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TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1: General requirements for basic safety and essential performance

Report Number. ..... :	**211100746SHA-001**
Date of issue ..... :	**2021-12-31**
Total number of pages ..... :	**196**
Name of Testing Laboratory preparing the Report ..... :	**Intertek Testing Services Shanghai** **Building No. 86, 1198 Qinzhou Road (North) 200233 Shanghai CHINA**
Applicant's name ..... :	**VINNO Technology (Suzhou) Co., Ltd.**
Address ..... :	**5F Building A, 4F Building C, No.27 Xinfa Rd., Suzhou Industrial Park, Suzhou, Jiangsu 215123, China**
Test specification:	
Standard ..... :	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	N/A
TRF template used ..... :	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No. ..... :	IEC60601_1T
Test Report Form(s) Originator .... :	UL(US)
Master TRF ..... :	2021-01-22

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

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

General disclaimer:

The test results presented in this report relate only to the object tested.
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Test item description ..... :	Ultrasound Diagnostic Systems
Trade Mark(s) ..... :	VINNO
Manufacturer ..... :	Same as applicant
Model/Type reference ..... :	VINNO E20, VINNO E10, VINNO E10E, VINNO E10P, VINNO X3, VINNO X2, VINNO X2E, VINNO X2P, VINNO X1, VINNO X1E, VINNO X1P
Ratings ..... :	100-240V~, 50/60Hz, 400VA, Class I

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):

☒	**CB Testing Laboratory:**	Intertek Testing Services Shanghai	
Testing location/ address.....:		Building No. 86, 1198 Qinzhou Road (North) 200233 Shanghai CHINA	
Tested by (name, function, signature).....:		Kay Luo / Yann Yan (Engineer)	Kay Luo Yann Yan
Approved by (name, function, signature)...:		Jack Cheng (Mandated reviewer)	Jack Cheng
☐	**Testing procedure: CTF Stage 1:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address.....:			
Tested by (name, function, signature).....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
Supervised by (name, function, signature) :			

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

Attachment 1: Software– IEC 62304:2006+AMD1:2015 (20 pages)

Attachment 2: Photo of EUT (24 pages)

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
4.11 Power Input 5.7 Humidity Preconditioning treatment 5.9.2 Determination of accessible parts 7.1.2 Legibility of markings 7.1.3 Durability of Marking test 8.4.3 Plug discharge test 8.6.4 Impedance and current-carrying capability of protective earth connections 8.7 Leakage current test 8.8.3 Dielectric strength test 8.8.4.1 Ball pressure test 8.9.3.2 Thermal cycling 9.4.2.1 Instability in transport position 9.4.2.2 Instability excluding transport\ 9.4.2.3 Instability from horizontal and vertical force 9.4.2.4.2 Force for propulsion 9.4.2.4.3 Movement over a threshold 9.4.3.1 Instability in transport position (including sliding) 9.4.3.2 Instability excluding transport (including sliding) 9.4.4c) Grips and other handling devices 9.6.2.1 Audible acoustic energy 11.1 Excessive temperatures test 11.6.5 Ingress of water or particulate matter into ME equipment and ME system 11.6.6 Cleaning and disinfection of ME equipment and ME system 11.8 Interruption of the power supply / supply mains to ME equipment 13.2 Single fault conditions 15.3 Mechanical strength tests 16.6.1 ME Systems – Leakage measurements	Intertek Testing Services Shanghai Building No. 86, 1198 Qinzhou Road (North) 200233 Shanghai CHINA

Summary of compliance with National Differences (List of countries addressed):

None

Statement concerning the uncertainty of the measurement systems used for the tests

☒ **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

Procedure number, issue date and title:

GMS-QC-12 Estimation of Measurement Uncertainty, 1-July-2012 Initial Release.

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

☐ **Statement not required by the standard used for type testing**

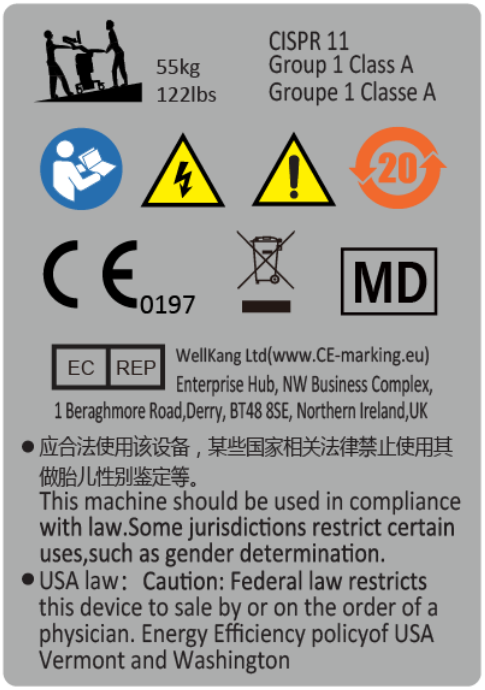
Copy of marking plate:

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

Marks on the main unit (typical model VINNO E20, other models were same except model name, REF number, SN number, date of manufacture and UDI number):

Rating Labels:

Safety Sign:



Marks on the ECG module kit:

Marks on the probes:

For models G1-4P

Note: The labels for other probes are the same as above except for model name, REF number, SN number and date of manufacture.

Test item particulars.....:	
Classification of installation and use.....:	Mobile
Supply Connection.....:	Appliance coupler
Device type (component/sub-assembly/ equipment/ system)……..:	Equipment
Intended use (Including type of patient, application location)……:	Ultrasound Diagnosis
Mode of operation……:	Continuous
Accessories and detachable parts included……...:	Ultrasound probes, ECG module kit, Medical use printer, Foot switch, Bluetooth adapter, Wireless adapter, USB DVDRW
Other options include……..:	N/A
Possible test case verdicts:	
- test case does not apply to the test object.....:	N/A
- test object does meet the requirement.....:	P (Pass)
- test object was not evaluated for the requirement……..:	N/E (collateral standards only)
- test object does not meet the requirement.....:	F (Fail)
Abbreviations used in the report	
- normal condition……: N.C.	- single fault condition .....: S.F.C.
- means of Operator protection ……: MOOP	- means of Patient protection ....: MOPP
Testing.....:	
Date of receipt of test item .....:	2021-12-01
Date (s) of performance of tests.....:	2021-12-01 to 2021-12-31

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

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

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

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ **Yes** ☒ **Not applicable**
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) ..... :	VINNO Technology (Suzhou) Co., Ltd. 5F Building A, 4F Building C, No.27 Xinfa Rd., Suzhou Industrial Park, Suzhou, Jiangsu 215123, China

General product information and other remarks:

The product covered by this report is an ultrasound diagnostic system.

The product is considered as Class I, mobile equipment, with type BF applied parts.

All the types are intended to use for the following ultrasound evaluation clinical applications: Abdominal, Fetal/Obstetrics, Gynecology, Transvignal, Urology(including prostate), Transrectal, Cardiac(adult and child), Peripheral Vascular, small Organs/Parts (thyroid, breast, testicle, Musculo-skeletal Conventional and Superficial), Pediatrics (including neonatal cephalic), interventional(nerve block and vascular access), Intraoperative (abdominal, brain) and Adult Cephalic diagnostic Ultrasound applications

Model differences:

These products are divided into eleven models: VINNO E20, VINNO E10, VINNO E10E, VINNO E10P, VINNO X3, VINNO X2, VINNO X2E, VINNO X2P, VINNO X1, VINNO X1E, VINNO X1P. The main difference between the models is software function differences, fit of different probes, minor mechanical differences, No other substantial difference.

Model	Software & Function	Mechanical construction
VINNO E10, VINNO E10E, VINNO E10P	Part functions of VINNO E20 Supported ultrasonic probe models: same as VINNO E20	1)Same as VINNO E20, or 2)Same as VINNO E20 except support arm of keyboard can't be lifted
VINNO X3	Part functions of VINNO E20 Supported ultrasonic probe models: same as VINNO E20	Same as VINNO E20
VINNO X2, VINNO X2E, VINNO X2P	Part functions of VINNO E20 Supported ultrasonic probe models: same as VINNO E20	Same as VINNO E20
VINNO X1, VINNO X1E, VINNO X1P	Part functions of VINNO E20 Supported ultrasonic probe models: same as VINNO E20 except model X4-12L	Same as VINNO E20 except support arm of keyboard can't be lifted and can support 15.6" monitor and 8" touch panel

The product models with suffix "E", "P" are same except software functions difference for commercial purpose.

After evaluation, throughout this report VINNO E20 and VINNO X1 are tested as typical models.

Additional Information

The ECG module kit is to assist the ultrasonic imaging function, through identify the duration of diastole and systole to support image reading and synchronization. The ECG result is just for observation for the physician, not intended for production of ECG report for diagnostic purpose. So the particular standards for ECG (IEC 60601-2-25 and IEC60601-2-27) are not applicable.

Condition of acceptability:

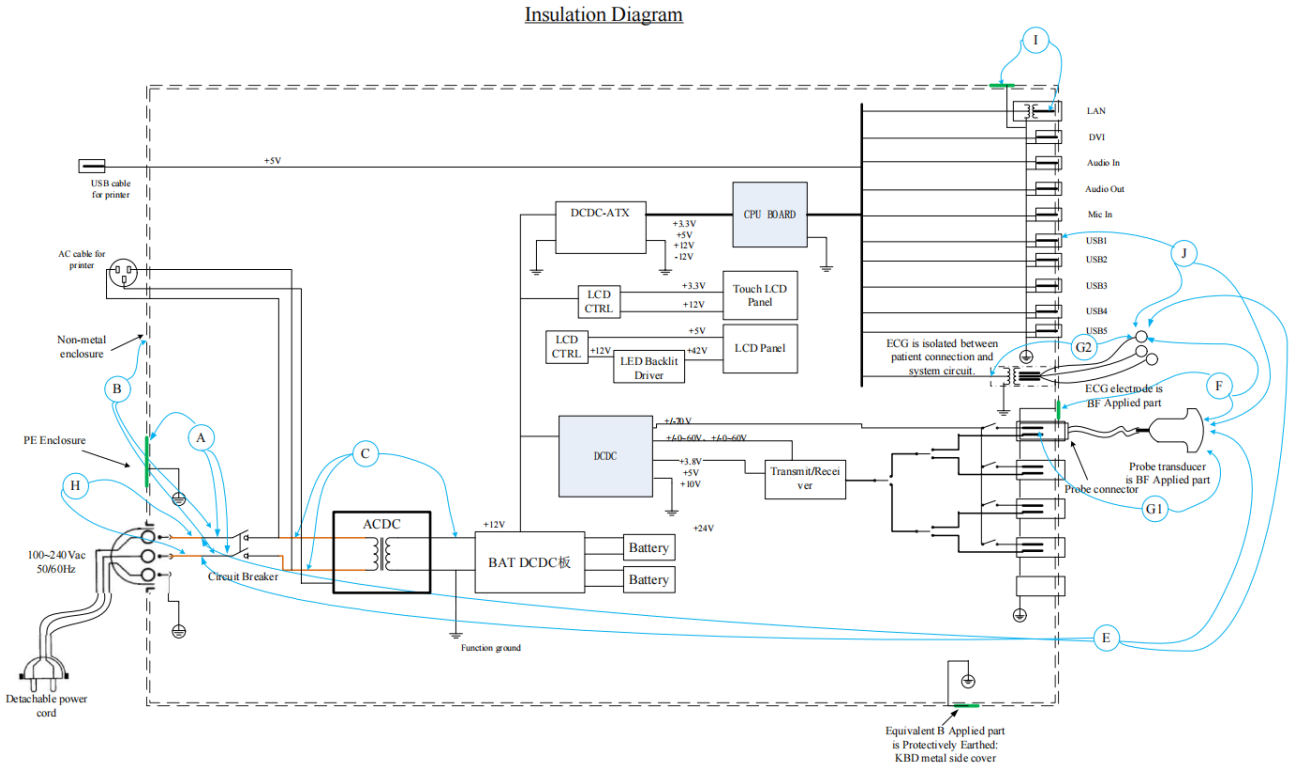
1) Clause 11.7 biocompatibility according to ISO 10993 is not evaluated in this test report.
2) Clause 17 EMC according to IEC 60601-1-2 is not evaluated in this report.
3) No alarm system for the product.

4) Any peripheral equipment for connecting with the product shall be separately approved by IEC60601-1 or IEC60950-1 as described in the user manual.
5) The network port on the product shall only be connected to the internal local area network which is treated as SELV circuit according to the definition of the manufacturer and the user manual.
6) ME equipment not intended for use in conjunction with flammable agents, which is described in User Manual.
7) ME equipment not intended for use in oxygen rich environment, which is described in User Manual.
8) The maximum safety load for the printer support on the product is 3kg as described in the user manual.

Determination of the test conclusion is based on IEC Guide 115 in consideration of measurement uncertainty.

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

INSULATION DIAGRAM



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

TABLE: INSULATION DIAGRAM		P
Pollution degree	**2**	—
Overvoltage category	**II**	—
Altitude	**Up to3000m (700-1060hPa)**	—
Additional details on parts considered as applied parts	☐ **None** ☒ **Areas: Housing and cable of all ultrasound transducers and ECG cable (See Clause 4.6 for details)**	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			V_{rms}	V_{pk}					
A	1MOPP	IIIb	240V	--	2.5	2.3	3.5	3.5	Earthed enclosure to mains
B	2MOOP	IIIb	240V	--	5.0	4.6	8.0	8.0	Not-earthed enclosure to mains
C	1MOPP	IIIb	240V	--	4	2.5	7.0	4.0	Probe to connector pins
D	1MOPP	IIIb	240V	--	4	2.5	6.3	6.3	ECG electrode to Secondary circuit
D	2MOPP	IIIb	--	65Vdc	6.0	3.2	6.3	6.3	ECG electrode to Secondary circuit
E	2MOOP	IIIb	240V	--	5.0	4.6	---	---	Recognized AC-DC
F	1MOOP	IIIb	240V	--	2.5	2.3	3.0	3.0	Mains opposite polarity
G1	2MOPP	IIIb	240V	--	8	5	>11	>11	Applied parts (Probe) to mains
G2	2MOPP	IIIb	240V	--	8	5	>11	>11	Applied parts (ECG) to mains
H	1MOPP	IIIb	240V	--	4	2.5	7.0	4.0	Secondary circuit to Applied parts (Probe)

IEC 60601-1									
Clause	Requirement + Test					Result - Remark			Verdict
H	2MOPP	IIIb	--	65Vdc	6.0	3.2	7.0	4.0	Secondary circuit to Applied parts (Probe)

Supplementary Information:

1) Multiplication factor for MOOP: 1.14.

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

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

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

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

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

4	**GENERAL REQUIREMENTS**		**P**
4.1	**Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse**		**P**
4.2	**RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS**		**P**
4.2.2	General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2019)…….:	See Appended RM Results Table 4.2.2.	**P**
4.2.3	Evaluating RISK		**P**
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level		**P**
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN…… :	RISK MANAGEMENT PLAN Document: Risk management plan (Doc#: RMP-TSUGA, VER#: 7) Chapter 4 “Risk acceptance criteria” A series products intended use and safety feature analysis (Doc#: SFA-TSUGA, VER#: 2)	**P**
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		**N/A**
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		**N/A**
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.		**P**
4.3	Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.	RM File Reference to Essential performance: SFA--TUSGA	**P**
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.		**P**
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		**P**
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE……:	See Appended Table 4.3	**P**
	- RISK CONTROL measures implemented		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		**P**
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE……:	Expected service life: 8 years	**P**
4.5	Alternative RISK CONTROL methods utilized:		**N/A**
	RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		**N/A**
	Alternative means based scientific data or clinical opinion or comparative studies ……:		**N/A**
4.6	RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10 ……..:	See Appended Insulation Diagram Table	**P**
	MANUFACTURER assesses the risk of accessible parts coming into contact with the patient: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. _5.2-5.5, 6, 7.1-7.4_) RMM-TUSGA REV2 Hazard ID H1.1-H1.5	**P**
	Assessment identified the APPLIED PART TYPE requirements ……..:	Type BF	**P**
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2……:		**P**
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested……: (ISO 14971 Cl. 4.2-4.4)	RISK ANALYSIS reference: (ISO 14971 Cl._4.2-4.4_) RMM-TUSGA REV2	**P**
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically……..:	See appended Table 13.2 for simulated physical test	**P**
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified ……..:	All components are used according to their applicable ratings. See appended critical component list	**P**
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings ……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		**N/A**
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION ……..:		**N/A**
	Components determined to be acceptable where used as a MEANS OF PROTECTION …….:		**N/A**
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following	See appended critical components list.	**P**
	a) Applicable safety requirements of a relevant IEC or ISO standard		**P**
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		**P**
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately……..:	No component with high integrity characteristics used	**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		**N/A**
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:		**N/A**
4.10	**Power supply**		**P**
4.10.1	ME EQUIPMENT is suitable for connection to indicated power source (select applicable) ……:	Supply mains	**P**
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:		**P**
	- 250 V for HAND-HELD ME EQUIPMENT (V)..... :	Not hand-held ME Equipment	**N/A**
	– 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V) ..... :	100-240V~, single-phase	**P**
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS		**N/A**
4.11	**Power input**		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%..... :	See appended Table 4.11	**P**
5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		**P**
5.1	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods ……..:	Test performed	**N/A**
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. (ISO 14971 Cl. 5.2-5.5)		**N/A**
5.3	Tests conducted within the environmental conditions specified in technical description		**P**
	Temperature (ºC), Relative Humidity (%) ……..:	Temperature:10 ℃ to 40 ℃ Humidity:30% to 75%	**—**
	Atmospheric Pressure (kPa) ……..:	70 to 106 kPa	**—**
5.5	a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V)……..:	(+/-10%) on range and/or rated values used for least favourable conditions.	**P**
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)..... :	50/60 Hz	**P**
	c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current ..... :		**N/A**
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered..... :	Not intended for d.c. supply connection	**N/A**
	e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions..... :	Probe	**P**
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	Not connected to a separate power supply	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3……..:	Humidity preconditioning performed prior to tests of Clauses 8.7.4 and 8.8.3	**P**
	ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +32°C for indicated time	T = 30°C	**—**
5.9	**Determination of APPLIED PARTS and ACCESSIBLE PARTS**		**P**
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS..... :	Refer to "Safety Classification" in the user manual.	**P**
5.9.2	**ACCESSIBLE PARTS**		**P**
5.9.2.1	Accessibility determined using standard test finger of Fig. 6	See Appended Table 5.9.2	**P**
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s		**P**
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS.....:	No such parts	**N/A**
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL ..... :		**N/A**
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		**P**
6.2	CLASS I ME EQUIPMENT, externally powered	Complied	**P**
	CLASS II ME EQUIPMENT, externally powered		**N/A**
	INTERNALLY POWERED ME EQUIPMENT		**N/A**
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements		**N/A**
	TYPE B APPLIED PART		**N/A**
	TYPE BF APPLIED PART	Ultrasound probe and ECG leads	**P**
	TYPE CF APPLIED PART		**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529..... :	Main unit: IPX0 Probe main part: IPX7 The cables of probes: IPX4 Approved foot switch: IP68.	**P**
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use..... :	Not intended to be sterilized.	**N/A**
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2	Not intended for use in oxygen rich environment.	**N/A**
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION..... :	Continuous operation	**P**
7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6……:	See Appended Table 7.1.2	**P**
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE	See appended Tables 7.1.3	**P**
7.2	**Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**		**P**
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ……..:	See copy of Marking Plate	**P**
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS ……:	Markings fully recorded in accompanying documents	**P**
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT		**P**
	Single use item marked……..:	No part for single use	**N/A**
7.2.2	ME EQUIPMENT marked with:		**P**
	– the name or trademark and contact information of the MANUFACTURER	See copy of Marking Plate	**P**
	– a MODEL OR TYPE REFERENCE	See copy of Marking Plate	**P**
	– a serial number or lot or batch identifier; and	See copy of Marking Plate	**P**
	– the date of manufacture or use by date	See copy of Marking Plate	**P**
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	Detachable components are marked individually.	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.3)		**N/A**

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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V)……:	100-240V~	**P**
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)…..:	Not multiple rated supply voltages	**N/A**
	– Nature of supply and type of current……..:	AC	**P**
	Symbols 1-5, Table D.1 (used for same parameters……:	~	**P**
	– RATED supply frequency or RATED frequency range in hertz……:	50/60Hz	**P**
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT……..:	Class I	**N/A**
7.2.7	RATED input in amps or volt-amps, (A, VA)……:	400VA	**P**
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W)……..:		**N/A**
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W)……..:	See marking plate	**P**
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W)……:		**N/A**
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA)……:	No long-time and momentary operation	**N/A**
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W)…….:		**N/A**
7.2.8	**Output connectors**		**N/A**
7.2.8.2	Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment		**N/A**
	Rated Voltage (V), Rated Current (A)……..:		**—**
	Rated Power (W), Output Frequency (Hz)…….:		**—**
7.2.9	ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2), marking optional for ME EQUIPMENT or parts rated IPX0….:	Probes main part: IPX7 The cables of probes: IPX4 Foot switch: IP68	**P**

IEC 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 ……..:	See marking labels	**P**
	TYPE B APPLIED PARTS with symbol 19 of Table D.1……..:		**N/A**
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1:	Type BF applied part symbol used in all transducer labels and ECG module kit.	**P**
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1……..:		**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1……:		**N/A**
	Proper symbol marked adjacent to or on connector for APPLIED PART……..:	Marked on each applied part connectors.	**P**
	SAFETY SIGN 2 of Table D.2 placed near relevant outlet……..:		**N/A**
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use……:		**N/A**
7.2.11	ME EQUIPMENT suitable for CONTINUOUS OPERATION		**P**
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum “on” and “off” time……..:		**N/A**
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder	No accessible fuse-holder. Circuit current provided.	**N/A**
	Fuse type……:		**—**
	Voltage (V) and Current (A) rating……:		**—**
	Operating speed (s) and Breaking capacity……:		**—**
7.2.13	Physiological effects – SAFETY SIGN and warning statements ……..:	Safety sign used.	**P**
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use……. (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	RMF Reference to specific RISKS: RMM-TSUGA Rev2, Row H1.31 (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	**P**
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1	No such hazard	**N/A**
7.2.15	Requirements for cooling provisions marked……:	No such hazard	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.2.17	Packaging marked with special handling instructions for transport and/or storage……:		**P**
	Permissible environmental conditions marked on outside of packaging……..:	Temperature, Pressure and Humidity	**P**
	Packaging marked with a suitable SAFETY SIGN indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK……..:	No such hazard	**N/A**
	RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK……: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)		**N/A**
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization	No sterilization needed.	**N/A**
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and ……..:	No such condition	**N/A**
	- the RATED flow rate also marked		**N/A**
7.2.19	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL……..:	No functional earth terminal	**N/A**
7.2.20	Removable protective means marked to indicate the necessity for replacement when the function is no longer needed……..:	No such condition	**N/A**
7.2.21	MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms.....	See attached copy of Marking Plate	**P**
7.3	**Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts**		**P**
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W)……:	No heating element	**N/A**
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL	No such condition	**N/A**
7.3.2	Symbol 24 of Table D.1, or SAFETY SIGN No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts……:	No high voltage parts.	**N/A**
7.3.3	Type of battery and mode of insertion marked..:	No battery	**N/A**
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL……..:		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK		**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an HAZARDOUS SITUATION if replaced incorrectly……: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)		**N/A**
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARDOUS SITUATION……:		**N/A**
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified ……..……..:	Approved SMPS power module used. Other fuses used in the T-power parts are SMT type and not replaceable.	**N/A**
	Voltage (V) and Current (A) rating……..		**—**
	Operating speed(s), size & breaking capacity….:		**—**
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1	Marked inside	**P**
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		**P**
7.3.6	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS	No functional earth terminals used.	**N/A**
7.3.7	Terminals for supply conductors marked adjacent to terminals……:	Approved appliance inlet used.	**N/A**
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings		**N/A**
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3		**N/A**
	Marking for connection to a 3-phase supply, complies with IEC 60445		**N/A**
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		**N/A**
7.3.8	“For supply connections, use wiring materials suitable for at least X °C” or equivalent, marked at the point of supply connections		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		**N/A**
7.4	**Marking of controls and instruments**		**P**
7.4.1	The “on” & “off” positions of switch to control power to ME EQUIPMENT, including mains switch, marked with symbols 12 and 13 of Table D.1 or		**P**
	– indicated by an adjacent indicator light, or		**N/A**
	– indicated by other unambiguous means	Also indicated by screen	**P**
	The “on” & “off” positions of switch to control power to parts of ME EQUIPMENT, marked with symbols 12 and 13 of Table D.1 or		**N/A**
	- marked with symbols 16 and 17 of Table D.1 or		**N/A**
	– indicated by an adjacent indicator light, or		**N/A**
	– indicated by other unambiguous means		**N/A**
	Switches that brings ME EQUIPMENT into “stand-by” may be indicated by symbol 29 of Table D.1		**P**
	The “on/off” positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, and		**N/A**
	– status indicated by adjacent indicator light		**N/A**
	– status indicated by other unambiguous means		**N/A**
	The “on/off” positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or	No such button used.	**N/A**
	– status indicated by adjacent indicator light		**N/A**
	– status indicated by other unambiguous means		**N/A**
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means		**P**
	RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1, 7.2)	RMF Reference to specific RISKS: RMM-TUSGA Rev2 H2.10-H2.11 H2.26-H2.28 H2.43-H2.44 List of controls: (ISO14971 Cl._5.2-5.5, 6, 7.1, 7.2_)	**P**
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE……..:	See above	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– or an indication of direction in which magnitude of the function changes		**P**
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units		**P**
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units		**P**
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3……:	See Appended Tables 7.1.2 and 7.1.3.	**P**
7.5	**SAFETY SIGNS**		**P**
	SAFETY SIGN with established meaning used		**P**
	RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR……: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	RMF Reference to specific RISK & Marking: RMM-TUSGA Rev2 H1.6 H1.38-H1.39 H1.51 SAFETY SIGN Used: (ISO 14971 Cl._5.2-5.5, 6, 7.2_)	**P**
	Affirmative statement together with SAFETY SIGN placed in instructions for use if insufficient space on ME EQUIPMENT		**P**
	Specified colours in ISO 3864-1 used for SAFETY SIGNS……:	Specified colours used	**P**
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		**P**
	SAFETY SIGNS including any supplementary text or symbols described in instructions for use	Refer to “Label Icon description” in the user manual	**P**
	- and in a language acceptable to the intended OPERATOR	English version checked	**P**
7.6	**Symbols**		**P**
7.6.1	Meanings of symbols used for marking described in instructions for use……:	Refer to “Label Icon description” in the user manual	**P**
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable		**P**
7.7	Colours of the insulation of conductors		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation	All PE conductors are coloured as specified by this clause.	**P**
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations		**P**
7.7.3	Green and yellow insulation identify only following conductors:		**P**
	– PROTECTIVE EARTH CONDUCTORS		**P**
	– conductors specified in 7.7.2		**P**
	– POTENTIAL EQUALIZATION CONDUCTORS		**P**
	– FUNCTIONAL EARTH CONDUCTORS		**N/A**
7.7.4	Neutral conductors of POWER SUPPLY CORDS are “light blue”		**P**
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1	Certified power supply cord used.	**P**
7.8	Indicator lights and controls		**P**
7.8.1	Red indicator lights, not flashing used only for Warning		**N/A**
	Yellow indicator lights, not flashing used only for Caution		**N/A**
	Green indicator lights used only for Ready for use		**P**
	Red flashing used only for HIGH PRIORITY ALARM CONDITION, interruption of current workflow needed		**N/A**
	Yellow flashing used only MEDIUM PRIORITY ALARM CONDITION, re-planning of workflow needed		**N/A**
	Yellow or Cyan, not flashing used for LOW PRIORITY ALARM CONDITION, planning of future workflow needed.		**N/A**
	Other colours: Meaning other than red, yellow, cyan or green (colour, meaning)……:	Orange indictor used for standby mode	**P**
7.8.2	Red used only for emergency control	no emergency controls	**N/A**
7.9	**ACCOMPANYING DOCUMENTS**		**P**
7.9.1	ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		**P**
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to……:	Described in chapter 1 general of user manual	**P**
	– MODEL or TYPE REFERENCE……:	Described in chapter 1 general of user manual	**P**
	When ACCOMPANYING DOCUMENTS provided electronically, USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT	Accompanying document has been provided as both hard copy and soft copy.	**N/A**
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	Described in chapter 2 safety of user manual	**P**
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	English used.	**P**
7.9.2	Instructions for use include the required information		**P**
7.9.2.1	– use of ME EQUIPMENT as intended by the MANUFACTURER:	Refer to "Intended Use" in the user manual.	**P**
	– frequently used functions,	Described in the user manual	**P**
	– known contraindication(s) to use of ME EQUIPMENT	Refer to "Contraindication" in the user manual.	**P**
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient	Described in chapter 2 safety of user manual	**P**
	– name or trademark and address of the MANUFACTURER	Described in chapter 1 general of user manual	**P**
	– MODEL OR TYPE REFERENCE	Described in chapter 1 general of user manual	**P**
	Instruction for use included the following when the PATIENT is an intended OPERATOR:	The patient is not an intended operator.	**N/A**
	– the PATIENT is an intended OPERATOR		**N/A**
	– warning against servicing and maintenance while the ME EQUIPMENT is in use		**N/A**
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and		**N/A**
	–maintenance the PATIENT can perform		**N/A**
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of SAFETY SIGNS and symbols marked on ME EQUIPMENT	Described in chapter 2 safety of user manual	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Instructions for use are in a language acceptable to the intended operator	English used.	**P**
7.9.2.2	Instructions for use include all warning and safety notices		**P**
	Warning statement for CLASS I ME EQUIPMENT included	Described in chapter 2 safety of user manual	**P**
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	Described in chapter 2 safety of user manual	**P**
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	Described in chapter 2 safety of user manual	**P**
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	No such MSO used	**N/A**
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	No ME system	**N/A**
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions	Not intended to receive power from other equipment	**N/A**
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source	No such additional power source used.	**N/A**
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries……: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)		**N/A**
	Where the RISK is unacceptable, the IFU includes a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time.		**N/A**
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided…….:	No replaceable internal electrical power source used.	**N/A**
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK……:		**N/A**
7.9.2.5	Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE	Described in the user manual.	**P**
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to	No such hazardous materials and ingredients used	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected	Refer to "Network" in the user manual.	**P**
	APPLIED PARTS specified	Described in chapter 11 Probes and biopsy and other parts of user manual	**P**
7.9.2.6	Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation	Described in chapter 1 General of user manual	**P**
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device	Described in chapter 3 Start the system of user manual	**P**
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation	Described in chapter 3 Start the system of user manual	**P**
7.9.2.9	Information provided to operate ME EQUIPMENT	Described in the user manual	**P**
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	Refer to "Label Icon description" in the user manual.	**P**
7.9.2.10	A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message	Described in chapter 4 Prepare for an examination and patient data archive of user manual	**P**
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	Described in chapter 3 Start the system of user manual	**P**
7.9.2.12	Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified	Described in chapter 15 Probe Maintenance of user manual	**P**
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	No single use items.	**N/A**
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	Described in chapter 14 Operator maintenance and technical data of user manual	**P**
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT		**P**
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	No such rechargeable battery used.	**N/A**
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	Described in chapter 13 accessories and peripherals of user manual	**P**
	Other equipment providing power to ME SYSTEM sufficiently described		**N/A**
7.9.2.15	Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for us……..:	Described in chapter 2 safety of user manual	**P**
7.9.2.16	Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)	Described in the user manual and advanced technical manual	**P**
7.9.2.17	Instruction for use for ME EQUIPMENT emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation		**N/A**
7.9.2.18	The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile indicate that they have been sterilized and the method of sterilization	No sterilization needed.	**N/A**
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization		**N/A**
7.9.2.19	The instructions for use contain a unique version identifier……..:	Version 13	**P**
7.9.3	**Technical description**		**P**
7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use including		**P**
	-information required in 7.2		**P**
	-permissible environmental conditions of use including conditions for transport and storage…….. :	Refer to " Environment" in the user manual.	**P**
	-characteristics of the ME EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found	Described in chapter 14 operator maintenance and technical data of user manual	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	-special installation requirements such as the maximum permissible apparent impedance of SUPPLY MAINS		**N/A**
	-permissible range of values of inlet pressure and flow, and the chemical composition of cooling liquid		**N/A**
	-description of the means for checking the oil level in partially sealed oil filled ME EQUIPMENT or its parts		**N/A**
	-warning statement that addresses the HAZARDS that can result from unauthorized modification of the ME EQUIPMENT		**P**
	-information pertaining to ESSENTIAL PERFORMANCE and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency		**P**
	Technical description separable from instructions for use contains required information, as follows		**N/A**
	-information required by 7.2		**N/A**
	–applicable classifications in Clause 6, warning and safety notices, and explanation of SAFETY SIGNS marked on ME EQUIPMENT		**N/A**
	– brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and		**N/A**
	a unique version identifier……..:		**N/A**
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description		**N/A**
7.9.3.2	**The technical description contains the following required information**		**P**
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT……:	Not permanently installed	**N/A**
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and	Detachable power cords used.	**N/A**
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	Described in the user manual	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment to determine if replacement of components results in any unacceptable RISKS……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: RMM-TUSGA Rev2 H1.6 (ISO 14971 Cl._5.2-5.5, 6, 7.1-7.4_)	**P**
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component		**P**
7.9.3.3	Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair	Described in chapter 14 operator maintenance and technical data of user manual	**P**
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description	Described in chapter 2 safety of user manual	**P**
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		**P**
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS		**P**
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION……: (ISO 14971 Cl. 4.3)	RMF Reference to specific RISKS: RMM-TUSGA Rev2 H3.10 (ISO 14971 Cl.4.3)	**P**
8.2	**Requirements related to power sources**		**N/A**
8.2.1	**Connection to a separate power source**		**N/A**
	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM	Not intended to receive power from separate power source	**N/A**
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		**N/A**
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		**N/A**
8.2.2	**Connection to an external d.c. power source**		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source	Not intended to be connected with an external d.c. source.	**N/A**
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE		**N/A**
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset		**N/A**
8.3	**Classification of APPLIED PARTS**		**P**
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF		**N/A**
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART	All probes and ECG leads	**P**
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF		**N/A**
8.4	**Limitation of voltage, current or energy**		**P**
8.4.2	**ACCESSIBLE PARTS and APPLIED PARTS**		**P**
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT……:	See appended Table 8.7	**P**
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT……:	See appended Table 8.7	**P**
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed		**P**
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.)……:	See appended Table 8.4.2	**P**
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J)…….:		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Limits in b) does not apply to SIP/SOP connectors and separate power supply connectors if the voltage measured is less than or equal to 60 V d.c. or 42,4 V peak a.c		**N/A**
	d) Voltage and energy limits specified in c) above also applied to the following:		**P**
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	Not touchable by test rod	**N/A**
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL	Not touchable by test rod	**N/A**
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		**P**
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N		**P**
	Test repeated with a TOOL specified in instructions for use		**P**
	Test rod freely and vertically suspended through openings on top of ENCLOSURE	No opening on top of enclosure	**N/A**
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION	No such parts.	**N/A**
	A TOOL is required when it is possible to prevent the devices from operating		**N/A**
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one sec after disconnecting the plug of ME EQUIPMENT or its parts (V)……:	See appended Table 8.4.3	**P**
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45µC….:	Voltage not exceed	**N/A**
8.4.4	Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC….:	No such parts.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		**N/A**
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description……:		**N/A**
8.5	**Separation of parts**		**P**
8.5.1	**MEANS OF PROTECTION (MOP)**		**P**
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4	See appended insulation diagram and insulation table	**P**
	A MEANS OF PROTECTION protecting APPLIED PARTS or parts identified by 4.6 as parts subject to the same requirements, considered as MEANS OF PATIENT PROTECTION……..:		**P**
	Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION		**P**
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		**P**
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		**P**
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test……:	See appended Table 8.8.3	**P**
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		**P**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6		**P**
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION ……..:		**N/A**
	Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c……..:		**N/A**
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		**N/A**
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (μF)……:		**—**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Optocouplers complying with IEC 60747-5-5:2007, or a later edition. Considered equivalent to requirements in 8.8.2 and 8.9.3	Approved SMPS used	**P**
	Measurement of Air Clearance and Creepage distance on the outside	See insulation table	**P**
	Dielectric strength test across optocoupler	See table 8.8.3	**P**
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)		**P**
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		**P**
	– dielectric strength test ……:	See appended Table 8.8.3	**P**
	– requirements of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for INSULATION CO-ORDINATION		**N/A**
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		**P**
	– limits of Tables 13 to 16 (inclusive); or		**P**
	– requirements of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for INSULATION CO-ORDINATION		**N/A**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6		**P**
	– or with requirements and tests of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for protective earthing……:		**N/A**
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION……:	Part of certified filter, See appended Tables 8.10	**P**
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION……..:	Part of certified filter, See appended Tables 8.10	**P**
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	Part of certified filter, See appended Tables 8.10	**N/A**
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (μF)……..:		**—**
	Optocouplers complying with IEC 60747-5-5:2007, or a later edition. Considered equivalent to requirements in 8.8.2 and 8.9.3	Approved SMPS used, See table 8.10	**P**
	Measurement of Air Clearance and Creepage distance on the outside	See insulation table	**P**
	Dielectric strength test across optocoupler	See table 8.8.3	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Points and applied parts at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 were examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION		**P**
8.5.2	**Separation of PATIENT CONNECTIONS**		**P**
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAX. MAINS VOLTAGE……:	For additional RM information, see appended Tables 8.7 and 8.8.3 See also Table 11.6.1	**P**
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		**N/A**
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function	ECG leads have been considered as one applied part.	**P**
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS……:		**N/A**
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	Refer to “Safety Classification” in the user manual.	**P**
	LEAKAGE CURRENT tests conducted per 8.7.4….:	See appended Table 8.7	**P**
	Dielectric strength test conducted per 8.8.3……:	See appended Table 8.8.3	**P**
	CREEPAGE and CLEARANCES measured ……:	Refer to Insulation Diagram	**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	No protective device used.	**N/A**
8.5.2.2	PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED…:		**N/A**
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low. In this case 8.7.4.7 d) does not apply		**N/A**
	LEAKAGE CURRENT tests conducted per 8.7.4…:		**N/A**
	Dielectric strength test conducted per 8.8.3 …..:		**N/A**
	Relevant CREEPAGE and CLEARANCES measured		**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISK of metal ACCESSIBLE PARTS contacting a source of voltage or LEAKAGE CURRENT above the limits……: (ISO 14971 Cl. 5.2-5.5, 6)		**N/A**
8.5.2.3	**A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable distal from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE**		**P**
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT……:	ECG connector cannot be connected to earth or hazardous voltage.	**P**
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter		**P**
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm	Clearance between connector pins and a flat surface is at least 0.5 mm.	**P**
	– conductive part pluggable into a mains socket protected from contacting parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1	Connector cannot be plugged into mains socket.	**N/A**
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,		**P**
	Test finger test (10 N)……..:	See appended Table 5.9.2	**P**
	Except when RISK MANAGEMENT PROCESS includes an assessment of RISKS resulting from contact with objects other than mains sockets or flat surfaces……..: (ISO 14971 Cl. 5.2-5.5, 6)		**N/A**
8.5.4	**WORKING VOLTAGE**		**P**
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V)……..:	For testing purpose, 240 VAC was assumed as maximum mains voltage.	**P**

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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Parts complying with IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 or IEC 62368-1:2018 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8		**N/A**
8.6.2	PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR…….:	Approved appliance inlet used for the product	**P**
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL		**P**
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside……..:	Unable to be loosen from outside	**P**
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL	Approved appliance inlet used for the product	**P**
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		**P**
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part,	No PE connection used for a moving part	**N/A**
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE ……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		**N/A**
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop……:	See appended Table 8.6.4	**P**
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits……:	Impedance is not exceeded	**N/A**
	DETACHABLE POWER SUPPLY CORD specified by manufacturer or delivered with product		**P**
8.6.5	**Surface coatings**		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Poorly conducting surface coatings on conductive elements removed at the point of contact		**P**
	Coating not removed when requirements for impedance and current-carrying capacity met		**N/A**
8.6.6	**Plugs and sockets**		**P**
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections	Approved appliance inlet and power supply cord set used for the product	**P**
	- applied also where interchangeable parts are PROTECTIVELY EARTHED	No such interchangeable protectively earthed parts	**N/A**
8.6.7	**Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR**		**N/A**
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE		**N/A**
	–accidental disconnection avoided in NORMAL USE		**N/A**
	– Terminal allows conductor to be detached without a TOOL		**N/A**
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		**N/A**
	– Terminal marked with symbol 8 of Table D.1		**N/A**
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		**N/A**
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		**N/A**
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION		**N/A**
8.6.9	**Class II ME EQUIPMENT**		**N/A**
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow	Not class II ME equipment	**N/A**
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS		**N/A**
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		**P**
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3……..:	See appended Tables 8.7	**P**
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7……..:	See appended Tables 8.7	**P**
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		**P**
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)	8.6.4a) test passed	**N/A**
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		**P**
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		**P**
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		**P**
8.7.3	**Allowable Values**		**P**
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b……..:	See appended Table 8.7	**P**
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz……:	See appended Table 8.7	**P**
	c) TOUCH CURRENT did not exceed 100µA in NORMAL CONDITION and 500µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC})……..:	See appended Table 8.7	**P**
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC})……..:	See appended Table 8.7	**P**

IEC 60601-1			
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……:	Not permanently installed equipment	**N/A**
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device……:	See appended Table 8.7	**P**
	f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION….:	No functional earth terminals used.	**N/A**
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements……..:	See appended Table 8.7	**P**
8.8	Insulation		**P**
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing		**P**
	Insulation exempted from test (complies with clause 4.8)		**P**
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		**N/A**
8.8.2	**Distance through solid insulation or use of thin sheet material**		**P**
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		**P**
	a) 0.4 mm, min, distance through insulation, or		**P**
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:	Evaluated as Part of Certified Power Supply Unit.	**P**
	– at least two layers of material, each passed the appropriate dielectric strength test.....	See appended Table 8.8.3	**N/A**
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test.....	Evaluated as Part of Certified Power Supply Unit.	**P**
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		**N/A**
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		**N/A**
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		**N/A**
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		**N/A**
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L		**N/A**
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		**N/A**
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		**N/A**
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		**N/A**
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values		**N/A**
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension……:		**N/A**
	Finished component complied with routine dielectric strength tests of 8.8.3……:		**N/A**
	Tests of Annex L not repeated since material data sheets confirm compliance……:		**N/A**
8.8.3	**Dielectric Strength**		**P**
	Solid insulating materials with a safety function withstood dielectric strength test voltages ……..:	See appended Table 8.8.3	**P**
8.8.4	**Insulation other than wire insulation**		**P**
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		**P**
	ME EQUIPMENT and design documentation examined……:	See appended table 8.10.	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: RMM-TUSGA Rev2 H1.1-H1.5 H1.7-H1.11 H1.18 H1.27-H1.28 H1.36-H1.37 H1.40-H1.47 H1.53 H1.55 (ISO 14971 Cl.5.2-5.5, 6, 7.1-7.4)	**P**
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat……..:		**N/A**
	Tests conducted in absence of satisfactory evidence for resistance to heat……..:	Test performed	**P**
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus…..:	See appended Table 8.8.4.1	**P**
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C)…….:		**N/A**
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION		**N/A**
8.8.4.2	**Resistance to environmental stress**		**P**
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9		**P**
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	No such materials used.	**N/A**
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	No heating conductors used.	**N/A**
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples	No such materials used.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h		**N/A**
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**		**P**
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive)……:	Refer to Insulation Diagram	**P**
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1		**N/A**
8.9.1.16	Conductive coatings applied to non-metallic surfaces, do not result in flaking or peeling reducing any AIR CLEARANCE or CREEPAGE DISTANCE		**P**
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION , min CREEPAGE and CLEARANCES not applied……..:	Minimum requirement applied and complied	**N/A**
8.9.3	**Spaces filled by insulating compound**		**P**
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound		**P**
	Thermal cycling, humidity preconditioning, and dielectric strength tests		**P**
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage)……:	See appended Table 8.9.3.2	**P**
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		**P**
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint		**N/A**
	A winding of solvent-based enamelled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		**N/A**
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage ……..:		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage		**N/A**
8.9.4	Minimum spacing of grooves transvers to the CREEPAGE DISTANCES considered a MEANS OF OPERATOR PROTECTION adjusted based on pollution degree ……:	Pollution degree: 2	**P**
	Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES	Refer to Insulation Diagram supplemental information for location and force used	**P**
8.10	**Components and wiring**		**P**
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely……:	Mounted securely	**P**
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		**N/A**
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment……:	Adequately secured	**P**
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS		**P**
8.10.3	Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken ……:	No such cords used	**N/A**
8.10.4	**Cord-connected HAND-HELD parts and cord-connected foot-operated control devices**		**P**
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION	Footswitch	**P**
8.10.4.2	Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3	Footswitch See appended Table 8.11.3.5	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3	This clause is not applied for probes according to clause 201.8.10.4 of particular standard IEC60601-2-37.	**N/A**
8.10.5	**Mechanical protection of wiring**		**P**
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges…….:	Internal cables and wiring adequately protected against from friction at sharp corners and edges.	**P**
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS		**P**
8.10.6	Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead	No guiding rollers used.	**N/A**
8.10.7	a) Insulating sleeve adequately secured…….:	See appended Table 8.10	**P**
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics		**P**
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C……:	See appended Table 8.10 Approved conductors used	**N/A**
8.11	**MAINS PARTS, components and layout**		**P**
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles……:	See appended Table 8.10 Main switch and appliance coupler	**P**
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	Not permanently installed ME equipment.	**N/A**
	PERMANENTLY INSTALLED ME EQUIPMENT provided with means to isolate its circuits electrically from the SUPPLY MAINS are capable of being locked in the off position		**N/A**
	- the isolation device specified in the ACCOMPANYING DOCUMENTS		**N/A**
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description ……:	See appended Table 8.10	**P**
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV……:	See appended Table 8.10	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead		**P**
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		**P**
	f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH……:	See appended Table 8.10	**P**
	g) A fuse or a semiconductor device not used as an isolating means		**P**
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device		**P**
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering	No such part	**N/A**
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage		**N/A**
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		**N/A**
	Standard test finger applied		**N/A**
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	No MSO	**N/A**
8.11.3	**POWER SUPPLY CORDS**		**P**
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD		**P**
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design 53):	See appended Table 8.10	**P**
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE ……:	No external metal parts with a temperature > 75 °C touchable by the cord in normal use.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17……:	See appended Table 8.10	**P**
	For ME EQUIPMENT utilizing POWER SUPPLY CORDS and operating at currents greater than 63 A, apply the electrical regulations appropriate for the jurisdiction in which the ME EQUIPMENT is to be used.	No such condition	**N/A**
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6 ……:	See appended Table 8.10	**P**
8.11.3.5	**Cord anchorage**		**N/A**
	a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage	Appliance coupler complies with IEC 60320-1.	**N/A**
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or		**N/A**
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		**N/A**
	– metal provided with an insulating lining affixed to cord anchorage		**N/A**
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		**N/A**
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components		**N/A**
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals		**N/A**
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		**N/A**
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18		**N/A**
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position		**N/A**
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		**N/A**
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged		**N/A**
8.11.3.6	POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment	Appliance coupler complies with IEC 60320-1.	**N/A**
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		**N/A**
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram attached to the free end of cord (g)……..:		**N/A**
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		**N/A**
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D ……..:		**N/A**
8.11.4	**MAINS TERMINAL DEVICES**		**N/A**
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection	No such mains terminal device	**N/A**
	Terminals alone are not used to keep conductors in position		**N/A**
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors		**N/A**
	Screws and nuts clamping external conductors do not serve to secure any other component		**N/A**
8.11.4.2	**Arrangement of MAINS TERMINAL DEVICES**		**N/A**
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection		**N/A**
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	e) MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction		**N/A**
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced after fastening and loosening a conductor of largest cross-sectional area 10 times		**N/A**
8.11.4.4	Terminals with clamping means for a rewireable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened		**N/A**
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewireable POWER SUPPLY CORD to allow for connection of conductors		**N/A**
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test		**N/A**
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		**P**
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection….:	See appended Table 8.10	**P**
	- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT……..:	Class I ME equipment.	**N/A**
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	Not permanently installed equipment	**N/A**
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART		**N/A**
	Protective devices have adequate breaking capacity based on MANUFACTURER'S expectation of the highest branch circuit current and/or prospective short circuit current:	See appended Table 8.10 Evaluated as Part of Certified Power Supply Unit.	**P**
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		**P**
	Justification for omission of fuses or OVER-CURRENT RELEASES documented……..:	No omission	**N/A**
8.11.6	**Internal wiring of the MAINS PART**		**P**
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable..		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient……:	See appended Table 8.10 for details	**P**
9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		**P**
9.2	**HAZARDS associated with moving parts**		**P**
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……:	All use scenarios analysed and required risk controls are implemented	**P**
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)		**P**
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and		**P**
	RISK CONTROLS implemented……..:	Provided a safety sign on ME equipment.	**P**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: RMM-TSUGA, Row H1.38-1.41 (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	**P**
	All RISKS associated with moving parts have been reduced to an acceptable level		**P**
9.2.2	**TRAPPING ZONE**		**N/A**
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:	No trapping zone, manually operated only	**N/A**
	– Gaps in Clause 9.2.2.2, or		**N/A**
	– Safe distances in Clause 9.2.2.3, or		**N/A**
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or		**N/A**
	– Continuous activation in Clause 9.2.2.5	Manually operated only	**N/A**
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM		**N/A**
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20….:	No trapping zone, manually operated only	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008 …:	No trapping zone, manually operated only	**N/A**
9.2.2.4	**GUARDS and other RISK CONTROL measures**		**N/A**
9.2.2.4.1	A TRAPPING ZONE do not to present a MECHANICAL HAZARD when GUARDS or other RISK CONTROL measures are of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK……:	No guards provided	**N/A**
9.2.2.4.2	FIXED GUARDS held in place by systems that can only be dismantled with a TOOL		**N/A**
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open		**N/A**
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,		**N/A**
	– absence or failure of one of their components prevents starting, and stops moving parts		**N/A**
	Movable GUARDS complied with any applicable tests		**N/A**
9.2.2.4.4	Other RISK CONTROL designed and incorporated into to the control system stops movement and		**N/A**
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or		**N/A**
	ME EQUIPMENT is SINGLE FAULT SAFE		**N/A**
9.2.2.5	**Continuous activation**		**N/A**
	Continuous activation used as a RISK CONTROL, complies with the following	The moving parts of the product can only be driven manually.	**N/A**
	a) movement was in OPERATOR'S field of view		**N/A**
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR		**N/A**
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or		**N/A**
	- the continuous activation system is SINGLE FAULT SAFE		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement	The moving parts of the product can only be driven manually.	**P**
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		**P**
9.2.3	**Other MECHANICAL HAZARDS associated with moving parts**		**P**
9.2.3.1	Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated	Cannot be accidentally actuated	**P**
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or		**P**
	- activation does not result in an unacceptable RISK		**P**
9.2.3.2	Over travel past range limits of the ME EQUIPMENT prevented……:	No overtravel	**N/A**
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse…..:		**N/A**
9.2.4	**Emergency stopping devices**		**N/A**
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power……:	No emergency stopping devices used.	**N/A**
	a) Emergency stopping device reduced RISK to an acceptable level		**N/A**
	RISK MANAGEMENT FILE indicates the use of an emergency stopping device reduces the RISK to an acceptable level……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.5)		**N/A**
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		**N/A**
	c) Emergency stopping device actuator was readily accessible to OPERATOR		**N/A**
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		**N/A**
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		**N/A**
	g) Means for stopping of movements operate as a result of one single action		**N/A**
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		**N/A**
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or "STOP"		**N/A**
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed		**N/A**
	k) Emergency stopping device is suitable for its application		**N/A**
9.2.5	Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping	No physical restriction against patient.	**N/A**
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		**N/A**
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented		**N/A**
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way		**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT ……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		**N/A**
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered……:	No rough surface, or sharp corners and edges.	**P**
9.4	**Instability HAZARDS**		**P**
9.4.1	ME EQUIPMENT and its parts, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.4.2	**Instability – overbalance**		**P**
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested ……:	See appended Table 9.4.2.1	**P**
9.4.2.2	**Instability excluding transport**		**P**
	ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE,.....:	See appended Table 9.4.2.2	**P**
	A warning provided when overbalance occurred during 10° inclined plane test	No overbalanced during 10°test	**N/A**
9.4.2.3	**Instability from horizontal and vertical forces**		**P**
	a) ME EQUIPMENT or its parts with a mass of 25kg or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it	55kg	**P**
	Surfaces of ME EQUIPMENT or its parts where a RISK of overbalancing exists from pushing, etc., permanently marked with a warning of the RISK		**N/A**
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)	See appended Table 9.4.2.3	**P**
	b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping	No sitting, no stepping during intended use	**N/A**
	ME EQUIPMENT or its parts, for use on the floor or on a table, where RISK of overbalancing exists, permanently marked with the RISK warning.....:		**N/A**
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b)……:		**N/A**
9.4.2.4	**Castors and wheels**		**P**
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE		**P**
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT did not exceed 200 N ……:	See appended Table 9.4.2.4.2	**P**
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold ……:	See appended Table 9.4.2.4.3	**P**
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	Not power-driven brake	**N/A**
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements	Locking castors provided.	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1	See appended Table 9.4.3.1	**P**
9.4.3.2	**Instability excluding transport**		**P**
	a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test ..... :	See appended Table 9.4.3.2	**P**
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test	See appended Table 9.4.3.2	**P**
9.4.4	**Grips and other handling devices**		**N/A**
	a) ME EQUIPMENT with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method		**N/A**
	Handles, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS		**N/A**
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying		**N/A**
	c) Carrying handles and grips and their means of attachment withstood loading test ..... :		**N/A**
9.5	**Expelled parts HAZARD**		**N/A**
9.5.1	Suitability of means of protecting against expelled parts determined by assessment and examination of RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
	All identified RISKS associated with expelled parts mitigated to an acceptable level		**N/A**
9.5.2	Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965 ..... :		**N/A**
9.6	**Acoustic energy (including infra- and ultrasound) and vibration**		**P**
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and		**P**
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity ..... :		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS:	**N/A**
	All identified RISKS mitigated to an acceptable level		**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		**P**
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA)	No cumulative exposure	**—**
	- 83 dBA (when halving the cumulative exposure time) (dBA)	No cumulative exposure	**—**
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB).....	58db	**—**
9.6.2.2	RISK MANAGEMENT FILE examined ..... (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: RMM-TUSGA Rev2 H1.31 H1.32 (ISO 14971 Cl._5.2-5.5, 6, 7.1-7.4_)	**P**
9.6.3	**Hand-transmitted vibration**		**N/A**
	Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values		**N/A**
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2)		**N/A**
	– Accelerations for different times, inversely proportional to square root of time (m/s^2).....		**N/A**
9.7	**Pressure vessels and parts subject to pneumatic and hydraulic pressure**		**N/A**
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE..... (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		**N/A**
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		**N/A**
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply		**N/A**
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		**N/A**
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity		**N/A**
9.7.4	MAXIMUM EQUIPMENT PRESSURE did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for the part, except allowed for pressure relief devices in 9.7.7confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests ..... :		**N/A**
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when MAXIMUM EQUIPMENT PRESSURE was more than 50 kPa, and product of MAXIMUM EQUIPMENT PRESSURE and volume was more than 200 kPa ..... :		**N/A**
9.7.6	Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE ..... :		**N/A**
9.7.7	Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests..... :		**N/A**
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		**N/A**
	b) Installed to be readily accessible for inspection, maintenance, and repair		**N/A**
	c) Could be adjusted or rendered inoperative without a TOOL		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	d) With discharge opening located and directed as to not to release material towards any person		**N/A**
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		**N/A**
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE EQUIPMENT PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure		**N/A**
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect		**N/A**
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		**N/A**
	RISK MANAGEMENT FILE includes an assessment of the risks associated with the discharge opening of the pressure relief device .....: ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
9.8	**HAZARDS associated with support systems**		**N/A**
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK ..... :		**N/A**
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		**N/A**
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		**N/A**
	– RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions .....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		**N/A**
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials		**N/A**
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		**N/A**
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest		**N/A**
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing.....		**N/A**
	RISK MANAGEMENT FILE includes an assessment of the structural integrity of support system..... (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
	All identified RISKS are mitigated to an acceptable level		**N/A**
	When test was conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK.....		**N/A**
	Where the equipment is not at equilibrium after 1 min, the RISK MANAGEMENT FILE includes an assessment of the test results..... (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
9.8.3	**Strength of PATIENT or OPERATOR support or suspension systems**		**N/A**
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints		**N/A**
	RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings..... (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts		**N/A**
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER		**N/A**
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications		**N/A**
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		**N/A**
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS		**N/A**
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance ..... :		**N/A**
9.8.3.2	a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m^2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR..... :		**N/A**
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests..... :		**N/A**
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK		**N/A**
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test ..... :		**N/A**
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE maintained BASIC SAFETY and ESSENTIAL PERFORMANCE confirmed test		**N/A**
9.8.4	**Systems with MECHANICAL PROTECTIVE DEVICES**		**N/A**
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided for the support system		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		**N/A**
	– Designed based on TOTAL LOAD		**N/A**
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		**N/A**
	– Activated before travel produced an unacceptable RISK		**N/A**
	– Considers Clauses 9.2.5 and 9.8.4.3		**N/A**
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests ..... :		**N/A**
9.8.4.2	Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE		**N/A**
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		**N/A**
9.8.4.3	**MECHANICAL PROTECTIVE DEVICE intended to function once**		**N/A**
	–use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE . :		**N/A**
	– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal		**N/A**
	– ME EQUIPMENT permanently marked with SAFETY SIGN 2 of Table D.		**N/A**
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE		**N/A**
	– Compliance confirmed by examination and following test..... :		**N/A**
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT		**N/A**
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		**N/A**
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.8.5	**Systems without MECHANICAL PROTECTIVE DEVICES**		**N/A**
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES..... :		**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		**N/A**
10.1	**X-Radiation**		**N/A**
10.1.1	The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT .....:		**N/A**
	Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE		**N/A**
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or .....:		**N/A**
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT ILE.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No such radiation	**N/A**
10.3	The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2	No such radiation	**N/A**
	Microwave radiation is propagated intentionally		**N/A**
10.4	Relevant requirements of IEC 60825-1:2014 applied to lasers including laser diodes, laser light barriers or similar with a wavelength range of 180nm to 1 mm.	No such radiation	**N/A**
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ...: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No such radiation	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
10.6	RISK associated with infrared radiation other than emitted by lasers addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No such radiation	**N/A**
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No such radiation	**N/A**
11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		**P**
11.1	**Excessive temperatures in ME EQUIPMENT**		**P**
11.1.1	Temperatures on ACCESSIBLE PARTS did not exceed values in Tables 22 and.....:	See appended Table 11.1.1	**P**
	Surfaces of test corner did not exceed 90 °C		**P**
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION		**P**
	RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISK: H1.32-H1.35 (ISO 14971 Cl._5.3-5.5, 6, 7.1-7.4_)	**P**
11.1.2	**Temperature of APPLIED PARTS**		**P**
11.1.2.1	APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply.....:		**N/A**
	Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use		**N/A**
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in NORMAL CONDITION and SINGLE FAULT CONDITION ..:		**P**
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:		**N/A**
	Maximum Temperature .....:		**—**
	Conditions for safe contact, e.g. duration or condition of the PATIENT.....:		**—**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Clinical effects with respect to characteristics taken or surface pressure documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
	APPLIED PARTS surface temperature of equal to or less than 41°C		**N/A**
	Analysis documented in the RISK MANAGEMENT FILE show that APPLIED PART temperatures are not affected by operation of the ME EQUIPMENT including SINGLE FAULT CONDITIONS. Measurement of APPLIED PART temperature according to 11.1.3 is not conducted		**N/A**
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS..... (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
11.1.3	Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE..... (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	Temperature measurement test carried out.	**N/A**
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE..... (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	Test corner used.	**N/A**
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE ..... (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE.....		**N/A**
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL		**N/A**
11.2	**Fire prevention**		**P**
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3		**P**
11.2.2	**Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS**		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of	Not used in conjunction with oxygen rich environments.	**N/A**
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions		**N/A**
	1) when temperature of material raised to its ignition temperature		**N/A**
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature		**N/A**
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating		**N/A**
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		**N/A**
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		**N/A**
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively……:		**N/A**
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three		**N/A**
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination ……..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3……:		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%)……:		**N/A**
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes		**N/A**
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE……..:		**N/A**
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases ……..:		**N/A**
11.2.2.2	RISK of ignition did not occur, and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT		**N/A**
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks		**N/A**
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		**N/A**
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		**N/A**
11.2.3	**SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered**		**N/A**
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2)……:		**N/A**
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3)……:		**N/A**
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a)……..:		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a)…….:		**N/A**
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas……..:		**N/A**
11.3	**Constructional requirements for fire ENCLOSURES of ME EQUIPMENT**		**P**
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2…….:		**P**
	Constructional requirements were met, or		**P**
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE …….. : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**
	Justification, when requirement not met…….:		**N/A**
	a) Flammability classification of insulated wire and connectors within fire ENCLOSURE is minimum V-2, , when test in accordance with IEC 60695-11-10 or :	See appended Table 8.10	**P**
	insulated with PVC, TFE, PTFE, FEP, polychloroprene or polyimide as determined by examination of data on materials……..:		**N/A**
	Flammability classification of printed circuit boards, and insulating material on which components are mounted is V-2, or better, based on IEC 60695-11-10 as decided by examination of materials data……:	See appended Table 8.10	**P**
	If no Certification, V tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings		**N/A**
	b) Fire ENCLOSURE met following:		**P**
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm		**P**
	2) No openings on the sides within the area included within the inclined line C in Fig 39 or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials……:	See appended Table 8.10	**P**
11.4	**ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics**		**N/A**
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G	Not intended for use with flammable anaesthetics	**N/A**
11.5	**ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents**		**N/A**
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE ……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	Not intended for use in conjunction with flammable agents	**N/A**
11.6	**Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT**		**P**
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT..... :	See Appended Table 11.6.1	**P**
11.6.2	**Overflow in ME EQUIPMENT**		**N/A**
	ME EQUIPMENT incorporates a reservoir or liquid storage that did not wet any MEANS OF PROTECTION, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE……:		**N/A**
	Maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.		**N/A**
11.6.3	**Spillage on ME EQUIPMENT and ME SYSTEM**		**P**
	ME EQUIPMENT and ME SYSTEMS handling liquids constructed that spillage does not wet parts as determined by review of the RISK MANAGEMENT FILE and test……..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	See appended Tables 11.6.1; 8.7, 8.8.3 and RMF Reference to specific RISK: RMM-TSUGA,	**P**
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill…….:	Volumn:200ml, Duration of spill:15s, Point of contact: on the keyboard	**P**
11.6.5	**Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**		**P**
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)…….:	See Appended Table 11.6.1 For the probes and foot switch only. The foot switch is separately approved.	**P**
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION..	See appended Tables 8.7 8.8.3	**P**
11.6.6	**Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS**		**P**
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use……..:	See Appended Tables 11.6.1, 8.7, and 8.8.3	**P**
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER……:	See Appended Tables 11.6.1	**P**
11.6.7	**Sterilization of ME EQUIPMENT and ME SYSTEMS**		**N/A**
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests……:	No sterilization needed.	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISKS associated with any deterioration following sterilization……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: RMM-TUSGA Rev2 H5.2 (ISO 14971 Cl.5.3-5.5, 6, 7.1-7.4)	**P**
11.7	Me equipment, me system, and accessories coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented	Biocompatibility is not investigated in this report	**N/A**
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		**P**
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		**P**
12.1	RISKS associated with accuracy of controls and instruments stated.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: RMM-TUSGA Rev2 H2.14 H2.17 H2.21-H2.24 (ISO 14971 Cl.5.3-5.5, 6, 7.1-7.4)	**P**
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING……:	See Report based on IEC 60601-1-6	**P**
12.3	MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020……:	No alarm system	**N/A**
12.4	**Protection against hazardous output**		**P**
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS……: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: RMM-TSUGA, Row H1.31 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**P**
12.4.2	- need for indication associated with hazardous output addressed in RISK MANAGEMENT PROCESS... (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Considered by 60601-2-37	**P**
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit addressed in RISK MANAGEMENT PROCESS.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	Replaced by 60601-2-37	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
12.4.4	RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS .....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: RMM-TSUGA, Row H1.31 (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	**P**
12.4.5	**Diagnostic or therapeutic radiation**		**N/A**
12.4.5.1	Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation		**N/A**
	Radiation safety ensured by compliance with requirements of appropriate standards		**N/A**
12.4.5.2	ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3 .....:		**N/A**
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		**N/A**
12.4.5.4	RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		**N/A**
12.4.6	RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		**N/A**
13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		**P**
13.1	**Specific HAZARDOUS SITUATIONS**		**P**
13.1.2	**Emissions, deformation of ENCLOSURE or exceeding maximum temperature**		**P**
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		**P**
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		**P**
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24	See appended Table 11.1.1	**P**
	– Temperatures of Accessible PARTS THAT ARE LIKELY TO BE TOUCHED, but not intended to be touched did not exceed limits in Table 34	See appended Table 11.1.1	**P**
	- Temperatures of ACCESSIBLE PARTS intended to be touched did not exceed limits in Table 23		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	–Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C were not exceeded		**P**
	Limits for windings in Tables 26, 27, and 31 not exceeded		**P**
	Table 22 not exceeded in all other cases		**P**
	Temperatures measured according to 11.1.3		**P**
	SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where:	No such conditions	**N/A**
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit in SINGLE FAULT CONDITION ..... :		**N/A**
	- or secondary circuits mounted on materials with a minimum flame rating of -V1, and		**N/A**
	- Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and		**N/A**
	- Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and		**N/A**
	- Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide		**N/A**
	- or components in the circuit have HIGH INTEGRITY CHARACTERISTICS..... :		**N/A**
	– or parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation		**N/A**
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		**N/A**
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed……..:	See appended Table 8.7	**P**
	– voltage limits for ACCESSIBLE PARTS and APPLIED PARTS did not exceed……..:	See appended Table 8.7	**P**
13. 2	**SINGLE FAULT CONDITIONS**		**P**
13.2.1	During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT complied with 13.2.2 -13.2.12…..:	See appended Table 13.2	**P**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		**N/A**
	RISK MANAGEMENT FILE defines the appropriate test conditions.....:		**N/A**
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of test environment temperature		**P**
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		**P**
13.2.13.2	**ME EQUIPMENT with heating elements**		**N/A**
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	No heating elements or heating lamps used.	**N/A**
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests		**N/A**
	a 3) other ME EQUIPMENT with heating elements met test		**N/A**
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		**N/A**
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration		**N/A**
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		**N/A**
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself		**N/A**
	b) ME EQUIPMENT with heating elements without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V)		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY		**N/A**
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		**N/A**
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION		**N/A**
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and		**N/A**
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS		**N/A**
	2) When more than one control provided, they were disabled in turn		**N/A**
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		**N/A**
13.2.13.3	**ME EQUIPMENT with motors**		**P**
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable	Cooling fan used	**P**
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		**P**
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition		**N/A**
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		**P**
	b) Motor met running overload protection test of this clause when:		**P**
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		**N/A**
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C).....:		**N/A**
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		**N/A**
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload		**N/A**
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		**N/A**
	Test not conducted based on other justifications (justification) .....:	Cooling fan used	**P**
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10		**N/A**
13.2.13.4	**ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION**		**N/A**
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated	Continuous operation.	**N/A**
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle		**N/A**
	Motor winding temperatures did not exceed values in 13.2.10……..:		**N/A**
	Insulation Class……..:		**—**
	Maximum temperature measured (°C)……..:		**—**
14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		**P**
14.1	Requirements in 14.2 to 14,12 not applied to PEMS when it provides no functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE, or	Software system provides basic safety and essential performance.	**N/A**
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK……..:	RMF showed that failure is possible to lead to unacceptable risk	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 5.2-5.5, 6)		**N/A**
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK		**N/A**
	When the requirements of 14.2 to 14.13 apply, the requirements of IEC 62304:2006 and IEC 62304:2006/AMD1:2015 clause 4.3, 5, 7, 8 and 9 apply for the development or modification of software of each PESS	Considered.	**P**
	Software development process for Software Classification applied in accordance with Clause 4.3 and 4.4 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015……..:	Software Class: B	**P**
	Software development process applied according to Clause 5 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015……:	Refer to Attachment-Software	**P**
	Software development process for Software risk management applied according to Clause 7 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015……..:	Refer to Attachment-Software	**P**
	Software development process Configuration Management applied according to Clause 8 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015……:	Refer to Attachment-Software	**P**
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015……..:	Refer to Attachment-Software	**P**
14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process……:	Document control process: QP 4.2-01, REV#: 18	**P**
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan	Risk management plan: RMP-TSUGA, REV#: 6	**P**
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented	Software development plan: DDP-TSUGA-003, REV#: 1, Section 4	**P**
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	VED-TSUGA-030, REV#: 1	**P**
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	Software development plan: DDP-TSUGA-003, REV#: 1, Section 4	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones		**P**
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	Document control process: QP 4.2-01, REV#: 18	**P**
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained	Bugzilla tool, Design and development verification procedure QP 7.3-05, REV#: 4	**P**
14.6	**RISK MANAGEMENT PROCESS**		**P**
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS……..:	Risk management plan, RMP-TSUGA, REV#: 6 Risk management report, RMR-TSUGA, REV#: 2	**P**
	RISK MANAGEMENT FILE includes known or foreseeable HAZARDS associated with software, hardware, incorporation of the PEMS into an IT-NETWORK, components of 3rd party origin and legacy subsystems……: (ISO 14971 Cl. 5.3)	RMF Reference to specific HAZARDS: Risk assessment and control (File No. RMM-TSUGA, version:2) Hazard ID: H6.1-H7.21 H11.1-H11.5 (ISO 14971 Cl. 5.3)	**P**
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2…:	Risk manage control procedure QP 7.1-01, VER#: 8	**P**
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure……: (ISO 14971 Cl. 7.1)	RMF Reference to specific RISKS: RISK MANAGE CONTROL PROCEDURE QP 7.1-01 RISK MANAGEMENT PLAN: RMP-TSUGA, REV#: 6 RMF REFERENCE TO SPECIFIC RISKS: RISK MANAGEMENT REPORT, APPENDIX 1 Hazard ID: H6.1-H7.21 H11.1-H11.5 (ISO 14971 Cl. 7.1)	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
14.7	A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem……: (ISO 14971 Cl. 7.2)	RMF Reference to specific RISK CONTROLS: DDS-TSUGA-003, REV#: 1, section 7 (ISO 14971 Cl. 7.2)	**P**
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems …..: (ISO 14971 Cl. 7.2)	RMF Reference to specific RISK CONTROLS: (ISO 14971 Cl. 7.2)	**P**
14.9	Design is broken up into sub systems and descriptive data on design environment documented……:	DDP-TSUGA-003, REV#: 1 ARC-TSUGA, REV#: 1	**P**
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures……..: (ISO 14971 Cl. 7.2)	RMF Reference to specific RISK CONTROLS: VEP-TSUGA-002, REV#: 1 VED-TSUGA-017, REV#: 1 (ISO 14971 Cl. 7.2)	**P**
	– milestone(s) when VERIFICATION is to be performed for each function	DDP-TSUGA-003, REV#: 1	**P**
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION	DDP-TSUGA-003, REV#: 1 VEP-TSUGA-002, REV#: 1	**P**
	– selection and utilization of VERIFICATION tools	Design verification by manual test	**P**
	– coverage criteria for VERIFICATION	VEP-TSUGA-114, REV#: 1	**P**
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented	VES-TSUGA-002~086 REV#: 1	**P**
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE	VAP-TSUGA-002, REV#: 1	**P**
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented	VAR-TSUGA-005, REV#: 1	**P**
	The person with overall responsibility for PEMS VALIDATION is independent	By application person	**P**
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 7.2)	RMF REFERENCE TO SPECIFIC RISK CONTROLS: Risk assessment and control (File No. RMM-TSUGA, version:2) (ISO 14971 Cl. 7.2)	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE	Design and development change procedure: QP 7.3-08 , VER#: 9	**P**
	Software Classification for Software changes applied in accordance with Clause 4.3 and 4.4 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015……:	Software Class: B	**P**
	Software Process for Software changes applied according to Clause 5 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015	Complied.	**P**
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015	Complied.	**P**
	Configuration management of software changes applied per Clause 8 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015……:	Complied.	**P**
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015	Complied.	**P**
14.13	For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following……:	Refer to section 12.5 “Network” in the user manual	**P**
	a) Purpose of the PEMS connection to an IT-NETWORK	Basic user manual, section 12.5	**P**
	b) required characteristics of the IT-NETWORK	Basic user manual, section 12.5	**P**
	c) required configuration of the IT-NETWORK	Basic user manual, section 12.5	**P**
	d) technical specifications of the network connection, including security specifications	Basic user manual, section 12.5	**P**
	e) intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK	Basic user manual, section 12.5	**P**
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the required characteristics (ISO 14971 Cl. 5.2-5.5, 6, 7.1, 7.2)	RMF Reference to specific hazardous situations: RMM-TSUGA, H11.1-H11.5 (ISO 14971 Cl. 5.2-5.5, 6, 7.1, 7.2)	**P**
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties	Basic user manual, section 12.5	**P**
	– Notification that the RESPONSIBLE ORGANIZATION identify, analyse, evaluate and control these RISKS	Basic user manual, section 12.5	**P**
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis	Basic user manual, section 12.5	**P**
	- Changes to the IT-NETWORK include: - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment	Basic user manual, section 12.5	**P**
15	**CONSTRUCTION OF ME EQUIPMENT**		**P**
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS……..:	See Attached IEC 60601-1-6	**P**
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance		**P**
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		**P**
15.3	**Mechanical strength**		**P**
15.3.1	Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		**P**
15.3.2	Push test conducted ……..:	See Appended Table 15.3	**P**
	No damage resulting in an unacceptable RISK sustained		**P**
15.3.3	Impact test conducted……:	See Appended Table 15.3	**P**
	No damage resulting in an unacceptable RISK sustained		**P**
15.3.4	**Drop test**		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested ……..:	See Appended Table 15.3 Tested for the probes	**P**
	No unacceptable RISK resulted		**P**
15.3.4.2	Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test……..:	See Appended Table 15.3	**P**
	No damage resulting in an unacceptable RISK sustained		**P**
15.3.5	MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests…….:	See Appended Table 15.3	**P**
	No damage resulting in an unacceptable RISK sustained		**P**
15.3.6	Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK	Approved plastic material	**P**
	Mould-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C……..:	See appended table 15.3.6	**P**
	No damage resulting in an unacceptable RISK		**P**
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT		**P**
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK		**P**
15.4	**ME EQUIPMENT components and general assembly**		**P**
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists,……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	Incorrect connection prevented	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions,……:	Plugs for connection of patient leads or patient cable designed to prevent connection to outlets for other function	**P**
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection……:		**N/A**
15.4.2	**Temperature and overload control devices**		**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 lead to a HAZARDOUS SITUATION……..: (ISO 14971 Cl. 5.2-5.5, 6)		**N/A**
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT		**N/A**
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided……..: (ISO 14971 Cl. 5.2-5.5)		**N/A**
	d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION or loss of ESSENTIAL PERFORMANCE ….: (ISO 14971 Cl. 5.2-5.5)		**N/A**
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		**N/A**
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests		**N/A**
	- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17		**N/A**
	- ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13……..:		**N/A**
	- SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards……:		**N/A**
	- In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions operated 200 times		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		**N/A**
	manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		**N/A**
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		**N/A**
	g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating		**N/A**
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating…..: (ISO 14971 Cl. 5.2-5.5)		**N/A**
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS		**N/A**
15.4.3	**Batteries**		**N/A**
15.4.3.1	Battery housings provided with ventilation…….: (ISO 14971 Cl. 5.2-5.5)	No battery	**N/A**
	Battery compartments designed to prevent accidental short circuiting		**N/A**
15.4.3.2	Means provided to prevent incorrect connection of polarity	No battery	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries……: (ISO 14971 Cl. 5.2-5.5)		**N/A**
15.4.3.3	Overcharging of battery prevented by virtue of design……:	No battery	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries……..: (ISO 14971 Cl. 5.2-5.5)		**N/A**
15.4.3.4	Primary lithium batteries comply with IEC 60086-4	No battery	**N/A**
	Secondary lithium batteries comply with IEC 62133 or IEC 62133-2		**N/A**
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire……..:	No battery	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Protective device has adequate breaking capacity		**N/A**
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented		**N/A**
	Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPS provided, or		**N/A**
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION		**N/A**
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for……:	Provided on control panel and monitor	**P**
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,		**N/A**
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational	No such heater	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with the use of indicator lights for EQUIPMENT incorporating non-luminous heaters……..: (ISO 14971 Cl. 5.2-5.5)		**N/A**
	Requirement not applied to heated stylus-pens for recording purposes	No heated stylus-pens used.	**N/A**
	Indicator lights provided on ME EQUIPMENT to indicate an output exists	Identified by LCD display	**P**
	Colours of indicator lights complied with 7.8.1	Identified by LCD display	**P**
	Charging mode visibly indicated		**N/A**
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	No such pre-set controls	**N/A**
15.4.6	**Actuating parts of controls of ME EQUIPMENT**		**P**
15.4.6.1	a) Actuating parts cannot be pulled off or loosened during NORMAL USE		**P**
	b) Controls secured so that the indication of any scale always corresponds to the position of the control		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL	Cannot separated without use of a tool	**N/A**
	When torque values per Table 30 applied knobs did not rotate ……..:.		**N/A**
	Tests conducted with no unacceptable RISK …..:		**N/A**
15.4.6.2	Stops on rotating/ movable parts of controls are of adequate mechanical strength ……..:		**N/A**
	Torque values in Table 30 applied……..:		**N/A**
	No unexpected change of the controlled parameter when tested……:		**N/A**
15.4.7	**Cord-connected HAND-HELD and foot-operated control devices**		**P**
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1	Probes complied with 15.3.4.1	**P**
	b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage……..:	Evaluated as part of certified footswitch.	**P**
15.4.7.2	Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface……..:		**P**
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		**P**
15.4.7.3	a) Foot-operated control device is at least rated IPX1……..:	Evaluated as part of certified footswitch. Rated IP68.	**P**
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6……:	Evaluated as part of certified footswitch. Rated IP68.	**P**
15.4.8	Aluminium wires less than 16 mm^2 in cross-sectional area are not used		**N/A**
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed		**N/A**
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		**N/A**
	A pressure-release device operating during NORMAL USE is provided		**N/A**
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		**N/A**
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.5	**MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5**		**N/A**
15.5.1	**Overheating**		**N/A**
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating……:		**N/A**
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		**N/A**
	Dielectric strength test conducted after short circuit and overload tests ……:		**N/A**
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved ……:		**N/A**
	Short circuit applied directly across output windings		**N/A**
15.5.1.3	Multiple overload tests conducted on windings:		**N/A**
15.5.2	Transformers operating at a frequency above 1kHz tested according to clause 8.8.3……:		**N/A**
	Transformer windings provided with adequate insulation		**N/A**
	Dielectric strength tests were conducted ……:		**N/A**
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with……..:		**N/A**
	- Means provided to prevent displacement of end turns		**N/A**
	- protective earth screens with a single turn have insulated overlap		**N/A**
	- Exit of wires form internal windings of toroid transformers protected with double sleeving		**N/A**
	- insulation between primary and secondary windings complies with 8.8.2		**N/A**
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4		**N/A**
16	**ME SYSTEMS**		**P**
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK		**P**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with installation and modification of an ME SYSTEM……: (ISO 14971 Cl. 5.2-5.5, 6)		**N/A**

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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard		**N/A**
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM		**P**
	– additional safety measures to be applied during installation of ME SYSTEM		**P**
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT		**P**
	– additional measures to be applied during preventive maintenance		**P**
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor	No socket-outlet.	**N/A**
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM	No socket-outlet.	**N/A**
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM		**P**
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM	No socket-outlet.	**N/A**
	– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM	No socket-outlet.	**N/A**
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer	No socket-outlet.	**N/A**
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET	No socket-outlet.	**N/A**
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage		**P**
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:		**P**
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES		**P**
	– assembly of ME SYSTEMS and modifications during actual service life evaluated based on the requirements of this standard		**P**
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements		**N/A**
	Transient currents restricted to allowable levels for the specified IPS or UPS		**N/A**
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified		**N/A**
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)		**P**
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	Leakage current does not exceed, no other separation device needed.	**N/A**
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION		**N/A**
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V)		**N/A**
16.6	**LEAKAGE CURRENTS**		**P**
16.6.1	TOUCH CURRENT in NORMAL CONDITION did not exceed 100µA	See appended Table 16.6.1	**P**
	TOUCH CURRENT did not exceed 500µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR	See appended Table 16.6.1	**P**
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA	No socket-outlet.	**N/A**
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values.....	See appended Tables 8.7 8.7.4.7 and 16.6.1	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
16.7	ME SYSTEM complied with applicable requirements of Clause 9	See applicable appended Tables in section 9	**P**
16.8	Interruption and restoration power to the ME SYSTEM or any part of the ME SYSTEM did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		**P**
16.9	**ME SYSTEM connections and wiring**		**P**
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result……:		**P**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with plugs for connection of PATIENT leads or cables likely to be located in the PATIENT ENVIRONMENT……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		**N/A**
	– Plugs for connection of PATIENT leads or PATIENT cables could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no unacceptable RISK results		**P**
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable	No medical gas used.	**N/A**
16.9.2	**MAINS PARTS, components and layout**		**N/A**
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or		**N/A**
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		**N/A**
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		**N/A**
	b) – MULTIPLE SOCKET-OUTLET marked with SAFETY SIGN 2 of Table D.2 visible in NORMAL USE, and		**N/A**
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		**N/A**
	– marked to indicate the equipment or equipment parts it may safely be attached to		**N/A**
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:		**N/A**
	– CREEPAGE and CLEARANCES complied with 8.9		**N/A**
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets		**N/A**
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:		**N/A**
	– ENCLOSURE complied with 8.4.2 d)		**N/A**
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable		**N/A**
	– RATINGS of components are not in conflict with conditions of use ……:		**N/A**
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL		**N/A**
	– POWER SUPPLY CORD complied with 8.11.3		**N/A**
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:		**N/A**
	– Separating transformer complied with this standard or IEC 61558-2-1,……:		**N/A**
	– Separating transformer is CLASS I		**N/A**
	– Degree of protection against ingress of water specified as in IEC 60529		**N/A**
	– Separating transformer assembly marked according to 7.2 and 7.3		**N/A**
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083		**N/A**
16.9.2.2	The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED and protected by only the SUPPLY MAINS circuit over-current release, did not exceed 200 mΩ		**P**
	The impedance of an earth pathway protected by an additional intermediate circuit breaker or fuse rated 13A or lower, did not exceed 400 mΩ		**N/A**

IEC 60601-1			
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 without simultaneous disconnection of electrical supply to that part		**P**
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL		**N/A**
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage		**N/A**
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		**N/E**
	RISKS associated confirmed by review……:		**N/E**
	RISK MANAGEMENT FILE includes an assessment of risks associated with the introduction of electromagnetic phenomena into the environment by the EQUIPMENT or SYSTEM……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)		**N/E**

ANNEX G	**PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		**N/A**
G.2	**Locations and basic requirements**		**N/A**
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5	The ME equipment is not intended for using with flammable anaesthetics.	**N/A**
G.2.2	FLAMMABLE AESTHETIC MIXTURE WITH		**N/A**
G.2.3	A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE		**N/A**
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5		**N/A**
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE comply with G.4 and G.6		**N/A**
	ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.6 conducted after tests of 11.6.6 and 11.6.7		**N/A**
G.3	**Marking, ACCOMPANYING DOCUMENTS**		**N/A**
G.3.1	CATEGORY APG ME EQUIPMENT prominently marked "APG" (symbol 23 in Table D.1) .....:		**N/A**

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

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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1		**N/A**
	No extrapolation made for voltages above 42 V		**N/A**
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2$ ≤ 1.2 mJ extrapolated from Fig G.2		**N/A**
	No extrapolation made for voltages above 242V		**N/A**
	U_{max} determined using actual resistance R		**N/A**
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3		**N/A**
	No extrapolation made for inductances larger than 900 mH		**N/A**
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open		**N/A**
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed		**N/A**
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks		**N/A**
	– Peak value considered when a.c. supplied		**N/A**
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit.....:		**N/A**
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max} , and C_{max} determined with application of Figs G.1-G.3.....:		**N/A**
	Alternatively, compliance was verified by examination of design data ..... :		**N/A**
G.5.4	**External ventilation with internal overpressure**		**N/A**
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:		**N/A**
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR t removed by ventilation before EQUIPMENT energized,		**N/A**
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa).....:		**N/A**

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

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

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

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

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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
L.3.4	**Retention of electric strength after bending**		**N/A**
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests		**N/A**
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		**N/A**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		**N/A**
	– 3000 V for REINFORCED INSULATION (V) ..... :		**N/A**
	Test voltage applied between the shot and conductor		**N/A**
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm^2)..... :		**N/A**
L.4	**Tests during manufacture**		**N/A**
L.4.1	Production line dielectric strength tests done by the manufacture per L.4.2 and L.4.3..... :		**N/A**
L.4.2	Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:		**N/A**
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V)..... :		**N/A**
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V) ..... :		**N/A**
L.4.3	Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1) ..... :		**N/A**
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:		**N/A**
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION..... :		**N/A**
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION..... :		**N/A**

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

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
4.1	QP 7.1-01 REV8	—	Risk Management Process (excluding production and post-production)	**P**
4.2	QP 7.1-01 REV8	—	Adequate Resources	**P**
4.2	QP 7.1-01 REV8	—	Assignment of qualified personnel	**P**
4.2	QP 7.1-01 REV8	—	Policy for determining criteria for risk acceptability	**P**
4.3	—	RMP-TUSGA REV7 Chapter 2	Competence of personnel	**P**
4.4a	—	RMP-TUSGA REV7 Chapter 3	Risk Management Plan - the scope of the planned risk management activities	**P**
4.4b	—	RMP-TUSGA REV7 Chapter 2	Risk Management Plan - assignment of responsibilities and authorities	**P**
4.4c	—	RMP-TUSGA REV7 Chapter 6	Risk Management Plan - requirements for review of risk management activities	**P**
4.4d	—	RMP-TUSGA REV7 Chapter 4	Risk Management Plan - criteria for risk acceptability	**P**
4.4e	—	RMP-TUSGA REV7 Chapter 4	Risk Management Plan - a method to evaluate the overall residual risk, and criteria for acceptability of the overall residual risk	**P**
4.4f	—	RMP-TUSGA REV7 Chapter 5	Risk Management Plan - activities for verification of the implementation and effectiveness of risk control measures	**P**
4.5	—	RMP-TUSGA REV7 RMR-TUSGA REV3 RMM-TUSGA REV2 SFA-TUSGA	Risk Management File	**P**
5.1	—	RMR-TUSGA REV3 RMM-TUSGA REV2	Risk Analysis - Process	**P**
5.2	—	SFA-TUSGA RMM-TUSGA REV2	Risk Analysis - Intended use and reasonably foreseeable misuse	**P**
5.3	—	SFA-TUSGA RMM-TUSGA REV2	Risk Analysis - Identification of characteristics related to safety	**P**
5.4	—	RMM-TUSGA REV2	Risk Analysis - Identification of hazards and hazardous situations	**P**

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

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
5.5	—	RMM-TUSGA REV2	Risk Analysis - Risk estimation	**P**
6	—	RMM-TUSGA REV2	Risk Evaluation	**P**
7.1	—	RMM-TUSGA REV2	Risk Control - Risk control option analysis	**P**
7.2	—	RMM-TUSGA REV2	Risk Control - Implementation of risk control measures	**P**
7.3	—	RMM-TUSGA REV2 RMR-TUSGA REV3 Chapter 3,section2	Risk Control - Residual risk evaluation	**P**
7.4	—	RMM-TUSGA REV2	Risk Control - Benefit-risk analysis	**P**
7.5a	—	RMM-TUSGA REV2	Risk Control - Risks arising from risk control measures (new hazards or hazardous situations introduced)	**P**
7.5b	—	RMM-TUSGA REV2	Risk Control - Risks arising from risk control measures (estimated risks for previously identified hazardous situations affected)	**N/A**
7.6	—	RMR-TUSGA REV3 Chapter 3	Risk Control - Completeness of risk control	**P**
8	—	RMR-TUSGA REV3 Chapter 3	Evaluation of overall residual risk	**P**
9	—	RMR-TUSGA REV3 RMM-TUSGA REV2	Risk management review	**P**

Supplementary Information:

Document Ref should be with regards to the policy/procedure documents and documents containing Risk Management Process -specific output.

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

4.3	TABLE: ESSENTIAL PERFORMANCE		P
List of ESSENTIAL PERFORMANCE functions	**MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)**	**Remarks**	
Free from the incorrect display, measurement, excessive surface temperature of transducer assembly and unintended or excessive ultrasound output	IEC 60601-2-37	-	
Supplementary Information: ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.			

4.11	TABLE: Power Input				P
Operating Conditions / Ratings	**Voltage (V)**	**Frequency (Hz)**	**Current (A)**	**Power (W or VA)**	**Power factor (cos φ)**
Model: E20, Normal condition, with 21-inch display	264	50/60	0.72	177.86 W	-
	240	50/60	0.74	169.82 W	-
	100	50/60	1.81	180.13 W	-
	90	50/60	2.05	183.93 W	-
Model: E20, Normal condition, with 18.5-inch display	264	50/60	0.59	140.30 W	-
	240	50/60	0.63	140.50 W	-
	100	50/60	1.49	148.30 W	-
	90	50/60	1.66	149.00 W	-
Model: X1, Normal condition, with 21-inch display	264	50/60	0.46	107.89 W	-
	240	50/60	0.49	107.97 W	-
	100	50/60	1.12	112.21 W	-
	90	50/60	1.27	113.19 W	-
Model: X1, Normal condition, with 18.5-inch display	264	50/60	0.372	86.00 W	-
	240	50/60	0.398	86.20 W	-
	100	50/60	0.900	90.00 W	-
	90	50/60	1.010	90.70 W	-

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

4.11	TABLE: Power Input					P
Operating Conditions / Ratings		**Voltage (V)**	**Frequency (Hz)**	**Current (A)**	**Power (W or VA)**	**Power factor (cos φ)**
Supplementary Information:						

5.9.2	TABLE: Determination of ACCESSIBLE parts	P
Location	**Determination method (NOTE1)**	**Comments**
LCD monitor	Visual	-
Control panel	Visual	-
Plastic enclosure	Visual	-
Metal enclosure	Visual	-
SIP/SOP	Visual; rigid test finger; test hook	-
Connector ports of probes	Visual; rigid test finger; test hook	-
Enclosure of probes	Visual	-
Supplementary information: 1) NOTE: The determination methods are: visual; rigid test finger; jointed test finger; test hook.		

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

7.1.2	TABLE: Legibility of Marking		P
Markings tested		**Ambient Illuminance (lx)**	**Remarks**
Outside Markings (Clause 7.2).....:		100lx/1500lx	Clearly legible
Inside Markings (Clause 7.3).....:		100lx/1500lx	Clearly legible
Controls & Instruments (Clause 7.4).....:		100lx/1500lx	Clearly legible
SAFETY SIGNS (Clause 7.5).....:		100lx/1500lx	Clearly legible
Symbols (Clause 7.6).....:		100lx/1500lx	Clearly legible
Supplementary information: Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR or if not defined at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.			

7.1.3	TABLE: Durability of marking test		P
Characteristics of the Marking Label tested:			**Remarks**
Material of Marking Label .....:		PC-	--
Ink/other printing material or process .....:		Silk print	--
Material (composition) of Warning Label .....:		PC	--
Ink/other printing material or process .....:		Silk print	--
Other.....:		-	--
Marking Label Tested:			**Remarks**
All product label, safety logo label and warning label			No damages and clearly legible
Supplementary information: Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96%, and then for 15 s with a cloth rag soaked with isopropyl alcohol.			

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

8.4.2	**TABLE: TABLE: Working Voltage / Power Measurement**					**P**
Test supply voltage/frequency (V/Hz)[1)] ..... :						**100-240V~, 50/60Hz**
Location From/To	**Measured values**					**Remarks**
	Vrms	**Vpk or Vdc**	**Peak-to-peak ripple[2)]**	**Power W/VA**	**Energy (J)**	
SIP/SOP to earth	**-**	**5Vdc**	**<10%**	**-**	**-**	**Including USB ports, LAN ports, DVI-D port, S-VIDEO port, etc.**

Supplementary Information:

[1)]The input supply voltage to the ME EQUIPMENT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4.

[2)]. If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2

[3)] Voltage measurement of all conductive ACCESSIBLE PARTS of the SIP/SOP connection or separate power supply output connections to earth used a resistor of 10 kΩ + 500 Ω. See clause 8.4.2

8.4.3	**TABLE: ME EQUIPMENT for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply**									**P**
Maximum allowable voltage (V) ..... :										**60**
Voltage measured (V)										
Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2	**24**	**20**	**20**	**20**	**21**	**20**	**20**	**21**	**18**	**17**
Plug pin 1 and plug earth pin	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Plug pin 2 and plug earth pin	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Maximum allowable stored charge when measured voltage exceeded 60 v (μc) ..... :										**45**
Calculated stored charge (μc)										
Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Plug pin 1 and plug earth pin	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Plug pin 2 and plug earth pin	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Supplementary information: Consider mains switch On and Off.										

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

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

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

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

Supplementary information:

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

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

Supplementary information:

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

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

Supplementary information:

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

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

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

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

8.6.4	**TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS**	P

Type of ME EQUIPMENT & impedance measured between parts	Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)
With appliance inlet 5120 series				
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part	25A/60s	1.5	60	100
ME EQUIPMENT with an APPLIANCE INLET, impedance between protective earth pin on the DETACHABLE POWER SUPPLY CORD and a protectively earthed part	25A/60s	2.425	97	200
With appliance inlet 6100 series / DB-14 series				
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part	25A/5s	1.03	41.2	100

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

ME EQUIPMENT with an APPLIANCE INLET, impedance between protective earth pin on the DETACHABLE POWER SUPPLY CORD and a protectively earthed part	25A/5s	2.27	90.8	200

Supplementary information:

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

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

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

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

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

Type of leakage current and test condition (including single faults)	**Supply voltage (V)**	**Supply frequency (Hz)**	**Measured max. value (µA)**	**Remarks**
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
Model E20, frequency-weighted				
ER; NC, S1=1, S5=0	264	60	270.6	With appliance inlet 5120 series
ER; NC, S1=1, S5=1	264	60	271.3	
ER; SFC, S1=0, S5=0	264	60	514.2	
ER; SFC, S1=0, S5=1	264	60	510.4	
Model E20, non-frequency-weighted				
ER; NC, S1=1, S5=0	264	60	467.5	With appliance inlet 5120 series
ER; NC, S1=1, S5=1	264	60	468.1	
ER; SFC, S1=0, S5=0	264	60	529.3	
ER; SFC, S1=0, S5=1	264	60	524.1	
Model E20, frequency-weighted				
ER; NC, S1=1, S5=0	264	60	20.3	With appliance inlet 6100 series / DB-14 series
ER; NC, S1=1, S5=1	264	60	20.2	
ER; SFC, S1=0, S5=0	264	60	36.3	
ER; SFC, S1=0, S5=1	264	60	36.2	
Model E20, non-frequency-weighted				
ER; NC, S1=1, S5=0	264	60	1447	With appliance inlet 6100 series / DB-14 series
ER; NC, S1=1, S5=1	264	60	1442	
ER; SFC, S1=0, S5=0	264	60	1381	
ER; SFC, S1=0, S5=1	264	60	1373	
Model X1, frequency-weighted				
ER; NC, S1=1, S5=0	264	60	264.2	With appliance inlet 5120 series
ER; NC, S1=1, S5=1	264	60	261.1	
ER; SFC, S1=0, S5=0	264	60	501.3	
ER; SFC, S1=0, S5=1	264	60	503.7	
Model X1, non-frequency-weighted				
ER; NC, S1=1, S5=0	264	60	530.3	With appliance inlet 5120 series
ER; NC, S1=1, S5=1	264	60	537.1	
ER; SFC, S1=0, S5=0	264	60	514.3	

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
ER; SFC, S1=0, S5=1	264	60	508.4	
Model X1, frequency-weighted				
ER; NC, S1=1, S5=0	264	60	19.9	With appliance inlet 6100 series / DB-14 series
ER; NC, S1=1, S5=1	264	60	19.7	
ER; SFC, S1=0, S5=0	264	60	35.1	
ER; SFC, S1=0, S5=1	264	60	35.0	
Model X1, non-frequency-weighted				
ER; NC, S1=1, S5=0	264	60	1339	With appliance inlet 6100 series / DB-14 series
ER; NC, S1=1, S5=1	264	60	1332	
ER; SFC, S1=0, S5=0	264	60	1289	
ER; SFC, S1=0, S5=1	264	60	1269	
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC
Model E20, frequency-weighted				
TC; NC, S1 = 1, S5 = 0, S7 = 1, S9=0	264	60	<4	
TC; NC, S1 = 1, S5 = 1, S7 = 1, S9=0	264	60	<4	
TC; NC, S1 = 1, S5 = 0, S7 = 1, S9=1	264	60	<4	
TC; NC, S1 = 1, S5 = 1, S7 = 1, S9=1	264	60	<4	
TC; SFC, S1 = 0, S5 = 0, S7 = 1, S9=0	264	60	<4	
TC; SFC, S1 = 0, S5 = 1, S7 = 1, S9=0	264	60	<4	
TC; SFC, S1 = 0, S5 = 0, S7 = 1, S9=1	264	60	<4	
TC; SFC, S1 = 0, S5 = 1, S7 = 1, S9=1	264	60	<4	
TC; SFC, S1 = 1, S5 = 0, S7 = 0, S9=0	264	60	9.6	
TC; SFC, S1 = 1, S5 = 1, S7 = 0, S9=0	264	60	9.5	
TC; SFC, S1 = 1, S5 = 0, S7 = 0, S9=1	264	60	17.2	
TC; SFC, S1 = 1, S5 = 1, S7 = 0, S9=1	264	60	16.8	
Model E20, non-frequency-weighted				
TC; NC, S1 = 1, S5 = 0, S7 = 1, S9=0	264	60	<4	
TC; NC, S1 = 1, S5 = 1, S7 = 1, S9=0	264	60	<4	
TC; NC, S1 = 1, S5 = 0, S7 = 1, S9=1	264	60	<4	
TC; NC, S1 = 1, S5 = 1, S7 = 1, S9=1	264	60	<4	
TC; SFC, S1 = 0, S5 = 0, S7 = 1, S9=0	264	60	<4	

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
TC; SFC, S1 = 0, S5 = 1, S7 = 1, S9=0	264	60	<4	
TC; SFC, S1 = 0, S5 = 0, S7 = 1, S9=1	264	60	<4	
TC; SFC, S1 = 0, S5 = 1, S7 = 1, S9=1	264	60	<4	
TC; SFC, S1 = 1, S5 = 0, S7 = 0, S9=0	264	60	83.5	
TC; SFC, S1 = 1, S5 = 1, S7 = 0, S9=0	264	60	82.3	
TC; SFC, S1 = 1, S5 = 0, S7 = 0, S9=1	264	60	82.6	
TC; SFC, S1 = 1, S5 = 1, S7 = 0, S9=1	264	60	84.3	
Model X1, frequency-weighted				
TC; NC, S1 = 1, S5 = 0, S7 = 1, S9=0	264	60	<4	
TC; NC, S1 = 1, S5 = 1, S7 = 1, S9=0	264	60	<4	
TC; NC, S1 = 1, S5 = 0, S7 = 1, S9=1	264	60	<4	
TC; NC, S1 = 1, S5 = 1, S7 = 1, S9=1	264	60	<4	
TC; SFC, S1 = 0, S5 = 0, S7 = 1, S9=0	264	60	<4	
TC; SFC, S1 = 0, S5 = 1, S7 = 1, S9=0	264	60	<4	
TC; SFC, S1 = 0, S5 = 0, S7 = 1, S9=1	264	60	<4	
TC; SFC, S1 = 0, S5 = 1, S7 = 1, S9=1	264	60	<4	
TC; SFC, S1 = 1, S5 = 0, S7 = 0, S9=0	264	60	<4	
TC; SFC, S1 = 1, S5 = 1, S7 = 0, S9=0	264	60	<4	
TC; SFC, S1 = 1, S5 = 0, S7 = 0, S9=1	264	60	<4	
TC; SFC, S1 = 1, S5 = 1, S7 = 0, S9=1	264	60	<4	
Model X1, non-frequency-weighted				
TC; NC, S1 = 1, S5 = 0, S7 = 1, S9=0	264	60	21.7	
TC; NC, S1 = 1, S5 = 1, S7 = 1, S9=0	264	60	22.3	
TC; NC, S1 = 1, S5 = 0, S7 = 1, S9=1	264	60	22.1	
TC; NC, S1 = 1, S5 = 1, S7 = 1, S9=1	264	60	21.9	
TC; SFC, S1 = 0, S5 = 0, S7 = 1, S9=0	264	60	21.7	
TC; SFC, S1 = 0, S5 = 1, S7 = 1, S9=0	264	60	22.3	
TC; SFC, S1 = 0, S5 = 0, S7 = 1, S9=1	264	60	23.4	
TC; SFC, S1 = 0, S5 = 1, S7 = 1, S9=1	264	60	21.8	
TC; SFC, S1 = 1, S5 = 0, S7 = 0, S9=0	264	60	233.2	
TC; SFC, S1 = 1, S5 = 1, S7 = 0, S9=0	264	60	225.8	

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
TC; SFC, S1 = 1, S5 = 0, S7 = 0, S9=1	264	60	230.6	
TC; SFC, S1 = 1, S5 = 1, S7 = 0, S9=1	264	60	228.4	
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)
Model E20, frequency-weighted				
P-Probe; NC S1=1, S5=0, S7=1	264	60	<4	
P-Probe; NC S1=1, S5=1, S7=1	264	60	<4	
P-Probe; SFC S1=0, S5=0, S7=1	264	60	<4	
P-Probe; SFC S1=0, S5=1, S7=1	264	60	<4	
P-Probe; SFC S1=1, S5=0, S7=0	264	60	7.1	
P-Probe; SFC S1=1, S5=1, S7=0	264	60	7.2	
P-ECG; NC S1=1, S5=0, S7=1	264	60	<4	
P-ECG; NC S1=1, S5=1, S7=1	264	60	<4	
P-ECG; SFC S1=0, S5=0, S7=1	264	60	<4	
P-ECG; SFC S1=0, S5=1, S7=1	264	60	<4	
P-ECG; SFC S1=1, S5=0, S7=0	264	60	<4	
P-ECG; SFC S1=1, S5=1, S7=0	264	60	<4	
Model E20, non-frequency-weighted				
P-Probe; NC S1=1, S5=0, S7=1	264	60	31.4	
P-Probe; NC S1=1, S5=1, S7=1	264	60	31.6	
P-Probe; SFC S1=0, S5=0, S7=1	264	60	31.7	
P-Probe; SFC S1=0, S5=1, S7=1	264	60	31.7	
P-Probe; SFC S1=1, S5=0, S7=0	264	60	43.1	
P-Probe; SFC S1=1, S5=1, S7=0	264	60	43.2	
P-ECG; NC S1=1, S5=0, S7=1	264	60	21.1	
P-ECG; NC S1=1, S5=1, S7=1	264	60	21.1	
P-ECG; SFC S1=0, S5=0, S7=1	264	60	21.3	
P-ECG; SFC S1=0, S5=1, S7=1	264	60	21.2	
P-ECG; SFC S1=1, S5=0, S7=0	264	60	28.2	
P-ECG; SFC S1=1, S5=1, S7=0	264	60	28.2	

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
Model X1, frequency-weighted				
P-Probe; NC S1=1, S5=0, S7=1	264	60	<4	
P-Probe; NC S1=1, S5=1, S7=1	264	60	<4	
P-Probe; SFC S1=0, S5=0, S7=1	264	60	<4	
P-Probe; SFC S1=0, S5=1, S7=1	264	60	<4	
P-Probe; SFC S1=1, S5=0, S7=0	264	60	6.7	
P-Probe; SFC S1=1, S5=1, S7=0	264	60	6.8	
P-ECG; NC S1=1, S5=0, S7=1	264	60	<4	
P-ECG; NC S1=1, S5=1, S7=1	264	60	<4	
P-ECG; SFC S1=0, S5=0, S7=1	264	60	<4	
P-ECG; SFC S1=0, S5=1, S7=1	264	60	<4	
P-ECG; SFC S1=1, S5=0, S7=0	264	60	<4	
P-ECG; SFC S1=1, S5=1, S7=0	264	60	<4	
Model X1, non-frequency-weighted				
P-Probe; NC S1=1, S5=0, S7=1	264	60	41.5	
P-Probe; NC S1=1, S5=1, S7=1	264	60	41.3	
P-Probe; SFC S1=0, S5=0, S7=1	264	60	41.7	
P-Probe; SFC S1=0, S5=1, S7=1	264	60	40.9	
P-Probe; SFC S1=1, S5=0, S7=0	264	60	41.7	
P-Probe; SFC S1=1, S5=1, S7=0	264	60	42.1	
P-ECG; NC S1=1, S5=0, S7=1	264	60	22.3	
P-ECG; NC S1=1, S5=1, S7=1	264	60	22.2	
P-ECG; SFC S1=0, S5=0, S7=1	264	60	22.3	
P-ECG; SFC S1=0, S5=1, S7=1	264	60	22.3	
P-ECG; SFC S1=1, S5=0, S7=0	264	60	22.4	
P-ECG; SFC S1=1, S5=1, S7=0	264	60	22.5	
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
Model E20, frequency-weighted				
PM-Probe; S1=1, S5=1,S7=1, S9=1	264	60	35.6	
PM-Probe; S1=1, S5=1,S7=1, S9=0	264	60	36.1	

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
PM-Probe; S1=1, S5=0,S7=1, S9=1	264	60	36.0	
PM-Probe; S1=1, S5=0,S7=1, S9=0	264	60	36.1	
PM-ECG; S1=1, S5=1,S7=1, S9=1	264	60	23.7	
PM-ECG; S1=1, S5=1,S7=1, S9=0	264	60	23.7	
PM-ECG; S1=1, S5=0,S7=1, S9=1	264	60	24.1	
PM-ECG; S1=1, S5=0,S7=1, S9=0	264	60	24.2	
Model E20, non-frequency-weighted				
PM-Probe; S1=1, S5=1,S7=1, S9=1	264	60	37.3	
PM-Probe; S1=1, S5=1,S7=1, S9=0	264	60	37.4	
PM-Probe; S1=1, S5=0,S7=1, S9=1	264	60	37.6	
PM-Probe; S1=1, S5=0,S7=1, S9=0	264	60	37.8	
PM-ECG; S1=1, S5=1,S7=1, S9=1	264	60	24.7	
PM-ECG; S1=1, S5=1,S7=1, S9=0	264	60	24.8	
PM-ECG; S1=1, S5=0,S7=1, S9=1	264	60	25.1	
PM-ECG; S1=1, S5=0,S7=1, S9=0	264	60	25.3	
Model X1, frequency-weighted				
PM-Probe; S1=1, S5=1,S7=1, S9=1	264	60	35.9	
PM-Probe; S1=1, S5=1,S7=1, S9=0	264	60	36	
PM-Probe; S1=1, S5=0,S7=1, S9=1	264	60	36.3	
PM-Probe; S1=1, S5=0,S7=1, S9=0	264	60	35.7	
PM-ECG; S1=1, S5=1,S7=1, S9=1	264	60	23.8	
PM-ECG; S1=1, S5=1,S7=1, S9=0	264	60	23.9	
PM-ECG; S1=1, S5=0,S7=1, S9=1	264	60	24.2	
PM-ECG; S1=1, S5=0,S7=1, S9=0	264	60	24.3	
Model X1, non- frequency-weighted				
PM-Probe; S1=1, S5=1,S7=1, S9=1	264	60	36.7	
PM-Probe; S1=1, S5=1,S7=1, S9=0	264	60	37.3	
PM-Probe; S1=1, S5=0,S7=1, S9=1	264	60	37.8	
PM-Probe; S1=1, S5=0,S7=1, S9=0	264	60	37.9	
PM-ECG; S1=1, S5=1,S7=1, S9=1	264	60	25.3	
PM-ECG; S1=1, S5=1,S7=1, S9=0	264	60	25.1	

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
PM-ECG; S1=1, S5=0,S7=1, S9=1	264	60	25.4	
PM-ECG; S1=1, S5=0,S7=1, S9=0	264	60	25.5	
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)
Model E20, frequency-weighted				
PSS-Probe; NC, S1=1, S5=0;S7=1, S9=0	264	60	<4	
PSS-Probe; NC, S1=1, S5=0;S7=1, S9=1	264	60	<4	
PSS-Probe; NC, S1=1, S5=1; S7=1, S9=0	264	60	<4	
PSS-Probe; NC, S1=1, S5=1; S7=1, S9=1	264	60	<4	
PSS-Probe; SFC, S1=0, S5=0; S7=1, S9=0	264	60	<4	
PSS-Probe; SFC, S1=0, S5=0; S7=1, S9=1	264	60	<4	
PSS-Probe; SFC, S1=0, S5=1; S7=1, S9=0	264	60	<4	
PSS-Probe; SFC, S1=0, S5=1; S7=1, S9=1	264	60	<4	
PSS-Probe; SFC, S1=1, S5=0, S7=0, S9=0	264	60	9.5	
PSS-Probe; SFC, S1=1, S5=0, S7=0, S9=1	264	60	9.5	
PSS-Probe; SFC, S1=1, S5=1, S7=0, S9=0	264	60	7.6	
PSS-Probe; SFC, S1=1, S5=1, S7=0, S9=1	264	60	7.3	
PSS-ECG; NC, S1=1, S5=0;S7=1, S9=0	264	60	<4	
PSS- ECG; NC, S1=1, S5=0;S7=1, S9=1	264	60	<4	
PSS- ECG; NC, S1=1, S5=1; S7=1, S9=0	264	60	<4	

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
PSS- ECG; NC, S1=1, S5=1; S7=1, S9=1	264	60	<4	
PSS- ECG; SFC, S1=0, S5=0; S7=1, S9=0	264	60	<4	
PSS- ECG; SFC, S1=0, S5=0; S7=1, S9=1	264	60	<4	
PSS- ECG; SFC, S1=0, S5=1; S7=1, S9=0	264	60	<4	
PSS- ECG; SFC, S1=0, S5=1; S7=1, S9=1	264	60	<4	
PSS- ECG; SFC, S1=1, S5=0, S7=0, S9=0	264	60	<4	
PSS- ECG; SFC, S1=1, S5=0, S7=0, S9=1	264	60	<4	
PSS- ECG; SFC, S1=1, S5=1, S7=0, S9=0	264	60	<4	
PSS- ECG; SFC, S1=1, S5=1, S7=0, S9=1	264	60	<4	
Model E20, non-frequency-weighted				
PSS-Probe; NC, S1=1, S5=0;S7=1, S9=0	264	60	57.0	
PSS-Probe; NC, S1=1, S5=0;S7=1, S9=1	264	60	56.9	
PSS-Probe; NC, S1=1, S5=1; S7=1, S9=0	264	60	56.7	
PSS-Probe; NC, S1=1, S5=1; S7=1, S9=1	264	60	56.9	
PSS-Probe; SFC, S1=0, S5=0; S7=1, S9=0	264	60	28.9	
PSS-Probe; SFC, S1=0, S5=0; S7=1, S9=1	264	60	28.7	
PSS-Probe; SFC, S1=0, S5=1; S7=1, S9=0	264	60	28.8	
PSS-Probe; SFC, S1=0, S5=1; S7=1, S9=1	264	60	28.9	
PSS-Probe; SFC, S1=1, S5=0, S7=0, S9=0	264	60	57.7	
PSS-Probe; SFC, S1=1, S5=0, S7=0,	264	60	58.1	

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
S9=1				
PSS-Probe; SFC, S1=1, S5=1, S7=0, S9=0	264	60	55.7	
PSS-Probe; SFC, S1=1, S5=1, S7=0, S9=1	264	60	56.3	
PSS-ECG; NC, S1=1, S5=0;S7=1, S9=0	264	60	32.0	
PSS- ECG; NC, S1=1, S5=0;S7=1, S9=1	264	60	32.1	
PSS- ECG; NC, S1=1, S5=1; S7=1, S9=0	264	60	32.0	
PSS- ECG; NC, S1=1, S5=1; S7=1, S9=1	264	60	32.1	
PSS- ECG; SFC, S1=0, S5=0; S7=1, S9=0	264	60	16.7	
PSS- ECG; SFC, S1=0, S5=0; S7=1, S9=1	264	60	16.9	
PSS- ECG; SFC, S1=0, S5=1; S7=1, S9=0	264	60	17.3	
PSS- ECG; SFC, S1=0, S5=1; S7=1, S9=1	264	60	17.1	
PSS- ECG; SFC, S1=1, S5=0, S7=0, S9=0	264	60	31.4	
PSS- ECG; SFC, S1=1, S5=0, S7=0, S9=1	264	60	30.3	
PSS- ECG; SFC, S1=1, S5=1, S7=0, S9=0	264	60	29.1	
PSS- ECG; SFC, S1=1, S5=1, S7=0, S9=1	264	60	29.2	
Model X1, frequency-weighted				
PSS-Probe; NC, S1=1, S5=0;S7=1, S9=0	264	60	<4	
PSS-Probe; NC, S1=1, S5=0;S7=1, S9=1	264	60	<4	
PSS-Probe; NC, S1=1, S5=1; S7=1, S9=0	264	60	<4	
PSS-Probe; NC, S1=1, S5=1; S7=1, S9=1	264	60	<4	

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
PSS-Probe; SFC, S1=0, S5=0; S7=1, S9=0	264	60	<4	
PSS-Probe; SFC, S1=0, S5=0; S7=1, S9=1	264	60	<4	
PSS-Probe; SFC, S1=0, S5=1; S7=1, S9=0	264	60	<4	
PSS-Probe; SFC, S1=0, S5=1; S7=1, S9=1	264	60	<4	
PSS-Probe; SFC, S1=1, S5=0, S7=0, S9=0	264	60	9.6	
PSS-Probe; SFC, S1=1, S5=0, S7=0, S9=1	264	60	9.6	
PSS-Probe; SFC, S1=1, S5=1, S7=0, S9=0	264	60	8.9	
PSS-Probe; SFC, S1=1, S5=1, S7=0, S9=1	264	60	8.7	
PSS-ECG; NC, S1=1, S5=0;S7=1, S9=0	264	60	<4	
PSS- ECG; NC, S1=1, S5=0;S7=1, S9=1	264	60	<4	
PSS- ECG; NC, S1=1, S5=1; S7=1, S9=0	264	60	<4	
PSS- ECG; NC, S1=1, S5=1; S7=1, S9=1	264	60	<4	
PSS- ECG; SFC, S1=0, S5=0; S7=1, S9=0	264	60	<4	
PSS- ECG; SFC, S1=0, S5=0; S7=1, S9=1	264	60	<4	
PSS- ECG; SFC, S1=0, S5=1; S7=1, S9=0	264	60	<4	
PSS- ECG; SFC, S1=0, S5=1; S7=1, S9=1	264	60	<4	
PSS- ECG; SFC, S1=1, S5=0, S7=0, S9=0	264	60	<4	
PSS- ECG; SFC, S1=1, S5=0, S7=0, S9=1	264	60	<4	
PSS- ECG; SFC, S1=1, S5=1, S7=0, S9=0	264	60	<4	

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
PSS- ECG; SFC, S1=1, S5=1, S7=0, S9=1	264	60	<4	
Model X1, non-frequency-weighted				
PSS-Probe; NC, S1=1, S5=0;S7=1, S9=0	264	60	43.3	
PSS-Probe; NC, S1=1, S5=0;S7=1, S9=1	264	60	44.1	
PSS-Probe; NC, S1=1, S5=1; S7=1, S9=0	264	60	42.8	
PSS-Probe; NC, S1=1, S5=1; S7=1, S9=1	264	60	42.7	
PSS-Probe; SFC, S1=0, S5=0; S7=1, S9=0	264	60	30.8	
PSS-Probe; SFC, S1=0, S5=0; S7=1, S9=1	264	60	30.8	
PSS-Probe; SFC, S1=0, S5=1; S7=1, S9=0	264	60	30.7	
PSS-Probe; SFC, S1=0, S5=1; S7=1, S9=1	264	60	30.8	
PSS-Probe; SFC, S1=1, S5=0, S7=0, S9=0	264	60	41.1	
PSS-Probe; SFC, S1=1, S5=0, S7=0, S9=1	264	60	42.3	
PSS-Probe; SFC, S1=1, S5=1, S7=0, S9=0	264	60	41.8	
PSS-Probe; SFC, S1=1, S5=1, S7=0, S9=1	264	60	41.5	
PSS-ECG; NC, S1=1, S5=0;S7=1, S9=0	264	60	19.8	
PSS- ECG; NC, S1=1, S5=0;S7=1, S9=1	264	60	19.7	
PSS- ECG; NC, S1=1, S5=1; S7=1, S9=0	264	60	19.4	
PSS- ECG; NC, S1=1, S5=1; S7=1, S9=1	264	60	19.4	
PSS- ECG; SFC, S1=0, S5=0; S7=1, S9=0	264	60	18.8	
PSS- ECG; SFC, S1=0, S5=0; S7=1,	264	60	18.9	

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
S9=1				
PSS- ECG; SFC, S1=0, S5=1; S7=1, S9=0	264	60	18.7	
PSS- ECG; SFC, S1=0, S5=1; S7=1, S9=1	264	60	18.8	
PSS- ECG; SFC, S1=1, S5=0, S7=0, S9=0	264	60	21.8	
PSS- ECG; SFC, S1=1, S5=0, S7=0, S9=1	264	60	21.9	
PSS- ECG; SFC, S1=1, S5=1, S7=0, S9=0	264	60	21.9	
PSS- ECG; SFC, S1=1, S5=1, S7=0, S9=1	264	60	21.3	
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
N/A				
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current)
Model E20, frequency-weighted				
PA; NC; S1=1; S5=0, S7=1	264	60	<4	
PA; NC; S1=1; S5=1, S7=1	264	60	<4	
PA; SFC; S1=0; S5=0, S7=1	264	60	<4	
PA; SFC; S1=0; S5=1, S7=1	264	60	<4	
PA; SFC; S1=1; S5=0; S7=0	264	60	<4	
PA; SFC; S1=1; S5=1; S7=0	264	60	<4	
Model E20, non-frequency-weighted				
PA; NC; S1=1; S5=0, S7=1	264	60	<4	
PA; NC; S1=1; S5=1, S7=1	264	60	<4	
PA; SFC; S1=0; S5=0, S7=1	264	60	<4	
PA; SFC; S1=0; S5=1, S7=1	264	60	<4	
PA; SFC; S1=1; S5=0; S7=0	264	60	<4	
PA; SFC; S1=1; S5=1; S7=0	264	60	<4	

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

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
Model X1, frequency-weighted				
PA; NC; S1=1; S5=0, S7=1	264	60	<4	
PA; NC; S1=1; S5=1, S7=1	264	60	<4	
PA; SFC; S1=0; S5=0, S7=1	264	60	<4	
PA; SFC; S1=0; S5=1, S7=1	264	60	<4	
PA; SFC; S1=1; S5=0; S7=0	264	60	<4	
PA; SFC; S1=1; S5=1; S7=0	264	60	<4	
Model X1, non-frequency-weighted				
PA; NC; S1=1; S5=0, S7=1	264	60	<4	
PA; NC; S1=1; S5=1, S7=1	264	60	<4	
PA; SFC; S1=0; S5=0, S7=1	264	60	<4	
PA; SFC; S1=0; S5=1, S7=1	264	60	<4	
PA; SFC; S1=1; S5=0; S7=0	264	60	<4	
PA; SFC; S1=1; S5=1; S7=0	264	60	<4	
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)
N/A				
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)
N/A				
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
N/A				
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
N/A				
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC

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

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

Supplementary information:

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

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

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

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

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

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

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

Insulation under test (area from insulation diagram)	**Insulation Type (1 or 2 MOOP/MOPP)**	**Reference Voltage**		**A.C. test voltages in V r.m.s[1)]**	**Dielectric breakdown after 1 minute Yes/No[2)]**
		PEAK WORKING VOLTAGE (U) V_{peak}	**PEAK WORKING VOLTAGE (U) V d.c.**		
With appliance inlet 5120 series					
A	1MOPP	240x1.414	--	1500	No
B	2MOOP	240x1.414	--	3000	No
C	1MOPP	240x1.414	--	1500	No
D	1MOPP	240x1.414	--	1500	No
F	1MOOP	240x1.414	--	1500	No
G1	2MOPP	240x1.414	--	4000	No
G2	2MOPP	240x1.414	--	4000	No
H	1MOPP	240x1.414	--	1500	No
With appliance inlet 6100 series / DB-14 series					
A	1MOPP	240x1.414	--	1500	No
B	2MOOP	240x1.414	--	3000	No
C	1MOPP	240x1.414	--	1500	No
D	1MOPP	240x1.414	--	1500	No
F	1MOOP	240x1.414	--	1500	No
G1	2MOPP	240x1.414	--	4000	No
G2	2MOPP	240x1.414	--	4000	No
H	1MOPP	240x1.414	--	1500	No

Supplementary information:

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

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

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)**
Non-metallic enclosure of the main unit	75	0.83
Non-metallic enclosure of the probes	75	0.76

Supplementary information:

resistance to heat for insulation of thermoplastic materials that used as SUPPLEMENTARY INSULATION or REINFORCED INSULATION established by performing the ball-pressure test in at a temperature 25 °C higher than the temperature of the insulation measured during the tests of 13.2.2 to 13.2.13 (inclusive).

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

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

8.9.3.2	Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts			P
Part Test	**8.9.3.4 - Test duration and temperature for 10 cycles after which the sample was subjected to Humidity Preconditioning per Cl. 5.7**	**Dielectric test voltage**	**Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No**	**Crack or voids in the insulating compound: Yes/No**
All probe listed in this report	68 h at T1 ± 2 °C = 85°C [1)]	1500*1.6= 2400	No	No
	1 h at 25 °C ± 2 °C			
	2 h at 0 °C ± 2 °C			
	1 or more h at 25 °C ± 2 °C			
Supplementary information: [1)] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.				

8.9.3.3	Table: Thermal cycling tests on one sample of cemented joint with other insulating parts (see 8.9.3.3)			N/A
Part tested	**Sample**	**Each test duration and temperature**	**Dielectric test voltage**	**Dielectric strength test Breakdown: Yes/No**
Supplementary information: [1)] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.				

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

8.10	TABLE: List of critical components				P
Component/ Part No.	**Manufacturer/ Trademark**	**Type No./model No./**	**Technical data**	**Standard No./, Edition**	**Mark(s) & Certificates of conformity[1)]**
Mains plug for EU	Changzhou Hong Chang Electronics Co. Ltd.	DTIII-2P-05	250V, 16A, DIN 49441-R2	VDE 0620-2-1	VDE 40015536
Power cord	Changzhou Hong Chang Electronics Co. Ltd.	H05VV-F	3x0.75mm^2	EN 50525-2-11	VDE 124978
Cord connector	Changzhou Hong Chang Electronics Co. Ltd.	DTII-3P-04	250V, 10A, type C13	IEC/EN 60320-1	VDE 40005918
Appliance inlet	Schurter AG	5120 series	250V, 10A, type C14	IEC/EN 60939-2	VDE 40016382
Alt.	Schurter AG	6100 series	250V, 10A, type C14	IEC/EN 60320-1	VDE 40015595
Alt.	LECI ELECTRONICS CO., LTD	DB-14 series	250V, 10A, type C14	IEC/EN 60320-1	VDE 40032137
Switch	Shanghai Liangxin Electrical Co., Ltd.	NDB3-50	250V~, 5A	IEC/EN 60934	TUV AN 50205406
AC-DC	MEAN WELL Enterprises Co., Ltd.	RPS-300-12	Input: 100-240V~, 50/60Hz, 3.5-1.8A; Output: 12Vdc, 25A	IEC/EN 60601-1	CB Certification (DK-52733-UL)
Main display	VINNO	21.5 inch display	12V, 4A max	IEC/EN 60601-1	Tested with appliance
Alt.	VINNO	18.5 inch display	12V, 4A max	IEC/EN 60601-1	Tested with appliance
Alternate main display for VINNO X1/X1E/X1P only	VINNO	15.6 inch display	12V, 4A max	IEC/EN 60601-1	Tested with appliance
Enclosure	SABIC INNOVATIVE PLASTICS US L L C	C6200	Min. 2.0mm, V-0, Min. 75℃	UL 746 IEC/EN 60601-1	Tested with appliance (UL E121562)

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

Internal primary wire	KUNSHAN XINGHONGMENG ELECTRONIC CO LTD	1672	18AWG, 300V, 105℃, VW-1	UL758 IEC/EN 60601-1	Tested with appliance (UL E315421)
Ground wire	KUNSHAN XINGHONGMEN G ELECTRONIC CO LTD	1015	18AWG, 600V, 105℃, VW-1	UL758 IEC/EN 60601-1	Tested with appliance (UL E315421)
PCB	LANTEK	LanTek-02	V-0, 130℃	UL796 IEC/EN 60601-1	Tested with appliance (UL E253430)
Fans near T-power part	ADDA Corporation	AD5012LS-D76	12Vdc, 0.96W	IEC/EN 60950-1	TUV R 50068602
Fans under SMPS power module	SUNONWEALTH ELECTRIC MACHINE INDUSTRY CO LTD	HA92251V4-000C-999	12Vdc, 1.06W	UL 507 IEC/EN 60601-1	Tested with appliance (UL E77551)
Alt.	RASCOM COMPUTERDISTRIBUTION GES M B H	NF-B9-1600	12Vdc, 1.32W	UL 507 IEC/EN 60601-1	Tested with appliance (UL E356416)
Alt.	ADDA Corporation	AD0912LB-A70GL(T)	12Vdc, 1.20W	IEC/EN 60950-1	TUV R 50068602
Probe 1	VINNO Technology (Suzhou) Co., Ltd.	F2-5C	Type BF, IPX7 for the probes main unit, IPX4 for the probe cable	IEC/EN 60601-1	Tested with appliance
Probe 2	VINNO Technology (Suzhou) Co., Ltd.	D3-6C	Type BF, IPX7 for the probes main unit, IPX4 for the probe cable	IEC/EN 60601-1	Tested with appliance
Probe 3	VINNO Technology (Suzhou) Co., Ltd.	D3-6CE	Type BF, IPX7 for the probes main unit, IPX4 for the probe cable	IEC/EN 60601-1	Tested with appliance
Probe 4	VINNO Technology (Suzhou) Co., Ltd.	F4-9E	Type BF, IPX7 for the probes main unit, IPX4 for the probe cable	IEC/EN 60601-1	Tested with appliance
Probe 5	VINNO Technology (Suzhou) Co.,	G4-9E	Type BF, IPX7 for the probes main unit, IPX4	IEC/EN 60601-1	Tested with appliance

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

	Ltd.		for the probe cable		
Probe 6	VINNO Technology (Suzhou) Co., Ltd.	G4-9M	Type BF, IPX7 for the probes main unit, IPX4 for the probe cable	IEC/EN 60601-1	Tested with appliance
Probe 7	VINNO Technology (Suzhou) Co., Ltd.	F4-12L	Type BF, IPX7 for the probes main unit, IPX4 for the probe cable	IEC/EN 60601-1	Tested with appliance
Probe 8	VINNO Technology (Suzhou) Co., Ltd.	X4-12L	Type BF, IPX7 for the probes main unit, IPX4 for the probe cable	IEC/EN 60601-1	Tested with appliance
Probe 9	VINNO Technology (Suzhou) Co., Ltd.	G1-4P	Type BF, IPX7 for the probes main unit, IPX4 for the probe cable	IEC/EN 60601-1	Tested with appliance
Probe 10	VINNO Technology (Suzhou) Co., Ltd.	D2-6C	Type BF, IPX7 for the probes main unit, IPX4 for the probe cable	IEC/EN 60601-1	Tested with appliance
Black & White Printer	SONY	UP-X898MD	AC 100-240V, 50/60Hz, 1.3-0.6A	IEC 60601-1:2005/AMD1:2012	CB Certification (US-29320-M1-UL)
Colour Printer	SONY	UP-D25MD	AC 100-240V, 50/60Hz, 1.7-1.0A	IEC 60601-1:2005/AMD1:20 12	CB Certification (US-29872-M1-UL)
Foot switch	Korea auto control	HRF-M5-U/ HRF-M52-U	IP68	IEC/EN 60529	Report No 2006-1454-467+ Tested with appliance
Wireless adapter	COMFRST	CF-812AC	WiFi USB Adapter	IEC 60601-1	Tested with appliance
Bluetooth adapter	ORICO	BTA-403/402	USB dual-mode Bluetooth	IEC 60601-1	Tested with appliance

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

USB DVD RW (Optional)	PIONEER	DVR-XU01C	5VDC, 1.5A	IEC/EN 60601	Test with appliance
ECG Kit (Optional)	VINNO	ECG Module Kit	Including the following	IEC/EN 60601	Tested with appliance
ECG kit - Enclosure	SABIC INNOVATIVE PLASTICS US L L C	C6200	Min. 2.0mm, V-0, Min. 75℃	UL 746 IEC/EN 60601	Tested with appliance (UL E121562)
ECG Module Kit PCB	LANTEK	LanTek-02	V-0, 130℃	UL796 IEC/EN 60601	Tested with appliance (UL E253430)
Isolation chip in ECG Kit	Texas Instruments Deutschland GmbH	ISO7841	8000VPK isolation	DIN VDE V 0884-10	VDE 40040142
Alt.	Texas Instruments Deutschland GmbH	ISO7842	8000VPK isolation	DIN VDE V 0884-10	VDE 40040142
Alt.	AVAGO TECHNOLOGIES PTE LTD	HCNW2601	5000Vac isolation	UL 1577 IEC 60601-1	Tested with appliance (UL E55361)

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

8.10 b	**TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS**				**N/A**
Object / part No.	**Manufacturer/ trademark**	**Type / model**	**Technical data**	**Standard**	**Mark(s) of conformity[1)]**
- Description:					

Supplementary information:
[1)] Provided evidence ensures the agreed level of compliance. See OD-CB2039.

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

8.11.3.5	TABLE: CORD ANCHORAGES			P
Cord under test	**Mass of equipment (kg)**	**Pull (N)**	**Torque Nm)**	**Remarks**
Footswitch	0.98	30	0.1	No break down
Supplementary information:				

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

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

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

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

9.4.2.1	TABLE: Instability—overbalance in transport position	P
ME EQUIPMENT preparation	**Test Condition (transport position)**	**Remarks**
EUT	10° inclined	No overbalance
Supplementary information:		

9.4.2.2	TABLE: Instability—overbalance excluding transport position	P
ME EQUIPMENT preparation	**Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)**	**Remarks**
EUT	10° inclined	No overbalance
Supplementary information:		

9.4.2.3	TABLE: Instability—overbalance from horizontal and vertical forces	P
ME EQUIPMENT preparation	**Test Condition (force used, direction of force, weight of equipment, location of force)**	**Remarks**
Entire EUT	150N	No overbalance
Supplementary information:		

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

9.4.2.4.2	TABLE: Castors and wheels – Force for propulsion	P
ME EQUIPMENT preparation	**Test Condition (force location and height)**	**Remarks**
Entire EUT	20N	
Supplementary information:		

9.4.2.4.3	TABLE: Castors and wheels – Movement over a threshold	P
ME EQUIPMENT preparation	**Test Condition (speed of movement)**	**Remarks**
EUT	10mm, 0.8m/s	Pass over
Supplementary information:		

9.4.3.1	TABLE: Instability from unwanted lateral movement (including sliding) in transport position	P
ME EQUIPMENT Preparation	**Test Condition (transport position, working load, locking device(s), caster position)**	**Remarks**
Entire EUT	10° inclined	<50mm
Supplementary information:		

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

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

ME EQUIPMENT Preparation	Test Condition (working load, locking device(s), caster position, force, force location, force direction)	Remarks
EUT	5 ° inclined	<50mm
EUT	150N	<50mm

Supplementary information:

9.4.4	TABLE: Grips and other handling devices	N/A

Clause and Name of Test	Test Condition	Remarks

Supplementary information:

9.7.5	TABLE: Pressure vessels	N/A

Hydraulic, Pneumatic or Suitable Media and Test Pressure	Vessel Burst	Permanent Deformation	Leaks	Vessel fluid substance	Remarks

Supplementary Information:

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

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

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

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

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

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

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT**				**P**
Model No. .....:	See below				
Test ambient (°C) .....:	See below				
Test supply voltage/frequency (V/Hz)[4] ..:	See below				
Model No.	**Thermo-couple No.**	**Thermocouple location[3]**	**Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)**	**Max measured temperature[2], (°C)**	**Remarks**
Model E20. 264V,60Hz, normal condition					
E20	-	Transformer T1 of AC-DC	105	79.69	
E20	-	PCB near Transformer T1 of AC-DC	130	80.07	
E20	-	Filter	120	43.16	
E20	-	Internal wire	105	43.42	
E20	-	Power switch	71	42.83	
E20	-	T1 of T-power board	130	53.45	
E20	-	PCB near C74	130	57.24	
E20	-	PCB near U29	130	51.25	
E20	-	PCB near U37	130	47.2	
E20	-	PCB near U1	130	44.29	
E20	-	PCB near Q8	130	55.49	
E20	-	PCB near C37	130	54.19	
E20	-	PCB near Q10	130	59.17	
E20	-	PCB near CPU	130	60.71	
E20	-	PCB near main board IC	130	63.13	
E20	-	Big board PCB	130	64.81	
E20	-	Middle board PCB	130	72.49	
E20	-	Small board PCB	130	66.4	
E20	-	PCB of connector board	130	44.76	
E20	-	Metal Enclosure	51	47.03	10 s ≤ t < 1 min
E20	-	PCB near U6	130	51.42	
E20	-	PCB near U14	130	53.87	
E20	-	PCB near U3	130	51.2	
E20	-	ECG module enclosure	60	44.28	10 s ≤ t < 1 min

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

E20	-	Printer enclosure	60	45.46	10 s ≤ t < 1 min
E20	-	Key board	60	41.51	10 s ≤ t < 1 min
E20	-	Touch panel	60	46.06	10 s ≤ t < 1 min
E20	-	Display	60	47.49	10 s ≤ t < 1 min
Model E20. 90V,60Hz, normal condition					
E20	-	Transformer T1 of AC-DC	105	92.01	
E20	-	PCB near Transformer T1 of AC-DC	130	90.59	
E20	-	Filter	120	47.1	
E20	-	Internal wire	105	47.35	
E20	-	Power switch	71	47.62	
E20	-	T1 of T-power board	130	52.77	
E20	-	PCB near C74	130	49.91	
E20	-	PCB near U29	130	50.63	
E20	-	PCB near U37	130	48.88	
E20	-	PCB near U1	130	45.19	
E20	-	PCB near Q8	130	56.96	
E20	-	PCB near C37	130	60.98	
E20	-	PCB near Q10	130	66.33	
E20	-	PCB near CPU	130	63.1	
E20	-	PCB near main board IC	130	61.67	
E20	-	Big board PCB	130	66.88	
E20	-	Middle board PCB	130	74.13	
E20	-	Small board PCB	130	67.54	
E20	-	PCB of connector board	130	44.7	
E20	-	Metal Enclosure	51	47.65	10 s ≤ t < 1 min
E20	-	PCB near U6	130	51.92	
E20	-	PCB near U14	130	53.96	
E20	-	PCB near U3	130	50.56	
E20	-	ECG module enclosure	60	43.29	10 s ≤ t < 1 min
E20	-	Printer enclosure	60	44.92	10 s ≤ t < 1 min
E20	-	Key board	60	40.74	10 s ≤ t < 1 min
E20	-	Touch panel	60	46.02	10 s ≤ t < 1 min
E20	-	Display	60	47.23	10 s ≤ t < 1 min

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

Model X1. 264V,60Hz, normal condition					
X1	-	Transformer of AC-DC	105	87.05	
X1	-	PCB near Transformer T1 of AC-DC	130	83.24	
X1	-	Filter	130	42.74	
X1	-	Internal wire	105	43.85	
X1	-	Power switch	130	43.18	
X1	-	PCB near Q5	130	52.69	
X1	-	PCB near F1	130	53.03	
X1	-	PCB near Q8	130	70.08	
X1	-	PCB near C37	130	75.57	
X1	-	PCB near Q10	130	73.29	
X1	-	PCB near CPU	130	78.38	
X1	-	PCB near main IC	130	65.98	
X1	-	Small board	130	76.18	
X1	-	Big board	130	87.3	
X1	-	PCB near U3	130	55.06	
X1	-	PCB of connector board	130	53.39	
X1	-	Metal Enclosure	51	46.4	10 s ≤ t < 1 min
X1	-	PCB near U6	130	57.93	
X1	-	PCB near U14	130	64.54	
X1	-	PCB near U3	130	58.52	
X1	-	ECG module enclosure	60	41.87	10 s ≤ t < 1 min
X1	-	Printer enclosure	60	41.5	10 s ≤ t < 1 min
X1	-	DVD enclosure	60	42.68	10 s ≤ t < 1 min
X1	-	Touch panel	60	44.93	10 s ≤ t < 1 min
X1	-	Display	60	48.49	10 s ≤ t < 1 min
X1	-	Key board	60	43.65	10 s ≤ t < 1 min
Model X1. 90V,60Hz, normal condition					
X1	-	Transformer of AC-DC	105	88.6	
X1	-	PCB near Transformer T1 of AC-DC	130	82.84	
X1	-	Filter	130	42.17	
X1	-	Internal wire	105	41.33	

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

X1	-	Power switch	130	42	
X1	-	PCB near Q5	130	51.27	
X1	-	PCB near F1	130	51.63	
X1	-	PCB near Q8	130	62.65	
X1	-	PCB near C37	130	63.38	
X1	-	PCB near Q10	130	68.08	
X1	-	PCB near CPU	130	78.78	
X1	-	PCB near main IC	130	62.86	
X1	-	Small board	130	73.81	
X1	-	Big board	130	92.14	
X1	-	PCB near U3	130	55.22	
X1	-	PCB of connector board	130	51.7	
X1	-	Metal Enclosure	51	46.14	10 s ≤ t < 1 min
X1	-	PCB near U6	130	54.55	
X1	-	PCB near U14	130	60.65	
X1	-	PCB near U3	130	46.89	
X1	-	ECG module enclosure	60	42.75	10 s ≤ t < 1 min
X1	-	Printer enclosure	60	43.61	10 s ≤ t < 1 min
X1	-	DVD enclosure	60	44.49	10 s ≤ t < 1 min
X1	-	Touch panel	60	43.72	10 s ≤ t < 1 min
X1	-	Display	60	47.84	10 s ≤ t < 1 min
X1	-	Key board	60	42.28	10 s ≤ t < 1 min

Supplementary information:

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

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

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

[4] Supply voltage:

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

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

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

Information from Risk Management, as applicable**:**

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

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

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

11.2.2.1	**TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source**	**N/A**

Areas where sparking might cause ignition:	**Remarks**
1.	
2.	
3.	
4.	
5.	
6.	

Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):	**Remarks**
1.	
2.	
3.	
4.	
5.	
6.	

Test parameters selected representing worst case conditions for ME EQUIPMENT:		**Remarks**
Oxygen concentration (%)..... :		
Fuel ..... :		
Current (A) ..... :		
Voltage (V)..... :		
Capacitance (μF) ..... :		
Inductance or resistance (h or Ω).... :		
No. of trials (300 Min) ..... :		
Sparks resulted in ignition (Yes/No) :		

Supplementary information: Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst-case values with other parameters set at worst case values to determine if ignition can occur.

Information from Risk Management, as applicable:

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

11.6.1	TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances		P
Clause / Test Name	**Test Condition**	**Part under test**	**Remarks**
11.6.3	Spillage	Entire EUT	Pass
11.6.5	IPX7	Parts of probe intended to be immersed during normal use.	Pass
11.6.5	IPX4	Other parts of probe and the cable of probes	Pass
11.6.6	Cleaning	Entire EUT	Pass
Supplementary information: Information from Risk Management, as applicable:			

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

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

13.2	**TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive**		**P**
Clause No.	**Description of SINGLE FAULT CONDITION**	**Results observed**	**HAZARDOUS SITUATION (Yes/No)**
13.2.2	**Electrical SINGLE FAULT CONDITIONS per Cl. 8.1:**	**—**	**—**
	MODEL E20		
	C66 S.C.	NORMAL WORKING	NO
	C142 S.C.	EUT PROTECT	NO
	C239 S.C.	EUT PROTECT	NO
	U37 S.C.	NORMAL WORKING	NO
	USB OVERLOAD	NORMAL WORKING	NO
	MODEL X1		
	J5 S.C.	EUT PROTECT	NO
	J9 S.C.	EUT PROTECT	NO
	Q4	NORMAL WORKING	NO
	USB OVERLOAD	NORMAL WORKING	NO
13.2.3	**Overheating of transformers per Clause 15.5:**	**—**	**—**
	N/A		
13.2.4	**Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:**	**—**	**—**
	N/A		
13.2.5	**Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:**	**—**	**—**
	N/A		
13.2.6	**Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)**	**—**	**—**
	N/A		
13.2.7	**Impairment of cooling that could result in a HAZARD using test method of 11.1:**	**—**	**—**
	Single ventilation fans locked consecutively	No high temperature	NO
	Ventilation blocked	No high temperature	NO

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.8	**Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:**	**—**	**—**
	N/A		
13.2.9	**Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10**	**—**	**—**
	N/A		
13.2.10	**Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:**	**—**	**—**
	N/A		
13.2.11	**Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:**	**—**	**—**
	N/A		
13.2.12	**Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):**	**—**	**—**
	N/A		

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

Information from Risk Management, as applicable:

15.3	**TABLE: Mechanical Strength tests [1]**		**P**
Clause	**Name of Test**	**Test conditions**	**Observed results/Remarks**
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	No damage
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	No damage
15.3.4.1	Drop Test (hand-held)	Free fall height (m) = 1	No damage
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5	No damage
15.3.5	Rough handling test	Travel speed (m/s) = 0.8	No damage
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) =70	No damage, no hazard

Supplementary information: [1] As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows or state N/A in Remarks field).

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

15.4.6	TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests				N/A
Rotating control under test	**Gripping diameter "d" of control knob (mm)[1)]**	**Torque from Table 30 (Nm)**	**Axial force applied (N)**	**Unacceptable RISK occurred Yes/No**	**Remarks**
Supplementary information: [1)] Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)					

15.5.1.2	TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION							N/A
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)[1)]....:								**—**
RATED input frequency (Hz).....:								**—**
Winding tested	**Class of insulation (A, B, E, F, or H)**	**Type of protective device (fuse, circuit breaker) /Ratings**	**Protective device operated Yes/No**	**Time to THERMAL STABILITY (when protective device did not operate)(Min)**	**Maximum allowed temp from Table 31 (ºC)**	**Maximum winding temp measured (ºC)**	**Ambient (ºC)**	
Supplementary information: [1)] Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.								

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

15.5.1.3	**TABLE: transformer overload test – conducted only when protective device under short-circuit test operated**	**N/A**
Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1)] ..... :		
RATED input frequency (Hz) ..... :		
Test current just below minimum current that would activate protective device and achieve THERMAL STABILITY under method a) (A) ..... :		
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A) ..... :		

Winding tested	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (ºC)	Maximum winding temp measured (ºC)	Ambient (ºC)

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

15.5.2	**TABLE: Transformer dielectric strength after humidity preconditioning of 5.7**				**N/A**
Transformer Model/Type/ Part No	**Test voltage applied between**	**Test voltage, (V)**	**Test frequency (Hz)**	**Breakdown Yes/No**	**Deterioration Yes/No**
	Primary & secondary windings				
	Primary winding & frame				
	Secondary winding & frame				

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

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

16.6.1	TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS				P
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	**Allowable TOUCH CURRENT in NORMAL CONDITION (μA)**	**Measured TOUCH CURRENT in NORMAL CONDITION (μA)**	**Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (μA)**	**Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (μA)**	
MODEL E20					
Between Black & White Printer and E20 enclosure (FREQUENCY-WEIGHTED)	100	<4	500	11.7	
TYPE BF AP WITH BLACK & WHITE PRINTER (FREQUENCY-WEIGHTED)	100	<4	500	<4	
Between Colour Printer and E20 enclosure (FREQUENCY-WEIGHTED)	100	<4	500	10.65	
Type BF AP with Black & White Printer (FREQUENCY-WEIGHTED)	100	<4	500	<4	
MODEL X1					
Between Black & White Printer and X1 enclosure (FREQUENCY-WEIGHTED)	100	<4	500	6.36	
TYPE BF AP WITH BLACK & WHITE PRINTER (FREQUENCY-WEIGHTED)	100	<4	500	<4	
Between Colour Printer and X1 enclosure (FREQUENCY-WEIGHTED)	100	<4	500	5.97	
Type BF AP with Black & White Printer (FREQUENCY-WEIGHTED)	100	<4	500	<4	
Supplementary information: Other test data please refer to table 8.7.					

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

SP	TABLE: Additional or special tests conducted	N/A

Clause and Name of Test	Test type and condition	Observed results

Supplementary information:

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

Attachment 1: Software– IEC 62304:2006+AMD1:2015

	Attachment - Software – IEC 62304:2006+AMD1:2015		—
4.3	**[A, B, C] Software safety classification**		—
	a) The MANUFACTURER assigns to each SOFTWARE SYSTEM a software safety class according to the RISK of HARM to the patient, operator, or other people resulting from a HAZARDOUS SITUATION to which the SOFTWARE SYSTEM can contribute in a worst-case-scenario	Class B	P
	The SOFTWARE SYSTEM is software safety class A if:		—
	– the SOFTWARE SYSTEM not contribute to a HAZARDOUS SITUATION; or		N/A
	– the SOFTWARE SYSTEM contribute to a HAZARDOUS SITUATION which does not result in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM		N/A
	The SOFTWARE SYSTEM is software safety class B if:		—
	– the SOFTWARE SYSTEM contribute to a HAZARDOUS SITUATION which results in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM and the resulting possible HARM is non-SERIOUS INJURY	Class B	P
	The SOFTWARE SYSTEM is software safety class C if:		—
	– the SOFTWARE SYSTEM contribute to a HAZARDOUS SITUATION which results in unacceptable RISK after consideration of RISK CONTROL measures external to the SOFTWARE SYSTEM and the resulting possible HARM is death or SERIOUS INJURY		N/A
	For a SOFTWARE SYSTEM initially classified as software safety class B or C, the MANUFACTURER has implemented additional RISK CONTROL measures external to the SOFTWARE SYSTEM and subsequently has assigned a new software safety classification to the SOFTWARE SYSTEM		N/A
	c) The MANUFACTURER documents the software safety class assigned to each SOFTWARE SYSTEM in the RISK MANAGEMENT FILE		N/A

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
	d) When a SOFTWARE SYSTEM is decomposed into SOFTWARE ITEMS, and when a SOFTWARE ITEM is decomposed into further SOFTWARE ITEMS, such SOFTWARE ITEMS inherit the software safety classification of the original SOFTWARE ITEM (or SOFTWARE SYSTEM) unless the MANUFACTURER documents a rationale for classification into a different software safety class		N/A
	A rationale explains how the new SOFTWARE ITEMS are segregated so that they may be classified separately		N/A
	e) The MANUFACTURER documents the software safety class of each SOFTWARE ITEM if that class is different from the class of the SOFTWARE ITEM from which it was created by decomposition		N/A
	f) When applied to a group of SOFTWARE ITEMS, the MANUFACTURER uses the PROCESSES and TASKS which are required by the classification of the highest-classified SOFTWARE ITEM in the group unless the MANUFACTURER documents in the RISK MANAGEMENT FILE a rationale for using a lower classification		N/A
	g) Class C requirements apply for each SOFTWARE SYSTEM, until a software safety class is assigned		N/A
4.4	**[A, B, C] LEGACY SOFTWARE**		—
	Clauses 5 through 9 have applied to demonstrate the compliance of LEGACY SOFTWARE		P
	As alternative, clauses 4.4.2 through 4.4.5 have applied to demonstrate the compliance of LEGACY SOFTWARE		N/A
4.4.2	[A, B, C] RISK MANAGEMENT ACTIVITIES		—
	The MANUFACTURER:		N/A
	a) assesses any feedback, including post-production information, on LEGACY SOFTWARE regarding incidents and / or near incidents, both from inside its own organization and / or from users		N/A
	b) performs RISK MANAGEMENT ACTIVITIES associated with continued use of the LEGACY SOFTWARE		N/A
	Considering the following aspects:		N/A
	– integration of the LEGACY SOFTWARE in the overall MEDICAL DEVICE architecture		N/A
	– continuing validity of RISK CONTROL measures, implemented as part of the LEGACY SOFTWARE		N/A

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
	– identification of HAZARDOUS SITUATIONS associated with the continued use of the LEGACY SOFTWARE		N/A
	– identification of potential causes of the LEGACY SOFTWARE contributing to a HAZARDOUS SITUATIONS		N/A
	– definition of RISK CONTROL measures for each potential cause of the LEGACY SOFTWARE contributing to a HAZARDOUS SITUATIONS		N/A
4.4.3	[A, B, C] Gap analysis		N/A
	Based on the software safety class of the LEGACY SOFTWARE, the MANUFACTURER performs a gap analysis of available DELIVERABLES against those required according to 5.2, 5.3, 5.7, and Clause 7		N/A
	a) The MANUFACTURER assesses the continuing validity of available DELIVERABLES		N/A
	b) Where gaps are identified, the MANUFACTURER EVALUATES the potential reduction in RISK resulting from the generation of the missing DELIVERABLES and associated ACTIVITIES		N/A
	c) Based on this evaluation, the MANUFACTURER determines the DELIVERABLES to be created and associated ACTIVITIES to be performed		N/A
	SOFTWARE SYSTEM test records are the minimum DELIVERABLES to be created		N/A
4.4.4	[A, B, C] Gap closure activities		N/A
	a) The MANUFACTURER establishes and executes a plan to generate the identified DELIVERABLES		N/A
	Objective evidences have used to generate required DELIVERABLES without performing ACTIVITIES required by 5.2, 5.3, 5.7 and Clause 7		N/A
	b) The plan addresses the use of the problem resolution PROCESS for handling problems detected in the LEGACY SOFTWARE and DELIVERABLES in accordance with Clause 9		N/A
	c) Changes to the LEGACY SOFTWARE have performed in accordance with Clause 6.		N/A
4.4.5	[A, B, C] Rationale for use of LEGACY SOFTWARE		N/A
	The MANUFACTURER documents the VERSION of the LEGACY SOFTWARE together with a rationale for the continued use of the LEGACY SOFTWARE		N/A

5	**SOFTWARE DEVELOPMENT PROCESS**	**—**

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
5.1	**Software development planning**		—
5.1.1	[A, B, C] The MANUFACTURER establishes a software development plan (or plans) for conducting the ACTIVITIES of the software development PROCESS appropriate to the scope, magnitude, and software safety classifications of the SOFTWARE SYSTEM to be developed.	DDP-PEONY-003, REV#: 1	P
	The SOFTWARE DEVELOPMENT LIFE CYCLE MODEL is either fully defined or be referenced in the plan (or plans).		P
	The plan addresses the following:		P
	a) the PROCESSES to be used in the development of the SOFTWARE SYSTEM	DDP-TSUGA-003, REV#: 1, section 5.1	P
	b) the DELIVERABLES (includes documentation) of the ACTIVITIES and TASKS	DDP-TSUGA-003, REV#: 1, section 3	P
	c) TRACEABILITY between SYSTEM requirements, software requirements, SOFTWARE SYSTEM test, and RISK CONTROL measures implemented in software	Need trace matrix, assign ID for all requirements. Matrix is created and software IDs is filled. DDP-TSUGA-003, REV#: 1	P
	d) software configuration and change management, including SOUP CONFIGURATION ITEMS and software used to support development	DDP-TSUGA-003, REV#: 1, section 10	P
	e) software problem resolution for handling problems detected in the MEDICAL DEVICE SOFTWARE, DELIVERABLES and ACTIVITIES at each stage of the life cycle	Bugzilla tool	P
5.1.2	[A, B, C] The MANUFACTURER updates the plan, as appropriate, as development proceeds		P
5.1.3	[A, B, C] Software development plan reference to SYSTEM design and development		P
	a) As inputs for software development, SYSTEM requirements are referenced in the software development plan by the MANUFACTURER	DDP- TSUGA-003, REV#: 1, section 6	P
	b) In the software development plan, the MANUFACTURER includes or references procedures for coordinating the software development with the system development necessary to satisfy 4.1 (such as system integration, verification, and validation)	DDP- TSUGA-003, REV#: 1, section 6	P
5.1.4	[C] Associated with the development of SOFTWARE ITEMS of class C, in the software development plan are included or referenced:		N/A
	a) standards		N/A
	b) methods		N/A
	c) tools		N/A

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
5.1.5	[B, C] The MANUFACTURER includes or references in the software development plan, a plan to integrate the SOFTWARE ITEMS (including SOUP) and performs testing during integration	DDP- TSUGA-003, REV#: 1, section 7.2 VEP-TSUGA-002, REV#: 1	P
5.1.6	[A, B, C] In the software development plan, the following VERIFICATION information are included or referenced:		P
	a) DELIVERABLES requiring VERIFICATION	DDP-TSUGA-003, REV#: 1, SECTION 7.2, VEP-TSUGA-002, REV#: 1	P
	b) the required VERIFICATION TASKS for each life cycle ACTIVITY	DDP-TSUGA-003, REV#: 1, SECTION 7.2, VEP-TSUGA-002, REV#: 1	P
	c) milestones at which the DELIVERABLES are VERIFIED	DDP-TSUGA-003, REV#: 1, SECTION 7.2, VEP-TSUGA-002, REV#: 1	P
	d) the acceptance criteria for VERIFICATION of the DELIVERABLES	DDP-TSUGA-003, REV#: 1, SECTION 7.2, VEP-TSUGA-002, REV#: 1	P
5.1.7	[A, B, C] In the software development plan the MANUFACTURER includes or references a plan to conduct the ACTIVITIES and TASKS of the software RISK MANAGEMENT PROCESS, including the management of RISKS relating to SOUP	Add a software risk management section in Risk Management Plan: RMP-TSUGA	P
5.1.8	[A, B, C] In the software development plan the MANUFACTURER includes or references information about the documents to be produced during the software development life cycle	DDP-TSUGA-003, REV#: 1, SECTION 6	P
	For each identified document or type of document the following information has included or referenced:		P
	a) title, name or naming convention		P
	b) purpose		P
	c) procedures and responsibilities for development, review, approval and modification		P
5.1.9	[A, B, C] The MANUFACTURER includes or references software configuration management information in the software development plan	DDP-TSUGA-003, REV#: 1, SECTION 10	P
	The software configuration management information includes or references:		P
	a) the classes, types, categories or lists of items to be controlled		P
	b) the software configuration management ACTIVITIES and TASKS		P

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) the organization(s) responsible for performing software configuration management and ACTIVITIES		P
	d) their relationship with other organizations, such as software development or maintenance		P
	e) when the items are to be placed under configuration control		P
	f) when the problem resolution PROCESS is to be used		P
5.1.10	[B, C] The items to be controlled include tools, items or settings, used to develop the MEDICAL DEVICE SOFTWARE, which could impact the MEDICAL DEVICE SOFTWARE	DDP-TSUGA-003, REV#: 1, SECTION 8	P
5.1.11	[B, C] The MANUFACTURER plans to place CONFIGURATION ITEMS under documented configuration management control before they are VERIFIED	DDP-TSUGA-003, REV#: 1, SECTION 10	P
5.1.12	[B, C] In the software development plan the MANUFACTURER includes or references a procedure for:		N/A
	a) identifying categories of defects that may be introduced based on the selected programming technology that are relevant to their SOFTWARE SYSTEM		N/A
	b) documenting evidence that demonstrates that these defects do not contribute to unacceptable RISK		N/A
5.2	**Software requirements analysis**		—
5.2.1	[A, B, C] For each SOFTWARE SYSTEM of the MEDICAL DEVICE, the MANUFACTURER defines and documents SOFTWARE SYSTEM requirements from the SYSTEM level requirements	DDS-TSUGA-003, REV#: 1	P
5.2.2	[A, B, C] As appropriate to the MEDICAL DEVICE SOFTWARE, the MANUFACTURER includes in the software requirements:		P
	a) functional and capability requirements	DDS-TSUGA-003, REV#: 1, SECTION 3	P
	b) SOFTWARE SYSTEM inputs and outputs	DDS-TSUGA-003, REV#: 1, SECTION 3	P
	c) interfaces between the SOFTWARE SYSTEM and other SYSTEMS	DDS-TSUGA-003, REV#: 1, SECTION 4	P
	d) software-driven alarms, warnings, and operator messages	DDS-TSUGA-003, REV#: 1, SECTION 6	P
	e) SECURITY requirements	DDS-TSUGA-003, REV#: 1, SECTION 6.6	P

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
	f) user interface requirements implemented by software	DDS-TSUGA-003, REV#: 1, SECTION 4	P
	g) data definition and database requirements	DDS-TSUGA-003, REV#: 1, SECTION 6.18	P
	h) installation and acceptance requirements of the delivered MEDICAL DEVICE SOFTWARE at the operation and maintenance site or sites	DDS-TSUGA-003, REV#: 1, SECTION 5	P
	i) requirements related to methods of operation and maintenance	DDS-TSUGA-003, REV#: 1, SECTION 6.13	P
	j) requirements related to IT-network aspects	DDS-TSUGA-003, REV#: 1, SECTION 6.14	P
	k) user maintenance requirements	DDS-TSUGA-003, REV#: 1, SECTION 6.13	P
	l) regulatory requirements	DDS-TSUGA-003, REV#: 1	P
5.2.3	[B, C] The MANUFACTURER includes RISK CONTROL measures implemented in software in the requirements as appropriate to the MEDICAL DEVICE SOFTWARE	DDS-TSUGA-003, REV#: 1, SECTION 7	P
5.2.4	[A, B, C] The MANUFACTURER re-EVALUATES the MEDICAL DEVICE RISK ANALYSIS when software requirements are established and update it as appropriate		P
5.2.5	[A, B, C] The MANUFACTURER ensures that existing requirements, including SYSTEM requirements, are re-EVALUATED and updated as appropriate as a result of the software requirements analysis ACTIVITY		P
5.2.6	[A, B, C] The MANUFACTURER verifies and documents that the software requirements:		P
	a) implement SYSTEM requirements including those relating to RISK CONTROL	TECHNICAL REVIEW OF DDS-TSUGA-003, REV#: 1	P
	b) do not contradict one another		P
	c) are expressed in terms that avoid ambiguity		P
	d) are stated in terms that permit establishment of test criteria and performance of tests		P
	e) can be uniquely identified		P
	f) are traceable to SYSTEM requirements or other source		P
5.3	**Software ARCHITECTURAL design**		**P**
5.3.1	[B, C] The MANUFACTURER transforms the requirements for the MEDICAL DEVICE SOFTWARE into a documented ARCHITECTURE that describes the software's structure and identifies the SOFTWARE ITEMS	ARC-TSUGA, REV#: 1	P

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
5.3.2	[B, C] The MANUFACTURER develops and documents an ARCHITECTURE for the interfaces between the SOFTWARE ITEMS and the components external to the SOFTWARE ITEMS (both software and hardware), and between the SOFTWARE ITEMS	ARC-TSUGA, REV#: 1	P
5.3.3	[B, C] If a SOFTWARE ITEM is identified as SOUP, the MANUFACTURER specifies functional and performance requirements for the SOUP item that are necessary for its intended use	DDS-TSUGA-003, REV#: 1, SECTION 2	P
5.3.4	[B, C] If a SOFTWARE ITEM is identified as SOUP, the MANUFACTURER specifies the SYSTEM hardware and software necessary to support the proper operation of the SOUP item	DDS-TSUGA-003, REV#: 1, SECTION 6.1	P
5.3.5	[C] The MANUFACTURER identifies any segregation between SOFTWARE ITEMS that is necessary for RISK CONTROl, and states how to ensure that such segregation is effective		N/A
5.3.6	[B, C] The MANUFACTURER verifies and documents that:		P
	a) the ARCHITECTURE of the software implements SYSTEM and software requirements including those relating to RISK CONTROL	ARC-TSUGA, REV#: 1	P
	b) the software ARCHITECTURE is able to support interfaces between SOFTWARE ITEMS and between SOFTWARE ITEMS and hardware	ARC-TSUGA, REV#: 1	P
	c) the MEDICAL DEVICE ARCHITECTURE supports proper operation of any SOUP items	ARC-TSUGA, REV#: 1	P
5.4	**Software detailed design**		**P**
5.4.1	[B, C] The MANUFACTURER subdivides the software until it is represented by SOFTWARE UNITS	ARC-TSUGA, REV#: 1, SECTION 6	P
5.4.2	[C] The MANUFACTURER documents a design with enough detail to allow correct implementation of each SOFTWARE UNIT		N/A
5.4.3	[C] The MANUFACTURER documents a design for any interfaces between the SOFTWARE UNIT and external components (hardware or software), as well as any interfaces between SOFTWARE UNITS, detailed enough to implement each SOFTWARE UNIT and its interfaces correctly		N/A
5.4.4	[C] The MANUFACTURER verifies and documents that the software detailed design:		N/A
	a) implements the software ARCHITECTURE		N/A
	b) is free from contradiction with the software ARCHITECTURE		N/A
5.5	**SOFTWARE UNIT implementation**		**P**

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
5.5.1	[A, B, C] The MANUFACTURER implements each SOFTWARE UNIT		P
5.5.2	[B, C] The MANUFACTURER establishes strategies, methods and procedures for verifying the SOFTWARE UNITS	Use code review as strategy and method for unit verification, add review records. Define strategy of unit and integration verification in software system verification plan	P
	Where VERIFICATION is done by testing, the test procedures are EVALUATED for adequacy		P
5.5.3	[B, C] The MANUFACTURER establishes acceptance criteria for SOFTWARE UNITS prior to integration into larger SOFTWARE ITEMS as appropriate, and ensures that SOFTWARE UNITS meet acceptance criteria	Coding guide	P
5.5.4	[C] When present in the design, the MANUFACTURER includes additional acceptance criteria as appropriate for:		N/A
	a) proper event sequence		N/A
	b) data and control flow		N/A
	c) planned resource allocation		N/A
	d) fault handling (error definition, isolation, and recovery)		N/A
	e) initialisation of variables		N/A
	f) self-diagnostics		N/A
	g) memory management and memory overflows		N/A
	h) boundary conditions		N/A
5.5.5	[B, C] The MANUFACTURER performs the SOFTWARE UNIT VERIFICATION and documents the results	See project source serve	P
5.6	**Software integration and integration testing**		**P**
5.6.1	[B, C] The MANUFACTURER integrates the SOFTWARE UNITS in accordance with the integration plan	Following software development procedure QP 7.3-10, section 5.5	P
5.6.2	[B, C] The MANUFACTURER verifies that the SOFTWARE UNITS have been integrated into SOFTWARE ITEMS and/or the SOFTWARE SYSTEM in accordance with the integration plan and retains records of the evidence of such verification		P
5.6.3	[B, C] The MANUFACTURER tests the integrated SOFTWARE ITEMS in accordance with the integration plan and documents the results		P

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
5.6.4	[B, C] For software integration testing, the MANUFACTURER addresses whether the integrated SOFTWARE ITEM performs as intended	VES-TSUGA-002~086 REV#: 1	P
5.6.5	[B, C] The MANUFACTURER EVALUATES the integration test procedures for adequacy	VES-TSUGA-002~086 REV#: 1	P
5.6.6	[B, C] When software items are integrated, the MANUFACTURER conducts REGRESSION TESTING appropriate to demonstrate that defects have not been introduced into previously integrated software	Following software development procedure QP 7.3-10, REV#: 2	P
5.6.7	[B, C] The MANUFACTURER:		P
	a) documents the test result (pass/fail and a list of ANOMALIES)	VES-TSUGA-002~086 REV#: 1	P
	b) retains sufficient records to permit the test to be repeated	VES-TSUGA-002~086 REV#: 1	P
	c) identifies the tester	VES-TSUGA-002~086 REV#: 1	P
5.6.8	[B, C] The MANUFACTURER enters ANOMALIES found during software integration and integration testing into a software problem resolution PROCESS	Following software development procedure QP 7.3-10, REV#: 2	P
5.7	**SOFTWARE SYSTEM testing**		**P**
5.7.1	[A, B, C] Establish tests for software requirements		—
	a) The MANUFACTURER establishes and performs a set of tests, expressed as input stimuli, expected outcomes, pass/fail criteria and procedures, for conducting SOFTWARE SYSTEM testing, such that all software requirements are covered	VEP-TSUGA-002, REV#: 1 VER-TSUGA-112, REV#: 1 VES-TSUGA-002~086 REV#: 1	P
	b) The MANUFACTURER EVALUATES the adequacy of VERIFICATION strategies and test procedures.		P
5.7.2	[A, B, C] The MANUFACTURER enters ANOMALIES found during software system testing into a software problem resolution PROCESS	DDP-TSUGA-003, REV#: 1, section 6	P
5.7.3	[A, B, C] When changes are made during SOFTWARE SYSTEM testing, the MANUFACTURER:		P
	a) repeats tests, performs modified tests or performs additional tests, as appropriate, to verify the effectiveness of the change in correcting the problem	DDP-TSUGA-003, REV#: 1, section 6	P
	b) conducts testing appropriate to demonstrate that unintended side effects have not been introduced	DDP-TSUGA-003, REV#: 1, section 6	P
	c) performs relevant RISK MANAGEMENT ACTIVITIES as defined in 7.4	DDP-TSUGA-003, REV#: 1, section 6	P

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
5.7.4	[A, B, C] Evaluate SOFTWARE SYSTEM testing		P
	The MANUFACTURER EVALUATES the appropriateness of VERIFICATION strategies and test procedures		P
	The MANUFACTURER verifies that:		P
	a) all software requirements have been tested or otherwise VERIFIED	VES-TSUGA-002~086 REV#: 1	P
	b) the TRACEABILITY between software requirements and tests or other VERIFICATION is recorded		P
	c) test results meet the required pass/fail criteria		P
5.7.5.	[A, B, C] In order to support the repeatability of tests, the MANUFACTURER documents:		P
	a) a reference to test case procedures showing required actions and expected results		P
	b) the test result (pass/fail and a list of ANOMALIES)	VES-TSUGA-002~086 REV#: 1	P
	c) the version of software tested	VES-TSUGA-002~086 REV#: 1	P
	d) relevant hardware and software test configurations	VES-TSUGA-002~086 REV#: 1	P
	e) relevant test tools	VES-TSUGA-002~086 REV#: 1	P
	f) date tested	VES-TSUGA-002~086 REV#: 1	P
	g) the identity of the person responsible for executing the test and recording the test results	VES-TSUGA-002~086 REV#: 1	P
5.8	**Software RELEASE for utilization at a SYSTEM level**		**P**
5.8.1	[A, B, C] The MANUFACTURER ensures that all software VERIFICATION ACTIVITIES has been completed and the results EVALUATED before the software is released	Formal Design review	P
5.8.2	[A, B, C] The MANUFACTURER documents all known residual ANOMALIES	Release Notes	P
5.8.3	[B, C] The MANUFACTURER ensured that all known residual ANOMALIES have been EVALUATED to ensure that they do not contribute to an unacceptable RISK	Formal Design review	P
5.8.4	[A, B, C] The MANUFACTURER documented the VERSION of the MEDICAL DEVICE SOFTWARE that is being released	TIN	P

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
5.8.5	[B, C] The MANUFACTURER documents the procedure and environment used to create the released software		P
5.8.6	[B, C] The MANUFACTURER ensures that all software development plan (or maintenance plan) ACTIVITIES and TASKS are complete along with the associated documentation		P
5.8.7	[A, B, C] For at least a period of time determined as the longer of: the life time of the MEDICAL DEVICE SOFTWARE as defined by the MANUFACTURER or a time specified by relevant regulatory requirements, the MANUFACTURER archives:		P
	a) the MEDICAL DEVICE SOFTWARE and CONFIGURATION ITEMS	Source code released version control	P
	b) the documentation		P
5.8.8	[A, B, C] The MANUFACTURER establishes procedures to ensure that the released MEDICAL DEVICE SOFTWARE can be reliably delivered to the point of use without corruption or unauthorised change	Source code released version control	P
	These procedures address the production and handling of media containing the MEDICAL DEVICE SOFTWARE including as appropriate:		P
	– replication	TIN for master copy	P
	– media labelling		P
	– packaging		P
	– protection		P
	– storage		P
	– delivery		P

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

7	**SOFTWARE RISK MANAGEMENT PROCESS**		**—**
7.1	**Analysis of software contributing to hazardous situations**		—
7.1.1	[B, C] The MANUFACTURER identifies SOFTWARE ITEMS that could contribute to a hazardous situation identified in the MEDICAL DEVICE RISK ANALYSIS ACTIVITY of ISO 14971	RMR-TSUGA, REV#: 2	P
7.1.2	[B, C] The MANUFACTURER identifies potential causes of the SOFTWARE ITEM identified above contributing to a hazardous situation	RMR-TSUGA, REV#: 2	P
	The MANUFACTURER considers potential causes including, as appropriate:		P
	a) incorrect or incomplete specification of functionality		P
	b) software defects in the identified SOFTWARE ITEM functionality		P
	c) failure or unexpected results from SOUP		P
	d) hardware failures or other software defects that could result in unpredictable software operation		P
	e) reasonably foreseeable misuse		P
7.1.3	[B, C] If failure or unexpected results from SOUP is a potential cause of the SOFTWARE ITEM contributing to a hazardous situation, the MANUFACTURER EVALUATES as a minimum any ANOMALY list published by the supplier of the SOUP item relevant to the VERSION of the SOUP item used in the MEDICAL DEVICE to determine if any of the known ANOMALIES result in a sequence of events that could result in a hazardous situation	RMR-TSUGA, REV#: 2	P
7.1.4	[B, C] The MANUFACTURER documents in the RISK MANAGEMENT FILE potential causes of the SOFTWARE ITEM contributing to a hazardous situation	RMR-TSUGA, REV#: 2	P
7.2	**RISK CONTROL measures**		—
7.2.1	[B, C] For each case documented in the RISK MANAGEMENT FILE where a SOFTWARE ITEM could contribute to a HAZARDOUS SITUATION, the MANUFACTURER defines and documents RISK CONTROL measures in accordance with ISO 14971	Following risk management control procedure QP 7.1-01, REV#: 8	P
7.2.2	[B, C] If a RISK CONTROL measure is implemented as part of the functions of a SOFTWARE ITEM, the MANUFACTURER:		P
	a) includes the RISK CONTROL measure in the software requirements	RMR-TSUGA, REV#: 2	P

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) assigns to each SOFTWARE ITEM that contributes to the implementation of a RISK CONTROL measure a software safety class based on the RISK that the RISK CONTROL measure is controlling		P
	c) develops the SOFTWARE ITEM in accordance with Clause 5		P
7.3	**VERIFICATION of RISK CONTROL measures**		—
7.3.1	[B, C] The implementation of each RISK CONTROL measure documented in 7.2 is VERIFIED, and this VERIFICATION is documented	RMR-TSUGA, REV#: 2 has verification report reference Trace matrix: DDS-TSUGA-003, REV#: 1	P
	The MANUFACTURER reviewers the RISK CONTROL measure and determines if it could result in a new HAZARDOUS SITUATION		P
7.3.3	[B, C] The MANUFACTURER documents TRACEABILITY of software HAZARDS as appropriate:		P
	a) from the hazardous situation to the SOFTWARE ITEM		P
	b) from the SOFTWARE ITEM to the specific software cause		P
	c) from the software cause to the RISK CONTROL measure		P
	d) from the RISK CONTROL measure to the VERIFICATION of the RISK CONTROL measure		P
7.4	**RISK MANAGEMENT of software changes**		—
7.4.1	[A, B, C] The MANUFACTURER analyses changes to the MEDICAL DEVICE SOFTWARE (including SOUP) to determine whether:		P
	a) additional potential causes are introduced contributing to a hazardous situation	Following design and development change procedure QP 7.3-08, REV#: 9	P
	b) additional software RISK CONTROL measures are required		P
7.4.2	[B, C] The MANUFACTURER analyses changes to the software, including changes to SOUP, to determine whether the software modification could interfere with existing RISK CONTROL measures		P
7.4.3	[B, C] The MANUFACTURER performs relevant RISK MANAGEMENT ACTIVITIES defined in 7.1, 7.2 and 7.3 based on these analyses		P

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
8	**SOFTWARE CONFIGURATION MANAGEMENT PROCESS**		**—**
8.1	**Configuration identification**		—
8.1.1	[A, B, C] The MANUFACTURER establishes a scheme for the unique identification of CONFIGURATION ITEMS and their VERSIONS to be controlled according to the development and configuration planning specified in 5.1	DDS-TSUGA-003, REV#: 1, section 6.17 include software system configuration, SOUP	P
8.1.2	[A, B, C] For each SOUP CONFIGURATION ITEM being used, including standard libraries, the MANUFACTURER documents:		P
	a) the title		P
	b) the MANUFACTURER		P
	c) the unique SOUP designator		P
8.1.3	[A, B, C] The MANUFACTURER documents the set of CONFIGURATION ITEMS and their VERSIONS that comprise the SOFTWARE SYSTEM configuration		P
8.2	**Change control**		—
8.2.1	[A, B, C] The MANUFACTURER changes CONFIGURATION ITEMS identified to be controlled according to 8.1 only in response to an approved CHANGE REQUEST	Following design and development change procedure QP 7.3-08, REV#: 9	P
8.2.2	[A, B, C] The MANUFACTURER implements the change as specified in the CHANGE REQUEST	Following design and development change procedure QP 7.3-08, REV#: 9	P
	The MANUFACTURER identifies and performs any ACTIVITY that needs to be repeated as a result of the change, including changes to the software safety classification of SOFTWARE SYSTEMS and SOFTWARE ITEMS		P
8.2.3	[A, B, C] The MANUFACTURER verifies the change, including repeating any VERIFICATION that has been invalidated by the change and taking into account 5.7.3 and 9.7	Following design and development change procedure QP 7.3-08, REV#: 9	P
8.2.4	[A, B, C] The MANUFACTURER maintains records of the relationships and dependencies between:		P
	a) CHANGE REQUEST	Following design and development change procedure QP 7.3-08, REV#: 9	P
	b) relevant PROBLEM REPORT		P
	c) approval of the CHANGE REQUEST		P
8.3	[A, B, C] The MANUFACTURER retains retrievable records of the history of controlled CONFIGURATION ITEMS including SYSTEM configuration		P

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

9	**SOFTWARE PROBLEM RESOLUTION PROCESS**		**—**
9.1	[A, B, C] The MANUFACTURER prepares a PROBLEM REPORT for each problem detected in the MEDICAL DEVICE SOFTWARE		P
	PROBLEM REPORTS include a statement of criticality (for example, effect on performance, SAFETY, or SECURITY) as well as other information that may aid in the resolution of the problem (for example, devices affected, supported accessories affected)		P
9.2	[A, B, C] The MANUFACTURER:		P
	a) investigates the problem and if possible identify the causes		P
	b) EVALUATES the problem's relevance to SAFETY using the software RISK MANAGEMENT PROCESS		P
	c) documents the outcome of the investigation and evaluation		P
	d) creates a CHANGE REQUEST(S) for actions needed to correct the problem, or document the rationale for taking no action		P
9.3	[A, B, C] The MANUFACTURER advises relevant parties of the existence of the problem, as appropriate		P
9.4	[A, B, C] The MANUFACTURER approves and implements all CHANGE REQUESTS, observing the requirements of the change control PROCESS		P
9.5	[A, B, C] The MANUFACTURER maintains records of PROBLEM REPORTS and their resolution including their VERIFICATION		P
	The MANUFACTURER updates the RISK MANAGEMENT FILE as appropriate		P
9.6	[A, B, C] The MANUFACTURER performs analysis to detect trends in PROBLEM REPORTS		P
9.7	[A, B, C] The MANUFACTURER verifies resolutions to determine whether:		P
	a) problem has been resolved and the PROBLEM REPORT has been closed		P
	b) adverse trends have been reversed		P
	c) CHANGE REQUESTS have been implemented in the appropriate MEDICAL DEVICE SOFTWARE and ACTIVITIES		P
	d) additional problems have been introduced		P

IEC 60601-1 Attachment 1			
Clause	Requirement + Test	Result - Remark	Verdict
9.8	[A, B, C] When testing, retesting or REGRESSION TESTING SOFTWARE ITEMS and SYSTEMS following a change, the MANUFACTURER includes in the test documentation:		P
	a) test results	Bugzilla record bug fixing verification result or refer to paper test result DOC#. VES-TSUGA-135	P
	b) ANOMALIES found	VER-TSUGA-112, REV#: 1, section 3	P
	c) the VERSION of software tested	VER-TSUGA-112, REV#: 1, section 2	P
	d) relevant hardware and software test configurations	VES-TSUGA-002~086 REV#: 1	P
	e) relevant test tools	VES-TSUGA-002~086 REV#: 1	P
	f) date tested	VES-TSUGA-002~086 REV#: 1	P
	g) identification of the tester	VES-TSUGA-002~086 REV#: 1	P

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

Attachment	**Software - Mapping of required evidence and manufacturer documents**			**P**
Standard Clause	Deliverables	Title	Revision #	Date
4.3	Software safety classification document	ARC-TSUGA	1	2014.7.15
4.3	Specification of risk control measures external to software system	N/A	N/A	
4.3	Rationale of classification for decomposed software system	ARC-TSUGA	1	2014.7.15
4.4.2	Risk management activities for legacy software	N/A	N/A	
4.4.3	Gap analysis for legacy software	N/A	N/A	
4.4.4	Gap closure plan for legacy software	N/A	N/A	
4.4.5	Rationale for use of legacy software	N/A	N/A	
5.1.1	Software development plan	DDP-TSUGA-003	1	2014.7.1
5.1.3	Software requirements reference to software design and development document	DDP-TSUGA-003	1	2014.7.1
5.1.4	Development standards, methods and tools records for class C software	N/A	N/A	
5.1.5	Software integration and integration testing plan	DDP-TSUGA-003	1	2014.7.1
5.1.6	Software verification plan	VEP-TSUGA-002	1	2018.12.13
5.1.7	Software risk management plan	RMP-TSUGA	6	2019.03.15
5.1.8	Document management procedures	DDP-TSUGA-003	1	2014.7.1
5.1.9	Software configuration management procedures	DDP-TSUGA-003	1	2014.7.1
5.2	Software system requirements specification	DDS-TSUGA-003	1	2014.7.21
5.2.3	Specification of risk control measure implemented in software	ARC-TSUGA	1	2014.7.15
5.3	Software system architecture design specification	ARC-TSUGA	1	2014.7.15
5.3	Software item architecture design specification	ARC-TSUGA	1	2014.7.15

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

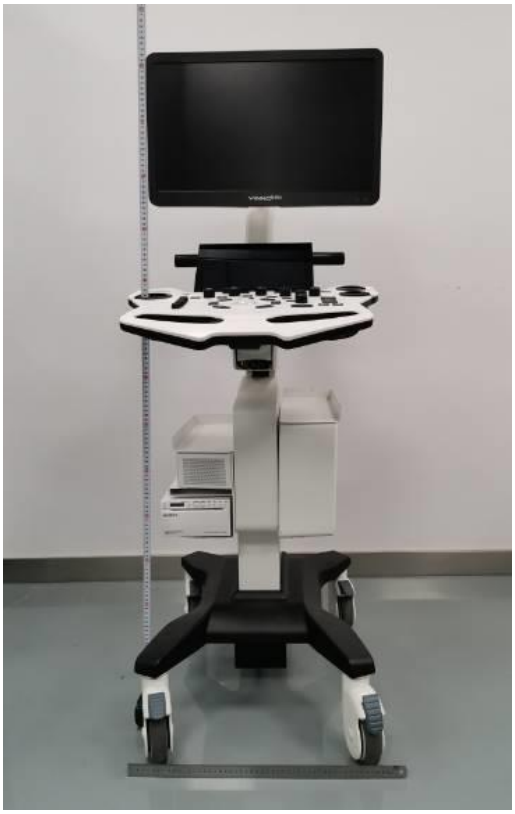
Attachment	**Software - Mapping of required evidence and manufacturer documents**			**P**
Standard Clause	Deliverables	Title	Revision #	Date
5.4	Software item detailed design specification	ARC-TSUGA	1	2014.7.15
5.4	Software unit detailed design specification	ARC-TSUGA	1	2014.7.15
5.5.1	Software unit implementation records	VER-TSUGA-112	1	2015.12.30
5.5.2	Software unit verification process	QP 7.3-05	4	2019-09-29
5.5.3	Software unit acceptance criteria	VEP-TSUGA-002	1	2015.8.17
5.5.5	Software unit verification records	VER-TSUGA-021	1	2015.12.30
5.6.1	Software unit integration process	QP 7.3-10	2	2019-11-04
5.6.2	Software unit integration records	VER-TSUGA-021	1	2015.12.30
5.6.4	Software unit integration testing records	VER-TSUGA-021	1	2015.12.30
5.6.5	Evaluation of software unit integration test	VER-TSUGA-021	1	2018.12.13
5.6.6	Software unit regression testing process	QP 7.3-10	2	2019-11-04
5.6.7	Software unit regression testing records	VER-TSUGA-112	1	2015.12.30
5.6.8	Software problem resolution process	QP 7.3-10	2	2019-11-04
5.7	Software system testing process	QP 7.3-05	4	2019-09-29
5.7	Software system testing records	VER-TSUGA-021	1	2015.12.30
5.8	Software system release process	QP 7.3-10	2	2019-11-04
5.8	Software system release record	VER-TSUGA-021	1	2015.12.30
5.8	Statement of known residual anomalies	VER-TSUGA-021	1	2015.12.30
7.1	Software hazard analysis process	RMR-TSUGA	2	2019.03.20
7.1	SOUP anomaly lists	N/A	N/A	N/A

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

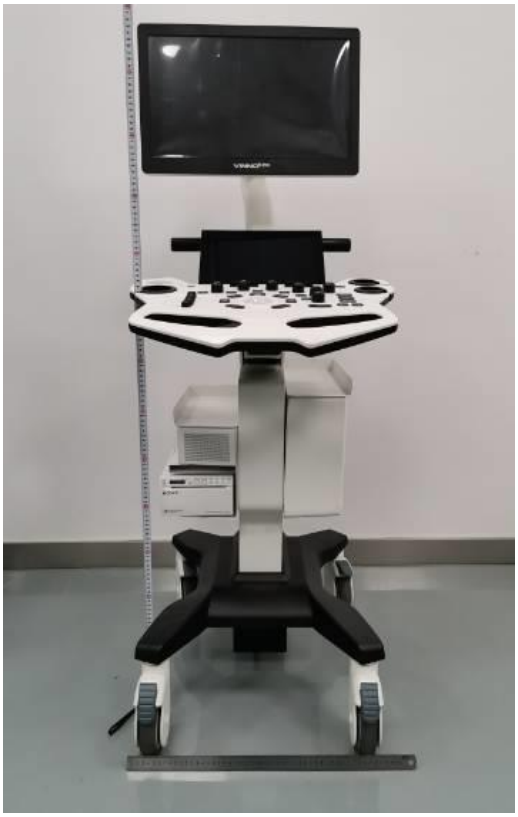
Attachment	**Software - Mapping of required evidence and manufacturer documents**			**P**
Standard Clause	Deliverables	Title	Revision #	Date
7.2	Risk control process	QP 7.1-01	8	2021-05-24
7.3	Risk control verification process	RMR-TSUGA	2	2019.03.20
7.4	Risk management of software change process	QP 7.3-08	9	2021-04-21
8.1	Configuration identification record	DDS-TSUGA-003	1	2014.7.21
8.2	Change control process	QP 7.3-08	9	2020-04-21
8.2	Records for traceability of change	DDP-TSUGA-003 section10.1.3	1	2014.7.1
9	Software problem resolution process	QP 7.3-10	2	2019-11-04
9	Software problem resolution records	DDP-TSUGA-003 Section 7.1,8.1.2	1	2014.7.1
Supplementary information:				

Attachment 2: Photo of EUT

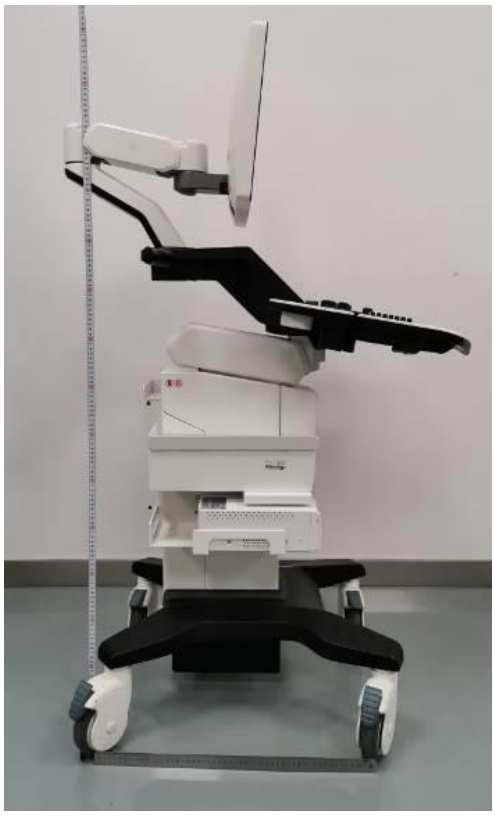
Overall - Front view- VINNO E20 with 21.5” monitor and 10.1” touch panel



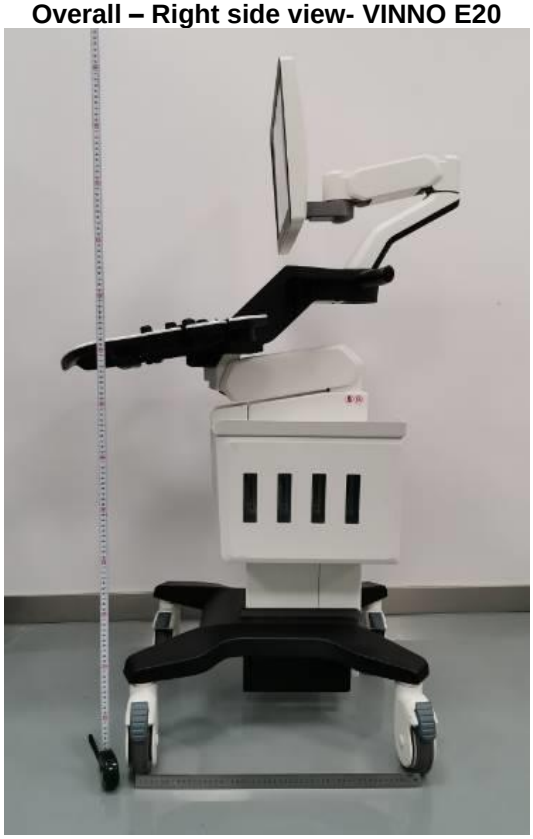
Overall - Front view- VINNO E20 with 18.5” monitor 10.1” touch panel



Overall – Left side view- VINNO E20

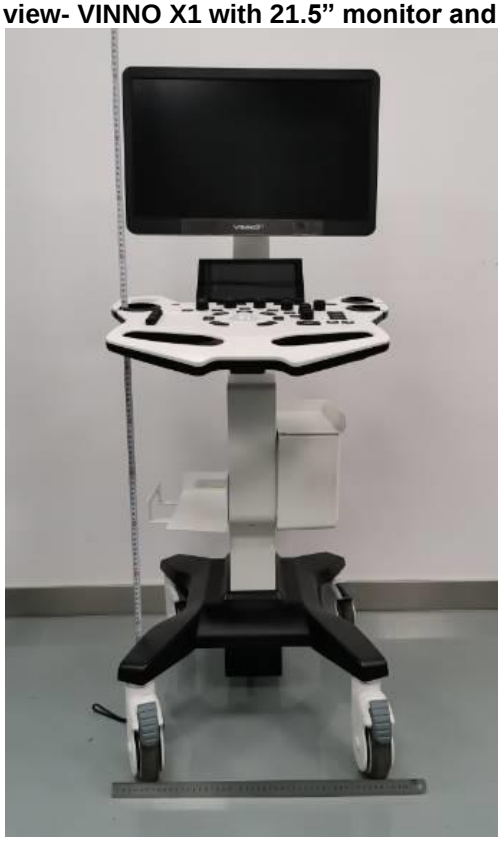


Overall – Right side view- VINNO E20



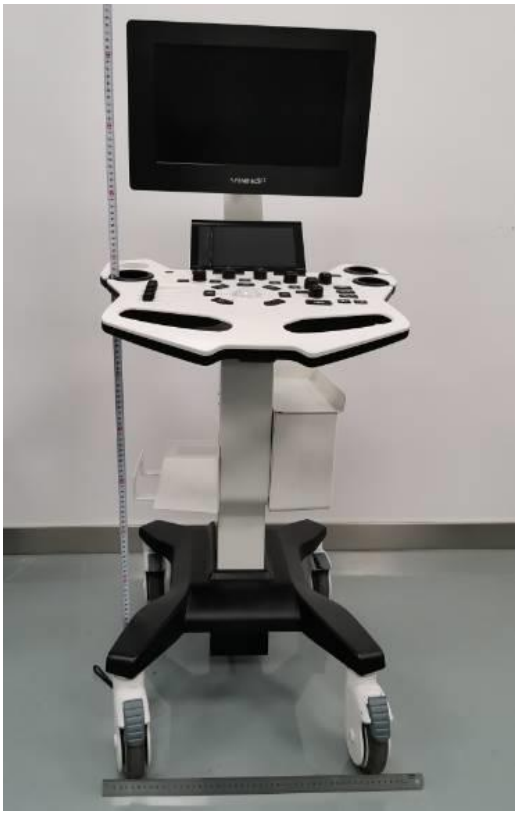
Overall – Rear view- VINNO E20

Overall - Front view- VINNO X1 with 21.5” monitor and 8” touch panel

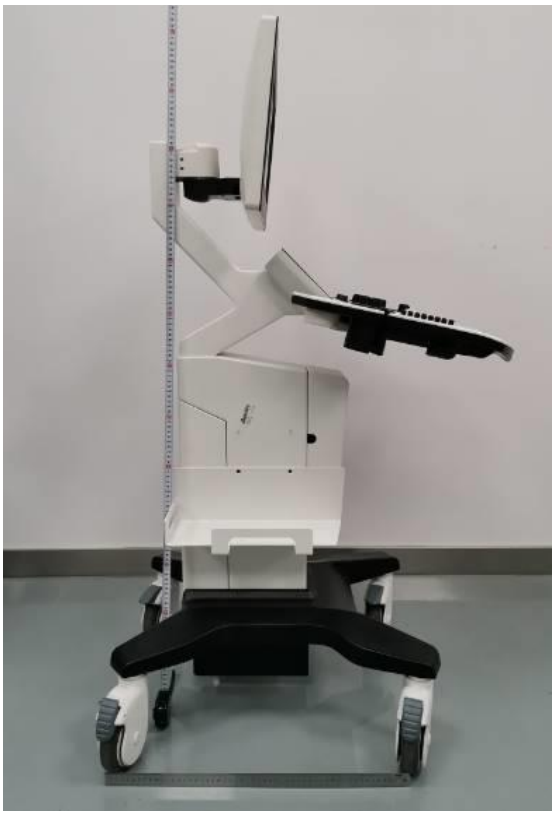


Overall - Front view- VINNO X1 with 18.5” monitor and 8” touch panel

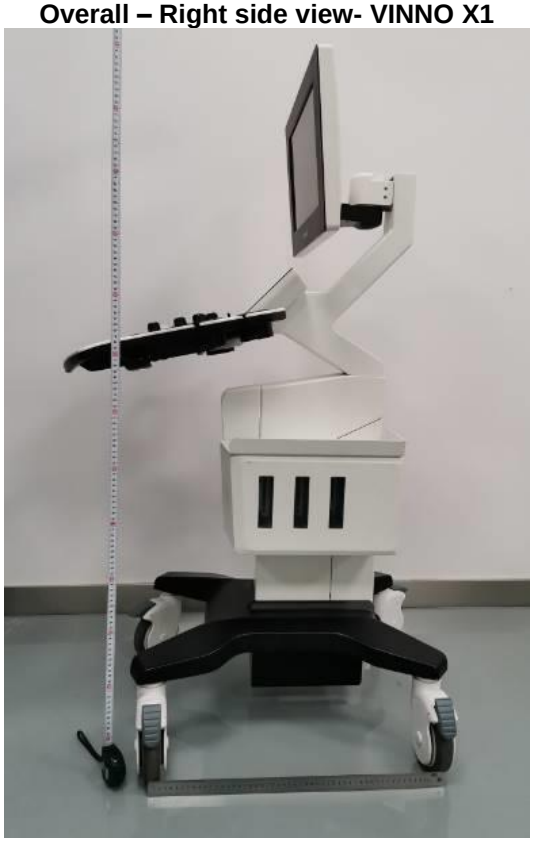
Overall - Front view- VINNO X1 with 15.6” monitor and 8” touch panel



Overall – Left side view- VINNO X1



Overall – Right side view- VINNO X1



Overall – Rear view- VINNO X1

Control panel with 10.1” touch panel

Control panel with 8” touch panel

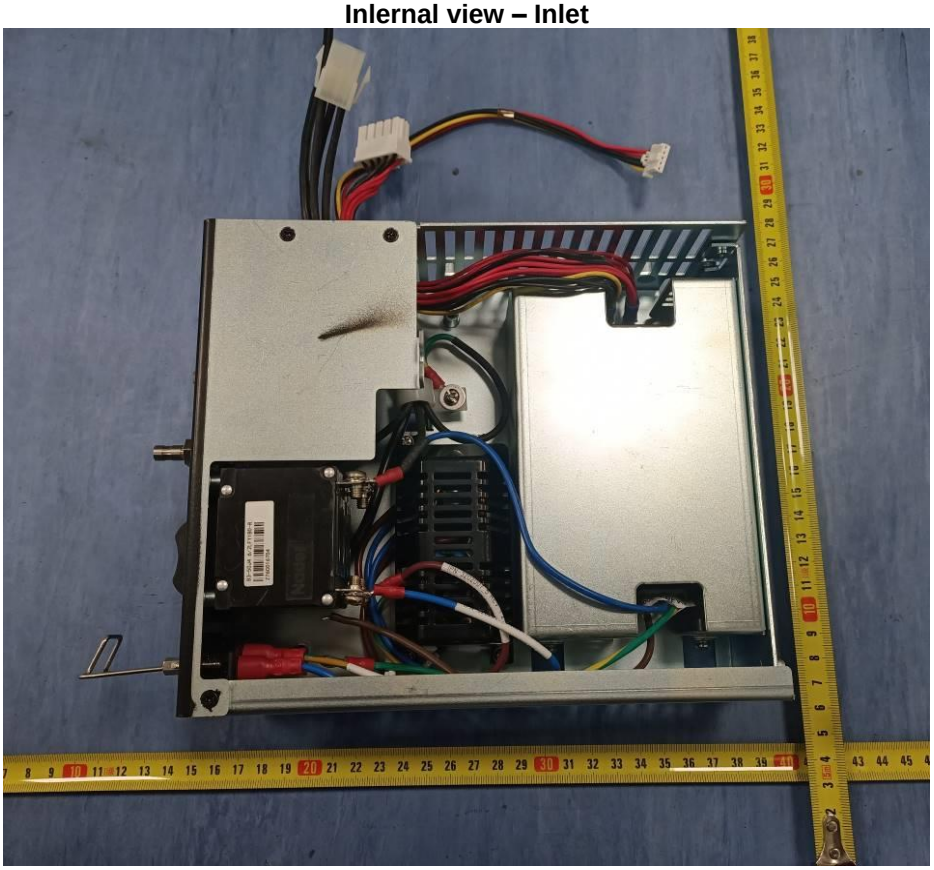
External view – Ports

Internal view – Front cover removed

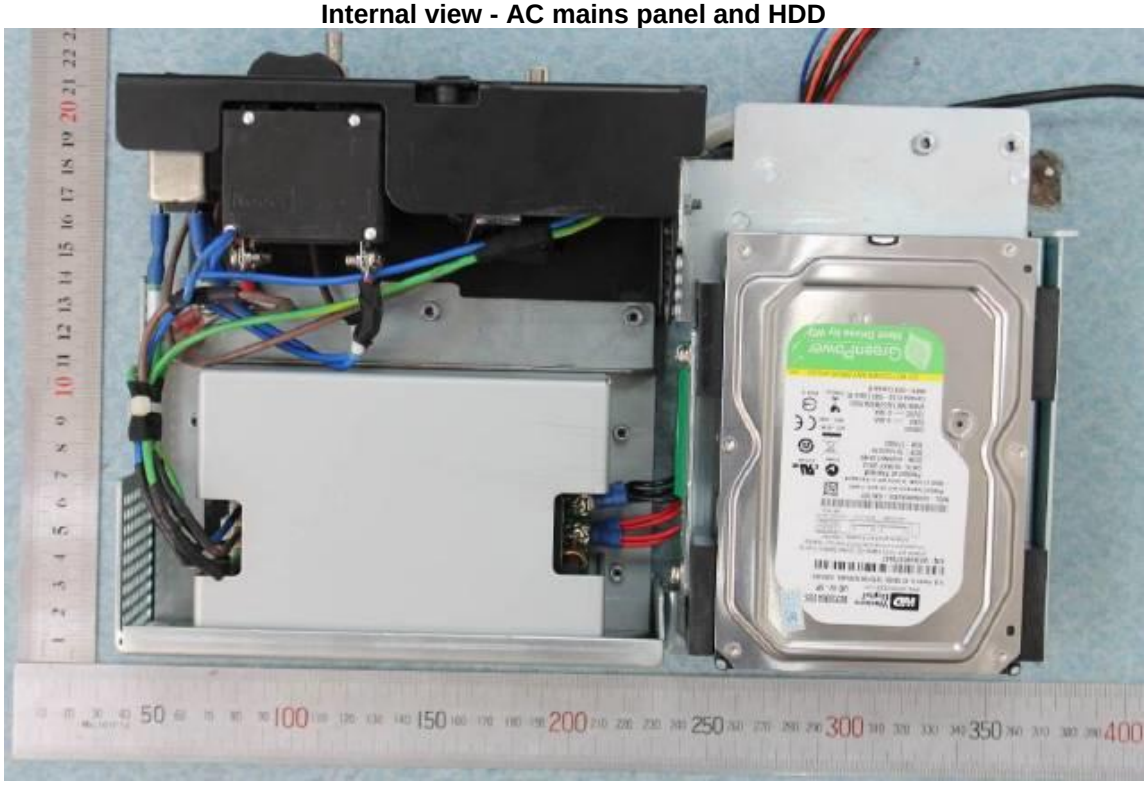
Internal view – Rear cover removed

Internal view – TT enclosure disassembled

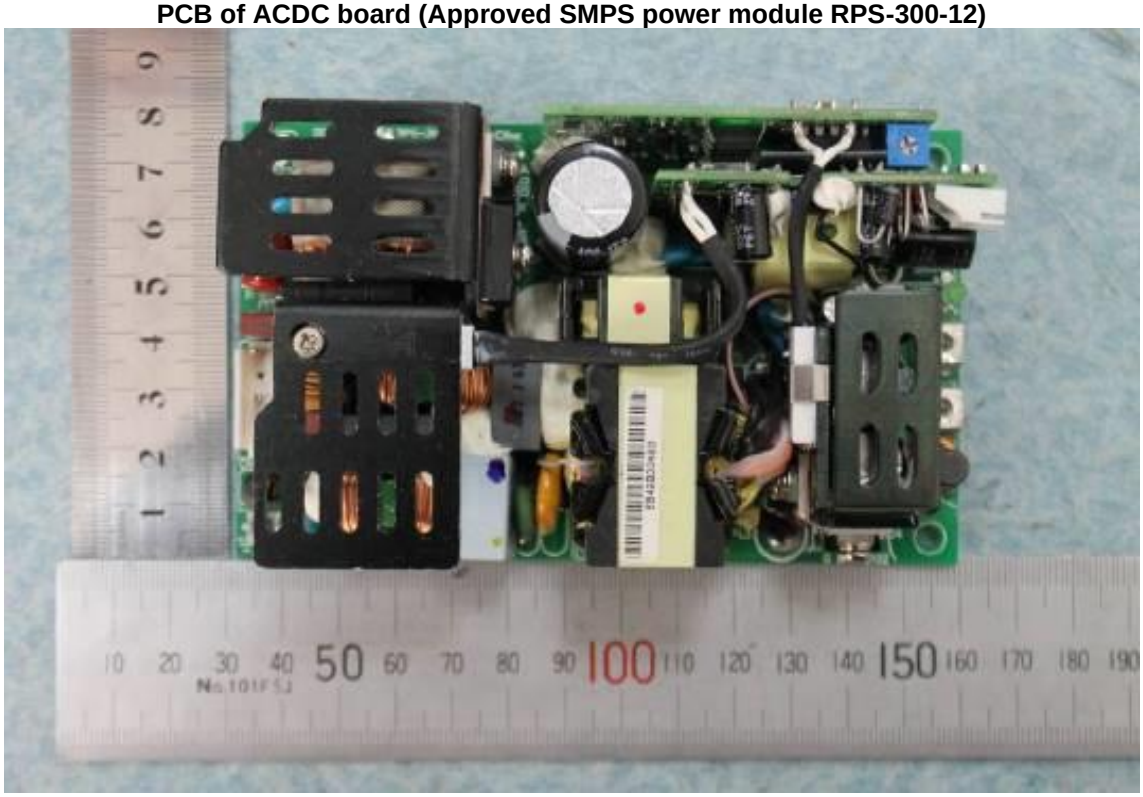
Inlernal view – Inlet



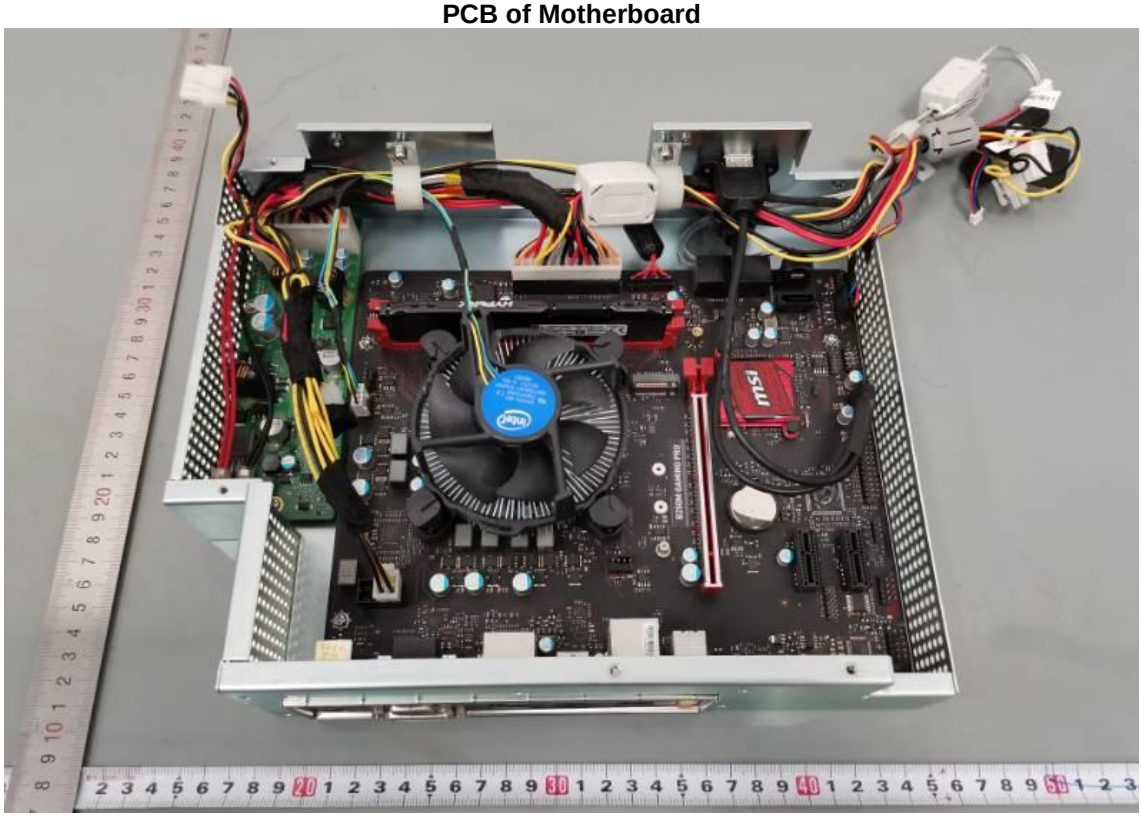
Internal view - AC mains panel and HDD



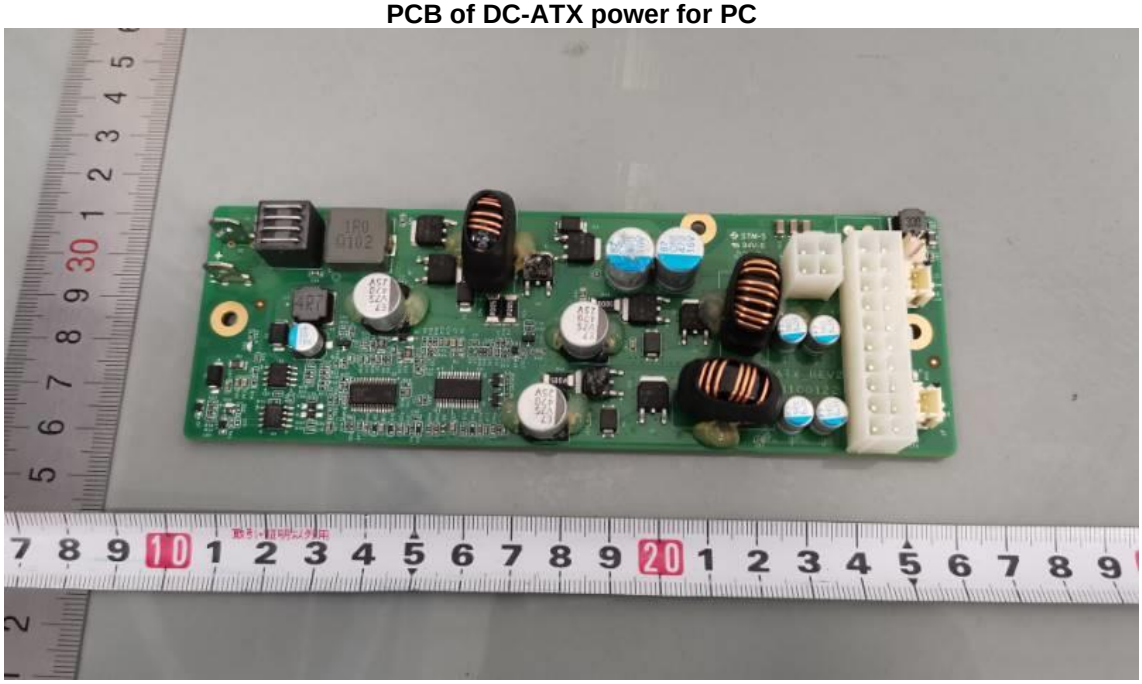
PCB of ACDC board (Approved SMPS power module RPS-300-12)



PCB of Motherboard

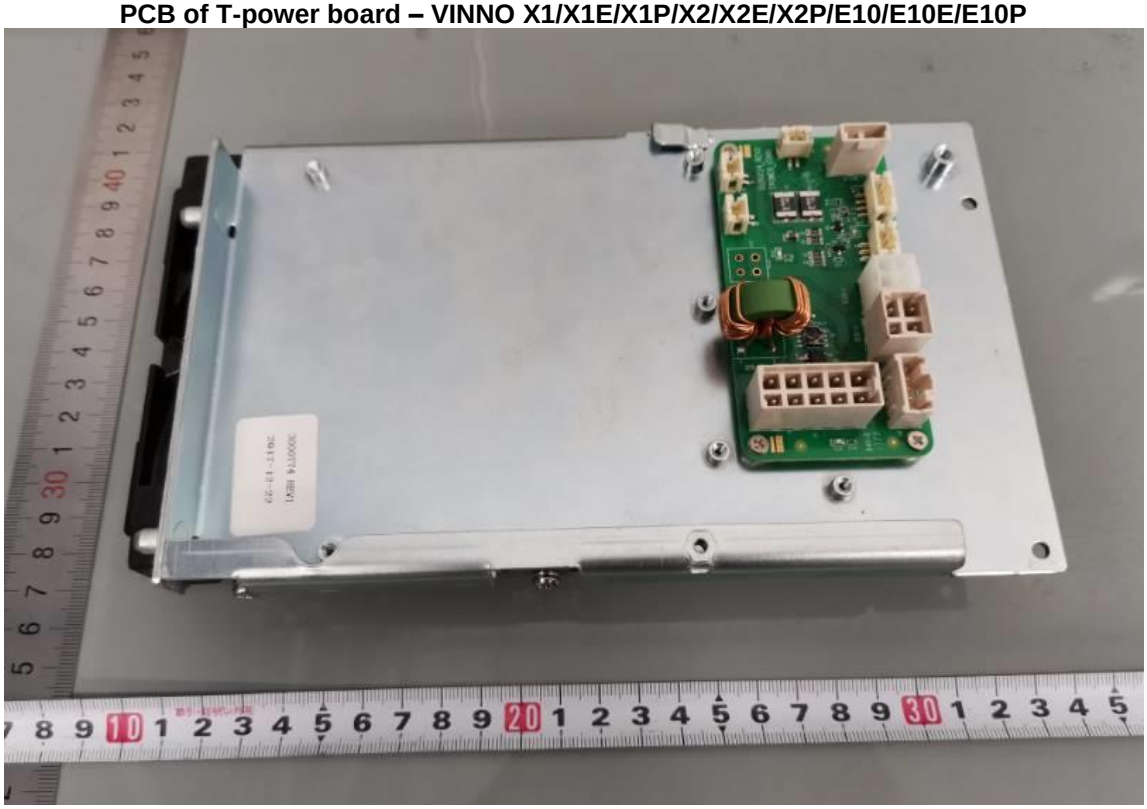


PCB of DC-ATX power for PC

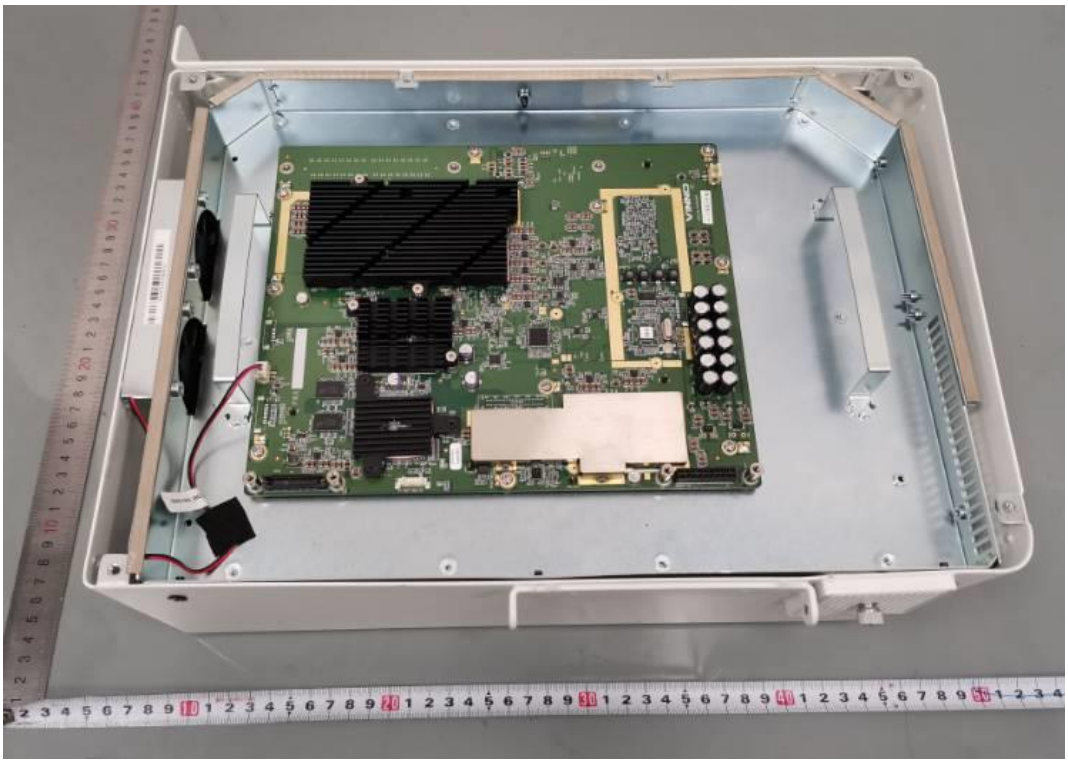


PCB of T-power board – VINNO E20/X3

PCB of T-power board – VINNO X1/X1E/X1P/X2/X2E/X2P/E10/E10E/E10P



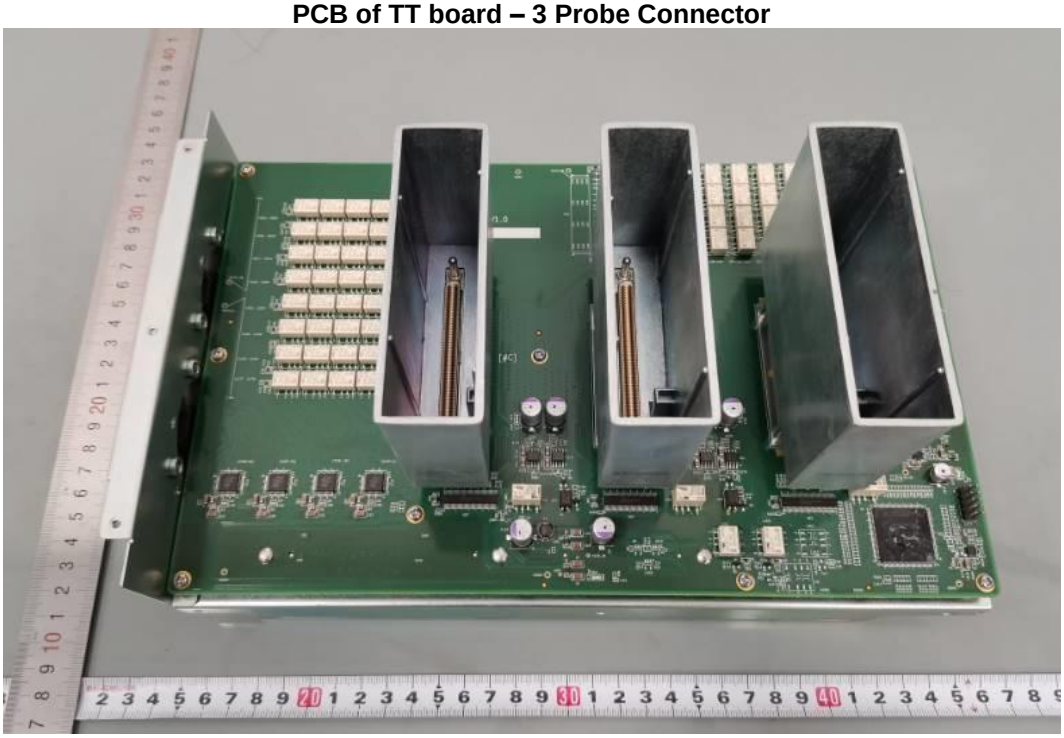
PCB of T-Main board – VINNO E20/X3



PCB of T-Main board – VINNO X1/X1E/X1P/X2/X2E/X2P/E10/E10E/E10P

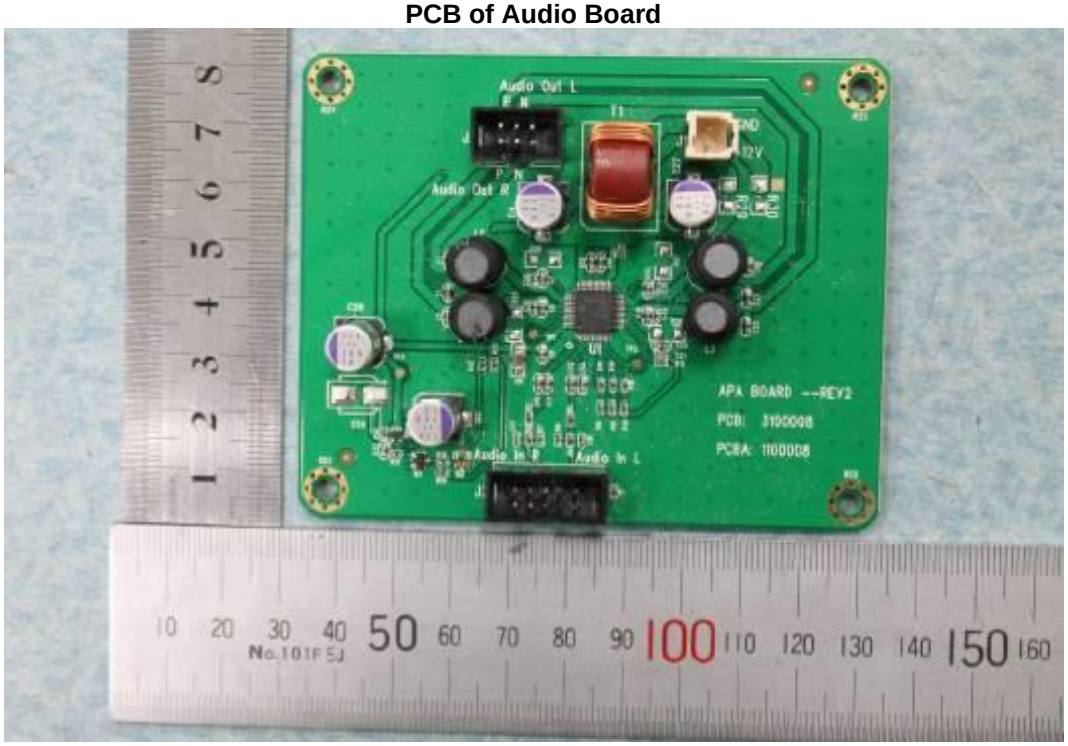
PCB of TT board – 4 Probe Connector

PCB of TT board – 3 Probe Connector

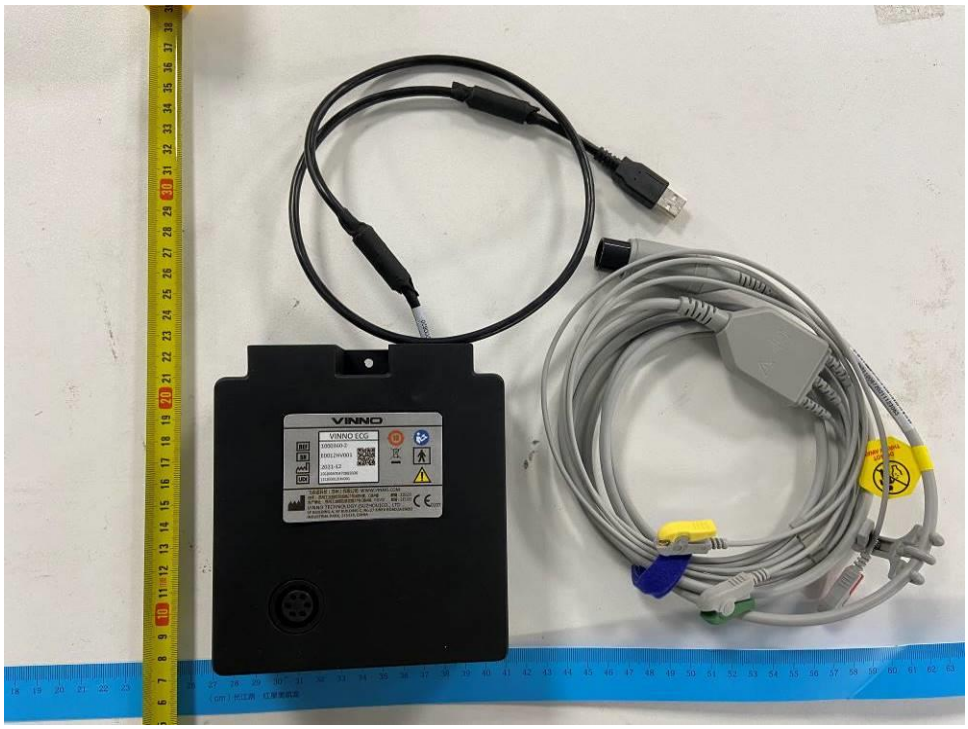


PCB of Control board

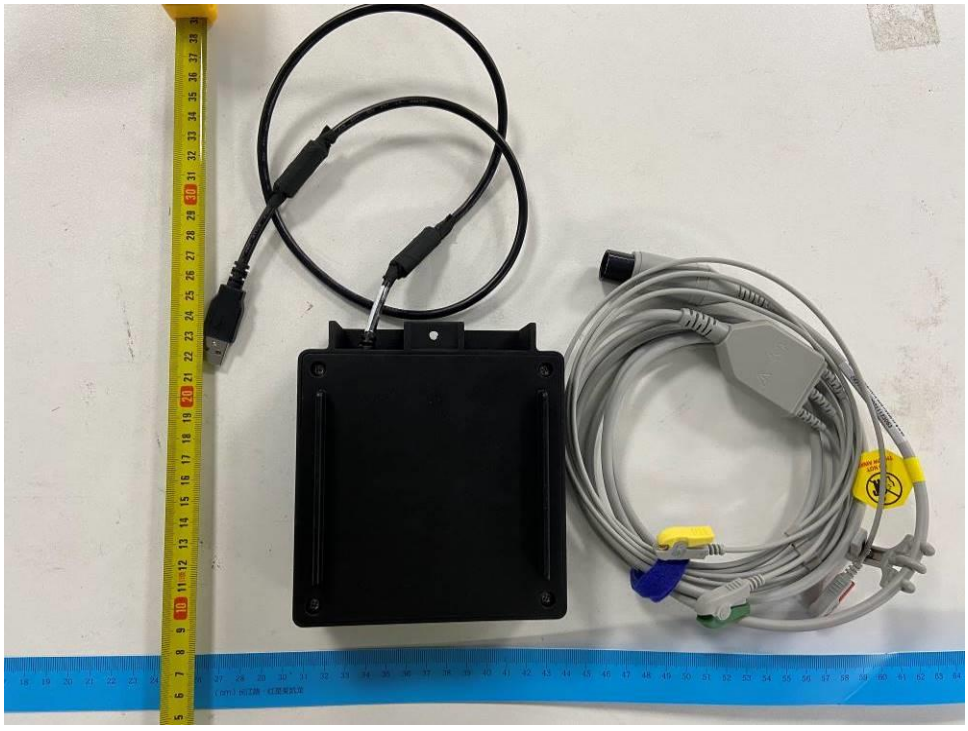
PCB of Audio Board



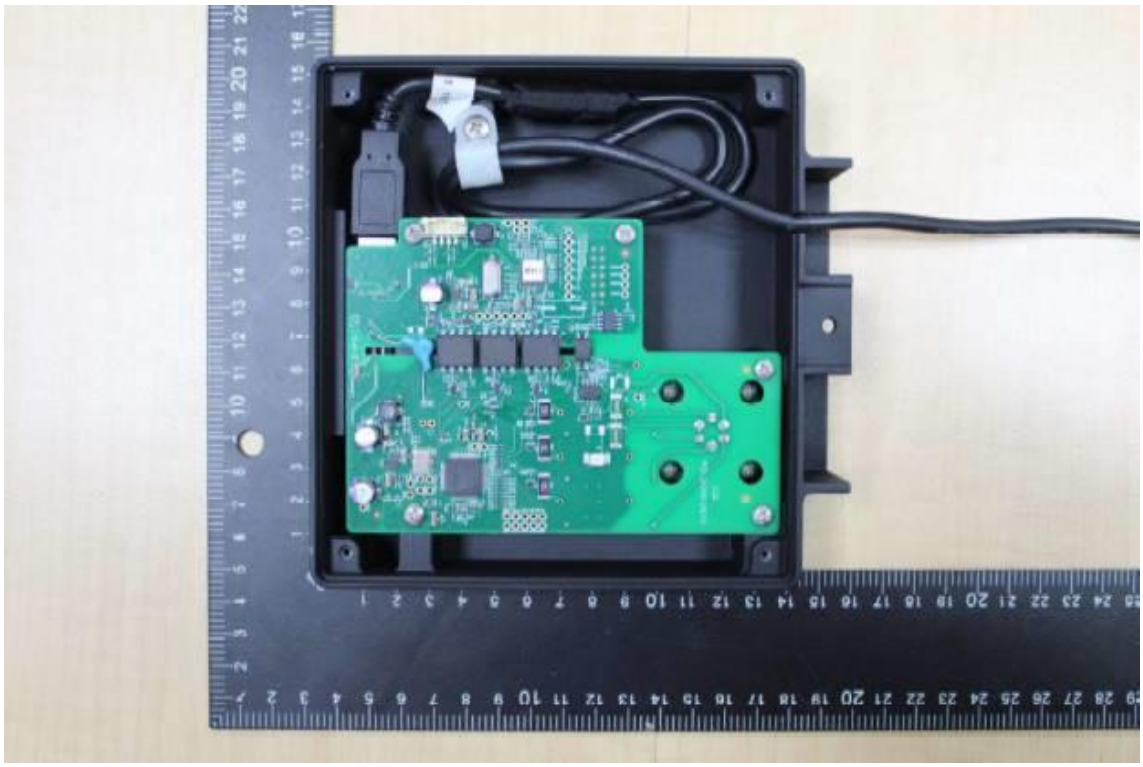
Front View of ECG module kit and ECG lead



Rear View of ECG module kit and ECG lead



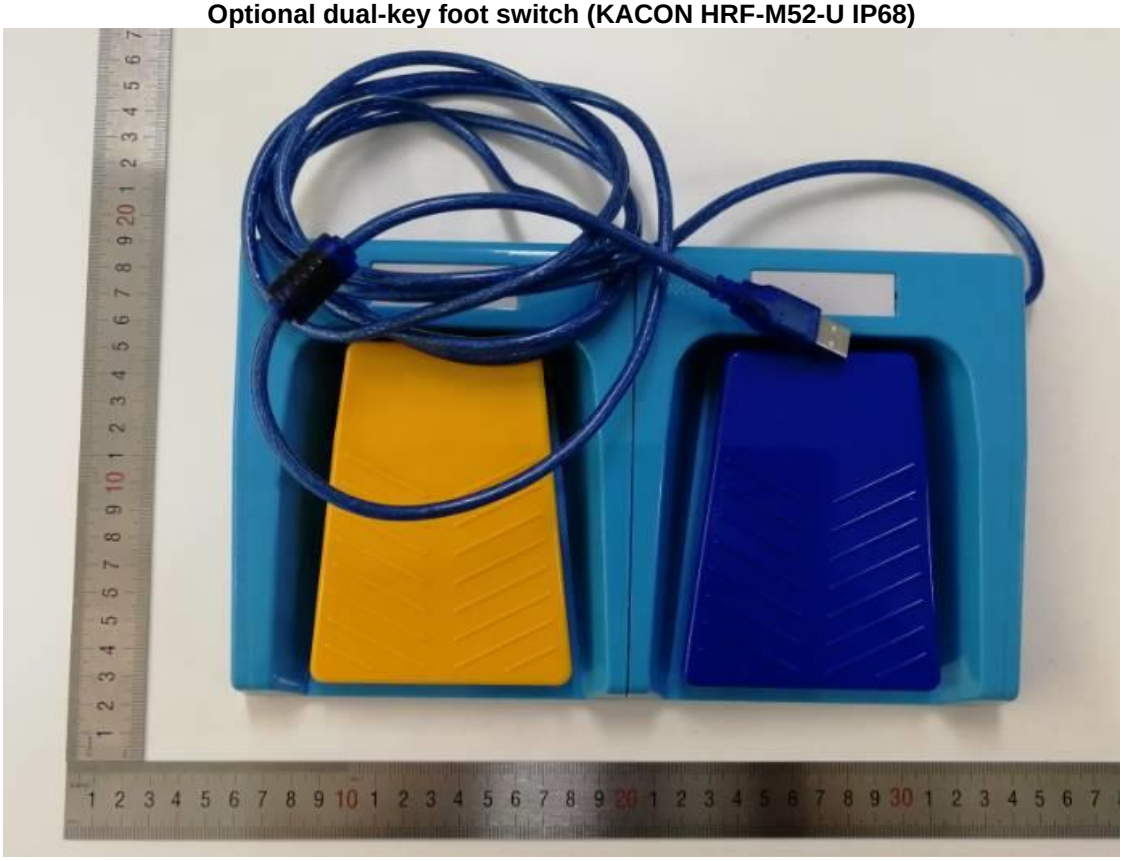
Internal View of ECG module kit



PCB of ECG module kit

Optional single-key foot switch (KACON HRF-M5-U IP 68)

Optional dual-key foot switch (KACON HRF-M52-U IP68)



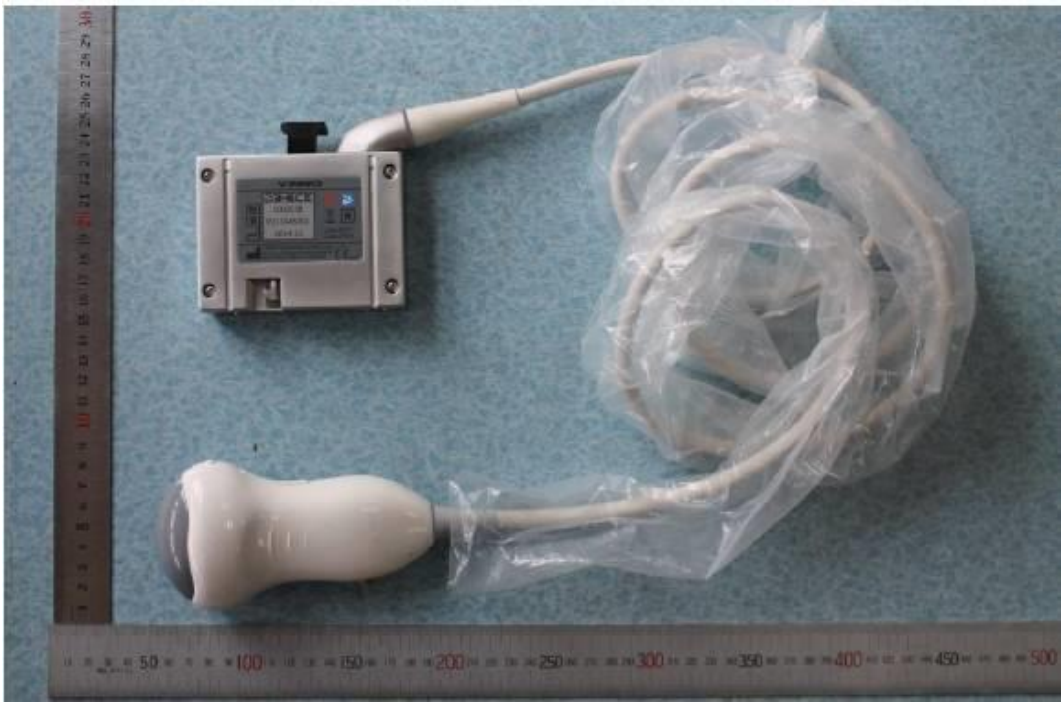
Optional medical use printer (UP-X898MD)

Optional medical use printer (UP-D25MD)

View of probe (F2-5C)

View of probe (D3-6C)

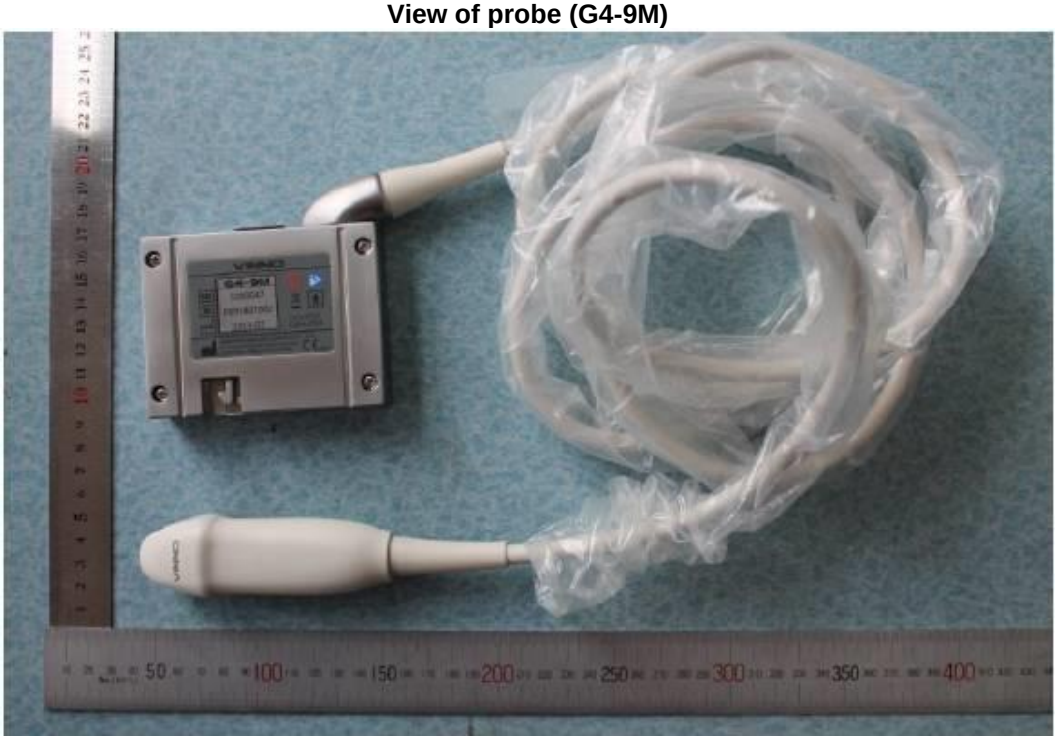
View of probe (D3-6CE)



View of probe (F4-9E)

View of probe (G4-9E)

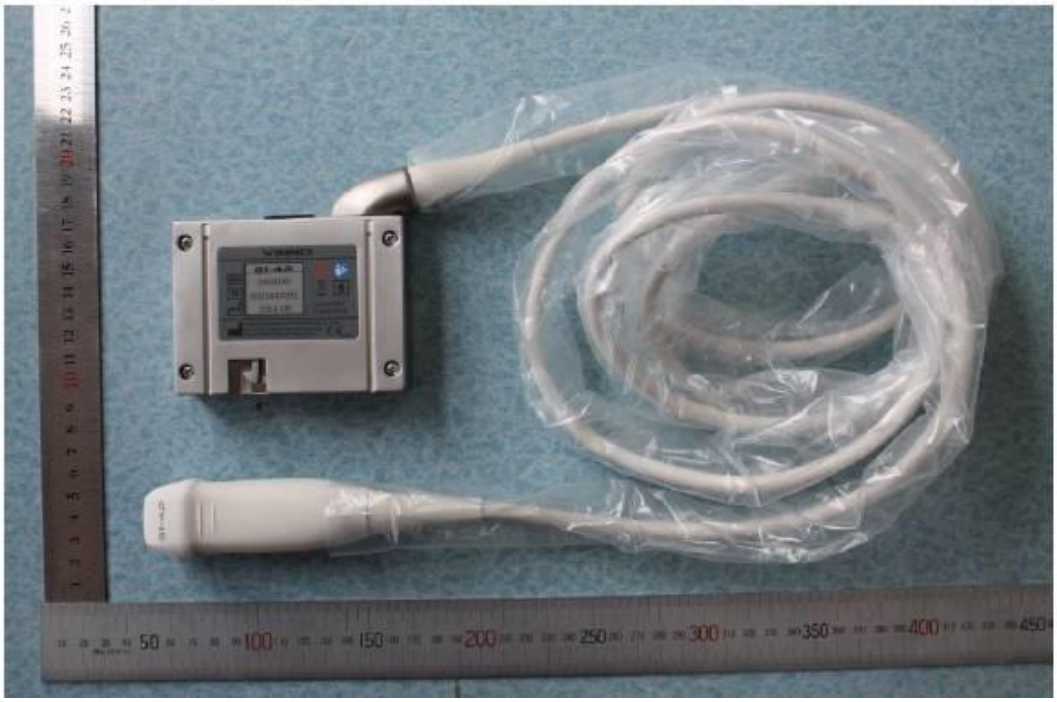
View of probe (G4-9M)



View of probe (F4-12L)

View of probe (X4-12L)

View of probe (G1-4P)



View of probe (D2-6C)