Test Report

SAFETY

Issued to:	3A HEALTH CARE S.r.l. Via Marziale Cerutti 90F/G, 25017 Lonato Del Garda (BS)
Item under test	SUCTION EQUIPMENT Manufacturer: **3A HEALTH CARE S.r.l.** Model: MAXIASPEED 6.2 Serial: 221785/ASP HW revision: 18/34016 SW revision: NA
Reference standard	EN 60601-1:2006/A11:2011/A1:2013 EN 10079-1:2015
Type of test	Safety
Result	Pass

Revision	1st	Dated	24/04/2018
Draft:	Doct. Eng. L. De Marco (tester)	Approval:	Doct. Eng. L. Spinelli (head of the laboratory)
Stamp			

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Certification Body approved according to EN 17065:2012

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1. SCOPE

This document has been drafted with the scope of documenting the tests executed to verify the conformity of the device with the safety prescriptions of reference documents.

The analysis conducted concerned the examination of the technical documentation referring to the device, the carrying out of a visual inspection in the aim of determining the applicable standards and, where requested, the performing of tests on the device. The tests has been executed in the conditions and with the methodologies defined in the applicable standards and their results are reported in the check lists inside paragraph 4.

This document must be inserted inside Technical File and it will be the technical reference regarding the observance of the prescriptions deriving from the applicable standards.

The analysis carried out concerns the device set up in conditions suitable for delivery to the customer: in the event of modifications being carried out it will be necessary to repeat the tests in order to validate the modifications made.

The report contains the results of the analysis executed on the described device and it doesn't entitle to affix any type of mark. Affixing the name of the laboratory in connection with the use, the promotion or other of the described device shall only be admitted against explicit written authorisation.

The results of the measurements recorded in this document refer exclusively to the sample examined and in the conditions of the measurements specified. Any extension of the results to other units or in other measuring conditions shall not enter within the scope of this document.

2. CONFORMITY ASSESMENT

IEC 60601-1 Medical electrical equipment. Part 1: General requirements for basic safety and essential performance	
Report Reference No.	R-EL-252-0418-14A
Date of issue	2018/04/24
Total number of pages	94
Testing Laboratory	**ELETTRA s.r.l.**
Address	Via Matteucci, 10 50041 Calenzano (Florence) - Italy
Applicant's name	**3A HEALTH CARE S.r.l.**
Address	Via Marziale Cerutti 90F/G, 25017 Lonato Del Garda (BS)
Test specification:	
Standard	EN 60601-1:2006/A11:2011/A1:2013
Test procedure	EL003; EL006; EL007; EL008
Non-standard test method…….:	NA
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Test item description	**SUCTION EQUIPMENT**
Trade mark	
Manufacturer	**3A HEALTH CARE s.r.l.**
Brand	**3A HEALTH CARE**
Model/Type reference	**MAXIASPEED 6.2**
Sn number	**221785/ASP**
Ratings	**230V 50/60Hz 300VA**

IP degree ……..	**IP20**
Functioning	**Continuous.**

Copy of marking plate and photo of device under test:

Summary of testing: **All applicable clauses (except for cl.14)……..:**	**PASS**
Particulars: test item vs. test requirements	
Classification……..:	**Portable** **Type B** **Class II**
Hardware version:……	Lot 18/34016
Software version:……..	N/A
Software designer (if different than end product manager) .....:	NA
Address.....:	NA
Accessories included in the evaluation:.....	
Test case verdicts	
Test case does not apply to the test object ……:	NA
Test item does meet the requirement:..... :	P (Pass)
Test item does not meet the requirement..... :	F (Fail)
Test clause not evaluated ……:	NE
Testing	
Date of receipt of test item ..... …….:	07/09/2017
Date(s) of performance of test..... :	29/09/2017 ÷ 16/03/2018
Internal reference number ..... :	29817A
Environmental laboratory conditions: ……:	24±4°C; 45±15% r.h. 860-1060hPa
Sampling: ……..:	Device tested was equipped up by the manufacturer.

INSULATION DIAGRAM

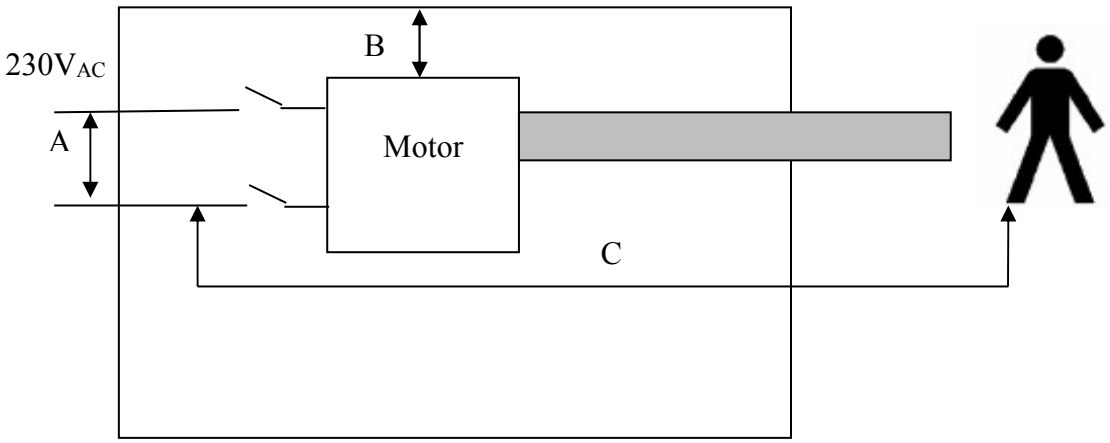

TABLE: To insulation diagram		P
Pollution degree……. :	2	--
Overvoltage category…….. :	II	--
Altitude.....:	Less than 2000m	--
Additional details on parts considered as applied part:	☒ None	--

Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working Voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Re-marks
			A.C.	C.C.					
A	basic between L-N (1MOOP)	IIIb	230		2,5	2,0	2,5	2,0	P
B	2MOPP	IIIb	230		8,0	5,0	105	43,0	P
C	2MOPP	IIIb	230		8,0	5,0	12	12	P

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.

3. REFERENCE DOCUMENTS

The considerations contained in this document are aimed at verifying the observance of the provisions deriving from the following Community Directives:

- Medical Equipment Directive CEE 93/42, and CE 2007/47

Observance of the above-mentioned directives has been obtained by making reference wherever applicable, to the following standards

EN 60601-1	”Medical electrical equipment. Part 1: General requirements for basic safety and essential performance” - 2006/A11:2011/A1:2013
EN 10079-1	“Medical suction equipment Part 1. Electrically powered suction equipment. 2015

4. CONFORMITY CHECK

EN 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
(4.0) GENERAL REQUIREMENTS			
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse and Definitions/ requirements using the term PATIENT considered as applicable to individual(s) for whom ME EQUIPMENT or ME SYSTEM is designed for	Normal use and foreseeable misuse evaluated	P
4.2	A RISK MANAGEMENT PROCESS complying with ISO 14971 was performed and ISO 14971applied with the specified considerations:	See risk analysis provided by the manufacturer with RMF Suction Equipment rev. 01	P
4.3	ESSENTIAL PERFORMANCE functions identified and maintained following particular tests as applicable	See risk analysis provided by the manufacturer	P
4.4	EXPECTED SERVICE LIFE	See risk analysis provided by the manufacturer (5 years)	P
4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME system	All standard clause applied	NA
4.6	ME EQUIPMENT or ME system parts that contact the patient	All parts which could came into contact with the patient are evaluated as applied parts (together with collection vessel, filter and pipes which are in contact with conductive liquids)	P
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by 4.2	See fault condition in cl. 13.2	P

EN 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used in accordance with their applicable ratings. Components used as MEANS OF PROTECTION comply with IEC or ISO standard, or requirements of this standard applied:	Used in accordance with ratings Conform with IEC requirements. See: - The technical file (master) - Collection of documentation of component parts	P
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS used when fault in a particular component can generate an unacceptable RISK:	--	NA
4.10	Power supply		P
4.10.1	ME EQUIPMENT is suitable for connection to a SUPPLY MAINS, specified to be connected to a separate power supply, can be powered by an INTERNAL ELECTRICAL POWER SOURCE, or a combination of the three:	Connection with plug to mains supply, specified for connection to a separate power supply and internal electrical power source	P
4.10.2	Maximum rated voltage for ME EQUIPMENT does not exceed the values specified in this clause, with SUPPLY MAINS characteristics being as specified in the standard:	230V ~ 50-60Hz	P
4.11	Steady-state measured power input of ME EQUIPMENT or ME SYSTEM did not exceed marked rating by more than 10 %:	Rated: 300VA Test passed. See appended table 4.11	P
(5.0) GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT			
5.1 – 5.6	General testing requirements for TYPE TESTS of clauses 5.1 to 5.8 are being met, including ambient and other conditions, supply, repairs and modifications, humidity conditioning and sequence of tests	Type test performed on one sample. Environmental conditions: Temperature between 20°C and 25°C, Relative humidity between 30% and 75% Pressure between 800hPa and 1100hPa	P
5.7	Humidity preconditioning treatment	48h 93% 25°C	P
5.8	Sequence of tests	According to annex B	P
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		P
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS:	Pipes, filter	P

EN 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.9.2	ACCESSIBLE PARTS identified by inspection, with accessibility determined using standard test finger and Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT, with conductive parts of actuating mechanisms of electrical controls considered ACCESSIBLE PARTS only when removal of handles, knobs, etc. requires use of a TOOL	Tested with jointed finger and unjointed finger	P
(6.0) CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS			
6.1	ME EQUIPMENT, parts thereof, and APPLIED PARTS, classified against electric shock as follows:		P
6.2	CLASS I , CLASS II, OR INTERNALLY POWERED:	Class II	P
	INTERNALLY POWERED EQUIPMENT with means of connection to a SUPPLY MAINS complied with the requirements specified in this clause		P
	APPLIED PART: TYPE B, BF CF, DEFIBRILLATION-PROOF?:	B	P
6.3	ENCLOSURES IP classification according IEC 60529:	IP20	P
6.4	Method of sterilization classified as indicated in instructions for use:	According to manufacturer's instructions (sterilisation with steam at 121°C)	P
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified	Not for use in oxygen rich environment	NA
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION:	Continuous operation	P
(7.0) ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS			
7.1.1	USABILITY of identification and marking	EN 60601-1-6 evaluation document provided rev. 15/01/18	P
7.1.2	Markings required by 7.2-7.6 clearly legible under the testing conditions and mounting conditions specified	Clearly legible	P
7.1.3	Durability of markings as specified in this clause	See appended Tables 7.1.3	P
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		P
7.2.1	Minimum requirements specified in this clause for marking on ME EQUIPMENT and on interchangeable parts met:	Provided	P

EN 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.2.2	Name or trademark of MANUFACTURER and MODEL OR TYPE REFERENCE marked, and Software forming part of a PEMS identified	Manufacturer with contact information: 3A HEALTH CARE s.r.l. (with address) Brand: 3A Model: MAXIASPEED 6.2 Sn: 221785/ASP	P
7.2.3	Appropriate symbol / safety sign (Table D.1, 11 or Table D.2, 10) used to advice OPERATOR to consult ACCOMPANYING DOCUMENTS; Any material, component, ACCESSORY or ME EQUIPMENT that is intended for a single use or its packaging shall be marked "Single Use Only", "Do Not Reuse" or with symbol 28 table D.1:	Provided symbol to read user manual accessories marked with symbol 28 table D.1	P
7.2.4	ACCESSORIES marked with (or on individual packaging when not practical) name or trademark of their MANUFACTURER or supplier, and with a MODEL or TYPE REFERENCE:	Marked in individual packaging	P
7.2.5	MODEL or TYPE REF. of equipment to be connected to ME EQUIPMENT to provide power, is marked as specified:	--	NA
7.2.6	Following markings appear on outside of part containing SUPPLY MAINS connection:		P
	NOMINAL supply voltage or range, nature of supply and rated frequency (range):	230V ~ 50-60Hz	P
	Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT:	Provided	P
7.2.7	Markings for RATED input power meet the requirements specified in this clause:	300VA	P
7.2.8	Output connectors of ME EQUIPMENT marked with RATED output voltage, RATED current or power and output frequency (when applicable): (See 16.9.2.1 b) for MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT)		NA
7.2.9	ME EQUIPMENT or its parts marked with the IP code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2):	IP20	NA

EN 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols, including safety sign where required, and explanations in instructions for use where required:	Type B	P
7.2.11	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION marked as specified:		NA
7.2.12	Fuse ratings marked adjacent to ACCESSIBLE fuse-holder:	T2,5A	P
7.2.13	Safety signs and warning statements for EQUIPMENT that produce physiological effects that are not obvious to OPERATOR provided:		NA
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		NA
7.2.15	Requirements for cooling provisions marked:		NA
7.2.16	ME EQUIPMENT with limited mechanical stability	Stable with 10° inclination	P
7.2.17	Protective packaging marked as specified:	Not under evaluation	NE
7.2.18	RATED maximum supply pressure and flow rate from an external source marked on ME EQUIPMENT adjacent to each input connector		NA
7.2.19	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL:		NA
7.2.20	Marking for removable protective mean:		NA
7.2.21	Mass of mobile ME equipment:	12Kg	P
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		
7.3.1	Markings for heating elements or lampholders:		NA
7.3.2	Symbol 24 of Table D.1 or safety sign 3 of Table D.2 used to mark presence for HIGH VOLTAGE parts:	No high voltage parts	NA
7.3.3	Battery markings and warnings:		NA
7.3.4	Markings and information for fuses and replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible only by a TOOL:		NA
7.3.5	PROTECTIVE EARTH TERMINAL marking, symbol 6 of Table D.1, provided as specified:		NA
7.3.6	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS:		NA

EN 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.3.7	Markings for supply terminals provided as specified		NA
7.3.8	Statement related to temperature of supply terminals		NA
7.4	Marking of controls and instruments		P
7.4.1	Markings or indicators for power switches provided as specified	Switch marked with dedicated symbol I/O	P
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means. Indication device provided if necessary Marking of stand-by control device		P
7.4.3	Units of measure as specified	mmHg and bar	P
7.5	Safety signs		NA
	Markings used to convey a warning, prohibition or mandatory action mitigating a RISK not obvious to OPERATOR are safety signs from ISO 7010, provided in specified colour, and (together with supplementary test or symbols) described in instructions for use.		NA
	One of the specified methods used when a safety sign was not available to indicate a particular desired meaning:	--	NA
7.6	Symbols		P
7.6.1	Meanings of symbols used for marking described in instructions for use	Described in the user manual	P
7.6.2	Symbols required by this standard conform to IEC or ISO publication referenced	Conform to IEC	P
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication	Conform to IEC	P
7.7	Colors of the insulation of conductors		P
7.7.1	PROTECTIVE EARTH CONDUCTOR green/yellow		NA
7.7.2	PROTECTIVE EARTH CONNECTIONS (internal) identified by green/yellow at least at terminations		NA
7.7.3	Green and yellow insulation only used as specified		NA
7.7.4	Neutral conductors of POWER SUPPLY CORDS are “light blue”		NA

EN 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.7.5	Colors of conductors in POWER SUPPLY CORDS are in accordance with IEC 60227-1 or IEC 60245-1		NA
7.8	Colors of indicator lights and controls and their meanings are are as specified in this clause, with Red used only for emergency control		NA
7.9	ACCOMPANYING DOCUMENTS		P
7.9.1	ME EQUIPMENT accompanied by at least instructions for use, and a technical description	User manual provided	P
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by name or trade-name of MANUFACTURER AND CONTACT INFORMATION, address the RESPONSIBLE ORGANIZATION and MODEL or TYPE REFERENCE:	Provided with contact information of manufacturer	P
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	Provided Temperature range 0°/+40° Not for use with flammable or explosive gas	P
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended May be provided electronically according to usability engineering process	Only use by qualified staff	P
7.9.2	Instructions for use include the required information		P
7.9.2.1	Intended use of ME EQUIPMENT, frequently used functions, and known contraindication(s) to use of ME EQUIPMENT	Provided	P
	Classifications specified in Clause 6, all markings specified in 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	Provided	P
7.9.2.2	Instructions for use include all warning and safety notices as specified in this clause	Provided	P
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply indicating “power supply is specified as a part of ME EQUIPMENT or combination is specified as a ME SYSTEM”		NA
7.9.2.4	Warning statements related to the electrical power source as specified		NA

EN 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.5	Instructions of use include description, function and significant physical and performance characteristics of ME EQUIPMENT, its functions, expected positions OPERATOR, PATIENT, and other persons materials and ingredients PATIENT or OPERATOR is exposed to, restrictions on other equipment or NETWORK/DATA COUPLINGS, and indicate any APPLIED PART.	Provided	P
7.9.2.6	If installation of ME EQUIPMENT required, location of instructions of use shall be specified or contact information provided		NA
7.9.2.7	Instructions related to isolation from SUPPLY MAINS	Provided	P
7.9.2.8	Start-up PROCEDURE and details on treatment/handling of the ME EQUIPMENT before put in use	Provided	P
7.9.2.9	Operating instructions and meanings of figures, symbols, warning statements, indicator lights etc	Provided	P
7.9.2.10	List of messages	Not required	NA
7.9.2.11	Shut-down PROCEDURE	--	NA
7.9.2.12	Cleaning, disinfection, and sterilization methods and parameters	Provided	P
7.9.2.13	Detailed instructions provided on preventive inspection, maintenance, calibration, and frequency of such maintenance	Provided	P
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	Provided	P
	Other equipment providing power to ME SYSTEM sufficiently described		NA
7.9.2.15	RISKS associated with disposal of waste products, residues, etc	Provided	P
7.9.2.16	Reference to the technical description	Provided	P
7.9.2.17	For ME EQUIPMENT emitting radiation for medical purposes, the instructions for use shall indicate the nature, type, intensity and distribution of this radiation.		NA
7.9.2.18	The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile shall indicate that they have been sterilized and indicate the method of sterilization.	Provided for accessories	P
7.9.2.19	The instructions for use shall contain a unique version identifier such as its date of issue.	3A4054 - rev. 00 - 04/2018	P

EN 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.23	Instruction for use shall document the use as intended, frequently used functions, known contraindication, parts to be serviced If patient is an intended operator the instructions for use shall indicate the patient is an intended operator, warning, functions that can safely used and those that cannot be used, maintenance	Provided	P
7.9.3	Technical description		
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 as specified in this clause	Provided in user manual	P
	Technical description separable from instructions for use contains information in Clause 7.2, all classifications, warnings and safety notices, brief description	Included in user manual	NA
	Minimum qualifications of SERVICE PERSONNEL documented in technical description	--	NA
7.9.3.2	Instructions related to replacement of fuses, POWER SUPPLY CORDS and other parts	Provided	P
7.9.3.3	A statement related to circuit diagrams, component part lists, etc	Only authorized	NA
7.9.3.4	Means used to comply with requirements of 8.11.1 for mains isolation identified	Provided	P
7.9.3.23	Information regarding essential performance and any necessary recurrent essential performance and basic safety testing including details of the means, methods and recommended frequency Description of ME and version identification (date of use)	Provided	P
(8.0) PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT			
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS	Accessible parts not exceed limit of voltage, current or energy in normal conditions or in single fault conditions	P
	NORMAL CONDITION considered as simultaneous occurrence of situations identified in Clause 8.1a)		P
	SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b)		P

EN 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ACCESSIBLE PARTS determined according to 5.9	Enclosure and applied parts	P
	LEAKAGE CURRENTS measured according to 8.7		P
8.2	Requirements related to power sources considered and taken into consideration for inspection and testing as specified in 8.2.1 when connected to a separate power source and as per 8.2.2 when connected to an external d.c. power source	Appliance tested with its dedicated power supply	P
8.3	Classification of APPLIED PARTS as specified in this clause for Types CF, BF, B and parts that are identified according to 4.6 as needing to be subject to the requirement for an APPLIED PART except markings	Type B	P
8.4	Limitation of voltage, current or energy		P
8.4.1	Limits specified in 8.4.2 not applied to currents intended to flow through body of PATIENT to produce a physiological effect during NORMAL USE	Not present current that flow through body of patient	NA
8.4.2	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT per Tables 3 and 4 when measured per Cl. 8.7.4:	See appended table 8.7	P
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT in Cl. 8.7.3 c) when measured per Clause 8.7.4 (mA):	See appended table 8.7	P
	c) Limits specified in b) not applied to accessible contacts of connectors, fuseholder or lampholders and parts inside an ACCESS COVER if conditions specified in this clause and the voltage and energy limits are not exceeded:	--	NA
	d) Voltage and energy limits specified in c) above also applied to the internal parts other than contacts of plugs, connectors and socket outlets , touchable by test pin and test rod when tested as specified in this clause inserted through an opening in an ENCLOSURE;	No accessible part from opening	NA

EN 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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, AND A TOOL is required when it is possible to prevent the devices from operating.	Only accessible with a tool	NA
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one s after disconnection or, when exceeded, stored charge did not 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, did not exceed 60 V or calculated stored charge did not exceed 45 µC:	See appended Table 8.4.4	NA
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL:	--	NA
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 and manual discharging device specified in technical description:	--	NA
8.5	Separation of parts		
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 Cl. 8.4. Each MEANS OF PROTECTION categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking into account 4.6, and flow chart in Fig A.12	Two means of protection for operator and patient respect live parts See the insulation diagram in this report.	P

EN 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.5.1.2	Solid insulation, CREEPAGE and CLEARANCES, PROTECTIVE EARTH CONNECTIONS and Y capacitors forming a MEANS OF PATIENT PROTECTION meet the requirements of this clause Where the working voltage across a barrier forming a MEANS OF PATIENT PROTECTION is less than 42,4 V peak a.c. or 60 V d.c., a single Y1 capacitor is acceptable for two MEANS OF PATIENT PROTECTION	Means of protection of patient adequate See the insulation diagram in this report.	P
8.5.1.3	Solid insulation, CREEPAGE and CLEARANCES, PROTECTIVE EARTH CONNECTIONS and Y capacitors forming a MEANS OF OPERATOR PROTECTION meet the requirements of this clause A Y1 capacitor can be used for two MEANS OF OPERATOR PROTECTION.	Means of protection of operator adequate See the insulation diagram in this report.	P
8.5.2	Separation of PATIENT CONNECTIONS		P
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART meet the requirements of this clause, including separation from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAX. MAINS VOLTAGE and complied with limit for PATIENT LEAKAGE CURRENT with 110 % of MAX. MAINS VOLTAGE applied (mA):	Type B applied part	NA
	LEAKAGE CURRENT tests conducted per 8.7.4, Dielectric strength test conducted per 8.8.3, and CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable	See appended Tables 8.7 and 8.8.3	P
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s	--	NA
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, except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low	Type B insulated applied part; no patient connection	NA

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Clause	Requirement + Test	Result - Remark	Verdict
	LEAKAGE CURRENT tests conducted per 8.7.4, Dielectric strength test conducted per 8.8.3, and relevant CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable	See appended Tables 8.7 and 8.8.3	NA
8.5.2.3	Constructional and test requirements for connector for electrical connections on a PATIENT lead of this clause are being met	No electrical patient connections	NA
8.5.3	MAXIMUM MAINS VOLTAGE determined as specified in this clause	230V_{AC}	P
8.5.4	WORKING VOLTAGE for each MEANS OF PATIENT PROTECTION determined as specified:	Rated for 230V_{AC}	P
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	Not present	NA
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety, but not separate functions of same APPLIED PART	--	NA
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as described in detail in a) and b), with compliance checked by the common-mode and differential-mode tests as specified, and ME EQUIPMENT continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE after the recovery time stated in ACCOMPANYING DOCUMENTS	See Appended Tables 8.5.5.1a and 8.5.5.1b	NA
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load to at least 90 % of energy delivered to this load with ME EQUIPMENT disconnected (J), with test voltage applied as specified:	See Appended Table 8.5.5.2	NA
8.6	Protective earthing, functional earthing and potential equalization of ME EQUIPMENT		NA
8.6.1	Requirements of 8.6.2 to 8.6.8 applied unless parts comply with IEC 60950-1 for protective earthing and service as MEANS OF OPERATOR PROTECTION only	Class II	NA
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:	--	NA
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and clamping means cannot be loosened without TOOL:	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
	Screws for internal PROTECTIVE EARTH CONNECTIONS are completely covered or protected against accidental loosening from outside:	--	NA
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL	--	NA
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing	--	NA
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part, except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE	--	NA
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop	See appended Table 8.6.4	NA
	Additionally, the impedance between the protective earth pin in the MAINS PLUG of any DETACHABLE POWER SUPPLY CORD supplied or specified by the MANUFACTURER, when attached to the ME EQUIPMENT, and any part of the ME EQUIPMENT that is PROTECTIVELY EARTHED shall not exceed 200 mΩ, except as allowed by 8.6.4 b).	See appended Table 8.6.4	NA
	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	--	NA
8.6.5	Poorly conducting surface coatings on conductive elements removed at the point of contact	--	NA
8.6.6	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	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR complies with the requirements specified in this clause, and POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR Accidental disconnection shall be avoided in NORMAL USE	--	NA
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION	--	NA
8.6.9	Requirements of this clause for CLASS II ME EQUIPMENT with isolated internal screens met	--	NA
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	Current not exceed limits See appended Tables 8.7	P
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Tables 8.7A, 8.7B, 8.7C, and 8.7.4.7	Leakage current measured in all conditions 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 as specified in this clause	Leakage current measured in all single fault conditions See appended tables 8.7	P
8.7.3	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), and limits apply to d.c., a.c., composite waveforms, and unless otherwise stated, they are d.c. or r.m.s	Values of leakage current measured with adequate measuring device MD	P
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 and 4, and values of a.c. are relative to currents having a frequency not less than 0.1 Hz	Test passed See appended Tables 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}):	Test passed See appended Tables 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 Tables 8.7	NA

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Clause	Requirement + Test	Result - Remark	Verdict
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 [10] (I_{ENC}, I_{ESFC}):	Not permanently installed equipment	NA
	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:	All leakage currents not exceed 10mA	P
	f) The allowable values of LEAKAGE CURRENTS that can flow in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION.	Not used	NA
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements		NA
8.7.4.1	Figs 13-19 used to measure LEAKAGE and PATIENT AUXILIARY CURRENTS. EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and AUXILIARY CURRENTS measured with ME EQUIPMENT running at operating temperature of 11.1.3 c)	Test executed with equipment running at operating temperature	NA
8.7.4.2	ME EQUIPMENT for connection to a SUPPLY MAINS connected to an appropriate power source, with tests on single-phase ME EQUIPMENT conducted at both supply polarities and INTERNALLY POWERED ME EQUIPMENT tested without connections to a measuring supply circuit	Test executed in both polarities	NA
8.7.4.3	Connection to the measuring supply circuit and measuring arrangements as specified in 8..8.4.3a) – d)	Test executed with power supply cable provided by manufacturer	NA
8.7.4.4	Measuring device (MD) used as specified in 8.7.4.4. a) – c)		NA
8.7.4.5	EARTH LEAKAGE CURRENT: CLASS I ME EQUIPMENT tested based on Fig 13, with requirements related to more than one PROTECTIVE EARTH CONDUCTOR and MANUFACTURER specifications related to PROCEDURE and configuration for measurement of EARTH LEAKAGE CURRENT for FIXED ME EQUIPMENT taken into account CLASS II ME EQUIPMENT with a functional earth connection according to 8.6.9 is tested as if it were CLASS I ME EQUIPMENT	See appended Table 8.7	NA

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Clause	Requirement + Test	Result - Remark	Verdict
8.7.4.6	TOUCH CURRENT: ME EQUIPMENT tested according to Fig 14, using an appropriate measuring supply circuit and procedures of a) – c) taken into account	Test passed See appended Table 8.7	P
8.7.4.7	PATIENT LEAKAGE CURRENT: ME EQUIPMENT with an APPLIED PART tested based on Fig 15, with procedures of a) to i) taken into account	Test passed See appended Table 8.7	P
8.7.4.8	PATIENT AUXILIARY CURRENT: ME EQUIPMENT with an APPLIED PART except for one with only a single PATIENT CONNECTION tested based on Fig 19 with a measuring supply circuit	Only one applied part	NA
8.7.4.9	PATIENT LEAKAGE and AUXILIARY CURRENTS for ME EQUIPMENT with multiple PATIENT CONNECTIONS did not exceed limits for NORMAL CONDITION while one or more PATIENT CONNECTIONS are disconnected from the PATIENT, AND disconnected from the PATIENT and earthed	Only one applied part	NA
8.8	Insulation		P
8.8.1	Subject to testing is Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION and insulation between parts of opposite polarity of MAINS PART on SUPPLY MAINS side of mains fuse or OVER-CURRENT RELEASE (as one MEANS OF PROTECTION), unless insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION or compliance with 4.8	Test passed for reinforced insulation	P
8.8.2	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V complies with either a) min. 0.4mm distance through insulation requirement or b) complies with specified number of layers, with compliance checked by inspection, measurement of thickness and dielectric strength test of 8.8.3		P
	For wound components, where BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings, separation by interleaved insulation provided, complying with a) or b), or both, except constructions were used as specified in c) to e), with compliance checked by inspection, measurement and if applicable as specified in Annex L	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
8.8.3	Solid insulating materials with a safety function withstood dielectric strength test voltages applied in accordance with methods and test conditions of this Clause	Test passed See appended Table 8.8.3A & 8.8.3B	P
8.8.4	Insulation other than wire insulation		P
8.8.4.1	Resistance to heat retained by all insulation during EXPECTED SERVICE LIFE of ME EQUIPMENT, Compliance checked by inspection and if necessary tests per 11.6, 8.8.3 and 15.3	Plastic enclosure of appliance	P
	Ball-pressure tests as per a) and b) conducted in absence of satisfactory evidence for resistance to heat for parts of ENCLOSURE and other external insulating parts and parts of insulating material that support uninsulated parts of MAINS PART (°C).:	Test executed for plastic of enclosure	P
	Impression made by the ball after 1 h was 2 mm or less in diameter (mm):	See appended Table 8.8.4.1	P
8.8.4.2	Any MEANS OF PROTECTION not likely to be impaired by environmental stresses within ME EQUIPMENT to the extent CREEPAGE and CLEARANCES would be reduced below 8.9, with Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION; Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION. Aging test for natural latex rubber: No cracks visible to naked eyes	Enclosure not impaired by environmental stress	P
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		P
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are ≥ to values in Tables 12 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15	Comply with the tables 11-16 in EN60601-1	P
8.9.1.2	Tables 12 to 16 (inclusive) not applied to CREEPAGE and CLEARANCES forming MEANS OF OPERATOR PROTECTION per IEC 60950-1 for INSULATION CO-ORDINATION and used under conditions compliance was tested	--	NA
8.9.1.3	Specified min CLEARANCE applied as min CREEPAGE for CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.1.4	When min CREEPAGE derived from Tables 11 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE	--	NA
8.9.1.5	ME EQUIPMENT RATED to operate at an altitude of max. 2000 m:	Max 2000m	P
	ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m):	--	NA
	Operating altitude corresponding to actual air pressure for ME EQUIPMENT intended for pressurized environments (e.g., aircraft) used in determining multiplication factor from Table 8, and AIR CLEARANCE was multiplied by this factor	--	NA
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE	--	NA
8.9.1.6	Rules for interpolation for determining CREEPAGE and CLEARANCES followed as specified	Not used	NA
8.9.1.7	Material groups classified in accordance with Table 9 (Material Group) and verified by test according to IEC 60112 using 50 drops of solution A. If material group is not known IIIb shall be assumed:	Class IIIb	P
8.9.1.8	Classification of pollution degrees 1-4 as specified in this clause, with pollution degree not acceptable for insulation providing a MEANS OF PROTECTION	Degree II	P
8.9.1.9	Applicable value of MAINS TRANSIENT VOLTAGE determined from overvoltage category according to IEC 60664-1 and NOMINAL a.c. MAINS VOLTAGE using Table 10 (V_{MT} peak, V_{MN} r.m.s.):	Category II	P
8.9.1.10	Required CLEARANCE for MAINS PARTS operating on RATED MAINS VOLTAGES up to 300 V were values for r.m.s. or d.c. RATED MAINS VOLTAGE in Table 13 plus additional CLEARANCE in Table 14 for PEAK WORKING VOLTAGE	Clearance and creepage less than limit in table 13 of EN60601-1 See table at page 6	P
8.9.1.11	Overvoltage category II applied according to IEC 60664-1. Specified requirements of this clause are followed if overvoltage category is III	--	NA
8.9.1.12	For SECONDARY CIRCUITS, requirements of this clause are followed for overvoltage category, and which table applies and which column to use.	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.1.13	Requirements for PEAK WORKING VOLTAGES above 1400 V peak or d.c. of this clause taken into consideration	--	NA
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION obtained by doubling values in Table 16 for one MEANS OF OPERATOR PROTECTION	--	NA
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	Defibrillation-proof applied parts not present	NA
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied		P
	b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths		P
	c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION as described, with normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE	Clearance not can be reduced	P
8.9.3	Spaces filled by insulating compound		NA
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound were such that CLEARANCES and CREEPAGE DISTANCES do not exist. Thermal cycling, humidity preconditioning, and dielectric strength tests in 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4 conducted	--	NA
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (clause 8.8.3), test voltage multiplied by 1.6 Cracks or voids in insulating compound affecting homogeneity of material did not occur	--	NA
8.9.3.3	For situations where insulating compound forms a cemented joint with other insulating parts, three samples tested as specified for reliability of joint	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.3.4	One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times	--	NA
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES using Figs 22 to 31 (inclusive) taken into consideration the measurement rules specified in this clause	Rules applied	P
	CREEPAGE and CLEARANCES through slots or openings in external parts measured to the standard test finger of Fig 6. Measurements made applying a 2 N force on points of bare conductors and a 30 N force to outside of metal ENCLOSURE using a standard test finger (as in Fig 6)	--	NA
	When relevant, CREEPAGE and CLEARANCES measured after use of test hook in 5.9.2.2	--	NA
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	Components well fixed	P
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION, where breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION	Conductors and connectors fixed inside the enclosure	P
8.10.3	Flexible cords detachable without a TOOL used to interconnect different parts of ME EQUIPMENT provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS of 8.4 when a connection is loosened or broken as indicated by measurement or using test finger	Not used	NA
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		P
8.10.4.1	Operating voltages limited to 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION	9V at secondary circuit	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 cable to control device complied with 8.11.3 when breaking free or shorting between conductors could result in a HAZARDOUS SITUATION		P

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Clause	Requirement + Test	Result - Remark	Verdict
	This requirement applied to other HAND-HELD parts when disturbance or breaking of one or more of connections could result in a HAZARDOUS SITUATION	--	NA
8.10.5	Mechanical protection of wiring		P
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION DESCRIBED IN 13.1	Internal wiring adequately guided and protected	P
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION DESCRIBED IN 13.1	Not possible to damage internal wiring	P
8.10.6	Guiding rollers of insulated conductors prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead concerned in NORMAL USE	Not used	NA
8.10.7	a) Insulating sleeve that can only be removed by breaking or cutting, or secured at both ends, is used on internal wiring of when needed	No need insulation sleeving	NA
	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	Sheath not used as a mean protection	NA
	c) Insulated conductors subject to temperatures > 70 °C in NORMAL USE provided with insulation of heat-resistant material when compliance is likely to be impaired due to deterioration of insulation	Temperature less than 70°C	NA
8.11	MAINS PARTS, components and layout		P
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles	Plug	P

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Clause	Requirement + Test	Result - Remark	Verdict
	For PERMANENTLY INSTALLED ME EQUIPMENT, the means provided to isolate its circuits electrically from the SUPPLY MAINS shall be capable of being locked in the off position if: - Reconnection would result in a HAZARDOUS SITUATION; or - Any OPERATOR including SERVICE PERSONNEL is unable to view the means of isolation from their intended position. The locking mechanism may be in a SUPPLY MAINS switch provided by the RESPONSIBLE ORGANIZATION. The requirements for the isolation device shall be specified in the ACCOMPANYING DOCUMENTS.	Not permanently installed	NA
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	Not permanently installed	NA
	b) Means of isolation incorporated in ME EQUIPMENT, and external means described in technical description	Plug	P
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE and CLEARANCES in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV	--	NA
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or other external flexible lead		P
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447	--	NA
	f) A suitable plug device such as an APPLIANCE COUPLER or a flexible cord with a MAINS PLUG used in non-PERMANENTLY INSTALLED ME EQUIPMENT to isolate it from SUPPLY MAINS considered to comply with 8.11.1 a)	cable with plug	P
	g) A fuse or a semiconductor device not used as an isolating means in the sense of this clause	Not used	P

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Clause	Requirement + Test	Result - Remark	Verdict
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an over current protection device	Not present	NA
	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	All parts deenergized after disconnecting power cable;	P
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage (symbol 10 of Table D.1 is insufficient)	--	NA
	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	--	NA
	Standard test finger of Fig 6 applied	--	NA
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	Not present	NA
8.11.3	POWER SUPPLY CORDS		P
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD	Only one	P
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, designation 53)	H05VVH2-F	P
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE	--	NA
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 (mm^2 Cu):	2x0,75mm^2	P
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6	Coupler complying with IEC 60320-1	P
8.11.3.5	Cord anchorage (for APPLIANCE COUPLERS not complying with IEC 60320-1)		NA

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Clause	Requirement + Test	Result - Remark	Verdict
	a) Conductors of POWER SUPPLY CORD provided with strain relieve and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage	Detachable connector	NA
	b) Cord anchorage of POWER SUPPLY CORD is made of and arranged as follows when a total insulation failure of POWER SUPPLY CORD caused conductive non-PROTECTIVELY EARTHED ACCESSIBLE PARTS to exceed limits of 8.4: insulating material, or metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or metal provided with an insulating lining	--	NA
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation	--	NA
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage	--	NA
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals when cord anchorage fails	--	NA
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR	--	NA
	Pull, torque and push tests as specified (see Table 18):	--	NA
8.11.3.6	POWER SUPPLY CORDS other than for STATIONARY ME EQUIPMENT protected against excessive bending at inlet opening of equipment or of MAINS CONNECTOR by means of an insulating cord guard or by means of an appropriately shaped opening. Cord guard complies either with test of IEC 60335-1:2001, Clause 25.14, or the test described in this clause:	--	NA
8.11.4	MAINS TERMINAL DEVICES		NA
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD replaceable by SERVICE PERSONNEL provided with MAINS TERMINAL DEVICES ensuring reliable connection	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
	Terminals alone are not used to keep conductors in position, except when barriers are provided such that CREEPAGE and CLEARANCES cannot be reduced below 8.9 if any conductor breaks away	--	NA
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked according to 7.3.7 used as terminals intended for external conductors	--	NA
	Screws and nuts clamping external conductors do not serve to secure any other component, except they also clamp internal conductors when unlikely to be displaced when fitting the supply conductors	--	NA
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		NA
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL closely grouped	--	NA
	b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6	--	NA
	c) Marking of MAINS TERMINAL DEVICES complied with 7.3	--	NA
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL	--	NA
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area in Table 17 stripped 8 mm and with a single free wire bent in every possible direction without pulling back insulating sheath or making sharp bends around partitions	--	NA
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced below 8.9 after fastening and loosening a conductor of largest cross-sectional area 10 times	--	NA
8.11.4.4	Terminals with clamping means for a rewritable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened as verified by test of 8.11.3.4	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewritable POWER SUPPLY CORD to allow easy introduction and connection of conductors, and covers fitted without damage to conductors or their insulation. Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation test	--	NA
8.11.5	Mains fuses and OVER-CURRENT RELEASES		P
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection according to 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT. Exceptions apply for PERMANENTLY INSTALLED EQUIPMENT and where to two MEANS OF PROTECTION are present as described	Fuse provided on one pole	P
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR	--	NA
	Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit	Adequate breaking capacity	P
8.11.6	Internal wiring of the MAINS PART		P
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE and protective devices is not < minimum required for POWER SUPPLY CORD as in 8.11.3.3 (mm^2 Cu).....	Minimum cable 0,75mm^2	P
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits sufficient to prevent fire in case of fault currents. When necessary, single fault simulation as described	Adequate	P
(9.0) PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS			
9.1	ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3)		P
9.2	HAZARDS associated with moving parts		P

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Clause	Requirement + Test	Result - Remark	Verdict
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 using protective measures. If exposure to moving parts is needed for ME EQUIPMENT to perform its function and HAZARDS persisted warnings are provided	Moving parts fully enclosed inside enclosure	P
9.2.2	TRAPPING ZONE		NA
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible: Gaps in Clause 9.2.2.2, or Safe distances in Clause 9.2.2.3, or GUARDS and protective measures in 9.2.2.4, or Continuous activation in Clause 9.2.2.5. 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	Trapping zone not present See appended Table 9.2.2.2	NA
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions specified in Table 20	--	NA
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. Distances measured from expected positions of OPERATOR, PATIENT, and others near EQUIPMENT in NORMAL USE or under foreseeable misuse	--	NA
9.2.2.4	GUARDS and protective measures		NA
9.2.2.4.1	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when GUARDS and protective measures were of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK based on results of applicable tests in 15.3 for ENCLOSURES	--	NA
9.2.2.4.2	FIXED GUARDS securely held in place by systems that cannot be dismantled without a TOOL	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open, are associated with an interlock device as described, and the absence or failure of one of their components prevents starting, and stops moving parts. Tests performed as applicable……:	--	NA
9.2.2.4.4	Protective measures provided in control system prevented moving parts from starting to move while in reach of persons, protective measures prevented TRAPPING ZONE from reach, or, when it was reached, system movement stopped once ME EQUIPMENT started to move, and in the latter case, no HAZARD or damage resulted. When protective measure was in a SINGLE FAULT CONDITION, and an unacceptable RISK could arise, one or more emergency stopping device(s) provided	--	NA
9.2.2.5	TRAPPING ZONE not considered to present a MECHANICAL HAZARD where impractical to make TRAPPING ZONE inaccessible when movement was in OPERATOR'S field of view, movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR as long as OPERATOR response to deactivate device relied upon to prevent HARM, and if necessary one or more emergency stopping device(s) provided in ME EQUIPMENT	--	NA
9.2.2.6	Speed of movement(s) that position parts of ME EQUIPMENT or PATIENT, and over travel limited	--	NA
9.2.3	Other HAZARDS associated with moving parts		NA
9.2.3.1	Unintended movement prevented by proper positioning or protection of controls	Moving parts always fully protected	NA
9.2.3.2	Over travel past range limits of ME EQUIPMENT parts shall be prevented. End stops or other stopping means shall be provided to act as the ultimate travel limiting measure. Such means shall have the mechanical strength to withstand the intended loading in NORMAL USE and reasonably foreseeable misuse.	--	NA
9.2.4	Where necessary to have one or more emergency stopping device(s), it shall comply with requirements a) to k) including location, function, performance, markings and described in this clause	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
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 protective measure, or emergency stopping	Release of patient not used	NA
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in an unacceptable RISK avoided or covered	No sharp edges See appended Table 9.3	P
9.4	Instability HAZARDS		P
9.4.1	ME EQUIPMENT, other than FIXED and hand-held, for placement on a surface did not overbalance (tip over) or move unexpectedly, to the degree that it could present an unacceptable RISK to PATIENT, or OPERATOR as tested in 9.4.2 to 9.4.4	Device stable	P
9.4.2	Instability – overbalance		P
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when placed in any transport position of NORMAL USE when tested as specified	Stable with 10° See appended table 9.4.2.1	P
9.4.2.2	ME EQUIPMENT or its parts prepared based on a) to g), inclusive, did not overbalance when placed in different positions of NORMAL USE, except transport positions, on a 5° inclined plane from horizontal consisting of a hard and flat surface	Stable with 10° See appended table 9.4.2.2	P
	A warning notice provided stating “Transport only under conditions clearly described in instructions for use or marked on ME EQUIPMENT with an indication of RESIDUAL RISK if ME EQUIPMENT or its parts overbalances” when overbalance occurred during 10° inclined plane test	--	NA
9.4.2.3	Instability from horizontal and vertical forces		NA
	a) ME EQUIPMENT with a mass of 25 kg or more, other than FIXED ME EQUIPMENT for use on floor, did not overbalance due to pushing, resting, etc when tested as specified	Mass less than 25kg See appended Table 9.4.2.3 a)	NA
	Surfaces of ME EQUIPMENT where a RISK of overbalancing exists from pushing, leaning, resting etc., permanently marked with a CLEARLY LEGIBLE warning of the RISK	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
	b) ME EQUIPMENT, other than FIXED ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping when tested as specified, except when a legible warning of this RISK provided on ME EQUIPMENT	See appended Table 9.4.2.3 b)	NA
9.4.2.4	Castors and wheels		P
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT (e.g., castors or wheels) did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE	See appended Table 9.4.2.4.2/ 9.4.2.4.3	P
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT along a hard and flat horizontal surface did not exceed 200 N except when instructions for use indicated more than one person needed (N).....	See appended Table 9.4.2.4.2/ 9.4.2.4.3	P
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg was able to pass over a 10 mm threshold when tested as specified using the pass and fail criteria as specified	Less than 45kg	NA
9.4.3	Instability from unwanted lateral movement (including sliding)		P
9.4.3.1	a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control	No mobile device See appended Table 9.4.3.1	NA
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements of ME EQUIPMENT or its parts in transport position	Brakes provided	P
	c) MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system to prevent unwanted movement on an incline of 10° when in its transport position.	4 brakes provided	P
9.4.3.2	Instability excluding transport		P
	a) MOBILE ME EQUIPMENT provided with wheel locks or with braking system with unintended movement prevented on an incline of 5° when tested as specified:	See appended Table 9.4.3.2	P
	b) TRANSPORTABLE or STATIONARY ME EQUIPMENT for use on the floor is prevented from unwanted lateral movement when tested as specified	--	NA
9.4.4	Grips and other handling devices		P

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Clause	Requirement + Test	Result - Remark	Verdict
	a) ME EQUIPMENT other than PORTABLE EQUIPMENT or its part with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method. Handles, when supplied, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons	See appended Table 9.4.4	P
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carring by two or more persons as confirmed by actual carrying	Handel and castors	P
	c) Carrying handles and grips and their means of attachment withstood application of a force four times weight of ME EQUIPMENT in different directions of NORMAL USE and transport (N) when tested as specified:		P
9.5	Expelled parts HAZARD		NA
9.5.1	Suitability of means of protecting against unacceptable RISK of expelled parts provided	Expelled parts not used	NA
9.5.2	Cathode ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965	Not used	NA
9.6	Acoustic energy (including infra- and ultrasound) and vibration		P
9.6.1	Human exposure to acoustic energy and vibration: Compliance with tests of 9.6.2 and 9.6.3	Comply with test	P
9.6.2	Acoustic Energy		P
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE, except for auditory alarm signals, exceeding the levels specified, when tested as specified in this clause:	No relevant acoustic energy See appended Table 9.6.2.1	P
9.6.2.2	RISK MANAGEMENT FILE examined for RISKS associated with infrasound or ultrasound, when present, addressed in RISK MANAGEMENT PROCESS	--	NA
9.6.3	Means provided, except for INTENDED USE vibrations, to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values when tested as specified	--	NA
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		NA

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Clause	Requirement + Test	Result - Remark	Verdict
9.7.1	Requirements of this clause applied to vessels and parts of ME EQUIPMENT subject to pressure resulting in rupture and unacceptable RISK. Parts of a pneumatic or hydraulic system used as a support system, additionally, complied with 9.8	--	NA
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES meet the design and performance criteria specified in this clause, taking under consideration loss of pressure/vacuum, fluid jet caused by leakage or component failure. Vessels automatically depressurized when ME EQUIPMENT isolated from power supply. For elements under pressure after isolation from power supply, identification of exhaust devices and warning label	--	NA
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: RATED maximum supply pressure from an external source, or Pressure setting of a pressure-relief device provided as part of assembly, or Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device	--	NA
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	--	NA
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was > 50 kPa, and product of pressure and volume was > 200 kPa.l when tested at specified	See appended Table 9.7.5	NA
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 under different conditions of NORMAL USE	--	NA
9.7.7	Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded. Compliance criteria of this clause met as specified for location and accessibility of device, discharge opening, discharge capacity, and min. number of operation cycles	--	NA
9.8	HAZARDS associated with support systems		NA

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Clause	Requirement + Test	Result - Remark	Verdict
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK, with the HAZARDS and likely failure effects specified in this clause to be considered in the RISK ANALYSIS	Not used See appended Table 9.8.1/9.8.2	NA
	Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD	--	NA
	Means of attachment of ACCESSORIES prevent possibility of incorrect attachment	--	NA
	ACCOMPANYING DOCUMENTS contain instructions on attachment of structures and advice on checking the adequacy of the surface of the structure	--	NA
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than Table 21 except as noted in this clause. Inspection of ME EQUIPMENT, material and processing specifications show compliance with 9.8.1 and 9.8.2. Loading test done as specified.:	--	NA
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		NA
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS minimize RISK of physical injuries and accidental loosening of secured joints	Not used See appended Table 9.8.3	NA
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is as specified in this clause:	--	NA
	If max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS; Max allowable PATIENT mass > 135 kg stated in ACCOMPANYING DOCUMENTS	--	NA
9.8.3.2	SAFE WORKING LOAD distribution representing the mass of the PATIENT or OPERATOR and of ACCESSORIES as described in this clause	--	NA
	a) Entire mass distributed over an area of 0.1 m^2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR with no damage or deflection resulting in an unacceptable risk when tested as specified	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK when tested as specified	--	NA
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE did not result in an unacceptable RISK when tested as specified:	--	NA
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES		NA
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided when a support system or its parts impaired by wear have a TENSILE SAFETY FACTOR ≥ to values in Table 21, rows 5 and 6, but less than 3 and 4	--	NA
	b) MECHANICAL PROTECTIVE was designed on the basis of the TOTAL LOAD (including effects of SAFE WORKING LOAD), activates before travel produces unacceptable RISK, and takes into account Clauses 9.2.5 and 9.8.4.3	--	NA
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 (which requires use of a TOOL to be reset or replaced)	--	NA
9.8.4.3	For MECHANICAL PROTECTIVE DEVICE intended to function once the further use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE.	--	NA
	ACCOMPANYING DOCUMENTS include information specified in this clause, and ME EQUIPMENT permanently marked with safety sign 2 of Table D.2 adjacent to MECHANICAL PROTECTIVE DEVICE	--	NA
	Tests as per requirements of this clause show no evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
9.8.5	MECHANICAL PROTECTIVE DEVICES not required if support system parts have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 1 and 2, and are not impaired by wear, or Support system parts impaired by wear, however, they have TENSILE SAFETY FACTORS ≥ to values in Table 21, rows 3 and 4	--	NA
(10.0) PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS			
10.1.1	X-radiation dose-rate for ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation was ≤ 36 pA/kg (5 µSv/h) (0.5 mR/h) 5 cm from surface of ME EQUIPMENT including background radiation for ME EQUIPMENT when tested as specified	See appended Table 10.1.1	NA
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE (see IEC 60601-1-3 & 1.3)	--	NA
10.2 – 10.6 (except 10.4)	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, microwave radiation, other visible electromagnetic radiation, infrared radiation and ultraviolet radiation addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE	Radiation are in form of e.m. fields at extremely low power as it can be seen by e.m. measurements.	P
10.4	Relevant requirements of IEC 60825-1:2007 applied to lasers, light emitting diodes (LEDs), and laser light barriers or similar products	--	NA
(11.0) PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS			
11.1	Excessive temperatures in ME EQUIPMENT		P
11.1.1	Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and 23 operating in worst-case NORMAL USE at maximum rated ambient operating temperature T; surfaces of test corner did not exceed 90 °C and THERMAL CUT-OUTS did not operate in NORMAL CONDITION	Temperatures inside limits. See appended Table 11.1.1	P
11.1.2	Temperature of APPLIED PARTS		P
11.1.2.1	Temperatures, hot or cold surfaces, and when appropriate, clinical effects of APPLIED PARTS supplying heat to a PATIENT determined and documented in RISK MANAGEMENT FILE and instructions for use	Applied part not supply heat to a patient See appended Table 11.1.2.1	NA

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Clause	Requirement + Test	Result - Remark	Verdict
11.1.2.2	APPLIED PARTS not supplying heat to a PATIENT met Table 24 with max surface temperatures > 41 °C disclosed in instructions for use, and clinical effects with respect to body surface, maturity of PATIENTS, medications taken, surface pressure, as documented in RISK MANAGEMENT FILE. Surfaces of APPLIED PARTS cooled below ambient temperatures that can also result in HAZARD evaluated as part of RISK MANAGEMENT PROCESS	Temperatures less than limit See appended Table 11.1.2.2	P
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	--	NA
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE	--	NA
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE	See risk analysis	P
	Temperature measurements done according a) to e) including requirements for positioning, supply, thermal stabilization and test criteria.	See appended Tables 11.1.1, 11.1.2.1, 11.1.2.2 and 11.1.3	P
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	Enclosures openable only with a tool	P
11.2	Fire prevention		P
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire caused by reasonably foreseeable misuse and met mechanical strength tests for ENCLOSURES in 15.3	Adequate strength	P
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		P
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of fire under NORMAL or SINGLE FAULT CONDITIONS when source of ignition is in contact with ignitable material	Not used in oxygen rich environment	NA
	a) Sources of ignition identified considering any of the conditions 1) to 5) and – alternatively to 5) test performed as described to determine if source of ignition exists	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
	b) The following configuration(s), alone or in combination used to provide an acceptable RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT: 1) Limited energy, 2) Ventilation of compartments, 3) Separation, 4) Fire ENCLOSURE.:	--	NA
11.2.2.2	External exhaust outlets of an OXYGEN RICH ENVIRONMENT located that no RISK of ignition occurs because of electrical components mounted on the outside of ME EQUIPMENT or an ME SYSTEM	--	NA
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks due to loosening or breaking, except when limited in power and energy to values in 11.2.2.1 a) 5). Methods to prevent loosening or breaking used as described in this clause:	--	NA
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered as described in this clause	--	NA
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT		P
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2. The Following constructional requirements were met:		P
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, and of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, with compliance checked by inspection of material data, or the tests as described.	Internal wiring better than FV-1	P
	b) Fire ENCLOSURE meets construction requirements 1) to 3) including dimensions of openings in bottom, sides, enclosure material, flammability classification (FV-2 or better for TRANSPORTABLE ME EQUIPMENT and FV-1 or better for fixed ME EQUIPMENT)	Enclosure fully closed except for lateral vent openings; material not FV-2; fault tests applied	NA
11.4	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable anesthetics (CATEGORY AP) or anesthetics with oxidants (CATEGORY APG) comply with Annex G	No used with flammable anaesthetics	NA

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Clause	Requirement + Test	Result - Remark	Verdict
11.5	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE for ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	See risk analysis	P
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	Adequate protection	P
11.6.2	If ME EQUIPMENT incorporates liquid reservoir liable to be overfilled or to overflow in NORMAL USE overflowing liquid shall not wet any MEANS OF PROTECTION. 15° tilt test performed on TRANSPORTABLE ME EQUIPMENT as specified, dielectric strength and LEAKAGE CURRENT tests passed as specified, and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet	Test passed	P
11.6.3	Spillage test performed on ME EQUIPMENT and ME SYSTEMS handling liquids in NORMAL USE as described, and with test conditions, type of liquied, volume, duration and location determined based on RISK MANAGEMENT PROCESS. ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet	Test passed with 1l in 15s according to risk management file	P
11.6.4	Leakage	--	NA
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS: ME EQUIPMENT with IP Code placed in least favorable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code): ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in a HAZARDOUS SITUATION in NORMAL CONDITION or in a SINGLE FAULT CONDITION	IP20	P

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Clause	Requirement + Test	Result - Remark	Verdict
11.6.6	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected in accordance with methods specified in instructions for use. ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there was no deterioration resulting in an unacceptable RISK. Effects of multiple cleanings/disinfections shall be evaluated by the MANUFACTURER.	Cleaning process indicate on user manual	P
11.6.7	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented according to ISO 11134, ISO 11135, or ISO 11137 as appropriate. After the test, ME EQUIPMENT complied with the appropriate dielectric strength and LEAKAGE CURRENT tests and there was no deterioration resulting in an unacceptable RISK	Sterilize parts only accessories; simulated a sterilization cycle for vessel	P
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE	No risk	NA
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented according to ISO 10993	See risk analysis regarding biocompatibility and validation documents	P
11.8	Interruption and restoration of power supply did not result in a HAZARDOUS SITUATION, except interruption of its intended function	Interruption of functioning	P
(12.0) ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS			
12.1	RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review	See risk analysis	P
12.2	RISK of poor USABILITY, including those associated with identification, marking, and documents addressed in a USABILITY ENGINEERING PROCESS as confirmed by review of provided records	See usability IEC 60601-1-6	P
12.3	If the MANUFACTURER has implemented an ALARM SYSTEM, this ALARM SYSTEM shall comply with IEC 60601-1-8.	No need for alarm system to reduce risk	P
12.4	Protection against hazardous output		P

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Clause	Requirement + Test	Result - Remark	Verdict
12.4.1 – 12.4.6	The following is addressed in the RISK MANAGEMENT FILE: RISKS associated with hazardous output arising from intentional exceeding of safety limits, the need for indication of parameters, accidental selection of excessive output values, incorrect output, RISKS associated with diagnostic X-ray and radiotherapy and other ME EQUIPMENT producing diagnostic or therapeutic radiation, and the RISKS associated with diagnostic X-ray or therapeutic acoustic pressure.	No hazardous output	NA
12.4.5.1 – 12.4.5.2	For ME EQUIPMENT producing radiation for diagnostic or therapeutic purposes, protection provisions are made. Refer to particular standards for requirements, limits and tests to ensure radiation safety. Refer to IEC 60601-1-3 for diagnostic X-ray equipment.	--	NA
(13.0) HAZARDOUS SITUATIONS AND FAULT CONDITIONS			
13.1	Specific HAZARDOUS SITUATIONS: None of HAZARDOUS SITUATIONS in 13.1.2-13.1.4, inclusive, occurred when SINGLE FAULT CONDITIONS applied, one at a time, as in 4.7 and 13.2. The following HAZARDOUS SITUATIONS did not occur as described in detail in this clause: Emissions, deformation of ENCLOSURE or exceeding maximum temperature, exceeding LEAKAGE CURRENT or voltage limits. SINGLE FAULT CONDITIONS in 4.7, 8.1.b), 8.7.2 and 13.2.2 with regard to the emission of flames etc shall not be applied to energy limited parts <15W in SFC or energy dissipation <900 J (to be confirmed by test as specified), or to parts completely contained within a fire ENCLOSURE.	See appended Tables 11.1.1, 11.1.2.1, 11.1.2.2 and 8.7 Tests in single fault condition: see details in test chart No emission of flame, no relevant deformation of enclosure, no excessive temperatures, no exceeding limits current or voltage	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– Secondary circuits meet all of the following conditions: □ mounted on material with a flammability classification of FV1 in accordance with IEC 60695-11-10 or better; □ they are energized at a voltage of 60 V d.c. or 42,2 V peak or less in NORMAL and SINGLE FAULT CONDITION; □ they are limited to 100 VA or are limited to 6 000 J in SINGLE FAULT CONDITION; □ they employ wire insulation of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide.		
13. 2	SINGLE FAULT CONDITIONS		P
13.2.1	During application of SINGLE FAULT CONDITIONS NORMAL CONDITIONS in 8.1 a) also applied in least favorable combination.	See appended Table 13.2	P
13.2.2 – 13.2.12	ME EQUIPMENT complied with the conditions of 13.2.2 -13.2.12 applied	See appended Table 13.2	P
13.2.13	ME EQUIPMENT remained safe after overload tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to within 3° of the test environment, with compliance determined by inspection or tests such as 8.8.3 and ball-pressure test as specified in this clause for insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION	Overload of motor	P
13.2.13.2	ME EQUIPMENT with heating elements tested as specified in (a) using the test conditions of b) and/or c)	--	NA
13.2.13.3	ME EQUIPMENT with motors checked for compliance as described in a), and b) for running overload protection, and c) for three-phase motors	Block of motor	P
13.2.13.4	ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION ME EQUIPMENT other than HAND-HELD EQUIPMENT, EQUIPMENT kept switched on manually or kept under load by hand, and with a timer and a back-up timer system, tested as specified in this clause Motor winding temperatures did not exceed values in 13.2.10 (Insulation Class, Maximum temperature measured °C):	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
(14.0) PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)			
	Software not evaluated		NE
(15.0) CONSTRUCTION OF ME EQUIPMENT			
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS, as confirmed by examination of RISK MANAGEMENT FILE	See risk analysis provided by the manufacturer	P
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, and environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance. This and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring	Accessible according to maintenance procedures	P
15.3	Mechanical strength		P
15.3.1	Mold stress relief, push, impact, drop, and rough handling tests did not result in unacceptable RISK and ME EQUIPMENT displayed adequate mechanical strength	See tests below	P
15.3.2	ENCLOSURES have sufficient rigidity, with compliance checked by push test as specified	no damage with 250 N force See appended Table 15.3.2	P
15.3.3	ENCLOSURES have sufficient resistance to impact, with compliance checked by impact test as specified	No damage with impact with steel ball 500g from 1,3m See appended table 15.3.3	P
15.3.4	Drop test		P
15.3.4	HAND-HELD ME EQUIPMENT and HAND-HELD parts and PORTABLE ME EQUIPMENT withstand the stress caused by a free fall when drop tests performed as specified in 15.3.4.1 and 15.3.4.2	Portable: dropped from 5cm three times along each axis in which can be placed during normal use See appended table 15.3.4	P
15.3.5	MOBILE ME EQUIPMENT and MOBILE parts withstand the stress caused by rough handling and movement, with compliance checked by tests specified in a) Ascending step shock, b) descending step shock, and c) Door frame shock	See appended table 15.3.5	P

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Clause	Requirement + Test	Result - Remark	Verdict
15.3.6	ENCLOSURE of molded or formed thermoplastic material constructed that shrinkage or distortion due to release of internal stress caused by moulding or forming operation does not result in an unacceptable RISK with compliance checked by inspection and available data or mould stress relief test as specified	Test passed See appended Table 15.3.6	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 with compliance checked by inspection of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations	See humidity preconditioning	P
15.4	ME EQUIPMENT components and general assembly		P
15.4.1	Plugs for connection of PATIENT leads or PATIENT cables shall be so designed that they cannot be connected to outlets on the same ME EQUIPMENT intended for other functions, unless it can be proven that no unacceptable RISK can result.	--	NA
15.4.2	Temperature and overload control devices		P
15.4.2.1	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could result in a HAZARDOUS SITUATION by resetting action	Thermal protection of motor	P
	b) THERMAL CUT-OUTS with a safety function to be reset by a soldering operation affecting operating value not fitted in ME EQUIPMENT	-	NA
	c) An independent non-SELF-RESETTING THERMAL CUT-OUT is, additionally, provided where a failure of a THERMOSTAT could constitute a HAZARD	--	NA
	d) Loss of function of ME EQUIPMENT due to operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION	--	NA
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS	--	NA
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety of ME EQUIPMENT as verified by the tests specified in this clause	Thermal protection of motor	P

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Clause	Requirement + Test	Result - Remark	Verdict
	g) ME EQUIPMENT incorporating a fluid filled container with heating means, provided with protection device against overheating in if heater being switched on with empty container	--	NA
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating in both leads where a conductive connection to earth could result in overheating	--	NA
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS	--	NA
15.4.3	Batteries		NA
15.4.3.1	Battery housings from which gases can escape during charging or discharging ventilated; battery compartments designed to prevent accidental short circuiting		NA
15.4.3.2	Means provided to prevent incorrect connection of polarity		NA
15.4.3.3	Overcharging protection provided		NA
15.4.3.4	Primary Lithium batteries comply with IEC 60086-4; secondary lithium battery shall comply with the requirements of IEC 62133		NA
15.4.3.5	A properly RATED protective device with adequate breaking capacity provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire caused by excessive currents in case of a short circuit The short circuit test between the positive pole and the negative pole of an INTERNAL ELECTRICAL POWER SOURCE in the area between the INTERNAL ELECTRICAL POWER SOURCE output contacts and the subsequent protection device may be omitted if two MEANS OF OPERATOR PROTECTION are provided. Alternatively, a short-circuit test shall not result in any of the HAZARDOUS SITUATIONS in 13.1.2.		NA

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Clause	Requirement + Test	Result - Remark	Verdict
15.4.4	Indicator lights provided as specified in detail in this clause to indicate that ME EQUIPMENT is ready for NORMAL USE, that non-luminous heaters are operational when a HAZARDOUS SITUATION could exist, to indicate an output exists where an accidental or prolonged operation of output circuit could constitute a HAZARDOUS SITUATION, and to indicate the charging mode for INTERNAL ELECTRICAL POWER SOURCE. An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s.		NA
15.4.6	Actuating parts of controls of ME EQUIPMENT		P
15.4.6.1	Requirements a) to c) related to fixing and prevention of maladjustment met, with compliance checked by torque and pull tests, where applicable.	See appended Table 15.4.6	P
15.4.6.2	Stops of adequate mechanical strength provided on rotating or movable parts of controls of ME EQUIPMENT where necessary, with compliance checked by manual tests as specified	Knob for vacuum regulation	P
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		P
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1	Not present	NA
	b) Foot-operated control device supported an actuating force of 1350 N for 1 min	Test passed	P
15.4.7.2	Accidental operation of HAND-HELD and foot-operated control devices does not result in an unacceptable RISK	--	NA
15.4.7.3	IP classification of foot-operated control devices as specified an a) and b) depending on their use with tests performed according IEC 60529 and information provided in ACCOMPANYING DOCUMENTS:	IP67	P
15.4.8	Aluminium wires less than 16 mm^2 in cross-sectional area not used	Not used	NA
15.4.9	Oil containers comply with requirements specified in a) to c) and manual test performed	Not used	NA
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		NA

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Clause	Requirement + Test	Result - Remark	Verdict
15.5.1	Transformers of ME EQUIPMENT are protected against overheating in the event of short circuit or overload of output windings and comply with this Clause and tests of 15.5.1.2 and 15.5.1.3. During tests, windings didn't open, maximum temperatures of windings did not exceed values in Table 31, and Dielectric strength test of 8.8.3 conducted on transformer after short circuit and overload tests		NA
15.5.2	Transformer windings provided with adequate insulation to prevent internal short-circuits that could cause overheating. Dielectric strength test performed between turns and layers of each winding after the humidity preconditioning treatment (see 5.7) following the test conditions specified in this clause, with no flashover or breakdown of any part o f the insulation and no detectable deterioration of the transformer.		NA
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with IEC 61558-1:1997, Clause 5.12		NA
(16.0) ME SYSTEMS			
16.1	ME SYSTEM did not result in an unacceptable RISK after installation or subsequent modification, with only HAZARDS arising from combining various equipment to form a ME SYSTEM taken into account	--	NA
	ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard , and outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards	--	NA
	Tests performed in NORMAL CONDITION, except as specified and under operating conditions specified by MANUFACTURER of ME SYSTEM, with previously conducted tests on individual equipment of ME SYSTEM according to relevant standards not repeated	--	NA
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards	--	NA
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM 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. ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM.	--	NA
	ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT and for each item of non-ME EQUIPMENT supplied by MANUFACTURER	--	NA
	include all information required as per 16.2.c)	--	NA
	ACCOMPANYING DOCUMENTS include the instruction specified in 16.2.d) for use by RESPONSIBLE ORGANIZATION	--	NA
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, sufficiently, describe the other equipment to ensure compliance with these requirements	--	NA
	If an ME SYSTEM: – is intended to receive its power from an isolated power supply (IPS) or an uninterruptible power supply (UPS), and – the ME SYSTEM can draw large transient currents when being switching on or off or when operating, the MANUFACTURER shall restrict such transient currents to the allowed level according to the specification of the IPS or the UPS from which the ME SYSTEM is intended to be supplied. If an IPS or UPS is not specified, the actual transient current level shall be disclosed in the technical description and any installation instructions.		
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, etc., after removal of covers, connectors, etc., without use of a TOOL operated at a voltage ≤ voltage in 8.4.2 c) supplied from a source separated from SUPPLY MAINS by two MEANS OF OPERATOR PROTECTION	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed, with the SEPARATION DEVICE having dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION appropriate for highest voltage occurring across SEPARATION DEVICE during a fault condition	--	NA
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V)	--	NA
16.6	LEAKAGE CURRENTS		NA
16.6.1	TOUCH CURRENTS in NORMAL CONDITION, from or between parts of ME SYSTEM within the PATIENT ENVIRONMENT, did not exceed 100 µA, and in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, from or between parts of ME SYSTEM within PATIENT ENVIRONMENT did not exceed 500 µA	See appended Table 16.6.1	NA
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET did not exceed 5 mA	--	NA
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values specified for ME EQUIPMENT in Tables 3 and 4	See appended Tables 8.7.3A to 8.7.3D, inclusive; and Tables 8.7.4.7 and 16.6.1	NA
16.6.4	Measurements	See appended Tables 8.7.3A to 8.7.3D, inclusive; and Tables 8.7.4.7 and 16.6.1	NA
16.6.4.1	General conditions specified in this clause, a) and b) applied for ME SYSTEMS	--	NA
16.6.4.2	Connection of the ME SYSTEM to the measuring supply circuit according to ACCOMPANYING DOCUMENTS with the reference earth of measuring circuits connected to protective earth of SUPPLY MAINS when an isolating transformer not used for LEAKAGE CURRENT measurements	--	NA
16.7	ME SYSTEM complied with applicable requirements of Clause 9 when a MECHANICAL HAZARD existed	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
16.8	Interruption and restoration of relevant power connections of ME SYSTEM one at a time and all connections simultaneously did not result in a HAZARDOUS SITUATION other than interruption of its intended function	--	NA
16.9	ME SYSTEM connections and wiring		NA
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented, with connectors complying with 15.4.1 and plugs for connection to PATIENT leads cannot connect to other outlets of the same ME SYSTEM	--	NA
16.9.2	MAINS PARTS, components and layout	--	NA
16.9.2.1	a) MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or is supplied via a separating transformer	--	NA
	b) MULTIPLE SOCKET-OUTLET marked as specified in this clause and may be a separate item or an integral part	--	NA
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the construction, component, ratings and other requirements specified in this clause PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS shall comply with 8.6.	--	NA
	d) Additional requirements applied as specified in this clause when MULTIPLE SOCKET-OUTLET combined with a separating transformer The separating transformer shall comply with this standard. Alternatively the separating transformer may comply with the requirements of IEC 61558-2-1, except that the requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 do not apply.	--	NA
16.9.2.2	For each part of an ME SYSTEM that shares a MAINS CONNECTION, the impedance and current carrying capability of the total protective earth path of an ME SYSTEM when tested as a unit shall comply with 8.6.4. The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED shall not exceed 200 mΩ.	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part of ME SYSTEM without simultaneous disconnection of electrical supply to that part, with additional PROTECTIVE EARTH CONDUCTORS detachable only by a TOOL	--	NA
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage	--	NA
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS** Test passed		P
G	**ANNEX G, PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		NA
	(see separate attachment if applicable)		
L	**ANNEX L, INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**		NA
	(see separate attachment if applicable)		

	RM RESULTS TABLE:		**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2	Risk Analysis doc. UT-04 rev. 0, and Annex A Suction equipment risk analysis rev. A. Risk Management File _Suction equipment Rev: 01	Paragraph of EN60601-1 applied: - 4.2; 4.3.;4.6; 4.7; 4.8; - 5.4; 5.7 - 7.2.2; 7.9.1; - 8.1; 8.3d, 8.4.2 a), 8.4.2 b); 8.8.4.1; - 8.10.1; 8.10.2; 8.10.5; - 9.2.1; 9.3 -11.1.1; 11.3; 11.6.5; 11.6.6; - 12.1; 12.4.4; 13.1 - 15.1; 15.3.2; 15.3.3; 15.3.4; 15.4.1; - 17	P
4.3	See above	See above	**P**
4.4	See above	See above	**P**
5	See above	See above	**P**
6.2	See above	See above	**P**
6.3	See above	See above	**P**
6.4	See above	See above	**P**
6.5	See above	See above	**P**

	RM RESULTS TABLE:		P
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
Supplementary Information:			

Check EN 10079:2015

EN 10079:2015			
Clause	Requirement + Test	Result - Remark	Verdict
4. General requirements			
4.1	Risk management	Normal use and foreseeable misuse evaluated. See risk management RMF Suction Equipment. Rev. 01 No unacceptable risk	P
4.2	Usability	Se usability analysis rev. 15/01/18	P
4.3	Clinical investigation	Device consolidated	NA
4.4	Biophysical or modelling research		NA
4.5	Test methods	EN 10079-1 methods used	P
5. Cleaning, disinfection and sterilization			
5	Part of equipment subjected to contamination single use or may be sterilized/disinfected/cleaned	Single use filter and valve. Vessels can be sterilized Tests performed after 30 cycles of sterilization	P
6. Design requirements			
6.1	Collection container		P
6.1.1	Level of contents in normal use shown	Transparent	P
6.1.2	Container capacity Suction equipment for field use with overfill protection usable volume not less than 300ml Suction equipment for field use which is intended to continue operating when the collection container is full usable volume not less than 200ml For all other equipment not less than 500ml	2000ml	P
6.1.3	Container strength Collection container shall not crack, implode, and	Test passed with 95kPa under atmospheric pressure; no breakage	P

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Clause	Requirement + Test	Result - Remark	Verdict
	permanently deformed if tested according to clause 7 and 9 and if subjected to vacuum pressure 120% of rated or 95kPa under atmospheric pressure (whichever is the less) below atmospheric pressure for 5 minutes		
6.2	Connections		P
6.2.1	Tubing connectors for collection containers designed to facilitate correct assembly	Easy way to connect and disconnect without any tool	P
6.2.2	The inlet port of the collection container shall have a fluid pathway of not less than 6 mm internal diameter. The inside diameter of the inside tubing connection shall be equal to or largest tubing size specified by the manufacturer. In addition, the inlet port shall not be compatible with any of the conical connectors specified in ISO 5356-1 or small-bore connectors specified in ISO 80369	6,8mm minimum measured	P
6.2.3	Exhaust port	No exhaust port	NA
6.3	Suction tubing		P
6.3.1	Suction tubing shall have an inside diameter of not less than 6mm The degree of collapse of the suction tubing shall be less than 0,5 throughout its entire length	Test of Annex A.4 passed Test pressure: -60kPa Degree of collapse: 0,1	P
6.3.2	Suction tubing provided by the manufacturer shall have a minimum length of 1,3 m	Length 1,305m	P
6.4	Vacuum level indicators		P
6.4.1	Suction equipment with an operator-adjustable vacuum regulator shall have a means of indicating the vacuum level at the patient end when attached to a suction catheter or drainage tube.	Provided manometer	P
6.4.2	Full scale no more than 200% of maximum vacuum level specified	-100 kPa full scale - 90kPa maximum	P
6.4.3	Analog displays shall have graduations not less than 2mm apart with each graduation representing not more than 5% of full-scale Movement of a rotary analog vacuum level indictor should be anti-clockwise for increase vacuum level	0,05 bar (5% of full scale)	P
6.4.4	Digital displays shall display vacuum level at intervals of not greater than 5% of full-scale	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
6.4.5	Vacuum level indicators on suction equipment intended for thoracic drainage shall be accurate to within ±5% of full-scale in The middle three-fifths of the operating range	--	NA
6.4.6	Vacuum level indicators on suction equipment except as specified in 6.4.5 shall be accurate to within ±5% of full-scale value	cl. 2,5	P
6.4.7	Low vacuum equipment shall be fitted with a vacuum level indicator between the vacuum source and collection container	High vacuum	NA
6.4.8	Suction equipment having a vacuum regulator with a variable control shall have a vacuum indicator displaying the vacuum level on the inlet side of the vacuum indicator		P
6.5	Spillage on electrical suction equipment Classification according to EN 60529 Remote foot switches IPX6	Classified IP20 according to EN 60529 Remote switch IP67	P
7	Operational requirements		P
7.1	Easy of operation	See also usability evaluation	P
7.2	Dismantling and reassembly Requirements of clause 9 after dismantling and reassembling	Correctly marked	P
7.3	Mechanical shock Suction equipment intended for field/transport (1m drop)	Not for field/transport	NA
7.4	Stability	Passed	P
7.4.1	Tilt 20° if intended for field/transport use		NA
7.4.2	Suction equipment non intended for field or transport use shall meet the requirements given in cl. 9 when placed in any position on a surface (10±1)° slope form the horizontal	Test passed	P
7.5	Protective devices		
7.5.1	Contamination protection	Filter provided	P
7.5.2	Overfill protection device When an overfill protection device is activated, suction shall cease and no more than 5ml of fluid	No fluid passage after activation of fluid protection device (< 1ml)	P

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Clause	Requirement + Test	Result - Remark	Verdict
	shall pass downstream of the overfill protection device within a period of 2min		
7.5.3	Pressure protection		P
7.5.3.1	Negative pressure protection If a limit to the maximum vacuum level is fitted the vacuum shall not exceed the maximum vacuum level by more than 10%	--	NA
7.5.3.2	Positive pressure protection Thoracic drainage system shall not develop a positive pressure in excess of 1kPa. Test A6	--	NA
7.6	Noise		P
7.6.1	Low vacuum/low flowrate equipment maximum 60dBA		NA
7.6.2	Suction equipment other than specified in 7.6.1 maximum 70dBA	Value measured less than 70dBA. See appended table	P
7.7	Air leakage		P
7.7.1	Collection containers for general use. Maximum leakage shall not exceed 200ml/min If intended for use for use with suction equipment having a free flow of more than 1l/min the pressure increase shall be less than 3,3kPa/V in 10s (V is the total volume)	Evacuate the collection container to 40 kPa below atmospheric pressure. Close off the vacuum source, and observe the pressure increase within 10s. Test passed. See appended table	P
7.7.2	Collection containers for thoracic drainage Maximum leakage shall be no more than three bubbles in 10s Collection containers intended for –reuse shall be tested after 30 cycles of cleaning and disinfection or sterilization		NA
8	Physical requirements for suction equipment for field use		NA
8.1	Dimensions Shall pass through a rectangular opening having dimensions of 600mmx300mm		NA
8.2	Mass shall not exceed 6kg included carrying case or frame		NA

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Clause	Requirement + Test	Result - Remark	Verdict
9	Performance requirements for vacuum level and flowrate		P
9.1	High vacuum/high flowrate Vacuum level of at least 60kPa within 10s and a free flowrate into the collection container of not less than 20l/min. Test A.9	Test passed see appended table	P
9.2	Medium vacuum equipment Shall develop a vacuum level of between 20kPa and 60kPa within 10s Medium vacuum for breast pumps shall not exceed 33kPa. Test A.9	--	NA
9.3	Low vacuum/low flowrate equipment Shall produce a vacuum of not more than 20kPa and a continuous free air flowrate of less than 20l/min. Test A10	--	NA
9.4	Low vacuum/high flowrate equipment Shall produce a vacuum of not more than 20kPa and a continuous free air flowrate of not less than 20l/min. Test A10	--	NA
9.5	Thoracic drainage equipment for adults Suction equipment marked “thoracic drainage” intended use in adults shall produce a free air flowrate of not lee than 15l/mi at the inlet of the collection container. Vacuum level shall not exceed 10Kpa. For most situations the vacuum level developed should not exceed 7kPa In some situations a higher flowrate (e.g. 25l/min) may be required and the ability to generate higher vacuum levels and higher flowrates is desirable. Equipment marked thoracic drainage shall badjustable to a static vacuum level of 7kPa. Such equipment shall produce a free air flowrate of a t least 15l/min and shall be capable of developing 95% of the set vacuum level within 5s when connected to a closed system of 4,5l total capacity. Suction equipment intended fot thoracic drainage shall not develop positive pressure in excess of 1kPa at the patient inlet with a free air flowrate of	--	NA

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Clause	Requirement + Test	Result - Remark	Verdict
	10l/min		
9.6	Intermittent vacuum equipment Shall produce a vacuum level ±10% of the vacuum level specified by the manufacturer or ±10% of the mid-range level if the vacuum level is adjustable. The cycling frequency shall be within 10% of the specified frequency or 10% of the middle frequency if the range is adjustable. Test A12	--	NA
9.7	Vacuum regulators with fixed setting; the vacuum level indicated shall not deviate by more than ±10% from the fixed setting Test A.13		NA
9.8	Vacuum regulators with variable settings Vacuum level indicated shall not deviate by more than ±10%when set within the middle three fifth of is range	Test passed see appended table	P
9.9	Equipment intended for pharyngeal suction shall evacuate 200ml of simulated vomitus in not more than 10s. test A.15	Test passed see appended table	P
9.10	Battery powered transportable suction equipment for field7transport use shall operate for at least 20 min during which time it shall produce a free air flowrate of not less than 20l/min and a vacuum level of not less than 40kPa		NA
9.11	Interruption of power supply shall not cause any hazard and the vacuum level and flowrate shall not vary by more than ±10% from the set value	No variation more than 3,3%; Turning off and on again there is no variation	P
10	Resistance to environment of suction equipment for field and/or transport use		NA
10.1	Operating conditions Meets the requirements of clause 7 and 9 after being subjected to temperatures -18°C and +50°C		NA
10.2	Storage Meets the requirements of clause 7 and 9 after being subjected to temperatures -40°C and +60°C		NA
11	Information to be supplied by the manufacturer		P

EN 10079:2015			
Clause	Requirement + Test	Result - Remark	Verdict
	(labelling and instruction for use)		
11.1	Information supplied by the manufacturer shall comply with EN 1041		P
11.2	Symbols complying with ISO 7000, ISO 15223-1 and IEC/TR60878		P
11.3	Labelling of equipment Information permanently and legibly marked:		P
a)	Name and trade name and address of the manufacturer and, in addition, the name and address of the authorized representative	3A HEALTH CARE srl with address	P
b)	Identification of device	Maxiaspeed 6.2	P
c)	World “sterile”	--	NA
d)	Batch code proceeded by word LOT or serial number	LOT number provided	P
e)	Date by which the device or parts can be used in safety expressed in year and month	Provided for filter, mediflow bag, cannula, aspirated flow manual command	P
f)	Single use part	Provided for filter, mediflow bag, cannula, aspirated flow manual command	P
g)	Exhaust port	Provided	P
h)	Inlet or equivalent icon at the connection to the collection container	Provided	P
i)	Collection container having a capacity of 500ml or greater the suable volume expressed in millimetres and graduations with intervals not less than 50ml and not more than 250ml	2000ml Interval 100ml	P
j)	All equipment generating suction shall be marked with words indicating suction, Marking visible from the normal working position	Provided	P

EN 10079:2015			
Clause	Requirement + Test	Result - Remark	Verdict
k)	Id for field/transport use the minimum and maximum ambient temperature on equipment case or equipment	--	NA
l)	Maximum vacuum level marked on the case	Marked -90 kPa	P
m)	Maximum vacuum level marked on equipment	Provided	P
n)	Units of measure	Provided	P
o)	Low vacuum equipment marked with the vacuum level or with words indicating low vacuum level	--	NA
p)	Intermittent vacuum equipment marked with words indicating intermitted suction; equipment which can provide both continuous and intermittent vacuum shall have the mode control clearly marked	--	NA
q)	Direction of adjustment to increase vacuum	Provided	P
r)	Performance category or vacuum and flowrate ranges	High Flow High Vacuum	P
11.4	Instructions for use		P
a)	Name or tradename and address	Provided	P
b)	Intended purpose	Provided	P
c)	Waring for persons who shall have received adequate instructions for use	Provided	P
d)	How to make the equipment operational	Provided	P
e)	Guidance on performance	Provided	P
f)	Dismantling and reassembly	Provided	P
g)	Test procedure	Provided	P
h)	Specification on environment operating/storage limits	Provided	P
i)	Method for cleaning, disinfection or sterilization	Provided	P
j)	Function test performed by the user	Provided	P
k)	Size and type of tubing and the connection to the collection container including any maximum length	Provided necessary tubing and collection container	P
l)	Usable volume of the collection container	Provided	P

EN 10079:2015			
Clause	Requirement + Test	Result - Remark	Verdict
m)	List of parts	Provided	P
n)	Overfill protection device	Provided	P
o)	Method of emptying the collection container	Provided	P
p)	Removal and servicing of the equipment if liquid or solid has been drawn into the vacuum pump	Provided	P
q)	Statement that suction ceases when the overfill protection device operates	Provided	P
r)	Method of controlling frothing in the collection container	Provided	P
s)	Operating the required vacuum level regulator	Provided	P
t)	Disclosure of any component	Provided	P
u)	Special storage/handling condition	Provided	P
v)	Recommendation for maintenance	Provided	P
w)	Fault-finding	Provided	P
x)	Suitable for use in MRI environment	--	P
y)	Warnings and precautions	Provided	P
z)	Date of publication and or revision of the manual or the version number	Provided	P

5. TEST PROCEDURES AND CONDITIONS

Tests and controls executed on the device indicated on paragraph 2 have been performed on no.2 example, in the same conditions in which it was prepared by the customer (in an use conform configuration) in the premises of the laboratory ELETTRA s.r.l. located in Matteucci, 10 50041 Calenzano (FI).

TEST EQUIPMENT LIST

Elettra Identification Number	Test instrument	Brand	Model	Serial
1	Luxmeter	Ht Italia	HT170N	812660
2	Thermoigrometer	Ht Italia	HT180	847107
3	Thermoanemometer	Ht Italia	HT190	847015
4	Multifunctional instrument	Ht Italia	HT2040	98094067
7	Multifunctionsafety tester	Metrawatt	SECUTEST 0751/601	M51326783
9	Caliber	Baty	RS 613-959	--
10	Meter distances	Bosh	DUS20	0603096201
12	Current probe	Chauvin Arnoux	F27	100428WAY
13	Datalogger	Agilent	34970A	US37028187
14	Defibrillator Analyzer	Metron	QA-40M	3481
15	Electrosurgery Analyzer	C.E.B.	400/C	0037
16	Current probe	Hioki	3283	0635472
24	Multimeter	Agilent Technologies	34401A	MY41001686
25	High voltage probe	Agilent Technologies	N2771A	20003473
26	Multifunctionsafety tester	Metrel	MI 2094	11020552
27	Thermometer	Chauvin Arnoux	CA-864	991011140
28	Sound level meter	Chavin Arnoux	CDA830	96065630
30	Oven	Titanox	PASTEUR	008
31	Current probe	Metrix	MX350	907359WJH
32	Ball test device	Omm Montenero	OMM1	--
34	Rigid test finger	Omm Montenero	OMM3	--
36	Test pin	Omm Montenero	OMM5	--
37	Impact test device	Omm Montenero	OMM6	--
38	Glowwire test device	Omm Montenero	OMM7	--
39	Torque screwdriver	Beta	582AF	6GY038447
40	Torque wrench	Beta	590/1	OJY052555
41	Function generator	Goldstar LG	FG-2002C	--
42	DC powersupply	Alpha Elettronica	AL862S	
43	Variac	Metrel	HSN0203	09386
44	Controller	Crouzet	Millennium	--
45	Mains Analyzer	Infratek	SM201	01114888

Elettra Identification Number	Test instrument	Brand	Model	Serial
47	PT100	RS Components	236-4299	ST-01
52	Voltage regulator	Metrel	HTN 0703	00298
53	Mains Analyzer	Chauvin Arnoux	C.A. 8334	144920ZDH
54	Three-phase transformer	LEF	310.375P3	16227
55	Dynamometer	Lutron	FG-20KG	P856675
56	Current shunt	Lutron	ST-50	--
57	Flowmeter	Key Instruments	MR3000	
59	Laser powermeter	Ophir	NOVA-DISPLAY	119017
60	Laser powermeter head	Ophir	30A-SH-V1	1702604
61	Laser powermeter head	Ophir	F150A-SH	118434
62	Manometer	Wika	9071687	
64	Mains Analyzer	Tti	HA1600	176786
65	Cimaticchamber	Perani	AC 520	11124
66	caliber for antenna sockets	Omm Montenero	OMM2	--
67	Current probe	Lem	PR20	P02202058525
68	Articulated test finger	Omm Montenero	OMM4	--
70	Powersupply	DF	DF1731SB	--
71	Powersupply Dc/Ac	Power Saver	SPS-450	25101621
77	Function generator	HP	33120A	E13266 US36026774
78	PowersupplyAc/Dc	ChromaAteInc.	C-61602	ABP000000204
80	Vibration controller	Dactron	COMET	7351258
81	Accelerometer	Dytran	3055A2	238
87	Crane	OMCN	GP5/DE	05
90	Stabilized power supply	LEF	AE020/22G-A	21106
91	High voltage probe	Testec	HVP-40	20040113
93	Thermoigrometer	RS components	408-6109	--
94	Bunsen	PLEN AIR	PL531	--
95	Dustchamber	Elettrolab	MINIDUSTY	0401
99	Datalogger	Omega	OMB-DAQ-56	248333
100	Multimeter	Omega	HHM93	0934020935
101	Portablewaterningdevice	Buzzi	IPX3-X4	9401
102	Pulse generator	Elettrolab	HV-DEF-SURGE	0401
103	Articulated UL test probe	Comm2000	UL ARTICULATED PROBE	--
104	Manual HydraulicPump	Ralston Instruments	XHGV-0000	
105	Manometer	Deltaohm	HD9220	04014530
106	Oven for calibration	EUROTRON	MT1922	72515-G52104
107	Sample mass	GEASS	10kg	--
108	Sample mass	GEASS	5kg	--
109	Sample mass	GEASS	2kg	--

Elettra Identification Number	Test instrument	Brand	Model	Serial
110	Sample mass	GEASS	2kg	--
111	Sample mass	GEASS	1kg	--
112	Sample mass	GEASS	500g	--
113	Oscilloscope	Lecroy	9310AM	93104781
114	Cimaticchamber	Perani	UC 450/40	11275
115	Flowmeter	Kei Instruments	COD. RS 1983013	S 9515
116	Multifunctionsafety tester	Chauvin Arnoux	CA 6160	14091452
117	Powersupply	DF	DF1730 SL	
119	Accelerometer	Dytran	3055A3	877
122	Voltmeter	HP	3400A	1641G04591
124	Balance	CK	6202	15687
127	Nozzle Ipx5	Omm Montenero		
128	Nozzle Ipx6	Omm Montenero		
129	Probe UL 1	Buzzi	(UL-1) PA130A	
130	Probe UL 2	Buzzi	UL-2 8PA-140A)	
131	Rigid test finger	Buzzi	DITO RIGIDO	
132	Voltage regulator	Metrel	HSN0303	01767
133	Voltage regulator	Metrel	HSN0303	01833
134	Voltage regulator	Metrel	HSN0303	02065
135	Manual pump	Ridgid	1450	--
136	Oscilloscope	Goodwill	GDS820C	EF200536
137	Electronic AC powersupply	Elgar	3001	-
140	Manometer	Wika	232.50	
141	Manometer	Wika	232.50	
143	Misuratore Di Campo Elttromagnetico	Chauvin Arnoux	CA42	100405AEK
146	Compressor	ABAC	A2BB104	286554
158	Datalogger	Agilent Technologies	34970A	MY44021941
159	Fonometer	Deltaohm	HD2010	32817
161	Transformer	LEF	A.M.3500VA 230/120	837.350I120
162	Motor test banch	Elettra	EL.BM.01	0701
163	Resistive load	Ofel	RC165	105560410000
164	Resistive load	Ofel	RC165	105560447000
165	Counter	Ez Digital	FC-7150	001/0770
166	Voltage regulator	Yaohua	TDGC2	--
167	Active load	Tecnodelta	DCL200	1220101B
168	Active load	Transistor Device	DLR-50-50-1000-A	10298
172	MD leakage current	ELETTRA	IDIS.CE.01	--
173	MD leakage current	ELETTRA	IDIS.UL.01	--
174	Powersupply Dc	Tti	EX752M	267875

Elettra Identification Number	Test instrument	Brand	Model	Serial
175	Digital inclinometer	Solatronic	EN 17	--
176	AC Powersupply	K-Factor	GMM07/H	0707017
177	Rule	Rs Components	30CM	BM01
178	Oscilloscope	Metrix	OX7102-C	134226EDH
180	Voltage regulator	Metrel	HTN 450/30	000076
184	Speedometer	Hofbauer	N0000.779C	9743009
185	Flowmeter	Key Instruments	FR4000	
186	Tester	Iso-Tech	IDM106N	75100317
187	Probe Ip4x	A.T.S. Galbusera	01.12	042/08
188	Probe Ip3x	A.T.S. Galbusera	01.11	041/08
189	Flame test appliance	A.T.S. Galbusera	02.07	046/08
190	Hammer test device	Ptl	F 22.50	5080111
191	Flowmeter Ipx5	Parker Hannifin (Uk)	LOWFLOW	--
192	Multifunctionsafety tester	Vitrek	V63	20066
193	Powersupply DC	DF	DF1730 SL	
194	Voltage regulator	Metrel	HSN 0103	000629
195	Ipx1-Ipx2-Ipx3-Ipx4 Appliance	A.T.S. Galbusera	03.39 E 03.10-M	--
196	Resistor	CROPICO	RM6	Z10-0665
197	HV pulse generator	Haefely	P6T	081750-015
200	1kg iron mass (Atex test)	A.T.S. Galbusera	02.30	125/08
201	MilliohmMeter	Lutron	MO-2002	--
203	Amplifier	Krhohn-Hite	7500	15/04
204	Hydrophone	Reson	TC4013	3208018
206	Scales	Mavre	PRO CHARGE	
209	Multimeter	Iso-Tech	IDM 99II	85003712
210	Elecrodes	Ats Galbusera	EN 60079-0 ART. 26.13	--
211	Flowmeter IP66	Riels Instruments	R/4 1"M	--
212	High voltage probe	Tektronix	P6015A	B00001
215	Scales	Kern&SohnGmbh	EOB300K200NXL	WOC08009331
216	Datalogger	Deltaohm	HD206-1	09008942
219	Multimeter	HP	3458A	2823A20321
221	LcrMeter	Lutron	LCR-9073	I.50035
224	Salt fogchamber	Erichsen	610/400 E	367
225	SpectrumAnalyzer	Rohde&Schwarz	FSL6	100568
226	Power Sensor	Rohde&Schwarz	NRP-Z11	1138.3004.02
230	Tester	Honeytek	SC12B	A07017577
231	Oscilloscope	Agilent	U1604A	KR46000236
232	Multimeter	Agilent	U1242A	MY49170012
233	Current probe	Tektronix	A6303	B025898

Elettra Identification Number	Test instrument	Brand	Model	Serial
234	Infrared thermometer	Ht Italia	HT3301	09062245
236	Multimeter	Fluke	233	10990080
237	ESD generator	EM TEST	DITO	V0912101730
238	Insulation transformer	LEF	837.K2I230B	0949
239	Tester for photovoltain system	Chavin Arnoux	FTV100	118767
240	Multifunction tester	Metrawatt	SECUTEST M7010	TL463407 0005
243	Radiometer	Gigahertz-Optik	X1-3	8842M
244	Calorimetric bridge	Samar	PS/DS	49329
245	Thermohygrometer	Deltaohm	HD 2101.2	10000548
246	Mechanical test press	Step Technology	A.P.P.	D02972P0
248	Datalogger	Agilent Technologies	34972/A	MY49001655
249	Ironhammers	Ats Galbusera	02.26	001-002-003-004-005
250	Resistive load	Ofel	RC 153	105530610000
251	Wattmeter	Yokogawa	WT230	27D921963
252	Oscilloscope	Fluke	196C	19020052
256	EM RF meter	Pmm-Narda	8053-B-2004-40	262WL80471
257	EM Probe	Pmm-Narda	EHP-50C	352WN80535
260	Oscilloscope	Tektronix	TDS 744A	B021555
262	Current probe	Fischer	F-51	110242
264	AcPower Source	Em Test	NETWAVE 7	V1049108071
266	Motor test banch	Samar	V.COMPOSIZIONE	
268	Ultrasoundpowermeter	Ohmic	UPM-DT-1AV	2355
270	Powersupply	HP	11899A	3110A00479
271	Powersupply	Agilent	6681A	3640A00479
273	MultifunctionSafetyAnalyzer	Fluke	620-04	1833050
275	Dynamometer	Chatillon	DPP-25KG	4214
276	Oven	Mpm Instruments	M400-VN	MY11110563
277	Multimeter	Fluke	115	17970612
279	MD leakage current	ELETTRA	MD1 EN 60601-1	--
280	Hood FlameTests	A.T.S. Galbusera	VANO 1M3	
281	Bunsen	Attrezzature Tecniche Galbusera	BRUCIATORE 02.25	
284	Test hook	A.T.S. Galbusera	ART. N.01.26	--
285	Field meter	Narda	ELT-400	N-0027
289	Calibration fixture	Pisher	FCC-BCICF-1	112419
291	Accelerometer	Dytran	3056B1	11736
292	Torque screwdrivers	Wera	7440; 7441	A11-11-16612; B11-12-16080
293	Caliber	Glm	700150 (200MM)	--

Elettra Identification Number	Test instrument	Brand	Model	Serial
295	Small test finger	A.T.S. Galbusera	01.14-A	086/12
296	Surface temperature test probe	A.T.S. Galbusera	31.07	087/12
297	Cable torque tester	A.T.S. Galbusera	IMQP-001/08	--
298	Pressure reducer	Eurofro	W000290227	HCL3171
299	Manometer	Cewal	91483011	--
300	Manometer	Cewal	91483011	--
301	Manometer	Cewal	91483310	--
302	Manometer	Cewal	91483310	--
303	Manometer	Cewal	91483410	--
304	Manometer	Cewal	91483410	--
305	Shunt current	IME	DER060C100	ELT.DC.01/12
306	Shunt current	IME	DER060B500	--
307	Shunt current	IME	DER060C300	307
308	High frequencydielectric tester	Elettra	SURGERY TESTER	1201
309	Power divider	HP	11636A	07657
310	High voltagedielectric tester	E. Pesatori	EPK300-30KV	2160M0010
313	Network Vector Analyzer	HP	8753D	3410A06664
314	LcrMeter	AgilentTechnolgies	4263B	MY40111314
315	Vibrationsystem	Ling	1512	36
316	Spettrometer	Avantes	AVASPEC-ULS2048XL	1212031U1
317	Humidifier	ELETTRA	--	--
318	Datalogger	Deltaohm	HD206.1	12013968
319	Wattmeter	Yokogawa	WT210	91N117123
320	Multimeter	Keithley	2015 THD	1197544
323	Spettrometer	Skyray	GENIUS 3000XRF	593
324	SpectrumAnalyzer	Advantest	R3371A	75060220
325	Current probeRf	Elettra	SC-HF-01	001
328	Laser powermeter	Laserpoint	A-40/200-D60-USB	131279
329	Datalogger	Agilent	34970A	MY41018570
330	Voltage probe	Tektronixs	P6015A	B026135
331	Caliber	Mitutoyo	CD-6" CSX (500-196-20)	12618098
332	Micrometer	Mitutoyo	293-340	35075044
333	Optical comparator	Ed&D	OC-20	R10430160
334	Feeler	Ed&D	CC-23	R074401104
335	Conducted immunity generator	EM TEST	UCS500	P1330120726
337	Termochamber	Flir	E6	63905278
338	Infusionpump Analyzer	Datrend Systems	SOLO	IS13120318

Elettra Identification Number	Test instrument	Brand	Model	Serial
339	Compressor	MA Compressori	FC2/50 CM2 CE	ITR0570953
340	Resistive load	Ofel	P/N05560510000; RC165	09/01/2014
341	Flussometer	Fluke	922	24620045
342	Continuity tester	Associated Research Inc.	3160	140507-3160_9390268
343	Resistor	Elettra	--	EL. CR. 01-14
344	Oscilloscope	Tektronix	TDS3054B	B034155
345	Ac Source	K-Factor	GTT21T	1201003
347	Voltage regulator	K-Factor	VAM10F-1N	1012673
348	Voltage regulator	K-Factor	VAM10F-1N	1012674
349	Ac Source	K-Factor	SMM05R	1407013
351	Softener	Pentair international	5600	1311-3675494-017
352	Optical device	PMM Narda	O3P	010WJ30505
354	Multimeter	Fluke	115	26511351
355	Shunt	Agilent	34330A	
356	Cronometer	Rs	DIGITAL STOPWATCH BLACK	8111818
357	Cronometer	Rs	SPORT TIMER	8111814
358	Defibrillator	Gima Spa	I-PAD CU-SP1	G1M0SB0437
359	Ball test device	Galbusera	02.04	0033
360	Cimaticchamber	Binder	MKFT 720	14-19278
364	Detector Head	Laser Point	PD-50-D9-IR-USB	15021730
365	Scles	Dymo	M1	1011444005245
366	Thermal chamber	Fasar	ELETTRA02	
367	Line Leakage Tester	Associated Research, Inc.	00620L	9610382
368	Oscilloscope	Fluke	123	DM9550317
369	Multimeter	Fluke	179	32320089
370	Multimeter	Keysight	U1241B	MY55090163
371	Insulation transformer	LEF	1MA400123007	147495
372	Insulation transformer	LEF	1TA2002400010	147494
373	Resistive load	Italohm	ROPPE 140-2-IP20	101640320001
374	Resistive load	Italohm	ROPPE 140-2-IP20	101640320001
375	Resistive load	Italohm	ROPPE 140-10-IP20	101640410007
376	Resistive load	Italohm	ROPPE 140-10-IP20	101640410007
377	Resistive load	Italohm	ROPPE 140-10-IP20	101640450004
378	Resistive load	Italohm	ROPPE 140-50-	101640450004

Elettra Identification Number	Test instrument	Brand	Model	Serial
			IP20	
379	Powersupply	Atten	PVR1101 DC POWER SUPPLY	755054100074
380	Datalogger	Fluke	HYDRA 2620A	5337501
381	Resistor	SIEMENS	Resistenze a decadi	--
382	Powersupply Dc	Elind	60HL20	146/ /03
383	Resistive load	Elettra		
388	Box for continuity and dielectric strenght test	Elettra	EL. BLB. 01	--
389	Insulation transformer		2000VA	--
390	Insulation transformer		1000VA	--
391	Resistor		EL-CR-01	--
392	Multimeter	Fluke	867B	DM7060229
393	Vibration Analyzer	Delta Ohm	HD2030	15041630284
395	Radiusmeter	Holex		00082408
396	Radiusmeter	Holex		00082409
397	Radiusmeter	Holex		00082410
398	Balance	CIBE	Acciaio inox	D12813
399	Flexometer	Metrica		141114
400	Current probe	Chauvin Arnoux	E3N	
401	Ac Source	Itech	IT7326	602146010707830004
402	Current probe	Fluke	I410	74356643
403	HV voltage probe	Fluke	80K-40	75470017
405	Datalogger	Cryopak	IMINI	MX-CE-111-0329
406	Oscilloscope	Gwinstek	GDS-210	GEQ110320
407	Differential probe	Gwinstek	GDP-040D	GPP170245
408	Electrosurgery Analyzer	S.P.L. Elektronik	HF400	1505HF400
409	Rigid test finger	GALBUSERA	01.02	223/16
410	Nail test finger	GALBUSERA	01.10	224/16
411	Balance	KERN	PCB 250-3	WD150004037
412	Flexometer	METRICA	5MT	8001066381654
414	CC Signaller	GALBUSERA	01.08	259/16
415	Climatic station	KONIG	KN-WS540	GP1210
419	Ball test 50mm	GALBUSERA	N.01.09	262/16
420	Small test finger 0,8	GALBUSERA	ART.N.01.14	264/16
421	Transconductance amplifier	FLUKE	5220A	2650011
422	Flexible current probe	FLUKE	I3000S	33780014
423	Differential pressure meter	TESTO	312-3	03119531
431	Device for flexing cable test	GALBUSERA	20.09-C	002787/16
436	Water Capacity IPX7	Elettrotecnica Agostini	2000lt	--

Elettra Identification Number	Test instrument	Brand	Model	Serial
438	Device for measure surface resistance	GALBUSERA	02.10	002797/17
439	Variac	K-FACTOR	VAM10F-1N	217053256\
440	Variac	K-FACTOR	VAM10F-1N	217053255
441	Network analyzer	Chavin Arnoux	8336MA	181864PMH
442	Datalogger	Agilent	34970A	MY31008749
443	Load	Aeroflex / Winschel	1433-4-LIM	NS581
445	Micrometer	CHAUVIN ARNOUX	C.A 6240	119618 QDV
450	Pressure meter	DIGITRON	2026P	5708263448
460	Datalogger	XS INSTRUMENTS	MINITH	LM730651
461	Datalogger	XS INSTRUMENTS	MINITH	LM730635
464	Pressure meter	FLUKE	700G10	4005063
465	Power sensor	MINI CIRCUITS	ZX10r-14-S+	1045
466	Laser Power meter	THORLABS	PM100USB	P2009433
467	Laser Meter head	THORLABS	S120VC	17111512
468	Pneumatic pump	GIUSSANI	LPP 40	03/17 0178
469	Accelerometer	DYTRAN	3100D24	7147

Instruments used are referred to national standards and calibrated according to calibration plan stated by internal quality system.

Environmental conditions remained inside 25±3°C and 45±10%.

MEASURE UNCERTAINTY

The expanded uncertainty evaluated is based on a standard uncertainty multiplied by a coverage factor of k=2, providing a confidence level of p = 95%.

Test	Range	Uncertainty
Insulation resistance	0 ÷ 1.999	5,99%
	2.00 ÷ 19.99	3,97%
	20.0 ÷ 199.9	3,97%
	200 ÷ 999	12,75%
Continuity of protection cable	0 ÷ 600mΩ	5,4%
Current/Power Absorption	50W÷12000W <50W 100mA÷30A <100mA	2,3% 4,3% 1,5% 4,2%
Leakage Current	30Hz ÷ 100kHz	5,8%
Leakage Current	100kHz ÷ 1MHz	8,0%
Leakage Current in medical device	30Hz ÷ 100kHz	2,5%
Temperature during temperature test	20°C-200°C	2,7°C
Voltage	0-1000V 1000-2000V	0,2% 1,5%
Resistance	0,1-10MΩ	0,3%
Current	0,1-100A 100-600A	0,5% 1,0%
Strenght	0-1000N	1%
Lenght	20mm 20-200mm 20cm-1m	0,2mm 0,3mm 0,5mm
Couple	15Nm	6%
Induction Field	1mT	1,5Db
Temperature during climatic test	-50°C-150°C	<2°C
Humidity during climatic test	5-95%	8,5%
Acceleration during vibration test	0-30g	5,1%
Frequency during vibration test	2kHz	1,0%
Sound Pressure	120dB	1,5Db
Dielectric strenght voltage	0-5kV 5kV-30kV	7,4% 9,2%

4.11	TABLE: Power input	P

4.11	TABLE: Power input					P
Operating Conditions / Ratings		Voltage (V)	Frequency (Hz)	Current (A)	Power (W or VA)	Power factor (cos φ)
Normal max speed		230	50	0,62	130	0.908
Normal max speed		230	60	0,65	145	0.978
Supplementary Information:						
Instruments used:	319; 349					

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	0.34	0.35	0.71	0.35	4.22	0.29	0.27	2.02	0.49	0.27
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										
Supplementary information:									
Instruments used:	252								

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
ER, NC	253	60		S1=1; S5=1; S7=1
ER, NC	253	60		S1=1; S5=0; S7=1
ER, SFC (Neutral Open)	253	60		S1=0; S5=1; S7=1
ER, SFC (Neutral Open)	253	60		S1=0; S5=0; S7=1
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC
TC, NC	253	50	0,5	S1=1; S5=1; S7=1
TC, NC	253	50	0,3	S1=1; S5=0; S7=1
TC, SFC (Neutral Open)	253	50	0,8	S1=0; S5=1; S7=1
TC, SFC (Neutral Open)	253	50	0,8	S1=0; S5=0; S7=1
TC, SFC (Ground Open)	253	50	NA	S1=1; S5=1; S7=0
TC, SFC (Ground Open)	253	50	NA	S1=1; S5=0; S7=0
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
P, NC AC/DC	253	60	AC 0,2 DC 0,2	S1=1; S5=1; S7=1; S13=1
P, NC AC/DC	253	60	AC 0,2 DC 0,2	S1=1; S5=0; S7=1; S13=1
P, SFC (Neutral Open) AC/DC	253	60	AC 0,2 DC0,2	S1=0; S5=1; S7=1; S13=1
P, SFC (Neutral Open) AC/DC	253	60	AC 0,2 DC 0,2	S1=0; S5=0; S7=1; S13=1
P, SFC (Ground Open) AC/DC	253	60	NA	S1=0; S5=1; S7=0; S13=1
P, SFC (Ground Open) AC/DC	253	60	NA	S1=0; S5=0; S7=0; S13=1

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
PM	230	50	0,5	All possible conditions for S5, S9, S13
PM	230	50	0,3	All possible conditions for S5, S9, S13
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
P - External voltage on port USB	230	50		All possible conditions for S5, S9, S13
P - External voltage on port USB	230	50		All possible conditions for S5, S9, S13
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
P - External voltage on metal foil around enclosure	230	50		All possible conditions for S5, S9, S13
P - External voltage on metal foil around enclosure	230	50		All possible conditions for S5, S9, S13
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)
PAUX, NC AC/DC	253	60	AC DC	S1=1; S5=1; S7=1; S13=1
PAUX, NC AC/DC	253	60	AC DC	S1=1; S5=0; S7=1; S13=1
PAUX, SFC (Neutral Open) AC/DC	253	60	AC DC	S1=0; S5=1; S7=1; S13=1
PAUX, SFC (Neutral Open) AC/DC	253	60	AC DC	S1=0; S5=0; S7=1; S13=1

PAUX, SFC (Ground Open) AC/DC	253	60	AC DC	S1=0; S5=1; S7=0; S13=1
PAUX, SFC (Ground Open) AC/DC	253	60	AC DC	S1=0; S5=0; S7=0; S13=1
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)
P, NC AC/DC	253	60	AC DC	S1=1; S5=1; S7=1; S13=1
P, NC AC/DC	253	60	AC DC	S1=1; S5=0; S7=1; S13=1
P, SFC (Neutral Open) AC/DC	253	60	AC DC	S1=0; S5=1; S7=1; S13=1
P, SFC (Neutral Open) AC/DC	253	60	AC DC	S1=0; S5=0; S7=1; S13=1
P, SFC (Ground Open) AC/DC	253	60	AC DC	S1=0; S5=1; S7=0; S13=1
P, SFC (Ground Open) AC/DC	253	60	AC DC	S1=0; S5=0; S7=0; S13=1
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)
P - External voltage on port USB	230	50		All possible conditions for S5, S9, S13
P - External voltage on port USB	230	50		All possible conditions for S5, S9, S13

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
PM	230	50		All possible conditions for S5, S9, S13
PM	230	50		All possible conditions for S5, S9, S13
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
P - External voltage on metal foil around enclosure	230	50		All possible conditions for S5, S9, S13
P - External voltage on metal foil around enclosure	230	50		All possible conditions for S5, S9, S13
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
Total earth leakage current	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
ER, NC	253	60		S1=1; S5=1; S7=1
ER, NC	253	60		S1=1; S5=0; S7=1

Supplementary information: test executed before and after preconditioning treatment 48h 25°±3C 93±3%

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

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

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

ER - Earth leakage current TC – Touch current P - Patient leakage current PA – Patient auxiliary current TP – Total Patient current PM - Patient leakage current with mains on the applied parts MD - Measuring device	A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition
Instruments used:	273; 371; 401

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

Insulation under test	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.		
L-N/Enclosure	2MOPP	326		4000	No
L-N/Internal metal parts	2MOPP	326		4000	No
L-N/Applied parts	2MOPP	326		4000	No
L-N with switch off	1MOPP	326		1500	No

Supplementary information: test executed before and after preconditioning treatment 48h 25°±3C 93±3%

[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).

Instruments used:	192; 388

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

Part/material	Test temperature (°C)	Impression diameter (mm)
Enclosure/External insulating parts	80	0.6

Supplementary information:					
Instruments used:	30; 359; 333				
Ambient cond. (Temp., Humidity, Pressure)	T=20÷28°C RH=30÷60% P=860÷1060hPa	Date:	08/02/18	Operator:	LD

8.9	TABLE: Clearances and creepage (*)						P
Part under test	Working voltage (V)	Type of insulation	Clearance		Creepage		Verdict
			Required	Measured	Required	Measured	
A	230	basic between L-N (1MOOP)	2,5	2,0	2,5	2,0	P
B	230	2MOPP	8,0	5,0	105	43,0	P
C	230	2MOPP	8,0	5,0	12	12	P
Supplementary information:							
Instruments used:	292; 293; 68; 332; 334						

9.4.2.1	TABLE: Instability—overbalance in transport position (*)		P
ME EQUIPMENT preparation	Test Condition (transport position)	Remarks	
On horizontal plane with wheels locked	Inclined 10°	Device stable	
Supplementary information:			
Instruments used:	175		

Ambient cond. (Temp., Humidity, Pressure)	T=20÷28°C RH=30÷60% P=860÷1060hPa	Date:	08/02/18	Operator:	LD

9.4.2.2	TABLE: Instability—overbalance excluding transport position (*)	P

ME EQUIPMENT preparation	Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)	Remarks
On horizontal plane with wheels locked	Inclined 10°	Device stable
Supplementary information:		
Instruments used:	175	

9.4.2.4.2 9.4.2.4.3	TABLE: Castors and wheels – Force for propulsion (*) Movement over a threshold (*)	P

ME EQUIPMENT preparation	Test Condition (force location and height, speed of movement)	Remarks
Device on horizontal plane	Device moving with 9N	Force of propulsion less than limit of 200N
Instruments used:		

9.4.3.1 9.4.3.2	TABLE: Instability from unwanted lateral movement (including sliding) in transport position/ excluding transport position (*)	P

ME EQUIPMENT Preparation	Test Condition (transport position, working load, locking device(s), caster position)	Remarks
Device on horizontal plane	Plane inclined 10° with 4 wheels locked	Device does not overturn or moe
Instruments used:		

9.6.2.1	TABLE: Sound pressure level measurements (*)	P

Operating mode	Maximum sound measured from operator's normal position [dBA] / [dBC]	Maximum sound measured 1 m from any position of device [dBA] / [dBC]
Normal mode maximum power	63.8 dBA / 69.3dBC	Front 58.4 dBA / 63.7 dBC
Normal mode maximum power		Back 63.2 dBA / 68.8 dBC
Normal mode maximum power		Left 59.1 dBA / 66.3 dBC
Normal mode maximum power		Right 59.8 dBA / 65.4 dBC
Normal mode maximum power		Up 60.4 dBA / 65.4 dBC
Supplementary information: Referenced background sound pressure measurement: ____39_ dBA		
Instruments used:	159	

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT - measurement of maximum temperature during NORMAL USE for parts other than APPLIED PARTS and parts likely to be touched	P

Test ambient (°C) .....:	23°C
Maximum rated ambient operating temperature (°C):…….	40°C
Test supply voltage/frequency (V/Hz)[4] .....:	264Vac/50 and 60Hz

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
11	External enclosure	71	63.6	No hazard
19	Handle	48	44.6	No hazard
9	Dihedral test	90	64.6	No hazard
13	Motor	--	80.9	No hazard
10	Frontal aspiration speed regulator	60	53.9	No hazard
20	Frontal button	71	58.7	No hazard
1	Pump connector	85	67.1	No hazard
15	Wiring	70	64.6	No hazard

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

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

Instruments used:	176; 158; 366; 251

11.1.2.2	TABLE: Excessive temperatures in ME EQUIPMENT – measurement of temperatures, hot or cold surfaces, during NORMAL USE for APPLIED PARTS not intended to supply heat to a PATIENT	P

Test ambient (°C) ..... :	23°C
Maximum rated ambient operating temperature (°C):…….	40°C
Test supply voltage/frequency (V/Hz)[4] ..... :	253Vac/50 and 60Hz

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
3	Applied part	43	42.4	No hazard

Supplementary information:
[1] See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

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

Instruments used:	176; 158; 366; 251

11.1.3	TABLE: Temperature of windings by change-of-resistance method						P
Temperature T of winding:	t_1 (°C)	R_1 (Ω)	t_2 (°C)	R_2 (Ω)	T (°C)	Allowed T_{max} (°C)	Insulation class
Power ON	23	41.2	23	54.3	81.9	130	B
Supplementary information:							
Instruments used:	329; 319; 349; 201; 357						

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
	1l from 1m in 15s	Entire enclosure	No water on electrical part

Supplementary information:	
Instruments used:	

11.8	TABLE: Interruption and restoration of power supply (*)			P
Test Condition (working condition, test voltage)	Length of interruption	Battery provided ? (Y/N)	Result	Remarks
Turned on in aspiration	10s	N	Recover function after restoration of power supply with the same vacuum level	No hazard
Supplementary information:				
Instruments used:				

13.2	TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive (*)		P
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2	Electrical SINGLE FAULT CONDITIONS per Clause 8.1:	—	—
13.2.3	Overheating of transformers per Clause 15.5:	—	—
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—

13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	—	—
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
	Motor blocked	Temperature of winding motor increase to 92.6°C and absorb 2.25 A	NO HAZARD
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	—	—
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:	—	—
	Tube aspiration blocked	Temperature of motor winding increase to 45.8°C and absorb 0.89 A	No hazard
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	—	—
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	—	—
Supplementary information: [1] Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.			
Instruments used:	167; 27		

15.3	TABLE: Mechanical Strength tests [1] (*)		P
Clause	Name of Test	Test conditions	Dielectric strength test Breakdown Y/N
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	No hazard
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	No hazard
15.3.4.1	Drop Test (hand-held)	Free fall height (m) =	N/A
15.3.4.2	Drop Test (portable)	Drop height (cm) =	N/A
15.3.5	Rough handling test	Travel speed (m/s) =	No hazard after ascending and descending step 40mm
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) =	No hazard
Supplementary information: [1]As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows).			
Instruments used:	275; 412; 30; 37		

15.4.6	TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests (*)				P
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
Frontal aspiration speed regulator	4.26	4.0	100	No	No hazard
Supplementary information: [1] Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)					
Instruments used:	40				

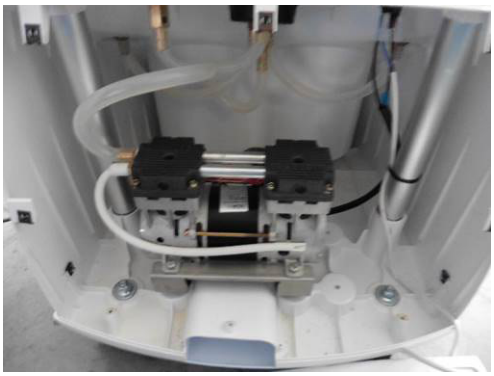
10079-1	TABLE: Electrically powered suction equipment – Safety requirements		P
Clause	Name of Test	Test conditions	Result
6.1.3	Container strenght	Test with 95kPa under atmospheric pressure	No hazard – no breakage or deformation
6.3.1	Collapse of suction tubing (ref. A.4)	Test pressure: -60kPa Degree of collapse: 0,1 Limit: 0,5	No hazard – no breakage
7.5.2	Fluid passed after overfill protection device is activated	< 1ml	No hazard. Test passed
7.7	Air leakage	Evacuate the collection container to 40kPa below atmospheric pressure. Close off the vacuum source, and observe the pressure increase within 10s. Value measured: -38,9kPa Limit: -38,35kPa (volume 2l)	No hazard. Test passed
9	Performance requirements - High vacuum/high flowrate (ref. A.9)	Vacuum level of at least 60kPa within 10s and a free flowrate into the collection container of not less than 20l/min. Value measured: -75,4kPa; 38l/min	No hazard. Test passed
9.8	Vacuum regulators	Value set: -0,6 bar; Value measured : -62.1kPa Limit: ±10%	No hazard. Test passed
9.9	Equipment intended for pharyngeal suction shall evacuate 200ml of simulated vomitus in not more than 10s. test A.15	Time to collect 200ml: <10s	No hazard. Test passed

9.10	Battery powered transportable suction equipment for field/transport use shall operate for at least 20 min during which time it shall produce a free air flowrate of not less than 20l/min and a vacuum level of not less than 40kPa	-	N/A
9.11	Interruption of power supply shall not cause any hazard and the vacuum level and flowrate shall not vary by more than ±10% from the set value	No variation more than 0,5% Turning off and on again there is no variation	No hazard. Test passed
Supplementary information:			
Instruments used:	105; 293; 215; 356		

6. PHOTOGRAPHIES








7. COMPONENTS LIST

	List of critical component parts				
Object/part No	**Manufacturer/ trademark**	**Type/model**	**Technical data**	**Standard**	**Mark(s) of Conformity**
Motor	Tecwell	TW200A-E (V) 101	230V ~ 50Hz, Class B with thermal protector 135°C	--	CE
Switch	Signal lux	SXLR28C1F00000	16(4)A/250VAC	EN61058	CE, ENEC, cURus
AC Inlet 2P with fuseholder	Jackson Electronic Industrial Corp.	JR-101-1FS	10A 250VAC	EN 60320-1 EN 60127-6	UL cert. E117978, VDE, ENEC
Cable with plug	Patelec	HC01-PC008 PC-790460+788	CABLE H05VVH2-F (2X0,75) 250V, 2,5A	IEC 50075	ENEC, VDE
Plastic enclosure	Cossa polimeri	ABS ESTADIENE 1640	HB; glow wire 650°C	UL94 IEC 695	UL cert. E194157

8. CONCLUSION

The evaluations pointed out in the last paragraph consent to express a result of conformity of the device to the Standard EN 60601-1 and EN 10079-1