TEST REPORT
IEC 60601-1-11
MEDICAL ELECTRICAL EQUIPMENT –
Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Report Reference No.	:	EED33K00055302
Compiled by (+ signature)	:	Koke Liu
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Date of issue	:	May 07, 2019
Testing Laboratory	:	Centre Testing International Group Co., Ltd.
Address	:	Hongwei Industrial Zone, Bao' an 70 District, Shenzhen, Guangdong, China
Applicant's name	:	Shenzhen Yimi Life Technology Co., Ltd
Address	:	305, Building A, Tengbo Industrial Park, Changshangjiang Street, Longbei Village, Pingshan District, 518118, Shenzhen, China
Test specification:		
Standard	:	IEC 60601-1-11: 2015
Test procedure	:	Test report only
Non-standard test method	:	N/A
Test Report Form No	:	IEC60601_1_11C
Test Report Form Originator	:	UL
Master TRF	:	2015-03
Test item description	:	Pulse Oximeter
Trade Mark	:	None
Manufacturer	:	Shenzhen Yimi Life Technology Co., Ltd
Address	:	305, Building A, Tengbo Industrial Park, Changshangjiang Street, Longbei Village, Pingshan District, 518118, Shenzhen, China
Model/Type reference	:	YM101, YM102, YM103, YM201, YM301
Ratings	:	Battery 2×1.5V AAA SIZE, Type BF applied part, IP22,

Check No.: 3177489357

Summary of testing:	
Tests performed (name of test and test clause): All applicable tests are performed, and test results comply with the standard requirements **Exceptions:** **The following clause/ collaterals were not evaluated:** Clause 7.1, 8.1, 8.2, 9, usability engineering file, Not evaluated in this report. Clause 12, EMC, Not evaluated in this report.	**Testing location:** Centre Testing International Group Co., Ltd. Hongwei Industrial Zone, Bao' an 70 District, Shenzhen, Guangdong, China
Summary of compliance with National Differences List of country addressed: N/A	
Copy of marking plate Refer to IEC 60601-1 report No. EED33K00055301 The above markings are the minimum requirements required by the safety standard, for the final production samples, the additional markings which do not give rise to misunderstanding may be added.	

Test item particulars.....:	
Classification of installation and use.....	Body-worn
Intended use (Including type of patient, application location).....:	The pulse oximeter is intended for measure oxygen saturation and pulse rate of adults or children in families, hospitals, oxygen bars, social medical care institutions, You can use this equipment for measurement before or after sports.
Mode of operation .....:	Continuous
Supply Connection.....:	Internally powered
Accessories and detachable parts included..... :	None
Possible test case verdicts:	
- test case does not apply to the test object.....:	N(N/A)
- test object does meet the requirement.....:	P (Pass)
- test object was not evaluated for the requirement.....:	N/E
- test object does not meet the requirement.....:	F (Fail)
Testing	
Date of receipt of test item.....:	Dec. 12, 2018
Date (s) of performance of tests.....:	Dec. 25, 2018 to Apr. 15, 2019

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tested sample(s) and the sample information are provided by the client.
This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.
This Test Report Form is intended for the evaluation of medical electrical equipment and medical electrical systems used in the home healthcare environment in accordance with IEC 60601-1-11.
This Test Report Form can be used to complement the IEC 60601-1 Test Report.

Name and address of factory (ies) :	Shenzhen Yimi Life Technology Co., Ltd 305, Building A, Tengbo Industrial Park, Changshangjiang Street, Longbei Village, Pingshan District, 518118, Shenzhen, China

General product information:

1. No any potential ignition source existed in such ME equipment as internally powered (2 x AAA battery) only, which limited internal power consumption within 5 VA max. as basic property of such battery.
2. The working environment specified in instruction manual is 10°C-40°C, 15%-95% R.H.
3. The difference between models:
All the models have the same circuit diagram and critical component. all the models are identical for the internal except for the following difference:

Model	YM101	YM102	YM103	YM201	YM301
Screen size	1.5inch	1.5inch	1.5inch	0.96inch	1.3inch
LED colour	Red	Green	White	Yellow, Blue	Blue

The above differences do not affect the basic safety and essential performance, so the model YM201 is selected for full test.

4. The devices can be used at home, hospital and health care center.
5. The Number of the Risk Management File is TCF-010, Version: A/0.

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Clause	Requirement + Test	Result - Remark	Verdict

4	GENERAL REQUIREMENTS		P
4.1	Characteristics of SUPPLY MAINS specified in 4.10.2 of Part 1 applied, except ME EQUIPMENT or ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT complied with the following:		N
	– SUPPLY MAINS in the HOME HEALTHCARE ENVIRONMENT did not exceed 110 % or was not below 85 % of NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% V)..... :		N
	– For ME EQUIPMENT OR ME SYSTEMS intended to actively keep alive or resuscitate a PATIENT, SUPPLY MAINS in the HOME HEALTHCARE ENVIRONMENT did not exceed 110 % or was not below 80 % of NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% V:	Not LIFE-SUPPORTING ME EQUIPMENT	N
	- RATED range of NOMINAL voltage did include at least 12.4 V to 15.1 V for operation from a 12 V dc supply mains	No dc supply mains	N
	- RATED range of NOMINAL voltage did include at least 24.8 V to 30.3 V for operation from a 12 V dc supply mains		N
	The equipment maintained BASIC SAFETY and ESSENTIAL PERFORMANCE during and following a 30 s dip to 10 V from a 12 V dc SUPPLY MAINS		N
	The equipment maintained BASIC SAFETY and ESSENTIAL PERFORMANCE during and following a 30 s dip to 20 V from a 24 V dc SUPPLY MAINS		N
4.2.2	**Environmental conditions of transport and storage between uses, indicated in instructions for use**		P
	ME EQUIPMENT, except STATIONARY EQUIPMENT, after being removed from its protective packaging, and subsequently between uses, operated within its specified NORMAL USE after transport or storage in the specified environmental conditions	Specified in User Manual: -20°C ～ 60°C, Humidity: 15%~95% RH	P
	temperature range:-25 °C to + 5 °C	The instructions for use state a more restricted range of environmental transport and storage conditions between uses.	N
	temperature range:+5 °C to +35 °C at a non-condensing relative humidity up to 90 %		N
	temperature range: >35 °C to 70 °C at a water vapour pressure up to 50 hPa		N

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Clause	Requirement + Test	Result - Remark	Verdict
	For more restricted range of environmental transport and storage conditions between uses, the environmental conditions are specified		P
	– Justified in the RISK MANAGEMENT FILE	See Risk management Table 4.2.2	P
	– Marked on the ME EQUIPMENT	The marking is not practicable	N
	When not practicable, the more restricted range is disclosed in the instructions for use	Indicated in the instructions for use and packaging	P
	– Marked on the carrying case when the instructions for use indicate the ME EQUIPMENT is intended to be transported or stored in a carrying case between uses	No carrying case used	N
	Symbol 5.3.5 (ISO 7000-0534), 5.3.6 (ISO 7000-0533), or 5.3.7 (ISO 7000-0632) of ISO 15223-1:2012 used to mark temperature range		N
	Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2012 used to mark humidity range		N
	Symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2012 used to mark atmospheric pressure range		N
	Where ME EQUIPMENT used different marking for conditions of transport and storage between uses, continuous operating conditions and transient operating conditions, markings accompanied by supplementary markings except where the respective applicability was obvious	No such symbols used	N
	Environmental transport and storage test		P
	a) ME EQUIPMENT prepared for transportation or storage according to instructions for use		P
	b) ME EQUIPMENT exposed to its lowest specified environmental transport and storage conditions (temperature $^{0}_{-4}$ °C) (°C)..... :	Stored at -20°C	P
	– For at least 16 h or, ensure ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	16h	P
	c) Then ME EQUIPMENT exposed to 34 °C ± 4 °C and 90 % - 0% + 6% relative humidity until the test chamber reached equilibrium and held for at least 2 hours. The transition from low to high temperature was made slowly enough to provide a non-condensing environment.	Exposed to 34° C, 93% Relative humidity and held for 2 h	P

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Clause	Requirement + Test	Result - Remark	Verdict
	d) ME EQUIPMENT exposed to its highest specified environmental transport and storage conditions, not requiring a water vapour pressure greater than 50 hPa (temperature $^{+4}_{0}$ °C); (°C, ± %)..... :	Stored at 60°C	P
	– For at least 16 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	16h	P
	e) At the end of this conditioning period, ME EQUIPMENT allowed to return and stabilize at the operating conditions of NORMAL USE		P
	f) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE	Keep BASIC SAFETY and ESSENTIAL PERFORMANCE after the above test.	P
4.2.3.1	Environmental operating conditions - Continuous operating conditions		P
	Instructions for use indicated permissible environmental operating conditions of the ME EQUIPMENT	10° C-40° C, 15%-95% R.H. 70Kpa~106Kpa.	P
	ME EQUIPMENT complied with its specifications and all requirements of the standard when operated in NORMAL USE within temperature + 5 °C to +40 °C,	The instructions for use state a more restricted range of environmental operating conditions	N
	Relative humidity range of 15 % to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa; and		N
	An atmospheric pressure range of 700 hPa to 1060 hPa		N
	For more restricted range of environmental operating conditions		P
	- justified in the risk management file;	See Risk management Table 4.2.3.1	P
	-marked on the equipment; or were nor practical in the instructions for use……:	The marking is not practicable, disclosed in the user manual.	P
	– Marked on the carrying case when the instructions for use indicate the ME EQUIPMENT is intended to be operated in a carrying case	No carrying case used	N
	Symbol 5.3.5 (ISO 7000-0534), 5.3.6 (ISO 7000-0533), or 5.3.7 (ISO 7000-0632) of ISO 15223-1:2012 used to mark temperature range		N
	Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2012 used to mark humidity range		N
	Symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2012 used to mark atmospheric pressure range		N

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Clause	Requirement + Test	Result - Remark	Verdict

	Where ME EQUIPMENT used different marking for conditions of continuous operating conditions and transient operating conditions, markings accompanied by supplementary markings	No such symbols used	N
	Environmental operating conditions test		P
	a) ME EQUIPMENT was set up for operation according to INTENDED USE		P
	b) ME EQUIPMENT exposed to 20 °C ± 4 °C for at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h, (h)..... :	24°C, 6h	P
	c) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE	Keep BASIC SAFETY and ESSENTIAL PERFORMANCE after the above test.	P
	d) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE while at the lowest specified atmospheric pressure.	70kPa	P
	e) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE while at the highest specified atmospheric pressure.	106kPa	P
	f) Pressure in chamber relieved		P
	g) ME EQUIPMENT cooled to its lowest specified environmental operating conditions	10°C, 15%RH	P
	h) ME EQUIPMENT held at lowest specified environmental operating conditions for at least 6 h or, ensured the ME EQUIPMENT reached THERMAL STABILITY for at least 2 h ..... :	6h	P
	i) ME EQUIPMENT met its specifications and BASIC SAFETY and ESSENTIAL PERFORMANCE	Keep BASIC SAFETY and ESSENTIAL PERFORMANCE after the above test.	P
	j) ME EQUIPMENT warmed to its highest specified continuous environmental operating conditions	40°C, 95%RH	P
	k) ME EQUIPMENT held the conditions of j) for at least 6 h or, ensured the ME EQUIPMENT reached THERMAL STABILITY for at least 2 h ..... :	6h	P
	l) ME EQUIPMENT met its specifications and BASIC SAFETY and ESSENTIAL PERFORMANCE	Keep BASIC SAFETY and ESSENTIAL PERFORMANCE after the above test.	P

4.2.3.2	Environmental shock to TRANSIT-OPERABLE EQUIPMENT	N

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Clause	Requirement + Test	Result - Remark	Verdict
	TRANSIT-OPERABLE EQUIPMENT with a stated wider range of continuous environmental operation conditions maintained BASIC SAFETY and ESSENTIAL PERFORMANCE in the presence of condensation and thermal shock from rapid changes in environmental temperature and humidity during INTENDED USE when test in accordance with 4.2.3.2 a)-j).	Not TRANSIT-OPERABLE EQUIPMENT	N
5	GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT		P
	In addition to the requirements of 5.9.2.1 of with IEC 60601-1 standard, accessibility determined as indicated below:		P
	ACCESSIBLE parts of ME EQUIPMENT identified by inspection and, when necessary, by testing	Inspection	P
	When in doubt, an ACCESSIBLE PART of ME EQUIPMENT determined by a test with the small finger probe of Fig 1, applied in a bent or straight position as follows:		N
	– for all positions of the ME EQUIPMENT operating in NORMAL USE		N
	– after opening ACCESS COVERS and removal of parts, including lamps, fuses, and fuse holders when:		N
	i) the ACCESS COVERS could be opened without the use of a TOOL, or	No safety hazard	N
	ii) the instructions for use instructed a LAY OPERATOR to open the relevant ACCESS COVER		N
6	CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS		P
	ME EQUIPMENT intended for HOME HEALTHCARE ENVIRONMENT classified as follows, except for PERMANENTLY INSTALLED EQUIPMENT and as required by Part 1, Sub-clause 6.2:		P
	– CLASS II or INTERNALLY POWERED.....:	Internally powered	P
	– Not provided with a FUNCTIONAL EARTH TERMINAL	No such terminal	P
	– When equipped with APPLIED PARTS, they are TYPE BF or CF..... :	TYPE BF APPLIED PART	P
7	ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS		P
7.1	USABILITY of identification, marking, and ACCOMPANYING DOCUMENTS intended for LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION evaluated by an OPERATOR whose PROFILE included minimum eight years of education		N/E

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT and ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT are simple to use and do not require referencing complex ACCOMPANYING DOCUMENTS.....:		N/E
7.2	In addition to requirements of 7.2.9 of the general standard, the carrying case provided some or all of the ingress protection against water or particulate matter, The ENCLOSURE is marked with the safety sign ISO 7010-W001 and “keep dry” or .....:	Not use the carrying case to provide the ingress protection against water or particulate matter	N
	Symbol ISO 15223-1:2012, 5.3.4 (ISO 7000-0626)		N
	A carrying case marked with degree of protection		N
	Carrying case inspected, and tests and criteria of 7.1.2 and 7.1.3 of Part 1 applied.....:		N
7.3	ACCOMPANYING DOCUMENTS		P
7.3.1	ACCOMPANYING DOCUMENTS indicate the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION should contact the MANUFACTURER or MANUFACTURER'S representative on the following issues:	Refer to the cover of instruction manual	P
	– Assistance in setting up, using, or maintaining the ME EQUIPMENT or ME SYSTEM when needed, or		P
	– To report unexpected operation or events		P
	ACCOMPANYING DOCUMENTS include a postal address and either a phone number or web address for the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION to contact the MANUFACTURER or MANUFACTURER'S representative	Refer to the cover of instruction manual	P
7.3.2	ACCOMPANYING DOCUMENTS include necessary details for healthcare professional to brief the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION on any known contraindication(s) to the use of ME EQUIPMENT or ME SYSTEM and any precautions to be taken, including the following:	Refer to Chapter 1 and 5 in the user manual	P
	– Precautions to be taken in the event of changes in the performance of ME EQUIPMENT or ME SYSTEM		P
	– Precautions to be taken regarding the exposure of the ME EQUIPMENT or ME SYSTEM to reasonably foreseeable environmental conditions		P
	– Adequate information regarding medicinal substances that ME EQUIPMENT is designed to administer, including any limitations in the choice of substances to be delivered as indicated below:	No medicinal substances.	N
	– Information on any medicinal substances or human blood derivatives incorporated into the ME EQUIPMENT or ACCESSORIES as an integral part; and	No such purpose	N

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Clause	Requirement + Test	Result - Remark	Verdict
	– The degree of accuracy claimed for ME EQUIPMENT with a measuring FUNCTION	Refer to Chapter 5 in the user manual	P
7.4	Instructions for use		P
7.4.1	Nature of the HAZARD, likely consequences that could occur if the advice is not followed, and precautions for reducing the RISK described in instructions for use corresponding to each warning and safety sign..... :	See RISK MANAGEMENT Table 7.4.1	P
	The instructions for use address the following issues, as applicable:		P
	– Strangulation due to cables and hoses, particularly due to excessive length		N
	– Inhalation or swallowing of small parts	No small parts	N
	– Potential allergic reactions to accessible materials used in the ME EQUIPMENT		N
	– Contact injuries	Smooth surface designed	N
	The instructions for use include warnings to the effect that the following actions could be unsafe as applicable:		P
	– Use of ACCESSORIES, detachable parts, and materials not described in the instructions for use (see 7.9.2.14 of Part 1)	No use accessories	N
	– Interconnection of this equipment to other equipment not described in the instructions for use (see 16.2 c) indent 9) of Part 1)		N
	– Modification of the equipment	Refer to Chapter 1 in the user manual	P
	– Use of the ME EQUIPMENT outside its carrying case when some part of the protection required by this standard is provided by that carrying case (see 8.3.1 and 10.1)	No such carrying case	N
7.4.2	When BASIC SAFETY or ESSENTIAL PERFORMANCE dependents on the INTERNAL ELECTRICAL POWER SOURCE, the instructions for use describes the following:	Refer to chapter 5 in the user manual	P
	– Typical operation time or number of procedures... :		P
	– Typical service life of the INTERNAL ELECTRICAL POWER SOURCE; and..... :		N
	– Behaviour of ME EQUIPMENT while the rechargeable INTERNAL ELECTRICAL POWER SOURCE is charging..... :		N

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Clause	Requirement + Test	Result - Remark	Verdict

7.4.3	Instructions for use for ME EQUIPMENT intended for use by a LAY OPERATOR include easily understood diagrams, illustrations, or photographs of the fully assembled and ready-to-operate ME EQUIPMENT including all controls, visual INFORMATION SIGNALS, and indicators provided (see 7.1)	Refer to chapter 4 in the user manual	P
7.4.4	Additional requirements for ME EQUIPMENT start-up PROCEDURE:		P
	– Easily understood diagrams, illustrations, or photographs showing proper connection of the PATIENT to the ME EQUIPMENT, ACCESSORIES and other equipment (see 7.1)	Refer to chapter 4 in the user manual	P
	– the time from switching "ON" until the ME EQUIPMENT is ready for NORMAL USE, when it exceeds 15 s (see 15.4.4 of Part 1) (s).....:	Not exceeds 15 s	N
	-the time required for ME EQUIPMENT to warm from the minimum storage temperature between uses until it is ready for intended use; and .....:	Refer to Chapter 4 in the user manual	P
	-the time required for ME EQUIPMENT to cool from the maximum storage temperature between uses until it is ready for intended use; and .....:	Refer to Chapter 4 in the user manual	P
7.4.5	Instructions for use for ME EQUIPMENT intended for use by a LAY OPERATOR include a description of generally known conditions in the HOME HEALTHCARE ENVIRONMENT that can unacceptably affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT	Refer to chapter 1 in the user manual	P
	The steps that can be taken by the LAY OPERATOR to identify and resolve the above conditions		P
	At least the following issues are also included as applicable		P
	- The effects of lint, dust, light (including sunlight), etc.	Refer to Chapter 1 in the user manual	P
	- A list of known devices or other sources that can potentially cause interference problems	Refer to chapter 1 in the user manual	P
	- The effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems		N
	- The effects caused by pets, pests or children		P
	The instructions for use explain the meaning of the IP classification marked on the ME EQUIPMENT, and on any carrying case provided with the ME EQUIPMENT as applicable	Refer to chapter 2 in the user manual	P
7.4.6	Instructions for use include a troubleshooting guide for use when there are indications of a ME EQUIPMENT malfunction during start-up or operation	Refer to chapter 8 in the user manual	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Troubleshooting guide discloses the necessary steps in the event of an TECHNICAl ALARM CONDITION		P
7.4.7	Instructions for use for ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES for other than single use that can be contaminated by contact with PATIENT, body fluids, or expired gases, during INTENDED USE, indicate the following:	See below	P
	– Frequency of cleaning, cleaning and disinfection, or cleaning and sterilization, as appropriate, for ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES used on the same PATIENT including rinsing methods, drying, handling, and storage between uses (see 8.1 and 8.2); and	Refer to chapter 6 in the user manual	P
	– It is necessary to clean and disinfect, clean and sterilize the ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES for multiple PATIENT use between uses on different PATIENTS, including rinsing methods, drying, handling, and storage until re-use (see 8.1 and 8.2), or	Refer to chapter 6 in the user manual	P
	– ME EQUIPMENT, ME SYSTEMS and ACCESSORIES require professional hygienic maintenance prior to re-use and provide contact details for the source of these services (see 7.5.2)	No such need	N
7.4.8	Instructions for use include:		P
	– EXPECTED SERVICE LIFE of the ME EQUIPMENT .....:	Refer to chapter 6 in the user manual	P
	– EXPECTED SERVICE LIFE of parts and ACCESSORIES shipped with the ME EQUIPMENT .....:		N
	– SHELF LIFE of parts and ACCESSORIES shipped with ME EQUIPMENT when SHELF LIFE is less than the EXPECTED SERVICE LIFE.....:		N
7.4.9	Instructions for use include:		P
	– A statement indicating the LAY RESPONSIBLE ORGANIZATION must contact its local authorities to determine the proper method of disposal of potentially bio hazardous parts and ACCESSORIES, as applicable	Refer to chapter 2 in the user manual	P
7.4.10	Instructions for use includes the recommended placement of the remote parts of the DISTRIBUTED ALARM SYSTEM, when applicable, to ensure the OPERATOR can be notified at all times by an appropriate element of DISTRIBUTED ALARM SYSTEM within its specified range	No such DISTRIBUTED ALARM SYSTEM	N
7.5	Technical description		N
7.5.1	The technical description for PERMANENTLY INSTALLED CLASS I ME EQUIPMENT includes:	Not PERMANENTLY INSTALLED Class I ME EQUIPMENT.	N

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Clause	Requirement + Test	Result - Remark	Verdict
	– A warning indicating the ME EQUIPMENT installation, including a correct PROTECTIVE EARTH CONNECTION, must only be carried out by qualified SERVICE PERSONNEL		N
	– Specifications of the PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR		N
	– A warning to verify the integrity of the external protective earthing system		N
	– A warning to connect and verify that the PROTECTIVE EARTH TERMINAL of the PERMANENTLY INSTALLED ME EQUIPMENT is connected to the external protective earthing system		N
7.5.2	Technical description includes methods for cleaning and disinfection or cleaning and sterilization for ME EQUIPMENT and ACCESSORIES requiring professional hygienic maintenance prior to reuse (see 7.4.7):	No such need	N
	– Before and after any type of service PROCEDURE		N
	– When the ME EQUIPMENT is transferred to another PATIENT		N
8	PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS		P
8.1	A LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT can perform the cleaning or cleaning and disinfection PROCESSES when intended (see 7.4.7)		N/E
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS.....:		N/E
8.2	A LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT can perform the cleaning and sterilization PROCESSES when intended (see 7.4.7)		N/E
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS		N/E
8.3	Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		P
8.3.1	TRANSIT-OPERABLE, HANDHELD, and BODY-WORN ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529 for at least IP 22.....:	IP22	P
	All other ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529 for at least IP21.....:		N

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Clause	Requirement + Test	Result - Remark	Verdict
	For PORTABLE ME EQUIPMENT intended to be used only while in a carrying case, IP21 met with the ME EQUIPMENT in its the carrying case	No carrying case used	N
	Maintenance of BASIC SAFETY and ESSENTIAL PERFORMANCE VERIFIED	Keep BASIC SAFETY and ESSENTIAL PERFORMANCE after IP22 test.	P
8.3.2	ENCLOSURES of the non-ME EQUIPMENT parts of the ME SYSTEMS provide the degree of protection against harmful ingress of water or particulate matter equivalent to equipment complying with their respective IEC or ISO safety standards	No such part	N
	Tests of IEC 60529:1989 conducted with the equipment placed in the least favourable position of NORMAL USE and the ENCLOSURES inspected		N
8.4	Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT and ME SYSTEM		N
	ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT maintained its ESSENTIAL PERFORMANCE for a sufficient time or for a sufficient number of PROCEDURES when loss or failure of SUPPLY MAINS or near depletion INTERNAL ELECTRICAL POWER SOURCE occurred	Not LIFE SUPPORTING ME EQUIPMENT	N
	The time or number of PROCEDURES remaining allowed alternative life-supporting methods to be employed		N
	Optionally, an INTERNAL ELECTRICAL POWER SOURCE was used to maintain ESSENTIAL PERFORMANCE.....:		N
	Optionally, independent means were used to provide ESSENTIAL PERFORMANCE.....:		N
	Instructions for use disclose the time or number of procedures available following a loss or failure of the SUPPLY MAINS or near depletion of the INTERNAL ELECTRICAL POWER SOURCE		N
	Instructions for use describes the alternative life-supporting methods to be employed		N
	The technical description describes methods that can be employed for longer periods		N
	ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT with no INTERNAL ELECTRICAL POWER SOURCE is equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY ALARM CONDITION indicating power failure .....:		N

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT with an INTERNAL ELECTRICAL POWER SOURCE is equipped with an automatic switchover to INTERNAL ELECTRICAL POWER SOURCE		N
	ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT with an INTERNAL ELECTRICAL POWER SOURCE is equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION indicating the INTERNAL ELECTRICAL POWER SOURCE is nearing insufficient remaining power for operation		N
	TECHNICAL ALARM CONDITION provides sufficient time or sufficient number of procedures for a LAY OPERATOR to act		N
	A TECHNICAL ALARM CONDITION of at least LOW PRIORITY remained active until the INTERNAL ELECTRICAL POWER SOURCE returned to a level above the ALARM LIMIT or until depleted		N
	It was not possible to inactivate the visual ALARM SIGNAL of this TECHNICAL ALARM CONDITION		N
	Functional tests conducted, and the RISK MANAGEMENT FILE inspected..... :	See RISK MANAGEMENT Table 8.4	N
8.5	Additional requirements for an INTERNAL ELECTRICAL POWER SOURCE		N
8.5.1	ME EQUIPMENT provided with a means for the OPERATOR to determine state of the INTERNAL ELECTRICAL POWER SOURCE when the is essential for BASIC SAFETY or ESSENTIAL PERFORMANCE or to control risks associated with loss of ESSENTIAL PERFORMANCE	No provided	N
	State of INTERNAL ELECTRICAL POWER SOURCE indicated by:		N
	- number of PROCEDURES remaining;		N
	-remaining operating time;		N
	-percentage of the remaining operating time or energy; or		N
	-“fuel” gauge		N
	Instructions described method to determine state of INTERNAL ELECTRICAL POWER SOURCE		N
8.5.2	Means, other than labelling, provided to prevent RISK of swallowing coin/button cells	No such parts	N
	Replacement of button cell require use of TOOL	No button cell used	N

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Clause	Requirement + Test	Result - Remark	Verdict

9	ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS		N/E
	The RISKS associated with USABILITY in the HOME HEALTHCARE ENVIRONMENT for OPERATOR PROFILES including a LAY OPERATOR when performing the USABILITY ENGINEERING PROCESS include at least the following considerations:		N/E
	– changes of controls	See USABILITY ENGINEERING FILE	N/E
	– unexpected movement		N/E
	– potential for misconnection		N/E
	– potential for improper operation, or unsafe use		N/E
	– potential for confusion as to current operational mode		N/E
	– change in the transfer of energy or substance		N/E
	- exposure to environmental conditions specified in this standard		N/E
	– exposure to biological materials, and		N/E
	– small parts being inhaled or swallowed		N/E
	Particular emphasis placed on the limited training of a LAY OPERATOR with respect to the ability to intervene and maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.		N/E
	The MANUFACTURER'S USABILITY ENGINEERING PROCESS included the least capable intended LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION	See USABILITY ENGINEERING FILE	N/E
	USABILITY ENGINEERING FILE inspected for compliance ..... :	See USABILITY ENGINEERING FILE	N/E

10	CONSTRUCTION OF ME EQUIPMENT		P
10.1	Additional requirements for mechanical strength		P
10.1.1	Additions to Table 28 Mechanical strength test of the base standard, conducted as indicated in Table 1, Mechanical strength test applicability, non-TRANSIT-OPERABLE, and Table 2, Mechanical strength test applicability, TRANSIT-OPERABLE	Table 1	P
10.1.2	ME EQUIPMENT, its parts, and mounting ACCESSORIES, intended for non-TRANSIT-OPERABLE use displayed adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, dropping and rough handling (not applicable to FIXED and STATIONARY ME EQUIPMENT)	NOT TRANSIT-OPERABLE	P

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after mechanical tests		P
	OPERATOR-re-settable protective devices that can be reset without the use of a TOOL were, optionally, reset prior to the evaluation of BASIC SAFETY and ESSENTIAL PERFORMANCE		P
	a) Shock tests conducted in accordance with IEC 60068-2-27:2008..... :	See Appended Table 10.1.2a	P
	b) Broad-band random vibration tests conducted in accordance with IEC 60068-2-64:2008, using the following conditions..... :	See Appended Table 10.1.2b	P
10.1.3	ME EQUIPMENT, parts, and mounting ACCESSORIES for TRANSIT-OPERABLE use displayed adequate mechanical strength when subjected to pushing, impact, dropping, rough handling, and rigorous conditions of PATIENT movement in NORMAL USE as well as transportation by trolleys, carts, road vehicles, trains, ships, and aircraft		N
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after the following tests:		N
	a) Shock tests conducted on other than HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-27:2008		N
	1) Test type: Type 1..... :		N
	2) Test type: Type 2..... :		N
	b) Shock tests conducted on HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-27:2008		N
	1) Test type: Type 1..... :		N
	2) Test type: Type 2..... :		N
	c) Broad-band random vibration test conducted on ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-64:2008..... :		P
	d) Free fall tests conducted on PORTABLE and MOBILE ME EQUIPMENT, parts, and mounting ACCESSORIES per IEC 60068-2-31:2008, using PROCEDURE 1 .....:		N
	BASIC SAFETY and ESSENTIAL PERFORMANCE were maintained		N
10.2	Controls of ME EQUIPMENT intended for use by a LAY OPERATORY that can affect BASIC SAFETY or ESSENTIAL PERFORMANCE protected from accidental or unauthorized changes or adjustments	No such part	N

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Clause	Requirement + Test	Result - Remark	Verdict
	OPERATOR-adjustable controls used for calibration include a means to prevent unintentional changes from the intended position		N
11	PROTECTION AGAINST STRANGULATION OR ASPHYXIATION		N
	Means provided to control the RISK of strangulation and asphyxiation of the PATIENT and others to an acceptable level		N
	EQUIPMENT and RISK MANAGEMENT FILE inspected.....:		N
12	ADDITIONAL REQUIREMENTS FOR ELECTROMAGNETIC EMISSIONS OF ME EQUIPMENT AND ME SYSTEMS		N/E
	ME EQUIPMENT and ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT are Class B according to CISPR 11:2009.....:		N/E
13	ADDITIONAL REQUIREMENTS FOR ALARM SYSTEMS OF ME EQUIPMENT AND ME SYSTEMS		N
13.1	Each HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITION causes generation of auditory ALARM SIGNALS per IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, except when equipment is connected to a DISTRIBUTED ALARM SYSTEM intended for confirmed deliver of ALARM CONDITIONS including the generation of auditory ALARM SIGNALS per IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012.....:	No ALARM SYSTEM	N
13.2	For ME EQUIPMENT and ME SYSTEMS intended to actively keep alive or resuscitate a PATIENT, reducing the auditory ALARM SIGNAL volume T below audible levels resulted in the following was not possible, except when the ALARM SYSTEM was connected to a DISTRIBUTED ALARM SYSTEM that included generation of auditory ALARM SIGNALS per IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012		N

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: Permissible environmental conditions of transport and storage, between uses, indicated in instructions for use		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	File No.: TCF-010 Version: A/0.	Intend use and identification of characteristics related to the safety of the medical device	P
4.3	File No.: TCF-010 Version: A/0.	Identification of hazards	P
4.4	File No.: TCF-010 Version: A/0.	Estimation of the risk(s) for each hazardous situation	P

4.2.3.1	RM RESULTS TABLE: Environmental operating conditions - Continuous operating conditions		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	File No.: TCF-010 Version: A/0.	Intend use and identification of characteristics related to the safety of the medical device	P
4.3	File No.: TCF-010 Version: A/0.	Identification of hazards	P
4.4	File No.: TCF-010 Version: A/0.	Estimation of the risk(s) for each hazardous situation	P

7.4.1	RM RESULTS TABLE: Additional requirements for warning and safety notices		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	File No.: TCF-010 Version: A/0.	Intend use and identification of characteristics related to the safety of the medical device	P
4.3	File No.: TCF-010 Version: A/0.	Identification of hazards	P
4.4	File No.: TCF-010 Version: A/0.	Estimation of the risk(s) for each hazardous situation	P
5	File No.: TCF-010 Version: A/0.	Risk evaluation	P
6.2	File No.: TCF-010 Version: A/0.	Risk control option analysis	P

7.4.5	RM RESULTS TABLE: : Additional requirements for operating instructions	P

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Clause	Requirement + Test	Result - Remark	Verdict

Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	File No.: TCF-010 Version: A/0.	Identification of hazards	P
4.4	File No.: TCF-010 Version: A/0.	Estimation of the risk(s) for each hazardous situation	P
5	File No.: TCF-010 Version: A/0.	Risk evaluation	P
6.2	File No.: TCF-010 Version: A/0.	Risk control option analysis	P

8.4	RM RESULTS TABLE: Additional requirements for interruption of power supply / supply mains to ME Equipment and ME Systems		N
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
5			
6.2			
6.3			
6.4			
6.5			
6.6			
6.7			

10.1.2a	TABLE: Shock test (IEC 60068-2-27:2008), using the following conditions*:		P
	Peak acceleration..... :	150 m/s^2 (15 g)	
	Duration..... :	11 ms	
	Pulse shape..... :	half-sine	
	Number of shocks..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
+X	X Axis	Yes	No damage after test
+X			
+X			
-X			
-X			

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Clause	Requirement + Test	Result - Remark	Verdict

-X			
+Y	Y Axis	Yes	No damage after test
+Y			
+Y			
-Y			
-Y			
-Y			
+Z	Z Axis	Yes	No damage after test
+Z			
+Z			
-Z			
-Z			
-Z			
Supplementary information:NON-TRANSIT-OPERABLE and PORTABLE Equipment *(NOTE 1 This represents Class 7M1 as described in IEC TR 60721-4-7:2001 [6])			

10.1.2b	TABLE: Broad-band random vibration test (IEC 60068-2-64:2008) using the following conditions*:		P
1	Acceleration amplitude..... :	10 Hz to 100 Hz: 1,0 $(m/s^2)^2/Hz$	
2	Acceleration amplitude..... :	100 Hz to 200 Hz: – 3 db per octave	
3	Acceleration amplitude..... :	200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2/Hz$	
	Duration..... :	30 min per perpendicular axis (3 total)	

Perpendicular axis subjected to broad-band random vibration test	Acceleration amplitude	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
1	1	Yes	No damage after test
2			
3			
1	2	Yes	No damage after test
2			
3			
1	3	Yes	No damage after test
2			
3			

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information: NON-TRANSIT-OPERABLE and PORTABLE Equipment * (NOTE 2 This represents Class 7M1 and 7M2 as described in IEC TR 60721-4-7:2001)

10.1.3a1	TABLE: Shock test (IEC 60068-2-27:2008) for other than HAND-HELD EQUIPMENT, parts, and mounting ACCESSORIES under the following conditions (Test Type 1):		N
	Peak acceleration..... :	150 m/s^2 (15 g)	
	Duration..... :	11 ms	
	Pulse shape..... :	half-sine	
	Number of shocks..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks

Supplementary information: * (NOTE 3 This represents Class 7M2 as described in IEC/TR 60721-4-7:2001 [6])

10.1.3a2	TABLE: Shock test (IEC 60068-2-27:2008) on other than HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES under the following conditions (Test Type 2):		N
	Peak acceleration..... :	300 m/s^2 (15 g)	
	Duration..... :	6 ms	
	Pulse shape..... :	half-sine	
	Number of shocks..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks

Supplementary information:

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict

10.1.3b1	TABLE: Shock test (IEC 60068-2-27:2008) on HAND-HELD ME EQUIPMENT parts, and mounting ACCESSORIES using the following conditions (Test Type 1):			N
	Peak acceleration..... :	300 m/s^2 (30 g)		
	Duration..... :	11 ms		
	Pulse shape..... :	half-sine		
	Number of shocks..... :	3 shocks per direction per axis (18 total)		
Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks	
Supplementary information: *(NOTE 4 This represents Class 7M3 as described in IEC/TR 60721-4-7:2001. (Test Type 1)				

10.1.3b2	TABLE: Shock test (IEC 60068-2-27:2008) on HAND-HELD ME EQUIPMENT parts, and mounting ACCESSORIES using the following conditions (Test Type 2):			N
	Peak acceleration..... :	1000 m/s^2 (100 g)		
	Duration..... :	6 ms		
	Pulse shape..... :	half-sine		
	Number of shocks..... :	3 shocks per direction per axis (18 total)		
Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks	
Supplementary information:				

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict

10.1.3c	TABLE: Broad-band random vibration test (IEC 60068-2-64:2008) on ME EQUIPMENT, parts, and mounting ACCESSORIES using the following conditions*:		N
1	Acceleration amplitude..... :	10 Hz to 100 Hz: 1,0 $(m/s^2)^2/Hz$	
2	Acceleration amplitude..... :	100 Hz to 200 Hz: - 3 db per octave	
3	Acceleration amplitude..... :	200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2/Hz$	
	Duration..... :	30 min per perpendicular axis (3 total)	

Perpendicular axis subjected to broad-band random vibration test	Acceleration amplitude	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks

Supplementary information:

*(NOTE 5 This represents Class 7M1 and 7M2 as described in IEC/TR 60721-4-7:2001)

10.1.3d	TABLE: Free fall test (IEC 60068-2-31:2008), using PROCEDURE 1, on PORTABLE and MOBILE ME EQUIPMENT, parts, and mounting ACCESSORIES (with carrying case if intended), under the following conditions*:		N
1	Fall height for mass ≤ 1 kg..... :	0,25 m	
2	Fall height for mass > 1 kg and ≤ 10 Kg..... :	0,1 m	
3	Fall height for mass > 10 kg and ≤ 50 Kg..... :	0,05 m	
4	Fall height for mass > 50 kg..... :	0,01 m	

Specified altitude (m)	Mass (Kg)	Fall No.	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
0,25	≤ 1	1		
0,25	≤ 1	2		
0,1	> 1 & ≤ 10	1		
0,1	> 1 & ≤ 10	2		
0,05	> 10 & ≤ 50	1		
0,05	> 10 & ≤ 50	2		
0,01	> 50	1		
0,01	> 50	2		

Supplementary information:

(*NOTE 6 This represents Class 7M2 as described in IEC/TR 60721-4-7:2001)

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Clause	Requirement + Test	Result - Remark	Verdict

11.0	**RM RESULTS TABLE: PROTECTION AGAINST STRANGULATION AND ASPHYXIATION**		
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
6.6			
Supplementary information:			

----- End of report -----