Test Report No. 7191355668-EEC25
dated 25 AUG 2025

PSB Singapore

Add value.
Inspire trust.

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

Subject

TEST REPORT ON COUGH WATCH

Client

Hyfe Inc
1209 N Orange Street, Wilmington, Delaware, 19802 USA

Attn: Tamsin Chislett

Sample Submission Date

08 MAY 2025

Description of Samples

Cough Watch

Model : H026
Rating : 3.8V, 300mAh (Internally powered), Type BF Applied Part

		LA-2007-0380-A LA-2007-0381-F LA-2007-0382-B LA-2007-0383-G LA-2007-0384-G LA-2007-0385-E	LA-2007-0386-C LA-2010-0464-D LA-2018-0702-B LA-2018-0703-G LA-2020-0747-L

The results reported herein have been performed in accordance with the terms of accreditation under the Singapore Accreditation Council. Inspections/Calibrations/Tests marked "Not SAC-SINGLAS Accredited" in this Report are not included in the SAC-SINGLAS Accreditation Schedule for our inspection body/laboratory.

Laboratory:
TÜV SÜD PSB Pte. Ltd.
15 International Business Park
TÜV SÜD @ IBP
Singapore 609937

Phone : +65-6778 7777
E-mail: info.sg@tuvsud.com
https://www.tuvsud.com/en-sg
Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
15 International Business Park
TÜV SÜD @ IBP
Singapore 609937

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

Report Number. .....:	7191355668-EEC25
Date of issue.....:	25 AUG 2025
Total number of pages .....:	154
Name of Testing Laboratory preparing the Report .....:	TÜV SÜD PSB Pte Ltd 15 International Business Park, TÜV SÜD @ IBP, Singapore 609937
Applicant's name.....:	Hyfe Inc
Address .....:	1209 N Orange Street, Wilmington, Delaware, 19802 USA
Test specification:	
Standard .....:	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Non-standard test method .....:	N/A
TRF template used .....:	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No.....:	IEC60601_1U
Test Report Form(s) Originator ....:	UL(US)
Master TRF .....:	2023-08-24

General disclaimer:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description ..... :	Cough Watch
Trade Mark(s) ..... :	Hyfe
Manufacturer ..... :	Hyfe Inc 1209 N Orange Street, Wilmington, Delaware, 19802 USA
Model/Type reference ..... :	H026
Ratings ..... :	3.8V, 300mAh (Internally powered), Type BF Applied Part

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

☒	**CB Testing Laboratory:**	TÜV SÜD PSB Pte Ltd	
Testing location/ address ..... :		15 International Business Park, TÜV SÜD @ IBP, Singapore 609937	
Tested by (name, function, signature) ..... :		Ng Chin Heng, tester	
Approved by (name, function, signature) .. :		Posen Fu, reviewer	
☐	**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 (including a total number of pages in each attachment):

Attachment 1: Photographs (7 pages)
Attachment 2: Packaging Label (1 page)
Attachment 3: United States National Differences to IEC 60601-1-:2020 (4 pages)
Attachment 4: IEC 60601-1-11:2015, AMD1:2020 (34 pages)
Attachment 5: United States National Differences to IEC 60601-1-11:2020 (1 page)

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
All applicable tests were performed. **Exceptions:** The following clauses were not part of the manufacturers order and therefore excluded from this testing: Clause 11.7 Biocompatibility, referencing ISO 10993. Clause 12.2, 15.1 Usability, referencing IEC 60601-1-6 Clause 17 EMC, referencing IEC 60601-1-2.	TÜV SÜD PSB Pte Ltd 15 International Business Park, TÜV SÜD @ IBP, Singapore 609937

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

- European Union (EN) (no declared national differences)
- United States (US)

☒ **The product fulfils the requirements of IEC 60601-1:2005/AMD2:2020; EN 60601-1:2006/A2:2021 and ANSI/ES60601-1:2005/AMD2:2021 except for those excluded clauses as listed in Summary of testing above.**

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

(may be required by the product standard or client)

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

Procedure number, issue date and title:

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**

(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

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.

Test item particulars.....:	
Classification of installation and use .....:	Body-worn
Supply Connection .....:	Internally powered
Device type (component/sub-assembly/ equipment/ system)……..:	Equipment
Intended use (Including type of patient, application location)……:	See General product information
Mode of operation……:	Continuous
Accessories and detachable parts included……..:	See General product information
Other options include……..:	None
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..... :	08 April 2025
Date (s) of performance of tests ..... :	08 April 2025 to 30 July 2025

General remarks:
"(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. The tests results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report. **Risk management files:** The RMF has been evaluated according plausibility and technical consistency based on respective requirements out of ISO 14971. The risk acceptance criteria have been set by the manufacturer. **Throughout this report a ☐ comma / ☒ point is used as the decimal separator.**

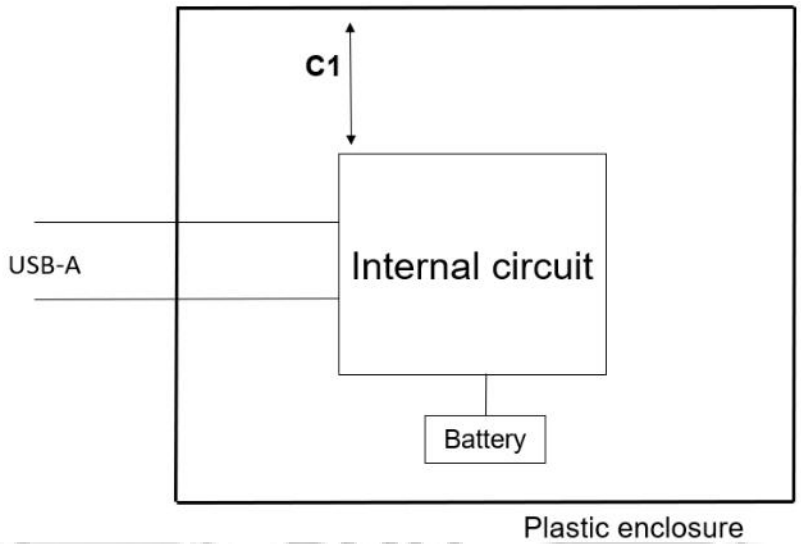
Name and address of factory (ies) .....:	Shenzhen DO Intelligent Technology Co., Ltd 6# Building, Guole Tech Park, Lirong Road, Dalang, Longhua District, Shenzhen, Guangdong, P.R.China.

General product information:	
Remark 1:	The Hyfe Cough Diary is intended to quantify coughing. It uses a software algorithm to passively detect coughs, and reports their timing and frequency, enabling long-term monitoring of cough patterns and trends. The Hyfe Cough Diary is an over-the-counter device intended to be used to quantify coughing by passively detecting and timestamping coughs, which are reported as coughs per hour. The Hyfe Cough Diary is intended to be used in daily living environments (i.e., home, day to day living and work environments) by people who are 21 and older and considering seeking health care for their problematic cough. A licensed health care professional's advice is required when making medical decisions based on the results from the Hyfe Cough Diary. The Hyfe Cough Diary output should only be interpreted in the context of all available clinical information
Remark 2:	Model: H206 is similar to model: ID206 (SGS Test Report SZES201200875201) except for firmware. The hardware for both models is the same.
Remark 2:	The applied part is considered as type BF as defined in the manual. The maximum operating ambient is 40°C.
Remark 3	The Medical Electrical Equipment includes the following: • Device (Cough Watch) • USB Charging Cable
Remark 4:	Testing/Evaluation considerations: The Cough Watch tested was a production equivalent and not a prototype. For charging condition, EUT is charged through a proprietary USB cable from a standard USB Type A port.
Remark 5:	Documentation inspection is performed based on the following provided by manufacturer: • HYF7-003-009-3 Hyfe Cough Diary User Guide • HYF7-003-010-2 Hyfe Cough Diary Quick Start Guide • HYF7-004-001 Hyfe Cough Diary Risk Management Plan • HYF7-004-003 Hyfe Cough Diary Risk Assessment • HYF7-004-003 Hyfe Cough Diary Risk Management Report • HYF7-004-002 Identification of hazards and characteristics related to safety • SOP_007_Risk Management Procedure

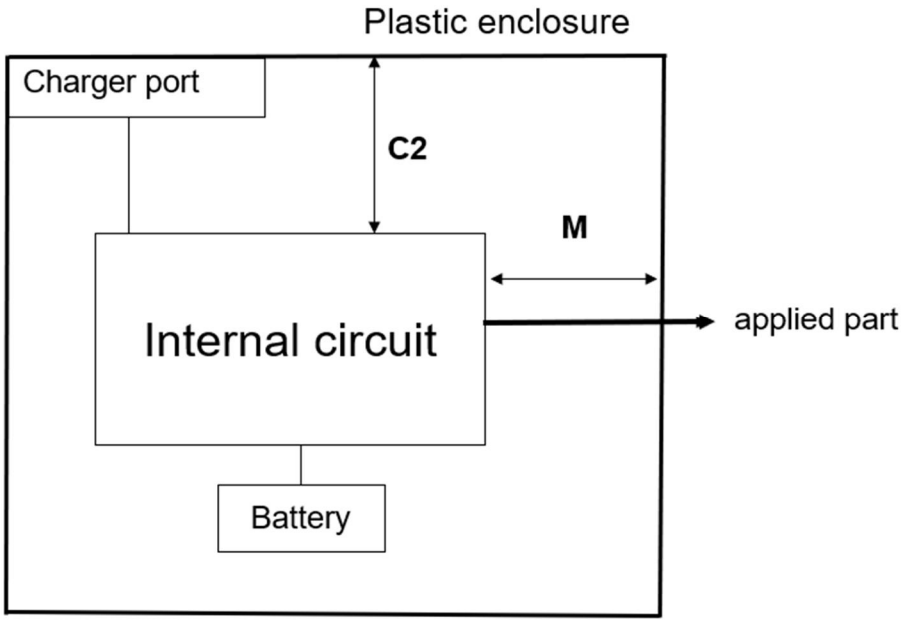
IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM

Charging configuration



Patient configuration



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

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

Area	**Number and type of Means of Protection: MOOP, MOPP**	**CTI**	**Working voltage**		**Required creepage (mm)**	**Required clearance (mm)**	**Measured creepage (mm)**	**Measured clearance (mm)**	**Remarks**
			V_{rms}	**V_{pk}**					
Charging Configuration									
C1	2 MOPP	IIIb	-	5 vdc	3.4	1.6	4.0	4.0	Internal circuits to enclosure
Patient Configuration									
C2	2 MOPP	IIIb	-	-	3.4	1.6	4.0	4.0	Internal circuits to enclosure
M	2 MOPP	IIIb	-	5 vdc	3.4	1.6	> 4.4	> 2.1	Between internal circuits (patient circuit of BF Applied Part) to enclosure. See Note 1

Supplementary Information:

Note 1: Measured value exceeds the limit by more than 30% is allowed for alternative reporting method according to OD-2020 Clause 5.6.1

Note 2: Applied Part (AP) is not electrically connected to patient. The whole watch is considered as applied part.

Description:	
Area	**Insulation between:**
C	LIVE and accessible parts that are not protectively earthed
M	Patient connection(s) of F-type applied part and all other parts, including the patient connection(s) of other applied parts

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

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

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

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

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

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

4	**GENERAL REQUIREMENTS**		**P**
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		P
4.2	RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS		P
4.2.2	General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2019)……..:	See Appended RM Results Table 4.2.2.	P
4.2.3	Evaluating RISK		P
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level		P
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN…… :	RISK MANAGEMENT PLAN Document: HYF7-004-001 Hyfe Cough Diary Risk Management Plan	P
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		P
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		P
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.		P
4.3	Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.	No essential performance	N/A
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.		N/A
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		N/A
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE……:	No essential performance	N/A
	- RISK CONTROL measures implemented		N/A
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		N/A
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE……..:	HYF7-004-003 Hyfe Cough Risk Management Report: 1 year	P
4.5	Alternative RISK CONTROL methods utilized:	No alternative risk control measure or test method used	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. 5.2-5.5, 6, 7.1-7.4)	No alternative risk control measure or test method used	N/A
	Alternative means based scientific data or clinical opinion or comparative studies ……..:	No alternative risk control measure or test method used	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. 5.2-5.5, 6, 7.1-7.4)	No such parts	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……..:	ME Equipment remained single fault safe	P
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested……..: (ISO 14971 Cl. 5.2-5.5)	RISK ANALYSIS reference: HYF7-004-003 Hyfe Cough Diary Risk Assessment (ISO 14971 Cl. 5.2-5.5)	P
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically……..:	See appended Table 13.2 for simulated physical test	P
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified ……..:	Components used within their ratings	P
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS		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. 5.2-5.5, 6, 7.1-7.4)	Components used within their ratings	N/A
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION ……..:	No such components	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Components determined to be acceptable where used as a MEANS OF PROTECTION …….:	No such components	N/A
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following		P
	a) Applicable safety requirements of a relevant IEC or ISO standard	Certified components used	P
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		P
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately……..:	See appended Table 8.10 b No high-integrity characteristics components used	N/A
	RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	See above	N/A
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:	See above	N/A
4.10	Power supply		P
4.10.1	ME EQUIPMENT is suitable for connection to indicated power source (select applicable) ……:	Internally powered	P
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:	Not intended to be connected to Supply Mains	N/A
	- 250 V for HAND-HELD ME EQUIPMENT (V) ..... :	See above	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)..... :	See above	N/A
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS	See above	N/A
4.11	Power input		N/A
	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 Internally powered equipment	N/A
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 relevant tests have been performed. No other test methods used	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. (ISO 14971 Cl. 5.2-5.5)	See above	N/A
5.3	Tests conducted within the environmental conditions specified in technical description		P
	Temperature (ºC), Relative Humidity (%) …….:	+5°C to +40°C 15% to 95% RH	—
	Atmospheric Pressure (kPa) ……:	70.0 kPa to 106.0 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)……..:	Internally powered equipment	N/A
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)..... :	Internally powered equipment	N/A
	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 ..... :	Internally powered equipment	N/A
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered..... :	Internally powered equipment	N/A
	e) ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions ..... :	No such parts	N/A
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	Internally powered equipment	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……..:	Humidity preconditioning performed	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 = 168H	P
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		P
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS..... :	Type BF Applied Part	P

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

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 such 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 .....:	No such parts	N/A
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		**P**
6.2	CLASS I ME EQUIPMENT, externally powered		N/A
	CLASS II ME EQUIPMENT, externally powered		N/A
	INTERNALLY POWERED ME EQUIPMENT		P
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements		N/A
	TYPE B APPLIED PART		N/A
	TYPE BF APPLIED PART		P
	TYPE CF APPLIED PART		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS		N/A
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529 ..... :	IP27	P
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use..... :	Not intended to be sterilized.	N/A
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2	Not intended for use in OXYGEN RICH ENVIRONMENT	N/A
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION ..... :	Continuous operation	P
7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		**P**
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6.....:	See Appended Table 7.1.2	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE	See appended Tables 7.1.3 and 8.10	P
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		P
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ……..:	See attached copy of Marking Plate	P
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS ……..:	User Guide: Symbols	P
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT	See copy of packaging label	P
	Single use item marked……..:	No such parts	N/A
7.2.2	ME EQUIPMENT marked with:		P
	– the name or trademark and contact information of the MANUFACTURER	See attached copy of Marking Plate. Captured in serial number	P
	– a MODEL OR TYPE REFERENCE	See attached copy of Marking Plate. Captured in serial number	P
	– a serial number or lot or batch identifier; and	See attached copy of Marking Plate. Captured in serial number	P
	– the date of manufacture or use by date	See attached copy of Marking Plate. Captured in serial number	P
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	No such parts	N/A
	RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.3)	No detachable parts	N/A
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and		N/A
	– a MODEL OR TYPE REFERENCE		N/A
	Software forming part of a PEMS identified with a unique identifier……..:	No PEMS provided within EUT	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.2.3	Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS	Symbol 11 on Table D.1 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 ……..:	No accessories	N/A
	- with a MODEL or TYPE REFERENCE		N/A
	– a serial number or lot or batch identifier		N/A
	– the date of manufacture or use by date		N/A
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		N/A
7.2.5	ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following	Not intended to receive power from other sources.	N/A
	- the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or		N/A
	– Table D.2, SAFETY SIGN No. 10 adjacent to the relevant connection point and listing of the required details in the instructions for use; or		N/A
	– Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use.		N/A
7.2.6	Connection to the Supply Mains		N/A
	Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point	Not intended to be connected to the Supply Mains. Internally powered equipment	N/A
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT	Not permanently installed ME Equipment	N/A
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V)……..:	Not intended to be connected to the Supply Mains	N/A
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)…..:	Not intended to be connected to the Supply Mains	N/A
	– Nature of supply and type of current……..:	Not intended to be connected to the Supply Mains	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Symbols 1-5, Table D.1 (used for same parameters……:	Not intended to be connected to the Supply Mains	N/A
	– RATED supply frequency or RATED frequency range in hertz……..:	Not intended to be connected to the Supply Mains	N/A
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT……..:	Not intended to be connected to the Supply Mains.	N/A
7.2.7	RATED input in amps or volt-amps, (A, VA)……:	Internally powered equipment	N/A
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W)……..:	Not intended to be connected to the Supply Mains	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)……..:	Not intended to be connected to the Supply Mains	N/A
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W)……..:	Not intended to be connected to the Supply Mains	N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA)……..:	Not intended to be connected to the Supply Mains	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 intended to be connected to the Supply Mains	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)……..:	See above	—
	Rated Power (W), Output Frequency (Hz)…….:	See above	—
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….:	IP27 marked in the packaging label and User Guide	P
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols ……..:	Type BF Applied Part	P
	TYPE B APPLIED PARTS with symbol 19 of Table D.1……..:	Not Type B Applied Part	N/A

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

	TYPE BF APPLIED PARTS with symbol 20 of Table D.1:	Type BF Applied Part Symbol 20 of Table D.1 used	P
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1……..:	Not Type CF Applied Part	N/A
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1…….:	Not defibrillation-proof Applied Part	N/A
	Proper symbol marked adjacent to or on connector for APPLIED PART……..:	Marked on watch	P
	SAFETY SIGN 2 of Table D.2 placed near relevant outlet……..:	Not defibrillation-proof Applied Part	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 defibrillation-proof Applied Part	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	No accessible fuse holder	N/A
	Fuse type……..…:	See above	—
	Voltage (V) and Current (A) rating…….:	See above	—
	Operating speed (s) and Breaking capacity……:	See above	—
7.2.13	Physiological effects – SAFETY SIGN and warning statements ……..:	Does not produce psychological effects that are not obvious to operator and can cause harm to patient	N/A
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use……: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	See above	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 high voltage terminal device	N/A
7.2.15	Requirements for cooling provisions marked……:	No cooling provisions provided	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.2.17	Packaging marked with special handling instructions for transport and/or storage……:	There are no special handling requirements during transport and storage. There is no known risk associated with premature unpacking of the system. The permissible conditions for transport and storage are marked on the device shipper.	N/A
	Permissible environmental conditions marked on outside of packaging……..:	See copy of packaging label	P
	Packaging marked with a suitable SAFETY SIGN indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK……..:	No special requirements for un-packing	N/A
	RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK……: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	No unacceptable risk associated with premature unpacking	N/A
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization	Not sterile ME equipment or accessories	N/A
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and ……..:	No external pressure source	N/A
	- the RATED flow rate also marked		N/A
7.2.19	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL……..:	No functional earth terminal	N/A
7.2.20	Removable protective means marked to indicate the necessity for replacement when the function is no longer needed……..:	No removable protective 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		N/A
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W)……:	Not designed for use with heating lamps	N/A
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.3.2	Symbol 24 of Table D.1, or SAFETY SIGN No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts……..:	No high voltage parts	N/A
7.3.3	Type of battery and mode of insertion marked..:	Only internal non-replaceable battery used	N/A
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL……..:	No replaceable batteries	N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK.....:	No replaceable batteries	N/A
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an HAZARDOUS SITUATION if replaced incorrectly……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	No replaceable batteries	N/A
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARDOUS SITUATION……..:	No replaceable batteries	N/A
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified ……..:	No such parts	N/A
	Voltage (V) and Current (A) rating……..	See above	—
	Operating speed(s), size & breaking capacity….:	See above	—
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1	No protective earth terminal	N/A
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		N/A
7.3.6	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS	No such terminals	N/A
7.3.7	Terminals for supply conductors marked adjacent to terminals……..:	No such terminals	N/A
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings		N/A
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3	Not permanently installed equipment	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Marking for connection to a 3-phase supply, complies with IEC 60445	Not intended to be connected to a 3-phase supply.	N/A
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		N/A
7.3.8	"For supply connections, use wiring materials suitable for at least X °C" or equivalent, marked at the point of supply connections	Not permanently installed equipment	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, including mains switch, marked with symbols 12 and 13 of Table D.1 or	No such controls	N/A
	– indicated by an adjacent indicator light, or		N/A
	– indicated by other unambiguous means		N/A
	The "on" & "off" positions of switch to control power to parts of ME EQUIPMENT, marked with symbols 12 and 13 of Table D.1 or	No such parts	N/A
	- marked with symbols 16 and 17 of Table D.1 or		N/A
	– indicated by an adjacent indicator light, or		N/A
	– indicated by other unambiguous means		N/A
	Switches that brings ME EQUIPMENT into "stand-by" may be indicated by symbol 29 of Table D.1		N/A
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, and	No such parts	N/A
	– status indicated by adjacent indicator light		N/A
	– status indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or		N/A
	– status indicated by adjacent indicator light		N/A
	– status indicated by other unambiguous means		N/A
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means	No such controls	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1, 7.2)	See above	N/A
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE……..:	See above	N/A
	– or an indication of direction in which magnitude of the function changes		N/A
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units	No numeric indications on device	N/A
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units		N/A
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3……..:	See Appended Tables 7.1.2 and 7.1.3.	N/A
7.5	SAFETY SIGNS		N/A
	SAFETY SIGN with established meaning used	No safety sign used	N/A
	RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	See above	N/A
	Affirmative statement together with SAFETY SIGN placed in instructions for use if insufficient space on ME EQUIPMENT	See above	N/A
	Specified colours in ISO 3864-1 used for SAFETY SIGNS……..:	See above	N/A
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)	See above	N/A
	SAFETY SIGNS including any supplementary text or symbols described in instructions for use		N/A
	- and in a language acceptable to the intended OPERATOR		N/A
7.6	Symbols		P
7.6.1	Meanings of symbols used for marking described in instructions for use……..:	User Guide: Symbols	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable		P
7.7	Colours of the insulation of conductors		N/A
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation	No protective earth conductor	N/A
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations		N/A
7.7.3	Green and yellow insulation identify only following conductors:		N/A
	– PROTECTIVE EARTH CONDUCTORS		N/A
	– conductors specified in 7.7.2		N/A
	– POTENTIAL EQUALIZATION CONDUCTORS		N/A
	– FUNCTIONAL EARTH CONDUCTORS		N/A
7.7.4	Neutral conductors of POWER SUPPLY CORDS are “light blue”	No power supply cord	N/A
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1	No power supply cord	N/A
7.8	Indicator lights and controls		N/A
7.8.1	Red indicator lights, not flashing used only for Warning	No safety related colours used. No such red indicator provided	N/A
	Yellow indicator lights, not flashing used only for Caution	No such yellow indicator provided	N/A
	Green indicator lights used only for Ready for use	No such green indicator provided	N/A
	Red flashing used only for HIGH PRIORITY ALARM CONDITION, interruption of current workflow needed	No such red flashing indicator provided	N/A
	Yellow flashing used only MEDIUM PRIORITY ALARM CONDITION, re-planning of workflow needed	No such yellow flashing indicator provided	N/A
	Yellow or Cyan, not flashing used for LOW PRIORITY ALARM CONDITION, planning of future workflow needed.	No such colours used	N/A
	Other colours: Meaning other than red, yellow, cyan or green (colour, meaning)……:	No such other colours used	N/A
7.8.2	Red used only for emergency control		N/A
7.9	ACCOMPANYING DOCUMENTS		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.1	ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description	User Guide	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……..:	User Guide – last page Manufacturer: Hyfe Inc.	P
	– MODEL or TYPE REFERENCE……..:	User Guide – Watch Model: H206	P
	When ACCOMPANYING DOCUMENTS provided electronically, USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT	User Guide is provided both in hard copy and electronically	N/A
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use		P
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended		P
7.9.2	Instructions for use include the required information		P
7.9.2.1	– use of ME EQUIPMENT as intended by the MANUFACTURER:	User Guide – Intended Use	P
	– frequently used functions,	User Guide	P
	– known contraindication(s) to use of ME EQUIPMENT	User Guide – Contraindications	P
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient	User Guide – Cautions	P
	– name or trademark and address of the MANUFACTURER	User Guide – Support	P
	– MODEL OR TYPE REFERENCE	1st page of User Guide	P
	Instruction for use included the following when the PATIENT is an intended OPERATOR:		P
	– the PATIENT is an intended OPERATOR	User Guide	P
	– warning against servicing and maintenance while the ME EQUIPMENT is in use	User Guide – Cautions	P
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and	User Guide – Warnings – Cautions	P

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

	–maintenance the PATIENT can perform	no maintenance to be performed by user	N/A
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of SAFETY SIGNS and symbols marked on ME EQUIPMENT	User Guide – Symbols	P
	Instructions for use are in a language acceptable to the intended operator	User Guide evaluated in English language	P
7.9.2.2	Instructions for use include all warning and safety notices	User Guide – Warnings – Cautions	P
	Warning statement for CLASS I ME EQUIPMENT included	Not Class I ME equipment	N/A
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	No risk posed by reciprocal interference	N/A
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	User Guide – Warnings – Cautions – Wireless Communication	P
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	No multiple socket-outlet used	P
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	Not considered as a ME System	P
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions		N/A
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source	Not Mains-Operated ME Equipment	N/A
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries……: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	Specific RISKS: HYF7-004-003 Hyfe Cough Diary Risk Assessment Hazard ID: 2.16 (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	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.....:	Battery not intended to be removed	N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided…….:	Internal battery is not replaceable	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK……:	Loss of power does not result in unacceptable risk	N/A
7.9.2.5	Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE	User Guide	P
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to		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		N/A
	APPLIED PARTS specified	User Guide – Technical Information: IEC 60601 Classification	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	No installation required	N/A
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device	No Appliance Coupler or Mains Plug used	N/A
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation	User Guide – Using the Cough Watch	P
7.9.2.9	Information provided to operate ME EQUIPMENT	User Guide	P
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	User Guide – Symbols; Warnings; Cautions	P
7.9.2.10	A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message	User Guide – Troubleshooting	P
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	User Guide – Discontinuing use of the Cough Watch	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	User Guide – Cautions	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	No such single use parts	N/A
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	Inspection, calibration, and maintenance are not to be performed by user	N/A
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	Maintenance is not to be performed by user	N/A
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	Maintenance is not to be performed by service personnel	N/A
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	Rechargeable battery is not intended to be maintained by user	N/A
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	User Guide – Replacement Parts / Accessories	P
	Other equipment providing power to ME SYSTEM sufficiently described	Not intended to receive power from other equipment	N/A
7.9.2.15	Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for us……..:	User Guide – Cautions	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)	User Guide – Technical Information	P
7.9.2.17	Instruction for use for ME EQUIPMENT emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation	No radiation emitted	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	Device not 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	Device not supplied sterile	N/A
7.9.2.19	The instructions for use contain a unique version identifier……..:	HYF7-003-009-3, where “IFU_1000.01” is the document identifier, and “3” is the version number	P

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

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	User Guide – Technical Information	P
	-information required in 7.2		P
	-permissible environmental conditions of use including conditions for transport and storage…….. :	User Guide – Technical Information	P
	-characteristics of the ME EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found	User Guide	P
	-special installation requirements such as the maximum permissible apparent impedance of SUPPLY MAINS	No special installation is required	N/A
	-permissible range of values of inlet pressure and flow, and the chemical composition of cooling liquid	No inlet pressure or cooling liquid	N/A
	-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	User Guide – Cautions	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	Equipment has no Essential Performance functions	N/A
	Technical description separable from instructions for use contains required information, as follows		N/A
	-information required by 7.2		N/A
	–applicable classifications in Clause 6, warning and safety notices, and explanation of SAFETY SIGNS marked on ME EQUIPMENT	Technical description is not separable from the User Guide	N/A
	– brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and	See above	N/A
	a unique version identifier……..:	See above	N/A
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description	See above	N/A
7.9.3.2	The technical description contains the following required information		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT……..:	Not permanently installed ME equipment	N/A
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and	No such power supply cord	N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	No replaceable parts by service personnel	N/A
	RISK MANAGEMENT FILE includes an assessment to determine if replacement of components results in any unacceptable RISKS……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	No such parts	N/A
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component	No user serviceable parts. To contact manufacturer for repairs	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	No serviceable parts	N/A
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description		N/A
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		**P**
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS		P
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION……..: (ISO 14971 Cl. 5.4)	No hazardous parts	N/A
8.2	Requirements related to power sources		P
8.2.1	Connection to a separate power source		P
	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	Only USB connection	N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined	No generic PSU	N/A
8.2.2	Connection to an external d.c. power source		N/A
	No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source	Wrong polarity is not possible. Only USB connection	N/A
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE		N/A
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset		N/A
8.3	Classification of APPLIED PARTS		P
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	No Type CF Applied Part	N/A
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART		N/A
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	Type BF Applied Part	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	No such parts	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.)……:	No such parts	N/A
	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)…….:	No such parts	N/A

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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description……:	No such capacitors	N/A
8.5	Separation of parts		P
8.5.1	MEANS OF PROTECTION (MOP)		P
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4	See Insulation Diagram	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	Method disregard	P
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		P
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		P
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test……..:	See appended Table 8.8.3	P
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		P
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6	No protective earth connections	N/A
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION ……..:	No such capacitors used	N/A
	Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c……..:	No such capacitors used	N/A
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	No such capacitors used	N/A
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF)……:	No such capacitors used	—
	Optocouplers complying with IEC 60747-5-5:2007, or a later edition. Considered equivalent to requirements in 8.8.2 and 8.9.3	No such parts	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Measurement of Air Clearance and Creepage distance on the outside		N/A
	Dielectric strength test across optocoupler		N/A
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	MOPP considered	N/A
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:	See above	N/A
	– dielectric strength test ……:	See above	N/A
	– requirements of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for INSULATION CO-ORDINATION		N/A
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		N/A
	– limits of Tables 13 to 16 (inclusive); or		N/A
	– requirements of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for INSULATION CO-ORDINATION		N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6		N/A
	– or with requirements and tests of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for protective earthing……:	No protective earth connections	N/A
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION……:	No such capacitors used	N/A
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION……:	No such capacitors used	N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N/A
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF)……:	No such capacitors used	—
	Optocouplers complying with IEC 60747-5-5:2007, or a later edition. Considered equivalent to requirements in 8.8.2 and 8.9.3		N/A
	Measurement of Air Clearance and Creepage distance on the outside		N/A
	Dielectric strength test across optocoupler		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Points and applied parts at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 were examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION		N/A
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION……:	No additional parts identified in clause 4.6	N/A
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION…..:	MOPP considered	N/A
8.5.2	Separation of PATIENT CONNECTIONS		P
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAX. MAINS VOLTAGE……:	For additional RM information, see appended Tables 8.7 and 8.8.3 See also Table 11.6.1.	P
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART	No multiple functions	N/A
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		N/A
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS……:	Single function applied part	N/A
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	Type BF Applied Part	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 protective device	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…:	Not Type B Applied Part	N/A
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low. In this case 8.7.4.7 d) does not apply		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4…:	Not Type B Applied Part	N/A
	Dielectric strength test conducted per 8.8.3 …..:	Not Type B Applied Part	N/A
	Relevant CREEPAGE and CLEARANCES measured	Not Type B Applied Part	N/A
	RISK MANAGEMENT FILE includes an assessment of the RISK of metal ACCESSIBLE PARTS contacting a source of voltage or LEAKAGE CURRENT above the limits……: (ISO 14971 Cl. 5.2-5.5, 6)	Not Type B Applied Part	N/A
8.5.2.3	A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable distal from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE		N/A
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT……:	No patient leads or patient cables	N/A
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter		N/A
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm		N/A
	– conductive part pluggable into a mains socket protected from 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		N/A
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,	No patient leads or patient cables	N/A
	Test finger test (10 N)……:	No patient leads or patient cables	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. 5.2-5.5, 6)	No patient leads or patient cables	N/A
8.5.4	WORKING VOLTAGE		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V)……..:	5 Vdc	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 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		P
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V)……..:		P
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	No DEFIBRILLATION-PROOF APPLIED 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 such motors	N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	No DEFIBRILLATION-PROOF APPLIED PARTS	N/A
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety	See above	N/A
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:	See above	N/A
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ……...:	See above	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……..:	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load……:	See above	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 PE or FE	N/A
	Parts complying with IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 or IEC 62368-1:2018 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8		N/A
8.6.2	PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR……:	No PE	N/A
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL		N/A
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside……..:	No PE	N/A
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		N/A
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		N/A
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part,		N/A
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE ……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	No PE	N/A
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop……:	No PE	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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 PE	N/A
	DETACHABLE POWER SUPPLY CORD specified by manufacturer or delivered with product		N/A
8.6.5	Surface coatings		N/A
	Poorly conducting surface coatings on conductive elements removed at the point of contact	No such coatings	N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		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 PE	N/A
	- applied also where interchangeable parts are PROTECTIVELY EARTHED		N/A
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR		N/A
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE	No Potential equalization conductor	N/A
	–accidental disconnection avoided in NORMAL USE		N/A
	– Terminal allows conductor to be detached without a TOOL		N/A
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		N/A
	– Terminal marked with symbol 8 of Table D.1		N/A
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		N/A
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		N/A
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION	No FE	N/A
8.6.9	Class II ME EQUIPMENT		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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	Equipment is internally powered only	N/A
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.		N/A
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS		N/A
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		P
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3……:	See appended Tables 8.7	P
	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	No exceptions considered	N/A
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		N/A
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		N/A
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		N/A
	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		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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz……:	See appended Table 8.7	P
	c) TOUCH CURRENT did not exceed 100µA in NORMAL CONDITION and 500µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC})……..:	See appended Table 8.7	P
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC})……..:	No earth connection	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……:	Not permanently installed ME equipment	N/A
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device……..:	See appended Table 8.7.	P
	f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION….:	No functional earth conductor	N/A
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements……..:	See appended Table 8.7	P
8.8	Insulation		P
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing		P
	Insulation exempted from test (complies with clause 4.8)		N/A
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		N/A
8.8.2	Distance through solid insulation or use of thin sheet material		N/A
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:	No solid insulation. Working voltage is less than 71 volts	N/A
	a) 0.4 mm, min, distance through insulation, or		N/A
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– at least two layers of material, each passed the appropriate dielectric strength test..... :	No thin sheet material	N/A
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test..... :	No thin sheet material	N/A
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		N/A
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		N/A
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when	No wound components	N/A
	c) Wire with solid insulation, other than solvent based enamel, complying with a)	See above	N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L	See above	N/A
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	See above	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……:	No wound components	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Tests of Annex L not repeated since material data sheets confirm compliance……:	No wound components	N/A
8.8.3	Dielectric Strength		P
	Solid insulating materials with a safety function withstood dielectric strength test voltages ……..:	See appended Table 8.8.3	P
8.8.4	Insulation other than wire insulation		P
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		P
	ME EQUIPMENT and design documentation examined……:	Inspection of device	P
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: HYF7-004-003 Hyfe Cough Diary Risk Assessment Hazard ID: 5.1; 6.2 (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	P
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat……:	Testing conducted	N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat……:	See below	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)…….:	No mains support via insulating material	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	No such components	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.8.4.2	Resistance to environmental stress		P
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9		P
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	No such parts	N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	No such parts	N/A
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples	No such parts	N/A
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h		N/A
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		P
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive)……:	Refer to Insulation Diagram	P
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1	No defibrillation-proof applied parts.	N/A
8.9.1.16	Conductive coatings applied to non-metallic surfaces, do not result in flaking or peeling reducing any AIR CLEARANCE or CREEPAGE DISTANCE	No such construction	N/A
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION , min CREEPAGE and CLEARANCES not applied……..:	No Mains parts	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	No such parts	N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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)……:	No insulating compounds used	N/A
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		N/A
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint	No insulating compounds 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:		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 ……..:	No insulating compounds 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		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 ……..……:	No such grooves	N/A
	Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES	See above	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 components are mounted securely	P
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	All components are securely mounted. No hazardous situations	N/A
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment……:	Adequately secured	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS		P
8.10.3	Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken ……:	No such cords	N/A
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 cord-connected hand-held parts or cord-connected foot-operated control devices used	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		N/A
	Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3		N/A
8.10.5	Mechanical protection of wiring		P
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges……..:	All internal cables and wiring are adequately protected	P
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS		P
8.10.6	Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead	No guiding rollers	N/A
8.10.7	a) Insulating sleeve adequately secured……..:	No insulating sleeve used	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	Not used	N/A
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C……..:	Device temperature does not exceed 70°C	N/A
8.11	MAINS PARTS, components and layout		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles……..:	No Mains part. Internally powered equipment	N/A
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	Not PERMANENTLY INSTALLED ME EQUIPMENT	N/A
	PERMANENTLY INSTALLED ME EQUIPMENT provided with means to isolate its circuits electrically from the SUPPLY MAINS are capable of being locked in the off position		N/A
	- the isolation device specified in the ACCOMPANYING DOCUMENTS		N/A
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description ……..:	No Mains part. Internally powered equipment	N/A
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV……..:	No supply mains switch	N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	No supply mains switch	N/A
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447	No supply mains switch	N/A
	f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH……..:	No Mains part	N/A
	g) A fuse or a semiconductor device not used as an isolating means	No such parts	N/A
	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 parts	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		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		N/A
	Standard test finger applied		N/A
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	No MULTIPLE SOCKET-OUTLETS	N/A
8.11.3	POWER SUPPLY CORDS		N/A
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD	No power supply cords	N/A
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design 53):	No power supply cords	N/A
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE ……..:	No power supply cords	N/A
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17……..:	No power supply cords	N/A
	For ME EQUIPMENT utilizing POWER SUPPLY CORDS and operating at currents greater than 63 A, apply the electrical regulations appropriate for the jurisdiction in which the ME EQUIPMENT is to be used.	No power supply cords	N/A
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6 ……..:	No power supply cords	N/A
8.11.3.5	Cord anchorage		N/A
	a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage		N/A
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or		N/A
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		N/A
	– metal provided with an insulating lining affixed to cord anchorage		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components		N/A
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals		N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18.....:	See appended Table 8.11.3.5	N/A
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests		N/A
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position		N/A
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N/A
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged		N/A
8.11.3.6	POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment	No power supply cords	N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N/A
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram attached to the free end of cord (g)……..:	No power supply cords	N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		N/A
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D ……..:	No power supply cords	N/A
8.11.4	MAINS TERMINAL DEVICES		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection	No Mains terminal devices or connections to a Supply Mains	N/A
	Terminals alone are not used to keep conductors in position		N/A
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors		N/A
	Screws and nuts clamping external conductors do not serve to secure any other component		N/A
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N/A
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection	No Mains terminals	N/A
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		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		N/A
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced after fastening and loosening a conductor of largest cross-sectional area 10 times	No connections to a Supply Mains	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 connections to a Supply Mains	N/A
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewireable POWER SUPPLY CORD to allow for connection of conductors		N/A
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test		N/A
8.11.5	Mains fuses and OVER-CURRENT RELEASES		N/A
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection….:	Internally powered equipment. No connection to Mains. No Mains components.	N/A
	- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT…….:	Not permanently installed ME equipment	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT		N/A
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART		N/A
	Protective devices have adequate breaking capacity based on MANUFACTURER'S expectation of the highest branch circuit current and/or prospective short circuit current:	Internally powered equipment. No connection to Mains.	N/A
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		N/A
	Justification for omission of fuses or OVER-CURRENT RELEASES documented……:	Internally powered equipment. No connection to Mains.	N/A
8.11.6	Internal wiring of the MAINS PART		N/A
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable .....:	Internally powered equipment. No connection to Mains.	N/A
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient……:	Internally powered equipment. No connection to Mains.	N/A
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 accessible moving parts	N/A
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)		N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and		N/A
	RISK CONTROLS implemented……..:	No accessible moving parts	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	No accessible moving parts	N/A

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

	All RISKS associated with moving parts have been reduced to an acceptable level		N/A
9.2.2	TRAPPING ZONE		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:	No trapping zones	N/A
	– Gaps in Clause 9.2.2.2, or		N/A
	– Safe distances in Clause 9.2.2.3, or		N/A
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or		N/A
	– Continuous activation in Clause 9.2.2.5		N/A
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM		N/A
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20….:	No trapping zones	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 zones	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 zones	N/A
9.2.2.4.2	FIXED GUARDS held in place by systems that can only be dismantled with a TOOL		N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open		N/A
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,		N/A
	– absence or failure of one of their components prevents starting, and stops moving parts		N/A
	Movable GUARDS complied with any applicable tests		N/A
9.2.2.4.4	Other RISK CONTROL designed and incorporated into to the control system stops movement and		N/A

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

	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or		N/A
	ME EQUIPMENT is SINGLE FAULT SAFE		N/A
9.2.2.5	Continuous activation		N/A
	Continuous activation used as a RISK CONTROL, complies with the following		N/A
	a) movement was in OPERATOR'S field of view		N/A
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR		N/A
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or		N/A
	- the continuous activation system is SINGLE FAULT SAFE		N/A
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement		N/A
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		N/A
9.2.3	Other MECHANICAL HAZARDS associated with moving parts		N/A
9.2.3.1	Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated		N/A
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or		N/A
	- activation does not result in an unacceptable RISK		N/A
9.2.3.2	Over travel past range limits of the ME EQUIPMENT prevented……..:	No trapping zones	N/A
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse…..:	No trapping zones	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 device	N/A
	a) Emergency stopping device reduced RISK to an acceptable level		N/A

IEC 60601-1			
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. 5.2-5.5, 6, 7.1-7.5)	No emergency stopping device	N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N/A
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD		N/A
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N/A
	g) Means for stopping of movements operate as a result of one single action		N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or "STOP"		N/A
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed		N/A
	k) Emergency stopping device is suitable for its application		N/A
9.2.5	Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping..... :	Equipment does not utilize any moving parts that might constrain the patient	N/A
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		N/A
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT ……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	Equipment does not utilize any moving parts that might constrain the patient	N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered……:	No rough surface, sharp corners or edges that will cause injury or damage	P
9.4	Instability HAZARDS		N/A
9.4.1	ME EQUIPMENT and its parts, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE	Body-worn device	N/A
9.4.2	Instability – overbalance		N/A
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested ……:	Body-worn device	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, ...:	Body-worn device	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	Equipment mass below 25kg	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)	See above	N/A
	b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping	Not for use on the floor or on a table	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 .....:	See above	N/A
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b)……:	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.4.2.4	Castors and wheels		N/A
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE	No castors or wheels. Not mobile ME equipment	N/A
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT did not exceed 200 N ……:	See above	N/A
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold ……:	See above	N/A
9.4.3	Instability from unwanted lateral movement (including sliding)		N/A
9.4.3.1	a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control	Not mobile ME equipment	N/A
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements	See above	N/A
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1	See 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 ME equipment	N/A
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test	See above	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	Equipment mass below 20kg	N/A
	Handles, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS		N/A
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying		N/A
	c) Carrying handles and grips and their means of attachment withstood loading test.....:	Equipment mass below 20kg	N/A
9.5	Expelled parts HAZARD		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.5.1	Suitability of means of protecting against expelled parts determined by assessment and examination of RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No expelled parts	N/A
	All identified RISKS associated with expelled parts mitigated to an acceptable level		N/A
9.5.2	Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965 .....:	No CRT	N/A
9.6	Acoustic energy (including infra- and ultrasound) and vibration		N/A
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and	No acoustic energy emitted	N/A
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity.....:	See above	N/A
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	See above	N/A
	All identified RISKS mitigated to an acceptable level	See above	N/A
9.6.2	Acoustic energy		N/A
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE	No acoustic energy emitted	N/A
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA).....:	See above	—
	- 83 dBA (when halving the cumulative exposure time) (dBA).....:	See above	—
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB) .....:	See above	—
9.6.2.2	RISK MANAGEMENT FILE examined .....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	No acoustic energy emitted	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 hand-transmitted vibration	N/A
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2).....:	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Accelerations for different times, inversely proportional to square root of time (m/s^2) .....:	See above	N/A
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N/A
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No pressure vessels or pressure components	N/A
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		N/A
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		N/A
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		N/A
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply		N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N/A
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity		N/A
9.7.4	MAXIMUM EQUIPMENT PRESSURE did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for the part, except allowed for pressure relief devices in 9.7.7confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests .....:	No pressure components	N/A
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when MAXIMUM EQUIPMENT PRESSURE was more than 50 kPa, and product of MAXIMUM EQUIPMENT PRESSURE and volume was more than 200 kPa.....:	No pressure vessels	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 .....:	No pressure components	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.7.7	Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests.....:	No pressure components	N/A
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair		N/A
	c) Could be adjusted or rendered inoperative without a TOOL		N/A
	d) With discharge opening located and directed as to not to release material towards any person		N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		N/A
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE EQUIPMENT PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure		N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect		N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N/A
	RISK MANAGEMENT FILE includes an assessment of the risks associated with the discharge opening of the pressure relief device .....: ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No pressure components	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 .....:	Body-worn device. No support system	N/A
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		N/A
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	No support system	N/A
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES		N/A
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials		N/A
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		N/A
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest	Body-worn device. No support system	N/A
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing.....:	See above	N/A
	RISK MANAGEMENT FILE includes an assessment of the structural integrity of support system.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	See above	N/A
	All identified RISKS are mitigated to an acceptable level		N/A
	When test was conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK .....:	No support system	N/A
	Where the equipment is not at equilibrium after 1 min, the RISK MANAGEMENT FILE includes an assessment of the test results .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No support system	N/A

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

9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		N/A
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints .....:	No patient, operator support or suspension systems used	N/A
	RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	See above	N/A
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts		N/A
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER		N/A
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications		N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		N/A
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS		N/A
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance .....:	No patient, operator support or suspension systems used	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 .....:	Body-worn device. No support system	N/A
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests.....:	See 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	See above	N/A
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test.....:	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE maintained BASIC SAFETY and ESSENTIAL PERFORMANCE confirmed test	Body-worn device. No support system	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	Not a support system. No mechanical protective device	N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		N/A
	– Designed based on TOTAL LOAD		N/A
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N/A
	– Activated before travel produced an unacceptable RISK		N/A
	– Considers Clauses 9.2.5 and 9.8.4.3		N/A
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests ….....:	No mechanical protective device	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	Not a support system. No mechanical protective device	N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		N/A
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		N/A
	–use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE .....:	Not a support system. No mechanical protective device	N/A
	– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal		N/A
	– ME EQUIPMENT permanently marked with SAFETY SIGN 2 of Table D.		N/A
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE		N/A
	– Compliance confirmed by examination and following test .....:	No mechanical protective device	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT		N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		N/A
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		N/A
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		N/A
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES.....:	Equipment does not provide patient or operator supports and is not a suspension system	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	See above	N/A
10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		**N/A**
10.1	X-Radiation		N/A
10.1.1	The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT.....:	No X-Radiation	N/A
	Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE		N/A
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or .....:	No X-Radiation	N/A
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT ILE.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No X-Radiation	N/A
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No such radiations	N/A

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

10.3	The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2	No such radiations	N/A
	Microwave radiation is propagated intentionally		N/A
10.4	Relevant requirements of IEC 60825-1:2014 applied to lasers including laser diodes, laser light barriers or similar with a wavelength range of 180nm to 1 mm.	No lasers	N/A
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No visible electromagnetic radiation	N/A
10.6	RISK associated with infrared radiation other than emitted by lasers addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ...: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No infrared radiations	N/A
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No ultraviolet radiations	N/A
11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		**P**
11.1	Excessive temperatures in ME EQUIPMENT		P
11.1.1	Temperatures on ACCESSIBLE PARTS did not exceed values in Tables 22 and.....:	See appended Table 11.1.1	P
	Surfaces of test corner did not exceed 90 °C	Body-worn device. Test corner not used	N/A
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	No thermal cut-outs	N/A
	RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISK: HYF7-004-003 Hyfe Cough Diary Risk Assessment Hazard ID: 5.4 (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	P
11.1.2	Temperature of APPLIED PARTS		P
11.1.2.1	APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply.....:	Applied parts not intended to supply heat to a patient	N/A
	Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use		N/A
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in NORMAL CONDITION and SINGLE FAULT CONDITION ..:		P
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:	Temperature of Applied Parts below 41°C	N/A
	Maximum Temperature .....:	See above	—
	Conditions for safe contact, e.g. duration or condition of the PATIENT .....:	See above	—
	Clinical effects with respect to characteristics taken or surface pressure documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	The surface temperature of Applied Part did not exceed 41°C	N/A
	APPLIED PARTS surface temperature of equal to or less than 41°C	Temperature of Applied Parts < 41 °C	P
	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 .....:	Measurement of APPLIED PART temperature conducted	N/A
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No such applied part	N/A
11.1.3	Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	Temperature measurements performed	N/A
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	Device is body-worn. Device does not have rear or side air vents and external enclosure temperature are well below 90°C	N/A

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

	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: HYF7-004-003 Hyfe Cough Diary Risk Assessment Hazard ID: 5.4 (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	P
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE.....:	No such device	N/A
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	No such guards	N/A
11.2	Fire prevention		P
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3		P
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		N/A
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of.....:	Not intended to be used in oxygen rich environment	N/A
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions		N/A
	1) when temperature of material raised to its ignition temperature		N/A
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature		N/A
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating		N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A

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

	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	Not intended to be used in oxygen rich environment	N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively……:	See above	N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three.....:	See 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. 5.3-5.5, 6, 7.1-7.4)	See above	N/A
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3……:	See above	N/A
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%)……:	See above	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	See above	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……:	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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 ……..:	See above	N/A
11.2.2.2	RISK of ignition did not occur, and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT		N/A
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks	Not intended to be used in oxygen rich environment	N/A
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		N/A
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		N/A
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered		N/A
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2)……..:	Not intended to be used in oxygen rich environment	N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3)……..:	See above	N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a)……..:	See above	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)…….:	See above	N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas……..:	See 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…….:	Requirements for this clause met as alternate means	P
	Constructional requirements were met, or	Constructional requirements were met	P

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

	- constructional requirements specifically analysed in RISK MANAGEMENT FILE …….. : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	See above	N/A
	Justification, when requirement not met…….:	Requirements are met	N/A
	a) Flammability classification of insulated wire and connectors within fire ENCLOSURE is minimum V-2, , when test in accordance with IEC 60695-11-10 or :	See below	N/A
	insulated with PVC, TFE, PTFE, FEP, polychloroprene or polyimide as determined by examination of data on materials……..:	Insulated with PVC	P
	Flammability classification of printed circuit boards, and insulating material on which components are mounted is V-2, or better, based on IEC 60695-11-10 as decided by examination of materials data……:	See appended Table 8.10	P
	If no Certification, V tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings		N/A
	b) Fire ENCLOSURE met following:		P
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm	No such openings	P
	2) No openings on the sides within the area included within the inclined line C in Fig 39 or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm	No such openings	P
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials……..:	See appended Table 8.10 Non-metallic enclosure	P
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics		N/A
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G	Not intended for use with flammable anaesthetics	N/A
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE ……..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	Not intended to be use in conjunction with flammable agents	N/A
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT		P
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT..... :	See Appended Table 11.6.1 IP27 conducted	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……..:	See Appended Table 11.6.1 No liquid reservoir	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
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.		N/A
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM		N/A
	ME EQUIPMENT and ME SYSTEMS handling liquids constructed that spillage does not wet parts as determined by review of the RISK MANAGEMENT FILE and test……..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No handling of liquids	N/A
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill…….:		N/A
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)……..:	See Appended Table 11.6.1 IP27 conducted	P
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION .....:	See appended Tables 8.7 8.8.3	P
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS		P
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use……:	See Appended Tables 11.6.1, 8.7, and 8.8.3	P
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER……:		P
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests……:	ME equipment not intended to be sterilized	N/A
	RISK MANAGEMENT FILE includes an assessment of the RISKS associated with any deterioration following sterilization……..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	See above	N/A
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No substances used	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	Excluded at client's request	N/E
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		P
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		**N/A**
12.1	RISKS associated with accuracy of controls and instruments stated.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No accuracy of controls	N/A
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING……:	Excluded at client's request	N/E

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
12.3	MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020……..:	No Alarm system	N/A
12.4	Protection against hazardous output		N/A
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS……..: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	The system does not intentionally exceed safety limits.	N/A
12.4.2	- need for indication associated with hazardous output addressed in RISK MANAGEMENT PROCESS....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	The system does not produce a hazardous output.	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. 5.2-5.5, 6, 7.1-7.4)	The system does not produce a hazardous output.	N/A
12.4.4	RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	The system does not produce a hazardous output.	N/A
12.4.5	Diagnostic or therapeutic radiation		N/A
12.4.5.1	Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation	Not intended to produce diagnostic or therapeutic radiation	N/A
	Radiation safety ensured by compliance with requirements of appropriate standards		N/A
12.4.5.2	ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3.....:	Not diagnostic X-ray device	N/A
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	Not radiotherapy device	N/A
12.4.5.4	RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	Not intended for radiotherapy purposes	N/A
12.4.6	RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT .....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	Not intended for diagnostic or therapeutic acoustic pressure	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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		P
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		P
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24.....:	See appended Table 11.1.1	P
	– Temperatures of Accessible PARTS THAT ARE LIKELY TO BE TOUCHED, but not intended to be touched did not exceed limits in Table 34.....:	See appended Tables 11.1.1, 11.1.2.1, and 11.1.2.2	P
	- Temperatures of ACCESSIBLE PARTS intended to be touched did not exceed limits in Table 23		P
	–Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C were not exceeded		P
	Limits for windings in Tables 26, 27, and 31 not exceeded		P
	Table 22 not exceeded in all other cases		P
	Temperatures measured according to 11.1.3		P
	SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where:	See below	P
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit in SINGLE FAULT CONDITION ..... :	See appended Table 13.1.2	N/A
	- or secondary circuits mounted on materials with a minimum flame rating of -V1, and		N/A
	- Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and		N/A
	- Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and		N/A
	- Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide		N/A
	- or components in the circuit have HIGH INTEGRITY CHARACTERISTICS..... :	No such components	N/A
	– or parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation		P

IEC 60601-1			
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	No such components used	N/A
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed……..:	See appended Table 8.7	P
	– voltage limits for ACCESSIBLE PARTS and APPLIED PARTS did not exceed……..:	See appended Table 8.7	P
13. 2	SINGLE FAULT CONDITIONS		P
13.2.1	During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination		P
	ME EQUIPMENT complied with 13.2.2 -13.2.12…..:	See appended Table 13.2	P
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	No leakage of liquids	N/A
	RISK MANAGEMENT FILE defines the appropriate test conditions.....:	See above	N/A
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of test environment temperature		P
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		P
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION, the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		P
13.2.13.2	ME EQUIPMENT with heating elements		N/A
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	No heating elements	N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests		N/A
	a 3) other ME EQUIPMENT with heating elements met test		N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration		N/A
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		N/A
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself		N/A
	b) ME EQUIPMENT with heating elements without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V).....:	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		N/A
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION		N/A
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and		N/A
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS		N/A
	2) When more than one control provided, they were disabled in turn		N/A
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		N/A
13.2.13.3	ME EQUIPMENT with motors		P
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable		P
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		N/A

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

	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition		N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		N/A
	b) Motor met running overload protection test of this clause when:		N/A
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended		N/A
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C).....:	Device is always attended when in use	N/A
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		N/A
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload		N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		N/A
	Test not conducted based on other justifications (justification).....:		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		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.....:	Continuous operation	N/A

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

	Insulation Class……:	Continuous operation	—
	Maximum temperature measured (°C)……..:	Continuous operation	—
14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		**P**
14.1	Requirements in 14.2 to 14,12 not applied to PEMS when it provides no functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE, or	Software provided no essential performance or basic safety	P
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK……..:	No unacceptable risks	P
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 5.2-5.5, 6)	RMF Reference to specific RISKS: HYF7-004-003 Hyfe Cough Diary Risk Assessment, Hazard IDs: 1,1; 1.2; 1.3; 1.8; 1.9; 1.10 ISO 14971 Cl. . 5.2-5.5, 6)	P
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK		N/A
	When the requirements of 14.2 to 14.13 apply, the requirements of IEC 62304:2006 and IEC 62304:2006/AMD1:2016 clause 4.3, 5, 7, 8 and 9 apply for the development or modification of software of each PESS	Requirements of 14.2 to 14.13 does not apply	N/A
	Software development process for Software Classification applied in accordance with Clause 4.3 and 4.4 of IEC 62304:2006 and IEC 62304:2006/AMD1:2016……..:	See above	N/A
	Software development process applied according to Clause 5 of IEC 62304:2006 and IEC 62304:2006/AMD1:2016……:	See above	N/A
	Software development process for Software risk management applied according to Clause 7 of IEC 62304:2006 and IEC 62304:2006/AMD1:2016……..:	See above	N/A
	Software development process Configuration Management applied according to Clause 8 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2016……:	See above	N/A
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304:2006 and IEC 62304:2006/AMD1:2016……..:	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process……:	Requirements of 14.2 to 14.13 does not apply	N/A
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan	Requirements of 14.2 to 14.13 does not apply	N/A
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented	Requirements of 14.2 to 14.13 does not apply	N/A
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		N/A
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone		N/A
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones		N/A
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		N/A
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained		N/A
14.6	RISK MANAGEMENT PROCESS		N/A
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS……..:	Requirements of 14.2 to 14.13 does not apply	N/A
	RISK MANAGEMENT FILE includes known or foreseeable HAZARDS associated with software, hardware, incorporation of the PEMS into an IT-NETWORK, components of 3rd party origin and legacy subsystems……: (ISO 14971 Cl. 5.3)		N/A
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2…:		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure……: (ISO 14971 Cl. 7.1)	Requirements of 14.2 to 14.13 does not apply	N/A
14.7	A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem……: (ISO 14971 Cl. 7.2)	Requirements of 14.2 to 14.13 does not apply	N/A
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems …..: (ISO 14971 Cl. 7.2)	Requirements of 14.2 to 14.13 does not apply	N/A
14.9	Design is broken up into sub systems and descriptive data on design environment documented……: (ISO 14971 Cl. 7.2)	Requirements of 14.2 to 14.13 does not apply	N/A
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures……..: (ISO 14971 Cl. 7.2)	Requirements of 14.2 to 14.13 does not apply	N/A
	– milestone(s) when VERIFICATION is to be performed for each function		N/A
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		N/A
	– selection and utilization of VERIFICATION tools		N/A
	– coverage criteria for VERIFICATION		N/A
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented		N/A
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE .....: (ISO 14971 Cl. 7.2)	Requirements of 14.2 to 14.13 does not apply	N/A
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented		N/A
	The person with overall responsibility for PEMS VALIDATION is independent		N/A

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

	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 7.2)		N/A
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE	Requirements of 14.2 to 14.13 does not apply	N/A
	Software Classification for Software changes applied in accordance with Clause 4.3 and 4.4 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2016……:	Requirements of 14.2 to 14.13 does not apply	N/A
	Software Process for Software changes applied according to Clause 5 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2016.....:		N/A
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2016.....:		N/A
	Configuration management of software changes applied per Clause 8 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2016……:		N/A
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2016.....:		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……:	Requirements of 14.2 to 14.13 does not apply	N/A
	a) Purpose of the PEMS connection to an IT-NETWORK		N/A
	b) required characteristics of the IT-NETWORK		N/A
	c) required configuration of the IT-NETWORK		N/A
	d) technical specifications of the network connection, including security specifications		N/A
	e) intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK		N/A
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the required characteristics (ISO 14971 Cl. 5.2-5.5, 6, 7.1, 7.2)		N/A
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties		N/A
	– Notification that the RESPONSIBLE ORGANIZATION identify, analyse, evaluate and control these RISKS		N/A
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis		N/A
	- Changes to the IT-NETWORK include: - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment		N/A
15	**CONSTRUCTION OF ME EQUIPMENT**		**P**
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS……..:	Excluded as per client's request	N/E
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	Service and inspection not required during design life of device.	N/A
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring	Service and inspection not required during design life of device.	N/A
15.3	Mechanical strength		P
15.3.1	Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		P
15.3.2	Push test conducted ……..:	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.3	Impact test conducted……..:	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.4	Drop test		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested ……:	See Appended Table 15.3.	P
	No unacceptable RISK resulted		P
15.3.4.2	Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test……:	See Appended Table 15.3	N/A
	No damage resulting in an unacceptable RISK sustained		N/A
15.3.5	MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests……..:	Not mobile device	N/A
	No damage resulting in an unacceptable RISK sustained		N/A
15.3.6	Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK		P
	Mould-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C……:	Device tested at 70ºC for 7 hours	P
	No damage resulting in an unacceptable RISK	No damage after test	P
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT		P
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK		P
15.4	ME EQUIPMENT components and general assembly		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists,……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF Reference to specific RISKS: Incorrect connection of connectors is not possible by design. Dedicated USB cable used HYF7-004-003 Hyfe Cough Diary Risk Assessment Hazard ID: 2.16 (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	P
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions,……..:	No such plugs	N/A
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection……..:	No such connection	N/A
15.4.2	Temperature and overload control devices		P
15.4.2.1	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION……..: (ISO 14971 Cl. 5.2-5.5, 6)	There are no automatically resettable thermal cut outs or over current releases present in the device	N/A
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT		N/A
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided……..: (ISO 14971 Cl. 5.2-5.5)	No such parts	N/A
	d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION or loss of ESSENTIAL PERFORMANCE ….: (ISO 14971 Cl. 5.2-5.5)	No temperature or overload devices used	N/A
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		N/A
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests		N/A
	- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	- ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13……:	No temperature or overload devices used	N/A
	- SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards……:	No such parts used	N/A
	- In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions operated 200 times		N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		N/A
	manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		N/A
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		N/A
	g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating		N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating…..: (ISO 14971 Cl. 5.2-5.5)	No heating elements used	N/A
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS	No thermostats used	N/A
15.4.3	Batteries		P
15.4.3.1	Battery housings provided with ventilation…….: (ISO 14971 Cl. 5.2-5.5)	No ventilated battery housing is required	N/A
	Battery compartments designed to prevent accidental short circuiting		N/A
15.4.3.2	Means provided to prevent incorrect connection of polarity	Battery not intended for replacement	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries……: (ISO 14971 Cl. 5.2-5.5)	See above	N/A
15.4.3.3	Overcharging of battery prevented by virtue of design……:	Battery pack complies with IEC 62133	P

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

	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries……..: (ISO 14971 Cl. 5.2-5.5)	RMF Reference to specific RISKS: HYF7-004-003 Hyfe Cough Diary Risk Assessment Hazard ID: 5.2 (ISO 14971 Cl. 5.2-5.5)	P
15.4.3.4	Primary lithium batteries comply with IEC 80086-4	No primary lithium batteries used	N/A
	Secondary lithium batteries comply with IEC 62133 or IEC 62133-2		N/A
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire……..:	Evaluated in approved Battery Pack	N/A
	Protective device has adequate breaking capacity		N/A
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented		N/A
	Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPS provided, or		N/A
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION		N/A
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for……..:	LCD display provided	P
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,	Stand-by state or warm-up state does not exceed 15 s	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. 5.2-5.5)	No non-luminous heaters	N/A
	Requirement not applied to heated stylus-pens for recording purposes		N/A
	Indicator lights provided on ME EQUIPMENT to indicate an output exists		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Colours of indicator lights complied with 7.8.1	No indicator lights	N/A
	Charging mode visibly indicated	Indicated on LCD Display	P
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	No pre-set controls	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 of controls	N/A
	b) Controls secured so that the indication of any scale always corresponds to the position of the control		N/A
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL		N/A
	When torque values per Table 30 applied knobs did not rotate ……..:	No actuating parts of controls	N/A
	Tests conducted with no unacceptable RISK …..:	No actuating parts of controls	N/A
15.4.6.2	Stops on rotating/ movable parts of controls are of adequate mechanical strength ……..:	No rotating/ movable parts of controls	N/A
	Torque values in Table 30 applied……..:	See above	N/A
	No unexpected change of the controlled parameter when tested……:	See above	N/A
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		N/A
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1	No hand-held control devices	N/A
	b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage……..:	No foot-operated control 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 hand-held control devices or foot-operated control devices	N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		N/A
15.4.7.3	a) Foot-operated control device is at least rated IPX1……..:	No foot-operated control devices	N/A
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6……:	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.8	Aluminium wires less than 16 mm^2 in cross-sectional area are not used	Aluminium wires not used	N/A
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed	No oil container used	N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		N/A
	A pressure-release device operating during NORMAL USE is provided		N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		N/A
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		N/A
15.5.1	Overheating		N/A
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating……..:	No transformers or connection to a Supply Mains	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 ……..:	No transformers	N/A
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved ……..:	No transformers	N/A
	Short circuit applied directly across output windings		N/A
15.5.1.3	Multiple overload tests conducted on windings:	No transformers	N/A
15.5.2	Transformers operating at a frequency above 1kHz tested according to clause 8.8.3…….:	No transformers	N/A
	Transformer windings provided with adequate insulation		N/A
	Dielectric strength tests were conducted …….:	No transformers	N/A
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with……..:	No transformers	N/A
	- Means provided to prevent displacement of end turns		N/A

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

	- 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 a ME System	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with installation and modification of an ME SYSTEM……..: (ISO 14971 Cl. 5.2-5.5, 6)	See above	N/A
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered		N/A
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard		N/A
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards		N/A
	– tests performed in NORMAL CONDITION, except as specified		N/A
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM		N/A
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated		N/A
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR		N/A
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards		N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM		N/A
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM		N/A

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

	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 a 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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer		N/A
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET		N/A
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage		N/A
	– 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	Not a ME System	N/A
	Transient currents restricted to allowable levels for the specified IPS or UPS .....:	See above	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)	Not a ME System	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) .....:	Not a ME System	N/A

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

16.6	LEAKAGE CURRENTS		N/A
16.6.1	TOUCH CURRENT in NORMAL CONDITION did not exceed 100µA ..... :	Not a ME System	N/A
	TOUCH CURRENT did not exceed 500µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR..... :	See above	N/A
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA..... :	Not a ME System	N/A
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values ..... :	Not a ME System	N/A
16.7	ME SYSTEM complied with applicable requirements of Clause 9..... :	Not a ME System	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 a 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……..:	Not a ME System	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. 5.2-5.5, 6, 7.1-7.4)	See above	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 a 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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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:		N/A
	– CREEPAGE and CLEARANCES complied with 8.9		N/A
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets		N/A
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:		N/A
	– ENCLOSURE complied with 8.4.2 d)		N/A
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable		N/A
	– RATINGS of components are not in conflict with conditions of use ……:	Not a ME System	N/A
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL		N/A
	– POWER SUPPLY CORD complied with 8.11.3		N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:		N/A
	– Separating transformer complied with this standard or IEC 61558-2-1,……:	Not a ME System	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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
16.9.2.2	The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED and protected by only the SUPPLY MAINS circuit over-current release, did not exceed 200 mΩ	Not a ME System	N/A
	The impedance of an earth pathway protected by an additional intermediate circuit breaker or fuse rated 13A or lower, did not exceed 400 mΩ		N/A
	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 a ME System	N/A
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		**N/E**
	RISKS associated confirmed by review……:	Excluded	N/E
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS……:		N/E
	RISK MANAGEMENT FILE includes an assessment of risks associated with the introduction of electromagnetic phenomena into the environment by the EQUIPMENT or SYSTEM……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	Excluded	N/E
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems	Excluded	N/E

ANNEX G	**PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		N/A
G.2	**Locations and basic requirements**		N/A
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5		N/A
G.2.2	FLAMMABLE AESTHETIC MIXTURE WITH		N/A
G.2.3	A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE		N/A

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

G.2.4	ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5		N/A
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE comply with G.4 and G.6		N/A
	ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.6 conducted after tests of 11.6.6 and 11.6.7		N/A
G.3	Marking, ACCOMPANYING DOCUMENTS		N/A
G.3.1	CATEGORY APG ME EQUIPMENT prominently marked "APG" (symbol 23 in Table D.1) ..... :	See copies of Marking Labels	N/A
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case		N/A
	When above marking not possible, relevant information included in instructions for use..... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.2	CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle "AP" (symbol 22 in Table D.1) ..... :	See copies of Marking Labels	N/A
	Marking is as large as possible for the particular case		N/A
	When above marking not possible, the relevant information included in instructions for use..... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.3	The marking placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts		N/A
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts		N/A
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG		N/A
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT		N/A
G.4.1	a) CREEPAGE and CLEARANCES are according to Table 12 for one MEANS OF PATIENT PROTECTION		N/A
	b) Connections protected against accidental disconnection		N/A

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

	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD,		N/A
G.4.2	Construction details		N/A
	a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL		N/A
	b) ENCLOSURE complies with..... :	See appended Table 8.10	N/A
	– no openings on top covers of ENCLOSURE,		N/A
	– openings in side-covers prevented penetration of a solid cylindrical test rod		N/A
	– openings in base plates prevented penetration of a solid cylindrical test		N/A
	c) Short circuiting conductor(s) to a conductive part (when no explosive gasses) did not result in loss of integrity of the part, an unacceptable temperature, or any HAZARDOUS SITUATION		N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures		N/A
	– Use of antistatic materials with a limited electrical resistance..... :	See appended Table 8.10	N/A
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor		N/A
	b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882 ..... :		N/A
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5		N/A
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components		N/A
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5		N/A

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

	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5 ..... :		N/A
G.5.2	Temperature limits..... :	See appended Tables 11.1.1 and 11.2.2.1	N/A
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1.....:	U_{max} = __V U_{zR} = __V I_{zR} = __A	N/A
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 .....:	U_{max} = __V U_c = __V C_{max} = __µF	N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 .....:	I_{max} = __A I_{zR} = __A U_{zR} = __V	N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3 .....:	I_{max} = __A I_{zL} = __A L_{max} = __mH	N/A
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1		N/A
	No extrapolation made for voltages above 42 V		N/A
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2		N/A
	No extrapolation made for voltages above 242V		N/A
	U_{max} determined using actual resistance R		N/A
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3		N/A
	No extrapolation made for inductances larger than 900 mH		N/A
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed		N/A
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks		N/A
	– Peak value considered when a.c. supplied		N/A
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		N/A
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max} , and C_{max} determined with application of Figs G.1-G.3 .....:	See appended Table 11.1.1	N/A
	Alternatively, compliance was verified by examination of design data .....:		N/A
G.5.4	External ventilation with internal overpressure		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:		N/A
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR t removed by ventilation before EQUIPMENT energized,		N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa).....:		N/A
	Overpressure maintained at the site of potential ignition		N/A
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE		N/A
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present		N/A
	c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa).....:		N/A
	d) External surface of ENCLOSURE did not exceed 150 °C in 25 °C .....:		N/A
G.5.5	ENCLOSURES with restricted breathing		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing		N/A
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h . :	See appended Table 8.10	N/A
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained		N/A
	Cords are fitted with adequate anchorages to limit stresses as determined by test		N/A
	Overpressure not reduced below 200 Pa		N/A
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		N/A
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C) .....:		N/A
	Steady state operating temperature of ENCLOSURE also measured (°C).....:		N/A
G.6	CATEGORY APG ME EQUIPMENT, parts and components thereof		N/A
G.6.1	ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION		N/A
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test		N/A
G.6.2	Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION ..... :		N/A
G.6.3	Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS ..... :		N/A
	a) no sparks produced and temperatures did not exceed 90 °C, or	See Tables 11.1.1, 11.2.2.1 and 13.2	N/A

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

	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U_{max} and I_{max} occurring in their circuits complied with requirements, taking C_{max} and L_{max} into consideration:	See Tables 11.1.1 and 13.2	N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 .....:	U_{max} = __V U_{zR} = __V I_{zR} = __A	N/A
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5 .....:	U_{max} = __V U_c = __V C_{max} = __µF	N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 .....:	I_{max} = __A I_{zR} = __A U_{zR} = __V	N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 .....:	I_{max} = __A I_{zL} = __A L_{max} = __mH	N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated		N/A
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in Cl. 4.10		N/A
	– I_{max} was the highest current flowing in the circuit under investigation, considering MAINS VOLTAGE variations as in Cl. 4.10		N/A
	– C_{max} and L_{max} are values occurring in relevant circuit		N/A
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω		N/A
	– Peak value considered when a.c. supplied		N/A
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		N/A
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	- requirement not applied to transformers complying with this standard		N/A
	- requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture		N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or		N/A
	Temperature measurements made in accordance with 11.1.....:	See Table 11.1.1	N/A
	- or U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6 .....:	U_{max} = __V I_{max} = __A R = __Ω L_{max} = __mH C_{max} = __µF	N/A
	Alternatively, compliance verified by comparison with design data .....:		N/A
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1 .....:	See appended Table 8.10	N/A
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE		N/A
G.7	Test apparatus for flammable mixtures according to this Clause and Fig G.7		N/A
ANNEX L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**		N/A
L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex		N/A
L.2	Wire construction		N/A
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component		N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		N/A
L.3	Type Test		N/A

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

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

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

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

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
4.1	SOP_007_Risk Management Procedure	—	Risk Management Process (excluding production and post-production)	P
4.2	SOP_007_Risk Management Procedure Section: Responsibility	—	Adequate Resources	P
4.2	SOP_007_Risk Management Procedure Section: Responsibility	—	Assignment of qualified personnel	P
4.2	HYF7-004-001 Hyfe Cough Diary Risk Management Plan Section 9: Risk Policy	—	Policy for determining criteria for risk acceptability	P
4.3	—	SOP_007_Risk Management Procedure Section: Risk Management Plan, Role Table	Competence of personnel	P
4.4a	—	HYF7-004-001 Hyfe Cough Diary Risk Management Plan Section 2: Scope	Risk Management Plan - the scope of the planned risk management activities	P
4.4b	—	HYF7-004-001 Hyfe Cough Diary Risk Management Plan Section 8: Responsibility and Authority	Risk Management Plan - assignment of responsibilities and authorities	P
4.4c	—	HYF7-004-001 Hyfe Cough Diary Risk Management Plan	Risk Management Plan - requirements for review of risk management activities	P

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

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
4.4d	—	HYF7-004-001 Hyfe Cough Diary Risk Management Plan Section 11: Risk Acceptance Criteria	Risk Management Plan - criteria for risk acceptability	P
4.4e	—	HYF7-004-001 Hyfe Cough Diary Risk Management Plan Section 14: Overall Residual Risk Analysis	Risk Management Plan - a method to evaluate the overall residual risk, and criteria for acceptability of the overall residual risk	P
4.4f	—	HYF7-004-001 Hyfe Cough Diary Risk Management Plan Section 12: Verification of Risk Controls	Risk Management Plan - activities for verification of the implementation and effectiveness of risk control measures	P
4.5	—	HYF7-004-001 Hyfe Cough Diary Risk Management Plan HYF7-004-003 Hyfe Cough Diary Risk Assessment HYF7-004-003 Hyfe Cough Risk Management Report	Risk Management File	P
5.1	—	SOP_007_Risk Management Procedure Section: Process Flow	Risk Analysis - Process	P
5.2	—	HYF7-004-001 Hyfe Cough Diary Risk Management Plan Section 6: Intended Use	Risk Analysis - Intended use and reasonably foreseeable misuse	P
5.3	—	HYF7-004-002 Identification of hazards and characteristics related to safety	Risk Analysis - Identification of characteristics related to safety	P
5.4	—	HYF7-004-003 Hyfe Cough Diary Risk Assessment	Risk Analysis - Identification of hazards and hazardous situations	P

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

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
5.5	—	HYF7-004-003 Hyfe Cough Diary Risk Assessment	Risk Analysis - Risk estimation	P
6	—	HYF7-004-003 Hyfe Cough Diary Risk Assessment	Risks Evaluation	P
7.1	—	HYF7-004-003 Hyfe Cough Diary Risk Assessment	Risk Control - Risk control option analysis	P
7.2	—	HYF7-004-003 Hyfe Cough Diary Risk Assessment	Risk Control - Implementation of risk control measures	P
7.3	—	HYF7-004-003 Hyfe Cough Diary Risk Assessment	Risk Control - Residual risk evaluation	P
7.4	—	HYF7-004-003 Hyfe Cough Diary Risk Assessment HYF7-004-003 Hyfe Cough Risk Management Report	Risk/Benefit analysis.	P
7.5a	—	HYF7-004-003 Hyfe Cough Diary Risk Assessment	Risk Control - Risks arising from risk control measures (new hazards or hazardous situations introduced)	P
7.5b	—	HYF7-004-003 Hyfe Cough Diary Risk Assessment	Risk Control - Risks arising from risk control measures (estimated risks for previously identified hazardous situations affected)	P
7.6	—	HYF7-004-003 Hyfe Cough Diary Risk Assessment	Risk Control - Completeness of risk control	P
8	—	HYF7-004-003 Hyfe Cough Risk Management Report	Evaluation of overall residual risk	P
9	—	HYF7-004-001 Hyfe Cough Diary Risk Management Plan	Risk management review	P

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

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

4.3	**TABLE: ESSENTIAL PERFORMANCE**	**N/A**
List of ESSENTIAL PERFORMANCE functions	**MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)**	**Remarks**
Supplementary Information: ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk. RM is not included for component power supply, the acceptability of risk of the power supply is determined as part of the end product.		

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

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

5.9.2	TABLE: Determination of ACCESSIBLE parts	P
Location	**Determination method (NOTE1)**	**Comments**
Enclosure	Visual, Rigid test finger, Jointed test finger	No access to internal parts
Supplementary information: [1)] NOTE: The determination methods are: visual; rigid test finger; jointed test finger; test hook.		

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

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

7.1.3	TABLE: Durability of marking test		P
Characteristics of the Marking Label tested:			**Remarks**
Material of Marking Label .....:		Direct marking on back of watch via laser engraving	-
Ink/other printing material or process.....:		Laser engraving	-
Material (composition) of Warning Label .....:		N/A	-
Ink/other printing material or process.....:		N/A	-
Other .....:		N/A	-
Marking Label Tested:			**Remarks**
Marking label			Markings remained legible.
Supplementary information: Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96%, and then for 15 s with a cloth rag soaked with isopropyl alcohol.			

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						

IEC 60601-1			
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**	**N/A**

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										
Plug pin 1 and plug earth pin										
Plug pin 2 and plug earth pin										
Plug pin 1 and enclosure										
Plug pin 2 and enclosure										

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

Calculated stored charge (µc)

Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2										
Plug pin 1 and plug earth pin										
Plug pin 2 and plug earth pin										
Plug pin 1 and enclosure										
Plug pin 2 and enclosure	-	-	-	-	-	-	-	-	-	-

Supplementary information:

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

8.4.4	TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT		N/A
Maximum allowable residual voltage (V)..... :			**60 V**
Maximum allowable stored charge when residual voltage exceeded 60 V ... :			**45 µC**
Description of the capacitive circuit (i.e., accessible capacitor or circuit parts)	**Measured residual voltage (V)**	**Calculated stored charge (µC)**	**Remarks**
-	-	-	-
Supplementary information:			

8.5.5.1a	TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies				N/A
Test Condition: Figs. 9 & 10	**Measurement made on accessible part**	**Applied part with test voltage**	**Test voltage polarity**	**Measured voltage between Y1 and Y2 (mV)**	**Remarks**
-	-	-	-	-	-
Supplementary information:					

8.5.5.1b	TABLE: defibrillation-proof applied parts – verification of recovery time			N/A
Applied part with test voltage	**Test voltage polarity**	**Recovery time from documents (s)**	**Measured recovery time (s)**	**Remarks**
-	-	-	-	-
Supplementary information:				

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

8.5.5.2	**TABLE: DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load**			**N/A**
Test Voltage applied to		**Measured Energy E1 (mJ)**	**Measured Energy E2 (mJ)**	**Energy E1 as % of E2 (%)**
PATIENT CONNECTION 1 or APPLIED PART with PATIENT CONNECTIONS 2, 3, and 4 of the same APPLIED PART connected to earth		-	-	-
PATIENT CONNECTION 2 or APPLIED PART with PATIENT CONNECTIONS 1, 3, and 4 of the same APPLIED PART connected to earth		-	-	-
PATIENT CONNECTION 3 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 4 of the same APPLIED PART connected to earth		-	-	-
PATIENT CONNECTION 4 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 3 of the same APPLIED PART connected to earth		-	-	-
Supplementary information: For compliance: E1 must at least 90% of E2 E1= Measured energy delivered to 100 Ω with ME Equipment connected; E2= Measured energy delivered to 100 Ω without ME equipment connected.				

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

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

8.7	TABLE: leakage current	P

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)		Remarks
Fig. 13 - Earth Leakage (ER)	—	—	—		Maximum allowed values: 5 mA NC; 10 mA SFC
-	-	-	-		-
Fig. 14 - Touch Current (TC)	—	—	—		Maximum allowed values: 100 µA NC; 500 µA SFC
-		-	-		-
Fig. 15 - Patient Leakage Current (P)	—	—	B	A	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
P, NC, S15=1	Internally powered	-	0.5	0.5	-
P, NC, S15=0	Internally powered	-	0.5	0.5	-
P, NC, S15=1	Internally powered	-	0.4	0.4	Non-frequency weighted measurement
P, NC, S15=0	Internally powered	-	0.4	0.4	
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—		Maximum allowed values: Type B: N/A Type BF AP: 5000 µA Type CF AP: 50 µA
PM, SFC, S9=1, S15=1	Internally powered	-	27.4	27.7	-
PM, SFC, S9=1, S15=0	Internally powered	-	27.4	27.7	-
PM, SFC, S9=0, S15=1	Internally powered	-	27.4	27.7	-
PM, SFC, S9=0, S15=0	Internally powered	-	27.4	27.7	-

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**
PM, SFC, S9=1, S15=1	Internally powered	-	8.1	8.3	Non-frequency weighted measurement
PM, SFC, S9=1, S15=0	Internally powered	-	8.1	8.3	
PM, SFC, S9=0, S15=1	Internally powered	-	8.1	8.3	
PM, SFC, S9=0, S15=0	Internally powered	-	8.1	8.3	
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 (act) ; Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
-	-	-	-		-
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—		Maximum allowed values: Type B or BF AP: 500 µA Type CF: N/A
-	-		-		-
Fig. 19 – Patient Auxiliary Current	—	—	—		Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current)
-	-	-	-	-	-

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. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together		—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
-		-	-	-	-
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP		—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC;1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
-		-	-	-	-
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP		—	—	—	Maximum allowed values: Type B: NA Type BF: 5000 µA Type CF: 100 µA
-		-	-	-	-
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed		—	—	—	Maximum allowed values: Type B & BF: 1000 µA Type CF: N/A
-		-	-	-	-
Function Earth Conductor Leakage Current (FECLC)		—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
-		-	-	-	-

Supplementary information:

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

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

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**	
Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).					
ER - Earth leakage current TC – Touch current P - Patient leakage current PA – Patient auxiliary current TP – Total Patient current PM - Patient leakage current with mains on the applied parts MD - Measuring device			A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition		

8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				P
Insulation under test (area from insulation diagram)	**Insulation Type (1 or 2 MOOP/MOPP)**	**Reference Voltage**		**A.C. test voltages in V r.m.s[1]**	**Dielectric breakdown after 1 minute Yes/No[2]**
		PEAK WORKING VOLTAGE (U) V peak	**PEAK WORKING VOLTAGE (U) V d.c.**		
C (Internal circuits to Enclosure)	2 MOPP	-	5 Vdc	1000	No
M (Internal circuits to Enclosure)	2 MOPP	-	5 Vdc	1000	No
Supplementary information: [1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used. [2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization). Conducted Before Humidity Precondition; After Humidity Preconditioning; After Cleaning; After IP Test					

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

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

Part/material	**Test temperature (°C)**	**Impression diameter (mm)**
Enclosure/External insulating parts	**-**	**-**
Enclosure	75	0.6

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

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

8.9.3.2	**Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts**			**N/A**
Part Test	**8.9.3.4 - Test duration and temperature for 10 cycles after which the sample was subjected to Humidity Preconditioning per Cl. 5.7**	**Dielectric test voltage**	**Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No**	**Crack or voids in the insulating compound: Yes/No**
	68 h at T1 ± 2 °C = ___°C [1)]			
	1 h at 25 °C ± 2 °C			
	2 h at 0 °C ± 2 °C			
	1 or more h at 25 °C ± 2 °C			

Supplementary information:

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

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

Supplementary information:

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

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

8.10	TABLE: List of critical components				P
Component/ Part No.	**Manufacturer/ Trademark**	**Type No./model No./**	**Technical data**	**Standard No./, Edition**	**Mark(s) & Certificates of conformity [1]**
Smart Watch	Shenzhen DO Intelligent Technology Co., Ltd.	ID206	3.8V, 300mAh (Internally powered)	EN 62368-1:2014 +A11:2017	SGS SZES201200875 201
PWB	Shenzhen HopeSearch PCB Manufacturing Co Ltd	F-M, F-D	94V-0, 130°C	UL796	UL (E351308)
Plastic material of enclosure	Covestro Deutschland AG (PC Resins)	FR3020+	PC, V-0, 80°C, Min. thickness 1.5 mm	UL94	UL E(41613)
Lithium Battery	ZhongShan ZhongWangDe New Energy Technology Co., Ltd	552123V	3.8V, 300mAh, 1.14Wh	IEC 62133-2:2017/AMD1:2021 UL 2054:2021	TUV SUD CB (SG PSB-BT-05062) TUV Rh (US 72407622)
Motor	Guang'an Chaoying Electronic Technology Co., Ltd.	CY0827-00-P13-115WF	3.0 Vdc, 90mA Max., 12000 ± 3000rpm	EN 62368-1	Tested within standard
LCD	Jiangxi Huaersheng Technology Co., Ltd.	ZC-T1D69HP-002	1.69 inch	EN 62368-1	Tested within standard

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

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

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

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

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

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

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

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

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

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:		

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

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

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

9.4.3.1	**TABLE: Instability from unwanted lateral movement (including sliding) in transport position**	**N/A**

ME EQUIPMENT Preparation	**Test Condition (transport position, working load, locking device(s), caster position)**	**Remarks**

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:

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

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

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

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:				

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

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

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

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

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT**	**P**
Model No. .....:	**ID206**	**-**
Test ambient (°C) .....:	**Normalized to 40°C**	**-**
Test supply voltage/frequency (V/Hz)[4]...:	**Internally powered**	**-**

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
Condition: Charging only					
-	1	PWB (near U36)	130	51.6	-
-	2	PWB (near U3)	130	47.7	-
-	3	PWB (near U1)	130	46.1	-
-	4	Surface of Lithium battery	60	47.3	-
-	5	Enclosure inside	80	48.3	-
-	6	Surface of screen	48	43.3	-
-	7	Non-metallic button	48	42.4	-

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

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

Note: Test results referenced from SGS Test Report SZES201200875201
Measured temperature has been normalized to maximum operating ambient of 40°C

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

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT**	**P**
Model No. .....:	**ID206**	**-**
Test ambient (°C) .....:	**Normalized to 40°C**	**-**
Test supply voltage/frequency (V/Hz)[4]...:	**Internally powered**	**-**

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
Condition: Discharging					
-	1	PWB (near U36)	130	46.5	-
-	2	PWB (near U3)	130	48.4	-
-	3	PWB (near U1)	130	47.1	-
-	4	Surface of Lithium battery	60	44.8	-
-	5	Enclosure inside	80	46.1	-
-	6	Surface of screen	48	42.0	-
-	7	Non-metallic button	48	42.2	-

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

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

Note: Test results referenced from SGS Test Report SZES201200875201
Measured temperature has been normalized to maximum operating ambient of 40°C

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

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT**	**P**
Model No. .....:	**H026**	**-**
Test ambient (°C) .....:	**40°C**	**-**
Test supply voltage/frequency (V/Hz)[4]...:	**Internally powered**	**-**

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
	1	Surface of screen	41	40.9	-
	2	Non-metallic enclosure surface (Bottom)	41	40.8	-
	3	Non-metallic enclosure surface (Side Button)	41	40.7	-
					-
					-
					-
					-
					-

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

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

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

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

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

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

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

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

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

Information from Risk Management, as applicable:

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

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

Clause / Test Name	Test Condition	Part under test	Remarks
11.6.5 / IP test	IP27 according to IEC60529	Complete device	No water entered enclosure. No hazard.
11.6.6 / Cleaning	Cleaning according to IFU	Complete device	No hazard.

Supplementary information:

Information from Risk Management, as applicable:

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

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

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

Supplementary information:

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

13.2	**TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive**		**P**
Clause No.	**Description of SINGLE FAULT CONDITION**	**Results observed**	**HAZARDOUS SITUATION (Yes/No)**
13.2.2	**Electrical SINGLE FAULT CONDITIONS per Cl. 8.1:**	—	—
	U36 (overcharge at fully battery) s-c pin 1/10	EUT shuts down immediately. No component damage. No hazard. Lithium battery: Ucharge = 5Vdc. Icharge = 0A	No
	U36 (overcharge at empty battery) s-c pin 1/10	After < 1s, no component damage, input change to 1.86W, no hazard. For EUT: In = 0.374A Lithium Battery: Ucharge = 3.9→4.3Vdc. Icharge = 0A	No
	C244 s-c	EUT shuts down immediately. No component damage. No hazard. Lithium battery: Udischarge = 4.2Vdc. Idischarge = 0A	No
	C243 s-c (overcharge)	EUT Shuts Down Immediately. No Component Damage. No Hazard. Lithium Battery: Udischarge = 0vdc. Idischarge = 0A	No
13.2.3	**Overheating of transformers per Clause 15.5:**	—	—
	-	-	-
13.2.4	**Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:**	—	—
	-	**-**	**-**
13.2.5	**Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:**	—	—
	-	-	-

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.6	**Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)**	—	—
	-	-	-
13.2.7	**Impairment of cooling that could result in a HAZARD using test method of 11.1:**	—	—
	Single ventilation fans locked consecutively	**-**	**-**
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls	**-**	**-**
	SIMULATED BLOCKING OF FILTERS	**-**	**-**
	Flow of a cooling agent interrupted	**-**	**-**
	Blocking Of Air Inlet Filter	**-**	**-**
13.2.8	**Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:**	—	—
	Motor locked	EUT Shuts Down Immediately. No Component Damage. No Hazard. No ignition for wrapping tissue or cheesecloth Lithium Battery: Udischarge = 4.0Vdc. Idischarge = 0.136A max.	NO
13.2.9	**Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1)] – Also see 13.10**	—	—
	-	**V measured =**	-
13.2.10	**Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:**	—	—
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or upper limit of RATED voltage range for specified time:	-	-

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices	-	-
	Temperatures measured as specified in 11.1.3 d)	-	-
	Temperatures did not exceed limits of Table 26	-	-
13.2.11	**Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:**	—	—
	-	-	-
13.2.12	**Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):**	—	—
	-	-	-

Supplementary information:

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

Information from Risk Management, as applicable:

Note: Test results referenced from SGS Test Report SZES201200875201

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

15.3	**TABLE: Mechanical Strength tests [1)]**		**P**
Clause	**Name of Test**	**Test conditions**	**Observed results/Remarks**
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	No damage to enclosure. No access to internal parts. No hazards.
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	No damage to enclosure. No access to internal parts. No hazards.
15.3.4.1	Drop Test (hand-held/body worn)	Free fall height (m) = 1	No damage to enclosure. No access to internal parts. No hazards
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5	N/A
15.3.5	Rough handling test	Travel speed (m/s) =	N/A
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) = 70	Enclosure not deformed. No access to internal parts. No hazards.
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).			

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)					

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

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) ...:	**264**	**—**
RATED input frequency (Hz) .....:	**50**	**—**

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 (°C)	Maximum winding temp measured (°C)	Ambient (°C)

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 (°C)	Maximum winding temp measured (°C)	Ambient (°C)

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.

IEC 60601-1			
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**
-	Primary & secondary windings	-	-	-	-
-	Primary winding & frame	-	-	-	-
-	Secondary winding & frame	-	-	-	-
Supplementary information: Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details					

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)**	
-	100	-	500	-	
-	100	-	500	-	
-	100	-	500	-	
-	100	-	500	-	
-	100	-	500	-	
Supplementary information:					

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

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

	Attachment - Software – IEC 62304:2006		—
4.3	**[A, B, C] Software safety classification**		—
	a) The MANUFACTURER assigned to each SOFTWARE SYSTEM a software safety class (A, B, or C) according to the possible effects on the patient, operator, or other people resulting from a HAZARD to which the SOFTWARE SYSTEM can contribute.		N/A
	The software safety classes initially be assigned based on severity as follows:		—
	Class A: No injury or damage to health is possible		N/A
	Class B: Non-SERIOUS INJURY is possible		N/A
	Class C: Death or SERIOUS INJURY is possible		N/A
	If the HAZARD could arise from a failure of the SOFTWARE SYSTEM to behave as specified, the probability of such failure assumed to be 100 per cent		N/A
	If the RISK of non- SERIOUS INJURY arising from a software failure is similarly reduced to an acceptable level by a hardware RISK CONTROL measure, the software safety classification may be reduced from B to A.		N/A
	b) The MANUFACTURER assigned to each SOFTWARE SYSTEM that contributes to the implementation of a RISK CONTROL measure a software safety class based on the possible effects of the HAZARD that the RISK CONTROL measure is controlling.		N/A
	c) The MANUFACTURER documented the software safety class assigned to each SOFTWARE SYSTEM in the RISK MANAGEMENT FILE		N/A
	d) When a SOFTWARE SYSTEM is decomposed into SOFTWARE ITEMS, and when a SOFTWARE ITEM is decomposed into further SOFTWARE ITEMS, such SOFTWARE ITEMS inherited the software safety classification of the original SOFTWARE ITEM (or SOFTWARE SYSTEM) unless the MANUFACTURER documents a rationale for classification into a different software safety class.		N/A
	A rationale explained how the new SOFTWARE ITEMS are segregated so that they may be classified separately		N/A
	e) The MANUFACTURER documented the software safety class of each SOFTWARE ITEM if that class is different from the class of the SOFTWARE ITEM from which it was created by decomposition		N/A

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

	Attachment - Software – IEC 62304:2006		—
	f) Wherever a PROCESS is required for SOFTWARE ITEMS of a specific classification and the PROCESS is necessarily applied to a group of SOFTWARE ITEMS, the MANUFACTURER used the PROCESSES and TASKS which are required by the classification of the highest-classified SOFTWARE ITEM in the group unless the MANUFACTURER documents in the RISK MANAGEMENT FILE a rationale for using a lower classification		N/A
	g) For each SOFTWARE SYSTEM, until a software safety class is assigned, Class C requirements applied.		N/A
5	**SOFTWARE DEVELOPMENT PROCESS**		**—**
5.1	**Software development planning**		—
5.1.1	[A, B, C] The MANUFACTURER establishes a software development plan (or plans) for conducting the ACTIVITIES of the software development PROCESS appropriate to the scope, magnitude, and software safety classifications of the SOFTWARE SYSTEM to be developed.		N/A
	The SOFTWARE DEVELOPMENT LIFE CYCLE MODEL is either fully defined or be referenced in the plan (or plans).		N/A
	The plan addresses the following:		N/A
	a) the PROCESSES to be used in the development of the SOFTWARE SYSTEM		N/A
	b) the DELIVERABLES (includes documentation) of the ACTIVITIES and TASKS		N/A
	c) TRACEABILITY between SYSTEM requirements, software requirements, SOFTWARE SYSTEM test, and RISK CONTROL measures implemented in software		N/A
	d) software configuration and change management, including SOUP CONFIGURATION ITEMS and software used to support development		N/A
	e) software problem resolution for handling problems detected in the SOFTWARE PRODUCTS, DELIVERABLES, DELIVERABLES and ACTIVITIES at each stage of the life cycle		N/A
5.1.2	[A, B, C] The MANUFACTURER updates the plan, as appropriate, as development proceeds		N/A
5.1.3	[A, B, C] Software development plan reference to SYSTEM design and development		N/A

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

	Attachment - Software – IEC 62304:2006		—
	a) As inputs for software development, SYSTEM requirements are referenced in the software development plan by the MANUFACTURER		N/A
	b) The MANUFACTURER included or referenced in the software development plan procedures for coordinating the software development and the design and development validation necessary to satisfy 4.1		N/A
5.1.4	[C] Associated with the development of SOFTWARE ITEMS of class C, in the software development plan are included or referenced:		N/A
	a) standards		N/A
	b) methods		N/A
	c) tools		N/A
5.1.5	[B, C] The MANUFACTURER includes or references in the software development plan, a plan to integrate the SOFTWARE ITEMS (including SOUP) and performs testing during integration		N/A
5.1.6	[A, B, C] In the software development plan, the following VERIFICATION information are included or referenced:		N/A
	a) DELIVERABLES requiring VERIFICATION		N/A
	b) the required VERIFICATION TASKS for each life cycle ACTIVITY		N/A
	c) milestones at which the DELIVERABLES are VERIFIED		N/A
	d) the acceptance criteria for VERIFICATION of the DELIVERABLES		N/A
5.1.7	[A, B, C] In the software development plan the MANUFACTURER includes or references a plan to conduct the ACTIVITIES and TASKS of the software RISK MANAGEMENT PROCESS, including the management of RISKS relating to SOUP		N/A
5.1.8	[A, B, C] In the software development plan the MANUFACTURER includes or references information about the documents to be produced during the software development life cycle		N/A
	For each identified document or type of document the following information has included or referenced:		N/A
	a) title, name or naming convention		N/A
	b) purpose		N/A
	c) intended audience of document		N/A

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

	Attachment - Software – IEC 62304:2006		—
	d) procedures and responsibilities for development, review, approval and modification		N/A
5.1.9	[A, B, C] The MANUFACTURER includes or references software configuration management information in the software development plan		N/A
	The software configuration management information includes or references:		N/A
	a) the classes, types, categories or lists of items to be controlled		N/A
	b) the software configuration management ACTIVITIES and TASKS		N/A
	c) the organization(s) responsible for performing software configuration management and ACTIVITIES		N/A
	d) their relationship with other organizations, such as software development or maintenance		N/A
	e) when the items are to be placed under configuration control		N/A
	f) when the problem resolution PROCESS is to be used		N/A
5.1.10	[B, C] The items to be controlled include tools, items or settings, used to develop the MEDICAL DEVICE SOFTWARE, which could impact the MEDICAL DEVICE SOFTWARE		N/A
5.1.11	[B, C] The MANUFACTURER plans to place CONFIGURATION ITEMS under documented configuration management control before they are VERIFIED		N/A
5.2	**Software requirements analysis**		—
5.2.1	[A, B, C] For each SOFTWARE SYSTEM of the MEDICAL DEVICE, the MANUFACTURER defines and documents SOFTWARE SYSTEM requirements from the SYSTEM level requirements		N/A
5.2.2	[A, B, C] As appropriate to the MEDICAL DEVICE SOFTWARE, the MANUFACTURER includes in the software requirements:		N/A
	a) functional and capability requirements		N/A
	b) SOFTWARE SYSTEM inputs and outputs		N/A
	c) interfaces between the SOFTWARE SYSTEM and other SYSTEMS		N/A
	d) software-driven alarms, warnings, and operator messages		N/A

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

	Attachment - Software – IEC 62304:2006		—
	e) SECURITY requirements		N/A
	f) usability engineering requirements that are sensitive to human errors and training		N/A
	g) data definition and database requirements		N/A
	h) installation and acceptance requirements of the delivered MEDICAL DEVICE SOFTWARE at the operation and maintenance site or sites		N/A
	i) requirements related to methods of operation and maintenance		N/A
	j) user documentation to be developed		N/A
	k) user maintenance requirements		N/A
	l) regulatory requirements		N/A
5.2.3	[B, C] The MANUFACTURER included RISK CONTROL measures implemented in software for hardware failures and potential software defects in the requirements as appropriate to the MEDICAL DEVICE SOFTWARE		N/A
5.2.4	[A, B, C] The MANUFACTURER re-EVALUATES the MEDICAL DEVICE RISK ANALYSIS when software requirements are established and update it as appropriate		N/A
5.2.5	[A, B, C] The MANUFACTURER ensures that existing requirements, including SYSTEM requirements, are re-EVALUATED and updated as appropriate as a result of the software requirements analysis ACTIVITY		N/A
5.2.6	[A, B, C] The MANUFACTURER verifies and documents that the software requirements:		N/A
	a) implement SYSTEM requirements including those relating to RISK CONTROL		N/A
	b) do not contradict one another		N/A
	c) are expressed in terms that avoid ambiguity		N/A
	d) are stated in terms that permit establishment of test criteria and performance of tests to determine whether the test criteria have been met		N/A
	e) can be uniquely identified		N/A
	f) are traceable to SYSTEM requirements or another source		N/A
5.3	**Software ARCHITECTURAL design**		

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

	Attachment - Software – IEC 62304:2006		—
5.3.1	[B, C] The MANUFACTURER transforms the requirements for the MEDICAL DEVICE SOFTWARE into a documented ARCHITECTURE that describes the software's structure and identifies the SOFTWARE ITEMS		N/A
5.3.2	[B, C] The MANUFACTURER develops and documents an ARCHITECTURE for the interfaces between the SOFTWARE ITEMS and the components external to the SOFTWARE ITEMS (both software and hardware), and between the SOFTWARE ITEMS		N/A
5.3.3	[B, C] If a SOFTWARE ITEM is identified as SOUP, the MANUFACTURER specifies functional and performance requirements for the SOUP item that are necessary for its intended use		N/A
5.3.4	[B, C] If a SOFTWARE ITEM is identified as SOUP, the MANUFACTURER specifies the SYSTEM hardware and software necessary to support the proper operation of the SOUP item		N/A
5.3.5	[C] The MANUFACTURER identified the segregation between SOFTWARE ITEMS that is essential to RISK CONTROL, and state how to ensure that the segregation is effective		N/A
5.3.6	[B, C] The MANUFACTURER verifies and documents that:		N/A
	a) the ARCHITECTURE of the software implements SYSTEM and software requirements including those relating to RISK CONTROL		N/A
	b) the software ARCHITECTURE can support interfaces between SOFTWARE ITEMS and between SOFTWARE ITEMS and hardware		N/A
	c) the MEDICAL DEVICE ARCHITECTURE supports proper operation of any SOUP items		N/A
5.4	**Software detailed design**		
5.4.1	[B, C] The MANUFACTURER refined the software ARCHITECTURE until it is represented by SOFTWARE UNITS		N/A
5.4.2	[C] The MANUFACTURER developed and document a detailed design for each SOFTWARE UNIT of the SOFTWARE ITEM		N/A

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

	Attachment - Software – IEC 62304:2006		—
5.4.3	[C] The MANUFACTURER developed and documented a detailed design for any interfaces between the SOFTWARE UNIT and external components (hardware or software), as well as any interfaces between SOFTWARE UNITS		N/A
5.4.4	[C] The MANUFACTURER verifies and documents that the software detailed design:		N/A
	a) implements the software ARCHITECTURE		N/A
	b) is free from contradiction with the software ARCHITECTURE		N/A
5.5	**SOFTWARE UNIT implementation**		
5.5.1	[A, B, C] The MANUFACTURER implements each SOFTWARE UNIT		N/A
5.5.2	[B, C] The MANUFACTURER establishes strategies, methods and procedures for verifying the SOFTWARE UNITS		N/A
	Where VERIFICATION is done by testing, the test procedures are EVALUATED for adequacy		N/A
5.5.3	[B, C] The MANUFACTURER establishes acceptance criteria for SOFTWARE UNITS prior to integration into larger SOFTWARE ITEMS as appropriate, and ensures that SOFTWARE UNITS meet acceptance criteria		N/A
5.5.4	[C] When present in the design, the MANUFACTURER includes additional acceptance criteria as appropriate for:		N/A
	a) proper event sequence		N/A
	b) data and control flow		N/A
	c) planned resource allocation		N/A
	d) fault handling (error definition, isolation, and recovery)		N/A
	e) initialisation of variables		N/A
	f) self-diagnostics		N/A
	g) memory management and memory overflows		N/A
	h) boundary conditions		N/A
5.5.5	[B, C] The MANUFACTURER performs the SOFTWARE UNIT VERIFICATION and documents the results		N/A
5.6	**Software integration and integration testing**		
5.6.1	[B, C] The MANUFACTURER integrates the SOFTWARE UNITS in accordance with the integration plan		N/A

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

	Attachment - Software – IEC 62304:2006		—
5.6.2	[B, C] The MANUFACTURER verified and recorded the following aspects of the software integration in accordance with the integration plan		N/A
	a) the SOFTWARE UNITS have been integrated into SOFTWARE ITEMS and the SOFTWARE SYSTEM		N/A
	b) the hardware items, SOFTWARE ITEMS, and support for manual operations of the SYSTEM have been integrated into the SYSTEM		N/A
5.6.3	[B, C] The MANUFACTURER tests the integrated SOFTWARE ITEMS in accordance with the integration plan and documents the results		N/A
5.6.4	[B, C] For software integration testing, the MANUFACTURER addresses whether the integrated SOFTWARE ITEM performs as intended		N/A
5.6.5	[B, C] The MANUFACTURER EVALUATED the integration test procedures for correctness		N/A
5.6.6	[B, C] When software items are integrated, the MANUFACTURER conducts REGRESSION TESTING appropriate to demonstrate that defects have not been introduced into previously integrated software		N/A
5.6.7	[B, C] The MANUFACTURER:		N/A
	a) documents the test result (pass/fail and a list of ANOMALIES)		N/A
	b) retains sufficient records to permit the test to be repeated		N/A
	c) identifies the tester		N/A
5.6.8	[B, C] The MANUFACTURER enters ANOMALIES found during software integration and integration testing into a software problem resolution PROCESS		N/A
5.7	**SOFTWARE SYSTEM testing**		
5.7.2	[B, C] The MANUFACTURER established and performed a set of tests, expressed as input stimuli, expected outcomes, pass/fail criteria and procedures, for conducting SOFTWARE SYSTEM testing, such that all software requirements are covered		N/A
5.7.2	[B, C] The MANUFACTURER entered ANOMALIES found during software system testing into a software problem resolution PROCESS		N/A
5.7.3	[B, C] When changes are made during SOFTWARE SYSTEM testing, the MANUFACTURER		N/A

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

	Attachment - Software – IEC 62304:2006		—
	a) repeats tests, performs modified tests or performs additional tests, as appropriate, to verify the effectiveness of the change in correcting the problem		N/A
	b) conducts testing appropriate to demonstrate that unintended side effects have not been introduced		N/A
	c) performs relevant RISK MANAGEMENT ACTIVITIES as defined in 7.4		N/A
5.7.4	[B, C] The MANUFACTURER verified that:		N/A
	a) the VERIFICATION strategies and the test procedures used are appropriate		N/A
	b) SOFTWARE SYSTEM test procedures trace to software requirements		N/A
	c) all software requirements have been tested or otherwise VERIFIED		N/A
	d) test results meet the required pass/fail criteria		N/A
5.7.5.	[B, C] The MANUFACTURER:		N/A
	a) document the test result (pass/fail and a list of ANOMALIES)		N/A
	b) retain sufficient records to permit the test to be repeated		N/A
	c) identify the tester		N/A
5.8	**Software RELEASE for utilization at a SYSTEM level**		
5.8.1	[B, C] The MANUFACTURER ensured that software VERIFICATION has been completed and the results EVALUATED before the software is released		N/A
5.8.2	[B, C] The MANUFACTURER documented all known residual ANOMALIES		N/A
5.8.3	[B, C] The MANUFACTURER ensured that all known residual ANOMALIES have been EVALUATED to ensure that they do not contribute to an unacceptable RISK		N/A
5.8.4	[A, B, C] The MANUFACTURER documented the VERSION of the SOFTWARE PRODUCT that is being released		N/A
5.8.5	[B, C] The MANUFACTURER documents the procedure and environment used to create the released software		N/A
5.8.6	[B, C] The MANUFACTURER ensured that all ACTIVITIES and TASKS are complete along with all the associated documentation		N/A

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

	Attachment - Software – IEC 62304:2006		—
5.8.7	[A, B, C] For at least a period of time determined as the longer of: the life time of the device as defined by the MANUFACTURER or a time specified by relevant regulatory requirements, the MANUFACTURER archived:		N/A
	a) the SOFTWARE PRODUCT and CONFIGURATION ITEMS		N/A
	b) the documentation		N/A
5.8.8	[B, C] The MANUFACTURER establishes procedures to ensure that the released SOFTWARE PRODUCT can be reliably delivered to the point of use without corruption or unauthorised change		N/A
	These procedures address the production and handling of media containing the SOFTWARE PRODUCT including as appropriate:		N/A
	– replication		N/A
	– media labelling		N/A
	– packaging		N/A
	– protection		N/A
	– storage		N/A
	– delivery		
7	**SOFTWARE RISK MANAGEMENT PROCESS**		**—**
7.1	**Analysis of software contributing to hazardous situations**		—
7.1.1	[B, C] The MANUFACTURER identifies SOFTWARE ITEMS that could contribute to a hazardous situation identified in the MEDICAL DEVICE RISK ANALYSIS ACTIVITY of ISO 14971		N/A
7.1.2	[B, C] The MANUFACTURER identifies potential causes of the SOFTWARE ITEM identified above contributing to a hazardous situation		N/A
	The MANUFACTURER considers potential causes including, as appropriate:		N/A
	a) incorrect or incomplete specification of functionality		N/A
	b) software defects in the identified SOFTWARE ITEM functionality		N/A
	c) failure or unexpected results from SOUP		N/A
	d) hardware failures or other software defects that could result in unpredictable software operation		N/A
	e) reasonably foreseeable misuse		N/A

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

	Attachment - Software – IEC 62304:2006		—
7.1.3	[B, C] If failure or unexpected results from SOUP is a potential cause of the SOFTWARE ITEM contributing to a hazardous situation, the MANUFACTURER EVALUATED as a minimum any ANOMALY list published by the supplier of the SOUP item relevant to the VERSION of the SOUP item used in the MEDICAL DEVICE to determine if any of the known ANOMALIES result in a sequence of events that could result in a hazardous situation		N/A
7.1.4	[B, C] The MANUFACTURER documents in the RISK MANAGEMENT FILE potential causes of the SOFTWARE ITEM contributing to a hazardous situation		N/A
	[B, C] The MANUFACTURER documented in the RISK MANAGEMENT FILE sequences of events that could result in a hazardous situation that are identified in 7.1.2		N/A
7.2	**RISK CONTROL measures**		—
7.2.1	[B, C] For each potential cause of the software item contributing to a hazardous situation documented in the risk management file, the manufacturer defined and documented risk control measures		N/A
7.2.2	[B, C] If a RISK CONTROL measure is implemented as part of the functions of a SOFTWARE ITEM, the MANUFACTURER:		N/A
	a) includes the RISK CONTROL measure in the software requirements		N/A
	b) assign a software safety class to the SOFTWARE ITEM based on the possible effects of the HAZARD that the RISK CONTROL measure is controlling		N/A
	c) develops the SOFTWARE ITEM in accordance with Clause 5		N/A
7.3	**VERIFICATION of RISK CONTROL measures**		—
7.3.1	[B, C] The implementation of each RISK CONTROL measure documented in 7.2 is VERIFIED, and this VERIFICATION is documented		N/A
7.3.2	[B, C] If a RISK CONTROL measure is implemented as a SOFTWARE ITEM, the MANUFACTURER EVALUATED the RISK CONTROL measure to identify and document in the RISK MANAGEMENT FILE any new sequences of events that could result in a hazardous situation		N/A
7.3.3	[B, C] The MANUFACTURER documents TRACEABILITY of software HAZARDS as appropriate:		N/A

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

	Attachment - Software – IEC 62304:2006		—
	a) from the hazardous situation to the SOFTWARE ITEM		N/A
	b) from the SOFTWARE ITEM to the specific software cause		N/A
	c) from the software cause to the RISK CONTROL measure		N/A
	d) from the RISK CONTROL measure to the VERIFICATION of the RISK CONTROL measure		N/A
7.4	**RISK MANAGEMENT of software changes**		—
7.4.1	[A, B, C] The MANUFACTURER analyses changes to the MEDICAL DEVICE SOFTWARE (including SOUP) to determine whether:		N/A
	a) additional potential causes are introduced contributing to a hazardous situation		N/A
	b) additional software RISK CONTROL measures are required		N/A
7.4.2	[B, C] The MANUFACTURER analyses changes to the software, including changes to SOUP, to determine whether the software modification could interfere with existing RISK CONTROL measures		N/A
7.4.3	[B, C] The MANUFACTURER performs relevant RISK MANAGEMENT ACTIVITIES defined in 7.1, 7.2 and 7.3 based on these analyses		N/A
8	**SOFTWARE CONFIGURATION MANAGEMENT PROCESS**		**—**
8.1	**Configuration identification**		—
8.1.1	[A, B, C] The MANUFACTURER establishes a scheme for the unique identification of CONFIGURATION ITEMS and their VERSIONS to be controlled for the project.		N/A
8.1.2	[A, B, C] For each SOUP CONFIGURATION ITEM being used, including standard libraries, the MANUFACTURER documents:		N/A
	a) the title		N/A
	b) the MANUFACTURER		N/A
	c) the unique SOUP designator		N/A
8.1.3	[A, B, C] The MANUFACTURER documents the set of CONFIGURATION ITEMS and their VERSIONS that comprise the SOFTWARE SYSTEM configuration		N/A
8.2	**Change control**		—
8.2.1	[A, B, C] The MANUFACTURER changed CONFIGURATION ITEMS only in response to an approved CHANGE REQUEST		N/A

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

	Attachment - Software – IEC 62304:2006		—
8.2.2	[A, B, C] The MANUFACTURER implements the change as specified in the CHANGE REQUEST		N/A
	The MANUFACTURER identifies and performs any ACTIVITY that needs to be repeated as a result of the change, including changes to the software safety classification of SOFTWARE SYSTEMS and SOFTWARE ITEMS		N/A
8.2.3	[A, B, C] The MANUFACTURER verifies the change, including repeating any VERIFICATION that has been invalidated by the change and taking into account 5.7.3 and 9.7		N/A
8.2.4	[A, B, C] The MANUFACTURER created an audit trail where can be traced each:		N/A
	a) CHANGE REQUEST		N/A
	b) relevant PROBLEM REPORT		N/A
	c) approval of the CHANGE REQUEST		N/A
8.3	[A, B, C] The MANUFACTURER retains retrievable records of the history of controlled CONFIGURATION ITEMS including SYSTEM configuration		N/A
9	**SOFTWARE PROBLEM RESOLUTION PROCESS**		—
9.1	[A, B, C] The MANUFACTURER prepares a PROBLEM REPORT for each problem detected in the SOFTWARE PRODUCT		N/A
	PROBLEM REPORTS classified as follows:		N/A
	a) type		N/A
	b) scope		N/A
	c) criticality		N/A
9.2	[A, B, C] The MANUFACTURER:		N/A
	a) investigates the problem and if possible identify the causes		N/A
	b) EVALUATES the problem's relevance to SAFETY using the software RISK MANAGEMENT PROCESS		N/A
	c) documents the outcome of the investigation and evaluation		N/A
	d) creates a CHANGE REQUEST(S) for actions needed to correct the problem, or document the rationale for taking no action		N/A
9.3	[A, B, C] The MANUFACTURER advises relevant parties of the existence of the problem, as appropriate		N/A

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

	Attachment - Software – IEC 62304:2006		—
9.4	[A, B, C] The MANUFACTURER approves and implements all CHANGE REQUESTS, observing the requirements of the change control PROCESS		N/A
9.5	[A, B, C] The MANUFACTURER maintains records of PROBLEM REPORTS and their resolution including their VERIFICATION		N/A
	The MANUFACTURER updates the RISK MANAGEMENT FILE as appropriate		N/A
9.6	[A, B, C] The MANUFACTURER performs analysis to detect trends in PROBLEM REPORTS		N/A
9.7	[A, B, C] The MANUFACTURER verifies resolutions to determine whether:		N/A
	a) problem has been resolved and the PROBLEM REPORT has been closed		N/A
	b) adverse trends have been reversed		N/A
	c) CHANGE REQUESTS have been implemented in the appropriate MEDICAL DEVICE SOFTWARE and ACTIVITIES		N/A
	d) additional problems have been introduced		N/A
9.8	[A, B, C] When testing, retesting or REGRESSION TESTING SOFTWARE ITEMS and SYSTEMS following a change, the MANUFACTURER includes in the test documentation:		N/A
	a) test results		N/A
	b) ANOMALIES found		N/A
	c) the VERSION of software tested		N/A
	d) relevant hardware and software test configurations		N/A
	e) relevant test tools		N/A
	f) date tested		N/A
	g) identification of the tester		N/A

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

Attachment	**Software - Mapping of required evidence and manufacturer documents**			**N/A**
Standard Clause	Deliverables	Title	Revision #	Date
4.3	Software safety classification document			
5.1.1	Software development plan			
5.1.3	Software requirements reference to software design and development document			
5.1.4	Development standards, methods and tools records for class C software			
5.1.5	Software integration and integration testing plan			
5.1.6	Software verification plan			
5.1.7	Software risk management plan			
5.1.8	Document management procedures			
5.1.9	Software configuration management procedures			
5.2	Software system requirements specification			
5.3	Software system architecture design specification			
5.3	Software item architecture design specification			
5.4	Software item detailed design specification			
5.4	Software unit detailed design specification			
5.5.1	Software unit implementation records			
5.5.2	Software unit verification process			
5.5.3	Software unit acceptance criteria			
5.5.5	Software unit verification records			
5.6.1	Software unit integration process			
5.6.2	Software unit integration records			

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

Attachment	**Software - Mapping of required evidence and manufacturer documents**			**N/A**
Standard Clause	Deliverables	Title	Revision #	Date
5.6.4	Software unit integration testing records			
5.6.5	Evaluation of software unit integration test			
5.6.6	Software unit regression testing process			
5.6.7	Software unit regression testing records			
5.6.8	Software problem resolution process			
5.7	Software system testing process			
5.8	Software system release process			
7.1	Software hazard analysis process			
7.1	SOUP anomaly lists			
7.2	Risk control process			
7.3	Risk control verification process			
7.4	Risk management of software change process			
8.1	Configuration identification record			
8.2	Change control process			
9	Software problem resolution process			
Supplementary information:				

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.

2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.

3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.

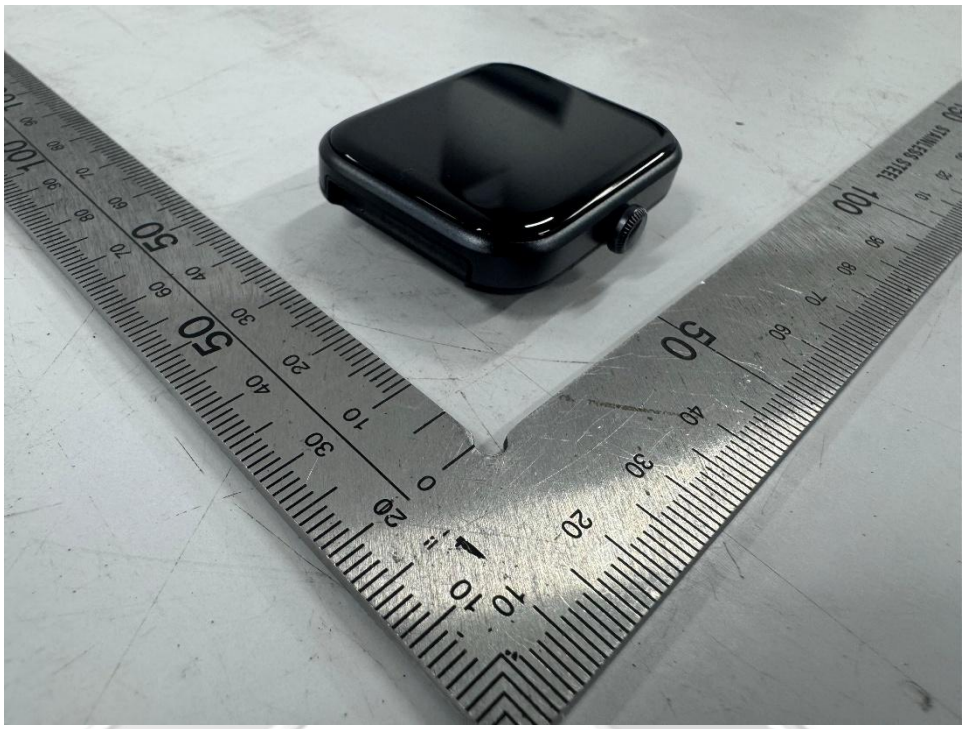
5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, 15 International Business Park TÜV SÜD @ IBP Singapore 609937.

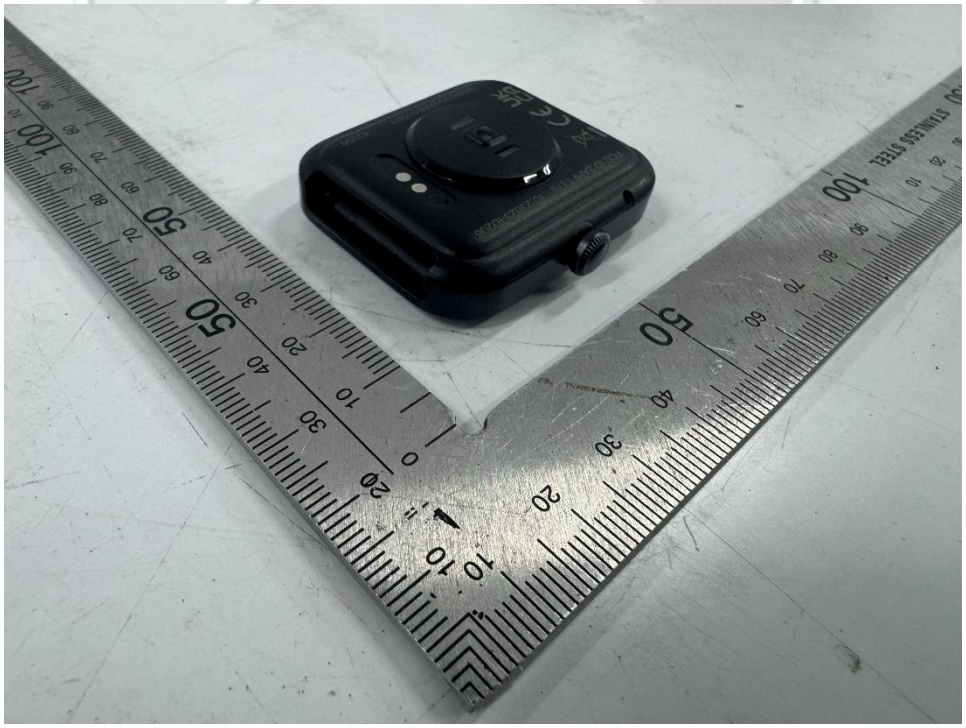
6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 27 March 2024

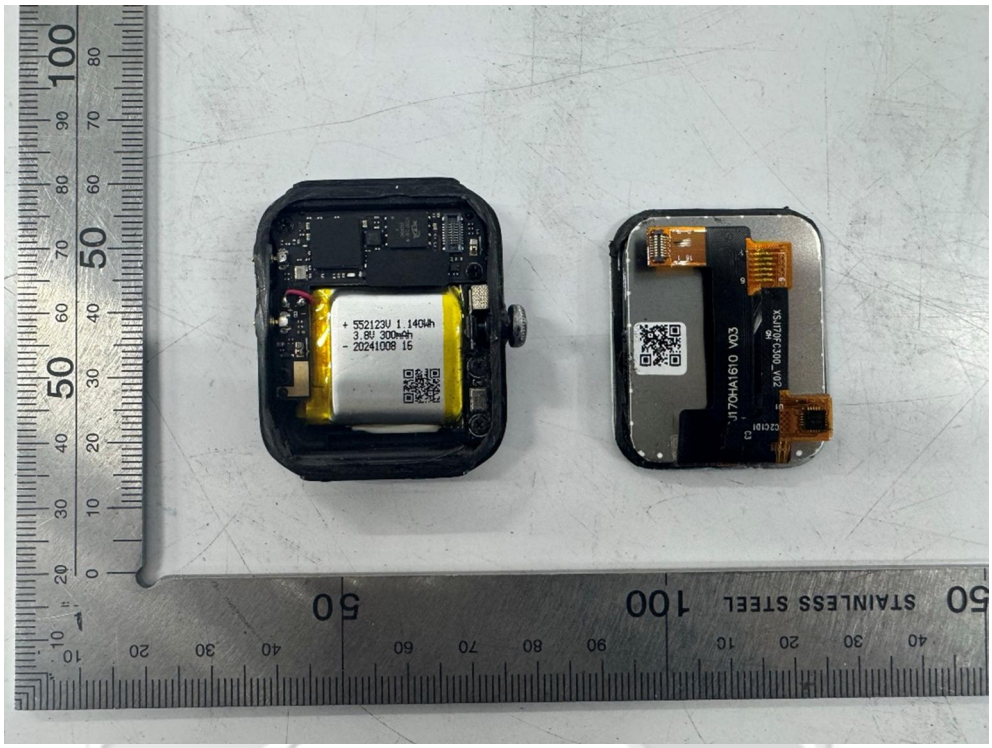
External views

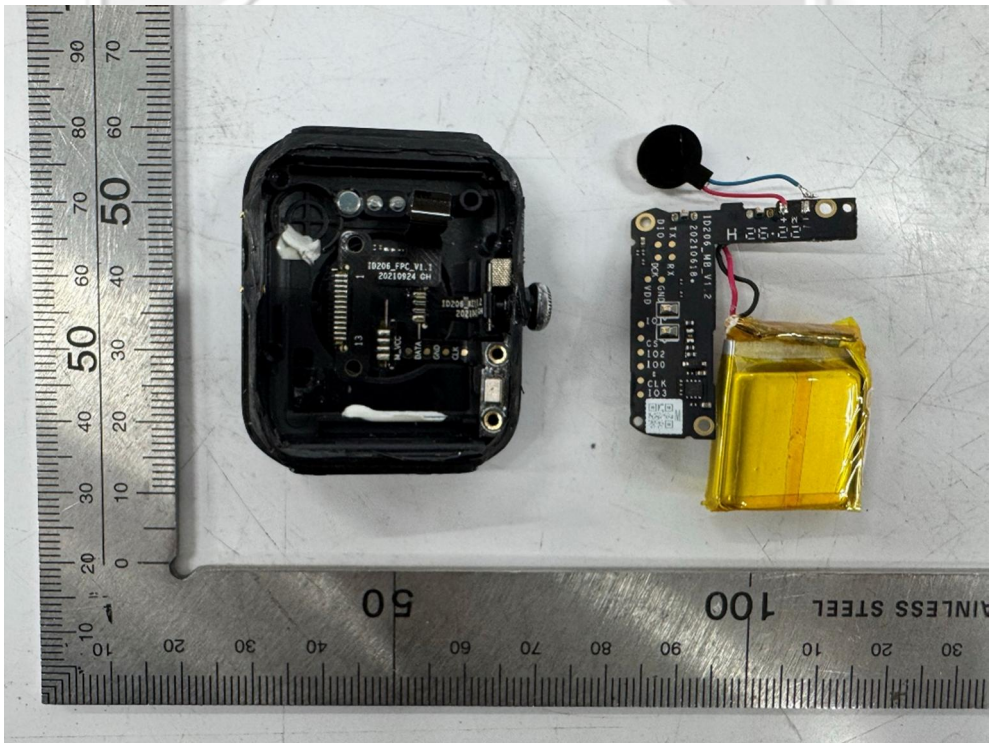
External views



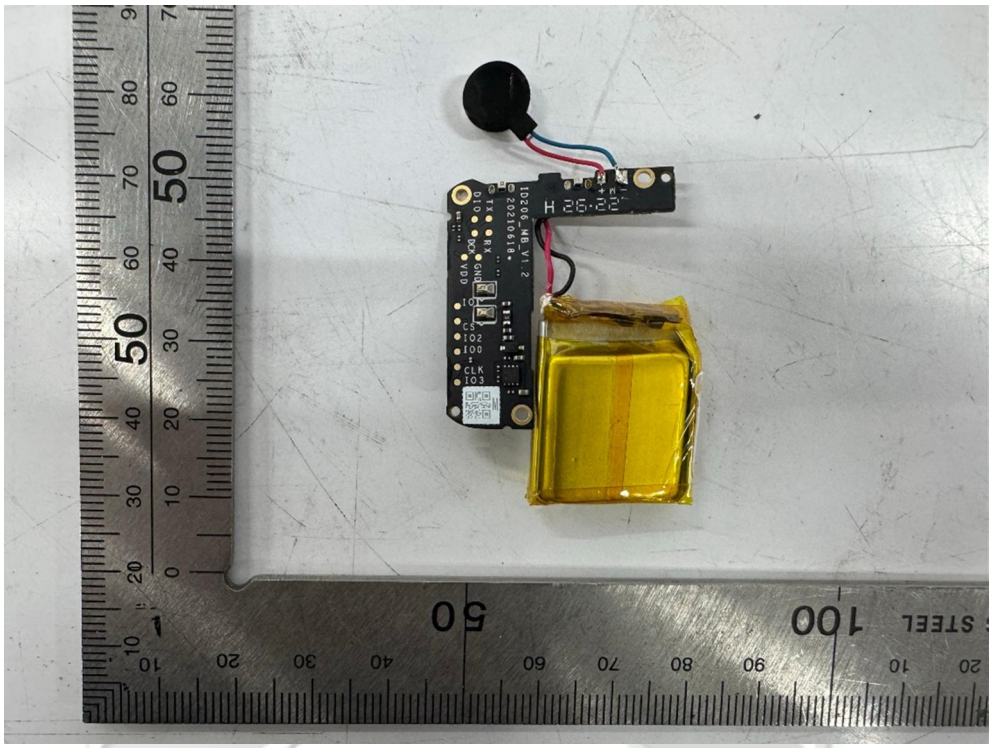


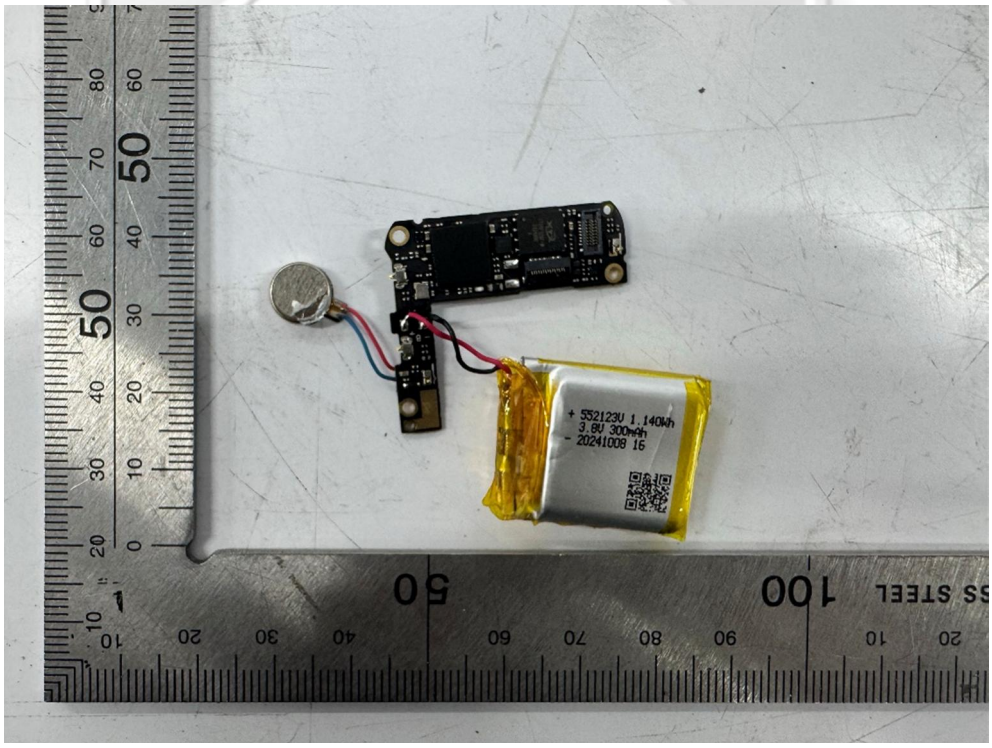
Internal views



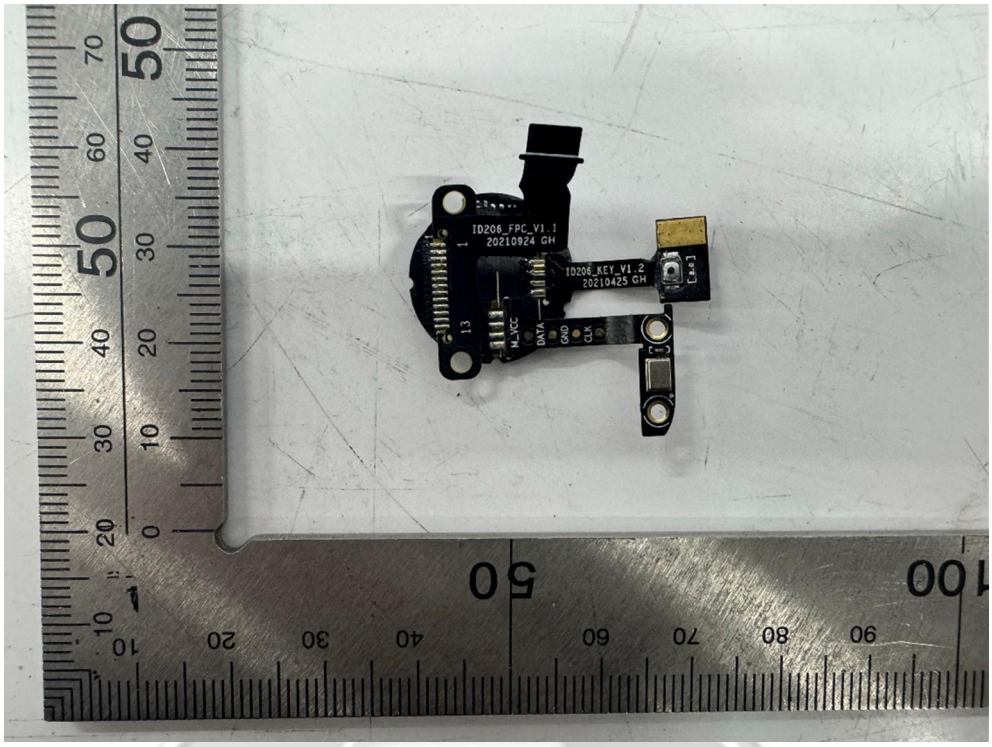


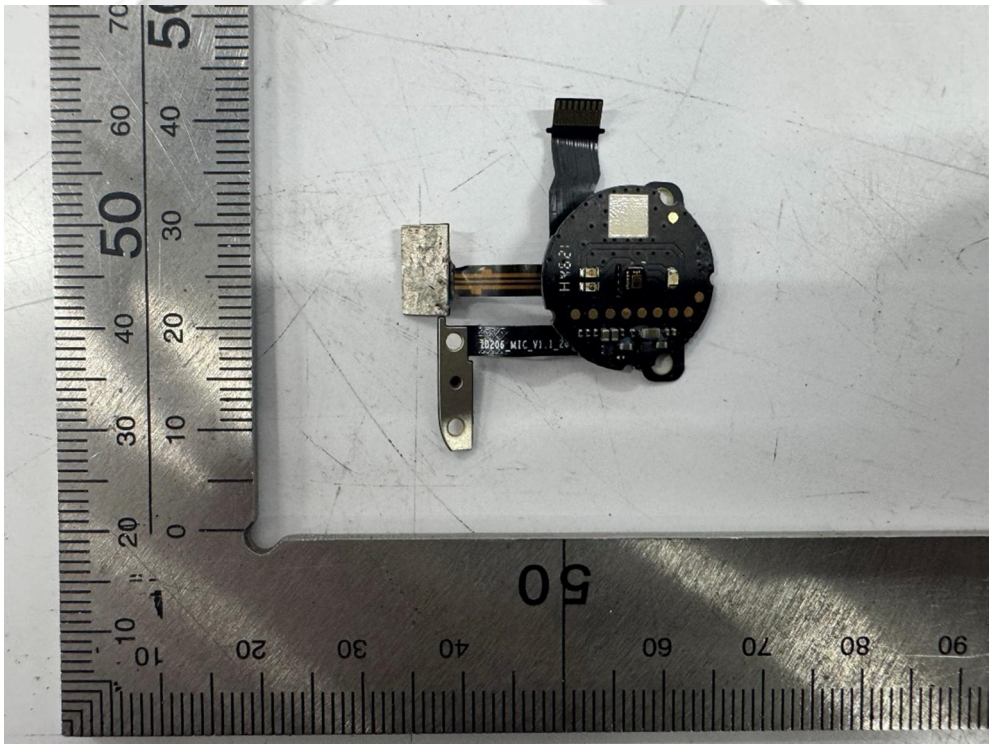
Internal views



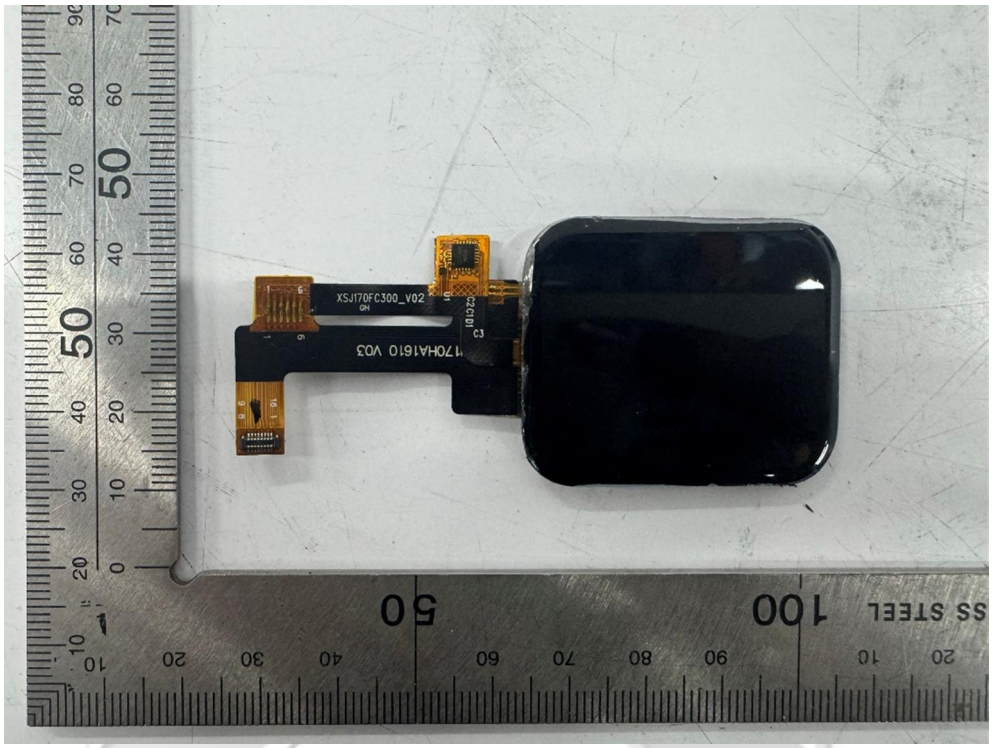


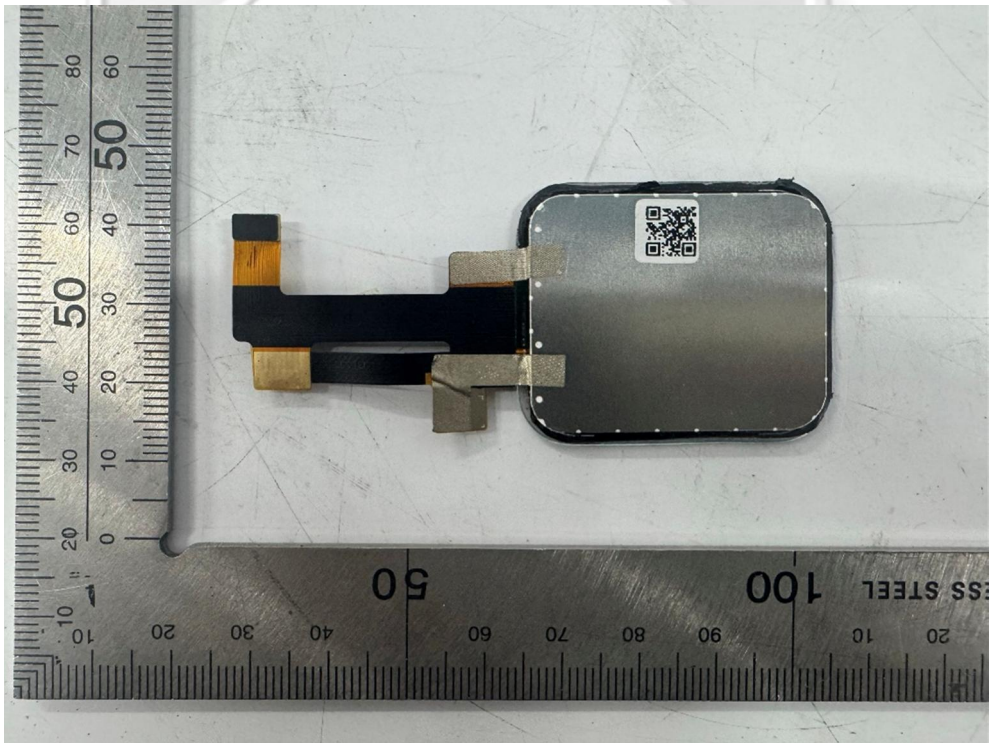
PCB views


ID206_FPC_V1.1
20210924 GH
ID206_KEY_V1.2
20210425 GH
A_VCC
DATA
GND
CLK


ID206_MIC_V1.1

Screen views





USB charging cable

Packaging Label

IEC60601_1U ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
ATTACHMENT TO TEST REPORT **IEC 60601-1** **US NATIONAL DIFFERENCES** **MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE**			
Differences according to..... :	National standard AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021		
TRF template used:..... :	IECEE OD-2020-F3, Ed. 1.1		
Attachment Form No. ..... : **Attachment Originator**..... : **Master Attachment**..... :	US_ND_IEC60601_1U UL(US) 2022-07-01		
	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*)		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.		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"		P
6.0	**Classification of ME EQUIPMENT and ME SYSTEMS**		**N/A**
6.6	Mode of operation	Not X-Ray systems	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 systems	N/A
7.0	**ME EQUIPMENT identification, marking and documents**		**N/A**
7.2.11	Mode of operation	Not X-Ray systems	N/A

IEC60601_1U ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
	(Addition to reflect agreement with NFPA 70) X-Ray systems are marked as long time operation or momentary operation.	Not X-Ray systems	N/A
7.2.22	(*Addition of new item*) Colours of medical gas cylinders	No cylinders containing medical gases	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.	No cylinders containing medical gases	N/A
8.0	**Protection against electrical hazards from ME EQUIPMENT**		**N/A**
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 ME EQUIPMENT or PERMANENTLY INSTALLED ME 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 ME 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 ME 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 PE	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 CONNECTED ME EQUIPMENT	N/A

IEC60601_1U ATTACHMENT			
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 ME 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:		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		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.		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.		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.		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..... :	No power supply cords	N/A
8.11.3.3	Cross-sectional area of POWER SUPPLY CORDS	No power supply cords	N/A

IEC60601_1U ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict
	(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 ME 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.	Not X-Ray ME EQUIPMENT	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.	Not X-Ray ME EQUIPMENT	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.	Not X-Ray ME EQUIPMENT	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.	Not X-Ray ME EQUIPMENT	N/A

TEST REPORT
IEC 60601-1-11
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 Number. ..... :	7191355668-EEC25
Date of issue ..... :	25 AUG 2025
Total number of pages ..... :	33
Name of Testing Laboratory preparing the Report ..... :	TÜV SÜD PSB Pte Ltd 15 International Business Park, TÜV SÜD @ IBP, Singapore 609937
Applicant's name..... :	Hyfe Inc
Address..... :	1209 N Orange Street, Wilmington, Delaware, 19802 USA
Test specification:	
Standard ..... :	IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020 for use in conjunction with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Non-standard test method ..... :	N/A
TRF template used ..... :	IECEE OD-2020-F1:2021, Ed.1.4
Test Report Form No. ..... :	IEC60601_1_11G
Test Report Form(s) Originator.... :	UL(US)
Master TRF..... :	2021-09-16

Test item description.....:	Cough Watch
Trade Mark ..... :	Hyfe
Manufacturer .....:	Hyfe Inc 1209 N Orange Street, Wilmington, Delaware, 19802 USA
Model/Type reference.....:	H026
Ratings.....:	3.8V, 300mAh (Internally powered), Type BF Applied Part

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
☒	**Testing Laboratory:**	TÜV SÜD PSB Pte Ltd	
Testing location/ address ..... :		15 International Business Park, TÜV SÜD @ IBP, Singapore 609937	
☐	**Associated CB Testing Laboratory:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :		Ng Chin Heng, tester	
Approved by (name, function, signature) .. :		Posen Fu, reviewer	
☐	**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 (including a total number of pages in each attachment): N/A	
Summary of testing:	
Tests performed (name of test and test clause): All applicable clauses except for the following clauses that were excluded at client's request: Clause 7.1; 8.1; 8.2, 9 : Usability Clause 12 : Additional Requirements for Electromagnetic Compatibility of ME Equipment and ME Systems.	**Testing location:** TÜV SÜD PSB Pte Ltd 15 International Business Park, TÜV SÜD @ IBP, Singapore 609937
Summary of compliance with National Differences (List of countries addressed): **- European Union (EN) (no declared national differences)** ☒ **The product fulfils the requirements of IEC 60601-1-11:2015, AMD1:2020 and EN 60601-1-11:2015/A1 except for the exclusion clauses stated in the above Summary of testing.**	

Use of uncertainty of measurement for decisions on conformity (decision rule) :

☒ No decision rule is specified by the IEC standard, when comparing the measurement result with the applicable limit according to the specification in that standard. The decisions on conformity are made without applying the measurement uncertainty ("simple acceptance" decision rule, previously known as "accuracy method").

☐ Other:… (to be specified, for example when required by the standard or client, or if national accreditation requirements apply)

Information on uncertainty of measurement:
The uncertainties of measurement are calculated by the laboratory based on application of criteria given by OD-5014 for test equipment and application of test methods, decision sheets and operational procedures of IECEE.
IEC Guide 115 provides guidance on the application of measurement uncertainty principles and applying the decision rule when reporting test results within IECEE scheme, noting that the reporting of the measurement uncertainty for measurements is not necessary unless required by the test standard or customer.

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

Copy of marking plate:

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

See IEC 60601-1 Test Report

Test item particulars .....:	
Classification of installation and use.....	See IEC 60601-1 Test Report
Supply Connection .....:	See IEC 60601-1 Test Report
Accessories and detachable parts included .....:	See IEC 60601-1 Test Report
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 does not meet the requirement.....:	F (Fail)
Testing .....:	
Date of receipt of test item.....:	08 April 2025
Date (s) of performance of tests .....:	08 April 2025 to 30 July 2025

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.

Risk management file:
The RMF has been evaluated according plausibility and technical consistency based on respective requirements out of ISO 14971. The risk acceptance criteria have been set by the manufacturer.

Name and address of factory (ies).....:	See IEC 60601-1 Test Report

General product information:

Remark 1: Refer to General product information in IEC 60601-1 test report for product description.

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

4	**GENERAL REQUIREMENTS**		
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:	Not intended to be connected to Supply Mains	N/A
	– 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).....:	Not intended to be connected to Supply Mains	—
	– 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 intended to be connected to Supply Mains	—
	- 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	Not intended to be connected to DC Supply Mains	N/A
	- 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	Not intended to be connected to DC Supply Mains	N/A
	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/A
	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/A
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	More restricted range stated in the instructions for use	N/A
	temperature range:-25 °C to + 5 °C		N/A
	temperature range:+5 °C to +35 °C at a non-condensing relative humidity up to 90 %		N/A
	temperature range: >35 °C to 70 °C at a water vapour pressure up to 50 hPa		N/A
	For more restricted range of environmental transport and storage conditions between uses, the environmental conditions are specified	IFU: -20°C to 50°C	P

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
	– Justified in the RISK MANAGEMENT FILE	See RISK MANAGEMENT Table 4.2.1	P
	– Marked on the ME EQUIPMENT	See below	N/A
	When not practicable, the more restricted range is disclosed in the instructions for use	Marking on the enclosure is not practical due to small size. More restricted range is disclosed in the instructions for use and packaging label	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	N/A
	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/A
	Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2012 used to mark humidity range		N/A
	Symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2012 used to mark atmospheric pressure range		N/A
	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		N/A
	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).....:	-20°C	P
	– For at least 16 h or, ensure ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	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.		P
	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, ± %) .....:	50°C	P

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
	– For at least 16 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	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	Basic safety checked.	P
4.2.3.1	**Environmental operating conditions - Continuous operating conditions**		**P**
	Instructions for use indicated permissible environmental operating conditions of the ME EQUIPMENT		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,	+ 5 °C to +40 °C	P
	Relative humidity range of 15 % to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa; and	15 % to 90%	P
	An atmospheric pressure range of 700 hPa to 1060 hPa	700 hPa to 1060 hPa	P
	For more restricted range of environmental operating conditions	Not more restricted range	N/A
	- justified in the risk management file;	See RISK MANAGEMENT Table 4.2.3.1 Not more restricted range	N/A
	-marked on the equipment; or were nor practical in the instructions for use……..:	Not more restricted range	N/A
	– Marked on the carrying case when the instructions for use indicate the ME EQUIPMENT is intended to be operated in a carrying case	N/A	N/A
	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/A
	Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2012 used to mark humidity range		N/A
	Symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2012 used to mark atmospheric pressure range		N/A
	Where ME EQUIPMENT used different marking for conditions of continuous operating conditions and transient operating conditions, markings accompanied by supplementary markings		N/A
	Environmental operating conditions test		P

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
	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) .....:	Thermal stability maintained for at least 2 h.	P
	c) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE	Basic safety checked.	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.	Basic safety checked.	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.	Basic safety checked.	P
	f) Pressure in chamber relieved		N/A
	g) ME EQUIPMENT cooled to its lowest specified environmental operating conditions	5 °C	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 .....:	Thermal stability maintained for at least 2 h.	P
	i) ME EQUIPMENT met its specifications and BASIC SAFETY and ESSENTIAL PERFORMANCE	Basic safety checked.	P
	j) ME EQUIPMENT warmed to its highest specified continuous environmental operating conditions	40°C	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 .....:	Thermal stability maintained for at least 2 h.	P
	l) ME EQUIPMENT met its specifications and BASIC SAFETY and ESSENTIAL PERFORMANCE	Basic safety checked.	P
4.2.3.2	**Environmental shock to TRANSIT-OPERABLE EQUIPMENT**		N/A
	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).	No wider range stated in the IFU	N/A
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

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

	ACCESSIBLE parts of ME EQUIPMENT identified by inspection and, when necessary, by testing		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:		P
	– for all positions of the ME EQUIPMENT operating in NORMAL USE		P
	– after opening ACCESS COVERS and removal of parts, including lamps, fuses, and fuse holders when:	No access covers	N/A
	i) the ACCESS COVERS could be opened without the use of a TOOL, or		N/A
	ii) the instructions for use instructed a LAY OPERATOR to open the relevant ACCESS COVER		N/A

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:	See below	P
	– CLASS II or INTERNALLY POWERED.....:	Internally powered	P
	– Not provided with a FUNCTIONAL EARTH TERMINAL		P
	– When equipped with APPLIED PARTS, they are TYPE BF or CF.....:	Type BF Applied Part	P

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

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	See USABILITY ENGINEERING FILE Excluded as per client's request	N/A
	ME EQUIPMENT and ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT are simple to use and do not require referencing complex ACCOMPANYING DOCUMENTS ..... :	See USABILITY ENGINEERING FILE Excluded as per client's request	N/A
7.2	In addition to requirements of 7.2.9 of the general standard, the ME EQUIPMENT or its parts and, when appropriate, a carrying case are marked with the appropriate IP classification as tested in 8.3.1.. :	No carrying case	N/A
	If the carrying case provide some or all of the ingress protection against water or particulate matter:		N/A
	a) The ENCLOSURE is marked with the safety sign ISO 7010-W001 and "keep dry" or symbol ISO 15223-1:2012, 5.3.4 (ISO 7000-0626) ..... :	No carrying case	N/A
	b) the carrying case marked with its degree of protection ..... :	No carrying case See IEC 60601-1 Test report, Sub-clauses 7.1.2 and 7.1.3	N/A
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:		P
	– Assistance in setting up, using, or maintaining the ME EQUIPMENT or ME SYSTEM when needed, or	Information provided in the User Guide	P
	– To report unexpected operation or events	Information provided in the User Guide	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	User Guide: Support	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:	Information provided in the User Guide	P
	– Precautions to be taken in the event of changes in the performance of ME EQUIPMENT or ME SYSTEM		N/A

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
	– Precautions to be taken regarding the exposure of the ME EQUIPMENT or ME SYSTEM to reasonably foreseeable environmental conditions	User Guide: Safety information – Warnings	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 used.	N/A
	– Information on any medicinal substances or human blood derivatives incorporated into the ME EQUIPMENT or ACCESSORIES as an integral part; and		N/A
	– The degree of accuracy claimed for ME EQUIPMENT with a measuring FUNCTION		N/A
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/A
	– Inhalation or swallowing of small parts	User Guide: Safety information – Warnings	P
	– Potential allergic reactions to accessible materials used in the ME EQUIPMENT	User Guide: Safety information – Cautions	P
	– Contact injuries	User Guide: Safety information – Cautions	P
	The instructions for use include warnings to the effect that the following actions could be unsafe as applicable:	See below	P
	– Use of ACCESSORIES, detachable parts, and materials not described in the instructions for use (see 7.9.2.14 of Part 1)	User Guide: Safety information – Warnings	P
	– Interconnection of this equipment to other equipment not described in the instructions for use (see 16.2 c) indent 9) of Part 1)	No interconnection to other equipment	N/A
	– Modification of the equipment	User Guide: Safety information – Cautions	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)		N/A

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
7.4.2	When BASIC SAFETY or ESSENTIAL PERFORMANCE dependents on the INTERNAL ELECTRICAL POWER SOURCE, the instructions for use describes the following:	User Guide	P
	– Typical operation time or number of procedures.. :	User Guide: Operating Instructions – Battery: Battery run time: up to 48 hours	P
	– Typical service life of the INTERNAL ELECTRICAL POWER SOURCE; and..... :	User Guide: Technical Information – Battery: Battery Service Life – 500 recharges cycles	P
	– Behaviour of ME EQUIPMENT while the rechargeable INTERNAL ELECTRICAL POWER SOURCE is charging ..... :	User Guide: - Battery - Nighttime instructions	P
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)	Diagrams and illustrations provided in the Flow Generator and Power Station II User Guides and Flow Generator Clinical Guide	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)	User Guide: Cough Watch Overview	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) ..... :	No such functions	N/A
	-the time required for ME EQUIPMENT to warm from the minimum storage temperature between uses until it is ready for intended use; and ..... :	No such functions	N/A
	-the time required for ME EQUIPMENT to cool from the maximum storage temperature between uses until it is ready for intended use; and ..... :	No such functions	N/A
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		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

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
	- The effects of lint, dust, light (including sunlight), etc.		N/A
	- A list of known devices or other sources that can potentially cause interference problems	User Guide : Electromagnetic Interference	P
	- The effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems		N/A
	- The effects caused by pets, pests or children	User Guide: Safety information – Warnings	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	See RISK MANAGEMENT Table 7.4.5 User Guide: Technical Information	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	User Guide : Troubleshooting	P
	Troubleshooting guide discloses the necessary steps in the event of an TECHNICAL ALARM CONDITION	No alarm.	N/A
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:		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	User Guide: Safety information – Cautions	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		N/A
	– 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)		N/A
7.4.8	Instructions for use include:		P
	– EXPECTED SERVICE LIFE of the ME EQUIPMENT ..... :	User Guide: Technical Information – 1 year	P

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
	– EXPECTED SERVICE LIFE of parts and ACCESSORIES shipped with the ME EQUIPMENT ..... :		N/A
	– SHELF LIFE of parts and ACCESSORIES shipped with ME EQUIPMENT when SHELF LIFE is less than the EXPECTED SERVICE LIFE ..... :	No accessories	N/A
7.4.9	Instructions for use include:		N/A
	– 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	No bio hazardous parts	N/A
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 distributed alarm system	N/A
7.5	**Technical description**		N/A
7.5.1	The technical description for PERMANENTLY INSTALLED CLASS I ME EQUIPMENT includes:	Not permanently installed Class I equipment	N/A
	– A warning indicating the ME EQUIPMENT installation, including a correct PROTECTIVE EARTH CONNECTION, must only be carried out by qualified SERVICE PERSONNEL		N/A
	– Specifications of the PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR		N/A
	– A warning to verify the integrity of the external protective earthing system		N/A
	– 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/A
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):	Professional hygienic maintenance is not required.	N/A
	– Before and after any type of service PROCEDURE		N/A
	– When the ME EQUIPMENT is transferred to another PATIENT		N/A

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

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)		P
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS .....:	See USABILITY ENGINEERING FILE Excluded as per client's request	N/A
8.2	A LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT can perform the cleaning and sterilization PROCESSES when intended (see 7.4.7)	No sterilization required	N/A
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS	See USABILITY ENGINEERING FILE Excluded as per client's request	N/A
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 .....:	TRANSIT-OPERABLE IP 27 conducted	P
	All other ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529 for at least IP21 .....:	See above	N/A
	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		N/A
	Maintenance of BASIC SAFETY and ESSENTIAL PERFORMANCE VERIFIED	Basic safety checked	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		N/A
	Tests of IEC 60529:1989 conducted with the equipment placed in the least favourable position of NORMAL USE and the ENCLOSURES inspected		N/A
8.4	**Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT and ME SYSTEM**		N/A

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
	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	Non-life-supporting ME Equipment	N/A
	The time or number of PROCEDURES remaining allowed alternative life-supporting methods to be employed		N/A
	Optionally, an INTERNAL ELECTRICAL POWER SOURCE was used to maintain ESSENTIAL PERFORMANCE.....:	Non-life-supporting ME Equipment	N/A
	Optionally, independent means were used to provide ESSENTIAL PERFORMANCE .....:	See above	N/A
	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/A
	Instructions for use describes the alternative life-supporting methods to be employed		N/A
	The technical description describes methods that can be employed for longer periods		N/A
	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/A
	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/A
	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/A
	TECHNICAL ALARM CONDITION provides sufficient time or sufficient number of procedures for a LAY OPERATOR to act		N/A

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
	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/A
	It was not possible to inactivate the visual ALARM SIGNAL of this TECHNICAL ALARM CONDITION		N/A
	Functional tests conducted, and the RISK MANAGEMENT FILE inspected.....:	Non-life-supporting ME Equipment	N/A
8.5	**Additional requirements for an INTERNAL ELECTRICAL POWER SOURCE**		N/A
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 essential performance.	N/A
	State of INTERNAL ELECTRICAL POWER SOURCE indicated by:		N/A
	- number of PROCEDURES remaining;		N/A
	-remaining operating time;		N/A
	-percentage of the remaining operating time or energy; or		N/A
	-"fuel" gauge		N/A
	Instructions described method to determine state of INTERNAL ELECTRICAL POWER SOURCE		N/A
8.5.2	Means, other than labelling, provided to prevent RISK of swallowing coin/button cells		N/A
	Replacement of button cell require use of TOOL		N/A
8.5.3	For ME EQUIPMENT or ME SYSTEM with an INTERNAL ELECTRICAL POWER SOURCE, if simultaneous connection of the ME EQUIPMENT to the PATIENT and the SUPPLY MAINS is possible, then APPLIED PARTS and parts that are likely to come into contact with the PATIENT have two MOPP from the SUPPLY MAINS	No Internal Electrical Power Source	N/A
	Parts which the PATIENT intentionally handles as the intended OPERATOR while the ME EQUIPMENT is not being used for its intended medical function are insulated with two MOOP or two MOPP from SUPPLY MAINS.		P

IEC 60601-1-11			
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		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		N/E
	USABILITY ENGINEERING FILE inspected for compliance .....:	See USABILITY ENGINEERING FILE Excluded as per client's request	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 2, Mechanical strength test applicability, TRANSIT-OPERABLE	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)	TRANSIT-OPERABLE	N/A
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after mechanical tests		N/A

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
	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		N/A
	a) Shock tests conducted in accordance with IEC 60068-2-27:2008..... :	TRANSIT-OPERABLE	N/A
	b) Broad-band random vibration tests conducted in accordance with IEC 60068-2-64:2008, using the following conditions..... :	TRANSIT-OPERABLE	N/A
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		P
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after the following tests:		P
	a) Shock tests conducted on other than HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-27:2008		P
	1) Test type: Type 1..... :	See Appended Table 10.1.3a1	N/A
	2) Test type: Type 2..... :	See Appended Table 10.1.3a2	P
	b) Shock tests conducted on HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-27:2008		N/A
	1) Test type: Type 1..... :	See Appended Table 10.1.3b1	N/A
	2) Test type: Type 2..... :	See Appended Table 10.1.3b2	N/A
	c) Broad-band random vibration test conducted on ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-64:2008 ..... :	See Appended Table 10.1.3c	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 ..... :	See Appended Table 10.1.3d	P
	BASIC SAFETY and ESSENTIAL PERFORMANCE were maintained		P
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		P
	OPERATOR-adjustable controls used for calibration include a means to prevent unintentional changes from the intended position		N/A

IEC 60601-1-11			
Clause	Requirement + Test	Result - Remark	Verdict
11	**PROTECTION AGAINST STRANGULATION OR ASPHYXIATION**		N/A
	Means provided to control the RISK of strangulation and asphyxiation of the PATIENT and others to an acceptable level	No defined risk	N/A
	EQUIPMENT and RISK MANAGEMENT FILE inspected.... :	See RISK MANAGEMENT Table 11. No defined risk.	N/A
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..... :	Excluded as per client's request	N/E
13	**ADDITIONAL REQUIREMENTS FOR ALARM SYSTEMS OF ME EQUIPMENT AND ME SYSTEMS**		N/A
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.	N/A
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/A

IEC 60601-1-11			
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**
5.2	HYF7-004-001 Hyfe Cough Diary Risk Management Plan, Section 6: Intended Use	Risk Analysis - Intended use and reasonably foreseeable misuse	P
5.3	HYF7-004-002 Identification of hazards and characteristics related to safety	Risk Analysis - Identification of characteristics related to safety	P
5.4	HYF7-004-003 Hyfe Cough Diary Risk Assessment: Hazard ID: 6.5	Risk Analysis - Identification of hazards and hazardous situations	P
5.5	HYF7-004-003 Hyfe Cough Diary Risk Assessment: Hazard ID: 6.5	Risk Analysis - Risk estimation	P

4.2.3.1	RM RESULTS TABLE: Environmental operating conditions - Continuous operating conditions		N/A
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
5.2			
5.3			
5.4			
5.5			

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

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**
5.2	HYF7-004-001 Hyfe Cough Diary Risk Management Plan, Section 6: Intended Use	Risk Analysis - Intended use and reasonably foreseeable misuse	P
5.3	HYF7-004-002 Identification of hazards and characteristics related to safety	Risk Analysis - Identification of characteristics related to safety	P
5.4	HYF7-004-003 Hyfe Cough Diary Risk Assessment: Hazard IDs: 2.6; 2.17; 4.1; 4.2; 4.3; 4.4; 5.5; 6.3	Risk Analysis - Identification of hazards and hazardous situations	P
5.5	HYF7-004-003 Hyfe Cough Diary Risk Assessment: Hazard IDs: 2.6; 2.17; 4.1; 4.2; 4.3; 4.4; 5.5; 6.3	Risk Analysis - Risk estimation	P
6	HYF7-004-003 Hyfe Cough Diary Risk Assessment: Hazard IDs: 2.6; 2.17; 4.1; 4.2; 4.3; 4.4; 5.5; 6.3	Risk Evaluation	P
7.1	HYF7-004-003 Hyfe Cough Diary Risk Assessment: Hazard IDs: 2.6; 2.17; 4.1; 4.2; 4.3; 4.4; 5.5; 6.3	Risk Control - Risk control option analysis	P

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

7.4.5	**RM RESULTS TABLE: : Additional requirements for operating instructions**		**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
5.4	HYF7-004-003 Hyfe Cough Diary Risk Assessment: Hazard IDs: 2.6; 2.17; 4.1; 4.2; 4.3; 4.4; 5.5; 6.3	Risk Analysis - Identification of hazards and hazardous situations	P
5.5	HYF7-004-003 Hyfe Cough Diary Risk Assessment: Hazard IDs: 2.6; 2.17; 4.1; 4.2; 4.3; 4.4; 5.5; 6.3	Risk Analysis - Risk estimation	P
6	HYF7-004-003 Hyfe Cough Diary Risk Assessment: Hazard IDs: 2.6; 2.17; 4.1; 4.2; 4.3; 4.4; 5.5; 6.3	Risk Evaluation	P
7.1	HYF7-004-003 Hyfe Cough Diary Risk Assessment: Hazard IDs: 2.6; 2.17; 4.1; 4.2; 4.3; 4.4; 5.5; 6.3	Risk Control - Risk control option analysis	P

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

8.4	RM RESULTS TABLE: Additional requirements for interruption of power supply / supply mains to ME Equipment and ME Systems		N/A
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
5.2		Non-Life-Supporting ME equipment.	
5.3			
5.4			
6			
7.1			
7.2			
7.3			
7.4			
7.5			

10.1.2a	TABLE: Shock test (IEC 60068-2-27:2008), using the following conditions*:	N/A
	Peak acceleration..... :	150 m/s2 (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 1 This represents Class 7M1 as described in IEC TR 60721-4-7:2001 [6])

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

10.1.2b	**TABLE: Broad-band random vibration test (IEC 60068-2-64:2008) using the following conditions*:**		**N/A**
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	-	-
2	1	-	-
3	1	-	-
1	2	-	-
2	2	-	-
3	2	-	-
1	3	-	-
2	3	-	-
3	3	-	-

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

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

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/A**
	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])
Test results are applicable to Flow Generator and Power Station II.

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

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):**		**P**
	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
Positive	Z	Yes	Basic safety was check after test.
Negative	Z		
Positive	Y		
Negative	Y		
Positive	X		
Negative	X		
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/A**
	Peak acceleration..... :	300 m/s² (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)

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

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/A**
	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*:**		**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	Basic safety was checked after test
2	1		
3	1		
1	2		
2	2		
3	2		
1	3		
2	3		
3	3		

Supplementary information:
*(NOTE 5 This represents Class 7M1 and 7M2 as described in IEC/TR 60721-4-7:2001)
Test results are applicable to Flow Generator and Power Station II.

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

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*:**		**P**
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	Yes	Basic safety was checked after test
0,25	≤ 1	2	Yes	Basic safety was checked after test
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**)**
Test results are applicable to Flow Generator and Power Station II.

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

11.0	**RM RESULTS TABLE: PROTECTION AGAINST STRANGULATION AND ASPHYXIATION**		**N/A**
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
5.4			
5.5			
6			
7.1			
7.2			
7.3			
7.4			
7.6			
Supplementary information:			

ATTACHMENT to TRF IEC60601_1_11G
ATTACHMENT TO TEST REPORT **IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020 FOR USE IN CONJUNCTION WITH IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020** **US NATIONAL DIFFERENCES** **Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance for medical electrical equipment and medical electrical systems used in the home healthcare environment**
Differences according to.....: National standard AAMI HA66001-1-11:2015
TRF template used:.....: IECEE OD-2020-F3:2024, Ed. 1.3
Attachment Form No.....: US_ND_IEC60601_1_11G **Attachment Originator .....**: UL Solutions (US) **Master Attachment**.....: Dated 2025-05-08

Clause	Requirement + Test	Result - Remark	Verdict
	National Differences		P
3	Terms and definitions		P
3.1	Note 2 modified to indicate Elder Care facilities in US are considered a professional care facility		P
8.4	Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT and ME SYSTEM		N/A
	Additional sentence added to paragraph proceeding note 2. Actions associated with providing the alternative life-supporting methods considered as PRIMARY OPERATING FUNCTIONS when applying USABILITY ENGINEERING PROCESS	Non-life-supporting ME Equipment	N/A
10.2	Additional requirements for actuating parts of controls of ME EQUIPMENT		N/A
	Compliance statement modified: Compliance checked by inspection and inspection of the USABILITY ENGINEERING FILE as appropriate	Usability excluded as per client's request	N/A
	Index of defined terms use in this collateral standard		
	Addition of defined term: PRIMARY OPERATING FUNCTION		N/A