM CONDITION shall not be less than 85 % *Sp*O2	See appended Table 208.6.5.4.101	P
	ALARM limit of SpO2 level PHYSIOLOGICAL ALARM CONDITION (%)..........................:	90 %	---
	Unless the low *Sp*O2 ALARM LIMIT is displayed continuously, the low *Sp*O2 ALARM LIMIT of any OPERATOR configured ALARM PRESET shall not be less than the low *Sp*O2 ALARM LIMIT stored in the DEFAULT ALARM PRESET..................................:		P
208.6.8.5.101	Additional requirements for ALARM SIGNAL inactivation states, indication and access		
	The MANUFACTURER-configured default AUDIO PAUSED or ALARM PAUSED interval of PULSE OXIMETER EQUIPMENT shall not exceed 2 min	See appended Table 208.6.8.5.101 Alarm cannot be paused as intended by this sub-clause only muted for 2 minutes.	P

201.4.101	ESSENTIAL PERFORMANCE		P
Distributed Essential Performance requirements			
Requirements	Document Ref (Document No. & paragraph)	Result - Remarks	Verdict

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.4.101	ESSENTIAL PERFORMANCE		P
Distributed Essential Performance requirements			
Requirements	Document Ref (Document No. & paragraph)	Result - Remarks	Verdict
For PULSE OXIMETER EQUIPMENT provided with an ALARM SYSTEM that includes the capability to detect a PHYSIOLOGICAL ALARM CONDITION: *Sp*O2 ACCURACY , PULSE RATE ACCURACY* and limit ALARM CONDITIONS (Sub clause- 201.12.1.101, 201.12.1.104 and 208.6.1.2.101) or	See document RA05-02, clause 4.3 and appended table	- SpO2 accuracy - Heart rate accuracy - Alarm Limit - Battery condition alarm	P
Generation of a TECHNICAL ALARM CONDITION (Sub clause – 201.11.8.101.1, 201.12.4 and 201.13.101)	See document RA05-02, IEC 60601-1-8 table	Physiological conditions: - High/low heart rate limits violated : Medium - High/low SpO2 limits violated : Medium - Unable to determine pulse rate or SpO2 : Low Technical conditions: - Communication error : High - SpO2 cable/sensor disconnect : Low - Finger off from SpO2 sensor: Low - Low battery: Medium - Low internal coin battery : Low - Clock setting lost : Low	P
For PULSE OXIMETER EQUIPMENT not provided with an ALARM SYSTEM that includes the capability to detect a PHYSIOLOGICAL ALARM CONDITION:*Sp*O2 ACCURACY* and PULSE RATE ACCURACY (Sub clause- 201.12.1.101 and 201.12.1.104) or			N
or indication of abnormal operation (Sub clause – 201.12.4 and 201.13.101)			N

* Note: Subclause 202.6.2.1.7 indicates methods of evaluating *Sp*O2 ACCURACY and PULSE RATE ACCURACY as acceptance criteria following specific tests required by this standard.

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.7.9.2.14.101	RM RESULTS TABLE: information regarding toxicity or the effect on tissues of materials with which the PATIENT or any other person can come into contact and information on residual RISKS for children, pregnant or nursing women and, if applicable, any appropriate precautionary measures		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
6.4	See document RA05-02 Refer to clause 6.4 and appended table	The residual risk has been evaluated. Recorded as the following : - Severity : 2 - Probability : 1 - Risk: A1(Broadly acceptable)	P

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.11	TABLE: Protection against excessive temperatures in ME EQUIPMENT	N/E
Pulse Oximeter Model No.....:		
Test supply voltage/frequency (V/Hz)[4].....:		
Skin temperature and color (℃, white/dark)..... .....:		
Thermocouple Type and Size.....: Note: Type K ≤ 0.25 mm wire		
Measurement expected accuracy.....:		
Maximum allowable temperature.....: Note: All patients 41℃; Patients less than 1 year old 41℃; Adults for up to 8 hours 42℃; Adults for up to 4 hour 43℃		
Environmental ambient during test (℃, %RH, atmospheric pressure)... .....:		

SpO_2 Sensor Model No.	Thermocouple location[3]	Max measured temperature[2], (°C)	Remarks

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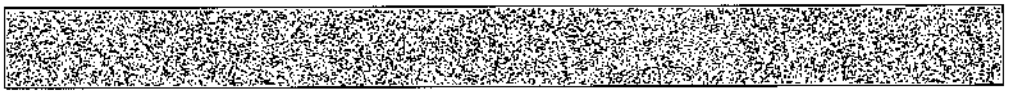


ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

This International Standard does not require a particular method of measuring the skin temperature beneath the PULSE OXIMETER PROBE. There are many different widely known and accepted methods of measuring surface temperatures. Different PULSE OXIMETER PROBE MANUFACTURERS have evolved their own methods of measuring temperature, using either human test subjects or thermo-mechanical simulators. It would be impractical today to find a single universally acceptable test method, and the excellent thermal safety record of pulse oximetry suggests that such a method is not necessary. PULSE OXIMETER PROBE designers who wish to take advantage of the higher temperatures should keep the following cautions in mind

– Measurement tolerances are required to be evaluated carefully. The MANUFACTURER should know the true ACCURACY of temperature measurement when designing PULSE OXIMETER PROBES for use at temperatures above 41 ℃ since a higher temperature reduces the margin of safety

– Temperature sensors are required to be small enough so as not to distort the measurement. The largest temperature sensors that have been found acceptable have characteristic dimensions near 0,5 mm (e.g. the bead of a thermocouple welded from 0,25 mm wire). Often still smaller temperature sensors are used

– The temperature sensor is required to not reduce the measured peak temperature by conducting a significant amount of heat away from the measurement region. Thus, it would usually be inappropriate to use the copper-constantan type T thermocouples that are common in medical investigation, since the high thermal conductivity of the copper wire could cause a falsely low temperature measurement

– The temperature sensor is required to be located precisely at the warmest point on the interface between the skin and the PULSE OXIMETER PROBE. This is often, but not invariably, a point on the PULSE OXIMETER PROBE that is midway between the two LED chips that are typically used in emitters. The warmest point is found by testing

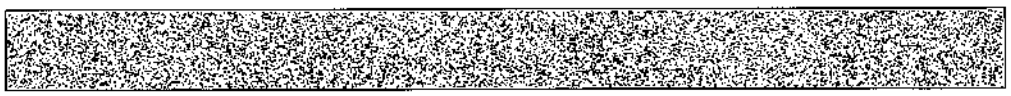
– Experimental methods are required to be adequate to ensure that recommended temperature limits are met under "reasonable worst case" conditions. As an example, reasonable worst case for neonatal PULSE OXIMETER PROBES might include the following conditions

- The PATIENT has poor peripheral circulation. There is therefore little forced-convection heat transfer by blood to increase the effective thermal conductivity of surface tissue

- The LEDs in the PULSE OXIMETER PROBE are driven at the maximum current which the PULSE OXIMETER MONITOR is capable of providing during normal operation (this condition can occur when the PATIENT has very dark skin or a thick foot)

- An active heat source is in use to raise the baby's abdominal skin temperature artificially to 37 ℃

Not every model of PULSE OXIMETER PROBE is required to be tested directly on or representing "worst-case" PATIENTS. The MANUFACTURER should select methods for evaluation of the thermal performance of the PULSE OXIMETER PROBE that lead to confident prediction of thermal safety on such PATIENTS



ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.11.6.5.101	TABLE: Ingress of water		N
☐	IPX1	Not intended for use during professional transport of a PATIENT outside a professional healthcare facility	
☐	IPX2	Intended for use during professional transport of a PATIENT outside a professional healthcare facility	

Test Condition/Method	Part under test	Remarks

Supplementary information:

201.11.8.101.1 a)	TABLE: Supply failure TECHNICAL ALARM CONDITION			P
Power Supply	Voltage triggering a Technical Alarm Condition (V)	Indication of medium priority technical alarm condition	Observed behaviour as voltage continues to decrease	Remarks
Battery Operation	3.4V	Alarm, Message	Power Off	

Supplementary information:

201.11.8.101.1 b)	TABLE: Supply failure TECHNICAL ALARM CONDITION			P
Automatic switchover to an internal electrical power source	Voltage triggering a Technical Alarm Condition or Information Signal (V)	Indication of Information Signal	Indication of Low Priority Technical Alarm Condition	Remarks
Detach AC Connector	3.5Vdc	AC LED off And DC LED on	Low Priority Alarm	Information Signal

Supplementary information: A medium priority technical alarm condition shall not be activated

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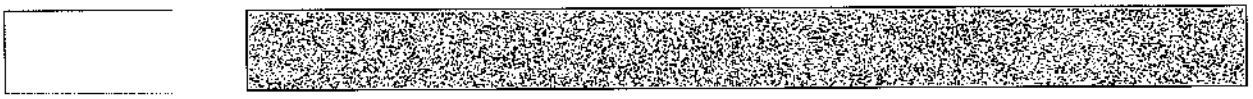
Clause	Requirement + Test	Result - Remark	Verdict

201.11.8.101.2	TABLE: Settings and data storage following short interruptions or automatic switchover			P
Automatic switchover to an internal electrical power source (Yes/No)	Settings before power interruption	Settings after power interruption	Data storage before power interruption	Data storage after power interruption
YES	AC LED on	LED on	All stored	unchanged
Supplementary information: A medium priority technical alarm condition shall not be activated				

201.13.101	TABLE: Detection of PULSE OXIMETER PROBE faults and PROBE CABLE EXTENDER faults			P
Pulse Oximeter Probe(s):	SpO2 Probe and Pulse Oximeter Cable are integrated			
Pulse Oximeter Cable(s)				
Pulse Oximeter probe cable extender(s):				
Identify active (used) wire in the pulse oximeter (probe, cable and/or extender)	Fault introduced (opened or shorted)	Continues Normal Operation	Technical Alarm Condition	Indication of probe faults
SpO2 cable/sensor	opened	Pulse oximeter probe fault is indicated "SENSOR OFF" displayed	Low priority alarm	Sensor off
Supplementary information: IFU describes these indications				



ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5.10 1.1 a) (Type 1)	TABLE: Shock test (IEC 60068-2-27:2008) for an Pulse Oximeter Equipment or its parts <u>not intended</u> for use during professional transport of a patient outside a professional health care facility under the following conditions (Test Type 1):		N
	Peak acceleration..:	150 m/s^2 (15 g)	
	Duration ....:	11 ms	
	Pulse shape ....:	half-sine	
	Number of shocks ....:	3 shocks per direction per axis (18 total)	

Applied Shock Direction	Applied Shock Axis	Method	Remarks
BASIC SAFETY Verification:			
ESSENTIAL PERFORMANCE Verification:			
Supplementary information: NOTE: This represents Class 7M2 as described in IEC/TR 60721-4-7:2001			

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5.10 1.1 a) (Type 2)	TABLE: Shock test (IEC 60068-2-27:2008) for a Pulse Oximeter Equipment or its parts not intended for use during professional transport of a patient outside a professional health care facility under the following conditions (Test Type 2):		N
	Peak acceleration.....	300 m/s^2 (30 g)	
	Duration	6 ms	
	Pulse shape.....	half-sine	
	Number of shocks	3 shocks per direction per axis (18 total)	

Applied Shock Direction	Applied Shock Axis	Method	Remarks

BASIC SAFETY Verification:		
ESSENTIAL PERFORMANCE Verification:		

Supplementary information:

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

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5.10 1.1 b) (Broad-band random)	TABLE: Vibration Test (IEC 60068-2-64:2008) for a Pulse Oximeter Equipment or its parts not intended for use during professional transport of a patient outside a professional health care facility under the following conditions (Broad-band random vibration test):		N
1	Acceleration amplitude	10 Hz to 100 Hz: 1,0 $(m/s^2)^2/Hz$	
2	Acceleration amplitude	100 Hz to 200 Hz: - 3 db per octave	
3	Acceleration amplitude	200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2/Hz$	
	Duration	10 min* per perpendicular axis (3 total) or 30 min per perpendicular axis (3 total) is recommended	

Perpendicular axis subjected to broad-band random vibration test	Acceleration amplitude	Method	Remarks
1	1		
	2		
	3		
2	1		
	2		
	3		
3	1		
	2		
	3		
BASIC SAFETY Verification:			
ESSENTIAL PERFORMANCE Verification:			
Supplementary information: NOTE : This represents Class 7M1 and 7M2 as described in IEC/TR 60721-4-7:2001			

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5.10 1.2 a) (Type 1)	TABLE: Shock test for professional transportation (IEC 60068-2-27:2008) for a Pulse Oximeter Equipment or its parts intended for use during professional transportation of a PATIENT outside a healthcare facility under the following conditions (Test Type 1):		N
	Peak acceleration	300 m/s^2 (30 g)	
	Duration	11 ms	
	Pulse shape	half-sine	
	Number of shocks	3 shocks per direction per axis (18 total)	

Applied Shock Direction	Applied Shock Axis	Method	Remarks

BASIC SAFETY Verification:		
ESSENTIAL PERFORMANCE Verification:		

Supplementary information:

NOTE This represents Class 7M3 as described in IEC/TR 60721-4-7:2001

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5.10 1.2 a) (Type 2)	TABLE: Shock test (IEC 60068-2-27:2008) for a Pulse Oximeter Equipment or its parts intended for use during professional transport of a patient outside a professional health care facility under the following conditions (Test Type 2):		N
	Peak acceleration ....:	1000 m/s^2 (100 g)	
	Duration ....:	6 ms	
	Pulse shape ....:	half-sine	
	Number of shocks..:	3 shocks per direction per axis (18 total)	

Applied Shock Direction	Applied Shock Axis	Method	Remarks
BASIC SAFETY Verification:			
ESSENTIAL PERFORMANCE Verification:			
Supplementary information: NOTE: This represents Class 7M3 as described in IEC/TR 60721-4-7:2001			

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5.10 1.2 b) (Broad-band random)	TABLE: Vibration Test (IEC 60068-2-64:2008) for a Pulse Oximeter Equipment or its parts <u>intended</u> for use during professional transport of a patient outside a professional health care facility under the following conditions (Broad-band random vibration test):		N
1	Acceleration amplitude..	10 Hz to 100 Hz: 5,0 $(m/s^2)^2/Hz$	
2	Acceleration amplitude..	100 Hz to 200 Hz: - 7 db per octave	
3	Acceleration amplitude..	200 Hz to 2 000 Hz: 1,0 $(m/s^2)^2/Hz$	
	Duration	30 min per perpendicular axis (3 total)	

Perpendicular axis subjected to broad-band random vibration test	Acceleration amplitude	Method	Remarks
1	1		
	2		
	3		
2	1		
	2		
	3		
3	1		
	2		
	3		
BASIC SAFETY Verification:			
ESSENTIAL PERFORMANCE Verification:			

Supplementary information:

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

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.15.3.5.101.2 c) (Free - Fall)	TABLE: Free fall test (IEC 60068-2-31:2008), using PROCEDURE 1, for an RGM or its parts intended for use during professional transport of a patient outside a professional health care facility under the following conditions (Free-Fall):	N
1	Fall height for mass ≤ 1 kg..... :	0,25 m
2	Fall height for mass > 1 kg and ≤ 10 Kg ..... :	0,1 m
3	Fall height for mass > 10 kg and ≤ 50 Kg ..... :	0,05 m
4	Fall height for mass > 50 kg ..... :	0,01 m

Specified Attitude (Orientation)	Mass (Kg)	Fall No.	Remarks
		1	
		2*	
		1	
		2*	
		1	
		2*	
		1	
		2*	

Verification Type	Verification Method	Remarks
BASIC SAFETY		
ESSENTIAL PERFORMANCE		

Supplementary information:

2*: Number of falls: 1 in each specified attitude. Two falls in each specified attitude is recommended.

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

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

201.103.1	RM RESULTS TABLE: Failure of equipment connected to or disruptions of connections to Signal Input/Output parts		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
4.2		No Signal Input/Output parts	
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.6			

201.103.1	TABLE: Failure of equipment connected to or disruptions of connections to Signal Input/Output parts			N
Signal Input/Output part	Failure Mode	Basic Safety Verification	Essential Performance Verification	Remarks
				No Signal Input/Output parts
Supplementary information: A medium priority technical alarm condition shall not be activated				

201.103.2	TABLE: Electronic Health Record connection			N
Identification of Pulse Oximeter Equipment	SpO_2 Reading	Pulse Rate	Alarm System Status	Remarks
				No Signal Input/Output parts
Supplementary information: The network/data coupling should be provided in accordance with ASTM F2761-09. Alarm systems with physiological alarm conditions should be equipped with a signal input/output part that permits connection to a DISTRIBUTED ALARM SYSTEM.				

ISO 80601-2-61			
Clause	Requirement + Test	Result - Remark	Verdict

208.6.1.2.101	TABLE: Alarm Condition Priority	P
SpO_2 Low Alarm Limit Setting	SpO_2 Low Measurement (% SpO_2)	Medium Priority Alarm Condition
	≤ 90 %	Medium Priority
Supplementary information:		

208.6.5.4.101	TABLE: Default Alarm Preset	P
SpO_2 Low Alarm Limit Setting – Manufacturer-configured Alarm Preset	SpO_2 Low Alarm Limit Displayed Continuously (% SpO_2)	SpO_2 Low Alarm Limit Operator Configurable Alarm Preset (% SpO_2)
90 %	SpO_2 Low Alarm Limit Displayed Continuously	20% or Alarm off
Supplementary information:		

208.6.8.5.101	TABLE: Alarm Signal Inactivation States, Indication and Access	P
Default AUDIO PAUSED Interval maximum	Default ALARM PAUSED Interval maximum	Remarks
120s	120s	Not exceed 2min
Supplementary information: