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

Report Number. .....:	S239800.01
Date of issue .....:	18 September 2022
Total number of pages.....:	135
Name of Testing Laboratory preparing the Report.....:	ITL (Product Testing) Ltd.
Applicant's name.....:	Flight Medical Innovations Ltd.
Address .....:	7 Hatnufa St., Petach Tikva 4951025, Israel
Test specification:	
Standard.....:	IEC 60601-1:2005, AMD1:2012
Test procedure .....:	PM120
Non-standard test method .....:	N/A
TRF template used .....:	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No.....:	IEC60601_1S
Test Report Form(s) Originator ....:	UL(US)
Master TRF.....:	2020-12-17

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Test item description ..... :	Critical Care Lung Ventilator		
Trade Mark(s)..... :	Flight Medical		
Manufacturer ..... :	Same as applicant		
Model/Type reference ..... :	Ventoux 8", Ventoux 12"		
Ratings ..... :	100-240Vac, 50-60Hz, 6A Max.; DC input: 11-30Vdc, 4.8A Max.; 21.6Vdc, 3400 mAh (from Li-Ion rechargeable batteries x2); Input O_2 pressure: 2.4-6.2 bar, 35-90 PSI		
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
☒	**Testing Laboratory:**	ITL (Product Testing) Ltd.	
Testing location/ address.....:		1 Bat Sheva St., Lod 7110603, Israel	
Tested by (name, function, signature).....:		Slava Shapira, Safety Department Engineer	
Approved by (name, function, signature)...:		Slava Pilyagin, Safety Department Team Leader	
☐	**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 + 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:

Attachment #	Description
1	National Differences
2	Maximum ambient operating temperature rationale
3	Declaration of model's similarity
4	Photos

Appendix #	Description
1	Biologic Risk Assessment and Evaluation Report by Ophir Lavon (dated: 4 June 2018)
2	Over Pressure Relief Valve test report by Flight Medical Innovations (DOC-0805, A00)
3	VX-Regulator Working Pressure test report by Flight Medical Innovations (DOC-0804, A00)
4	VX-O2 Saturation Inside Ventilator While Respirating Test Report by Flight Medical Innovations (DOC-0806, A00)

- IEC 60601-1-6 evaluated in Test Report S239801.01
- IEC 60601-1-8 evaluated in Test Report S239802.01
- ISO 80601-2-12 evaluated in Test Report S239804.01
- ISO 80601-2-55 evaluated in Test Report S239805.01
- ISO 80601-2-61 evaluated in Test Report S239806.01
- ISO 80601-2-84 evaluated in Test Report S239807.01
- EN 794-3 evaluated in Test Report S239808.01
- IEC 62304 evaluated in Test Report S239809.01

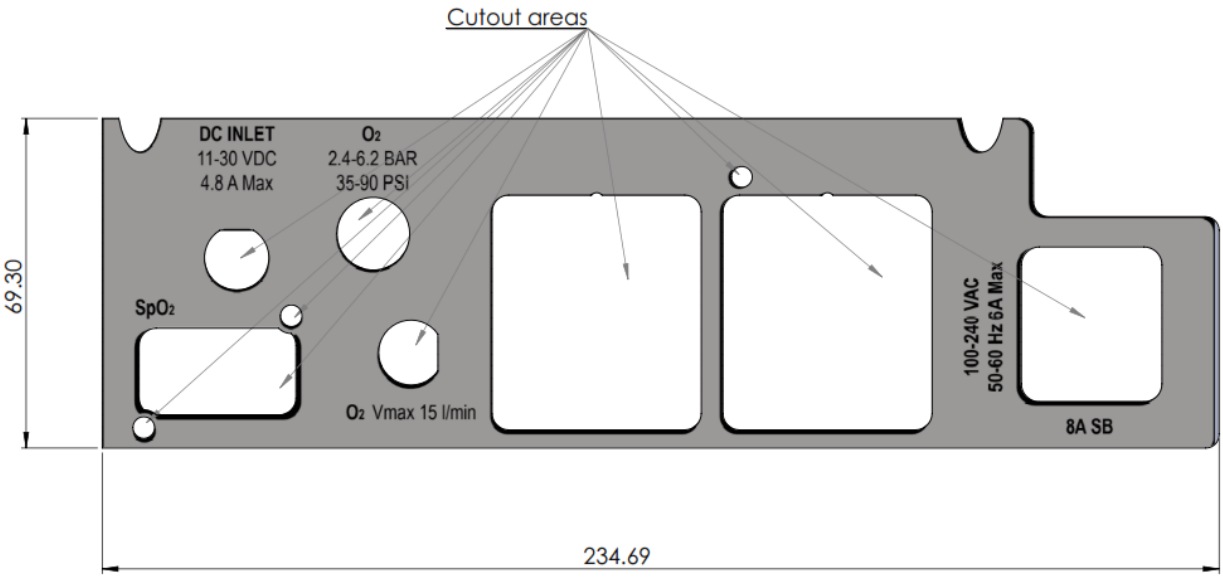
Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
4.11 Power consumption (input) single phase 5.9.2 Determination of applied parts and accessible parts 7.1.2; 7.1.3 Durability and legibility of marking 8.4.3 Measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply 8.7 Leakage current 8.8.3 Dielectric strength 8.8.4.1 Ball pressure test 9.4.2.1 Instability - overbalance 11.1.1 Normal heating 11.6.5 Ingress of water or particulate matter (IP34) 11.6.6 Cleaning 11.8 Interruption of power supply 13.2 Single Fault Conditions 15.3 Mechanical Strength tests	ITL (Product Testing) Ltd. 1 Bat Sheva St., Lod 7110603, Israel

Summary of compliance with National Differences List of countries addressed: US, CA, EU Group Differences US=United States, EU=Europe Group- and national differences for the CENELEC countries according to EN 60601-1:2006 + A11:2011 + A1:2013. The text of the International Standard IEC 60601-1:2005/A1:2012 was approved by CENELEC as a European Standard without any modification. ☒ The product fulfils the requirements of **US (**US National standard AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(r)2012 and A2:2010/(r)2012) ☒ The product fulfils the requirements of IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012
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: PM 196, Version: V4, dated: 4 June 2019, Measurement Uncertainty 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
Statement concerning the ASCA program specifications: * We hereby declare that current test report meets ASCA program specifications. ** More details regarding that matter can be observed in ASCA Summary Test Report

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.



FLIGHT MEDICAL INNOVATIONS

Part No:
Description:
Serial No:
UDI:

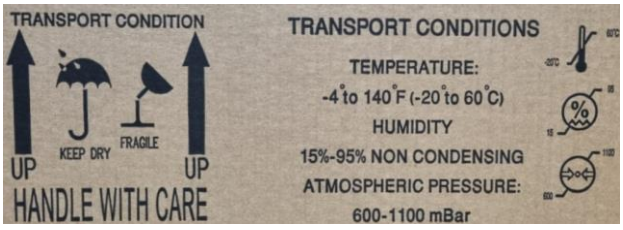
Flight Medical Innovations LTD, 7 HaTnufa St., Petach Tikva 4951025, Israel

Caution! USA Federal Law restricts this device to sale by or on the order of the physician!

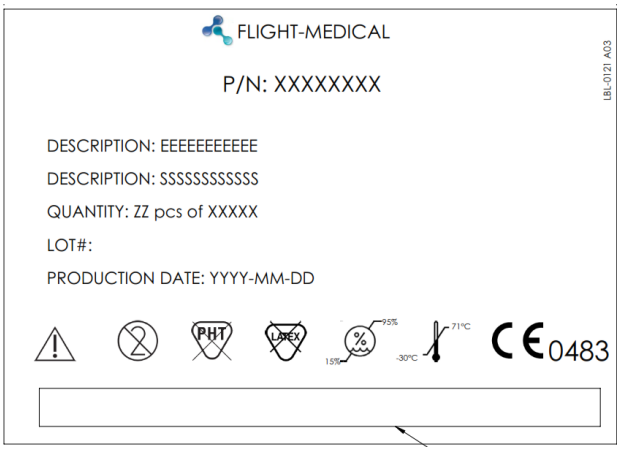
Danger! Explosion hazard if used in the presence of flammable anesthetics

Caution! This device includes Lithium - ION batteries

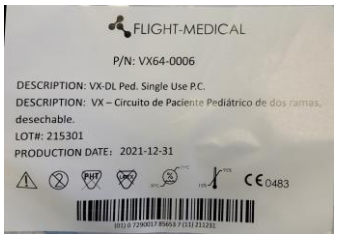
Packaging labels:

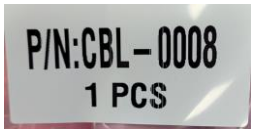


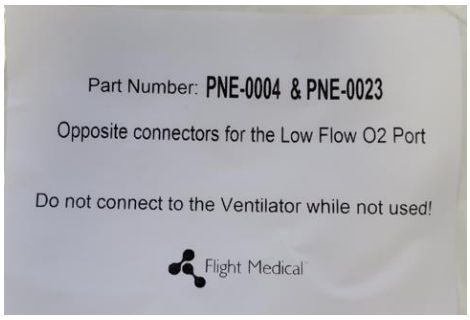
Patient circuit label:

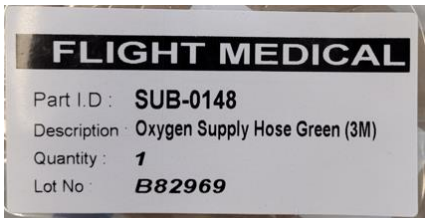


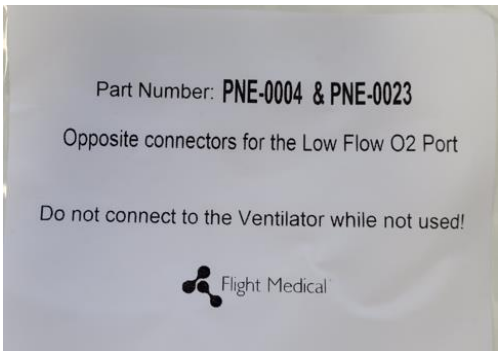
Accessories labels:



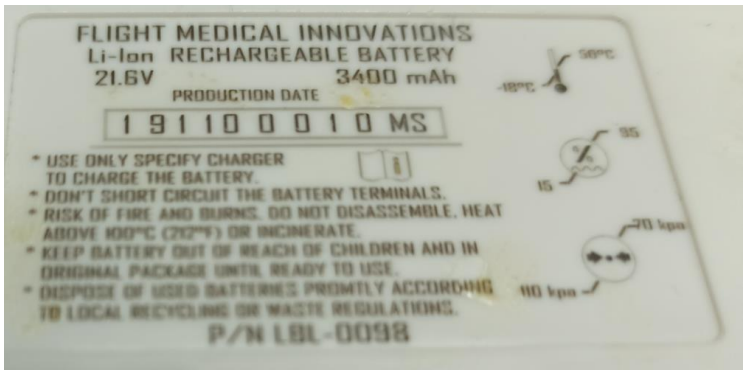








Battery label:



Test item particulars:	
Classification of installation and use .....:	Portable
Supply Connection.....:	AC inlet, DC inlet, detachable batteries
Device type (component/sub-assembly/ equipment/ system) .....:	Equipment
Intended use (Including type of patient, application location) .....:	The Ventoux Ventilator is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. Specifically, the Ventoux is applicable for adult, and pediatric (i.e., infant, child, and adolescent) patients who weigh at least 5 kg. The Ventoux Ventilator provide auto-leak compensation up to 100L/min allowing acute non-invasive ventilation. The Ventoux Ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician; it is suitable for use in hospitals, sub-acute emergency rooms, and emergency response applications. Ventoux is intended for use on one patient at a time and is not intended to ventilate multiple patients at once.
Mode of operation.....:	Continuous
Accessories and detachable parts included.....:	Patient circuit, Inspiratory filter, Flow sensor, Expiratory valve, Philips Respironics CAPNOSTAT 5 Mainstream sensor, Philips Respironics C5 LoFlo side stream sensor, CO_2 airway adapter, SpO_2 pulse oximeters, SPO2 Cable, Capnography, CUFF control, Remote Alarm Cable, Oxygen Supply Hose Green (3M), Dual Limb Adult Single Use Patient Circuit, opposite connectors for the Low Flow O2 port
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 .....:	14.11.2021
Date (s) of performance of tests.....:	14.11.2021 – 06.03.2022

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) .....: Same as applicant	

General product information:

The VENTOUX Ventilator is an electrically powered, microprocessor-controlled multi-parameter ventilator, which can be: Time, Pressure, Flow or Volume triggered; Volume or Pressure controlled; Time or Flow cycled.

Manual inflation is allowed, and the Ventoux supports the emergency intake of ambient air which permits the patient to pull ambient air into the breathing circuit in the event of a complete loss of air/gas supply.

Volume triggered is based on Inspiratory trig response time ≤100 ms from pressure drop/flow rise to PEEP level.

The inspiratory and expiratory gas pathway resistance is validated over a range of 5 to 200 cm H20/l/s and the compliance over a range of 3 to 100 ml/cm H2O.

Ventilation is possible in both Invasive and Noninvasive settings.

The system can be expanded to include additional parameter monitoring to allow for SpO_2, $etCO_2$ and Cuff Pressure Control.

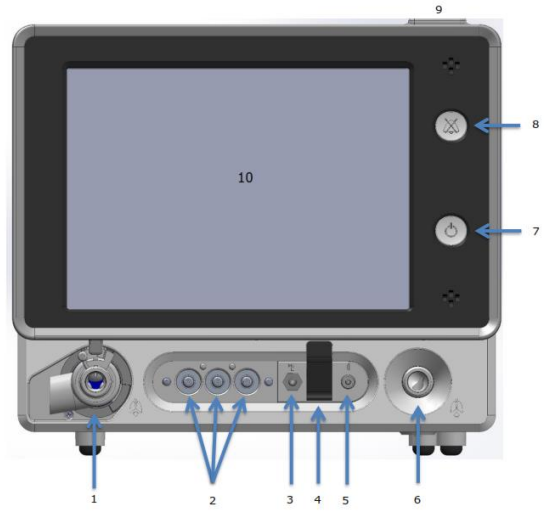
The Ventoux can be powered by external power (100 – 240 VAC, 50-60 HZ or 10 – 30 VDC) and/or by its two swappable internal Li Ion rechargeable batteries, which provide full operating power the to the ventilator for a minimal operating time of 5 hours when operating on standard ventilation parameters.

The ventilator maintains accuracy of controlled and displayed under an array of pressure transducers, monitoring the airway & O_2 pressure and flow variables continuously. This includes periodic zeroing of the flow sensor and periodic purging. In addition, an FiO_2 sensor is integrated within the system. The active control is performed both via the Ventilator's turbine blower, and groups of solenoids which control gas pressure and flow.

Zeroing and Purge operations are performed automatically to keep the relevant sensors aligned.

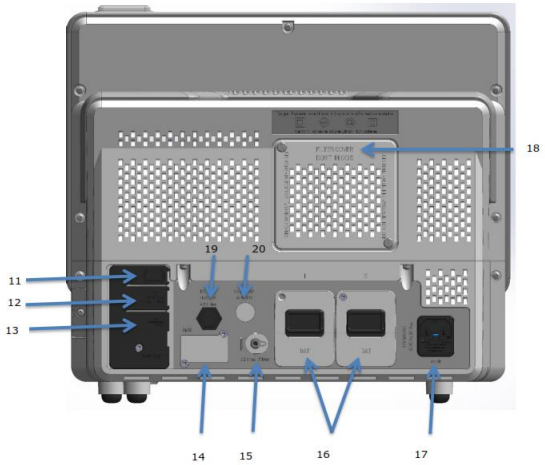
The input flow for the oxygen is control by a solenoid valve, and for the air is controlled by a turbine engine. The maximal air flows of the Ventoux for air and O_2 are: Air – 220 l/min at free flow and O_2 – 110 l/min at free flow.

Maximal turbine RPM, combined with complete occlusion of the exhalation valve membrane is the means by which maximum working pressure is ensured.



Front Panel

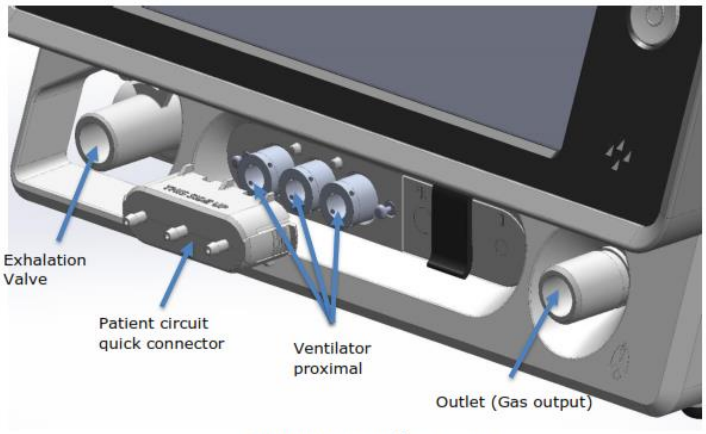
Item No.	Name	Description
1	Dual Limb Exhalation Valve	Connects the patient circuit expiratory limb.
2	Proximal Connection Ports	For Connecting to the patient circuit if a proximal flow sensor is used or single limb patient circuit is used
3	Nebulizer Port (optional)	For connecting to a pneumatic nebulizer.
4	Capnography CO_2 Port (optional)	For connecting to a Capnography Filter line
5	Cuff Port (optional)	For connecting to the patient Cuff tube
6	Patient Circuit Connector	Gas outlet, connects the patient circuit inspiratory limb.
7	On/Off button	Turns the ventilator on and stops ventilation. A green LED on the button indicates connection to an external electric power.
8	Mute	When pressed temporarily silences the audible alarm for 2 minutes; when repressed during alarm silence - resets silence status. When alarms are muted the LED indicator of the mute button is lit.
9	360° Alarm LED	Flashes red or yellow to indicate there is an alarm.
10	Display touch screen	Enables the user to modify the ventilation, alarm, and technical settings, and to view real time patient data, alarms, battery status and logs.



Back Panel

Label	Name	Description
11	COM1 (RJ11)	Remote alarm/ Nurse call connector
12	LAN (RJ45)	LAN for network logging ( )
13	USB 1, USB 2	USB ports for SW loading to the ventilator or for log files exportation. For authorized and qualified service technicians only
14	SpO_2 port (optional)	Connects to SpO_2 finger probe
15	Low Flow Oxygen Port	Low flow oxygen enrichment source (up to 345 kPa, 0 – 15 L/min)
16	Detachable Batteries	Li-Ion 22.2 VDC
17	AC Inlet with Fuse	100 – 240 V AC, 50 – 60 Hz, Fuse 8A (SB or TL)
18	Air Intake with Filter	Enables the patient to pull ambient air into the patient circuit. Acts as emergency air inlet in the event of complete system failure.
19	DC Inlet	10 – 30 VDC
20	High Pressure O_2 Port (optional)	Connects to high pressure O_2 (240 – 620 kPa, 21% - 100%)

Label	Name	Description
1	Alarms bar	Display of signaled alarms
2	Ventilation mode selector	Button for ventilation mode change
3	Indicators bar	Batteries status DC/AC external connection Oxygen supply connection Time and date/alarm mute counter Network connectivity – WiFi/Wire
4	Main Monitoring Parameters	Display of 6 constant main breathing parameters
5	Graphic Display	Display of graphical data
6	Operational control bar	Operating of additional features (see clause 5.7)
7	Controllers lines selectors	Used for controllers' lines selectors
8	Main Controllers	Controllers for changing ventilation parameters



Patient circuit quick connector

Specifications:

Physical Characteristic	Specification
Ventilator Weight	8 Inch Screen: 7.6/7.2 kg (with/without internal O_2 Mixer) 12 Inch Screen: 8.2/7.8 kg (with/without internal O_2 Mixer)
Ventilator Dimensions	8 Inch Screen: 34W x 26D x 25H cm 12 Inch Screen: 34W x 26D x30H cm
Reusable Single Patient Circuit	Reusable (single patient) 22 mm ID 180 cm. length adult/pediatric circuit with 2.75 mm ID proximal pressure sensing line, 2.75 mm ID exhalation valve control drive line, 2.75 mm I.D. flow sensing line, exhalation valve, flow sensing orifice and quick connector.
Single Use Patient Circuit	Single use 22 mm ID 180 cm. length adult/pediatric circuit with 2.75 mm ID proximal pressure sensing line, 2.75 mm ID exhalation valve control drive line, 2.75 mm I.D. flow sensing line, exhalation valve, flow sensing orifice and quick connector.
Connectors	Gas Outlet: ISO 22 mm OD conical. Air/Oxygen Inlet: ISO 30 mm female fitting.
Add-ons	$etCO_2$ –monitoring of the partial pressure of carbon dioxide in exhaled breath. Cuff pressure control - provides an automatic cuff pressure in tracheal tubes and tracheotomy tubes according to an adjustable target pressure. SpO_2- monitoring of the ratio of oxy-hemoglobin to the total concentration of hemoglobin present in the blood.

Item	Specification
Over Pressure Relief Valve	Limits the maximum airway pressure to 120 ± 5 cmH_2O
FiO_2 sensor	MAX 16 by MAXTEC; range from 0 to 100% oxygen. Warm up time: less than 30 minutes after replacement.

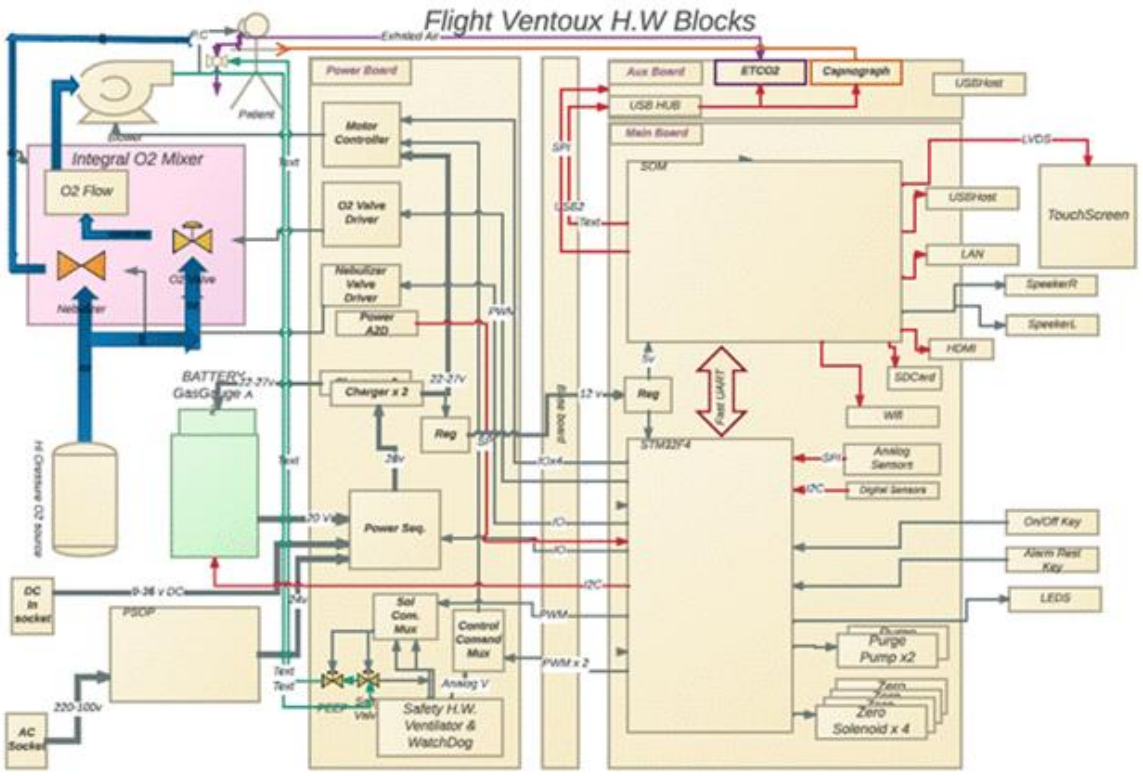
Item	Specification
Maximum error of delivered volume in relation to set value	± (4,0 ml + 15 % of the actual V) for V > 50ml; ±15ml for V < 50ml
Maximum PEEP error in relation to set value	±1cmH2OIP for PEEP <= 5; ±2cmH2O for 5<PEEP<=20; ±10% for PEEP>20
Maximum FiO_2 error in relation to set value	± (2.5 + 2.5% of set FiO_2)
Maximum error of the airway pressure at the end of the inspiratory phase in relation to the set value	± (2 cmH2O + 4 % of the actual PIP for PC+PEEP < 40cmH2O; ±10% of the actual PIP for PC+PEEP≥ 40 cmH2O
Maximum limited gas flow	The maximal gas flow of the Ventoux for air and O_2 is: Air – 220 l/min at free flow and O_2 – 110 l/min at free flow.

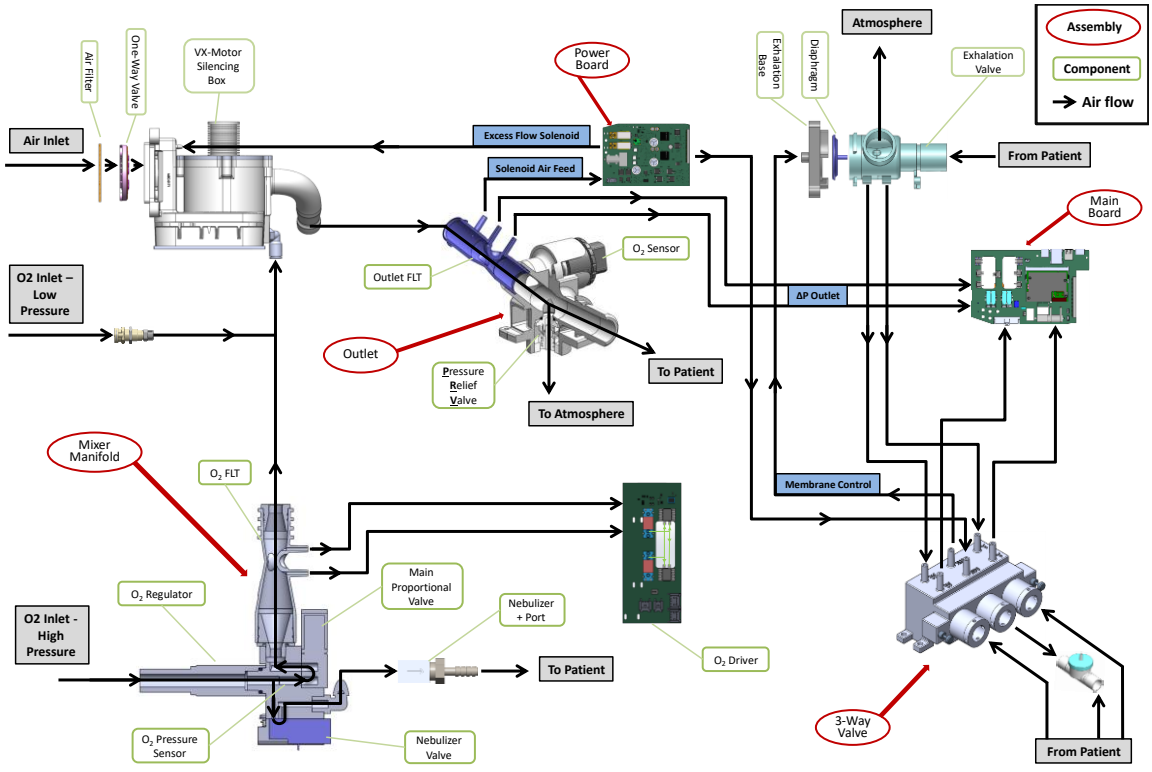
Condition	Range
Operating Temperature	-18 ^{O}C to 50 ^{O}C / -0.4 ^{O}F to 122 ^{O}F
Storage Temperature	-30 ^{O}C to 71 ^{O}C / -22 ^{O}F to 160 ^{O}F
Operating Pressure (Altitude)	70 kPa to 110 kPa (0 to 8000 ft)
Humidity	15% to 95% RH at 31 ^{O}C
Water Resistance	IP34 (dust/splash proof) IEC 60529

Feature	Specification
Connector Type	DISS
Input Pressure – Oxygen	35-90 psig/240-620 kPa
FiO_2	21% to 100%
Accuracy	±5%
21% to 90% FiO_2 Response Time	Up to 20 seconds

Item	Specification
Oxygen Flow	0 to 15 L/min
Oxygen Pressure	Below 50 psig

Block Diagram





*Note: For differences between models – see attachment 6

Insulation Diagram

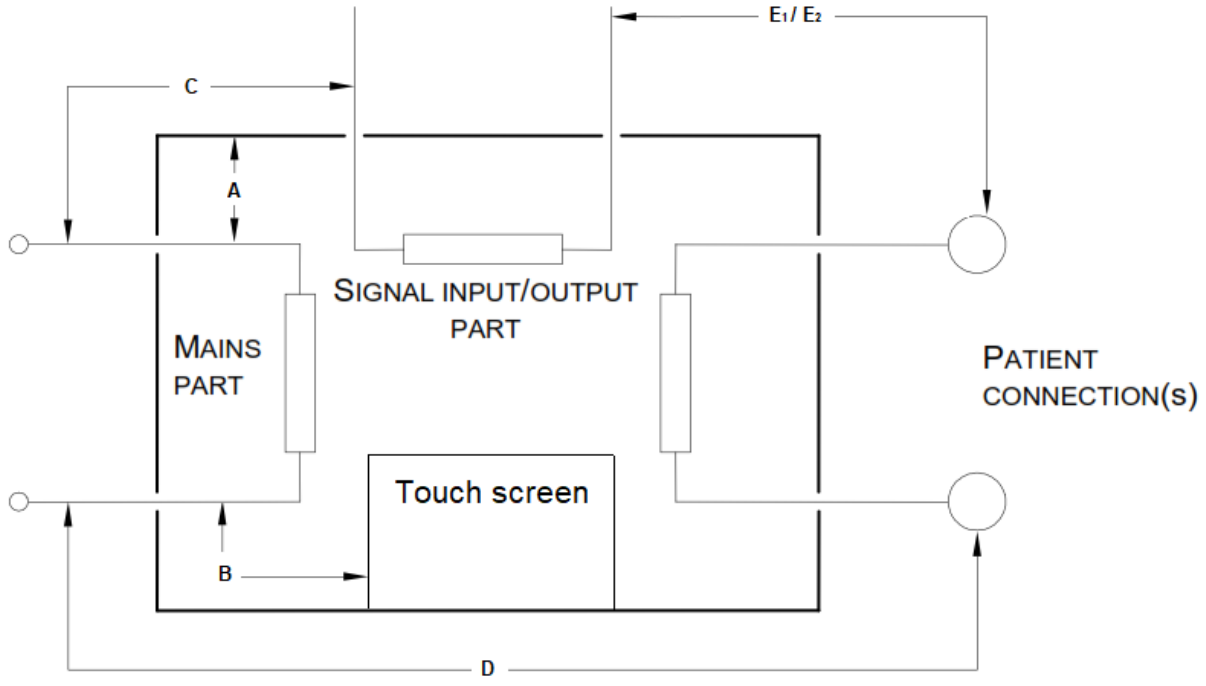


TABLE: INSULATION DIAGRAM		P
Pollution degree .....:	2	—
Overvoltage category .....:	II	—
Altitude.....:	Up to 2000m	—
Additional details on parts considered as applied parts .....:	☒ None ☐ Areas	—

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	2MOOP	IIIb	240Vac	340Vac	5	4	Reinforced insulation is achieved by solid insulation and certified power supply		L&N to enclosure (plastic/metal parts)
B	2MOOP	IIIb	240Vac	340Vac	5	4	Reinforced insulation is achieved by solid insulation and certified power supply		L&N to touch screen
C	2MOOP	IIIb	240Vac	340Vac	5	4	Reinforced insulation is achieved by solid insulation and certified power supply		L&N to SIP/SOP

D	2MOPP	IIIb	240Vac	340Vac	8	5	Reinforced insulation is achieved by solid insulation and certified power supply	L&N to Applied parts (pulse oximeter, CUFF control, patient circuit)
E_1	2MOPP	IIIb	---	24Vdc	8	5	Reinforced insulation is achieved by solid insulation	SIP/SOP to Applied parts (pulse oximeter, CUFF control, patient circuit)
E_2	1MOPP	IIIb	240Vac	340Vac	4	2.5	Reinforced insulation is achieved by solid insulation	

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	Complied	**P**
4.2	RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS		**P**
4.2.2	General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007) ..... :	See Appended RM Results Table 4.2.2	**P**
4.2.3	Evaluating RISK		**P**
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04)	**P**
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN..... :	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04)	**P**
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04)	**P**
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04)	**P**
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.	No such addressed hazards or hazardous situations.	**N/A**
4.3	Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.	Complied	**P**
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.	Considered, not identified specifically in RMF	**P**
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated	Same as above	**P**
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE ..... :	See appended table 4.3	**P**
	- RISK CONTROL measures implemented	See DOC-0556 A03 Ventoux Verification and Validation Plan	**P**
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented	Same as above	**P**
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE ..... :	Defined in DOC-0489 – stated in risk analysis – section 4.7 Hardware Mechanical Related Hazards, item 126	**P**
4.5	Alternative RISK CONTROL methods utilized:	No alternative methods	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
	Alternative means based scientific data or clinical opinion or comparative studies ..... :	No such means	**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 ..... :	No such parts	**N/A**
	MANUFACTURER assesses the risk of accessible parts coming into contact with the patient..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
	Assessment identified the APPLIED PART TYPE requirements..... :	No such parts	**N/A**
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2 ..... :	EUT remained single fault safe	**P**
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested..... : (ISO 14971 Cl. 4.2-4.4)	No such risks	**N/A**
	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 ..... :	Complied	**P**
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS	No exception	**N/A**
	RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION..... :	No components are used outside their ratings	**N/A**
	Components determined to be acceptable where used as a MEANS OF PROTECTION ..... :	Complied	**P**
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following	Complied	**P**
	a) Applicable safety requirements of a relevant IEC or ISO standard	Certified components used, see appended table 8.10	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard	Certified components used, see appended table 8.10	**P**
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately ..... :	No components with high-integrity characteristics required	**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:	No 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) ..... :	AC inlet, DC inlet, detachable batteries	**P**
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:		**P**
	- 250 V for HAND-HELD ME EQUIPMENT (V) ..... :	Not hand-held	**N/A**
	– 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V) ..... :	Complied	**P**
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS	Maximum rated voltage does not exceed 250 V., single phase	**N/A**
4.11	Power input		**P**
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10% .... :	See appended Table 4.11	**P**

5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		**P**
5.1	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods..... :	All applicable tests performed	**N/A**
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. (ISO 14971 Cl. 4.2-4.4)	No such risks	**N/A**
5.3	Tests conducted within the environmental conditions specified in technical description:	See Ventoux Operating Manual, 14.8 Environmental Specifications	**P**
	Temperature (ºC), Relative Humidity (%) ..... :	-18-50 °C, 15-95%	—
	Atmospheric Pressure (kPa) ..... :	70-110 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) ..... :	Rechargeable Batteries: 21.6Vdc, AC inlet: 100-240Vac	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz) ..... :	50-60Hz	**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 ..... :	Considered and complied	**P**
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered ..... :	Considered	**P**
	e) ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions ..... :	All the relevant accessories were tested with EUT	**P**
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	No separate power supply	**N/A**
5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3 ..... :	Tested and complied	**P**
	ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +32°C for indicated time	T = 25°C Time: 168 hours	**—**
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		**P**
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS ..... :	See Ventoux Operating Manual, 11 Accessories	**P**
5.9.2	ACCESSIBLE PARTS		**P**
5.9.2.1	Accessibility determined using standard test finger of Fig. 6	See Appended Table 5.9.2	**P**
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s	No openings	**N/A**
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS ..... :	No such parts	**N/A**
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL ..... :	Same as above	**N/A**
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		**P**
6.2	CLASS I ME EQUIPMENT, externally powered	Not Class I equipment	**N/A**
	CLASS II ME EQUIPMENT, externally powered	Class II equipment	**P**
	INTERNALLY POWERED ME EQUIPMENT	Complied	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	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	Class II and internally powered	**P**
	TYPE B APPLIED PART	No such applied parts	**N/A**
	TYPE BF APPLIED PART	BF Applied parts: Patient Circuit, CUFF control, Pulse Oximeter	**P**
	TYPE CF APPLIED PART	No such applied parts	**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS	No such applied parts	**N/A**
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529 .....:	IP34	**P**
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use .....:	No parts intended to be sterilized	**N/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	The EUT does not intended for use in an oxygen rich environment	**N/A**
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION .....:	Continuous operation	**P**

7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		**P**
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6 .....:	See Appended Table 7.1.2	**P**
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE	See appended Tables 7.1.3	**P**
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		**P**
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings .....:	See attached copy of Marking Plate	**P**
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS .....:	Only symbols included, section 1.2 in UM	**N/A**
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT	Complied	**P**
	Single use item marked..... :	Marked on accessories labels	**P**
7.2.2	ME EQUIPMENT marked with:		**P**
	– the name or trademark and contact information of the MANUFACTURER	Marked	**P**
	– a MODEL OR TYPE REFERENCE	Marked	**P**
	– a serial number or lot or batch identifier; and	Marked	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	– the date of manufacture or use by date	Part of serial number barcode. See DOC-0602. Indicated by YYMMDD at end of bar code	**P**
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	Not marked	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.4)	No such risks	**N/A**
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and	Not marked	**N/A**
	– a MODEL OR TYPE REFERENCE	Not marked	**N/A**
	Software forming part of a PEMS identified with a unique identifier ..... :	Software Release Version 1.20	**P**
7.2.3	Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS	Symbol 11 used	**P**
	Safety sign 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	Not used	**N/A**
7.2.4	ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and.... :	Marked	**P**
	- with a MODEL or TYPE REFERENCE	Marked	**P**
	– a serial number or lot or batch identifier	Marked	**P**
	– the date of manufacture or use by date	Marked	**P**
	Markings applied to individual packaging when not practical to apply to ACCESSORIES	Complied	**P**
7.2.5	ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following:		**N/A**
	- the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or	EUT is not intended to receive power from other equipment	**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	Same as above	**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.	Same as above	**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	Complied	**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**

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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) ..... :	100-240Vac	**P**
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V) ..... :	No such voltages	**N/A**
	– Nature of supply and type of current ..... :	AC supply for power supply, DC from DC inlet and batteries to electrical circuits	**P**
	Symbols 1-5, Table D.1 (used for same parameters ..... :	Not used	**N/A**
	– RATED supply frequency or RATED frequency range in hertz ..... :	50/60 Hz	**P**
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT..... :	Complied	**P**
7.2.7	RATED input in amps or volt-amps, (A, VA) ..... :	Amps	**P**
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) ..... :	Same as above	**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) ... :	Complied	**P**
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W) ..... :	Continuous operation, no momentary volt-ampere ratings	**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 such means	**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) ..... :	Not required	**N/A**
7.2.8	Output connectors		**N/A**
7.2.8.2	Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment	No multiple socket-outlets	**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. ..... :	IP34	**P**
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols ..... :	Complied, See attached copy of Marking Plate	**P**
	TYPE B APPLIED PARTS with symbol 19 of Table D.1	No such applied parts	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1:	See attached copy of Marking Plate	**P**
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1:	No such applied parts	**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 ..... :	No such applied parts	**N/A**
	Proper symbol marked adjacent to or on connector for APPLIED PART ..... :	Marked on label	**P**
	Safety sign 2 of Table D.2 placed near relevant outlet ..... :	No such symbol	**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 ..... :	Not relevant, no such applied parts	**N/A**
7.2.11	ME EQUIPMENT suitable for CONTINUOUS OPERATION	Continuous operation	**P**
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum “on” and “off” time..... :	Continuous operation	**N/A**
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder	See appended table 8.10	**P**
	Fuse type ..... :	Mains fuse	**—**
	Voltage (V) and Current (A) rating..... :	250V, 8A	**—**
	Operating speed (s) and Breaking capacity ..... :	Time-Lag type, Interrupting Rating: 100A@500VAC	**—**
7.2.13	Physiological effects – safety sign and warning statements ..... :	Contraindications: Patient must not be obtunded and should be spontaneously breathing. Contraindications to HFOT (High Flow Oxygen Therapy) include abnormalities or surgery of the face, nose, or airway that preclude an appropriate-fitting nasal cannula. Complications are rare and include abdominal distension, aspiration, rarely barotrauma and facial burns.	**P**
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	No such risks	**N/A**
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1	No such devices	**N/A**
7.2.15	Requirements for cooling provisions marked ..... :	No cooling provisions	**N/A**
7.2.17	Packaging marked with special handling instructions for transport and/or storage..... :	See attached copy of Marking Plate	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	Permissible environmental conditions marked on outside of packaging ..... :	See attached copy of Marking Plate	**P**
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK ..... :	See attached copy of Marking Plate	**P**
	RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK. ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.3-6.4)	No such risks	**N/A**
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization	Not supplied sterile	**N/A**
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and ..... :	Marked on back panel	**P**
	- the RATED flow rate also marked	Same as above	**P**
7.2.19	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL ..... :	No functional earth terminals	**N/A**
7.2.20	Removable protective means marked to indicate the necessity for replacement when the function is no longer needed..... :	No such means	**N/A**
7.2.21	MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms..... :	Not mobile equipment	**N/A**
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		**P**
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W)..... :	No such parts	**N/A**
	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 marking	**N/A**
7.3.2	Symbol 24 of Table D.1, or safety sign No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts :	No such parts	**N/A**
7.3.3	Type of battery and mode of insertion marked..... :	Provided on battery label	**P**
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL ..... :	No such marking and not only service personnel can replace the batteries	**N/A**
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK..... :	No such warning	**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an unacceptable RISK if replaced incorrectly ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	No such risks, the batteries cannot be incorrectly placed, they are swappable	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARD ..... :	No such warning	**N/A**
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL identified ..... :	See appended table 8.10	**P**
	Voltage (V) and Current (A) rating..... :	250V, 8A	**—**
	Operating speed(s), size & breaking capacity..... :	Time-Lag type, Interrupting Rating: 100A@500VAC	**—**
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1	No protective earth	**N/A**
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made	Same as above	**N/A**
7.3.6	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS	No functional earth terminals	**N/A**
7.3.7	Terminals for supply conductors marked adjacent to terminals ..... :	No supply terminals	**N/A**
	Terminals for supply connections are not marked, the RISK MANAGEMENT FILE includes an assessment of the RISKS resulting from misconnections ..... : (ISO 14971 Cl. 4.3)	No supply terminals	**N/A**
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	Not such case	**N/A**
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3	Not permanently installed equipment	**N/A**
	Marking for connection to a 3-phase supply, complies with IEC 60445	Single phase	**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	Not such case	**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	Not required	**N/A**
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		**N/A**
7.4	Marking of controls and instruments		**N/A**
7.4.1	The “on” & “off” positions of switch to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 or	No ON/OFF switch, turning off the EUT is performed by software application	**N/A**
	– indicated by an adjacent indicator light, or	Same as above	**N/A**
	– indicated by other unambiguous means	Same as above	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	The “on/off” positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, and	No ON/OFF switch, turning off the EUT is performed by software application	**N/A**
	– status indicated by adjacent indicator light	Same as above	**N/A**
	– status indicated by other unambiguous means	Same as above	**N/A**
	The “on/off” positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or	No ON/OFF switch, turning off the EUT is performed by software application	**N/A**
	– status indicated by adjacent indicator light	Same as above	**N/A**
	– status indicated by other unambiguous means	Same as above	**N/A**
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means	Complied	**P**
	RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2, 6.3)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04), hazard 16	**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..... :	Incorrect reading of flow or pressure sensor	**P**
	– or an indication of direction in which magnitude of the function changes	No such control	**N/A**
	Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009	Marked, provided on front panel	**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	Complied	**P**
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units	Complied	**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	Marked on labels and on EUT	**P**
	RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	No such risks	**N/A**
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT	No such statement	**N/A**
	Specified colours in ISO 3864-1 used for safety signs ..... :	No safety signs used on label	**N/A**
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)	No such notices	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Safety signs including any supplementary text or symbols described in instructions for use	Not described	**N/A**
	- and in a language acceptable to the intended OPERATOR	English	**P**
7.6	Symbols		**P**
7.6.1	Meanings of symbols used for marking described in instructions for use ..... :	See section 1.2 in UM	**P**
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable	Complied	**P**
7.7	Colours of the insulation of conductors		**N/A**
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation	No protective earth	**N/A**
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations		**N/A**
7.7.3	Green and yellow insulation identify only following conductors:	No PE	**N/A**
	– PROTECTIVE EARTH CONDUCTORS	No PE	**N/A**
	– conductors specified in 7.7.2	No PE	**N/A**
	– POTENTIAL EQUALIZATION CONDUCTORS	No PE	**N/A**
	– FUNCTIONAL EARTH CONDUCTORS	No such conductors	**N/A**
7.7.4	Neutral conductors of POWER SUPPLY CORDS are “light blue”	Complied	**P**
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1	Complied	**P**
7.8	Indicator lights and controls		**P**
7.8.1	Red indicator lights used only for Warning	Complied	**P**
	Yellow indicator lights used only for Caution	Complied	**P**
	Green indicator lights used only for Ready for use	Complied	**P**
	Other colours: Meaning other than red, yellow, or green (colour, meaning) ..... :	No such indicators	**N/A**
7.8.2	Red used only for emergency control	No emergency control	**N/A**
7.9	ACCOMPANYING DOCUMENTS		**P**
7.9.1	ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description	Complied	**P**
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		**P**
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to..... :	Cover page	**P**
	– MODEL or TYPE REFERENCE..... :	Cover page	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	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 documents are provided electronically	**P**
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	Pages 3, 4, 10, 14, 25, 36, 111, 112	**P**
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	Considered	**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:	Section 2	**P**
	– frequently used functions,	Section 3	**P**
	– known contraindication(s) to use of ME EQUIPMENT	Section 2.3	**P**
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient	Section 12	**P**
	– name or trademark and address of the MANUFACTURER	Section 13.5	**P**
	– MODEL OR TYPE REFERENCE	Section 3.4	**P**
	Instruction for use included the following when the PATIENT is an intended OPERATOR:	Patient is not an operator	**N/A**
	– the PATIENT is an intended OPERATOR	Patient is not an operator	**N/A**
	– warning against servicing and maintenance while the ME EQUIPMENT is in use	Patient is not an operator	**N/A**
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and	Patient is not an operator	**N/A**
	–maintenance the PATIENT can perform	The patient cannot perform maintenance	**N/A**
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	Section 1.2	**P**
	Instructions for use are in a language acceptable to the intended operator	English	**P**
7.9.2.2	Instructions for use include all warning and safety notices	Warning and safety instructions throughout the UM	**P**
	Warning statement for CLASS I ME EQUIPMENT included	EUT is not Class I	**N/A**
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	Section 1.2	**P**
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	Section 14.4	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	No multiple socket-outlet	**N/A**
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	Not considered as ME system	**N/A**
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions	Section 4	**P**
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source	No additional power source, integral certified power supply used	**N/A**
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04), hazard 5	**P**
	Where the RISK is unacceptable, the IFU includes a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time .....:	Section 2.2	**P**
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided ..... :	Section 14.6	**P**
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK ..... :	Section 2.2	**P**
7.9.2.5	Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE	Section 3	**P**
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to	No unsafe materials exposed	**N/A**
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected	Section 2.1	**P**
	APPLIED PARTS specified	Sections 4, 11	**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	Section 4	**P**
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device	Section 2	**P**
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation	Section 5	**P**
7.9.2.9	Information provided to operate ME EQUIPMENT	Section 5	**P**
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	Section 1.2	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
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	Section 13	**P**
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	Section 5.5	**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	Section 12	**P**
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	Section 11	**P**
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	Section 12	**P**
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	Section 12	**P**
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	Section 12	**P**
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	Sections 4.4, 12	**P**
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	Section 11	**P**
	Other equipment providing power to ME SYSTEM sufficiently described	The EUT is not ME system	**N/A**
7.9.2.15	Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for use ..... :	Section 14.11	**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)	Section 14.12	**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	The EUT does not emit radiation for medical purposes	**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	Neither the device nor its accessories are supplied sterile	**N/A**
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization	Same as above	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.19	The instructions for use contain a unique version identifier ..... :	DOC-0468 Rev. A02	**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	Section 14	**P**
	-information required in 7.2	Section 1.2	**P**
	-permissible environmental conditions of use including conditions for transport and storage..... :	Section 14.8	**P**
	-characteristics of the ME EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found	Sections 6, 8, 9	**P**
	-special installation requirements such as the maximum permissible apparent impedance of SUPPLY MAINS	No such requirements	**N/A**
	-permissible range of values of inlet pressure and flow, and the chemical composition of cooling liquid	Section 4	**P**
	-description of the means for checking the oil level in partially sealed oil filled ME EQUIPMENT or its parts	No oil used	**N/A**
	-warning statement that addresses the HAZARDS that can result from unauthorized modification of the ME EQUIPMENT	Section 2	**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	Not specified for Safety, for EMC - see section 14.4.1	**P**
	Technical description separable from instructions for use contains required information, as follows		**P**
	-information required by 7.2	Not specified	**N/A**
	–applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT	Not specified	**N/A**
	– brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and	Not specified	**N/A**
	a unique version identifier ..... :	Not specified	**N/A**
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description	Not specified	**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 a permanently installed ME equipment	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and	The power cord is detachable	**N/A**
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	Section 4 in UM	**P**
	RISK MANAGEMENT FILE includes an assessment to determine if replacement of components results in any unacceptable RISKS.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04), hazard 130	**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	No such warnings	**N/A**
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	Section 14.12	**P**
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description	Not specified	**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	Not exceeded	**P**
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION .....: (ISO 14971 Cl. 4.3)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04), hazard 12	**P**
8.2	Requirements related to power sources		**P**
8.2.1	Connection to a separate power source		**N/A**
	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM	No separate power source specified	**N/A**
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified	Same as above	**N/A**
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined	Same as above	**N/A**
8.2.2	Connection to an external d.c. power source		**P**
	No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source	DC inlet protected by construction of connector and by reverse input protection component (LTC4364HS-2)	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE	Complied	**N/A**
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset	Not such case	**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	No such applied parts	**N/A**
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART	No such applied parts	**N/A**
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	BF Applied parts: Patient Circuit, CUFF control, Pulse Oximeter	**P**
8.4	Limitation of voltage, current or energy		**P**
8.4.2	ACCESSIBLE PARTS and APPLIED PARTS		**P**
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT..:	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	Limits are applied	**N/A**
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.).....:	Not exceed	**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).....:	Not exceed	**P**
	d) Voltage and energy limits specified in c) above also applied to the following:	No touchable internal parts	**N/A**
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	Same as above	**N/A**
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL	No touchable internal parts	**N/A**
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N	Same as above	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N	No touchable internal parts	**N/A**
	Test repeated with a TOOL specified in instructions for use	No tool specified	**N/A**
	Test rod freely and vertically suspended through openings on top of ENCLOSURE	No openings on top	**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 access cover	**N/A**
	A TOOL is required when it is possible to prevent the devices from operating	Same as above	**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 .....:	Test voltage not exceeded 60V	**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 accessible capacitive circuits	**N/A**
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL	No such parts	**N/A**
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description ..... :	No such parts	**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	Provided	**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	No such parts	**N/A**
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10	Complied, see appended table 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:	Complied	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12	Refer to Insulation Diagram	**P**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6	No protective earth connectors	**N/A**
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION .....:	Evaluated as part of certified integral power supply	**P**
	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. .....:	Evaluated as part of certified integral power supply	**P**
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	Evaluated as part of certified integral power supply	**P**
	Voltage Total Working (V) and C Nominal (µF) .....:	Evaluated as part of certified integral power supply	**—**
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	Complied	**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 for INSULATION CO-ORDINATION	Not used	**N/A**
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:	See insulation diagram	**P**
	– limits of Tables 13 to 16 (inclusive); or	Inspected	**P**
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION	Not used	**N/A**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6	No protective earth	**N/A**
	– or with requirements and tests of IEC 60950-1 for protective earthing ..... :	No protective earth	**N/A**
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION..... :	Evaluated as part of certified integral power supply	**P**
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION..... :	Evaluated as part of certified integral power supply	**P**
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	Evaluated as part of certified integral power supply	**P**
	Voltage Total Working (V) and C Nominal (µF) .....:	Evaluated as part of certified integral power supply	**—**
	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	No such parts	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION.....:	Considered	**P**
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION.....:	Considered	**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 .....:	Inspected and complied	**P**
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART	No multiple functions on 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	Considered	**P**
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS .....:	No multiple functions on single F-type applied part	**N/A**
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	Considered and complied	**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 such devices	**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 ..... :	No B type applied parts	**N/A**
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and	No B type applied parts	**N/A**
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low	No B type applied parts	**N/A**
	LEAKAGE CURRENT tests conducted per 8.7.4 ..... :	No B type applied parts	**N/A**
	Dielectric strength test conducted per 8.8.3..... :	No B type applied parts	**N/A**
	Relevant CREEPAGE and CLEARANCES measured	No B type applied parts	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISK of metal ACCESSIBLE PARTS contacting a source of voltage or LEAKAGE CURRENT above the limits .....: (ISO 14971 Cl. 4.2-4.4, 5)	No B type applied parts	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
8.5.2.3	A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE	No accessible conductive parts on patient connections	**N/A**
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT ..... :	Same as above	**N/A**
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter	Same as above	**N/A**
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm	Same as above	**N/A**
	– 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	Same as above	**N/A**
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,	Same as above	**N/A**
	Test finger test (10 N)..... :	Same as above	**N/A**
	Except when RISK MANAGEMENT PROCESS includes an assessment of RISKS resulting from contact with objects other than mains sockets or flat surfaces . : (ISO 14971 Cl. 4.2-4.4, 5)	No such risks	**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) .....:	The maximum mains voltage is the highest rated supply voltage 240VAC	**P**
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V) .....:	No d.c. voltages with superimposed ripple	**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	No such risks	**N/A**
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V) .....:	No such applied parts	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	No such applied parts	**N/A**
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V) .....:	No motor capacitors	**N/A**
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	No such applied parts	**N/A**
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety	No such applied parts	**N/A**
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:	No such applied parts	**N/A**
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ..... :	No such applied parts	**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..... :	No such applied parts	**N/A**
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load..... :	No such applied parts	**N/A**
8.6	Protective and functional earthing and potential equalization of ME EQUIPMENT		**N/A**
8.6.1	Requirements of 8.6.2 to 8.6.8 applied	No protective and functional earthing	**N/A**
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8	No protective and functional earthing	**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.....:	No protective and functional earthing	**N/A**
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL	No protective and functional earthing	**N/A**
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside .....:	No protective and functional earthing	**N/A**
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL	No protective and functional earthing	**N/A**
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing	No protective and functional earthing	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part,	No protective and functional earthing	**N/A**
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop ..... :	No protective and functional earthing	**N/A**
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits..... :	No protective and functional earthing	**N/A**
8.6.5	Surface coatings		**N/A**
	Poorly conducting surface coatings on conductive elements removed at the point of contact	No coating	**N/A**
	Coating not removed when requirements for impedance and current-carrying capacity met	No such requirements	**N/A**
8.6.6	Plugs and sockets		**N/A**
	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	No protective earth connection	**N/A**
	- applied also where interchangeable parts are PROTECTIVELY EARTHED	Same as above	**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	No potential equalization conductor	**N/A**
	–accidental disconnection avoided in NORMAL USE	No potential equalization conductor	**N/A**
	– Terminal allows conductor to be detached without a TOOL	No potential equalization conductor	**N/A**
	– Terminal not used for a PROTECTIVE EARTH CONNECTION	No potential equalization conductor	**N/A**
	– Terminal marked with symbol 8 of Table D.1	No potential equalization conductor	**N/A**
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard	No potential equalization conductor	**N/A**
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR	No potential equalization conductor	**N/A**
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION	No functional earth terminal	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
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 such case	**N/A**
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.	Not such case	**N/A**
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS	Not such case	**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	See appended Tables 8.7	**P**
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)	No protective earth connections	**N/A**
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time	No protective earth connections	**N/A**
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION	Considered	**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	No protective earth connections	**N/A**
8.7.3	Allowable Values		**P**
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b..... :	See appended Table 8.7	**P**
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz..... :	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**

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Clause	Requirement + Test	Result - Remark	Verdict
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC}) ..... :	No protective earth	**N/A**
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 ..... :	EUT not permanently installed	**N/A**
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device..... :	Measurements conducted by non-frequency-weighted MD (were conducted before and after humidity conditioning) did not exceed 10 mA rms in both NC/SFC, only maximum results were recorded, see Note 6 in 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 connection	**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	Compiled	**P**
	Insulation exempted from test (complies with clause 4.8)	No exemption	**N/A**
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	Not used	**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	Complied for plastic enclosure	**P**
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:	No such part	**N/A**
	– at least two layers of material, each passed the appropriate dielectric strength test ..... :	No such part	**N/A**
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test ..... :		**N/A**
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		**N/A**
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when	No wound components	**N/A**
	c) Wire with solid insulation, other than solvent based enamel, complying with a)	No wire with solid insulation	**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	No excessive temperatures, see appended table 11.1	**P**
	ME EQUIPMENT and design documentation examined ..... :	Inspected	**P**
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See Ventoux- DOC0428- A00 Risk Analysis	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat..... :	Satisfactory evidence was not provided	**N/A**
	Tests conducted in absence of satisfactory evidence for resistance to heat ..... :	Tested with acceptable results	**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) ..... :	Only integral certified power supply used, no need to repeat the tests	**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	Not performed on such materials	**P**
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	Complied	**P**
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	No such materials	**N/A**
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	No embedded 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	Natural latex rubber not used	**N/A**
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h	No such condition	**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	Not defibrillation-proof parts	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION, min CREEPAGE and CLEARANCES not applied..... :	No such test required	**N/A**
8.9.3	Spaces filled by insulating compound		**N/A**
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound	Insulation compound not used	**N/A**
	Thermal cycling, humidity preconditioning, and dielectric strength tests	Same as above	**N/A**
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage) ..... :	Insulation compound not used	**N/A**
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur	Same as above	**N/A**
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint	Insulation compound not used	**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:	Same as above	**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 ..... :	Insulation compound not used	**N/A**
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage	Same as above	**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	No outside metal enclosure	**N/A**
8.10	Components and wiring		**P**
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely ..... :	All unit components are mounted securely	**P**
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components .....: (ISO 14791 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment ..... :	Inspected, Conductors and connectors are adequately secured or insulated	**P**
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS	No such conductors	**N/A**
8.10.3	Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken . :	Complied	**P**
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		**N/A**
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION	No such parts	**N/A**
8.10.4.2	Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3	Same as above	**N/A**
	Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3	No such parts	**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..... :	Inspected and complied	**P**
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS	Inspected and complied	**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 such parts	**N/A**
8.10.7	a) Insulating sleeve adequately secured.....:	No such parts	**N/A**
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics	No such cord	**N/A**
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C..... :	No such temperatures	**N/A**
8.11	MAINS PARTS, components and layout		**P**
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles ..... :	By manual disconnection of power cord	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	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	Same as above	**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 . :	Not specified	**N/A**
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV..... :	No mains switch used	**N/A**
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	Same as above	**N/A**
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447	Same as above	**N/A**
	f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH ..... :	No such parts	**N/A**
	g) A fuse or a semiconductor device not used as an isolating means	Not used as 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	No such device	**N/A**
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering	No such parts	**N/A**
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage	No such hazard	**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	No such parts	**N/A**
	Standard test finger applied	Not required	**N/A**
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	No multiple socket-outlets	**N/A**
8.11.3	POWER SUPPLY CORDS		**P**
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD	One plug per one power cord	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design 53)..... :	See appended Table 8.10	**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 in excess of 75 °C, touchable by the cord in normal use	**P**
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17.....:	Complied	**P**
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6 ..... :	See appended Table 8.10	**P**
8.11.3.5	Cord anchorage		**N/A**
	a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage	Detachable certified power cord used	**N/A**
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or	Detachable certified power cord used	**N/A**
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or	Detachable certified power cord used	**N/A**
	– metal provided with an insulating lining affixed to cord anchorage	Detachable certified power cord used	**N/A**
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation	Detachable certified power cord used	**N/A**
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components	Detachable certified power cord used	**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	Detachable certified power cord used	**N/A**
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR	Detachable certified power cord used	**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 ..... :	Detachable certified power cord used	**N/A**
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests	Detachable certified power cord used	**N/A**

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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	Detachable certified power cord used	**N/A**
	CREEPAGE and CLEARANCES not reduced below limits in 8.9	Detachable certified power cord used	**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	Detachable certified power cord used	**N/A**
8.11.3.6	POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment	Detachable certified power cord used	**N/A**
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or	Detachable certified power cord used	**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) ..... :	Detachable certified power cord used	**N/A**
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance	Detachable certified power cord used	**N/A**
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D..... :	Detachable certified power cord used	**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	Not permanently installed	**N/A**
	Terminals alone are not used to keep conductors in position	No mains terminals	**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	Same as above	**N/A**
	Screws and nuts clamping external conductors do not serve to secure any other component	Same as above	**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	No terminals	**N/A**
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL	Same as above	**N/A**
	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	Same as above	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
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	No terminals	**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	No terminals	**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	No terminals	**N/A**
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test	No terminals	**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..... :	One of the poles is fused	**P**
	– 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	Not such case	**N/A**
	Protective devices have adequate breaking capacity to interrupt the max. fault current ..... :	See appended Table 8.10	**P**
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR	No protective earth conductor	**N/A**
	Justification for omission of fuses or OVER-CURRENT RELEASES documented.....:	Not required	**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 .....:	Inspected between appliance coupler and input of power supplies	**P**
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient ..... :	Evaluated as part of integral certified power supply	**P**
9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		**P**
9.2	HAZARDS associated with moving parts		**N/A**
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level..... :	No moving parts	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)	No such risks	**N/A**
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and	No such risks	**N/A**
	RISK CONTROLS implemented ..... :	No such risks	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
	All RISKS associated with moving parts have been reduced to an acceptable level	No such risks	**N/A**
9.2.2	TRAPPING ZONE		**N/A**
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:	No trapping zone	**N/A**
	– Gaps in Clause 9.2.2.2, or	No trapping zone	**N/A**
	– Safe distances in Clause 9.2.2.3, or	No trapping zone	**N/A**
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or	No trapping zone	**N/A**
	– Continuous activation in Clause 9.2.2.5	No trapping zone	**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	No trapping zone	**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	**N/A**
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008 .....:	No trapping zone	**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 trapping zone	**N/A**
9.2.2.4.2	FIXED GUARDS held in place by systems that can only be dismantled with a TOOL	No fixed guards	**N/A**
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open	No movable guards	**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,	Same as above	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	– absence or failure of one of their components prevents starting, and stops moving parts	No movable guards	**N/A**
	Movable GUARDS complied with any applicable tests	Same as above	**N/A**
9.2.2.4.4	Other RISK CONTROL designed and incorporated into to the control system stops movement and	No trapping zone	**N/A**
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or	Same as above	**N/A**
	ME EQUIPMENT is SINGLE FAULT SAFE	Same as above	**N/A**
9.2.2.5	Continuous activation		**N/A**
	Continuous activation used as a RISK CONTROL, complies with the following	No continuous activation	**N/A**
	a) movement was in OPERATOR'S field of view	Same as above	**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	No continuous activation	**N/A**
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement	No continuous activation	**N/A**
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK	No such risk	**N/A**
9.2.3	Other MECHANICAL HAZARDS associated with moving parts		**N/A**
9.2.3.1	Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated	No trapping zone	**N/A**
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or	No trapping zone	**N/A**
	- activation does not result in an unacceptable RISK	No trapping zone	**N/A**
9.2.3.2	Over travel past range limits of the ME EQUIPMENT prevented..... :	No moving parts	**N/A**
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse ..... :	No movable parts	**N/A**
9.2.4	Emergency stopping devices		**N/A**
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power ..... :	No emergency stopping devices	**N/A**
	a) Emergency stopping device reduced RISK to an acceptable level	Same as above	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE indicates the use of an emergency stopping device reduces the RISK to an acceptable level.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.6)	No such risks	**N/A**
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM	No emergency stopping devices	**N/A**
	c) Emergency stopping device actuator was readily accessible to OPERATOR	No emergency stopping devices	**N/A**
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT	No emergency stopping devices	**N/A**
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD	No emergency stopping devices	**N/A**
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like	No emergency stopping devices	**N/A**
	g) Means for stopping of movements operate as a result of one single action	No emergency stopping devices	**N/A**
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls	No emergency stopping devices	**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"	No emergency stopping devices	**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	No emergency stopping devices	**N/A**
	k) Emergency stopping device is suitable for its application	No emergency stopping devices	**N/A**
9.2.5	Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping..... :	No such means	**N/A**
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented	No such risk	**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**

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered ..... :	Inspected	**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	Not overbalanced	**P**
9.4.2	Instability – overbalance		**N/A**
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested ..... :	Not mobile equipment	**N/A**
9.4.2.2	Instability excluding transport		**N/A**
	ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE,.....:	Not mobile equipment	**N/A**
	A warning provided when overbalance occurred during 10° inclined plane test		**N/A**
9.4.2.3	Instability from horizontal and vertical forces		**N/A**
	a) ME EQUIPMENT or its parts with a mass of 25kg or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it	Not mobile equipment	**N/A**
	Surfaces of ME EQUIPMENT or its parts where a RISK of overbalancing exists from pushing, etc., permanently marked with a warning of the RISK		**N/A**
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)		**N/A**
	b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping	Not mobile equipment	**N/A**
	ME EQUIPMENT or its parts, for use on the floor or on a table, where RISK of overbalancing exists, permanently marked with the RISK warning.....:		**N/A**
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b) ..... :		**N/A**
9.4.2.4	Castors and wheels		**N/A**
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE	Not mobile equipment	**N/A**
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT did not exceed 200 N ..... :	As above	**N/A**
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold ..... :	As above	**N/A**
9.4.3	Instability from unwanted lateral movement (including sliding)		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
9.4.3.1	a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control	No power-driven mobile equipment	**N/A**
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements	Not mobile medical device	**N/A**
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1	Same as above	**N/A**
9.4.3.2	Instability excluding transport		**N/A**
	a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test .....:	Not mobile equipment	**N/A**
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test		**N/A**
9.4.4	Grips and other handling devices		**N/A**
	a) ME EQUIPMENT with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method	The mass of EUT is less than 20 kg (9.7 Kg)	**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	Same as above	**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	The mass of EUT is less than 20 kg (9.7 Kg)	**N/A**
	c) Carrying handles and grips and their means of attachment withstood loading test .....:	Same as above	**N/A**
9.5	Expelled parts HAZARD		**N/A**
9.5.1	Suitability of means of protecting against expelled parts determined by assessment and examination of RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)	No expelled parts	**N/A**
	All identified RISKS associated with expelled parts mitigated to an acceptable level	No such risks	**N/A**
9.5.2	Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965 ..... :	No such parts	**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	Considered	**P**
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity ..... :	No such risks	**N/A**

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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. 4.2-44, 5, 6.2-6.5)	No such risks	**N/A**
	All identified RISKS mitigated to an acceptable level	No such risks	**N/A**
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	No hazardous acoustic energy: • 60.4 dBA in normal use • 79.1 dBA in high priority alarm	**P**
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA) .....:	No hazardous acoustic energy	**—**
	- 83 dBA (when halving the cumulative exposure time) (dBA) .....:	Same as above	**—**
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB) .....:	Same as above	**—**
9.6.2.2	RISK MANAGEMENT FILE examined .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
9.6.3	Hand-transmitted vibration		**N/A**
	Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values	No vibration generated	**N/A**
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2) .....:	Same as above	**N/A**
	– Accelerations for different times, inversely proportional to square root of time (m/s^2).....:	Same as above	**N/A**
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		**P**
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04), hazards: 14, 16, 26, 30-33, 50, 52, 53, 55-67, 75-81, 96, 101-104, 165, 166, 171	**P**
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum	Complied	**P**
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure	Complied	**P**
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects	Complied	**P**
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply	No such parts	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible	Same as above	**P**
	– 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	In case of isolation from power supply, the EUT is operable from batteries	**P**
9.7.3	Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:	Complied, 80 CmH2O (limited by SW)	**P**
	a) RATED maximum supply pressure from an external source	Input Pressure – Oxygen: 35-90 psig / 240-620 kPa (21% - 100%)	**P**
	b) Pressure setting of a pressure-relief device provided as part of assembly	110 ± 5 cmH2O	**P**
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device	Limited by pressure-relief device, which is actually Flight Medical designed spring-loaded relief valve	**P**
9.7.4	Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests ..... :	Not exceeded	**P**
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was more than 50 kPa, and product of pressure and volume was more than 200 kPa ..... :	No pressure vessel	**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 ..... :	Not specified	**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..... :	Inspected	**P**
	a) Connected as close as possible to pressure vessel or parts of system it is to protect	Inspected, located in the Ventilator outlet	**P**
	b) Installed to be readily accessible for inspection, maintenance, and repair	Inspected	**P**
	c) Could be adjusted or rendered inoperative without a TOOL	Inspected, not possible	**P**
	d) With discharge opening located and directed as to not to release material towards any person	Inspected	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK	Inspected	**P**
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure	Inspected	**P**
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect	Inspected	**P**
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)	Pressure-relief device will only be operated in case of serious malfunction of the ventilator. Its activation over the lifetime of the device would be expected to be less than 100 times, which may occur during calibration of the device. For calibration procedure see Service Manual.	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the risks associated with the discharge opening of the pressure relief device .....: (ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)	No such risks	**N/A**
9.8	HAZARDS associated with support systems		**N/A**
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK ..... :	No support systems	**N/A**
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD	Same as above	**N/A**
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK	Same as above	**N/A**
	– RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**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	No such risks	**N/A**
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	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	No support systems	**N/A**
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing.....:	Same as above	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the structural integrity of support system .....: (ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)	No such risks	**N/A**
	All identified RISKS are mitigated to an acceptable level	No support systems	**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 .....:	Same as above	**N/A**
	Where the equipment is not at equilibrium after 1 min, the RISK MANAGEMENT FILE includes an assessment of the test results.....: (ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)	No such risks	**N/A**
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		**N/A**
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints ..... :	No patient support system	**N/A**
	RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts	No support or suspension system	**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	Same as above	**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	Same as above	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS	No support or suspension system	**N/A**
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS	Same as above	**N/A**
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance ..... :	Same as above	**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 ..... :	No suspension systems	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests ..... :	Same as above	**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	No suspension systems	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test ..... :	Same as above	**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	No suspension systems	**N/A**
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES		**N/A**
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided for the support system	No such parts	**N/A**
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:	Same as above	**N/A**
	– Designed based on TOTAL LOAD	Same as above	**N/A**
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7	Same as above	**N/A**
	– Activated before travel produced an unacceptable RISK	Same as above	**N/A**
	– Considers Clauses 9.2.5 and 9.8.4.3	Same as above	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests ..... :	Same as above	**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	Same as above	**N/A**
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced	Same as above	**N/A**
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	–use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE . :	Same as above	**N/A**
	– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal	Same as above	**N/A**
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.	Same as above	**N/A**
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE	Same as above	**N/A**
	– Compliance confirmed by examination and following test..... :	Same as above	**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	Same as above	**N/A**
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR	Same as above	**N/A**
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function	Same as above	**N/A**
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		**N/A**
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES..... :	No such devices	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system .....: (ISO 14971 Cl. 4.3,4.4,5,6.2-6.5)	No such risks	**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 ..... :	EUT does not produce X-radiation	**N/A**
	Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE	No X-radiation	**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 :	No such risks	**N/A**
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Same as above	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**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	Not emitting radiation	**N/A**
	Microwave radiation is propagated intentionally		**N/A**
10.4	Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.	No such parts	**N/A**
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .. : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Same as above	**N/A**
10.6	RISK associated with infrared radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risk	**N/A**
11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		**P**
11.1	Excessive temperatures in ME EQUIPMENT		**P**
11.1.1	Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and..... :	See appended Table 11.1.1	**P**
	Surfaces of test corner did not exceed 90 °C	Not required	**N/A**
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	No such parts	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
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..... :	Not intended to supply heat	**N/A**
	Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use	No applied parts	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
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 . :	Complied	**P**
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:	Not specified	**N/A**
	Maximum Temperature ..... :	See appended table 11.1.1 for test results	**—**
	Conditions for safe contact, e.g. duration or condition of the PATIENT ..... :	Not specified	**—**
	Clinical effects with respect to characteristics taken or surface pressure documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
	APPLIED PARTS surface temperature of equal to or less than 41°C	No applied parts	**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 ..... :	No such risks	**N/A**
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
11.1.3	Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Measurements were made, see appended table 11.1.1	**N/A**
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Test corner measurements were not taken, no rationale provided	**P**
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE.....:	No such methods used	**N/A**
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	No such guards are used	**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	Met	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		**P**
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of..... :	Reduced by ventilation and protected by internal O_2 sensor	**P**
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions	Not discovered	**N/A**
	1) when temperature of material raised to its ignition temperature	Not raised	**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	Same as above	**N/A**
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating	No such parts	**N/A**
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton	No such temperatures	**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	Same as above	**N/A**
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively ..... :	Not required	**N/A**
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three .....:	Same as above	**N/A**
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04), hazards: 122, 139, 141	**P**
	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..... :	No such parts	**N/A**

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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 (%) .....:	Not measured	**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	No separations	**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..... :	No such effects	**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 ..... :	Not initiated	**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	Considered	**P**
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks	Not produced	**P**
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques	Not protected	**N/A**
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means	No such 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) ..... :	Not measured	**N/A**
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) ..... :	No separations	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) ..... :	Declared by manufacturer: The EUT has been so designed that there is no means of generating a spark during normal single fault use of the device when oxygen is used. This would require both an O2 leak and a spark to be generated. There are 3 fans which continuously work to vent the internal environment of the device. It is only one relay used, which is a dry contact. High Oxygen concentration is continuously vented from the device to the patient under normal use – the test is not required.	**N/A**
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a) ..... :	Same as above	**N/A**
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas ..... :	Same as above	**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..... :	No alternate means	**N/A**
	Constructional requirements were met, or	Constructional requirements are met	**P**
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**P**
	Justification, when requirement not met..... :	Met	**N/A**
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials ..... :	Complied	**P**
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of materials data ..... :	Complied	**P**
	If no FV Certification, FV tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings		**N/A**
	b) Fire ENCLOSURE met following:		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm	No openings at bottom	**P**
	2) No openings on the sides within the area included within the inclined line C in Fig 39	No openings on the sides	**P**
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials ..... :	Complied	**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 such environment	**N/A**
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		**N/A**
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Not intended to be used 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 ..... :	No reservoir or liquid storage chamber	**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**

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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. 4.2-4.4, 5, 6.2-6.5)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04), hazard 140	**P**
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill..... :	Not specified	**N/A**
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		**P**
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code) .....:	IP34	**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.....:	Complied, see appended table 11.6.1	**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 ..... :	Section 12	**P**
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER ..... :	Not specified	**N/A**
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 required	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISKS associated with any deterioration following sterilization ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented	See Appendix 1	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	Complied	**P**
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		**P**
12.1	RISKS associated with accuracy of controls and instruments stated ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING ..... :	See IEC 60601-1-6 Usability report	**P**
12.3	MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8. ..... :	See IEC 60601-1-8 alarms report	**P**
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)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04), hazard 11	**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)	No such risks	**N/A**
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
12.4.4	RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04), hazard 32	**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	Not relevant for EUT	**N/A**
	Radiation safety ensured by compliance with requirements of appropriate standards	Not relevant for EUT	**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 ..... :	No diagnostic or therapeutic radiation	**N/A**
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No diagnostic or therapeutic radiation	**N/A**
12.4.5.4	RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No diagnostic or therapeutic radiation	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
12.4.6	RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No diagnostic or therapeutic radiation	**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	Emission of flames, molten metal, poisonous or ignitable substance did not occur	**P**
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur	No deformation of enclosure	**P**
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 ..... :	Not exceeded	**P**
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 ..... :	See appended Table 11.1.1	**P**
	–Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C were not exceeded	See appended Table 11.1.1	**P**
	Limits for windings in Tables 26, 27, and 31 not exceeded	Not measured on windings	**N/A**
	Table 22 not exceeded in all other cases	Not exceeded	**P**
	Temperatures measured according to 11.1.3	Unit was tested in its normal position, in still air with using thermocouple method	**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:		**P**
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit in SINGLE FAULT CONDITION ..... :	Inspected	**P**
	- or secondary circuits mounted on materials with a minimum flame rating of FV1, and	Inspected	**P**
	- Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and	Inspected	**P**
	- Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and	Inspected	**P**
	- Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide	Inspected	**P**
	- or components in the circuit have HIGH INTEGRITY CHARACTERISTICS..... :	No such parts	**N/A**
	– or parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation	Inspected	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function	Complied	**P**
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed ..... :	See appended Table 8.7	**P**
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS did not exceed..... :	See appended Table 8.7	**P**
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	Tested using least favourable conditions	**P**
	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. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
	RISK MANAGEMENT FILE defines the appropriate test conditions.....:	No such risks	**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	No heating elements	**N/A**
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted	No such parts	**N/A**
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION, the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).	Complied	**P**
13.2.13.2	ME EQUIPMENT with heating elements		**N/A**
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	No heating elements	**N/A**
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests	Same as above	**N/A**
	a 3) other ME EQUIPMENT with heating elements met test	No heating elements	**N/A**
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively	Same as above	**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	Same as above	**N/A**

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

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Clause	Requirement + Test	Result - Remark	Verdict
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended	No such case	**N/A**
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C) .....:	Same as above	**N/A**
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps	Tested inside the unit	**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	Same as above	**N/A**
	Test not conducted where electronic drive circuits maintained a substantially constant drive current	Considered	**P**
	Test not conducted based on other justifications (justification) .....:	No other justifications	**N/A**
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10	No 3-phase motors	**N/A**
13.2.13.4	ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION		**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 .....:	Continuous operation	**—**
	Maximum temperature measured (°C).....:	Same as above	**—**
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	Complied	**P**
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK.....:	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04), hazards 27-51	**P**
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 4.2-4.4, 5)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04), hazards 27-51	**P**
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK	Applied	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	When the requirements of 14.2 to 14.13 apply, the requirements of IEC 62304:2006 clause 4.3, 5, 7, 8 and 9 apply for the development or modification of software of each PESS	See IEC 62304 Test report	**P**
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304.....:	See IEC 62304 Test report	**P**
	Software development process applied according to Clause 5 of IEC 62304 .....:	See IEC 62304 Test report	**P**
	Software development process for Software risk management applied according to Clause 7 of IEC 62304.....:	See IEC 62304 Test report	**P**
	Software development process Configuration Management applied according to Clause 8 of IEC 62304.....:	See IEC 62304 Test report	**P**
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304.....:	See IEC 62304 Test report	**P**
14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process .....:	Controlled by Manufacturer QA department	**P**
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan	System Software Validation is referenced as part of the Risk Analysis. See VENTOUX SW VALIDATION PLAN (DOC-0815 REV A01)	**P**
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented	Part of R&D design reviews See Ventoux Software Design Document (SDD) [DOCUMENT NUMBER: DOC-0489 A02]	**P**
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	Part of R&D design reviews	**P**
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	Part of R&D design reviews	**P**
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules	SW Life Cycle procedure per product	**P**
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	See QR-QA-SY-0403-Rev D SW Design - life cycle	**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	See in Software Bug control “Jira” and IEC 62304 Test report	**P**
14.6	RISK MANAGEMENT PROCESS		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS .....:	See QR-QA-SY-0403-Rev D SW Design - life cycle	**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. 4.3)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04) and DOC-0815 Cybersecurity Risk Assessment	**P**
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2 .....:	See Ventoux SW Validation Plan (Ventoux FiO2 Measurement Accuracy Validation Procedure). Calibration of tools is covered in procedure QR-QA-SY-1101-Rev.E Control of Monitoring & Measuring Devices	**P**
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure .....: (ISO 14971 Cl. 6.1)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04), section 3 - REFERENCE SYSTEM SAFETY SELF TESTS FOR FAULT DETECTION	**P**
14.7	A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem .....: (ISO 14971 Cl. 6.3)	See Ventoux Essential Requirements Checklist (DOCUMENT NUMBER: DOC-0427 Ver. A03)	**P**
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems .....: (ISO 14971 Cl. 6.3)	See Ventoux Software Design Document (SDD) [DOCUMENT NUMBER: DOC-0489 A02]	**P**
14.9	Design is broken up into sub systems and descriptive data on design environment documented..... :	See Ventoux System Validation	**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. 6.3)	See DOC-0556 A03 Ventoux Verification and Validation Plan	**P**
	– milestone(s) when VERIFICATION is to be performed for each function	See DOC-0556 A03 Ventoux Verification and Validation Plan	**P**
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION	See DOC-0556 A03 Ventoux Verification and Validation Plan	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	– selection and utilization of VERIFICATION tools	See DOC-0556 A03 Ventoux Verification and Validation Plan	**P**
	– coverage criteria for VERIFICATION	See DOC-0556 A03 Ventoux Verification and Validation Plan	**P**
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented	See DOC-0556 A03 Ventoux Verification and Validation Plan	**P**
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE .....:	See ATP document DOC-0419 A02 VX-ATP Test	**P**
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented	See DOC-0556 A03 Ventoux Verification and Validation Plan	**P**
	The person with overall responsibility for PEMS VALIDATION is independent		**P**
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 6.3)	See Risk Management Plan Ventoux DOC-0551-A02	**P**
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE	No previous design modification procedure	**N/A**
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304..... :	No previous design modification procedure	**N/A**
	Software Process for Software changes applied according to Clause 5 of IEC 62304 ..... :	No previous design modification procedure	**N/A**
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304 ..... :	No previous design modification procedure	**N/A**
	Configuration management of software changes applied per Clause 8 of IEC 62304 ..... :	No previous design modification procedure	**N/A**
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304 ..... :	No previous design modification procedure	**N/A**
14.13	For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following:		**P**
	a) Purpose of the PEMS connection to an IT-NETWORK	Sending observation values to a centralized hospital servers and for remote monitoring system to observe the ventilators parameters remotely	**P**
	b) required characteristics of the IT-NETWORK	Local Intranet network (wire or wireless connection [Wi-Fi])	**P**
	c) required configuration of the IT-NETWORK	Support of TCP/IP protocol and open ports	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	d) technical specifications of the network connection, including security specifications	Wi-Fi secure connection WPA2. Wire and Wi-Fi connection should be secured according to the Hospital security policy and protection for un-authorize access to the network	**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	Information flow is only from the ventilator to computers / server connected to the same network. The data sent by the ventilators might contain: • actual measurements • ventilation prescriptions • alarms • historical values and alarms.	**P**
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the required characteristics (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)	No such risks. Disconnecting the EUT from the network not intended to affect the ventilator performance	**N/A**
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		**N/A**
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties	No such statement	**N/A**
	– Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS	No such notification	**N/A**
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis	No such notification	**N/A**
	- Changes to the IT-NETWORK include: - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment	Not specified	**N/A**

15	**CONSTRUCTION OF ME EQUIPMENT**		**P**
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS . :	See Usability Test Report per 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	Complied	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring	Complied	**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	Tested with acceptable results	**P**
15.3.2	Push test conducted ..... :	See Appended Table 15.3	**P**
	No damage resulting in an unacceptable RISK sustained	Complied	**P**
15.3.3	Impact test conducted ..... :	See Appended Table 15.3	**P**
	No damage resulting in an unacceptable RISK sustained	Complied	**P**
15.3.4	Drop test		**P**
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested ..... :	See Appended Table 15.3	**P**
	No unacceptable RISK resulted	Complied	**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	Complied	**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 ..... :	EUT is not mobile	**N/A**
	No damage resulting in an unacceptable RISK sustained	Same as above	**N/A**
15.3.6	Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK	Tested with acceptable results	**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	**P**
	No damage resulting in an unacceptable RISK	Inspected	**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	Unit, accompanied documents and manufacturer's specifications inspected	**P**

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

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Clause	Requirement + Test	Result - Remark	Verdict
	- In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions operated 200 times	Certified components used	**N/A**
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards	No such parts	**N/A**
	manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times	No such parts	**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	No such devices	**N/A**
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating..... : (ISO 14971 Cl. 4.2-4.4)	No such risks	**N/A**
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS	No thermostats	**N/A**
15.4.3	Batteries		**P**
15.4.3.1	Battery housings provided with ventilation..... : (ISO 14971 Cl. 4.2-4.4)	No ventilation	**N/A**
	Battery compartments designed to prevent accidental short circuiting	Prevented by construction	**P**
15.4.3.2	Means provided to prevent incorrect connection of polarity.....:	Prevented by construction	**P**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries.....: (ISO 14971 Cl. 4.2-4.4)	No such risks	**N/A**
15.4.3.3	Overcharging of battery prevented by virtue of design.....:	Evaluated as part of approved battery pack with PCM protection	**P**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries ..: (ISO 14971 Cl. 4.2-4.4)	No such risks	**N/A**
15.4.3.4	Primary lithium batteries comply with IEC 80086-4	No such batteries	**N/A**
	Secondary lithium batteries comply with IEC 62133	Complied	**P**
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire.....:	Evaluated as part of approved battery pack with PCM protection	**P**
	Protective device has adequate breaking capacity	Inspected and complied	**P**
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented	Not required	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	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	Evaluated as part of approved battery pack with PCM protection	**P**
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION	No such case	**N/A**
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for:		**P**
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,	No warm-up state used	**N/A**
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational	No heaters	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with the use of indicator lights for EQUIPMENT incorporating non-luminous heaters...: (ISO 14971 Cl. 4.2-4.4)	No such risks	**N/A**
	Requirement not applied to heated stylus-pens for recording purposes	No heated stylus pens	**N/A**
	Indicator lights provided on ME EQUIPMENT to indicate an output exists	Indicated on display	**P**
	Colours of indicator lights complied with 7.8.1	Complied	**P**
	Charging mode visibly indicated	Complied	**P**
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
15.4.6	Actuating parts of controls of ME EQUIPMENT		**N/A**
15.4.6.1	a) Actuating parts cannot be pulled off or loosened during NORMAL USE	No actuating parts	**N/A**
	b) Controls secured so that the indication of any scale always corresponds to the position of the control	Same as above	**N/A**
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL	Same as above	**N/A**
	When torque values per Table 30 applied knobs did not rotate .....:	No actuating parts	**N/A**
	Tests conducted with no unacceptable RISK .....:	No actuating parts	**N/A**
15.4.6.2	Stops on rotating/ movable parts of controls are of adequate mechanical strength .....:	No rotating or movable parts	**N/A**
	Torque values in Table 30 applied .....:	As above	**N/A**
	No unexpected change of the controlled parameter when tested .....:	No rotating or movable parts	**N/A**
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1	No such devices	**N/A**
	b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage ..... :	No such devices	**N/A**
15.4.7.2	Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface ..... :	No such devices	**N/A**
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position	No such risks	**N/A**
15.4.7.3	a) Foot-operated control device is at least rated IPX1.....:	No such devices	**N/A**
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6 .....:	No such devices	**N/A**
15.4.8	Aluminium wires less than 16 mm^2 in cross-sectional area are not used	No aluminum wires	**N/A**
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed	No oil containers	**N/A**
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport	Same as above	**N/A**
	A pressure-release device operating during NORMAL USE is provided	Same as above	**N/A**
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage	Same as above	**N/A**
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements	Same as above	**N/A**
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5	Evaluated as part of certified power supply	**P**
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**

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Clause	Requirement + Test	Result - Remark	Verdict
	Transformer windings provided with adequate insulation		**N/A**
	Dielectric strength tests were conducted ..... :		**N/A**
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with..... :		**N/A**
	- Means provided to prevent displacement of end turns		**N/A**
	- protective earth screens with a single turn have insulated overlap		**N/A**
	- Exit of wires form internal windings of toroid transformers protected with double sleeving		**N/A**
	- insulation between primary and secondary windings complies with 8.8.2		**N/A**
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4		**N/A**
16	**ME SYSTEMS**		**N/A**
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK	Not considered as ME system	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with installation and modification of an ME SYSTEM..... : (ISO 14971 Cl. 4.2-4.4, 5)	No such risks	**N/A**
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered		**N/A**
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard		**N/A**
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards		**N/A**
	– tests performed in NORMAL CONDITION, except as specified		**N/A**
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM		**N/A**
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated		**N/A**
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR		**N/A**
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards		**N/A**
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM	Not considered as ME system	**N/A**

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

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

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Clause	Requirement + Test	Result - Remark	Verdict
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values..... :		**N/A**
16.7	ME SYSTEM complied with applicable requirements of Clause 9 ..... :		**N/A**
16.8	Interruption and restoration power to the ME SYSTEM or any part of the ME SYSTEM did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	Not considered as ME system	**N/A**
16.9	ME SYSTEM connections and wiring		**N/A**
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result..... :		**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with plugs for connection of PATIENT leads or cables likely to be located in the PATIENT ENVIRONMENT ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such risks	**N/A**
	– Plugs for connection of PATIENT leads or PATIENT cables could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no unacceptable RISK results		**N/A**
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable		**N/A**
16.9.2	MAINS PARTS, components and layout		**N/A**
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or	Not considered as ME system	**N/A**
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		**N/A**
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		**N/A**
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 visible in NORMAL USE, and		**N/A**
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		**N/A**
	– marked to indicate the equipment or equipment parts it may safely be attached to		**N/A**
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT		**N/A**
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:	Not considered as ME system	**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**

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

17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		**P**
	RISKS associated confirmed by review ..... :	See IEC 60601-1-2 test report	**P**
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS..... :	Section 14.4 in UM	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment of risks associated with the introduction of electromagnetic phenomena into the environment by the EQUIPMENT or SYSTEM ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See Risk Analysis for Ventoux (document №: DOC-0428, Rev. A04), hazard 2	**P**
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems	See IEC 60601-1-2 test report	**P**

ANNEX G	**PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**	_
	Not used with flammable anesthetic mixtures	**N/A**

ANNEX L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**	_
	No such wires	**N/A**

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
3.1	QR-QA-SY-0402-Rev. F Risk Management Procedure	—	Risk Management Process (excluding production and post-production)	**P**
3.2	QR-QA-SY-0000-Rev R FM Quality Manual	—	Adequate Resources	**P**
3.2	QR-QA-SY-0000-Rev R FM Quality Manual	—	Assignment of qualified personnel	**P**
3.2	QR-QA-SY-0000-Rev R FM Quality Manual	—	Policy for determining criteria for risk acceptability	**P**
3.3	—	QR-QA-SY-0000-Rev R FM Quality Manual	Qualification of personnel	**P**
3.4a	—	RM File - Risk Management Plan Ventoux DOC-0551-A02	Risk Management Plan: scope of the planned risk management activities	**P**
3.4b	—	RM File - Risk Management Plan Ventoux DOC-0551-A02	Risk Management Plan: assignment of responsibilities and authorities	**P**
3.4c	—	RM File - Risk Management Plan Ventoux DOC-0551-A02	Risk Management Plan: requirements for review of risk management activities	**P**
3.4d	—	RM File - Risk Management Plan Ventoux DOC-0551-A02	Risk Management Plan: criteria for risk acceptability	**P**

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
3.4e	—	RM File - Risk Management Plan Ventoux DOC-0551-A02	Risk Management Plan: verification activities	**P**
3.5	—	RM File - DOC-0465-A00 Identification of Qualitative and Quantitative Characteristics	Risk management file	**P**
4.1	—	QR-QA-SY-0201 Rev.C Managment Review Procedure	Risk analysis process	**P**
4.2	—	RM File - DOC-0465-A00 Identification of Qualitative and Quantitative Characteristics	Intended use and identification of characteristics related to the safety of the medical device	**P**
4.3	—	RM File - DOC-0465-A00 Identification of Qualitative and Quantitative Characteristics	Identification of hazards	**P**
4.4	—	RM File - DOC-0391-A00 Risk Level Guideline-Ventoux	Risk estimation	**P**
5	—	RM File - DOC-0428-A03 Ventoux Risk Analysis 30.03.22d	Risk evaluation	**P**
6.2	—	N/A	Risk control option analysis	**P**
6.3	—	SW Risk Analysis Reports and System Validation	Implementation of risk control measures	**P**
6.4	—	RM File - DOC-0428-A03 Ventoux Risk Analysis 30.03.22d	Residual risk evaluation	**P**
6.5	—	Part of Warnings, Cautions and Alarms generated for the device	Risk-Benefit Analysis	**P**
6.6a	—	RM File - DOC-0428-A03 Ventoux Risk Analysis 30.03.22d	Introduction of new hazards or hazardous situations	**P**
6.6b	—	RM File - DOC-0428-A03 Ventoux Risk Analysis 30.03.22d	Whether the estimated risks for previously identified hazardous situations are affected by the introduction of the risk control measures.	**P**
6.7	—	RM File - DOC-0428-A03 Ventoux Risk Analysis 30.03.22d	Completeness of risk control	**P**
7	—	RM File - DOC-0428-A03 Ventoux Risk Analysis 30.03.22d	Evaluation of overall residual risk acceptability	**P**

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
8	—	DOC-0429 A03 Ventoux Risk Management Summary Report 2022	Risk management report	**P**
Supplementary Information: **Document Ref should be with regards to the policy/procedure documents and documents containing device specific output.**				

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**
Delivery of ventilation at the PATIENT-CONNECTION PORT within the ALARM LIMITS set by the OPERATOR or generation of an ALARM CONDITION (oxygen level)	VENTOUX Environmental Validation Plan Essential Performance Requirements for Critical Care Ventilators ISO 80601-2-12; Document No. DOC-0548, Rev A00	Pass Criteria: □ 19>FiO2<25 □ Set FiO2 LOW alarm to 25 – verify alarm on Monitored Indicators: • Actual FiO2 • Alarms on the screen • Audio alarm • Video alarm
AIRWAY PRESSURE	VENTOUX Environmental Validation Plan Essential Performance Requirements for Critical Care Ventilators ISO 80601-2-12; Document No. DOC-0548, Rev A00	Pass Criteria: □ PIP end gauge reading error is within 20% of PCV Monitored Indicators: • PIP
Expired volume	VENTOUX Environmental Validation Plan Essential Performance Requirements for Critical Care Ventilators ISO 80601-2-12; Document No. DOC-0548, Rev A00	Pass Criteria: □ Error of DELIVERED VOLUME of individual breaths smaller than 35 % • error of the DELIVERED VOLUME averaged over a one minute interval smaller than 25 % Monitored Indicators: • Mechanical lung internal volume indicator • Actual VTe • Actual MVe
Electrical supply failure	VENTOUX Environmental Validation Plan Essential Performance Requirements for Critical Care Ventilators ISO 80601-2-12; Document No. DOC-0548, Rev A00	Pass Criteria: □ External power LED on when connected to AC Monitored Indicators: • External power LED • AC socket icon • "Switchover to batteries" alarm
INTERNAL ELECTRICAL POWER SOURCE nears depletion	VENTOUX Environmental Validation Plan Essential Performance Requirements for Critical Care Ventilators ISO 80601-2-12; Document No. DOC-0548, Rev A00	Pass Criteria: □ When using depleted battery, BATTERY EMPTY alarm is issued Monitored Indicators:

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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
		• Alarms on the screen • Audio alarm – different alarm sound for low battery and empty battery • Visual alarm (flashing) • Batteries icons color with percentage (green, yellow and red)
Component failures	VENTOUX Environmental Validation Plan Essential Performance Requirements for Critical Care Ventilators ISO 80601-2-12; Document No. DOC-0548, Rev A00	Pass Criteria: • Self-test pass • Time & date are correct Monitored Indicators: • Self-test
Changes in programmable parameters or settings	VENTOUX Environmental Validation Plan Essential Performance Requirements for Critical Care Ventilators ISO 80601-2-12; Document No. DOC-0548, Rev A00	Pass Criteria: □ Parameters set before test are equal to parameters loaded after reset Monitored Indicators: • Ventilation mode • Rate • Ti, Vt, PC, PS • PEEP • Trigger FiO2 • FiO2 Ventilation mode • Slope • PS TermPSV flow term • PS Ti • Waveform
Reset to default settings	VENTOUX Environmental Validation Plan Essential Performance Requirements for Critical Care Ventilators ISO 80601-2-12; Document No. DOC-0548, Rev A00	Pass Criteria: • Ventilator does not reset to default setting Monitored Indicators: • Ventilation mode • Rate • Ti, Vt, PC, PS • PEEP • Trigger FiO2 • FiO2 Ventilation mode • Slope • PS TermPSV flow term • PS Ti • Waveform
Change of operating mode	VENTOUX Environmental Validation Plan Essential Performance Requirements for Critical Care Ventilators ISO 80601-2-12; Document No. DOC-0548, Rev A00	Pass Criteria: • When off, ventilator stays off • When on, ventilator stays on • When in settings mode, ventilator stays in settings mode • When in charging mode,

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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**
		ventilator stays in charging mode Monitored Indicators: • Ventilator mode as reflected by LEDs, screen ant mechanical test lung
Initiation of an unintended operation	VENTOUX Environmental Validation Plan Essential Performance Requirements for Critical Care Ventilators ISO 80601-2-12; Document No. DOC-0548, Rev A00	Pass Criteria: • No change in the display that indicates unintended operation • Alarm reset LED does not change state Monitored Indicators: • Ventilator display • Alarm reset LED
Supplementary Information: ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.		

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

4.11	TABLE: Power Input				P
Operating Conditions / Ratings	**Voltage (Vac)**	**Frequency (Hz)**	**Current (mA)**	**Power (W)**	**Power factor (cos φ)**
Full Consumption mode (Maximum Normal Load) – Ventilation mode	Supplied from Mains				
	90	50	1950	176.5	0.99
	100	50	1750	174.2	0.99
	240	50	790	174.8	0.92
	264	50	710	178.5	0.95
	90	60	1920	170.9	0.99
	100	60	1630	162.7	0.99
	240	60	710	166.5	0.99
	264	60	640	170.6	0.99
	Battery Operated Mode				
	22.6Vdc	-	6.1Adc	137.8	-
Supplementary Information:					

5.9.2	TABLE: Determination of ACCESSIBLE parts	P
Location	**Determination method (NOTE1)**	**Comments**
Ventilator plastic enclosure (with built-in touch monitors, openings, foot supports)	visual; rigid test finger; jointed test finger; test hook	No access to internal live parts, no hazard
Oximeter (SPO2) port	visual; rigid test finger; jointed test finger	No access to internal live parts, no hazard
Microstream capnography connector (etCO2) and exhaust connector	visual; rigid test finger; jointed test finger	No access to internal live parts, no hazard
Ventilator cuff port	visual; rigid test finger; jointed test finger	No access to internal live parts, no hazard
Supplementary information: [1)] NOTE: The determination methods are: visual; rigid test finger; jointed test finger; test hook.		

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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).....:	100-1500	Correctly visible
Inside Markings (Clause 7.3).....:	100-1500	Correctly visible
Controls & Instruments (Clause 7.4).....:	100-1500	Correctly visible
Safety Signs (Clause 7.5) .....:	100-1500	Correctly visible
Symbols (Clause 7.6).....:	100-1500	Correctly visible

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 .....:	**Polymeric held by adhesive**	**Pass**
Ink/other printing material or process .....:	**Printed ink**	**Pass**
Material (composition) of Warning Label .....:	**Polymeric held by adhesive**	**Pass**
Ink/other printing material or process .....:	**Printed ink**	**Pass**
Other.....:	**---**	
Marking Label Tested:		**Remarks**
Product labels		**Pass**

Supplementary information:

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

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

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

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

Supplementary Information:

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

[2]. If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2.2

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Clause	Requirement + Test	Result - Remark	Verdict

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

Maximum allowable voltage (V).....:	60

Voltage measured (V)										
Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2	0	0	0	0	0	0	0	0	0	0
Plug pin 1 and plug earth pin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 2 and plug earth pin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 1 and enclosure	0	0	0	0	0	0	0	0	0	0
Plug pin 2 and enclosure	0	0	0	0	0	0	0	0	0	0

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

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

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:

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Clause	Requirement + Test	Result - Remark	Verdict

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:				

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 (%)**	
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				N/A
Type of ME EQUIPMENT & impedance measured between parts	**Test current (A) /Duration (s)**	**Voltage drop measured between parts (V)**	**Maximum calculated impedance (mΩ)**	**Maximum allowable impedance (mΩ)**	
Supplementary information: **PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 mΩME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part - Limit 100 mΩ** **ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a PROTECTIVELY EARTHED part - Limit 200 mΩ** **ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part - Limit 200 mΩ**					

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

8.7	TABLE: leakage current	P

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
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Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC
NC (S1-1, S5-0, S12-0)	264	60	13.9	Touch Screen (12”)
NC (S1-1, S5-0, S12-1)	264	60	13.9	
NC (S1-1, S5-1, S12-0)	264	60	13.9	
NC (S1-1, S5-1, S12-1)	264	60	13.9	
SFC (S1-0, S5-0, S12-0)	264	60	21.0	
SFC (S1-0, S5-0, S12-1)	264	60	21.2	
SFC (S1-0, S5-1, S12-0)	264	60	21.1	
SFC (S1-0, S5-1, S12-1)	264	60	21.2	
NC (S1-1, S5-0, S12-0)	264	60	11.5	Touch Screen (8”)
NC (S1-1, S5-0, S12-1)	264	60	11.6	
NC (S1-1, S5-1, S12-0)	264	60	11.5	
NC (S1-1, S5-1, S12-1)	264	60	11.6	
SFC (S1-0, S5-0, S12-0)	264	60	17.7	
SFC (S1-0, S5-0, S12-1)	264	60	17.6	
SFC (S1-0, S5-1, S12-0)	264	60	17.7	
SFC (S1-0, S5-1, S12-1)	264	60	17.7	

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NC (S1-1, S5-0, S12-0)	264	60	3.0	Front Panel – Black Plastic Enclosure
NC (S1-1, S5-0, S12-1)	264	60	3.0	
NC (S1-1, S5-1, S12-0)	264	60	3.0	
NC (S1-1, S5-1, S12-1)	264	60	3.1	
SFC (S1-0, S5-0, S12-0)	264	60	4.6	
SFC (S1-0, S5-0, S12-1)	264	60	4.6	
SFC (S1-0, S5-1, S12-0)	264	60	4.7	
SFC (S1-0, S5-1, S12-1)	264	60	4.6	
NC (S1-1, S5-0, S12-0)	264	60	1.0	EUT handle + top plastic enclosure
NC (S1-1, S5-0, S12-1)	264	60	1.0	
NC (S1-1, S5-1, S12-0)	264	60	1.0	
NC (S1-1, S5-1, S12-1)	264	60	1.0	
SFC (S1-0, S5-0, S12-0)	264	60	1.6	
SFC (S1-0, S5-0, S12-1)	264	60	1.7	
SFC (S1-0, S5-1, S12-0)	264	60	1.7	
SFC (S1-0, S5-1, S12-1)	264	60	1.7	
NC (S1-1, S5-0, S12-0)	264	60	0.7	Battery Plastic Enclosure
NC (S1-1, S5-0, S12-1)	264	60	0.8	
NC (S1-1, S5-1, S12-0)	264	60	0.7	
NC (S1-1, S5-1, S12-1)	264	60	0.8	
SFC (S1-0, S5-0, S12-0)	264	60	1.1	
SFC (S1-0, S5-0, S12-1)	264	60	1.0	
SFC (S1-0, S5-1, S12-0)	264	60	1.1	
SFC (S1-0, S5-1, S12-1)	264	60	1.1	
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
NC (S1-1, S5-0, S13-0)	264	60	0.6	Patient circuit
NC (S1-1, S5-0, S13-1)	264	60	0.5	
NC (S1-1, S5-1, S13-0)	264	60	0.6	
NC (S1-1, S5-1, S13-1)	264	60	0.5	
SFC (S1-0, S5-0, S13-0)	264	60	0.7	
SFC (S1-0, S5-0, S13-1)	264	60	0.6	
SFC (S1-0, S5-1, S13-0)	264	60	0.7	
SFC (S1-0, S5-1, S13-1)	264	60	0.6	

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NC (S1-1, S5-0, S13-0)	264	60	0.5	CUFF control
NC (S1-1, S5-0, S13-1)	264	60	0.5	
NC (S1-1, S5-1, S13-0)	264	60	0.6	
NC (S1-1, S5-1, S13-1)	264	60	0.4	
SFC (S1-0, S5-0, S13-0)	264	60	0.6	
SFC (S1-0, S5-0, S13-1)	264	60	0.6	
SFC (S1-0, S5-1, S13-0)	264	60	0.6	
SFC (S1-0, S5-1, S13-1)	264	60	0.6	
NC (S1-1, S5-0, S13-0)	264	60	0.6	Oxymeter
NC (S1-1, S5-0, S13-1)	264	60	0.6	
NC (S1-1, S5-1, S13-0)	264	60	0.6	
NC (S1-1, S5-1, S13-1)	264	60	0.6	
SFC (S1-0, S5-0, S13-0)	264	60	0.8	
SFC (S1-0, S5-0, S13-1)	264	60	0.7	
SFC (S1-0, S5-1, S13-0)	264	60	0.8	
SFC (S1-0, S5-1, S13-1)	264	60	0.7	
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
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Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
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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
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Clause	Requirement + Test	Result - Remark	Verdict

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)
NC (S1-1, S5-0)	264	60	0	Patient circuit to CUFF control
NC (S1-1, S5-1)	264	60	0	
SFC (S1-0, S5-0)	264	60	0	
SFC (S1-0, S5-1)	264	60	0	
NC (S1-1, S5-0)	264	60	0	Patient circuit to Oxymeter
NC (S1-1, S5-1)	264	60	0	
SFC (S1-0, S5-0)	264	60	0	
SFC (S1-0, S5-1)	264	60	0	
NC (S1-1, S5-0)	264	60	0	Oxymeter to CUFF control
NC (S1-1, S5-1)	264	60	0	
SFC (S1-0, S5-0)	264	60	0	
SFC (S1-0, S5-1)	264	60	0	
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)
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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)
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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
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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
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Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
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Supplementary information: *Tested also after tests of table 11.6.1, only maximum results were recorded

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.

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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).

Note 6: Measured with both configurations of measuring devices (MD): frequency-weighted and not frequency-weighted. Only the maximum values of test results were inserted.

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

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

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

Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1)]	Dielectric breakdown after 1 minute Yes/No[2)]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
L&N to enclosure (plastic/metal parts) [A]	2MOOP	340	---	3000	No
L&N to touch screen [B]	2MOOP	340	---	3000	No
L&N to SIP/SOP [C]	2MOOP	340	---	3000	No
L&N to Applied parts (pulse oximeter, CUFF control, patient circuit) [D]	2MOPP	340	---	4000	No
SIP/SOP to Applied parts (pulse oximeter, CUFF control, patient circuit) [E_1]	2MOPP	---	24	1000	No
SIP/SOP to Applied parts (pulse oximeter, CUFF control, patient circuit) [E_2]	1MOPP	340	---	1500	No

Supplementary information: *Tested also after tests of table 11.6.1, only maximum results were recorded

[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).

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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)**
EUT plastic enclosure	75	1.8

Supplementary information:

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

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

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

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

Part Test	**8.9.3.4 - Test duration and temperature for 10 cycles after which the sample was subjected to Humidity Preconditioning per Cl. 5.7**	**Dielectric test voltage**	**Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No**	**Crack or voids in the insulating compound: Yes/No**

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.

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Clause	Requirement + Test	Result - Remark	Verdict

8.10	TABLE: Critical components information				P
Object / part No.	**Manufacturer/ trademark**	**Type / model**	**Technical data**	**Standard**	**Mark(s) of conformity[1)]**
Power cord US	King-Cord	K80031C1250BR	125VAC, 10A; SJT; 75°C; 18AWG X 3C, length: 2.5m	UL 817, UL 60320-1	cULus: E85554
Power cord EU	King-Cord	K15031H6250BR-1	250VAC, 10A; H05VV-F 3G1.0mm^2; length: 2.5m	IEC 60320-1	Harmonized, VDE, NF, KEMA KEUR, CEBEC, OVE, S, D, N, FI
AC inlet	SCHURTER AG	1064	250V, 10A, UL 94V-0	UL 498, CSA-C22.2 No. 60320-1, IEC 60320-1	CUR: E93617 CSA, Semko
DC inlet	WEIPU	SP1312/P2	250V, 13A, IP68	IEC 60601-1	Evaluated
Surge Stopper U1 (for reverse polarity protection in DC inlet)	Linear Technology	LTC4364HS-2	24Vdc, max temp: 125 °C	IEC 60601-1	Evaluated
Mains fuse	Little Fuse	477008	250V, 8A; 5×20 mm, Time-Lag Fuse; Interrupting Rating: 100A@500VAC;	ANSI/UL 248-1, CSA-C22.2 No. 248.1	UR: E10480
Mains filter	TDK	RSEL-2002 WL	Isolation Resistance: 100MΩ minimum (500VDC, 1 Minute)	UL1283, CSA C22.2 No.8, EN60939	UR: E62388 CSA: 208777 Semko: SE/07115-1
Mains wiring	Alpha Wire	3055	18 (16/30) AWG (TC) 0.016" Wall, Nom. PVC 80C VW-1 300V	ANSI/UL 758	UR: E163869
Power supply	EOS	LFMWLP350-1303	In: 90-264Vac, 47-63 Hz, 200W Max. Out: 24Vdc, 8.33A; max temp: 70 °C	IEC/EN 60601-1, ANSI / AAMI ES60601-1	CB: NO85143; Nemko: Certificate No.P15219413; UL: E173812

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

Battery pack (Li-Ion Smart Battery Pack with I2C Interface)	Meircell Ltd.	PLI00467	Li-Ion battery pack (6 cells), 21.6Vdc, 3.4Ah, 74Wh Max.; Max. charging current is 2A; Max. charging time is 3h; Maximum Charging Voltage is 4.2V per cell (25.2V for battery pack); Cut-off Voltage is 2.5V per cell (15V for battery pack); Max charge temp: 45 °C; Max discharge temp: 65 °C; protected by PCM	IEC 60601-1	Evaluated
Battery cell	Panasonic	NCR18650B	Lithium-ion rechargeable battery 3.6Vdc, 3200mAh; Max charge temp: 45 °C; Max discharge temp: 60 °C	UL 1642, IEC 62133	UR: MH12210 CB certificate No: DK-36363-UL
Enclosure material (plastic)	COVESTRO DEUTSCHLAN D AG	Makrolon 2405	PC/(PC/APS), UL94 V-0	ANSI/UL 746	UR: E41613
Turbine motor	Micronel	U65H4-024KX-6 with integrated NTC Sensor Type: 10 Kohm Art B57421V2103J062 Characteristic: R/T 8502	Impeller - Mat. Polyamid (PA6) Lead wire, AWG 24, UL 3132, Silicone	IEC 60601-1	Evaluated
Turbine body	Micronel	U65H4-024KX-6 with integrated NTC Sensor Type: 10 Kohm Art. No. B57421V2103J062 Characteristic: R/T 8502	Housing Polycarbonate Motor support Aluminium anodised	IEC 60601-1	Evaluated

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

Inlet air filter	GM Incorporate	GSU-50+50	Polypropylene, Penetration 18.5% TSI AF8130, pressure drop 13.2Pa TSI AF8130, Makrolon 2405 by Bayer	IEC 60601-1	Evaluated
PCB	Various	Various	FR4, UL94 V-0	ANSI/UL 746	UR or similar
Touch screen 8”	DLC Display Co., Limited	DLC0800BBM36LB-R-1	Active matrix TFT module 8” diagonal, 800x600, 5Vdc, 220mA Max temp: 60 °C	IEC 60601-1	Evaluated
Touch screen 12”	AMPIRE CO., LTD.	AM-1024768RTNQW-T00H-A	The LCM is a colour active-matrix thin film transistor (TFT) liquid crystal display (LCD) 12.1” diagonal, 1024x768, 12Vdc, 240mA Max temp: 70 °C	IEC 60601-1	Evaluated
Fans	Hwajung Co., Ltd.	AGE 04020B24H-FMI	DC Axial Fan Input: 24Vdc, 0.06A, 1.44W, speed 8600 r.p.m, Max temp: 70 °C, PWM controlled UL: class A UL 1061 #26	IEC 60601-1	Evaluated
PEEP Proportional Solenoid	Parker	VSO - Series 11 brass	Series 11 Body: 360 HO2 Brass Stem Base: 430 FR Stainless Steel and Brass 360 HT All Others: FKM; FFKM; 430 FR Stainless Steel; 300 Series Stainless Steel	IEC 60601-1	Evaluated
PEEP Leak Solenoid	Parker	Loan Wolf	Body: 360 HO2 Brass Stem Base: 430 FR Stainless Steel and Brass 360 HT	IEC 60601-1	Evaluated

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

Flow sensors - high	Honey Well	ABP	Vibration MIL- STD-202G, Method 204D, Condition B Shock MIL-STD-202G, Method 213B, Condition C Meets IPC/JEDEC J-STD-020D.1 Moisture Sensitivity Level 1 requirement	IEC 60601-1	Evaluated
Flow sensors - low	Honey Well	HSC	Vibration MIL- STD-202G, Method 204D, Condition B Shock MIL-STD-202G, Method 213B, Condition C Meets IPC/JEDEC J-STD-020D.1 Moisture Sensitivity Level 1 requirement	IEC 60601-1	Evaluated
Pressure sensors	Honey Well	ABP	Vibration 15 g, 10 Hz to 2 kHz Shock 100 g, 6 ms duration Meets IPC/JEDEC J- STD-020D.1	IEC 60601-1	Evaluated
Over Pressure Relief Valve	Flight Medical Innovations Ltd.	MEC-0252	VX-Outlet OPRV Locking Ring; maximum airway pressure to 110 ± 5 cmH2O	IEC 60601-1	Evaluated, see appendix 2
O2 regulator	A.L.HDAS Technologies	ALH-30000-00	Schematic Dwg.	IEC 60601-1	Evaluated
Pressure regulator	Various	NANA-30001-00	Schematic Dwg.	IEC 60601-1	Evaluated

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Clause	Requirement + Test	Result - Remark	Verdict

O2 pressure sensor	Honey Well	HSC	Vibration MIL- STD-202G, Method 204D, Condition B Shock MIL-STD-202G, Method 213B, Condition C Meets IPC/JEDEC J- STD-020D.1 Moisture Sensitivity Level 1 requirement	IEC 60601-1	Evaluated
Gas connector low flow	CPC	PMCD 1204	Main components and valves: Acetal Thumb latch: Stainless steel Valve spring: 316 stainless steel External springs and pin: Stainless steel O-rings: Buna-N	IEC 60601-1	Evaluated
Gas connector high flow	A.L.HDAS Technologies	ALH-30000-00	Schematic Dwg.	IEC 60601-1	Evaluated
Air tubing	PISCO	PFA Fluororesine	Tube fitting stainless SUS316, Tube futtung SUS303 equiv. Tube fitting SUS304, Die Temperature control fitting	IEC 60601-1	Evaluated
Air connectors (internal)	legris	LF 3000	body: glass reinforced nylon 6.6 collar: nylon gripping ring: stainless steel "O" rings: nitrile (EPDM, FPM upon request)	IEC 60601-1	Evaluated
O2 solenoid	Parker	VSO Max	Body: C36000 Brass Stem Base: 430 FR Stainless Steel C36000 Brass All Others: FKM; 430 FR Stainless Steel; Stainless Steel	IEC 60601-1	Evaluated

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

Nebulizer solenoid	Parker	SRS	Bobbin/Body: Glass Reinforced PBT (Polybutylene terephthalate) Pole & Plunger: 430 FR Stainless Steel Seal: FKM	IEC 60601-1	Evaluated
Cuff solenoid	Parker	x-valve	Bobbin/Body: PBT (Polybutylene terephthalate) Pole & Plunger: 430 FR Series Stainless Steel Seal (Options): FKM, EPDM, Silicone Other: 302 Series Stainless Steel	IEC 60601-1	Evaluated
SPO2 module	Covidien Ltd.	Oximetry module (NELL1-SR)	Pulse Oximetry Integration Toolkit	IEC 60601-1, ISO 80601-2-61	Evaluated
Gas monitor module	Oridion	MicroMediCO2	USB 4.5-5.5Vdc, RS232 3.3-5.5Vdc, 2A max.	IEC 60601-1, ISO 80601-2-55	Evaluated
	Phillips	Capnography module: (CAPNOSTAT 5 : Ref 1015928);	USB 4.5-5.5Vdc, RS232 3.3-5.5Vdc, 2A max.		CSA 70174258 CSA 70174257
Supplementary information: [1] Provided evidence ensures the agreed level of compliance. See OD-CB2039.					

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

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

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Clause	Requirement + Test	Result - Remark	Verdict

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**
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:		

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

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

9.4.2.3	TABLE: Instability—overbalance from horizontal and vertical forces	N/A
ME EQUIPMENT preparation	**Test Condition (force used, direction of force, weight of equipment, location of force)**	**Remarks**
Supplementary information:		

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Clause	Requirement + Test	Result - Remark	Verdict

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

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

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

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

9.4.4	TABLE: Grips and other handling devices	N/A
Clause and Name of Test	**Test Condition**	**Remarks**
Supplementary information: 9.3 kg < 20 kg		

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:					

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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	
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			

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11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT						P
Model No.	Ventoux 12" (as representative)						
Test ambient (°C)	26	26.5	26.5	26.5	25.5	26.6	26.5
Test supply voltage/frequency (V/Hz)[4)]	264Vac/ 50Hz	90Vac/ 50Hz	264Vac/ 60Hz	90Vac/ 60Hz	264Vac/ 60Hz Blocked vents	264Vac/ 60Hz Fans Disconnected	Battery operated

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
264Vac/60Hz Normal Condition (test duration 30 min)					
Ventoux 12"	1	PS Heatsink	85	62.5 (49+40-26.5)	P
	2	Power PCB	105	63.9 (50.4+40+26.5)	P
	3	Main PCB	105	52.9 (39.4+40-26.5)	P
	4	Extended PCB	105	46.8 (33.3+40-26.5)	P
	5	Turbine Motor Metal Enclosure	70	54.4 (40.9+40-26.5)	P
	6	Battery Enclosure	60	42.5 (29+40-26.5)	P
	7	Appliance Inlet Plastic Enclosure	60	45.5 (32+40-26.5)	P
	8	Touch Screen	56	46.1 (33.3+40-26.5)	P
	9	EUT Plastic Enclosure	60	44.2 (30.7+40-26.5)	P
	10	Test Lung (AP)	43	41.9 (28.4+40-26.5)	P
	11	Lab ambient	---	26.5	P
	12	Oxymeter (SP02)(AP)	43	39.5(26+40-26.5)	P
90Vac/60Hz Normal Condition (test duration 30 min)					
Ventoux 12"	1	PS Heatsink	85	61.1(47.6+40+26.5)	P
	2	Power PCB	105	63.1(49.6+40+26.5)	P
	3	Main PCB	105	52.9(39.4+40+26.5)	P
	4	Extended PCB	105	46.8(33.3+40+26.5)	P
	5	Turbine Motor Metal Enclosure	70	52.2(38.7+40+26.5)	P
	6	Battery Enclosure	60	42.8(29.3+40+26.5)	P
	7	Appliance Inlet Plastic Enclosure	60	45.6(32.1+40+26.5)	P
	8	Touch Screen	56	46.1(32.6+40+26.5)	P
	9	EUT Plastic Enclosure	60	44.3(30.8+40+26.5)	P
	10	Test Lung (AP)	43	42.1(28.6+40+26.5)	P
	11	Lab ambient	---	26.5	P
	12	Oxymeter (SP02)(AP)	43	39.2(25.7+40-26.5)	P

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264Vac/50Hz Normal Condition (test duration 1 hour)					
Ventoux 12"	1	PS Heatsink	85	60.7(40.7+40-26)	**P**
	2	Power PCB	105	73(59+40-26)	**P**
	3	Main PCB	105	56.5(42.5+40-26)	**P**
	4	Extended PCB	105	50.7(36.7+40-26)	**P**
	5	Turbine Motor Metal Enclosure	70	58(44+40-26)	**P**
	6	Battery Enclosure	60	41.7(40.7+40-26)	**P**
	7	Appliance Inlet Plastic Enclosure	60	45(31+40-26)	**P**
	8	Touch Screen	56	44.9(30.9+40-26)	**P**
	9	EUT Plastic Enclosure	60	43.4(29.4+40-26)	**P**
	10	Test Lung (AP)	43	41(27+40-26)	**P**
	11	Lab ambient	---	26	**P**
	12	Oxymeter (SP02)(AP)	43	39.6(25.6+40-26)	**P**
90Vac/50Hz Normal Condition (test duration 30 min)					
Ventoux 12"	1	PS Heatsink	85	59.5(46+40-26.5)	**P**
	2	Power PCB	105	69.1(55.6+40-26.5)	**P**
	3	Main PCB	105	59.4(45.9+40-26.5)	**P**
	4	Extended PCB	105	55.1(41.6+40-26.5)	**P**
	5	Turbine Motor Metal Enclosure	70	58.3(44.8+40-26.5)	**P**
	6	Battery Enclosure	60	41.7(28.2+40-26.5)	**P**
	7	Appliance Inlet Plastic Enclosure	60	44.8(31.3+40-26.5)	**P**
	8	Touch Screen	56	45.3(31.8+40-26.5)	**P**
	9	EUT Plastic Enclosure	60	43.9(30.4+40-26.5)	**P**
	10	Test Lung (AP)	43	41.6(28.1+40-26.5)	**P**
	11	Lab ambient	---	26.5	**P**
	12	Oxymeter (SP02)(AP)	43	39.5(26+40-26.5)	**P**
264Vac/60Hz Blocked vents (30 min)					
Ventoux 12"	1	PS Heatsink	115	58.7(44.2+40-25.5)	**P**
	2	Power PCB	145	73.5(59+40-25.5)	**P**
	3	Main PCB	145	56.1(41.6+40-25.5)	**P**
	4	Extended PCB	145	49.6(35.1+40-25.5)	**P**
	5	Turbine Motor Metal Enclosure	92.5	60.5(46+40-25.5)	**P**
	6	Battery Enclosure	77.5	41.4(26.9+40-25.5)	**P**
	7	Appliance Inlet Plastic Enclosure	77.5	44.4(29.9+40-25.5)	**P**
	8	Touch Screen	71.5	43.6(29.1+40-25.5)	**P**
	9	EUT Plastic Enclosure	77.5	42.7(28.2+40-25.5)	**P**
	10	Test Lung (AP)	52	40.4(25.9+40-25.5)	**P**

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	11	Lab ambient	---	25.5	**P**
	12	Oxymeter (SP02)(AP)	52	40.1(25.6+40-25.5)	**P**
264Vac/60Hz Fans Disconnected					
Ventoux 12"	1	PS Heatsink	115	74.2(60.8+40-26.6)	**P**
	2	Power PCB	145	82.7(69.3+40-26.6)	**P**
	3	Main PCB	145	72.2(58.8+40-26.6)	**P**
	4	Extended PCB	145	65.1(51.7+40-26.6)	**P**
	5	Turbine Motor Metal Enclosure	92.5	76.2(62.8+40-26.6)	**P**
	6	Battery Enclosure	77.5	43.3(29.9+40-26.6)	**P**
	7	Appliance Inlet Plastic Enclosure	77.5	45.5(32.1+40-26.6)	**P**
	8	Touch Screen	71.5	45.8(32.4+40-26.6)	**P**
	9	EUT Plastic Enclosure	77.5	43.9(30.5+40-26.6)	**P**
	10	Test Lung (AP)	52	41(27.6+40-26.6)	**P**
	11	Lab ambient	---	26.6	**P**
	12	Oxymeter (SP02)(AP)	52	39.4(26+40-26.6)	**P**
Battery operated (30 min)					
Ventoux 12"	1	PS Heatsink	85	48.8(35.3+40-26.5)	**P**
	2	Power PCB	105	70(56.5+40-26.5)	**P**
	3	Main PCB	105	54.5(41+40-26.5)	**P**
	4	Extended PCB	105	47.6(34.1+40-26.5)	**P**
	5	Turbine Motor Metal Enclosure	70	64.5(51+40-26.5)	**P**
	6	Battery Enclosure	60	43.4(29.9+40-26.5)	**P**
	7	Appliance Inlet Plastic Enclosure	60	46.4(32.9+40-26.5)	**P**
	8	Touch Screen	56	44.7(31.2+40-26.5)	**P**
	9	EUT Plastic Enclosure	60	43.2(29.7+40-26.5)	**P**
	10	Test Lung (AP)	43	42.9(29.4+40-26.5)	**P**
	11	Lab ambient	---	26.5	**P**
	12	Oxymeter (SP02)(AP)	43	39.3(25.8+40-26.5)	**P**

Supplementary information:

[1] Maximum allowable temperature on surfaces of test corner is 90 °C
[2] Max temperature determined in accordance with 11.1.3e)
[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
[4] Supply voltage:

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

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

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

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

11.2.2.1	TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source	N/A
Areas where sparking might cause ignition:		**Remarks**
Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):		**Remarks**
Test parameters selected representing worst case conditions for ME EQUIPMENT:		**Remarks**
Supplementary information: Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst-case values with other parameters set at worst case values to determine if ignition can occur. Information from Risk Management, as applicable:		

11.6.1	TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances	P
Clause / Test Name	**Test Condition**	**Part under test**	**Remarks**
11.6.5 Ingress of water or particulate matter (IP34)	IP3x: The access probe of 2,5 mm ∅ not penetrated and not accessed to the hazardous parts IPx4: Water splashed against all the directions of the EUT enclosure not caused any harmful effects	Whole unit	The EUT was subjected to dielectric strength and leakage current tests, no hazard observed
11.6.6 Cleaning	Evaluated according to method of cleaning mentioned in instructions for use	Whole unit	The EUT was subjected to dielectric strength and leakage current tests, no hazard observed
Supplementary information: Information from Risk Management, as applicable:			

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13.1.2	**TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances**	**N/A**
Power dissipated less than (W) ..... :	**15**	
Energy dissipated less than (J) .....:	**900**	

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

Supplementary information:

13.2	TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive		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:**	**—**	**—**
	Disruption (interruption) of the gas delivery to the patient-connection port from the ventilator	The high alarm priority activated. With a red message No O2 supply. The unit recovered after reconnection. No hazard no fire, no adverse effect	No
	Disruption of the gas flow pathway from the patient-connection port to the ventilator	The high alarm priority activated. With a red message No O2 supply. The unit recovered after reconnection. No hazard no fire, no adverse effect	No
	Loss of communication between the ventilator and its remote (wired or wireless) control or monitoring module	The monitor is shunted off and the EUT cannot be controlled. Alarm (Audio and Video) appeared after 5 seconds. All the alarms continued to work. The unit recovered after reconnection. No hazard no fire, no adverse effect	No
	Following the failure of one gas supply connected to a high-pressure input port, a ventilator shall maintain normal use.	The high alarm priority activated. With a red message No O2 supply. The unit recovered after reconnection. No hazard no fire, no adverse effect	No

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Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	Following the failure of a functional connection to a ventilator control or monitoring means, the ventilator shall continue to ventilate the patient. The ventilator shall be equipped with an alarm system that detects a technical alarm condition to indicate this communication failure. Technical alarm shall be at least medium priority	The monitor is shunted off and the EUT cannot be controlled. Alarm (Audio and Video) appeared after 5 seconds. All the alarms continued to work. The unit recovered after reconnection. No hazard no fire, no adverse effect	No
	Pulse Oximeter is equipped with alarm system to detect physiological alarm conditions. Need to have indication if the wire if probe cable is shorted or opened	The Oximeter showed low priority alarm with a message on a screen “SPO2 disconnection”. The unit recovered after removing a fault. No hazard no fire, no adverse effect	No
	The ventilator shall be designed in such a manner that under conditions of power failure, either electrical or pneumatic, as applicable, the patient can breathe spontaneously	The Unit was shunted off and the patient can continue to breath by himself The unit recovered after removing a fault. No hazard no fire, no adverse effect	No
	Sensor O2 was disconnected, during EUT operation	Immediately, FiO2 sensor Failure and Calibrate FiO2 Sensor Alarm messages were appeared. No hazard no fire, no adverse effect	No
	Flow Sensor disconnected from patient circuit	High alarm appeared. Messages on the screen appeared: “Check circuit, low pressure, low VTE” The unit recovered after removing a fault. No hazard no fire, no adverse effect	No

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Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	Power supply fan was mechanically stuck	After EUT was powered ON, the ventilator tried to work and critical alarm appeared on the monitor: "[BIST] FAIL:FansSelfTest The unit recovered after removing a fault and resetting the EUT. No hazard no fire, no adverse effect	No
	Turbine was mechanically stuck before EUT activation	After EUT was powered ON, the turbine tried to work and an critical alarm appeared on the monitor "[BIST] FAIL:TurbineSelfTest" The unit recovered after removing a fault and resetting the EUT. No hazard no fire, no adverse effect	No
	Main Turbine voltage was shunted off	When the EUT was turned on Critical Alarm [Bist] Fail: Turbine self test fail The unit recovered after removing a fault. No hazard no fire, no adverse effect	No
	3-way valve (flow sensor) Inner plastic tube jammed (right - white)	Monitor showed “Check circuit”, “low pressure message”. High alarm priority activated. The unit recovered after removing a fault. No hazard no fire, no adverse effect	No
	3-way valve (flow sensor) Inner plastic tube jammed (left)	After 3-4 seconds monitor shower an error of "High pressure" and Audio alarm activated. The unit recovered after removing a fault. No hazard no fire, no adverse effect	No

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Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	3-way valve (flow sensor) Inner plastic tube jammed (right)	After 3-4 seconds monitor shower an error of "Check circuit" and Audio alarm activated. The unit recovered after removing a fault. No hazard no fire, no adverse effect	No
	CO2 “Oridion” module disconnected from ventilator	Monitor showed an error: ”CO2 line disconnected”, low priority alarm activated. The unit recovered after removing a fault. No hazard no fire, no adverse effect	No
	CUFF module was disconnected from the ventilator	Monitor showed an error: ”Low CUFF pressure”, low priority alarm activated. The unit recovered after removing a fault. No hazard no fire, no adverse effect.	No
	CUFF module air inlet pressure was blocked mechanically	Immediately after blocking Nasal CO2 filter line, CO2 Occlusion message was appeared. No hazard no fire, no adverse effect	No
	Interruption of nasal CO2 filter line	Immediately nasal apnoea alarm was appeared. No hazard no fire, no adverse effect	No
	CO2 module sensor was disconnected	Immediately upon disconnection of CO2 alarm filter, CO2 disconnection alarm was appeared. No hazard no fire, no adverse effect	No
	MCU between SOM communication was disconnected by connecting jumper to main board JP2 -> activated BOOT mode	The EUT turned on and Alarm (Audio + Visual) was activated. The unit was rebooted and recovered after removing a fault. No hazard no fire, no adverse effect	No

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Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	SOM (graphical card) was disconnected by connecting jumper to main board (No SD Card)	While EUT is turned on, the monitor not worked. Alarm (Audio and Visual) appeared after 1 min. The device was rebooted and recovered after removing a fault. No hazard no fire, no adverse effect	No
	Battery was shorted	No adverse effect	No
13.2.3	**Overheating of transformers per Clause 15.5:**	**—**	**—**
	Mains transformer evaluated as part of certified power supply	N/A	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:**	**—**	**—**
	No thermostats	N/A	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:**	**—**	**—**
	No temperature limiting devices	N/A	N/A
13.2.6	**Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)**	**—**	**—**
	Not handling liquids	N/A	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	EUT continued normal operation without any errors, see table 11.1 for test results. No hazard, no adverse effect	No
	Ventilation openings impaired by covering	EUT continued normal operation without any errors, see table 11.1 for test results. No hazard, no adverse effect	No
13.2.8	**Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:**	**—**	**—**
	No moving parts	N/A	N/A
13.2.9	**Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1)] – Also see 13.10**	**—**	**—**
	No such capacitors	N/A	N/A

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Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.10	**Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:**	**—**	**—**
	N/A	N/A	N/A
13.2.11	**Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:**	**—**	**—**
	Oxygen flow from balloon + electrical short	Declared by manufacturer: The EUT has been so designed that there is no means of generating a spark during normal single fault use of the device when oxygen is used. This would require both an O2 leak and a spark to be generated. There are 3 fans which continuously work to vent the internal environment of the device. It is only one relay used, which is a dry contact. High Oxygen concentration is continuously vented from the device to the patient under normal use – the test is not required.	N/A
13.2.12	**Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):**	**—**	**—**
	No such risks, no need for any additional tests	N/A	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.			

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 adverse effect
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	No adverse effect
15.3.4.1	Drop Test (hand-held)	Free fall height (m) = 1	No adverse effect
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5	No adverse effect
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) = 70	No adverse effect
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).			

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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.							

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.					

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Clause	Requirement + Test	Result - Remark	Verdict

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

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

SP	**TABLE: Additional or special tests conducted**	**P**
Clause and Name of Test	**Test type and condition**	**Observed results**
11.8 Interruption of power supply	The power supply was interrupted – the power cable was disconnected from the EUT	Interruption and restoration of power supply did not result in a hazardous situation. Immediately the EUT switched to battery supply. No hazards, no fire, no adverse effect observed
Supplementary information:		

	Attachment - Software – IEC 62304:2006			**P**
Attachment	**Software - Mapping of required evidence and manufacturer documents**			
Standard Clause	Deliverables	Title	Revision #	Date
Supplementary information: See IEC 62304 software report				

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

Attachment 1
National Differences

ATTACHMENT TO TEST REPORT
IEC 60601-1:2005 + AMD 1:2012
US NATIONAL DIFFERENCES
MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE

Differences according to ..... : National standard AAMI/IEC 60601-1:2005 + AMD1:2012

Attachment Form No. ..... : US_ND_IEC60601_1S

Attachment Originator..... : UL(US)

Master Attachment ..... : 2020-12-17

	National Differences		**P**
4.8	**Components of ME EQUIPMENT**		**P**
	b) where there is no relevant IEC/ISO standard, the relevant ANSI standard applied; if no relevant ANSI standard exists, the requirements of this standard were applied. (*Replacement of clause 4.8 b*)	All components were evaluated as part of this standard	**P**
4.10.2	**SUPPLY MAINS FOR ME EQUIPMENT AND ME SYSTEMS**		**P**
	(Replacement to reflect agreement with the National Electrical Code (NEC): The reference to "500 V" replaced with "600 V" in the second and third dashes.	Considered	**P**
	(Addition to reflect agreement with the NEC) In the text of the second-to-last dash of this sub-clause, "and the NEC" added after reference to "IEC 60364-4-41"	Considered	**P**

6.0	**Classification of ME EQUIPMENT and ME SYSTEMS**		**N/A**
6.6	Mode of operation	Not x-ray equipment	**N/A**
	(Addition to reflect agreement with NFPA 70) X-Ray systems are classified as long-time operation (> 5 min) or momentary operation (< 5 sec).	Not x-ray equipment	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.0	**ME EQUIPMENT identification, marking and documents**		**N/A**
7.2.11	Mode of operation		**N/A**
	(Addition to reflect agreement with NFPA 70) X-Ray systems are marked as long-time operation or momentary operation.	Not x-ray equipment	**N/A**
7.2.22	(*Addition of new item*) Colours of medical gas cylinders	Not required	**N/A**
	To reflect agreement with NFPA 99: Cylinders containing medical gases and their connection points are coloured in accordance with the requirements of NFPA 99.	Same as above	**N/A**
8.0	**Protection against electrical hazards from ME EQUIPMENT**		**P**
8.2	Requirements related to power sources		**N/A**
	(Addition to reflect agreement with the NEC) All FIXED ME EQUIPMENT and PERMANENTLY INSTALLED ME EQUIPMENT are CLASS I ME EQUIPMENT.	Not fixed or permanently installed equipment	**N/A**
8.6.1	Application of requirements		**N/A**
	(Addition to reflect agreement with NFPA 99) The enclosure of X-ray ME EQUIPMENT operating over 600 Vac, 850 Vdc MAINS VOLTAGE, or containing voltages up to 50 V peak and enclosed in protectively earthed enclosure as well as connections to X-ray tubes and other high voltage components that include high voltage shielded cables are PROTECTIVELY EARTHED.	Not x-ray equipment	**N/A**
	(Addition to reflect agreement with NFPA 99) Non-current carrying conductive parts of X-Ray ME EQUIPMENT likely to become energized are PROTECTIVELY EARTHED	Not x-ray equipment	**N/A**
8.7.3	Allowable values		**N/A**
	(Deletion to reflect agreement with NFPA 99 which does not allow for allowance greater than the stated values) Delete the second sentence and note to sub-clause 8.7.3 d) so that it reads: d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION	No earth	**N/A**
8.11	MAINS PARTS, components and layout		**N/A**
	(Addition to reflect agreement with the NEC) Permanently connected ME EQUIPMENT has provision for the connection of one of the wiring systems that is in accordance with the NEC.	Not permanently installed	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Exception: Fixed and stationary X-ray ME EQUIPMENT supplied from a branch circuit rated at 30 A or less, and ME EQUIPMENT that is not strictly portable but obviously is intended to be stationary, may be acceptable if provided with a length of attached hard service flexible cord - such as Type S, or the equivalent, for supply connection.	Not x-ray equipment	**N/A**
	The installation of connecting cords between EQUIPMENT parts meets the requirements of the NEC, as applicable. Cable used as external interconnection between units are as follows:	No external interconnection cables	**N/A**
	1) If exposed to abuse, the cables are Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord or similar multiple-conductor appliance-wiring material such as computer cable	Same as above	**N/A**
	2) If not exposed to abuse, the cables are as indicated in item 1) above or are: i) Type SPT-2, SP-2, or SPE-2, or equivalent, ii) Type SVr, SVRO, SVE, or equivalent flexible cord or similar multiple-conductor appliance wiring material, or iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more, enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more.	Same as above	**N/A**
	Receptacles provided as part of ME EQUIPMENT or ME SYSTEMS for use in the patient care areas of paediatric wards, rooms, or areas are listed tamper resistant or employ a listed tamper resistant cover in accordance with the NEC.	Same as above	**N/A**
	b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, 250 V/20 A “Hospital Grade” mains plug is provided and the POWER SUPPLY CORD is marked.	Same as above	**N/A**
8.11.3.2	*(Addition to reflect agreement with the NEC)* The flexible cord is of a type that is acceptable for the particular application. It is acceptable for use at a voltage not less than the rated voltage of the appliance and has an ampacity, as given in the NEC, not less than the current rating of the appliance ..... :	Same as above	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.3.3	Cross-sectional area of POWER SUPPLY CORDS		**N/A**
	(Addition to reflect agreement with NFPA 99) For X-Ray ME EQUIPMENT with an attachment plug, the current rating on a hospital grade plug should be 2X the maximum input current of the equipment.	Not x-ray equipment	**N/A**
	1) If exposed to abuse, the cables are Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord or similar multiple-conductor appliance-wiring material such as computer cable.	Same as above	**N/A**
	2) If not exposed to abuse, the cables are as indicated in item 1) above or are: i) Type SPT-2, SP-2, or SPE-2, or equivalent, ii) Type SVr, SVRO, SVE, or equivalent flexible cord or similar multiple-conductor appliance wiring material, or iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more, enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more.	Same as above	**N/A**
	Receptacles provided as part of ME EQUIPMENT or ME SYSTEMS for use in the patient care areas of paediatric wards, rooms, or areas are listed tamper resistant or employ a listed tamper resistant cover in accordance with the NEC.	Same as above	**N/A**
	b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, 250 V/20 A “Hospital Grade” mains plug is provided and the POWER SUPPLY CORD is marked.	Same as above	**N/A**

Attachment 2
Maximum ambient operating temperature rationale

Flight Medical®

Ventoux "8 and 12" Devices

Rational for Declaring that the maximum operating temperature of the Ventoux Ventilator takes precedence over the maximum operating temperature of add-on and attachable devices.

Prepared by: Ken Raichman, QA and Regulatory

Date: 19.04.22

1. **Purpose:**

   The purpose of this document is to show that the maximum Operating Temperature of the Ventoux takes precedence over the maximum Operating Temperature of any add-on or secondary device connected to the Ventoux.

2. **Devices being compared:**

   Ventoux without Oximetry or Capnography

   Ventoux with Oximetry monitoring capability

   Ventoux with Capnography capability

3. **Overview**

   3.1. The Ventoux as a life-supporting device

   The Ventoux is considered to be a life-supporting device. As a result, when in use, its primary function is to deliver continuous ventilation to the patient according to the prescription setting of the device under the supervision of physician. Failure to do so could result in harm or result in death to the patient.
   Should any emergency failure be detected that can affect the operation of the device, the device will:

   1. Provide a Warning about the failure detected, but will still maintain its operation of providing ventilation to the patient until corrective action has taken place, if possible.
      or
   2. If, in the worst case, should a device shutdown be required, will provide a warning alarm to the effect that it needs to shut down and that a replacement unit should be provided. Under this condition the patient can still breath ambient air.

Flight Medical

3.2. Add-on Units Oximetry and Capnography

The Add-on Units for Oximetry and Capnography are "optional" auxiliary devices that can provide supporting information (in the form of Oxygen Saturation and CO2 levels) for the ventilation of a patient. They are not considered primary life-supporting devices that maintain the breathing of a patient.

Any limitations of the devices operations can be addressed in the Operating Instructions of the Ventoux ventilator

Both the Oximetry and Capnography devices can connected to the patient independent of the Ventoux ventilator.

3.3. Rational

1. The Ventoux Ventilator is a life-supporting device.
2. The Ventoux Ventilator is under continuous supervision by a physican
3. The Add-on devices are "optional" device and not required for the operation for the Ventilator.
4. Add-on units are not life-supporting devices
5. Any limitations in the operation of the add-on units can be addressed in the operating instructions of the Ventoux ventilator

Based on the above, the maximum operating temperature of the Ventoux ventilator is considered to take precedence over the that of the add-on units.

Attachment 3
Declaration of model's similarity

Flight Medical

Ventoux – Compliance Declaration

We, Flight Medical Innovations, declare that the Ventoux 8" (VC2) ventilator is identical to the Ventoux 12" (VC3) ventilator in all respects (electrically and mechanically) except for the size of the Display Screen, where the VC2 has an 8" screen and the VC3 has a 12" screen.

Date: 06.04.2022

Ken Raichman,
Regulatory & QA Manager

Attachment 4
Photos

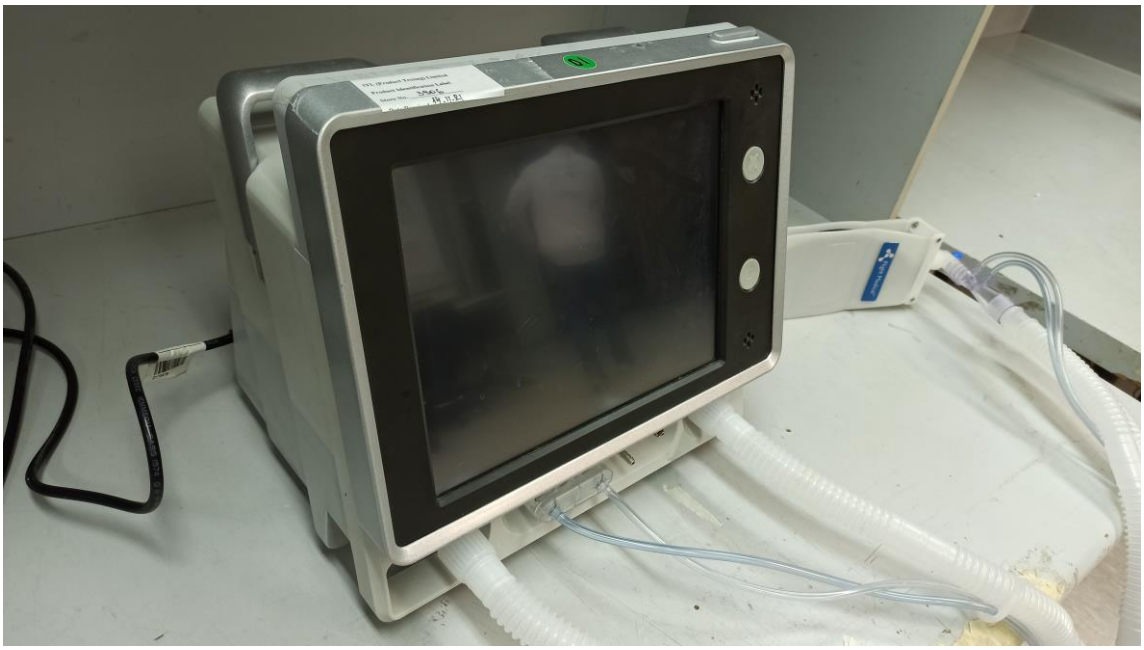

Fig. 1 - General View

Fig. 2 - Front View

Fig. 3 – Front panel

Fig. 4 – Rear panel

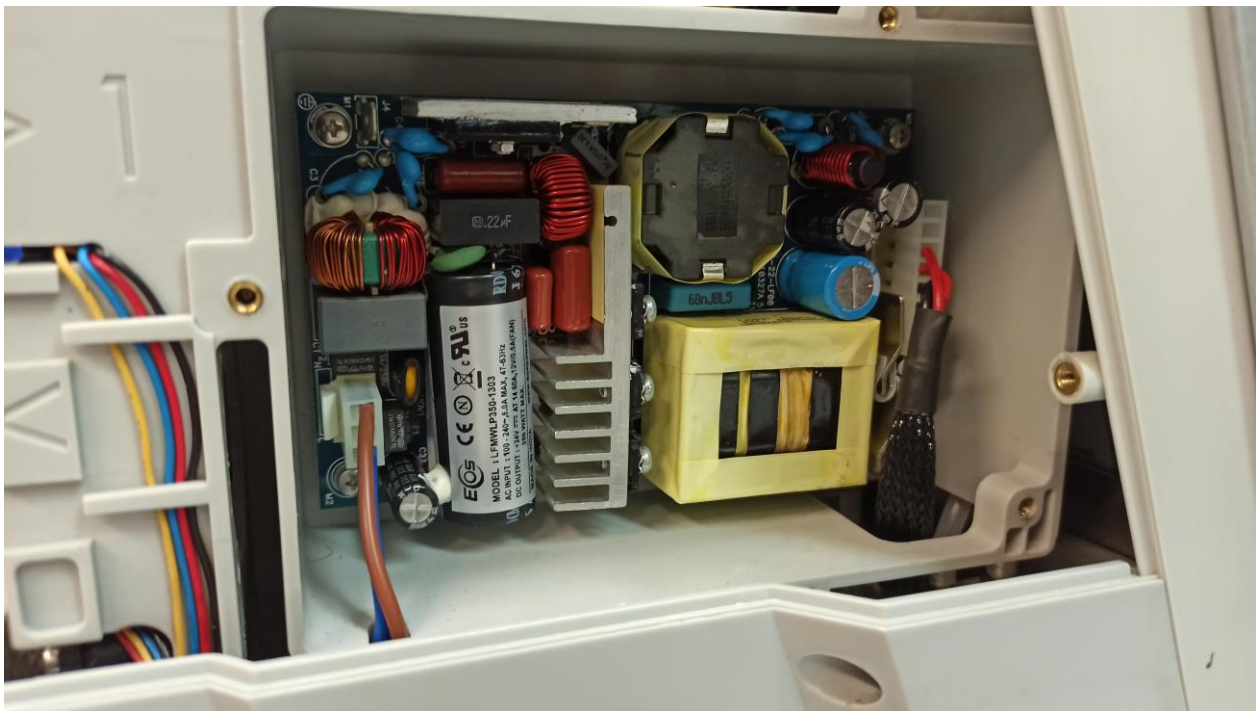

Fig. 5 – Power Supply compartment

Fig. 6 – Batteries + Filter compartments

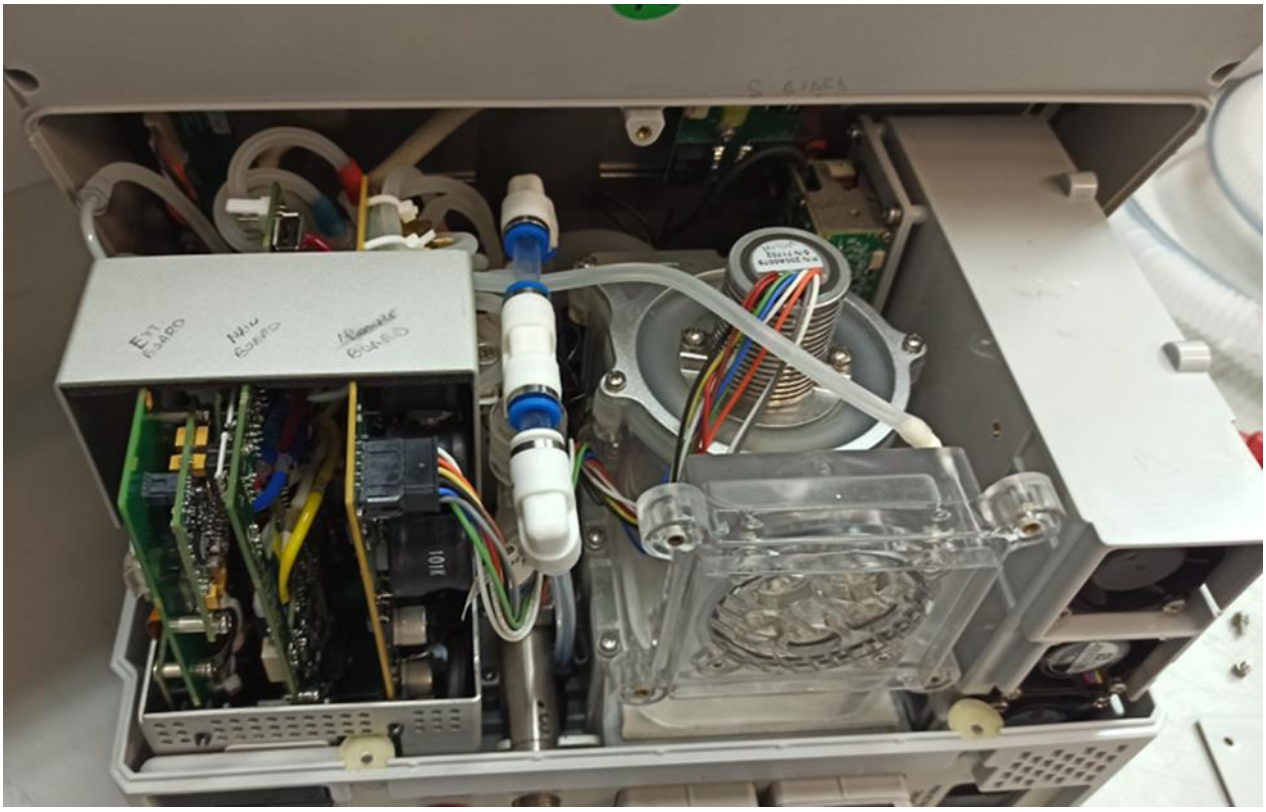

Fig. 7 – Internal view

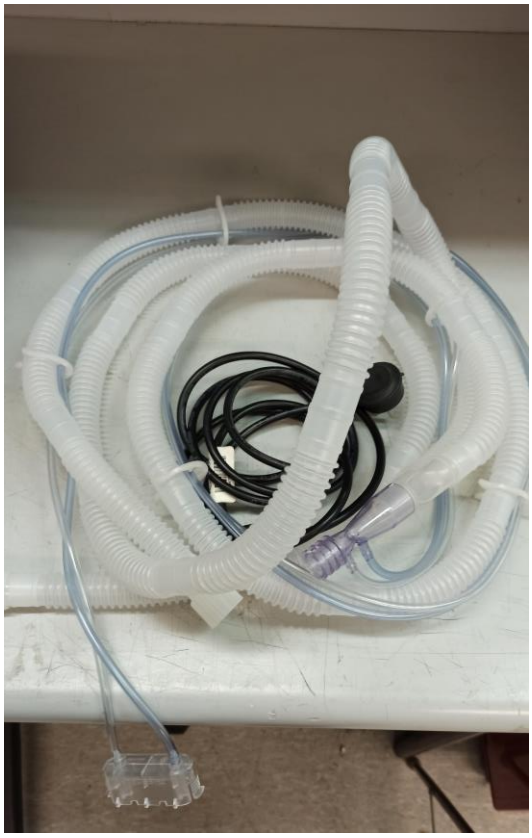

Fig. 8 – Patient circuit

Fig. 9 – EUT weight

End of Test Report