primara
Test- und Zertifizier-GmbH

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

Report Reference No.....:	**15PP090-01_0**
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Total number of pages.....:	**130**
Tested by.....:	**Thomas Rogg**
(printed name and signature).....:	
Approved by.....:	**Valentin Haug**
(printed name and signature).....:	
Testing Laboratory.....:	**Primara Test und Zertifizier GmbH**
Address .....:	Germany 87600 Kaufbeuren, Gewerbestrasse 28
Applicant's name.....:	**NOVAFON GmbH**
Address .....:	Daimlerstr. 13 71384 Weinstadt – Beutelsbach;Germany
Test specification:	
Standard.....:	**IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)** **EN 60601-1:2006 + Cor. :2010 + A1:2013** DIN EN 60601-1:2013-12; VDE 0750-1:2013-12
Test procedure.....:	**CE**
Non-standard test method……..:	--
Test Report Form No.....:	IEC60601_1K
Test Report Form Originator.....:	UL(US)
Master TRF.....:	2015-11

General disclaimer:

The test results presented in this report relate only to the object tested.
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Test item description .....:	**Therapeutic handheld device**
Trade Mark .....:	NOVAFON
Manufacturer.....:	NOVAFON
Model/Type reference.....:	NOVAFON(PRO), NOVAFON power, NOVAFON classic, NOVAFON soft
Ratings .....:	230Vac, 50Hz, 65mA (identical for all models)

List of Attachments (including a total number of pages in each attachment):	
Appendix 1: Pictures of the Unit	**4 Pages**
Appendix 2: Technical Documentation	**3 Pages**
Appendix 3: Test Equipment List	**1 Page**

History Sheet:				
Date	Project Engineer	Signature Proj. Eng.	What was changed What was required to implant the change (like retest)	Report Number with Revision
2016-03-18	Thomas Rogg		Initial report written	0

Summary of testing

The unit under test (UUT) has been judged on the basis of the Standard for Medical electrical equipment as detailed on page 1 of this report.

The UUT is a protection class II product with external approved power supply. All secondary output circuits are separated from mains by reinforced insulation and rated SELV non-hazardous energy levels.

The UUT provides an
- approved external direct-plugin power supply with thermal cut-out protection
- Electrical and fire enclosure according to this standard.

The UUT does not have circuits for direct connection to the patient and is not intended for use in the presence of flammable anaesthetic mixtures with air, oxygen or nitrous oxide.

Applied part is a isolated plastic surface for therapeutic treatment to the human skin.

The UUT was tested to be suitable for connection to single phase 16 A IEC branch circuit. The unit is approved for TN connection.

The UUT has been evaluated for use in a Pollution Degree 2 and over voltage category II environment and a maximum altitude of 2000 m.

The UUT was evaluated for a maximum ambient temperature of 30 °C. The temperature test was performed 100 mm above bench without additional forced air cooling and the internal fans operating.

A Copy of the Risk Analysis and all needed accompanying documents (manual, technical description) of the end product are stored at PRIMARA . Compliance of the risk management process was checked by inspection of the Risk Management File.

The following standard parts were not evaluated within this Test report and have to be fulfilled by other means (e.g. additional Test Reports according to the specific standard):

- Clause 11.6.8/ 11.7: Biocompability (ISO 10993)
- Clause 12.2: Usability (60601-1-6)
- Clause 17: Electromagnetic compability (60601-1-2)

Tests performed (name of test and test clause):	**Testing location:**
All as relevant, see relevant clause below, if not tested by Primara, clause gives reference to external Test Report, Laboratory and testing location.	Primara Test und Zertifizier GmbH Gewerbestraße 28 87600 Kaufbeuren

Summary of compliance with National Differences

List of countries addressed:

EU

Related documents:
(Stored at Primara Test- und Zertifizier GmbH)
Risk Management and Usability Engineering

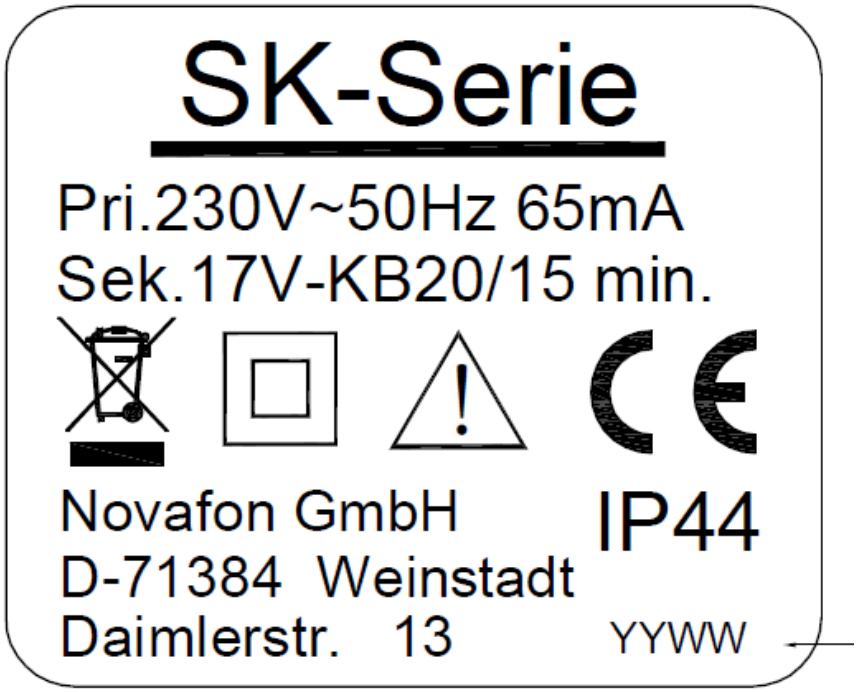
Doc. No.	Rev.	Title
1	2015-09-01	TD-SK-C7V01 C7 Risikoanalyse
2	2015-09-01	TD-SK-C7V01 Risikoanalyse Anlage 1 Deckblatt
3	2015-09-01	TD-SK-C7V01 Risikoanalyse Anlage 2 FMEA - 01.09.2015_CL
4	2015-09-01	TD-SK-C7V01 Risikoanalyse Anlage 3 Risikokontrolle
5	2015-09-01	TD-SK-C7V01 Risikoanalyse Anlage 4 Risikomanagementbericht
6	2015-09-01	TD-SK-C7V01 Risikoanalyse Anlage 5 Risikoreview
7	2015-09-01	AA-QM-08 Risikoamangement
8	2015-09-01	14971 Risikomanagement für Medizinprodukte

Manual and Labelling:

Doc. No.	Rev.	Title
9	2015	Bedienungsanleitung_deutsch_2015

Copy of marking plate

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



Marking labels on device:

NOVAFON

NOVAFON pro

NOVAFON power

NOVAFON classic

NOVAFON soft

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	hand-held
Device type (component/sub-assembly/ equipment/ system) :	equipment
Intended use (Including type of patient, application location) :	The device is a handheld therapeutic massage device which produces periodic mechanically vibration to be applied on the human skin.
Mode of operation .....:	non-continuous (20/15 min)
Supply connection	Direct plug in power supply
Accessories and detachable parts included.....:	Different massage heads, connected via screw connection
Other options include .....:	--
Testing	
Date of receipt of test item(s) .....:	2015-09-21
Dates tests performed.....:	2015-10-16 – 2016-03-17
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement.....:	Pass (P)
- test object was not evaluated for the requirement ..... :	N/E (collateral standards only)
- test object does not meet the requirement.....:	Fail (F)
Abbreviations used in the report:	
- normal condition.....: N.C.	- single fault condition.....: S.F.C.
- means of Operator protection .....: MOOP	- means of Patient protection ....: MOPP

General remarks:

Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version "J" of TRF for IEC for 60601-1 3rd edition with Amendment 1.

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

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

General product information:

The device is a handheld therapeutic massage device which produces periodic mechanically vibration to be applied on the human skin.

Description of model differences:

NOVAFON (pro)

The NOVAFON pro sonic instrument comes equipped with a dual switch setting. It includes:

- Setting 1 = 100 vibrations per second
- Setting 2 = 50 vibrations per second.

It is also fitted with a retractable, extendable handle

NOVAFON power,

It is fitted with a dual setting.

1. Setting 1 = 100 vibrations per second
2. Setting 2 = 50 vibrations per second.

this instrument has been extra heavily calibrated.

NOVAFON classic,

This particular model is the NOVAFON classic sonic wave instrument in its earliest form.
Setting 1: 100 vibrations per second

NOVAFON soft

The plastic sonic instrument operates with a penetrative effect which is lower than the other two models.

Setting 1: 100 vibrations per second

The plastic instrument is available in white, blue, red or yellow.

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

INSULATION DIAGRAM

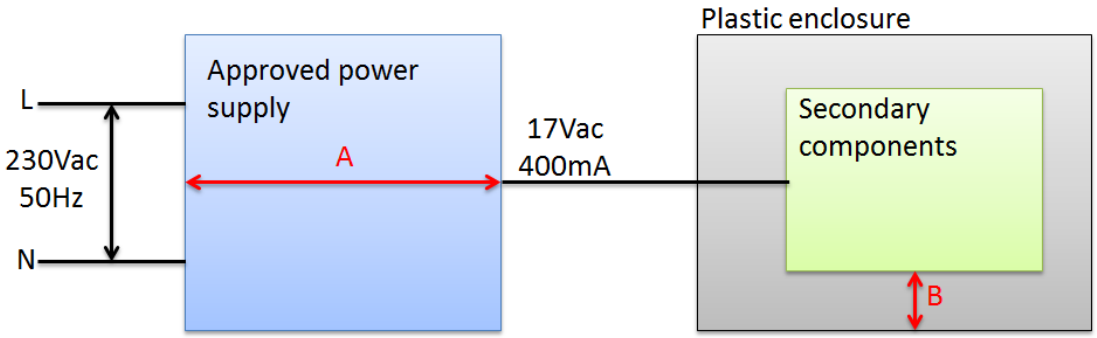


TABLE: INSULATION DIAGRAM		P
Pollution degree ..... :	**2**	—
Overvoltage category ..... :	**II**	—
Altitude..... :	**Up to 2000m**	—
Additional details on parts considered as applied parts ..... :	☐ **None** ☐ **Areas** _____ **(See Clause 4.6 for details)**	—

Area	**Number and type of Means of Protection: MOOP, MOPP**	**CTI**	**Working voltage**		**Required creepage (mm)**	**Required clearance (mm)**	**Measured creepage (mm)**	**Measured clearance (mm)**	**Remarks**
			V_{rms}	**V_{pk}**					
A	**2 MOPP**	**IIIb**	**247**	**349**	**8**	**5**	**9**	**9**	
B	**1 MOPP**	**IIIb**	**17**	**24,6**	**3,4**	**1,6**	**>10**	**>10**	

Supplementary Information:

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

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

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

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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
4	**GENERAL REQUIREMENTS**		P
4.1	**Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse**		P
4.2	**RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS**		P
4.2.2	**General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007) .....:**	See Appended RM Results Table 4.2.2.	P
4.2.3	**Evaluating RISK**		P
4.2.3.1	**a) Compliance with the standard reduces residual risk to an acceptable level**		P
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN .....:	RISK MANAGEMENT PLAN Document: TD-SK-C7V01 Risikoanalyse Anlage 2 FMEA - 01.09.2015_CL	P
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		N/A
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		N/A
4.2.3.2	**MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.**		N/A
4.3	**Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.**		N/A
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.		P
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		P
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE..... :	No unacceptable risk	N/A
	- RISK CONTROL measures implemented		P
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		P
4.4	**EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE .....:**	**5 Years**	P
4.5	**Alternative RISK CONTROL methods utilized:**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
	Alternative means based scientific data or clinical opinion or comparative studies ..... :		N/A
4.6	**RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10..... :**	See Appended Insulation Diagram Table	P
	MANUFACTURER assesses the risk of accessible parts coming into contact with the patient ....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF REFERENCE TO SPECIFIC RISKS: TD-SK-C7V01 RISIKOANALYSE ANLAGE 2 FMEA - 01.09.2015_CL (ISO 14971 CL. 4.2-4.4, 5, 6.2-6.5)	P
	Assessment identified the APPLIED PART TYPE requirements..... :	TYPE B	P
4.7	**ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2..... :**	SINGLE FAULT SAFE	P
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested.....: **(ISO 14971 Cl. 4.2-4.4)**	RISK ANALYSIS reference: TD-SK-C7V01 Risikoanalyse Anlage 2 FMEA - 01.09.2015_CL (ISO 14971 Cl4.2-4.4)	P
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically ..... :	See appended Table 13.2 for simulated physical test	P
4.8	**All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified ... :**		P
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS	See list of critical components	P
	RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No such components	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION... :	No such parts	N/A
	Components determined to be acceptable where used as a MEANS OF PROTECTION ..... :	No such components	N/A
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following	Reliability of components was assessed	P
	a) Applicable safety requirements of a relevant IEC or ISO standard	See list of critical components	P
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		N/A
4.9	**A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately..... :**	No such components	N/A
	RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:		N/A
4.10	**Power supply**		
4.10.1	**ME EQUIPMENT is suitable for connection to indicated power source** (select applicable)**.....:**	Supply mains	P
4.10.2	**Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:**		P
	- 250 V for HAND-HELD ME EQUIPMENT (V)..... :	230Vac	P
	– 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/A
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS		N/A
4.11	**Power input**		P
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%..... :	See appended Table 4.11	P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		P
5.1	**Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods .....:**		N/A
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. **(ISO 14971 Cl. 4.2-4.4)**	No such combinations	N/A
5.3	**Tests conducted within the environmental conditions specified in technical description**		P
	Temperature (ºC), Relative Humidity (%) ..... :	30°C, 50%	—
	Atmospheric Pressure (kPa) ..... :	1060hPa	—
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) ..... :**	253Vac	P
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)..... :	50Hz	P
	c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current..... :	Only one rated voltage	P
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered..... :	No d.c. supply connection	N/A
	e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions..... :		N/A
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	No separate power supply	N/A
5.7	**ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3..... :**	No such parts	N/A
	ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +32°C for indicated time	No influence by climatic conditions	—

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

6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		P
6.2	**CLASS I ME EQUIPMENT, externally powered**	Class II	N/A
	CLASS II ME EQUIPMENT, externally powered	Class II; Direct plug in power supply	P
	INTERNALLY POWERED ME EQUIPMENT		N/A
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements		P
	TYPE B APPLIED PART		P
	TYPE BF APPLIED PART	Type B	N/A
	TYPE CF APPLIED PART	Type B	N/A
	DEFIBRILLATION-PROOF APPLIED PARTS		N/A
6.3	**ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529 ..... :**	IP44	P
6.4	**ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use..... :**	ME equipment or its parts are not intended to be sterilized	N/A
6.5	**ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2**	ME equipment not investigated for oxygen rich environment	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
6.6	**CONTINUOUS or Non-CONTINUOUS OPERATION ..... :**	Non continuous operation Maximum activation (on) time is 20min and maximum activation (off) time is 15min	P
7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		P
7.1.2	**Legibility of Markings Test for Markings specified in Clause 7.2-7.6 ..... :**	See Appended Table 7.1.2	P
7.1.3	**Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE**	See appended Tables 7.1.3 and 8.10	P
7.2	**Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**		P
7.2.1	**At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ..... :**	See attached copy of Marking Plate	P
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS..... :	See manual	P
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT		N/A
	Single use item marked ..... :	No single use equipment	N/A
7.2.2	**ME EQUIPMENT marked with:**		P
	– the name or trademark and contact information of the MANUFACTURER	Novafon GmbH	P
	– a MODEL OR TYPE REFERENCE	See attached copy of Marking Plate	P
	– a serial number or lot or batch identifier; and	Batch identifier is the same as date code. See next point	P
	– the date of manufacture or use by date	With date code: YYWW YY is year and WW is week	P
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	Not marked but no unacceptable risk	P
	RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.4)**	No such parts	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and	See above	N/A
	– a MODEL OR TYPE REFERENCE		N/A
	Software forming part of a PEMS identified with a unique identifier .....:		N/A
7.2.3	**Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS**		N/A
	Safety sign 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	Safety sign 10 is used	P
7.2.4	**ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and..... :**	Accessories marked with name and type reference number	P
	- with a MODEL or TYPE REFERENCE		P
	– a serial number or lot or batch identifier		N/A
	– the date of manufacture or use by date		N/A
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		N/A
7.2.5	**ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following**		N/A
	- the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or		N/A
	– Table D.2, safety sign No. 10 adjacent to the relevant connection point and listing of the required details in the instructions for use; or		N/A
	– Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use.		N/A
7.2.6	**Connection to the Supply Mains**		P
	Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point		P
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT		P
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V)..... :	230Vac	P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V) ..... :	No multiple rated supply voltages	N/A
	– Nature of supply and type of current ..... :	a.c. supply	P
	Symbols 1-5, Table D.1 (used for same parameters ..... :	Symbol 1 from Table D.1 is used	P
	– RATED supply frequency or RATED frequency range in hertz ..... :	50Hz	P
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT ..... :		P
7.2.7	**RATED input in amps or volt-amps, (A, VA).....:**	65mA	P
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W).....:		N/A
	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) ..... :		N/A
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W)..... :		N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA) ..... :		N/A
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W) ..... :		N/A
7.2.8	**Output connectors**		N/A
7.2.8.2	**Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment**		N/A
	Rated Voltage (V), Rated Current (A) .....:		—
	Rated Power (W), Output Frequency (Hz) .....:		—
7.2.9	**ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2), marking optional for ME EQUIPMENT or parts rated IPX0… :**	IP44	P
7.2.10	**Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols ..... :**	No Applied Parts in equipment	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	TYPE B APPLIED PARTS with symbol 19 of Table D.1		P
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 ..... :		N/A
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 ..... :		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 ..... :		N/A
	Proper symbol marked adjacent to or on connector for APPLIED PART ..... :		N/A
	Safety sign 2 of Table D.2 placed near relevant outlet ..... :		N/A
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use ..... :		N/A
7.2.11	**ME EQUIPMENT suitable for CONTINUOUS OPERATION**	Non-continuous operation	N/A
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time ..... :	ME equipment is marked with KB20/15 On time = 20min Off time = 15min	P
7.2.12	**Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder**	No fuses	N/A
	Fuse type..... :		—
	Voltage (V) and Current (A) rating.....:		—
	Operating speed (s) and Breaking capacity.....:		—
7.2.13	**Physiological effects – safety sign and warning statements ..... :**		N/A
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**	NO SUCH RISK	N/A
7.2.14	**HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1**		N/A
7.2.15	**Requirements for cooling provisions marked .. :**	No cooling	N/A
7.2.17	**Packaging marked with special handling instructions for transport and/or storage..... :**	No special handling instructions necessary	N/A
	Permissible environmental conditions marked on outside of packaging .....:		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK..... :		N/A
	RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK. .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3-6.4)**		N/A
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization		N/A
7.2.18	**RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and .....:**		N/A
	- the RATED flow rate also marked		N/A
7.2.19	**Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL..... :**	No functional earth terminal	N/A
7.2.20	**Removable protective means marked to indicate the necessity for replacement when the function is no longer needed ..... :**		N/A
7.2.21	**MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms.... :**		N/A
7.3	**Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts**		N/A
7.3.1	**Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W)..... :**	No inside markings	N/A
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL		N/A
7.3.2	**Symbol 24 of Table D.1, or safety sign No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts..... :**		N/A
7.3.3	**Type of battery and mode of insertion marked:**		N/A
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL..... :		N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK .....:		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an unacceptable RISK if replaced incorrectly.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**		N/A
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARD .....:		N/A
7.3.4	**Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified ..... :**	Not accessible by the use of a tool	N/A
	Voltage (V) and Current (A) rating.....:		**—**
	Operating speed(s), size & breaking capacity .:		**—**
7.3.5	**PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1**	No protective earth terminal	N/A
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		N/A
7.3.6	**Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS**		N/A
7.3.7	**Terminals for supply conductors marked adjacent to terminals ..... :**		N/A
	Terminals for supply connections are not marked, the RISK MANAGEMENT FILE includes an assessment of the RISKS resulting from misconnections.....: **(ISO 14971 Cl. 4.3)**		N/A
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings		N/A
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3		N/A
	Marking for connection to a 3-phase supply, complies with IEC 60445		N/A
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		N/A
7.3.8	**"For supply connections, use wiring materials suitable for at least X °C" or equivalent, marked at the point of supply connections**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		N/A
7.4	**Marking of controls and instruments**		P
7.4.1	**The "on" & "off" positions of switch to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 or**		P
	– indicated by an adjacent indicator light, or		N/A
	– indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, and		N/A
	– status indicated by adjacent indicator light		N/A
	– status indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or		P
	– status indicated by adjacent indicator light		N/A
	– status indicated by other unambiguous means		N/A
7.4.2	**Different positions of control devices/switches indicated by figures, letters, or other visual means**	Rotary control marked with "+" and "-"	P
	RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2, 6.3)**		N/A
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE .....:		N/A
	– or an indication of direction in which magnitude of the function changes		N/A
	Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009		N/A
7.4.3	**Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units		N/A
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3 .....:	See Appended Tables 7.1.2 and 7.1.3.	N/A
7.5	**Safety signs**		P
	Safety sign with established meaning used	Sign 2 of Table D.2 is used on marking label	P
	RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**	No such risk	N/A
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT		N/A
	Specified colours in ISO 3864-1 used for safety signs.....:		N/A
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		N/A
	Safety signs including any supplementary text or symbols described in instructions for use		N/A
	- and in a language acceptable to the intended OPERATOR		N/A
7.6	**Symbols**		P
7.6.1	**Meanings of symbols used for marking described in instructions for use .....:**	See Appended Instruction for Use	P
7.6.3	**Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable**		P
7.7	**Colours of the insulation of conductors**		P
7.7.1	**PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation**	No protective earth conductor	N/A
7.7.2	**Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations**		N/A
7.7.3	**Green and yellow insulation identify only following conductors:**		N/A
	– PROTECTIVE EARTH CONDUCTORS		N/A
	– conductors specified in 7.7.2		N/A
	– POTENTIAL EQUALIZATION CONDUCTORS		N/A
	– FUNCTIONAL EARTH CONDUCTORS		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.7.4	**Neutral conductors of POWER SUPPLY CORDS are "light blue"**	Direct plug in power supply. No mains power supply cord used	N/A
7.7.5	**Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1**	Direct plug in power supply. No mains power supply cord used	N/A
7.8	**Indicator lights and controls**		N/A
7.8.1	**Red indicator lights used only for Warning**	No lights used	N/A
	Yellow indicator lights used only for Caution		N/A
	Green indicator lights used only for Ready for use		N/A
	Other colours: Meaning other than red, yellow, or green (colour, meaning) .....:		N/A
7.8.2	**Red used only for emergency control**	No lights used	N/A
7.9	**ACCOMPANYING DOCUMENTS**		P
7.9.1	**ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description**	See manual	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 .....:	Novafon GmbH	P
	– MODEL or TYPE REFERENCE.....:	See manual	P
	When ACCOMPANYING DOCUMENTS provided electronically, USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT	No documents provided electronical	N/E
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	No skills, trainings required	N/A
	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:**		P
	– frequently used functions,		P
	– known contraindication(s) to use of ME EQUIPMENT		P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient	No parts serviced	N/A
	– name or trademark and address of the MANUFACTURER		P
	– MODEL OR TYPE REFERENCE		P
	Instruction for use included the following when the PATIENT is an intended OPERATOR:		P
	– the PATIENT is an intended OPERATOR		P
	– warning against servicing and maintenance while the ME EQUIPMENT is in use	No servicing or maintenance	N/A
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and		P
	–maintenance the PATIENT can perform	No maintenance	P
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT		P
	Instructions for use are in a language acceptable to the intended operator		P
7.9.2.2	**Instructions for use include all warning and safety notices**		N/A
	Warning statement for CLASS I ME EQUIPMENT included	Non class I ME equipment	N/A
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	No reciprocal interference	N/A
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	No electromagnetic or other interference	N/A
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	No multiple socket-outlet	N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS		N/A
7.9.2.3	**Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions**	No separate power supply	N/A
7.9.2.4	**Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source**	No additional power source	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**		N/A
	Where the RISK is unacceptable, the IFU includes a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time.....:		N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided.....:		N/A
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK .....:		N/A
7.9.2.5	**Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE**		P
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to	No materials which can constitute an unacceptable risk	N/A
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected	No signal input/output parts	N/A
	APPLIED PARTS specified		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/A
7.9.2.7	**Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device**		P
7.9.2.8	**Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation**		P
7.9.2.9	**Information provided to operate ME EQUIPMENT**		P
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use		
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**	No messages	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.9.2.11	**Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT**		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**		P
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use		P
7.9.2.13	**Instructions provided on preventive inspection, calibration, maintenance and its frequency**		P
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT		P
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application		P
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	No batteries	N/A
7.9.2.14	**A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided**		P
	Other equipment providing power to ME SYSTEM sufficiently described	No other equipment providing power	N/A
7.9.2.15	**Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for use .....:**		P
7.9.2.16	**Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)**		P
7.9.2.17	**Instruction for use for ME EQUIPMENT emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation**	No radiation	N/A
7.9.2.18	**The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile indicate that they have been sterilized and the method of sterilization**	No sterilization	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization		N/A
7.9.2.19	**The instructions for use contain a unique version identifier .....:**	Version 2015	**P**
7.9.3	**Technical description**		P
7.9.3.1	**All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use**		P
	Technical description separable from instructions for use contains required information, as follows		N/A
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT	Technical description is part of the manual	N/A
	– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and		N/A
	a unique version identifier .....:		N/A
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description		N/A
7.9.3.2	**The technical description contains the following required information**		P
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT .....:	No permanently installed equipment	N/A
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and		N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and		N/A
	RISK MANAGEMENT FILE includes an assessment to determine if replacement of components results in any unacceptable RISKS.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No such risk	N/A
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component	No such hazards	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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**		N/A
7.9.3.4	**Means used to comply with requirements of 8.11.1 clearly identified in technical description**		P
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		P
8.1	**Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS**		P
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION ..... : (ISO 14971 Cl. 4.3)	RMF Reference to specific RISKS: TD-SK-C7V01 Risikoanalyse Anlage 2 FMEA - 01.09.2015_CL (ISO 14971 Cl. Cl. 4.3)	P
8.2	**Requirements related to power sources**		N/A
8.2.1	**Connection to a separate power source**		N/A
	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM	No connection to a separate power source	N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		N/A
8.2.2	**Connection to an external d.c. power source**		N/A
	No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source	No connection to an external d.c. power source	N/A
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE		N/A
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset		N/A
8.3	**Classification of APPLIED PARTS**		P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	Type B applied parts	N/A
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART		N/A
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	Type B	P
8.4	**Limitation of voltage, current or energy**		P
8.4.2	**ACCESSIBLE PARTS and APPLIED PARTS**		P
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT :	No patient connections	N/A
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT..... :	See appended Table 8.7	P
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed		P
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.) ..... :	See appended Table 8.4.2	P
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J) ..... :	See appended Table 8.4.2	P
	d) Voltage and energy limits specified in c) above also applied to the following:		P
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	No internal parts touchable by test pin	N/A
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL	No internal parts touchable by a metal rod with a diameter of 4mm	N/A
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N		N/A
	Test repeated with a TOOL specified in instructions for use		N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE		N/A
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION	No access covers	N/A
	A TOOL is required when it is possible to prevent the devices from operating		N/A
8.4.3	**Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one sec after disconnecting the plug of ME EQUIPMENT or its parts (V)..... :**	See appended Table 8.4.3	P
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC .. :	See appended Table 8.4.3	P
8.4.4	**Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC .. :**	No capacitive circuits	N/A
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description ..... :		N/A
8.5	**Separation of parts**		P
8.5.1	**MEANS OF PROTECTION (MOP)**		P
8.5.1.1	**Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4**		P
	Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		P
8.5.1.2	**MEANS OF PATIENT PROTECTION (MOPP)**		P
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test..... :		N/A
	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	No protective earthing	N/A
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION ..... :	No such capacitors	N/A
	Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c. ..... :		N/A
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N/A
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) ..... :		—
8.5.1.3	**MEANS OF OPERATOR PROTECTION (MOOP)**	Only MOPP	N/A
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		N/A
	– dielectric strength test ..... :		N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N/A
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		N/A
	– limits of Tables 13 to 16 (inclusive); or		N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6		N/A
	– or with requirements and tests of IEC 60950-1 for protective earthing..... :		N/A
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION ..... :		N/A
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION ..... :		N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) ..... :		—
	Points and applied parts at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 were examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION		N/A
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION..... :		N/A
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION .... :		N/A
8.5.2	**Separation of PATIENT CONNECTIONS**		N/A
8.5.2.1	**PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAX. MAINS VOLTAGE ..... :**	No patient connections	N/A
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		N/A
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		N/A
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS ..... :		N/A
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4 .... :		N/A
	Dielectric strength test conducted per 8.8.3.... :		N/A
	CREEPAGE and CLEARANCES measured ..... :		N/A
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s		N/A
8.5.2.2	**PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED .... :**		N/A
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4 .... :		N/A
	Dielectric strength test conducted per 8.8.3.... :		N/A
	Relevant CREEPAGE and CLEARANCES measured		N/A
	RISK MANAGEMENT FILE includes an assessment of the RISK of metal ACCESSIBLE PARTS contacting a source of voltage or LEAKAGE CURRENT above the limits .....: (ISO 14971 Cl. 4.2-4.4, 5)	No such risk	N/A
8.5.2.3	**A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE**		N/A
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT ..... :		N/A
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter		N/A
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm		N/A
	– conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1		N/A
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,		N/A
	Test finger test (10 N) ..... :		N/A
	Except when RISK MANAGEMENT PROCESS includes an assessment of RISKS resulting from contact with objects other than mains sockets or flat surfaces ..... : **(ISO 14971 Cl. 4.2-4.4, 5)**		N/A
8.5.4	**WORKING VOLTAGE**		P
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V) ..... :		P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V)..... :		N/A
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V)..... :	See Insulation Diagram and Insulation Table	P
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth		N/A
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V)..... :	Only type B connections	N/A
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	No defibrillation-proof applied parts	N/A
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V)..... :		N/A
8.5.5	**DEFIBRILLATION-PROOF APPLIED PARTS**	No Defibrillation-proof applied parts	N/A
8.5.5.1	**Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety**		N/A
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		N/A
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ..... :		N/A
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS..... :		N/A
8.5.5.2	**Means provided to limit energy delivered to a 100 Ω load..... :**		N/A
8.6	**Protective and functional earthing and potential equalization of ME EQUIPMENT**		N/A
8.6.1	**Requirements of 8.6.2 to 8.6.8 applied**	Class II, No earthing	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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/A
8.6.2	**PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR..... :**		N/A
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL		N/A
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside .... :		N/A
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		N/A
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		N/A
8.6.3	**PROTECTIVE EARTH CONNECTION not used for a moving part,**		N/A
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
8.6.4	**a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop..... :**		N/A
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits ..... :		N/A
8.6.5	**Surface coatings**		N/A
	Poorly conducting surface coatings on conductive elements removed at the point of contact		N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		N/A
8.6.6	**Plugs and sockets**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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/A
	- applied also where interchangeable parts are PROTECTIVELY EARTHED		N/A
8.6.7	**Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR**		N/A
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE		N/A
	–accidental disconnection avoided in NORMAL USE		N/A
	– Terminal allows conductor to be detached without a TOOL		N/A
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		N/A
	– Terminal marked with symbol 8 of Table D.1		N/A
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		N/A
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		N/A
8.6.8	**FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION**		N/A
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/A
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.		N/A
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS		N/A
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		P
8.7.1	**a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3..... :**	See appended Tables 8.7	P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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/A
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		N/A
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		P
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		P
8.7.3	**Allowable Values**		P
	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/A
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 ..... :	See appended Table 8.7	N/A
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device ..... :	See appended Table 8.7	P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION ..... :	See appended Table 8.7	N/A
8.7.4	**LEAKAGE and PATIENT AUXILIARY CURRENTS measurements ..... :**	See appended Table 8.7	P
8.8	**Insulation**		P
8.8.1	**Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing**		P
	Insulation exempted from test (complies with clause 4.8)		P
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		P
8.8.2	**Distance through solid insulation or use of thin sheet material**		P
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		P
	a) 0.4 mm, min, distance through insulation, or		P
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		N/A
	– at least two layers of material, each passed the appropriate dielectric strength test..... :		N/A
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test..... :		N/A
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		N/A
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		N/A
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		N/A
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L		N/A
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		N/A
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		N/A
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		N/A
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values		N/A
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension ..... :		N/A
	Finished component complied with routine dielectric strength tests of 8.8.3 ..... :		N/A
	Tests of Annex L not repeated since material data sheets confirm compliance ..... :		N/A
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**		N/A
	ME EQUIPMENT and design documentation examined ..... :		N/A
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat ..... :		N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat ..... :		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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 ... :		N/A
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C) ..... :		N/A
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION		N/A
8.8.4.2	**Resistance to environmental stress**		P
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9		P
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	No such parts	N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	No such parts	N/A
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples	No such parts	N/A
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h		N/A
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**		P
8.9.1.1	**CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive) ..... :**	Refer to Insulation Diagram	P
8.9.1.15	**CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1**	No such parts	N/A
8.9.2	**a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION , min CREEPAGE and CLEARANCES not applied ..... :**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.9.3	**Spaces filled by insulating compound**		N/A
8.9.3.1	**Only solid insulation requirements applied where distances between conductive parts filled with insulating compound**		N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests		N/A
8.9.3.2	**For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage) ..... :**		N/A
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		N/A
8.9.3.3	**Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint**		N/A
	A winding of solvent-based enamelled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		N/A
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage ..... :		N/A
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage		N/A
8.9.4	**Minimum spacing of grooves transvers to the creepage distances considered a means of operator protection adjusted based on pollution degree ……**	**Pollution degree: 2**	P
	Force was applied between bare conductors and outside metal enclosure when measuring creepage distances and air clearances	**Refer to Insulation Diagram supplemental information for location and force used**	P
8.10	**Components and wiring**		P
8.10.1	**Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely ..... :**		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components ..... : **(ISO 14791 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.10.2	**Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment ..... :**		N/A
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS		N/A
8.10.3	**Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken ..... :**	Interconnecting cord is not detachable without a tool	N/A
8.10.4	**Cord-connected HAND-HELD parts and cord-connected foot-operated control devices**		P
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**		P
8.10.4.2	**Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3**		N/A
	Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3		N/A
8.10.5	**Mechanical protection of wiring**		P
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges ..... :	Internal wiring adequately protected again contact with moving parts	P
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS	No such parts	N/A
8.10.6	**Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead**	No such parts	N/A
8.10.7	**a) Insulating sleeve adequately secured..... :**	No such parts	N/A
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics		N/A
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C ..... :		N/A
8.11	**MAINS PARTS, components and layout**		P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.11.1	**a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles..... :**	By approved direct plug in power supply	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)	No permanently installed ME Equipment	N/A
	PERMANENTLY INSTALLED ME EQUIPMENT provided with means to isolate its circuits electrically from the SUPPLY MAINS are capable of being locked in the off position		N/A
	- the isolation device specified in the ACCOMPANYING DOCUMENTS		N/A
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description ..... :		N/A
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV..... :	No supply mains switch used	N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	No supply mains switch incorporated in a power supply cord	N/A
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447	No supply mains switch	N/A
	f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH ..... :	Class II plug without PE connection	P
	g) A fuse or a semiconductor device not used as an isolating means	No fuse or semiconductor device used as an isolating means	P
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device		P
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering		P
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause	No such parts	N/A
	Standard test finger applied		N/A
8.11.2	**MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2**	No multiple socket-outlets	N/A
8.11.3	**POWER SUPPLY CORDS**		N/A
8.11.3.1	**MAINS PLUG not fitted with more than one POWER SUPPLY CORD**	No power supply cord	N/A
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)... :**		N/A
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE ..... :		N/A
8.11.3.3	**NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17..... :**		N/A
8.11.3.4	**APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6..... :**		N/A
8.11.3.5	**Cord anchorage**		N/A
	a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage		N/A
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or		N/A
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		N/A
	– metal provided with an insulating lining affixed to cord anchorage		N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals		N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 ..... :		N/A
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests		N/A
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position		N/A
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N/A
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged		N/A
8.11.3.6	**POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment**		N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N/A
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram attached to the free end of cord (g) ..... :		N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		N/A
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D ..... :		N/A
8.11.4	**MAINS TERMINAL DEVICES**		N/A
8.11.4.1	**PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection**	No such parts	N/A
	Terminals alone are not used to keep conductors in position		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors		N/A
	Screws and nuts clamping external conductors do not serve to secure any other component		N/A
8.11.4.2	**Arrangement of MAINS TERMINAL DEVICES**		N/A
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection		N/A
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		N/A
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction		N/A
8.11.4.3	**Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced after fastening and loosening a conductor of largest cross-sectional area 10 times**		N/A
8.11.4.4	**Terminals with clamping means for a rewireable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened**		N/A
8.11.4.5	**Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewireable POWER SUPPLY CORD to allow for connection of conductors**		N/A
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test		N/A
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		N/A
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection . :	Only in approved power supply	N/A
	- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT ..... :		N/A
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT		N/A
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Protective devices have adequate breaking capacity to interrupt the max. fault current ..... :		N/A
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		N/A
	Justification for omission of fuses or OVER-CURRENT RELEASES documented ..... :		N/A
8.11.6	**Internal wiring of the MAINS PART**		N/A
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable ..... :		N/A
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient..... :		N/A
9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		N/A
9.2	**HAZARDS associated with moving parts**		N/A
9.2.1	**When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level .....:**	No hazards with moving parts	N/A
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)		N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and		N/A
	RISK CONTROLS implemented ..... :		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
	All RISKS associated with moving parts have been reduced to an acceptable level		N/A
9.2.2	**TRAPPING ZONE**		N/A
9.2.2.1	**ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:**	No trapping zone	N/A
	– Gaps in Clause 9.2.2.2, or		N/A
	– Safe distances in Clause 9.2.2.3, or		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or		N/A
	– Continuous activation in Clause 9.2.2.5		N/A
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM		N/A
9.2.2.2	**A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20 .....:**		N/A
9.2.2.3	**A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008 ..... :**		N/A
9.2.2.4	**GUARDS and other RISK CONTROL measures**		N/A
9.2.2.4.1	**A TRAPPING ZONE do not to present a MECHANICAL HAZARD when GUARDS or other RISK CONTROL measures are of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK .....:**		N/A
9.2.2.4.2	**FIXED GUARDS held in place by systems that can only be dismantled with a TOOL**		N/A
9.2.2.4.3	**Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open**		N/A
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,		N/A
	– absence or failure of one of their components prevents starting, and stops moving parts		N/A
	Movable GUARDS complied with any applicable tests		N/A
9.2.2.4.4	**Other RISK CONTROL designed and incorporated into to the control system stops movement and**		N/A
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or		N/A
	ME EQUIPMENT is SINGLE FAULT SAFE		N/A
9.2.2.5	**Continuous activation**		N/A
	Continuous activation used as a RISK CONTROL, complies with the following		N/A
	a) movement was in OPERATOR'S field of view		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR		N/A
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or		N/A
	- the continuous activation system is SINGLE FAULT SAFE		N/A
9.2.2.6	**Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement**		N/A
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		N/A
9.2.3	**Other MECHANICAL HAZARDS associated with moving parts**		N/A
9.2.3.1	**Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated**		N/A
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or	Usability engineering process not evaluated	N/E
	- activation does not result in an unacceptable RISK		N/A
9.2.3.2	**Over travel past range limits of the ME EQUIPMENT prevented .....:**		N/A
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse....:		N/A
9.2.4	**Emergency stopping devices**		N/A
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power .....:	No emergency stopping devices	N/A
	a) Emergency stopping device reduced RISK to an acceptable level		N/A
	RISK MANAGEMENT FILE indicates the use of an emergency stopping device reduces the RISK to an acceptable level .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.6)**		N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD		N/A
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N/A
	g) Means for stopping of movements operate as a result of one single action		N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or "STOP"		N/A
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed		N/A
	k) Emergency stopping device is suitable for its application		N/A
9.2.5	**Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping ..... :**		N/A
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		N/A
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented		N/A
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.3	**Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered .....:**		N/A
9.4	**Instability HAZARDS**		N/A
9.4.1	**ME EQUIPMENT and its parts, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE**	Hand-held equipment	N/A
9.4.2	**Instability – overbalance**		N/A
9.4.2.1	**ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested .....:**	See appended Table 9.4.2.1	N/A
9.4.2.2	**Instability excluding transport**		N/A
	ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE, ...:		N/A
	A warning provided when overbalance occurred during 10° inclined plane test		N/A
9.4.2.3	**Instability from horizontal and vertical forces**		N/A
	a) ME EQUIPMENT or its parts with a mass of 25kg or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it		N/A
	Surfaces of ME EQUIPMENT or its parts where a RISK of overbalancing exists from pushing, etc., permanently marked with a warning of the RISK		N/A
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)		N/A
	b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping		N/A
	ME EQUIPMENT or its parts, for use on the floor or on a table, where RISK of overbalancing exists, permanently marked with the RISK warning.....:		N/A
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b).....:		N/A
9.4.2.4	**Castors and wheels**		N/A
9.4.2.4.1	**Means used for transportation of MOBILE ME EQUIPMENT did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE**	No castors and wheels	N/A
9.4.2.4.2	**Force required to move MOBILE ME EQUIPMENT did not exceed 200 N .....:**		N/A
9.4.2.4.3	**MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold .....:**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.4.3	**Instability from unwanted lateral movement (including sliding)**		N/A
9.4.3.1	**a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control**		N/A
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements		N/A
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1	See appended Table 9.4.3.1	N/A
9.4.3.2	**Instability excluding transport**		N/A
	a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test .....:		N/A
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test		N/A
9.4.4	**Grips and other handling devices**		N/A
	a) ME EQUIPMENT with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method		N/A
	Handles, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS		N/A
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying		N/A
	c) Carrying handles and grips and their means of attachment withstood loading test .....:		N/A
9.5	**Expelled parts HAZARD**		N/A
9.5.1	**Suitability of means of protecting against expelled parts determined by assessment and examination of RISK MANAGEMENT FILE .....:** **(ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)**	No such hazards	N/A
	All identified RISKS associated with expelled parts mitigated to an acceptable level		N/A
9.5.2	**Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965 .....:**		N/A
9.6	**Acoustic energy (including infra- and ultrasound) and vibration**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.6.1	**Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and**	No acoustic energy	N/A
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity .....:		N/A
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and **(ISO 14971 Cl. 4.2-44, 5, 6.2-6.5)**		N/A
	All identified RISKS mitigated to an acceptable level		N/A
9.6.2	**Acoustic energy**		N/A
9.6.2.1	**PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE**	No acoustic energy	N/A
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA).....:		-
	- 83 dBA (when halving the cumulative exposure time) (dBA).....:		-
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB).....:		-
9.6.2.2	**RISK MANAGEMENT FILE examined.....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		-
9.6.3	**Hand-transmitted vibration**		P
	Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values		P
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2) .....:		N/A
	– Accelerations for different times, inversely proportional to square root of time (m/s^2).....:		N/A
9.7	**Pressure vessels and parts subject to pneumatic and hydraulic pressure**		N/A
9.7.2	**Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE .....:** **(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**	No such parts	N/A
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		N/A
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		N/A
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply		N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N/A
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity		N/A
9.7.3	**Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:**		N/A
	a) RATED maximum supply pressure from an external source		N/A
	b) Pressure setting of a pressure-relief device provided as part of assembly		N/A
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device		N/A
9.7.4	**Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests .....:**		N/A
9.7.5	**A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was more than 50 kPa, and product of pressure and volume was more than 200 kPal .....:**		N/A
9.7.6	**Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE .:**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.7.7	**Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests .....:**		N/A
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair		N/A
	c) Could be adjusted or rendered inoperative without a TOOL		N/A
	d) With discharge opening located and directed as to not to release material towards any person		N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		N/A
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure		N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect		N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N/A
	RISK MANAGEMENT FILE includes an assessment of the risks associated with the discharge opening of the pressure relief device .....: **(ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)**		N/A
9.8	**HAZARDS associated with support systems**		N/A
9.8.1	**ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK ...:**	No support system	N/A
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		N/A
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES		N/A
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials		N/A
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		N/A
9.8.2	**Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest**		N/A
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing...:		N/A
	RISK MANAGEMENT FILE includes an assessment of the structural integrity of support system ..: **(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**		N/A
	All identified RISKS are mitigated to an acceptable level		N/A
	When test were conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK.....:		N/A
	Where the equipment is not at equilibrium after 1 min, the RISK MANAGEMENT FILE includes an assessment of the test results.....: **(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.8.3	**Strength of PATIENT or OPERATOR support or suspension systems**		N/A
9.8.3.1	**ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints .....:**		N/A
	RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts		N/A
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER		N/A
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications		N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		N/A
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS		N/A
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance .....:		N/A
9.8.3.2	**a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m^2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR .....:**		N/A
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests .....:		N/A
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK		N/A
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test .....:		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.8.3.3	**Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE maintained BASIC SAFETY and ESSENTIAL PERFORMANCE confirmed test**		N/A
9.8.4	**Systems with MECHANICAL PROTECTIVE DEVICES**		N/A
9.8.4.1	**a) A MECHANICAL PROTECTIVE DEVICE provided for the support system**		N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		N/A
	– Designed based on TOTAL LOAD		N/A
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N/A
	– Activated before travel produced an unacceptable RISK		N/A
	– Takes into account Clauses 9.2.5 and 9.8.4.3		N/A
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests .....:		N/A
9.8.4.2	**Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE**		N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		N/A
9.8.4.3	**MECHANICAL PROTECTIVE DEVICE intended to function once**		N/A
	–use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE :		N/A
	– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal		N/A
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.		N/A
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE		N/A
	– Compliance confirmed by examination and following test .....:		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT		N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		N/A
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		N/A
9.8.5	**Systems without MECHANICAL PROTECTIVE DEVICES**		N/A
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES .....:		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system .....: **(ISO 14971 Cl. 4.3,4.4,5,6.2-6.5)**		N/A

10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		N/A
10.1	**X-Radiation**		N/A
10.1.1	**The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT .....:**	No x radiation	N/A
	Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE		N/A
10.1.2	**RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or .....:**		N/A
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
10.2	**RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE .....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
10.3	**The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2**		N/A
	Microwave radiation is propagated intentionally		N/A
10.4	**Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.**		N/A
10.5	**RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
10.6	**RISK associated with infrared radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
10.7	**RISK associated with ultraviolet radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		P
11.1	**Excessive temperatures in ME EQUIPMENT**		P
11.1.1	**Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and ..... :**	See appended Table 11.1.1	P
	Surfaces of test corner did not exceed 90 °C	Not tested in test corner due to design of EUT	N/A
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	Thermal cut-out in approved power supply	P
	RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISK: TD-SK-C7V01 Risikoanalyse Anlage 2 FMEA - 01.09.2015_CL (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	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 ..... :**	No such parts	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Clinical effects determined and documented in the RISK MANAGEMENT FILE **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use		N/A
11.1.2.2	**APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in NORMAL CONDITION and SINGLE FAULT CONDITION. :**		P
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:		P
	Maximum Temperature ..... :	31,8	—
	Conditions for safe contact, e.g. duration or condition of the PATIENT..... :	Limited duration	—
	Clinical effects with respect to characteristics taken or surface pressure documented in the RISK MANAGEMENT FILE **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
	APPLIED PARTS surface temperature of equal to or less than 41°C		N/A
	Analysis documented in the RISK MANAGEMENT FILE show that APPLIED PART temperatures are not affected by operation of the ME EQUIPMENT including SINGLE FAULT CONDITIONS. Measurement of APPLIED PART temperature according to 11.1.3 is not conducted ..... :		N/A
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
11.1.3	**Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE ..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE..... :		N/A
11.1.4	**GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL**	No such guards	N/A
11.2	**Fire prevention**		P
11.2.1	**ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3**		P
11.2.2	**Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS**		N/A
11.2.2.1	**RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of..... :**	No such parts	N/A
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions		N/A
	1) when temperature of material raised to its ignition temperature		N/A
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature		N/A
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating		N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively ..... :		N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three..... :		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3..... :		N/A
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%)..... :		N/A
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes		N/A
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE..... :		N/A
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases ..... :		N/A
11.2.2.2	**RISK of ignition did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT**		N/A
11.2.2.3	**Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		N/A
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		N/A
11.2.3	**SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered**		N/A
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2) ..... :		N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) ..... :		N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) ..... :		N/A
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a) ..... :		N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas ..... :		N/A
11.3	**Constructional requirements for fire ENCLOSURES of ME EQUIPMENT**		N/A
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2 ..... :		N/A
	Constructional requirements were met, or		N/A
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
	Justification, when requirement not met ..... :		N/A
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials ..... :		N/A
	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 ..... :		N/A
	If no FV Certification, FV tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings		N/A
	b) Fire ENCLOSURE met following:		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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		N/A
	2) No openings on the sides within the area included within the inclined line C in Fig 39		N/A
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials ..... :		N/A
11.4	**ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics**		N/A
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G		N/A
11.5	**ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents**		N/A
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
11.6	**Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT**		P
11.6.1	**Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT.....:**	See Appended Table 11.6.1	P
11.6.2	**Overflow in ME EQUIPMENT**		N/A
	ME EQUIPMENT incorporates a reservoir or liquid storage that did not wet any MEANS OF PROTECTION, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE ..... :	No reservoir or liquid storage	N/A
	Maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.		N/A
11.6.3	**Spillage on ME EQUIPMENT and ME SYSTEM**		N/A
	ME EQUIPMENT and ME SYSTEMS handling liquids constructed that spillage does not wet parts as determined by review of the RISK MANAGEMENT FILE and test ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No handling with liquids	N/A
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill ..... :		N/A
11.6.5	**Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**		P
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)..... :	See Appended Table 11.6.1	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.. :		N/A
11.6.6	**Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS**		P
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use ..... :	See Appended Tables 11.6.1, 8.7, and 8.8.3	P
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER ..... :		P
11.6.7	**Sterilization of ME EQUIPMENT and ME SYSTEMS**		N/A
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests..... :	No sterilization	N/A
	RISK MANAGEMENT FILE includes an assessment of the RISKS associated with any deterioration following sterilization ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
11.6.8	**RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/E
11.7	**ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented**	Not evaluated within this Report	N/E
11.8	**Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**		P
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		P
12.1	**RISKS associated with accuracy of controls and instruments stated..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	NO SUCH RISK	N/A
12.2	**RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING..... :**	Not evaluated within this Report	N/E
12.3	**MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8. ..... :**	NO ALARM SYSTEM	N/A
12.4	**Protection against hazardous output**		N/A
12.4.1	**RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No hazardous outputs	N/A
12.4.2	**- need for indication associated with hazardous output addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
12.4.3	**RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
12.4.4	**RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
12.4.5	**Diagnostic or therapeutic radiation**		N/A
12.4.5.1	**Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation**	No radiation	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Radiation safety ensured by compliance with requirements of appropriate standards		N/A
12.4.5.2	**ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3 ..... :**		N/A
12.4.5.3	**RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
12.4.5.4	**RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
12.4.6	**RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A

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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
13. 2	**SINGLE FAULT CONDITIONS**		P
13.2.1	**During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination**		P
	ME EQUIPMENT complied with 13.2.2 -13.2.12 ..... :	See appended Table 13.2	P
	RISK MANAGEMENT FILE includes and assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	RISK MANAGEMENT FILE defines the appropriate test conditions.....:		
13.2.13	**ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of test environment temperature**		P
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		P
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION, the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		P
13.2.13.2	**ME EQUIPMENT with heating elements**		N/A
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	No heating elements	N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests		N/A
	a 3) other ME EQUIPMENT with heating elements met test		N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		N/A
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration		N/A
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself		N/A
	b) ME EQUIPMENT with heating elements without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V) ..... :		N/A
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY		N/A
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION		N/A
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and		N/A
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS		N/A
	2) When more than one control provided, they were disabled in turn		N/A
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		N/A
13.2.13.3	**ME EQUIPMENT with motors**		P
	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		P
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		N/A
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition	No heating elements	N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		P
	b) Motor met running overload protection test of this clause when:		P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended		P
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C)..... :	See table 11.1.1	P
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		P
	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	Overload test performed	P
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		N/A
	Test not conducted based on other justifications (justification)..... :		N/A
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10	No 3-phase motors	N/A
13.2.13.4	**ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION**		P
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated	Hand-held equipment	N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle		N/A
	Motor winding temperatures did not exceed values in 13.2.10 ..... :		N/A
	Insulation Class ..... :		—
	Maximum temperature measured (°C)..... :		—

14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		N/A
14.1	**Requirements in 14.2 to 14,12 not applied to PEMS when it provides no functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE, or**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK ..... :		N/A
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 4.2-4.4, 5)		N/A
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK		N/A
	When the requirements of 14.2 to 14.13 apply, the requirements of IEC 6204:2006 clause 4.3, 5, 7, 8 and 9 apply for the development or modification of software of each PESS		N/A
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304 ..... :		N/A
	Software development process applied according to Clause 5 of IEC 62304..... :		N/A
	Software development process for Software risk management applied according to Clause 7 of IEC 62304 ..... :		N/A
	Software development process Configuration Management applied according to Clause 8 of IEC 62304..... :		N/A
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304 ..... :		N/A
14.2	**Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process ..... :**		N/A
14.3	**RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan**		N/A
14.4	**A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented**		N/A
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		N/A
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone		N/A
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules		N/A
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
14.5	**A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained**		N/A
14.6	**RISK MANAGEMENT PROCESS**		N/A
14.6.1	**MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS..... :**		N/A
	RISK MANAGEMENT FILE includes known or foreseeable HAZARDS associated with software, hardware, incorporation of the PEMS into an IT-NETWORK, components of 3rd party origin and legacy subsystems..... : (ISO 14971 Cl. 4.3)		N/A
14.6.2	**Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2 :**		N/A
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure..... : (ISO 14971 Cl. 6.1)		N/A
14.7	**A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem ..... : (ISO 14971 Cl. 6.3)**		N/A
14.8	**An architecture satisfying the requirement is specified for PEMS and each of subsystems .... : (ISO 14971 Cl. 6.3)**		N/A
14.9	**Design is broken up into sub systems and descriptive data on design environment documented ..... :**		N/A
14.10	**A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures..... : (ISO 14971 Cl. 6.3)**		N/A
	– milestone(s) when VERIFICATION is to be performed for each function		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		N/A
	– selection and utilization of VERIFICATION tools		N/A
	– coverage criteria for VERIFICATION		N/A
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented		N/A
14.11	**A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE ..... :**		N/A
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented		N/A
	The person with overall responsibility for PEMS VALIDATION is independent		N/A
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 6.3)		N/A
14.12	**Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE**		N/A
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304 ..... :		N/A
	Software Process for Software changes applied according to Clause 5 of IEC 62304 ..... :		N/A
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304 ..... :		N/A
	Configuration management of software changes applied per Clause 8 of IEC 62304 .... :		N/A
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304 .... :		N/A
14.13	**For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following ..... :**		N/A
	a) Purpose of the PEMS connection to an IT-NETWORK		N/A
	b) required characteristics of the IT-NETWORK		N/A
	c) required configuration of the IT-NETWORK		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	d) technical specifications of the network connection, including security specifications		N/A
	e) intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK		N/A
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the required characteristics (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)		N/A
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		N/A
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties		N/A
	– Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS		N/A
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis		N/A
	- Changes to the IT-NETWORK include: **- changes in network configuration** **- connection of additional items** **- disconnection of items** **- update of equipment** **- upgrade of equipment**		N/A

15	**CONSTRUCTION OF ME EQUIPMENT**		P
15.1	**RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS..... :**	No Risk associated with arrangement of controls and indicators	N/A
15.2	**Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance**	No such parts	N/A
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		P
15.3	**Mechanical strength**		P

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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK		P
15.4	**ME EQUIPMENT components and general assembly**		P
15.4.1	**Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, ... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No accessible connectors	N/A
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions, ... :		N/A
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection ..... :		N/A
15.4.2	**Temperature and overload control devices**		N/A
15.4.2.1	**a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION ..... : (ISO 14971 Cl. 4.2-4.4, 5)**	Only in approved power supply	N/A
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT		N/A
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided ..... : (ISO 14971 Cl. 4.2-4.4)		N/A
	d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION or loss of ESSENTIAL PERFORMANCE .... : (ISO 14971 Cl. 4.2-4.4)		N/A
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		N/A
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests		N/A
	- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17		N/A
	- ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13 ..... :		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards.....		N/A
	- In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions operated 200 times		N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		N/A
	manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		N/A
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		N/A
	g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating		N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating : (ISO 14971 Cl. 4.2-4.4)		N/A
15.4.2.2	**Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS**		N/A
15.4.3	**Batteries**		N/A
15.4.3.1	**Battery housings provided with ventilation.... :** **(ISO 14971 Cl. 4.2-4.4)**	No batteries	N/A
	Battery compartments designed to prevent accidental short circuiting		N/A
15.4.3.2	**Means provided to prevent incorrect connection of polarity ..... :**		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries ..... : (ISO 14971 Cl. 4.2-4.4)		N/A
15.4.3.3	**Overcharging of battery prevented by virtue of design ..... :**		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries..... : (ISO 14971 Cl. 4.2-4.4)		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
15.4.3.4	**Primary lithium batteries comply with IEC 80086-4**		N/A
	Secondary lithium batteries comply with IEC 62133		N/A
15.4.3.5	**A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire ..... :**		N/A
	Protective device has adequate breaking capacity		N/A
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented		N/A
	Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPS provided, or		N/A
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION		N/A
15.4.4	**Indicator lights provided to indicate ME EQUIPMENT is ready for ..... :**	No Indicator lights	N/A
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,		N/A
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with the use of indicator lights for EQUIPMENT incorporating non-luminous heaters ..... : (ISO 14971 Cl. 4.2-4.4)		N/A
	Requirement not applied to heated stylus-pens for recording purposes		N/A
	Indicator lights provided on ME EQUIPMENT to indicate an output exists		N/A
	Colours of indicator lights complied with 7.8.1		N/A
	Charging mode visibly indicated		N/A
15.4.5	**RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
15.4.6	**Actuating parts of controls of ME EQUIPMENT**		P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
15.4.6.1	**a) Actuating parts cannot be pulled off or loosened during NORMAL USE**		P
	b) Controls secured so that the indication of any scale always corresponds to the position of the control		N/A
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL		N/A
	When torque values per Table 30 applied knobs did not rotate ..... :	See appended Table 15.4.6	P
	Tests conducted with no unacceptable RISK . :	See appended Table 15.4.6	P
15.4.6.2	**Stops on rotating/ movable parts of controls are of adequate mechanical strength ..... :**	See appended Table 15.4.6	P
	Torque values in Table 30 applied ..... :	See appended Table 15.4.6	P
	No unexpected change of the controlled parameter when tested ..... :	See appended Table 15.4.6	P
15.4.7	**Cord-connected HAND-HELD and foot-operated control devices**		N/A
15.4.7.1	**a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1**	No control devices	N/A
	b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage ..... :		N/A
15.4.7.2	**Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface ..... :**		N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		N/A
15.4.7.3	**a) Foot-operated control device is at least rated IPX1** ..... :		N/A
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6.... :		N/A
15.4.8	**Aluminium wires less than 16 mm^2 in cross-sectional area are not used**	No aluminium wires	N/A
15.4.9	**a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed**	No oil container	N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		N/A
	A pressure-release device operating during NORMAL USE is provided		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		N/A
15.5	**MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5**		N/A
15.5.1	**Overheating**		N/A
15.5.1.1	**Transformers of ME EQUIPMENT are protected against overheating..... :**	Only in approved power supply	N/A
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		N/A
	Dielectric strength test conducted after short circuit and overload tests ..... :		N/A
15.5.1.2	**Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved ..... :**		N/A
	Short circuit applied directly across output windings		N/A
15.5.1.3	**Multiple overload tests conducted on windings ..... :**		N/A
15.5.2	**Transformers operating at a frequency above 1kHz tested according to clause 8.8.3..... :**		N/A
	Transformer windings provided with adequate insulation		N/A
	Dielectric strength tests were conducted ..... :		N/A
15.5.3	**Transformers forming MEANS OF PROTECTION as required by 8.5 comply with ..... :**		N/A
	- Means provided to prevent displacement of end turns		N/A
	- protective earth screens with a single turn have insulated overlap		N/A
	- Exit of wires form internal windings of toroid transformers protected with double sleeving		N/A
	- insulation between primary and secondary windings complies with 8.8.2		N/A
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
16	**ME SYSTEMS**		N/A
16.1	**After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK**	No ME System	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with installation and modification of an ME SYSTEM.....: (ISO 14971 Cl. 4.2-4.4, 5)		N/A
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered		N/A
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard		N/A
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards		N/A
	– tests performed in NORMAL CONDITION, except as specified		N/A
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM		N/A
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated		N/A
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR		N/A
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards		N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM		N/A
16.2	**ACCOMPANYING DOCUMENTS of an ME SYSTEM**		N/A
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM		N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM		N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER		N/A
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	c) the required information is provided:		N/A
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM		N/A
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard		N/A
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM		N/A
	– additional safety measures to be applied during installation of ME SYSTEM		N/A
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT		N/A
	– additional measures to be applied during preventive maintenance		N/A
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor		N/A
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM		N/A
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM		N/A
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM		N/A
	– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM		N/A
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer		N/A
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET		N/A
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT		N/A
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:		N/A
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES		N/A
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard		N/A
16.3	**Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements**		N/A
	Transient currents restricted to allowable levels for the specified IPS or UPS ..... :		N/A
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified		N/A
16.4	**Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)**		N/A
16.5	**Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed**		N/A
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION		N/A
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V)..... :		N/A
16.6	**LEAKAGE CURRENTS**		N/A
16.6.1	**TOUCH CURRENT in NORMAL CONDITION did not exceed 100 µA.....:**		N/A
	TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR .....:		N/A
16.6.2	**Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA....:**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
16.6.3	**PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values .....:**		N/A
16.7	**ME SYSTEM complied with applicable requirements of Clause 9.....:**		N/A
16.8	**Interruption and restoration power to the ME SYSTEM or any part of the ME SYSTEM did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**		N/A
16.9	**ME SYSTEM connections and wiring**		N/A
16.9.1	**Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result .....:**		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with plugs for connection of PATIENT leads or cables likely to be located in the PATIENT ENVIRONMENT.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	– Plugs for connection of PATIENT leads or PATIENT cables could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no unacceptable RISK results		N/A
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable		N/A
16.9.2	**MAINS PARTS, components and layout**		N/A
16.9.2.1	**a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or**		N/A
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		N/A
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		N/A
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 visible in NORMAL USE, and		N/A
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		N/A
	– marked to indicate the equipment or equipment parts it may safely be attached to		N/A
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:		N/A
	– CREEPAGE and CLEARANCES complied with 8.9		N/A
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets		N/A
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:		N/A
	– ENCLOSURE complied with 8.4.2 d)		N/A
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable		N/A
	– RATINGS of components are not in conflict with conditions of use ..... :		N/A
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL		N/A
	– POWER SUPPLY CORD complied with 8.11.3		N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:		N/A
	– Separating transformer complied with this standard or IEC 61558-2-1, ... :		N/A
	– Separating transformer is CLASS I		N/A
	– Degree of protection against ingress of water specified as in IEC 60529		N/A
	– Separating transformer assembly marked according to 7.2 and 7.3		N/A
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083		N/A
16.9.2.2	**The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED did not exceed 200 mΩ**		N/A
	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part		N/A
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
16.9.2.3	**Conductors connecting different items within an ME SYSTEM protected against mechanical damage**		N/A
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		N/E
	RISKS associated confirmed by review..... :	EMC not part of this evaluation	N/E
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS ..... :		N/E
	RISK MANAGEMENT FILE includes an assessment of risks associated with the introduction of electromagnetic phenomena into the environment by the EQUIPMENT or SYSTEM..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/E
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems		N/E
ANNEX G	**PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		N/A
G.2	**Locations and basic requirements**		N/A
G.2.1	**Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5**		N/A
G.2.2	**FLAMMABLE AESTHETIC MIXTURE WITH**		N/A
G.2.3	**A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE**		N/A
G.2.4	**ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5**		N/A
G.2.5	**ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE comply with G.4 and G.6**		N/A
	ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7		N/A
G.3	**Marking, ACCOMPANYING DOCUMENTS**		N/A
G.3.1	**CATEGORY APG ME EQUIPMENT prominently marked "APG" (symbol 23 in Table D.1)..... :**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case		N/A
	When above marking not possible, relevant information included in instructions for use ... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.2	**CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle "AP" (symbol 22 in Table D.1)..... :**	**See copies of Marking Labels**	N/A
	Marking is as large as possible for the particular case		N/A
	When above marking not possible, the relevant information included in instructions for use ... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.3	**The marking placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts**		N/A
G.3.4	**ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts**		N/A
G.3.5	**Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG**		N/A
G.4	**Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT**		N/A
G.4.1	**a) CREEPAGE and CLEARANCES are according to Table 12 for one MEANS OF PATIENT PROTECTION**		N/A
	b) Connections protected against accidental disconnection		N/A
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD,		N/A
G.4.2	**Construction details**		N/A
	a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL		N/A
	b) ENCLOSURE complies with..... :		N/A
	– no openings on top covers of ENCLOSURE,		N/A
	– openings in side-covers prevented penetration of a solid cylindrical test rod		N/A
	– openings in base plates prevented penetration of a solid cylindrical test		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	c) Short circuiting conductor(s) to a conductive part (when no explosive gasses) did not result in loss of integrity of the part, an unacceptable temperature, or any HAZARDOUS SITUATION		N/A
G.4.3	**a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures**		N/A
	– Use of antistatic materials with a limited electrical resistance ..... :		N/A
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor		N/A
	b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882 ..... :		N/A
G.4.4	**Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5**		N/A
G.5	**Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components**		N/A
G.5.1	**ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5**		N/A
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5 ..... :		N/A
G.5.2	**Temperature limits..... :**		N/A
G.5.3	**ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:**		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1..... :		N/A
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 ..... :		N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3 ..... :		N/A
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	No extrapolation made for voltages above 42 V		N/A
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2		N/A
	No extrapolation made for voltages above 242V		N/A
	U_{max} determined using actual resistance R		N/A
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3		N/A
	No extrapolation made for inductances larger than 900 mH		N/A
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open		N/A
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed		N/A
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks		N/A
	– Peak value considered when a.c. supplied		N/A
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit… :		N/A
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max} , and C_{max} determined with application of Figs G.1-G.3 .. :		N/A
	Alternatively, compliance was verified by examination of design data .....:		N/A
G.5.4	**External ventilation with internal overpressure**		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:		N/A
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR t removed by ventilation before EQUIPMENT energized,		N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa)..... :		N/A
	Overpressure maintained at the site of potential ignition		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE		N/A
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present		N/A
	c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa) ..... :		N/A
	d) External surface of ENCLOSURE did not exceed 150 °C in 25 °C ..... :		N/A
G.5.5	**ENCLOSURES with restricted breathing**		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:		N/A
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing		N/A
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h :		N/A
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained		N/A
	Cords are fitted with adequate anchorages to limit stresses as determined by test		N/A
	Overpressure not reduced below 200 Pa		N/A
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		N/A
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C) ..... :		N/A
	Steady state operating temperature of ENCLOSURE also measured (°C) ..... :		N/A
G.6	**CATEGORY APG ME EQUIPMENT, parts and components thereof**		N/A
G.6.1	**ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION**		N/A
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
G.6.2	**Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION..... :**		N/A
G.6.3	**Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS..... :**		N/A
	a) no sparks produced and temperatures did not exceed 90 °C, or		N/A
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U_{max} and I_{max} occurring in their circuits complied with requirements, taking C_{max} and L_{max} into consideration:		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 ..... :		N/A
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 ..... :		N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 ..... :		N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated		N/A
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10		N/A
	– I_{max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10		N/A
	– C_{max} and L_{max} are values occurring in relevant circuit		N/A
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω		N/A
	– Peak value considered when a.c. supplied		N/A
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components		N/A
	- requirement not applied to transformers complying with this standard		N/A
	- requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture		N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or		N/A
	Temperature measurements made in accordance with 11.1..... :		N/A
	- or U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6 ..... :		N/A
	Alternatively, compliance verified by comparison with design data.....:		N/A
G.6.4	**ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1..... :**		N/A
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE		N/A
G.7	**Test apparatus for flammable mixtures according to this Clause and Fig G.7**		N/A

ANNEX L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**		N/A
L.1	**BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex**	No insulated winding wires	N/A
L.2	**Wire construction**		N/A
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component		N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
L.3	**Type Test**		N/A
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified		N/A
	Temperature (°C)..... :		—
	Humidity (%)..... :		—
L.3.1	**Dielectric strength**		N/A
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted with no breakdown:		N/A
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 6000 V for REINFORCED INSULATION (V) ..... :		N/A
L.3.2	**Flexibility and adherence**		N/A
	Sample subjected to flexibility and adherence		N/A
	Sample examined per IEC 60851-3: 1997, cl. 5.1.1.4, followed by dielectric test of cl. 8.8.3, with no breakdown		N/A
	Test voltage was at least the voltage in Tables 6 and 7 but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa ..... :		N/A
L.3.3	**Heat Shock**		N/A
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Oven temperature based on Table L.2 (°C)..... :		N/A
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm^2)..... :		N/A
	Dielectric strength test conducted at room temperature after removal from the oven		N/A
L.3.4	**Retention of electric strength after bending**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Test voltage applied between the shot and conductor		N/A
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm^2) ..... :		N/A
L.4	**Tests during manufacture**		N/A
L.4.1	**Production line dielectric strength tests done by the manufacture per L.4.2 and L.4.3 .....:**		N/A
L.4.2	**Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:**		N/A
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V).....:		N/A
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V) .....:		N/A
L.4.3	**Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1) .....:**		N/A
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:		N/A
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION..... :		N/A
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION ..... :		N/A

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

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
3.1	**Doc. No. 7**	—	Risk Management Process (excluding production and post-production)	**P**
3.2	**Doc. No. 7**	—	Adequate Resources	**P**
3.2	**Doc. No. 7**	—	Assignment of qualified personnel	**P**
3.2	**Doc. No. 7**	—	Policy for determining criteria for risk acceptability	**P**
3.3	—	Doc. No 2	Qualification of personnel	**P**
3.4a	—	Doc. No 1-5	Document name:	**P**
3.4b	—	Doc. No 1-5	Document name:	**P**
3.4c	—	Doc. No 1-5	Document name:	**P**
3.4d	—	Doc. No 1-5	Document name:	**P**
3.4e	—	Doc. No 1-5	Document name:	**P**
3.5	—	Doc. No 1-5	Document name:	**P**
4.1	—	Doc. No 1-5	Document name:	**P**
4.2	—	Doc. No 1-5	Product Specifications (intended use and characteristics related to the safety)	**P**
4.3	—	Doc. No 1-5		**P**
4.4	—	Doc. No 1-5		**P**
5	—	Doc. No 3		**P**
6.2	—	Doc. No 3		**P**
6.3	—	Doc. No 3		**P**
6.4	—	Doc. No 3		**P**
6.5	—	Doc. No 3		**P**
6.6a	—	Doc. No 3		**P**
6.6b	—	Doc. No 3		**P**
6.7	—	Doc. No 3		**P**
7	—	Doc. No 3		**P**
8	—	Doc. No 4/5		**P**

Supplementary Information:

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

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

4.3	**TABLE: ESSENTIAL PERFORMANCE**		**N/A**
List of ESSENTIAL PERFORMANCE functions	**MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)**	**Remarks**	
No essential performances defined by the manufacturer			

Supplementary Information:

ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.

4.11	**TABLE: Power Input**					P
Operating Conditions / Ratings	**Voltage (V)**	**Frequency (Hz)**	**Current (A)**	**Power (W or VA)**	**Power factor (cos φ)**	
Normal condition	**207**	**50**	**57.16mA**	**7.1**	**—**	
Normal condition	**230**	**50**	**68.5mA**	**9.2**	**—**	
Normal condition	**253**	**50**	**87.2mA**	**11.9**	**—**	

Supplementary Information:

The DUT **is/**marked in accordance with Subclause 7.2.7 of IEC 60601-1:2005（The measured input of the ME EQUIPMENT at RATED voltage and at operating settings specified by the MANUFACTURER is not to exceed the marked rating by more than 10 %)

The measured input current/power **did not exceed** 110 % of the DUT ratings

5.9.2	**TABLE: Determination of ACCESSIBLE parts**	**P**
Location	**Determination method (NOTE1)**	**Comments**
Enclosure	**Visual**	**No openings**
Transformer	**Visual**	**No openings**
Screw Connection of magnetic coil	**Visual**	**No openings**

Supplementary information:

[1)] NOTE: The determination methods are: visual; rigid test finger; jointed test finger; test hook.

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

7.1.2	**TABLE: Legibility of Marking**		**P**
Markings tested		**Ambient Illuminance (lx)**	**Remarks**
Outside Markings (Clause 7.2) .....:		**100lx**	**Type label**
Inside Markings (Clause 7.3) .....:			
Controls & Instruments (Clause 7.4) .....:			
Safety Signs (Clause 7.5).....:			
Symbols (Clause 7.6) .....:			
Supplementary information: Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR or if not defined at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.			

7.1.3	**TABLE: Durability of marking test**	P
Characteristics of the Marking Label tested:		**Remarks**
Material of Marking Label ..... :	**Polyester**	**-**
Ink/other printing material or process..... :		**-**
Material (composition) of Warning Label ..... :		**-**
Ink/other printing material or process..... :		**-**
Other..... :		**-**
Marking Label Tested:		**Remarks**
Marking label on power supply		**P**
Label on rotar button		**P**
Type label on top of plastic enclosure		**P**
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. The marking was not damaged. The label was not easily removed.		

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

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)**	
+ to – after Transformer	**16, 9**	**24,6**	**--**	**6,8(13)**		
Supplementary Information: [1)]The input supply voltage to the ME EQUIPMENT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4. [2)]. If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2.2						

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

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

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

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

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

Supplementary information:

The residual voltage of internal capacitors after ACCESS COVERS have been removed ☐ **does /** ☐ **does not** exceed 60 V.

The stored charge of internal capacitors after ACCESS COVERS have been removed ☐ **does /** ☐ **does not** exceed 45 µC.

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

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

Supplementary information:

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

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

Supplementary information:

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

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

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

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

E1 ☐ **is /** ☐ **is not** at least 90 % of E2.

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

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

Supplementary information:

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

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

8.7	**TABLE: leakage current**	**P**

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
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
Plastic Enclosure wrapped in aluminium foil				
NC; S5=1, e=1	253V	50Hz	2,5µA	
NC; S5=0 e=1	253V	50Hz	2,3µA	
SFC: S5=1 e=0	253V	50Hz	2,8µA	
SFC: S5=0 e=0	253V	50Hz	2,8µA	
Screw Connection of magnetic coil				
NC; S5=1, e=1	253V	50Hz	2,7µA	
NC; S5=0 e=1	253V	50Hz	2,8µA	
SFC: S5=1 e=0	253V	50Hz	3,6µA	
SFC: S5=0 e=0	253V	50Hz	3,4µA	
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)
Plastic Enclosure wrapped in aluminium foil				
NC; S5=1, e=1	253V	50Hz	2,49µA	
NC; S5=0 e=1	253V	50Hz	2,34µA	
SFC: S5=1 e=0	253V	50Hz	2,80µA	
SFC: S5=0 e=0	253V	50Hz	2,77µA	
Screw Connection of magnetic coil				
NC; S5=1, e=1	253V	50Hz	2,71µA	
NC; S5=0 e=1	253V	50Hz	2,82µA	
SFC: S5=1 e=0	253V	50Hz	3,60µA	
SFC: S5=0 e=0	253V	50Hz	3,42µA	
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 µA Type CF AP: 50 µA
-	-	-	-	-
Fig. 17 - Patient leakage current with	—	—	—	Maximum allowed values:

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
external voltage on Signal Input/Output part (SIP/SOP)				Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
-	-	-	-	-
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 µA Type CF: N/A
-	-	-	-	-
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current)
-	-	-	-	-
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
-	-	-	-	-
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC;1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
-	-	-	-	-
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000 µA Type CF: 100 µA
-	-	-	-	-
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 µA Type CF: N/A
-	-	-	-	-
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
-	-	-	-	-

Supplementary information:

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

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
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	

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.		
C	2 MOPP	325	-	4000	No
D	2 MOPP	349	-	4000	No
E	2 MOPP	24,6	-	1000	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)
Outer enclosure	75	1mm

Supplementary information:

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

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

8.9.3.2	**Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts**			N/A
Part Test	**8.9.3.4 - Test duration and temperature for 10 cycles after which the sample was subjected to Humidity Preconditioning per Cl. 5.7**	**Dielectric test voltage**	**Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No**	**Crack or voids in the insulating compound: Yes/No**
	68 h at T1 ± 2 °C = ___°C [1)]			
	1 h at 25 °C ± 2 °C			
	2 h at 0 °C ± 2 °C			
	1 or more h at 25 °C ± 2 °C			
Supplementary information: [1)] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.				

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

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

Supplementary information:

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

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

8.10	**TABLE: List of critical components**				**P**
Component/ Part No.	**Manufacturer/ Trademark**	**Type No./model No./**	**Technical data**	**Standard No./, Edition**	**Mark(s) & Certificates of conformity[1)]**
Enclosure	**Novafon**	**--**	**Overall dimensions:** **200mm x 60mm x 40mm** **Min. Thickness 1.5mm**	**—**	**Tested as part of the product**
Power Supply	**Kober Electronics GmbH**	**9641G4509TL3GP**	**Input: 230Vac 50Hz Output: 17Vac 400mA**	**IEC 60601-1:2012**	**Primara Test report:** **15PP063-01_0**
Supplementary information: 1) Indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.					

8.10 b	**TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS**				N/A
Component/ Part No.	**Manufacturer/ Trademark**	**Type No./model No./**	**Technical data**	**Standard No./, Edition**	**Mark(s) & Certificates of conformity[1)]**
Supplementary information: 1) Indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.					

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

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

8.11.3.6	**TABLE: Cord guard**			**N/A**
The unit is placed so that the axis of the cord guard, where the cord leaves it, is projected at an angle of 45º when the cord is free from stress. A mass in grams, equal to 10 times the square of the overall diameter (mm) of the cord, or for flat cords, the minor radius of the cord, is attached to the free end of the cord. Flat cords are bent in the plane of least resistance. Immediately after attaching the mass, the radius of curvature of the cord is measured.				
Cord under test	**Test mass**	**Measured curvature**	**Remarks**	
Supplementary information:				

9.2.2.2	**TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996)**				**N/A**
Inspect for TRAPPING ZONES according to Table 7, considering various parts of the human body relative to the DUT and its associated parts.					
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:					

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

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

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

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

9.4.2.3	**TABLE: Instability—overbalance from horizontal and vertical forces**		**N/A**
ME EQUIPMENT preparation	**Test Condition (force used, direction of force, weight of equipment, location of force)**	**Remarks**	
Supplementary information: The DUT ☐**did/** ☐ **did not** overbalance. A legible warning of the RISK of stepping or sitting **is/is not** provided on the DUT The DUT, any ACCESSORY, or any parts did/did not overbalance.			

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

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

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/A
ME EQUIPMENT Preparation	**Test Condition (transport position, working load, locking device(s), caster position)**	**Remarks**	
Preparation as described in manual	Breaks active, working load: 150 kg, placed on a 10° inclined plane from horizontal consisting of a hard and flat surface, no movement >50mm		
Supplementary information:			

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

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

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

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

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

9.8.3.3	**TABLE: Support/Suspension System – Dynamic forces due to loading from persons**			**N/A**
For the area of support/suspension where a PATIENT or OPERATOR can sit, a mass (as defined in Figure 12) equivalent to the SAFE WORKING LOAD representing the PATIENT or OPERATOR as defined in the instructions for use is dropped from a distance of 150 mm above the seat area. Any loss of function or structural damage that could result in an unacceptable RISK constitutes a failure.				
ME EQUIPMENT part or area	**Position**	**Safe Working Load**	**Area**	**Remarks**
Supplementary Information:				

10.1.1	**TABLE: Measurement of X - radiation**		**N/A**
Maximum allowable radiation pA/kg (µSv/h) (mR/h)		**36 (5 µSv/h) (0.5 mR/h)**	
Surface area under test Surface no./ Description[1)]		**Measured Radiation, pA/kg (µSv/h) (mR/h)**	**Remarks**
1/ /			
Supplementary information:			

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

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT**	**P**
Model No. ..... :	**NOVAFON**	
Test ambient (°C) ..... :	**a)22,2°C b)22,0°C**	
Test supply voltage/frequency (V/Hz)[4] .. :	**a)253V, 50Hz b)207V, 50Hz**	

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)		Remarks
	1	Transformer enclosure top	60	54,8	55,1	
	2	Output wiring	60	30	30,3	
	3	Switch	60	34,9	35,1	
	4	Magnet coil	105	83,4	83,6	
	5	Enclosure front (Applied part)	41	31,8	29,6	
	6	Enclosure back	48	31,4	29,7	
	7	Enclosure Top	48	47,3	47,2	
	8	Ambient	—	30	30	

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 - S**ee RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

Information from Risk Management, as applicable:

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

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

11.2.2.1	**TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source**	**N/A**
Areas where sparking might cause ignition:		**Remarks**
1.		
2.		
Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):		**Remarks**
1.		
2.		
3.		
Test parameters selected representing worst case conditions for ME EQUIPMENT:		**Remarks**
Oxygen concentration (%).....:		
Fuel .....:		
Current (A) .....:		
Voltage (V) .....:		
Capacitance (μF).....:		
Inductance or resistance (h or Ω).....:		
No. of trials (300 Min) .....:		
Sparks resulted in ignition (Yes/No) :		
Supplementary information: Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur. **Information from Risk Management, as applicable:**		

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

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

Clause / Test Name	Test Condition	Part under test	Remarks
11.6.5 Protection acc. 60529	**IPXX**	**Whole unit**	**Unit was tested**
11.6.6 Cleaning and disinfection	**Cleaning with wet cloth** **Cleaning as described in the instructions for use, Environmental conditions as specified in the technical description.**	**Whole unit**	**No unacceptable Risk**

Supplementary information:

Information from Risk Management, as applicable:

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

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

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

Supplementary information:

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

13.2	**TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive**		**P**
Clause No.	**Description of SINGLE FAULT CONDITION**	**Results observed**	**HAZARDOUS SITUATION (Yes/No)**
13.2.2	**Electrical SINGLE FAULT CONDITIONS per Cl. 8.1:**	**—**	**—**
	Unintermitted loaded operation	**The temperature of the magnet coil rise up to 115,1°C at an ambient of 22,3°C. No Hazard no defect.**	**NO**
13.2.3	**Overheating of transformers per Clause 15.5:**	**—**	**—**
	Magnetic coil short	**Unit switched off after 5min (Thermal cut-off of transformer opened). The measured Temperature on Transformer was 130,2°C at an ambient of 24,9°C. No hazard no defect. No excessive temperature rise.**	**NO**
13.2.4	**Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:**	**—**	**—**
	-	**-**	**-**
13.2.5	**Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:**	**—**	**—**
	No temperature limiting devices	**-**	**-**
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		

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1)] – Also see 13.10	—	—
	No motor capacitors	-	-
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:	—	—
	No oxygen rich environments	-	-
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	—	—
	No such parts	-	-

Supplementary information:

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

Information from Risk Management, as applicable:

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

15.3	**TABLE: Mechanical Strength tests** [1)]		**P**
Clause	**Name of Test**	**Test conditions**	**Observed results/Remarks**
15.3.2	Push Test For ME EQUIPMENT with non-metallic ENCLOSURES, this test is performed at the maximum ambient temperature indicated in the technical description for NORMAL USE.	Force = 250 N ± 10 N for 5 s, 30 mm diameter	There **was no** cracking of the ENCLOSURE that could cause an unacceptable RISK. There **was no** reduction of CREEPAGE DISTANCES and AIR CLEARANCES. There **were no** live parts that became accessible. There **was not** an indication of dielectric strength breakdown.
15.3.3	Impact Test Cathode ray tubes, flat panel displays and platen glass are excluded.	Steel ball 50 mm in diameter, 500 g falling from a 1.3 m once onto each relevant part of the ENCLOSURE	There **was no** cracking of the ENCLOSURE that could cause an unacceptable RISK. There **were no** barriers damaged or loosened. There **was no** damage that could cause moving parts to become hazardous. There **was no** damage that could cause spread of fire. There **was not** an indication of dielectric strength breakdown.
15.3.4.1	Drop Test (hand-held)	three different starting orientations Free fall height (m) = 1m onto a 50 mm ± 5 mm thick hardwood board	Parts, which are hazardous live, **have not** become accessible. ENCLOSURES **show no** cracks that could cause an unacceptable RISK. AIR CLEARANCES **are not** less than their permitted values and the insulation of internal wiring remains undamaged. Barriers **have not** been damaged or loosened. There **has been no** damage, which could cause moving parts to become hazardous. There **has been no** damage that could cause spread of fire. There **was no** damage to the interior or exterior of the DUT. There **was not** an indication of dielectric strength breakdown.
15.3.5	Rough handling test Ascending Step	Travel speed (m/s) = 0,4 m/s ± 0,1 m/s 40 mm ascending hardwood step	The mechanical integrity of the DUT was not maintained Measured CREEPAGE DISTANCES and AIR CLEARANCES were satisfactory after the tests. There was not an indication of dielectric strength breakdown

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

15.3.6	Mould Stress Relief (Moulded Plastic enclosure only)	7 h in oven at temperature (°C) = 10 °C above maximum temperature observed on the enclosure during temp test or 70 °C	There **was no** cracking of the ENCLOSURE that could cause an unacceptable RISK. There **were no** barriers damaged or loosened. There **was no** damage that could result in reduction of CREEPAGE DISTANCES and AIR CLEARANCES. There **was no** warping that enabled access to hazardous parts using the test pin, test finger and test hook.
Supplementary information: [1)]As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows).			

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

1) Where an axial pull is required in NORMAL USE, or is likely to be applied to the rotating or moveable parts of controls in NORMAL USE an axial force of 60 N for electrical components and 100 N for other components was applied for 1 min to the OPERATOR accessible knobs indicated below and in a direction to effect their removal. During this test, no torque was applied.

2) For rotating controls and stops, the torques as shown in Table 9 are applied between the control knob and the shaft for not less than 2 s in each direction alternately. The test is repeated 10 times.

The knob should not rotate with respect to the shaft.

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:

15.5.1.2	**TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION**	**P**
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)[1)] ... :	**253Vac**	**—**
RATED input frequency (Hz) ..... :	**50Hz**	**—**

Winding tested	Class of insulation (A, B, E, F, or H)	Type of protective device (fuse, circuit breaker) /Ratings	Protective device operated Yes/No	Time to THERMAL STABILITY (when protective device did not operate)(Min)	Maximum allowed temp from Table 31 (ºC)	Maximum winding temp measured (ºC)	Ambient (ºC)
Secondary winding	**B**	**Thermal cut-out 120°C (5min)**	**YES**	**--**	**175**	**130,2**	**24,9**

Supplementary information:

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

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

Multiple overload tests may be needed to fully evaluate the worst-case NORMAL USE loading and fusing for windings with more than one protective device.

Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1)] ..... :	**253**
RATED input frequency (Hz) ..... :	**50**
Test current just below minimum current that would activate protective device and achieve THERMAL STABILITY under method a) (A) ..... :	**2A**
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)
Secondary	**B**	**Thermal cut-out 120°C**	**175**	**130,2**	**24,9**

Supplementary information:

15.5.2	**TABLE: Transformer dielectric strength after humidity preconditioning of 5.7**	**P**

Transformer Model/Type/ Part No	Test voltage applied between	Test voltage, (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No
T1	**Primary to secondary windings**	**4000**	**50**	**No**	**No**
T1	**Primary to secondary windings**	**1150**	**250**	**No**	**No**

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

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

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

Supplementary information:

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

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

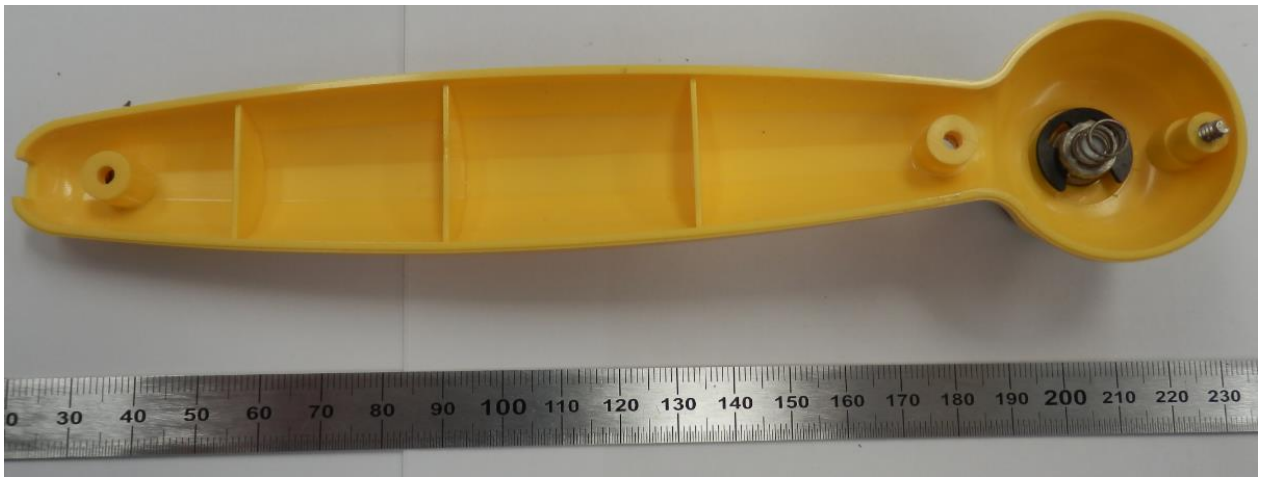
IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

Appendix 1
Pictures of the Unit

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

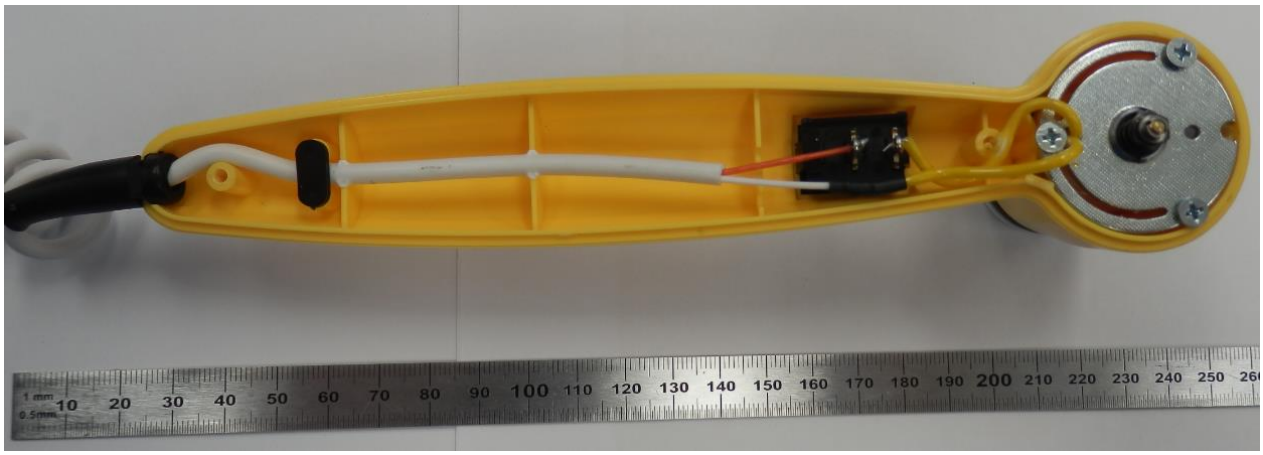
Overall view of SK1

Inside view of SK1



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

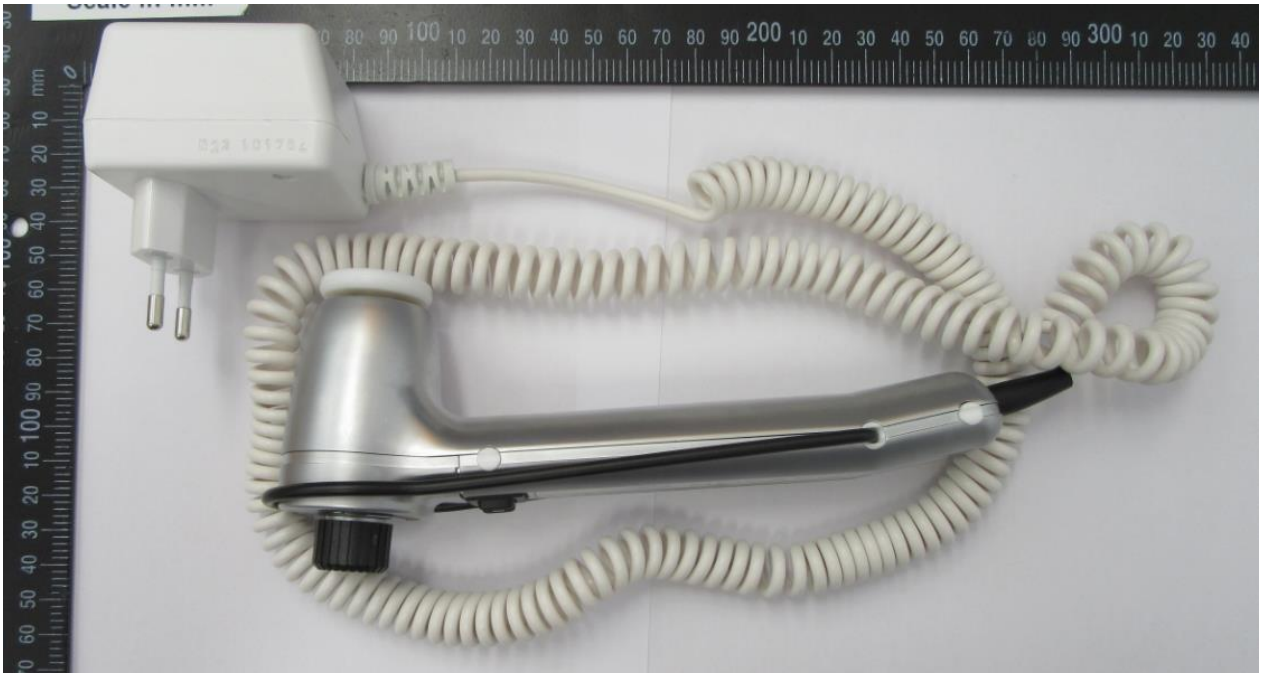
Inside view of SK1



Inside view of SK1

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

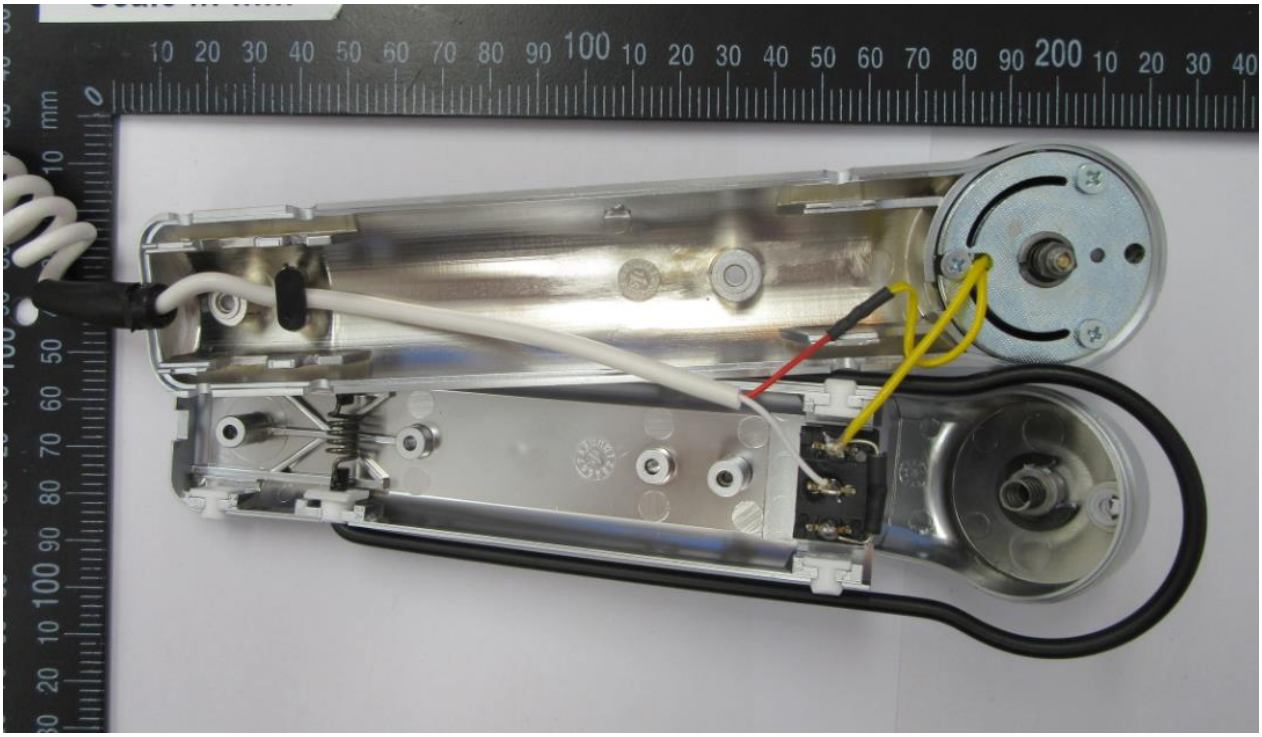
Overall view of SK2



Overall view of SK2

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

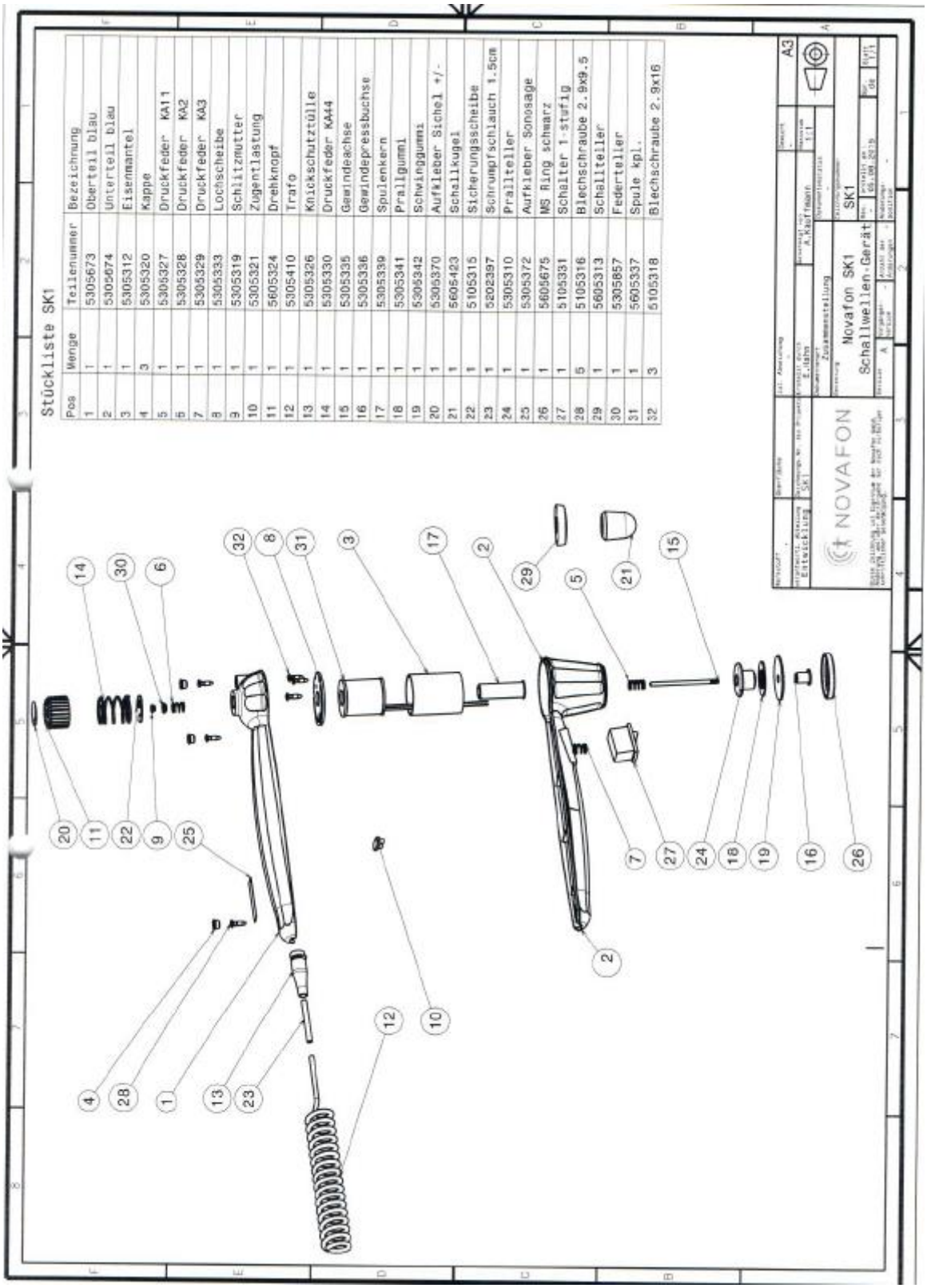
Inside view of SK2



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

Appendix 2
Technical Documentation

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



Stückliste SK1

Pos	Menge	Teilenummer	Bezeichnung
1	1	5305673	Oberteil blau
2	1	5305674	Unterteil blau
3	1	5305312	Eisenmantel
4	3	5305320	Kappe
5	1	5305327	Druckfeder KA11
6	1	5305328	Druckfeder KA2
7	1	5305329	Druckfeder KA3
8	1	5305333	Lochscheibe
9	1	5305319	Schlitzmutter
10	1	5305321	Zugentlastung
11	1	5605324	Drehknopf
12	1	5305410	Trafo
13	1	5305326	Knickschutztülle
14	1	5305330	Druckfeder KA44
15	1	5305335	Gewindeachse
16	1	5305336	Gewindepressbuchse
17	1	5305339	Spulenkern
18	1	5305341	Prallgummi
19	1	5305342	Schwinggummi
20	1	5305370	Aufkleber Sichel +/-
21	1	5605423	Schallkugel
22	1	5105315	Sicherungsscheibe
23	1	5202397	Schrumpfschlauch 1.5cm
24	1	5305310	Prallteller
25	1	5305372	Aufkleber Sonosage
26	1	5605675	MS Ring schwarz
27	1	5105331	Schalter 1-stufig
28	5	5105316	Blechschraube 2.9x9.5
29	1	5605313	Schallteller
30	1	5305857	Federteller
31	1	5605337	Spule kpl.
32	3	5105318	Blechschraube 2.9x16

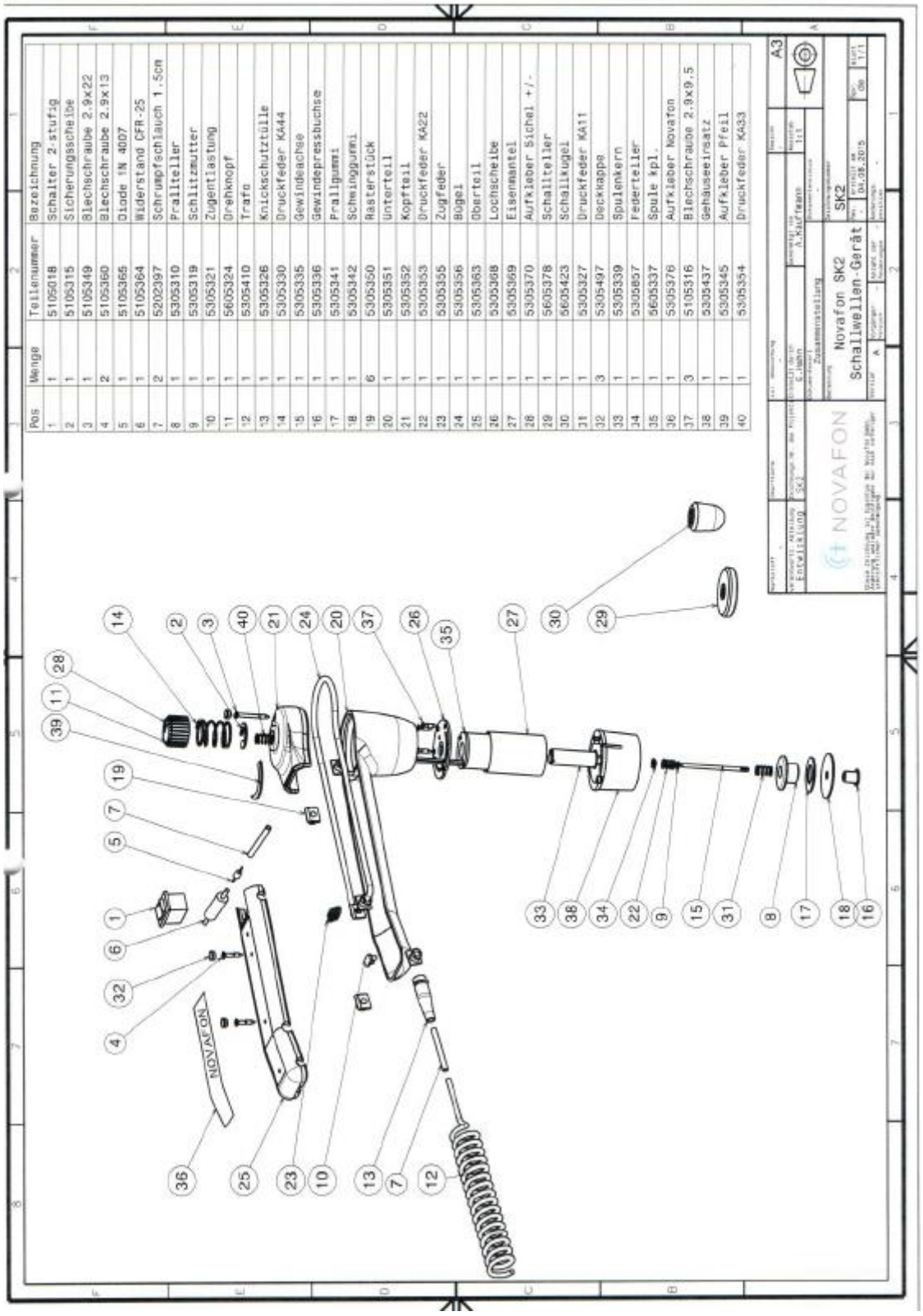
NOVAFON

Novafon SK1
Schallwellen-Gerät

SK1

A3

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



Pos	Menge	Teilenummer	Bezeichnung
1	1	5105018	Schalter 2-stufig
2	1	5105315	Sicherungsscheibe
3	1	5105349	Blechschraube 2.9x22
4	2	5105360	Blechschraube 2.9x13
5	1	5105365	Diode IN 4007
6	1	5105364	Widerstand CFR-25
7	2	5202397	Schrumpfschlauch 1.5cm
8	1	5305310	Prallteller
9	1	5305319	Schlitzmutter
10	1	5305321	Zugentlastung
11	1	5605324	Drehknopf
12	1	5305410	Trafo
13	1	5305326	Knickschutztülle
14	1	5305330	Druckfeder KA44
15	1	5305335	Gewindeachse
16	1	5305336	Gewindepressbuchse
17	1	5305341	Prallgummi
18	1	5305342	Scheinggummi
19	6	5305350	Rasterstück
20	1	5305351	Unterteil
21	1	5305352	Kopfteil
22	1	5305353	Druckfeder KA22
23	1	5305355	Zugfeder
24	1	5305356	Bügel
25	1	5305363	Oberteil
26	1	5305368	Lochscheibe
27	1	5305369	Eisenmantel
28	1	5305370	Aufkleber Sichel +/-
29	1	5605378	Schallteller
30	1	5605423	Schallkugel
31	1	5305327	Druckfeder KA11
32	3	5305497	Deckkappe
33	1	5305339	Spulenkern
34	1	5305857	Federteller
35	1	5605337	Spule kpl.
36	1	5305376	Aufkleber Novafon
37	3	5105316	Blechschraube 2.9x9.5
38	1	5305437	Gehäuseeinsatz
39	1	5305345	Aufkleber Pfeil
40	1	5305354	Druckfeder KA33

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

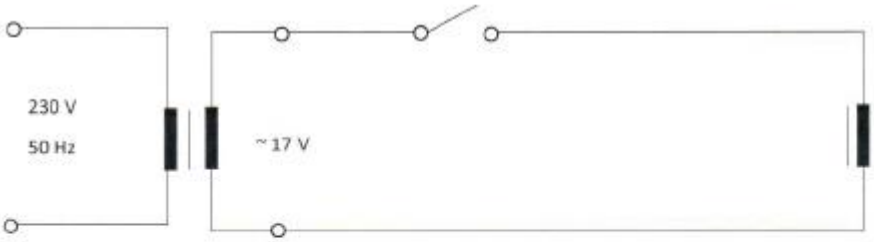
TD	Technische Dokumentation der NOVAFON Schallwellengeräte	NOVAFON
	B3 Schaltung- und Funktionsbeschreibung	Dok.-Nr.: TD-SK-B3V01 Ersetzt: -

2. Schaltplan

Die Schaltpläne der SK1 und SK2 Geräte unterscheiden sich aufgrund der unterschiedlichen Anzahl an Schaltstufen.

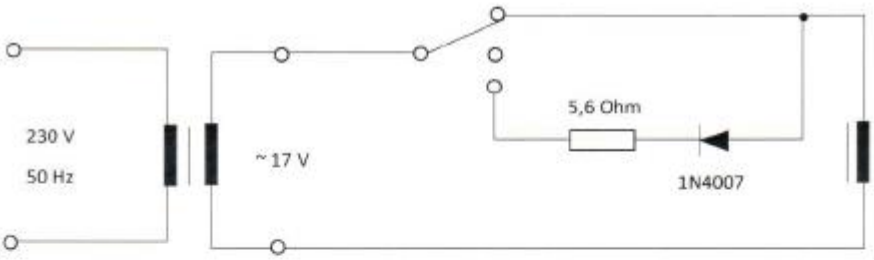
2.1. Schaltplan einstufig

Die Geräte SK1 verchromt und SK1 Kunststoff haben nur eine Schaltstufe und daher eine Reihenschaltung.



2.2. Schaltplan zweistufig

Die Geräte SK2 verchromt und SK1 vergoldet haben zwei Schaltstufen und daher eine Parallelschaltung.
Um eine Perkussion zu erreichen werden auf der zweiten Stufe ein Widerstand und eine Diode zwischen geschaltet.



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

Appendix 3
List of Test Equipment

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

Internal No.	Equipment	Manufacturer	Type	Serial No.	Last Calibration	Next Calibration
031	Test Hook	Stahl	MP-700-30A	J49002	18.03.2013	18.03.2016
036	Similar to IEC61032, Figure 2, test probe 2	Stahl	MP-100.04A	J39038	18.03.2013	18.03.2016
038	Leakage Meter IEC 60601, F15	SBF Electronic	ALS-CL-19	2010ALS01V 01-QPS	04.08.2015	04.08.2016
054	Digital Multimeter / Datalogger (Temp.)	Keithley	2701	2700-307 B	01.12.2015	01.12.2016
077	Force Meter	Chatillon	DFX-050-NIST	WO2617	24.11.2015	24.11.2016
083	Rigid test finger IEC 60950	Stahl	MP-100.04Y	G49003	18.09.2013	18.09.2016
090	timer / stop watch	Orion	JS-506	160844	31.12.2015	31.12.2016
094	Climatic Chamber	Weiss Umwelttechnik	WK3-340/40	58226103910 010	28.04.2015	28.04.2016
117	Dielectric Tester	SPS electronic GmbH	HA 3881G	11030102	16.03.2015	16.03.2016
124	Oscilloscope	Yokogawa	DLM2022	91L846393	20.10.2015	20.10.2016
151	Ethanol	Th. Geyer	Ethanol	2286.1000	14.12.2012	ICO
165	Digital Multimeter	Fluke	175	23450679	04.05.2015	04.05.2016

The Equipment fulfills the requirements of PDSH 251E.
The uncertainties from the measurement method and the uncertainties of the test equipment has been identified and can be provided on request.