CONFORMANCE TEST REPORT

FOR

VPro Vibration Device
Model: ASM-20018

Prepared for

PROPEL Orthodontics, LLC, 394 South Abbott Avenue Milpitas, CA 95035

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NVLAP TESTING
NVLAP LAB CODE 200527-0

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This report contains data that are not covered by the NVLAP accreditation.

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Description of Changes

Report No	Project No	Edition	Date Issued	Description
D00225S1	20LF2841	1	2/28/20	Evaluation of Model ASM-20018

This report consists of the following:

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General Report Summary

This product safety test report is generated by Compatible Electronics Inc., which is an independent testing and consulting firm. The test report is based on testing performed by Compatible Electronics personnel according to the measurement procedures described in the test specifications given below.

The measurement data and conclusions appearing herein relate only to the sample tested and this report may not be reproduced without the written permission of Compatible Electronics, unless done so in full. This report is issued errors and omissions exempt. This report can be subject to withdrawal, or alteration at Compatible Electronics' discretion.

This report must not be used to claim product endorsement by NVLAP, NIST, any NRTL or any other agency of the U.S. Government.

The client Equipment referred to in this Test Report was found to comply with the requirements of standard,

- IEC 60601-1:2005 +A1: 2012 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- EN 60601-1: 2006 +A1: 2013 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
- AAMI ES 60601-1: 2005, +C1:2009 A2: 2010 & +A1:2012 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Deviations from IEC 60601-1:2005
- EN 1639: 2009 - Dentistry - Medical devices for dentistry - Instruments
- EN 1640: 2009 - Dentistry - Medical devices for dentistry - Equipment

Test Specifications covered by accreditation:

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Relevant Product Safety Medical Requirements
IEC 60601-1: 2005
IEC 60601-1: 2005 +A1:2012
EN 60601-1: 2006 +A1: 2013
AAMI ES 60601-1:2005
AAMI ES 60601-1:2005 +C1:2009
AAMI ES 60601-1:2005 +A2:2010
AAMI ES 60601-1:2005 +A1: 2012

Test Specifications not covered by accreditation;

EN 1639: 2009
EN 1640: 2009

Description of Equipment Tested

Description:	VPro Vibration Device
Model:	ASM-20018
Ratings:	5V 1A (USB) Battery 3.7Vdc 115mAh
Serial Number:	None
Date Received:	February 24, 2020
Class of equipment:	Class II
Plug Type:	Pluggable Type A
Equipment mobility:	HandHeld Mobile
Mass of Equipment:	0.018 kg (0.0396lb)
Operating Condition:	Continuous
Environment:	25ºC
Enclosure Rating:	IPX3
Power System:	N/A
Pollution Degree:	2
Overvoltage Category:	I
Disconnect Device:	N/A
Power Cord:	N/A

ME Equipment Description

The VPro is a rechargeable portable vibration device used by orthodontic patients during treatment with aligners to facilitate minor anterior tooth movement. When wearing removeable aligners, the patient would slightly bite down on the mouthpiece and turn on the device. VPro is intended to be used for 5 minutes each day in their home. VPro comes with a vibration unit, a mouthpiece, and a USB to USB-C charging cable.

Intended Use

The VPro Vibration Device is intended to be use by the orthodontic patient to aid with seating of removable aligners during orthodontic treatment.

Grounding and Bonding Details:

None

Markings

The markings on the enclosure read as follows:

Accompanying Documentation

A copy of the documentation is on file at the manufacturer. Manufacturer has indicated that the appropriate sections of the documentation will be provided in the language of the end user.

Safety Critical Components

The following components are considered critical to the safety of the apparatus.

Item No	Component Description	Manufacturer	Type Number and Ratings	Standard	Test Mark
1	Enclosure	Various	Description: Plastic enclosure shaped as shown in the photos.		
			Plastic Enclosure Materials: ABS material type: Polylac PA-747 flammability rating: HB	IEC 6095-11-10	CE, UL E56070
			Overall charging assembly Measures: 7cm by 10.6cm by 3.5cm Vibrator dimensions: Measures: 2.7cm by 2.4cm by 4cm Ventilation Openings: None		
2	Vibrator Battery Pack	Renata	PN: ICP501421PS-01 3.7V 110mAh 0.4Wh	IEC 62133	CE, CB TUV, UL
3	PCB Material	PROPEL Orthodontics	NAN YA Plastics Corp. Mat type: NP175F Min flammability: V-0	IEC 6095-11-10	CE UL E98983

Conformance Check List 60601-1

All mandatory tests required by the standard and relevant to the product have been completed. Detailed test results are provided in the "Test Results" section of this report.

Clause 1 – Scope, Object and Related Standards

This equipment is covered by the scope of this standard.

Clause 2 – Normative References

All normative references have been noted and taken into consideration in the evaluation of this equipment

Clause 3 – Terminology and Definitions

All terminology and definitions have been noted and taken into consideration in the evaluation of this equipment.

Verdict	Meaning
Pass	Meets the requirement of the standard.
Fail	Does not meet the requirement of the standard.
Noted	Information found in the risk management file as required by the standard. The test lab did not assess the clinical adequacy of the information.
N/A	Not applicable.
N/E	Not evaluated.

Verdict	Meaning
(A1)	IEC 60601-1: 2005 +A1: 2012 & EN 60601-1: 2006 +A1: 2013
(A2)	AAMI ES 60601-1:2005 +A2:2010
(C1)	AAMI ES 60601-1:2005 /C1:2009

Clause 4 – General Requirements

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
4.1	Conditions for application to the ME Equipment or ME System	Noted	
4.2	Risk management process for ME Equipment or ME System	See Risk Management File	Pass
4.2.1	Introduction to risk management	(A1)	Pass
4.2.2	General requirement for risk management	(A1)	Pass
4.2.3	Evaluation risk	(A1)	Noted
4.2.3.1	Hazards identified in the IEC 60601-series	(A1)	Noted
4.2.3.2	Hazards not identified in the IEC 60601-series	(A1)	Noted
4.3	Essential performance	(A1) Noted, See Risk Management File	Noted
4.4	Expected Service Life	Noted, See Risk Management File	Noted
4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	(A1) Noted See Risk Management File	Noted
4.6	ME Equipment or ME System parts that contact the patient	(A1) Noted, See Risk Management File	Noted
4.7	Single fault condition for ME Equipment		Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
a)	it employs a single means for reducing a RISK that has a negligible probability of failure (e.g. REINFORCED INSULATION, suspended masses without ECHANICAL PROTECTIVE DEVICES employing a TENSILE SAFETY FACTOR of 8X, COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS), or		Pass
b)	SINGLE FAULT CONDITION occurs, but:		Pass
4.8	Components of ME Equipment	(A1) Noted See Risk Management File	Pass
a)	the applicable safety requirements of a relevant IEC or ISO standard;		Pass
b)	where there is no relevant IEC or ISO standard, the requirements of this standard have to be applied.	Ref AAMI deviation	Pass
4.9	Use of components with high-integrity characteristics in ME Equipment	See Safety Critical Components List	Pass
4.10	Power supply		
4.10.1	Source of power for ME Equipment	Noted	Pass
4.10.2	Supply Mains for ME Equipment and ME Systems	Noted, Ref AAMI deviation	Pass
4.11	Power input	(A1)	Pass

Clause 5 – General Requirements for Testing ME Equipment

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
5.1	Type Tests	(A1) See Risk Management File	Pass
5.2	Number of samples	one sample given	Pass
5.3	Ambient temperature, humidity, atmospheric pressure		
a)	After the ME EQUIPMENT to be tested has been set up for NORMAL USE (according to 5.7), tests are performed within the range of environmental conditions indicated in the technical description (see 7.9.3.1).	See Test Results	Pass
b)	ME EQUIPMENT is shielded from other influences (for example, draughts), that might affect the validity of the tests	See Test Results	Pass
c)	In cases where ambient temperatures cannot be maintained, the test conditions are to be consequently modified and results adjusted accordingly	Specified environment was maintained during testing	N/A
5.4	Other conditions		
a)	Unless otherwise specified in this standard, ME EQUIPMENT is to be tested under the least favorable working conditions as specified in the instructions for use that are identified during RISK ANALYSIS	(A1) Noted	Pass
b)	ME EQUIPMENT having operating values that can be adjusted or controlled by anyone other than SERVICE PERSONNEL shall be adjusted as part of the tests to values least favorable for the relevant test, but in accordance with the instructions for use		Pass
c)	If the test results are influenced by the inlet pressure and flow or chemical composition of a cooling liquid, the test is performed within the limits for these characteristics as prescribed in the technical description.		Pass
d)	Where cooling water is required, potable water is used	No water is used for cooling	N/A
5.5	Supply voltages, type of current, nature of supply, frequency		

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
a)	Where test results are influenced by deviations of the supply voltage from its RATED value, the effect of such deviations is taken into account.	(A1) See Test Results	Pass
b)	. ME EQUIPMENT having a MAINS PART intended for connection to a.c. SUPPLY MAINS is only tested with a.c. at RATED frequency (if marked) +/- 1 Hz up to and including 100 Hz and +/- 1 % above 100 Hz. ME EQUIPMENT marked with a RATED frequency range is tested at the least favorable frequency within that range.		Pass
c)	ME EQUIPMENT designed for more than one RATED voltage, or for both a.c. and d.c., is tested in conditions (described in 5.4) related to the least favorable voltage and nature of supply, for example, number of phases (except for single-phase supply) and type of current. It could be necessary to perform some tests more than once in order to establish which supply configuration is least favorable.	(A1)	Pass
d)	ME EQUIPMENT having a MAINS PART intended for connection to d.c. SUPPLY MAINS is only tested with d.c. When performing the tests, the possible influence of polarity on the operation of the ME EQUIPMENT is taken into consideration, according to the instructions for use. See also 8.2.2.		Pass
e)	ME EQUIPMENT for which alternative ACCESSORIES or components specified in the ACCOMPANYING DOCUMENTS (see 7.9.2.14 and 7.9.3.2) are available is tested with those ACCESSORIES or components that give the least favorable conditions.		Pass
f)	If the instructions for use specify that ME EQUIPMENT is intended to receive its power from a separate power supply, it is connected to such a power supply. See also 7.2.5 and 8.2.1. NOTE What was referred to in the first and second editions of this standard as a “specified power supply” is now considered either as another part of the same ME EQUIPMENT or as another equipment in an ME SYSTEM.		Pass
5.6	Repairs and modifications		Pass
5.7	Humidity preconditioning treatment	(A1) See Test Results	Pass
5.8	Sequence of tests		Pass
5.9	Determination of applied parts and accessible parts		
5.9.1	Applied parts		Pass
5.9.2	Accessible parts		
5.9.2.1	Test finger		Pass
5.9.2.2	Test hook	(A1)	Pass
5.9.2.3	Actuation mechanisms	(A1) No actuating parts provided	N/A

Clause 6 – Classification of ME Systems

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
6.1	General		Pass
6.2	Protection against electric shock	Class II ME Equipment Type BF Applied Part	Pass
6.3	Protection against ingress of water	Ref IEC 60529 (IPX3)	Pass
6.4	Method(s) of sterilization	No specified method	N/A
6.5	Suitability for use in an oxygen rich environment	Equipment not suitable for use in oxygen rich environment	N/A
6.6	Mode of operation:	(A2) Continuous Operation	Pass

Clause 7 – ME Equipment - Identification, Marking and Documents

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
7.1	General		
7.1.1	Usability of the identification, marking and documents	(A1) See Manufacturer Risk Management Documentation	Pass
7.1.2	Legibility of markings	(A1) see markings	Pass
7.1.3	Durability of markings	(A1)	Pass
a)	After all the tests of this standard have been performed (see the recommended sequence of tests in Annex B):		Pass
b)	For markings required by 7.2, 7.4, 7.5 and 7.6, an additional test for durability is to be performed. Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with Methylated spirit and then for 15 s with a cloth rag soaked with isopropyl alcohol.	(A1) Uses Certified label	Pass
7.2	Marking on the outside of ME equipment or ME equipment parts		
7.2.1	Minimum requirement for marking on ME equipment and on interchangeable parts	(A1) See Markings and User manual	Pass
7.2.2	Identification	(A1) See Risk Management File See markings	Pass
7.2.3	Consult accompanying documents	(C1) Instruction for Use	Pass
7.2.4	Accessories	(A1)	Pass
7.2.5	ME equipment intended to receive power from other equipment	(A1) does not connect to other equipment for power	N/A
7.2.6	Connection to the supply Mains	(A1)	Pass
7.2.7	Electrical input power from the supply Mains	(A1)	Pass
7.2.8	Output connectors		
7.2.8.1	Mains power output	No multiple-socket outlet provided	N/A
7.2.8.2	Other power outputs	No output power sockets provided	N/A
7.2.9	IP classification	rated IPX3	Pass
7.2.10	Applied parts	(A1)	Pass
7.2.11	Mode of operation	(A2)	Pass
7.2.12	Fuses		Pass
7.2.13	Physiological effects (safety signs and warning statements)	See Risk Management File	Pass
7.2.14	High voltage terminal devices	(A1)	Pass
7.2.15	Cooling conditions		Pass
7.2.16	Mechanical stability		Pass
7.2.17	Protective packaging	(A1) See Risk Management File	Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
7.2.18	External pressure source	(A1) No external pressure source	N/A
7.2.19	Functional earth terminals	(A1)	Pass
7.2.20	Removable protective means	(A2) No removable protective means	N/A
7.2.21	Mass of mobile ME Equipment	(A1)	Pass
7.3	Markings on the inside of ME equipment or ME equipment parts		
7.3.1	Heating elements or lampholders	No heating elements or lampholders	N/A
7.3.2	High voltage parts	(A1) No high voltage parts	N/A
7.3.3	Batteries	See Risk Management File	Pass
7.3.4	Fuses, thermal cut-offs and over-current releases	(A1) No fuses or thermal cut-offs	N/A
7.3.5	Protective earth terminals	(A1)	Pass
7.3.6	Functional earth terminals	(A1)	Pass
7.3.7	Supply terminals	(A1) See Risk Management File	Pass
7.3.8	Temperature of supply terminals		Pass
7.4	Marking of controls and instruments (see also table C.3)		
7.4.1	Power switches	(A1) See Markings	Pass
7.4.2	Control devices	(A1) See Risk Management File No control switches provided	N/A
7.4.3	Units of measure	(A1)	Pass
7.5	Safety signs	(A1) See Risk Management File	Pass
a)	Constructing a safety sign according to ISO 3864-1:2002, Clause 7 (for the corresponding templates, see Table D.2, safety signs 1, 4 and 8).		Pass
b)	Using the general warning sign ISO 7010:2003-W001 (see Table D.2, safety sign 2) placed together with a supplementary symbol or text. The text associated with the general warning sign shall be an affirmative statement (i.e., a safety notice) describing the principal RISK(S) foreseen (e.g. “Causes burns”, “Risk of explosion”, etc.).		Pass
c)	Using the general prohibition sign ISO 7010:2003-P001 (see Table D.2, safety sign 4) placed together with a supplementary symbol or text. The text associated with the general prohibition sign shall be a statement (i.e. a safety notice) describing what is prohibited (e.g. “Do not open”, “Do not drop”, etc.).		Pass
d)	Using the general mandatory action sign ISO 7010:2003-M001 (see Table D.2, safety sign 9) placed together with a supplementary symbol or text. The text associated with the general mandatory action sign shall be a command (i.e. a safety notice) describing required action (e.g. “Wear protective gloves”, “Scrub before entering”, etc.).		Pass
7.6	Symbols		
7.6.1	Explanation of symbols	Inspected	Pass
7.6.2	Symbols from Annex D	Inspected	Pass
7.6.3	Symbols for controls and performance	(A1) Inspected	Pass
7.7	Colours of the insulation of conductors		
7.7.1	Protective earth conductor	Inspected	Pass
7.7.2	Protective earth connections	Inspected	Pass
7.7.3	Green and yellow insulation	(A1) Inspected	Pass
7.7.4	Neural conductor	Inspected	Pass
7.7.5	Power supply cord conductors	Inspected	Pass
7.8	Indicator lights and controls		

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
7.8.1	Colours of indicator lights	Inspected	Pass
7.8.2	Colours of controls	Inspected	Pass
7.9	Accompanying documents		
7.9.1	General (see also table C.4)	(A1) See Risk Management File	Pass
7.9.2	Instructions for use (see also table C.5)		Pass
7.9.2.1	General	(A1)	Pass
7.9.2.2	Warning and safety notices	See Risk Management File	Pass
7.9.2.3	ME equipment specified for connection to a separate power supply		Pass
7.9.2.4	Electrical power source	See Risk Management File See Instructions For Use	Pass
7.9.2.5	ME equipment description	Inspected	Pass
7.9.2.6	Installation		Pass
7.9.2.7	Isolation from the supply Mains	(A1)	Pass
7.9.2.8	Start-up procedure	See Instructions For Use	Pass
7.9.2.9	Operating instructions	See Instructions For Use	Pass
7.2.9.10	Messages	See Instructions For Use	Pass
7.9.2.11	Shutdown procedure	See Instructions For Use	Pass
7.9.2.12	Cleaning, disinfection and sterilization		Pass
7.9.2.13	Maintenance		Pass
7.9.2.14	Accessories, supplementary equipment, used material	(A1)	Pass
7.9.2.15	Environmental protection	(A1)	Pass
7.9.2.16	Reference to the technical description		Pass
7.9.2.17	ME Equipment emitting radiation	(A1)	Pass
7.9.2.18	ME EQUIPMENT and ACCESSORIES supplied sterile	(A1) does not require sterilization	N/A
7.9.2.19	Unique version identifier	(A1)	Pass
7.9.3	Technical description		
7.9.3.1	General	(C1)(A1)	Pass
7.9.3.2	Replacement of fuses, power supply cords and other parts		Pass
7.9.3.3	Circuit diagrams, component part lists, etc.		Pass
7.9.3.4	Mains isolation	See Isolation diagram	Pass

Clause 8 – Protection Against Electrical Hazards from ME Equipment

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
8.1	Fundamental rule of protection against electric shock	Inspected	Pass
a)	Normal condition includes all of the following simultaneously:	Noted	
b)	Single fault condition includes:	Noted	
8.2	Requirements related to power sources	Ref AAMI deviation	
8.2.1	Connection to a separate power source		N/A
8.2.2	Connection to an external d.c. power source	(C1)(A1) Not connected to external DC source	N/A
8.3	Classification of applied parts		Pass
a)	Type CF Applied Part	(A1) Type B and Type BF	N/A
b)	Deleted	(A1)	
c)	Type B Applied Part or Type BF Applied Part or Type CF Applied Part		Pass
d)	Type B Applied Part		Pass
8.4	Limitation of voltage, current or energy		
8.4.1	Patient connections intended to deliver current		Pass
8.4.2	Accessible parts including applied parts	See Risk Management File	Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
a)	The currents from, to or between PATIENT CONNECTIONS shall not exceed the limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT specified in Table 3 and Table 4 when measured as specified in 8.7.4.	See test results	Pass
b)	The LEAKAGE CURRENTS from, to or between ACCESSIBLE PARTS shall not exceed the limits for TOUCH CURRENT specified in 8.7.3 c) when measured as specified in 8.7.4.	(A1)	Pass
c)	The limits specified in b) above do not apply to the following parts if the probability of a connection to a PATIENT, either directly or through the body of the OPERATOR, through which a current exceeding the allowable TOUCH CURRENT could flow, is negligible in NORMAL USE, and the instructions for use instruct the OPERATOR not to touch the relevant part and the PATIENT simultaneously:	See Risk Management File	Pass
-	accessible contacts of connectors;		Pass
-	contacts of fuseholders that are accessible during replacement of the fuse;		Pass
-	contacts of lampholders that are accessible after removal of the lamp;		Pass
-	parts inside an ACCESS COVER that can be opened without the use of a TOOL, or where a TOOL is needed but the instructions for use instruct any OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER.	No access without tool provided	N/A
d)	The voltage and energy limits specified in c) above also apply to:		Pass
-	internal parts, other than contacts of plugs, connectors and socket-outlets, that can be touched by the test pin shown in Figure 8 inserted through an opening in an ENCLOSURE; and	Inspected	Pass
-	internal parts that can be touched by a metal test rod with a diameter of 4 mm and a length of 100 mm, inserted through any opening in the top of an ENCLOSURE or through any opening provided for the adjustment of pre-set controls that may be adjusted by the RESPONSIBLE ORGANIZATION in NORMAL USE by using a TOOL.	Inspected	Pass
e)	Where an ACCESS COVER that can be opened without the use of a TOOL gives access to parts that are at voltages above the levels permitted by this subclause, but these parts are automatically de-energized when the ACCESS COVER is opened, the device(s) used to deenergize the parts shall meet the requirements specified in 8.11.1 for mains isolating switches and shall remain effective in SINGLE FAULT CONDITION. If it is possible to prevent these devices from operating, a TOOL shall be required.	Inspected	Pass
8.4.3	ME equipment intended to be connected to a power source by a plug	(A1) None provided	N/A
8.4.4	Internal capacitive circuits	(A1) USB powered	N/A
8.5	Separation of parts		
8.5.1	Means of protection (MOP)		

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
8.5.1.1	General	(A1)	Pass
8.5.1.2	Means of patient protection (MOPP)	(A1) See Risk Management File	Pass
8.5.1.3	Means of operator protection (MOOP)	(A1)	Pass
8.5.2	Separation of patient connections		
8.5.2.1	F-Type Applied Part		Pass
8.5.2.2	Type B Applied Part	See Risk Management File	Pass
8.5.2.3	Patient leads or patient cables	(A1) See Risk Management File	Pass
8.5.3	Maximum Mains voltage	Inspected	Pass
8.5.4	Working voltage		Pass
8.5.5	Defibrillation-Proof Applied Part		
8.5.5.1	Defibrillation protection	(A1) Not defibrillation proof	N/A
8.5.5.2	Energy reduction test	(A1)	N/A
a)	Connect the APPLIED PART or PATIENT CONNECTION to the test circuit. The parts described in 8.5.5.1 a) are connected to earth.	(A1)	N/A
b)	Charge capacitor C to 5 kV d.c. with switch S in position A.		N/A
c)	Discharge capacitor C by actuating the switch S to position B, and measure the energy E1delivered to the 100 Ω load.		N/A
d)	Remove the ME EQUIPMENT under test from the test circuit and repeat steps b) and c) above, measuring the energy E2 delivered to the 100 Ω load.		N/A
e)	Verify that the energy E1 is at least 90 % of E2.		N/A
f)	Repeat the test with V_t reversed	(A1)	N/A
8.6	Protective earthing, functional earthing and potential equalization of ME equipment		
8.6.1	Applicability of requirements	(A2)	Pass
8.6.2	Protective earth terminal		Pass
8.6.3	Protective earthing of moving parts	See Risk Management File	Pass
8.6.4	Impedance and current-carrying capability		
a)	PROTECTIVE EARTH CONNECTIONS shall be able to carry fault currents reliably and without excessive voltage drop.	(A1) See test results	Pass
b)	The impedance of PROTECTIVE EARTH CONNECTIONS is allowed to exceed the values specified above if the relevant circuits have limited current capability such that, in case of short circuit of relevant insulation, the allowable values of the TOUCH CURRENT and the PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION are not exceeded.		Pass
8.6.5	Surface coatings	Inspected	Pass
8.6.6	Plugs and sockets		Pass
8.6.7	Potential equalization conductor	(A1)	Pass
8.6.8	Functional earth terminal		Pass
8.6.9	Class II ME equipment	(A1) Class I	N/A
8.7	Leakage current and patient auxiliary currents		
8.7.1	General requirements		
a)	The electrical isolation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the values specified in 8.7.3.		Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
b)	The specified values of the EARTH LEAKAGE CURRENT, the TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT apply in any combination of the following conditions: – at operating temperature and following the humidity preconditioning treatment, as described in 5.7; – in NORMAL CONDITION and in the SINGLE FAULT CONDITIONS specified in 8.7.2; – with ME EQUIPMENT energized in stand-by condition and fully operating and with any switch in the MAINS PART in any position; – with the highest RATED supply frequency; – with a supply equal to 110 % of the highest RATED MAINS VOLTAGE.	(A1)	Pass
8.7.2	Single fault conditions		Pass
8.7.3	Allowable values		
a)	The allowable values specified in 8.7.3 b), c) and d) apply to currents flowing through the network of Figure 12 a) and measured as shown in this figure (or by a device measuring the frequency contents of the currents as defined in Figure 12 b)). The values apply to d.c. and a.c. and composite waveforms. Unless stated otherwise they may be d.c. or r.m.s.	See test results	Pass
b)	The allowable values of the PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS are stated in Table 3 and Table 4. The values of a.c. apply to currents having a frequency not less than 0,1 Hz.		Pass
c)	The allowable values of the TOUCH CURRENT are 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION.		Pass
d)	The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION. For PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit that supplies only this ME EQUIPMENT, a higher value of EARTH LEAKAGE CURRENT is allowed.	(A1) Ref AAMI deviation	Pass
e)	Additionally, regardless of waveform and frequency, no LEAKAGE CURRENT shall exceed 10 mA r.m.s. in NORMAL CONDITION or in SINGLE FAULT CONDITION when measured with a non-frequency-weighted device.		Pass
f)	The allowable values of LEAKAGE CURRENTS that can flow in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION.	(A1) Functional earth not provided	N/A
8.7.4	Measurements		
8.7.4.1	General	See Test Results	Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
a)	The EARTH LEAKAGE CURRENT, the TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT are measured after the ME EQUIPMENT has been brought up to operating temperature in accordance with the requirements of 11.1.3 c).		Pass
b)	Where examination of the circuit arrangement and the arrangement of components and material of the ME EQUIPMENT shows no possibility of any HAZARDOUS SITUATION, the number of tests can be reduced.	(A1)	Pass
8.7.4.2	Measuring supply circuits		Pass
8.7.4.3	Connection to the measuring supply circuit		
a)	ME EQUIPMENT provided with a POWER SUPPLY CORD is tested using this cord.		Pass
b)	ME EQUIPMENT provided with an APPLIANCE INLET is tested while connected to the measuring supply circuit via a DETACHABLE POWER SUPPLY CORD having a length of 3 m or a length and type specified in the instructions for use.		Pass
c)	PERMANENTLY INSTALLED ME EQUIPMENT is tested while connected to the measuring supply circuit by the shortest possible connection.	Not permanently installed	N/A
d)	Measuring arrangement 1) APPLIED PARTS, including PATIENT cables (when present), are placed on an insulating surface with a dielectric constant of approximately 1 (for example, expanded polystyrene) and approximately 200 mm above an earthed metal surface. NOTE 1 The measuring supply circuit and the measuring circuit should be positioned as far as possible away from unscreened power source leads. Placing the ME EQUIPMENT on or near a large earthed metal surface should be avoided. NOTE 2 Where APPLIED PARTS are such that the test results can depend upon how they are placed on the insulating surface, the test is repeated as necessary to determine the worst possible positioning. 2) If an isolating transformer is not used for LEAKAGE CURRENT measurements (e.g. when measuring LEAKAGE CURRENT for very high input power ME EQUIPMENT), the reference earth of the measuring circuits is connected to protective earth of the SUPPLY MAINS.	See test results	Pass
8.7.4.4	Measuring device (MD)		
a)	The measuring device loads the source of LEAKAGE CURRENT or PATIENT AUXILIARY CURRENT with a resistive impedance of approximately 1 000 Ω for d.c., a.c. and composite waveforms with frequencies up to and including 1 MHz		Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
b)	The evaluation of current or current components according to 8.7.3 a) is obtained automatically if a measuring device according to Figure 12 a) or a similar circuit with the same frequency characteristic is used. This allows measurement of the total effect of all frequencies with a single instrument.		Pass
c)	The voltage measuring instrument as shown in Figure 12 a) has an input resistance of at least 1 MΩ and input capacitance of no more than 150 pF. It indicates the true r.m.s. value of the voltage being d.c., a.c. or a composite waveform having components with frequencies from 0,1 Hz up to and including 1 MHz, with an indicating error not exceeding +/- 5 % of the indicated value.		Pass
8.7.4.5	Measurement of the EARTH LEAKAGE CURRENT and current in functional earth connection		
a)	CLASS I ME EQUIPMENT is tested according to Figure 13. CLASS II ME EQUIPMENT with a functional earth connection according to 8.6.9 is tested as if it were CLASS I ME EQUIPMENT.	(A1)	Pass
b)	If ME EQUIPMENT has more than one PROTECTIVE EARTH CONDUCTOR (for example, one connected to the main ENCLOSURE and one to a separate power supply unit), then the current to be measured is the aggregate current that would flow into the protective earthing system of the installation.		Pass
c)	For FIXED ME EQUIPMENT that can have connections to earth through the building structure, the MANUFACTURER specifies a suitable test procedure and configuration for measurement of EARTH LEAKAGE CURRENT.	Not fixed equipment	N/A
8.7.4.6	Measurement of the touch current		Pass
a)	ME EQUIPMENT is tested according to Figure 14, using an appropriate measuring supply circuit.		Pass
b)	If ME EQUIPMENT has an ENCLOSURE or a part of the ENCLOSURE made of insulating material, metal foil of maximum 20 cm x 10 cm is applied in intimate contact with the ENCLOSURE or relevant part of the ENCLOSURE.		Pass
c)	ME EQUIPMENT with a SIGNAL INPUT/OUTPUT PART is, when required (see 8.1 a)), additionally tested using transformer T2.		Pass
8.7.4.7	Measurement of the patient leakage current		Pass
a)	ME EQUIPMENT with an APPLIED PART is tested according to Figure 15.		Pass
b)	ME EQUIPMENT with an F-TYPE APPLIED PART is additionally tested according to Figure 16.		Pass
c)	ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART is, when required (see 8.1 a)), additionally tested according to Figure 17.		Pass
d)	ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED or a TYPE BF APPLIED PART and with metal ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED is additionally tested according to Figure 18.		Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
e)	An APPLIED PART consisting of a surface made of insulating material is tested using metal foil as mentioned under 8.7.4.6. Alternatively a 0,9 % saline solution is used in which the APPLIED PART is immersed.		Pass
f)	Where the PATIENT CONNECTION is formed by a fluid which contacts the PATIENT, the fluid is replaced by 0,9 % saline solution, an electrode is placed in the saline solution and this electrode is considered as the PATIENT CONNECTION for the APPLIED PART concerned.	No patient connection formed by fluid	N/A
g)	The PATIENT LEAKAGE CURRENT is measured (see also Annex E): – for TYPE B APPLIED PARTS, from all PATIENT CONNECTIONS connected directly together. – for TYPE BF APPLIED PARTS, from and to all PATIENT CONNECTIONS of a single function either connected directly together or loaded as in NORMAL USE. – for TYPE CF APPLIED PARTS, from and to every PATIENT CONNECTION in turn. In the existing second paragraph of list item g), replace "PATIENT leads and electrodes" with "PATIENT leads or PATIENT cables and electrodes".	(A1)	Pass
h)	The total PATIENT LEAKAGE CURRENT is measured from and to all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together. See Figure 20. If necessary, a functional earth may be disconnected before conducting this test. NOTE Measurement of total PATIENT LEAKAGE CURRENT of TYPE B APPLIED PARTS is only necessary if there are two or more PATIENT CONNECTION that belong to different functions and that are not electrically connected directly together.		Pass
i)	If the PATIENT CONNECTIONS of the APPLIED PART are loaded in NORMAL USE, the measuring device is connected to each PATIENT CONNECTION in turn.		Pass
8.7.4.8	Measurement of the patient auxiliary current		Pass
8.7.4.9	ME equipment with multiple patient connections		Pass
8.8	Insulation		
8.8.1	General	(A1)	Pass
8.8.2	Distance through solid insulation or use of thin sheet material		Pass
a)	have a distance through insulation of at least 0,4 mm, or		Pass
b)	not form part of an ENCLOSURE and not be subject to handling or abrasion during NORMAL USE, and comprise:		Pass
c)	wire that has solid insulation, other than solvent based enamel, complying with a) above;		Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
d)	wire that has multi-layer extruded or spirally wrapped insulation (where the layers can be individually tested for dielectric strength) complying with b) above and passes the tests of Annex L;		Pass
e)	wire that has multi-layer extruded or spirally wrapped insulation (where only the finished wire can be tested) and passes the tests of Annex L. The minimum number of constructional layers applied to the conductor shall be as follows:		Pass
8.8.3	Dielectric strength	See Test Results	Pass
a)	The test voltage has a waveform and frequency such that the dielectric stress on the insulation is at least equal to that occurring in NORMAL USE. The waveform and frequency of the test voltage can differ from the voltage applied in NORMAL USE if it can be demonstrated that the dielectric stress on the insulation tested will not be diminished.		Pass
b)	During the test, breakdown constitutes a failure. Insulation breakdown is considered to have occurred when the current which flows as a result of the application of the test voltage rapidly increases in an uncontrolled manner, that is, the insulation does not restrict the flow of the current. Corona discharge or a single momentary flashover is not regarded as insulation breakdown.		Pass
c)	If it is not possible to test individual solid insulations, it is then necessary to test a large part of the ME EQUIPMENT or even the whole ME EQUIPMENT. In this case, it is important not to overstress different types and levels of insulation and the following must be taken into account.		Pass
8.8.4	Insulation other than wire insulation		
8.8.4.1	Mechanical strength and resistance to heat	(A1) See Risk Management File See Test Results	Pass
a)	For parts of the ENCLOSURE and other external insulating parts, the deterioration of which could result in an unacceptable RISK, by the ball-pressure test:		Pass
b)	For parts of insulating material that support uninsulated parts of the MAINS PART, the deterioration of which could influence the safety of the ME EQUIPMENT, by the ball-pressure test:		Pass
8.8.4.2	Resistance to environmental stress		Pass
8.9	Creepage distances and air clearance		
8.9.1	Values		
8.9.1.1	General	(A1)	Pass
8.9.1.2	Creepage distance and air clearance complying with IEC 60950-1	(A1)	Pass
8.8.1.3	Creepage distances across glass, mica, ceramic and similar materials		Pass
8.9.1.4	Minimum creepage distance	(A1)	Pass
8.9.1.5	ME equipment rated for high altitudes	(A1)	Pass
8.9.1.6	Interpolation	(A1)	Pass
8.9.1.7	Material groups classification		Pass
8.9.1.8	Pollution degree classification	(A1)	Pass
8.9.1.9	Overvoltage category classification		Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
8.9.1.10	Air Clearance for mains parts		Pass
8.9.1.11	Supply mains overvoltage		Pass
8.9.1.12	Secondary circuits		Pass
8.9.1.13	Peak working voltage above 1400 V peak or d.c.		N/A
8.9.1.14	Minimum creepage distance for two means of operator protection		Pass
8.9.1.15	Creepage distances and air clearance for defibrillation-proof applied parts	(A1)	N/A
8.9.2	Application		
a)	For insulation in the MAINS PART between parts of opposite polarity, the minimum CREEPAGE DISTANCES and AIR CLEARANCES are not required if short circuiting of each single one of these CREEPAGE DISTANCES and AIR CLEARANCES in turn does not result in a HAZARDOUS SITUATION.	(A1)	Pass
b)	The contribution to the CREEPAGE DISTANCES of any groove or air gap less than 1 mm wide shall be limited to its width (see Figure 23 to Figure 31 [inclusive]).		Pass
c)	If AIR CLEARANCE provides a MEANS OF PROTECTION, the relative positioning shall be such that the relevant parts are rigid and located by moulding or the design shall be otherwise such that there is no reduction of a distance below the specified value by deformation or movement of the parts.		Pass
8.9.3	Spaces filled by insulating compound		
8.9.3.1	General	No compound used	N/A
8.9.3.2	Insulating compound forming solid insulation between conductive parts		N/A
8.9.3.3	Insulating compound forming a cemented joint with other insulating parts		N/A
8.9.3.4	Thermal cycling		N/A
8.9.4	Measurement of creepage distances and air clearance	(A1)	N/A
8.10	Components and wiring		
8.10.1	Fixing of components	(A1) See Risk Management File	Pass
8.10.2	Fixing of wiring	(A1) See Risk Management File	Pass
8.10.3	Connections between different parts of ME equipment		Pass
8.10.4	Cord-connected hand-held parts and cord-connected foot-operated control devices (see also 15.4.7)		
8.10.4.1	Limitation of operating voltages	Inspected (15Vdc)	Pass
8.10.4.2	Connection cords	(A1) See Risk Management File	Pass
8.10.5	Mechanical protection of wiring	See Risk Management File	Pass
a)	Internal cables and wiring shall be adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION.	(A1) Inspected	Pass
b)	ME EQUIPMENT shall be so designed that wiring, cord forms or components are not likely to be damaged during assembly or the opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION.	(A1)	Pass
8.10.6	Guiding rollers for insulated conductors		Pass
8.10.7	Insulation of internal wiring		Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
a)	If insulating sleeving is needed on internal wiring of ME EQUIPMENT, it shall be adequately secured. Sleeving that can only be removed by breaking or cutting or that is secured at both ends may be used to satisfy this requirement.		Pass
b)	Inside ME EQUIPMENT the sheath of a flexible cord shall not be used as a MEANS OF PROTECTION if it is subject to mechanical or thermal stresses outside its RATED characteristics.		Pass
c)	Insulated conductors of ME EQUIPMENT that in NORMAL USE are subject to temperatures exceeding 70 °C shall have insulation of heat-resistant material if compliance with this standard is likely to be impaired by deterioration of the insulation.		Pass
8.11	Mains parts, components and layout		
8.11.1	Isolation from the supply Mains		
a)	ME EQUIPMENT shall have means to isolate its circuits electrically from the SUPPLY MAINS on all poles simultaneously.	(A1) (A2) inspected	Pass
b)	Means for isolation either shall be incorporated in ME EQUIPMENT or, if external, shall be described in the technical description (see 7.9.3.1).		Pass
c)	A SUPPLY MAINS switch that is used to comply with 8.11.1 a) shall comply with the CREEPAGE DISTANCES and AIR CLEARANCES as specified in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV.		Pass
d)	A SUPPLY MAINS switch shall not be incorporated in a POWER SUPPLY CORD or any other external, flexible lead.		Pass
e)	The actuator of a SUPPLY MAINS switch that is used to comply with 8.11.1 a) shall comply with IEC 60447.	(A1)	Pass
f)	In non-PERMANENTLY INSTALLED ME EQUIPMENT that has no SUPPLY MAINS switch, a suitable plug device used to isolate ME EQUIPMENT from the SUPPLY MAINS shall be considered as complying with the requirements of 8.11.1 a). An APPLIANCE COUPLER or a flexible cord with a MAINS PLUG may be used.	(A1)	Pass
g)	A fuse or a semiconductor device shall not be used as an isolating means in the sense of this subclause.		Pass
h)	ME EQUIPMENT shall not include a device that causes disconnection of the ME EQUIPMENT from the SUPPLY MAINS by producing a short circuit that results in operation of an overcurrent protection device.		Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
i)	Any part within the ENCLOSURE of ME EQUIPMENT with a circuit voltage exceeding 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 that is accessible at all times shall be protected against being touched even after opening of the ENCLOSURE by an additional covering or, in the case of a spatially separated arrangement, shall be marked clearly as exceeding the permitted voltage for parts that can be touched. The use of the symbol ISO 7000-0434 (see Table D.1, symbol 10) is not sufficient. A warning notice on the outside of the ME EQUIPMENT may be used.		Pass
8.11.2	Multiple socket-outlets	None provided	N/A
8.11.3	Power supply cords		
8.11.3.1	Application	inspected	Pass
8.11.3.2	Types		Pass
8.11.3.3	Cross-sectional area of power supply cord conductors	(A2)	Pass
8.11.3.4	Appliance Couplers		Pass
8.11.3.5	Cord anchorage		
a)	The conductors of a POWER SUPPLY CORD shall be relieved from strain, including twisting, and the insulation of the conductors shall be protected from abrasion at the point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage.		N/A
b)	If a total insulation failure of the POWER SUPPLY CORD could cause conductive ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED to exceed the limits specified in 8.4, the cord anchorage of a POWER SUPPLY CORD shall be made:		N/A
c)	The cord anchorage of a POWER SUPPLY CORD shall be so designed that the cord is not clamped by a screw that bears directly on the cord insulation.		N/A
d)	Screws, if any, that have to be operated when replacing the POWER SUPPLY CORD shall not serve to fix any component other than parts of the cord anchorage.		N/A
e)	Conductors of the POWER SUPPLY CORD shall be so arranged that if the cord anchorage fails the PROTECTIVE EARTH CONDUCTOR is not subject to strain as long as the phase conductors are in contact with their terminals.		N/A
f)	The cord anchorage shall prevent the POWER SUPPLY CORD from being pushed into the ME EQUIPMENT or MAINS CONNECTOR.		N/A
8.11.3.6	Cord guards		N/A
8.11.4	Mains terminal devices		
8.11.4.1	General requirements for Mains terminal devices		Pass
8.11.4.2	Arrangement of Mains terminal devices		
a)	For ME EQUIPMENT with rewirable cords where terminals are provided for the connection of external cords or POWER SUPPLY CORDS, these terminals together with any PROTECTIVE EARTH TERMINAL shall be closely grouped, so as to provide a convenient means of connection.		N/A

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
b)	For details of PROTECTIVE EARTH CONDUCTOR connections, see 8.6.		N/A
c)	For marking of MAINS TERMINAL DEVICES, see 7.3.		N/A
d)	MAINS TERMINAL DEVICES shall not be accessible without the use of a TOOL.		N/A
e)	MAINS TERMINAL DEVICES shall be so located or shielded that, if a wire of a stranded conductor escapes when the conductors are fitted, short circuiting a MEANS OF PROTECTION is unlikely.		N/A
8.11.4.3	Fixing of Mains terminals		N/A
8.11.4.4	Connection to mains terminals		N/A
8.11.4.5	Accessibility of the connection		N/A
8.11.5	Mains fuses and over-current releases	(A1) See Risk Management File Certified Power Supply	N/A
8.11.6	Internal wiring of the Mains parts		
a)	Internal wiring in a MAINS PART between the MAINS TERMINAL DEVICE or the APPLIANCE INLET and the protective devices shall have a cross-sectional area not less than the minimum required for the POWER SUPPLY CORD as specified in 8.11.3.3.	(A1)	Pass
b)	The cross-sectional area of other wiring in the MAINS PART and the sizes of tracks on printed wiring circuits of ME EQUIPMENT shall be sufficient to prevent fire in case of possible fault currents.		Pass

Clause 9 – Protection against Mechanical Hazards of ME Equipment and ME Systems

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
9.1	Mechanical hazards of ME equipment		Pass
9.2	MECHANICAL HAZARDS associated with moving parts	A1	
9.2.1	General	(A1) See Risk Management File	Pass
9.2.2	Trapping zone		
9.2.2.1	General	(A1) See List of Modifications	Pass
9.2.2.2	Gaps		Pass
9.2.2.3	Safe distance	(A1)	Pass
9.2.2.4	GUARDS and other RISK CONTROL measures	A1	
9.2.2.4.1	Access to trapping zones	(A1) See Risk Management File	Pass
9.2.2.4.2	Fixed guards	See Risk Management File	Pass
9.2.2.4.3	Movable guards	(A1) See Risk Management File	Pass
9.2.2.4.4	Other RISK CONTROL measures	(A1) See Risk Management File	Pass
9.2.2.5	Continuous activation	(A1) See Risk Management File	Pass
a)	the movement is in the OPERATOR'S field of view;	Inspected	Pass
b)	movement of the ME EQUIPMENT or its parts is possible only by the continuous activation of the control by the OPERATOR as long as the response of the OPERATOR to deactivate the device can be relied on to prevent HARM;	See labelling and IFU	Pass
c)	the continuous activation system is defeated in a SINGLE FAULT CONDITION, then a second RISK CONTROL measure shall be provided, such as one or more emergency stopping device(s) (see 9.2.4), or the ME EQUIPMENT shall otherwise be SINGLE FAULT SAFE (see 4.7).	(A1) See Risk Management File	Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
9.2.2.6	Speed of movement(s)	(A1) See Risk Management File	Pass
9.2.3	Other MECHANICAL HAZARDS associated with moving parts	A1	
9.2.3.1	Unintended movement	(A1) See Risk Management File	Pass
9.2.3.2	Overtravel end Stops	(A1) See Risk Management File	Pass
9.2.4	Emergency stopping devices	See Risk Management File None provided	N/A
a)	The emergency stopping device shall reduce the RISK to an acceptable level.		N/A
b)	The proximity and response of the OPERATOR to actuate the emergency stopping device can be relied on to prevent HARM.		N/A
c)	The emergency stopping device actuator shall be readily accessible to the OPERATOR.		N/A
d)	Emergency stopping device(s) shall not be part of the normal operation of the ME EQUIPMENT.		N/A
e)	Operation of an emergency switching or stopping means shall neither introduce a further HAZARD nor interfere with the complete operation necessary to remove the original HAZARD.	(A1)	N/A
f)	Emergency stopping device(s) shall be able to break the full load of the relevant circuit, taking into account possible stalled motor currents and the like.		N/A
g)	Means for stopping of movements shall operate as a result of one single action.		N/A
h)	The emergency stopping device shall have an actuator colored red designed to be distinctive and easily identifiable from that of other controls.		N/A
i)	An actuator that interrupts/opens mechanical movements shall be marked on, or immediately adjacent to, the face of the actuator with symbol IEC 60417-5638 (DB:2002- 10) (see Table D.1, symbol 18) or the word “STOP”.	(A1)	N/A
j)	The emergency stopping device, once actuated, shall maintain the ME EQUIPMENT in the disabled condition until a deliberate action, different from that used to actuate it, is performed.		N/A
k)	The emergency stopping device shall be shown to be suitable for its application.		N/A
9.2.5	Release of patient	(A1) See Risk Management File	N/A
9.3	Mechanical Hazards associated with surfaces, corners and edges	(A1) See Risk Management File Inspected	Pass
9.4	Instability hazards		
9.4.1	General	(A1) see test results	Pass
9.4.2	Instability - overbalance		
9.4.2.1	Instability in transport position	(A1) See IFU and Risk Management File See test Results	Pass
9.4.2.2	Instability excluding transport position	(A1) see test results	Pass
a)	ME EQUIPMENT is provided with all specified connection leads, the POWER SUPPLY CORD and any interconnecting cords. It is provided with the least favorable combination of possible detachable parts, ACCESSORIES and load as specified in NORMAL USE.		Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
b)	ME EQUIPMENT having an APPLIANCE INLET is provided with the specified DETACHABLE POWER SUPPLY CORD.		Pass
c)	The connection leads are laid down on the inclined plane in the position most unfavorable for stability.		Pass
d)	If castors/wheels are present, they are temporarily immobilized, if necessary by blocking, in their most disadvantageous position.		Pass
e)	Doors, drawers, shelves and the like are placed in the most disadvantageous position and fully loaded or unloaded whichever represents "worst case" as specified in NORMAL USE according to the ACCOMPANYING DOCUMENTS.		Pass
f)	ME EQUIPMENT having containers for liquids is tested with these containers completely or partly filled or empty, whichever is least favorable.		Pass
g)	The ME EQUIPMENT is not connected to the SUPPLY MAINS.		Pass
9.4.2.3	Instability from horizontal and vertical forces		
a)	ME EQUIPMENT or its parts having a mass of 25 kg or more other than FIXED ME EQUIPMENT that is intended to be used on the floor shall be permanently marked with a CLEARLY LEGIBLE warning of this RISK, e.g. by use of safety sign ISO 7010-P017 (see Table D.2, safety sign 5), or it shall not overbalance due to being pushed, leaned, rested upon etc.	(A1) See Risk Management File Documentation See test results	Pass
b)	ME EQUIPMENT or its parts, other than FIXED ME EQUIPMENT, that is intended to be used on the floor or on a table shall be permanently marked with a CLEARLY LEGIBLE warning of this RISK, e.g. by use of safety signs ISO 7010-P018 or ISO 7010-P019 as appropriate (see Table D.2, safety signs 6 and 7), or it shall not overbalance due to being sat or stepped upon.	(A1) See Risk Management File No means of step or Sitting provided See Markings in Documentation.	N/A
9.4.2.4	Casters and wheels		
9.4.2.4.1	General		Noted
9.4.2.4.2	Force for propulsion		Pass
9.4.2.4.3	Movement over a threshold	(A1) See Risk Management File See test results	Pass
9.4.3	Instability from unwanted lateral movement (including sliding)	(A1)	
9.4.3.1	Instability in transport		
a)	Brakes of power-driven MOBILE ME EQUIPMENT shall be designed so that they are normally activated and can only be released by continuous actuation of a control.	Not Power Driven	N/A
b)	MOBILE ME EQUIPMENT shall be fitted with means (such as locking devices) intended to prevent any unwanted movement of the ME EQUIPMENT or its parts in the transport position.	Inspected	Pass
c)	MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system to prevent unwanted movement on an incline of 10° when in its transport position.	A1 See Risk Management File Documentation See test results	Pass
9.4.3.2	Instability excluding transport position	(A1)	

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
a)	MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system to prevent unwanted movement on an incline of 5o when in any position excluding transport position.	(A1)	Pass
b)	TRANSPORTABLE or STATIONARY ME EQUIPMENT that is intended to be used on the floor shall not result in an unacceptable RISK due to unwanted lateral movement.	(A1)	Pass
9.4.4	Grips and other handling devices		
a)	ME EQUIPMENT other than PORTABLE ME EQUIPMENT or its part with a mass of more than 20 kg that needs to be lifted in NORMAL USE or transport shall either be provided with suitable handling devices (for example handles, lifting eyes, etc.) or the ACCOMPANYING DOCUMENTS shall indicate the points where it can be lifted safely, unless the method of handling is obvious and no HAZARDS can develop when this is done. If the means for lifting are handles, they shall be suitably placed to enable the ME EQUIPMENT or its part to be carried by two or more persons.	(A1) No means for lifting provided See IFU and Risk management File	N/A
b)	ME EQUIPMENT specified by the MANUFACTURER as PORTABLE ME EQUIPMENT with a mass of more than 20 kg shall have one or more carrying-handles suitably placed to enable the ME EQUIPMENT to be carried by two or more persons.	See Risk Management File Not a portable device	N/A
c)	Carrying handles or grips furnished on PORTABLE ME EQUIPMENT shall withstand loading as described in the following test:	Not Portable ME Equipment	N/A
9.5	Expelled parts hazard		
9.5.1	Protective means	See Risk Management File	N/A
9.5.2	Cathode ray tubes	None provided	N/A
9.6	Acoustic energy (including infra- and ultrasound) and vibration		
9.6.1	General	(A1) See Risk Management File and Manufacturer Documentation	**N/E**
9.6.2	Acoustic energy		
9.6.2.1	Audible acoustic energy	(A1) no significant source of audible noise	Pass
a)	The ME EQUIPMENT is operated under worst-case NORMAL CONDITION.		N/A
b)	Any protective means provided or called for in ACCOMPANYING DOCUMENTS are to be in place during sound measurement.		N/A
c)	Sound level meters used in the measurement conform to IEC 61672-1 and IEC 61672-2.		N/A
d)	The test room is semi-reverberant with a hard reflecting floor. The distance between any wall or other object and the surface of the ME EQUIPMENT is not less than 3 m.		N/A
e)	When sound measurements in a test room are not feasible (e.g. for a large PERMANENTLY INSTALLED ME EQUIPMENT), measurements may be done in situ.	(A1)	N/A
9.6.2.2	Infrasound and ultrasound energy	See Risk Management File	Noted

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
9.6.3	Hand-transmitted vibration		Pass
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		
9.7.1	General	See Product description Does not have or connect to Pneumatic or hydraulic parts	N/A
9.7.2	Pneumatic and hydraulic parts	See Risk Management file	N/A
9.7.3	Maximum pressure		N/A
a)	the RATED maximum supply pressure from an external source;		N/A
b)	the pressure setting of a pressure-relief device provided as part of the assembly;		N/A
c)	the maximum pressure that can be developed by a source of pressure that is part of the assembly, unless the pressure is limited by a pressure-relief device.		N/A
9.7.4	Pressure rating of ME equipment parts	(A1) See Manufacturer's Product Description and Risk Management file	N/A
9.7.5	Pressure vessels	(A1)	N/A
9.7.6	Pressure-control devices	(A1) See Risk Management file	N/A
9.7.7	Pressure-relief devices	See Risk Management file	N/A
a)	it shall be connected as close as reasonably practical to the pressure vessel or parts of the system that it is intended to protect;		N/A
b)	it shall be so installed that it is readily accessible for inspection, maintenance and repair;		N/A
c)	it shall not be capable of being adjusted or rendered inoperative without the use of a TOOL;		N/A
d)	it shall have its discharge opening so located and directed that the released material is not directed towards any person;		N/A
e)	it shall have its discharge opening so located and directed that operation of the device will not deposit material on parts that could result in an unacceptable RISK;		N/A
f)	it shall be of adequate discharge capacity to ensure that the pressure will not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE of the system to which it is connected by more than 10 % in the event of a failure in the control of the supply pressure;		N/A
g)	there shall be no shut-off valve between a pressure-relief device and the parts that it is intended to protect;		N/A
h)	the minimum number of cycles of operation shall be 100 000, except for one-time use devices such as bursting disks.		N/A
9.7.8	Rated maximum supply pressure	See 7.2.18	N/A
9.8	Mechanical Hazards associated with support systems	(A1)	
9.8.1	General	(A1) Not for patient support See IFU & Risk Management File	N/A
9.8.2	Tensile safety factor	(A1)	N/A
9.8.3	Strength of patient or operator support or suspension systems		
9.8.3.1	General	(A1) Not for patient or operator support See IFU & Risk Management File	N/A

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
9.8.3.2	Static force due to loading from persons	(A1)	N/A
a)	For a foot rest that is intended to temporarily support a standing PATIENT or OPERATOR, the whole mass of the PATIENT or OPERATOR is distributed over an area of 0,1 m2.	(A1)	N/A
b)	For an area of support/suspension where a PATIENT or OPERATOR can sit, deflection of a support surface from PATIENT or OPERATOR loading shall not result in an unacceptable RISK.	(A1)	N/A
9.8.3.3	Dynamic forces due to loading from persons	(A1)	N/A
9.8.4	Systems with mechanical protective devices		
9.8.4.1	General	No support system provided	N/A
a)	A MECHANICAL PROTECTIVE DEVICE shall be provided when a support system or any of its parts impaired by wear have a TENSILE SAFETY FACTOR greater than or equal to the values specified in rows 5 and 6 but less than those in rows 3 and 4 of Table 21.		N/A
b)	The MECHANICAL PROTECTIVE DEVICE shall:	(A1)	N/A
9.8.4.2	Use after activation of a mechanical protective device		N/A
9.8.4.3	Mechanical protective device intended for single activation	(A1)	N/A
9.8.5	Systems without mechanical protective devices	(A1)	N/A

Clause 10 – Protection against Unwanted and Excessive Radiation Hazards

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
10.1	X-Radiation	See Risk Management File Does not produce unwanted or excessive X-radiation	N/A
10.1.1	ME equipment not intended to produce diagnostic or therapeutic X-Radiation	(A1) Not a source for ionized radiation	N/A
10.1.2	ME Equipment intended to produce diagnostic or therapeutic X-Radiation	(A1) See Risk Management File Not a source of X-radiation	N/A
10.2	Alpha, beta, gamma, neutron and other particle radiation	See Risk Management File Not a source of particle radiation	N/A
10.3	Microwave radiation	(A1) See Risk Management File No source of microwave radiation	N/A
10.4	Laser	(A1) No lasers used	N/A
10.5	Other visible electromagnetic radiation	See Risk Management File	N/A
10.6	Infrared radiation	See Risk Management File	N/A
10.7	Ultraviolet radiation	See Risk Management File Not a source of UV radiation	N/A

Clause 11 – Protection against Excessive Temperature and Other Hazards

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
11.1	Excessive temperatures in ME equipment		
11.1.1	Maximum temperature during normal use	See Risk Management File See Test Results	Pass
11.1.2	Temperature of applied parts		
11.1.2.1	Applied parts intended to supply heat to a patient	See Risk Management File	N/A
11.1.2.2	Applied part not intended to supply heat to a patient	(A1) See Risk Management File See test results	Pass
11.1.3	Measurements	See test results	Pass
a)	Positioning		Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
b)	Supply		N/A
c)	Thermal stabilization		N/A
d)	Temperature measurement		N/A
e)	Test criteria	See Risk Management File	N/A
11.1.4	Guards		N/A
11.2	Fire prevention		
11.2.1	Strength and rigidity required to prevent fire in ME equipment		Pass
11.2.2	ME Equipment and ME systems used in conjunction with oxygen rich environment		
11.2.2.1	Risk of fire in an oxygen rich environment	See Risk Management File No for use in oxygen rich environments	N/A
a)	A source of ignition is considered to exist in an OXYGEN RICH ENVIRONMENT when any of the following conditions exist in NORMAL CONDITION and SINGLE FAULT CONDITIONS (including voltage and current):		N/A
b)	The following configurations, alone or in combination as appropriate (as determined by the application of the RISK MANAGEMENT PROCESS), are considered to provide an acceptable RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT.	(A1)	N/A
11.2.2.2	External exhaust outlets for oxygen rich environment	None provided	N/A
11.2.2.3	Electrical connections in oxygen rich environments	None provided	N/A
11.2.3	Single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems	See Risk Management File No for use in oxygen rich environments	N/A
11.3	Constructional requirements for fire enclosures of ME equipment	See Risk Management File	Pass
a)	Insulated wire within the fire ENCLOSURE shall have a flammability classification equivalent FV-1, or better, according to the appropriate parts of the IEC 60695 series. Connectors, printed circuit boards and insulating material on which components are mounted shall have a flammability classification FV-2, or better, according IEC 60695-11-10.		Pass
b)	The fire ENCLOSURE shall meet the following requirements:		Pass
11.4	ME equipment and ME systems intended for use with flammable anaesthetics	Not for use with flammable anaesthetics	N/A
11.5	ME equipment and ME systems intended for use with flammable agents	See Risk Management File No flammable liquids used	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		
11.6.1	General		Pass
11.6.2	Overflow in ME equipment	(A1 See Risk Management File No liquids used with device	N/A
11.6.3	Spillage on ME equipment and ME systems	(A1) See Risk Management File No liquids used with device	N/A
11.6.4	Leakage	See 13.2.6	
11.6.5	Ingress of water or particulate matter into ME equipment and ME systems	(A1) See Risk Management File IPX3	Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
11.6.6	Cleaning and disinfection of ME equipment and ME systems	(A1), See Risk Management File, Usable Life Documentaion No sterilized requirements	N/A
11.6.7	Sterilization of ME equipment and ME systems	(A1) See Risk Management File No sterilized requirements	N/A
11.6.8	Compatibility with substances used with the ME equipment	(A1) See Risk Management File	Pass
11.7	Biocompatibility of ME equipment and ME systems	See Manufacturer's documentation and Risk Management File	N/E
11.8	Interruption of the power supply/ supply Mains to ME equipment	(A1)	Pass

Clause 12 – Accuracy of Controls and Instruments and Protection against Hazardous Output

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
12.1	Accuracy of controls and instruments	See Risk Management File	Pass
12.2	Usability of ME Equipment	(A1) See Usability Engineering Process	N/E
12.3	Alarm systems	(A1) See Risk Management File	N/A
12.4	Protection against hazardous output		
12.4.1	Intentional exceeding of safety limits	See Risk Management File	Pass
12.4.2	Indication relevant to safety	(A1) See Risk Management File	Pass
12.4.3	Accidental selection of excessive output values	See Risk Management File	Pass
12.4.4	Incorrect output	See Risk Management File	Pass
12.4.5	Diagnostic or therapeutic radiation		
12.4.5.1	Limits	See Risk Management File Does not produce diagnostic or therapeutic radiation	N/A
12.4.5.2	Diagnostic X-ray equipment	(A1) See Risk Management File Does not produce x-rays	N/A
12.4.5.3	Radiotherapy equipment	See Risk Management File Not for therapeutic use	N/A
12.4.5.4	Other ME equipment producing diagnostic or therapeutic radiation	See Risk Management File	N/A
12.4.6	Diagnostic or therapeutic acoustic pressure	See Risk Management File Does not produce acoustic pressure	N/A

Clause 13 – Hazardous Situations and Fault Conditions for ME Equipment

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
13.1	Specific Hazardous situations		
13.1.1	General		Pass
13.1.2	Emissions, deformation of enclosure or exceeding maximum temperature	(A1)	Pass
13.1.3	Exceeding leakage current or voltage limits		Pass
13.1.4	Specific mechanical hazards		Pass
13.2	Single Fault conditions		
13.2.1	General		Pass
13.2.2	Electrical single fault conditions		Pass
13.2.3	Overheating of transformers in ME equipment		Pass
13.2.4	Failure of thermostats		Pass
13.2.5	Failure of temperature limiting devices		Pass

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
13.2.6	Leakage of liquids	See Risk Management File No liquids stored in device	N/A
13.2.7	Impairment of cooling that could result in a hazardous situation	(A1)	Pass
13.2.8	Locking of moving parts	No moving parts	N/A
13.2.9	Interruption and short circuit of motor capacitors	None provided	N/A
13.2.10	Additional test criteria for motor operated ME equipment		Pass
a)	30 s for: – HAND-HELD ME EQUIPMENT; – ME EQUIPMENT that has to be kept switched on by hand; – ME EQUIPMENT that has to be kept under physical load by hand;		Pass
b)	5 min for other ME EQUIPMENT intended only for attended use (attended use excludes automated or remotely controlled ME EQUIPMENT that could operate when the OPERATOR is not present);		Pass
c)	for the maximum period of a timer, if such a device terminates the operation, for ME EQUIPMENT not listed under a) or b);		Pass
d)	as long as necessary to establish THERMAL STABILITY for all the remaining ME EQUIPMENT.		Pass
13.2.11	Failure of components in ME equipment used in conjunction with oxygen rich environments	Not for oxygen rich environments	N/A
13.2.12	Failure of parts that might result in a mechanical hazard		Pass
13.2.13	Overloads		
13.2.13.1	General overload test conditions	(A1)	Pass
13.2.13.2	ME equipment with heating elements	No heating elements	N/A
a)	ME EQUIPMENT having heating elements is checked for compliance as follows:		N/A
b)	ME EQUIPMENT having heating elements is tested under the conditions specified in 11.1, but without adequate heat discharge, the supply voltage being 90 % or 110 % of the RATED supply voltage, whichever is the least favorable.		N/A
c)	Heating parts of ME EQUIPMENT are tested with the ME EQUIPMENT operated in NORMAL CONDITION, at a supply voltage 110 % of the RATED supply voltage and as specified in 11.1. The following test conditions are met.		N/A
13.2.13.3	ME equipment with motors		Pass
a)	ME EQUIPMENT having motors is checked for compliance as follows:		Pass
b)	Motors are checked for running overload protection if they are:		Pass
c)	ME EQUIPMENT with three-phase motors is operated with normal load, connected to a three phase (SUPPLY MAINS) with one phase disconnected. Periods of operation are according to 13.2.10.		Pass
13.2.13.4	ME equipment rated for non-continuous operation		Pass

Clause 14 – Programmable Electrical Medical Systems (PEMS)

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
14.1	General	(A1) See Risk Management File	N/E
14.2	Documentation	(A1) See Risk Management File	N/E
14.3	Risk management plan	(A1) See Risk Management File	N/E
14.4	PEMS development life-cycle	(A1) See Risk Management File	N/E
14.5	Problem resolution	See Risk Management File	N/E
14.6	Risk management process		
14.6.1	Identification of known and foreseeable hazards	(A1) See Risk Management File	N/E
14.6.2	Risk control	(A1) See Risk Management File	N/E
14.7	Requirement specification	See Risk Management File	N/E
14.8	Architecture	See Risk Management File	N/E
a)	Components with high-integrity characteristics;		N/E
b)	fail-safe functions;		N/E
c)	redundancy;		N/E
d)	diversity;		N/E
e)	partitioning of functionality;		N/E
f)	defensive design, e.g. limits on potentially hazardous effects by restricting the available output power or by introducing means to limit the travel of actuators. The architecture specification shall take into consideration:		N/E
g)	allocation of RISK CONTROL measures to subsystems and components of the PEMS; NOTE Subsystems and components include sensors, actuators, PESS and interfaces.		N/E
h)	failure modes of components and their effects;		N/E
i)	common cause failures;		N/E
j)	systematic failures;		N/E
k)	test interval duration and diagnostic coverage;		N/E
l)	maintainability;		N/E
m)	protection from reasonably foreseeable misuse;		N/E
n)	the IT-NETWORK specification, if applicable.	(A1)	N/A
14.9	Design and implementation	(A1) See Risk Management File	N/E
14.10	Verification	See Risk Management File	N/E
14.11	Pems validation	(A1) See Risk Management File	N/E
14.12	Modification	(A1)	N/E
14.13	PEMS intended to be incorporated into an IT-NETWORK	(A1) See Risk Management File See PEMS documentation: RPT-7401-0016	N/E
a)	the purpose of the PEMS's connection to an IT-NETWORK;	(A1)	N/E
b)	the required characteristics of the IT-NETWORK incorporating the PEMS;	(A1)	N/E
c)	the required configuration of the IT-NETWORK incorporating the PEMS;	(A1)	N/E
d)	the technical specifications of the network connection of the PEMS including security specifications;	(A1)	N/E
e)	the intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK; and	(A1)	N/E
f)	a list of the HAZARDOUS SITUATIONS resulting from a failure of the IT-NETWORK to provide the characteristics required to meet the purpose of the PEMS connection to the ITNETWORK.	(A1)	N/E

Clause 15 – Construction of ME Equipment

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
15.1	Arrangements of controls and indicators of ME equipment	(A1) See Risk Management File	Pass
15.2	Serviceability		Pass
15.3	Mechanical strength		
15.3.1	General	(A1)	Pass
15.3.2	Push test	(A1) See Risk Management File	Pass
15.3.3	Impact test	(A1) See Risk Management File	Pass
15.3.4	Drop test		
15.3.4.1	Hand-held ME equipment	(A1) See test Results	Pass
15.3.4.2	Portable ME equipment	(A1) See Risk Management File Not a portable device	N/A
15.3.5	Rough handling test	(A1) See Risk Management File	Pass
a)	Ascending step shock	(A1)	Pass
b)	Descending step shock	(A1)	Pass
c)	Door frame shock	(A1)	Pass
15.3.6	Mould stress relief test		Pass
15.3.7	Environmental influences		Pass
15.4	ME equipment components and general assemble		
15.4.1	Construction of connectors	See Risk Management File	Pass
a)	Plugs for connection of PATIENT leads or PATIENT cables shall be so designed that they cannot be connected to outlets on the same ME EQUIPMENT intended for other functions, unless it can be proven that no unacceptable RISK can result.	(A1)	Pass
b)	Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE shall not be interchangeable. See also ISO 407 [27].	No gas connections	N/A
15.4.2	Temperature and overload control devices		
15.4.2.1	Application		
a)	THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting shall not be used in ME EQUIPMENT if their use could lead to a HAZARDOUS SITUATION described in 13.1 by such resetting.	(A1) See Risk Management File None provided	N/A
b)	THERMAL CUT-OUTS with a safety function that have to be reset by a soldering operation that can affect the operating value shall not be fitted in ME EQUIPMENT.	(A1) See Risk Management File None provided	N/A
c)	In ME EQUIPMENT, where a failure of a THERMOSTAT could lead to a HAZARDOUS SITUATION described in 13.1, an independent non-SELF-RESETTING THERMAL CUT-OUT shall additionally be provided. The temperature of operation of the additional device shall be outside that attainable at the extreme setting of the normal control device (THERMOSTAT) but shall be within the safe temperature limit for the intended function of the ME EQUIPMENT.	(A1) See Risk Management File None provided	N/A

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
d)	Loss of function of the ME EQUIPMENT caused by operation of a THERMAL CUT-OUT or OVERCURRENT RELEASE shall not result in the loss of ESSENTIAL PERFORMANCE or any of the HAZARDOUS SITUATIONS described in 13.1.	(A1) See Risk Management File None provided	N/A
e)	Capacitors or other spark-suppression devices of ME EQUIPMENT shall not be connected between the contacts of THERMAL CUT-OUTS.		N/A
f)	The use of a THERMAL CUT-OUT or OVER-CURRENT RELEASE in the design shall not affect the safety of the ME EQUIPMENT.	(A1)	N/A
g)	ME EQUIPMENT that incorporates a fluid filled container having heating facilities shall be provided with a protection device to safeguard against overheating in the event of the heater being switched on with the container empty. An unacceptable RISK shall not occur from overheating.	None provided	N/A
h)	ME EQUIPMENT that incorporates tubular heating elements shall have protection against overheating in both leads where a conductive connection to earth could result in overheating.	None provided	N/A
15.4.2.2	Temperature settings	No temperature settings	N/A
15.4.3	Batteries	See Risk Management File	Pass
15.4.3.1	Housing	(A1) See Risk Management File	Pass
15.4.3.2	Connection	See Risk Management File	Pass
15.4.3.3	Protection against overcharging	See Risk Management File	Pass
15.4.3.4	Lithium batteries	(A1) See Risk Management File	Pass
15.4.3.5	Excessive current and voltage protection	(A1) See Risk Management File	N/A
15.4.4	Indicators	See Risk Management File	N/A
15.4.5	Pre-set controls	See Risk Management File	N/A
15.4.6	Actuating parts of controls of ME equipment		
15.4.6.1	Fixed. Prevention of maladjustment	See Risk Management File None provided	N/A
a)	All actuating parts of ME EQUIPMENT shall be so secured that they cannot be pulled off or work loose during NORMAL USE.		N/A
b)	Controls shall be so secured that the indication of any scale always corresponds with the position of the control.	(A1)	N/A
c)	Incorrect connection of the indicating device to the relevant component shall be prevented by an adequate construction, if it can be separated without the use of a TOOL.		N/A
14.4.6.2	Limitation of movement	(A1)	N/A
15.4.7	Cord-connected hand-held and foot operated control devices	See also 8.10.4	
15.4.7.1	Mechanical strength		
a)	HAND-HELD control devices of ME EQUIPMENT shall comply with 15.3.4.1.		Pass
b)	Foot-operated control devices of ME EQUIPMENT shall be able to support the weight of an adult human being.	Not a foot operated device	N/A
15.4.7.2	Accidental operation of ME equipment		N/A
15.4.7.3	Entry of Liquid		

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
a)	Foot-operated control devices of ME EQUIPMENT shall be at least IPX1 according to IEC 60529.	Not a foot operated devices	N/A
b)	In ME EQUIPMENT, ENCLOSURES of foot operated control devices used in areas such as emergency rooms or operating theatres where liquids are likely to be present at floor level and that contain electrical circuits shall be classified at least IPX6 according to IEC 60529.	(A1) See Risk Management File	N/A
15.4.8	Internal wiring of ME equipment		Pass
15.4.9	Oil containers	No oil containers	N/A
15.5	Mains supply transformers of ME equipment and transformers providing separation in accordance with 8.5	USB Powered Device	N/A
15.5.1	Overheating		N/A
15.5.1.1	Transformers	(A1)	N/A
15.5.1.2	Short-circuit test	(A1)	N/A
15.5.1.3	Overload test	(A1)	N/A
15.5.2	Dielectric strength	(A1)	N/A
15.5.3	Construction of transformers used to provide separation as required by 8.5	(A1)	N/A

Clause 16 – ME Systems

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
16.1	General requirements for the ME system	See Risk Management File	Pass
16.2	Accompanying documents of an ME system		Pass
16.3	Power supply	(A1) internal power supply	N/A
16.4	Enclosure	Inspected	Pass
16.5	Separation devices		Pass
16.6	Leakage Currents		
16.6.1	Touch Current		Pass
16.6.2	Earth leakage current of multiple socket-outlet	No multiple socket outlet	N/A
16.6.3	Patient leakage current		Pass
16.6.4	Measurements		
16.6.4.1	General conditions for ME equipment		Pass
a)	The TOUCH CURRENT, the PATIENT LEAKAGE CURRENT, the total PATIENT LEAKAGE CURRENT and the total EARTH LEAKAGE CURRENT are measured after the ME SYSTEM has been brought up to operating temperature as follows.	(A1)	Pass
b)	The ME SYSTEM is connected to a supply with a voltage equal to the highest RATED MAINS VOLTAGE. When the characteristics of an ME SYSTEM can only be measured properly after it has been installed at the site of the RESPONSIBLE ORGANIZATION, prior to its clinical use, the ME SYSTEM is connected to the local SUPPLY MAINS.		Pass
16.6.4.2	Connection of the ME system to the measuring supply circuit		Pass
16.7	Protection against mechanical hazards		Pass
16.8	Interruption of the power supply to parts of an ME system	(A1)	Pass
16.9	ME system connections and wiring		
16.9.1	Connection terminals and connectors	(A1) See Risk Management File	Pass
16.9.2	Mains parts, components and layout		
16.9.2.1	Multiple socket-outlet	No multiple socket outlet	N/A
a)	A MULTIPLE SOCKET-OUTLET shall:	No multiple socket outlet	N/A
b)	A MULTIPLE SOCKET-OUTLET:	No multiple socket outlet	N/A
c)	The MULTIPLE SOCKET-OUTLET shall comply with IEC 60884-1 and the following requirements.	(A1) No multiple socket outlet	N/A
d)	If the MULTIPLE SOCKET-OUTLET is combined with a separating transformer, the following additional requirements apply.	No multiple socket outlet	N/A
16.9.2.2	Protective earth connections in ME equipment	(A1)	Pass
16.9.2.3	Protection of conductors		Pass

Clause 17 – Electromagnetic Compatibility of ME Equipment and ME Systems

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
17	Electromagnetic Compatibility of ME Equipment and ME Systems	See Risk Management File	Pass

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Clause 4 – General Requirements

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
4.1	General	See Manufacturer's Risk Manage Documentation and Instructions For Use	Noted
4.2	Chemical and physical properties		
4.2.1	General	See Critical Components List	Noted
4.2.2	Contaminants and residues	See Manufacturer's Risk Management Documentation and	Noted
4.2.3	Contact with substances	See Manufacturer's Bio-compatibility documentation	Noted
4.3	Control of contamination		
4.3.1	General	See Manufacturer's Documentation and Instructions For Use	Noted
4.3.2	Instruments supplied sterile	See Manufacturer's Documentation and Instructions For Use	Noted
4.3.3	Instruments supplied non-sterile	See Manufacturer's Documentation and Instructions For Use	Noted
4.4	Construction and environmental properties		
4.5	Equipment connected to or equipped with an energy source	See test results	Pass
4.6	Protection against electrical risks	See test results	Pass
4.7	Protection against mechanical and thermal risks		
4.7.1	Vibration		Pass
4.7.2	Noise		Pass
4.7.3	Electricity, gas or hydraulic and pneumatic energy	None provided	N/A
4.7.4	Surface temperature	See test results	Pass
4.8	Controls and indicators	See Instructions for Use	Noted
4.9	Clinical evaluation	See manufacturer's Clinical Evaluation Documentation	Noted
4.10	Marking, labelling and information supplied by the manufacturer		
4.10.1	General	See Manufacturer's Documentation and Instructions for Use	Noted
4.10.2	Symbols	See Instructions for Use	Noted
4.10.3	Marking	See product sample and Manufacturer's documentation	Noted
4.10.4	Label	See manufacturer's label	Pass
4.10.5	Detachable components		Pass
4.10.6	Instructions for use		Pass

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Clause 4 – General Requirements

CLAUSE	DESCRIPTION	COMMENTS	VERDICT
4.1	General	Noted	
4.2	Chemical and physical properties	See manufacturer's Documentation	Pass
4.2.1	Materials		Pass
4.2.2	Contaminants and residues		Pass
4.2.3	Contact with substances		Pass
4.2.4	Ingress and leaking of substances		Pass
4.3	Control of contamination		Pass
4.4	Construction and environmental properties		Pass
4.5	Protection against radiation		Pass
4.6	Equipment connected to or equipped with an energy source		Pass
4.7	Programmable electronic subsystems (software programmes)		Pass
4.8	Protection against electrical risks		Pass
4.9	Protection against electrical risks		Pass
4.9.1	Mechanical stability		Pass
4.9.2	Vibration		Pass
4.9.3	Noise		Pass
4.9.4	Electricity, gas, hydraulic and pneumatic energy		Pass
4.9.5	Surface temperature		Pass
4.10	Controls and indicators		
4.11	Clinical evaluation	See Manufacturer's Documentation	Pass
4.12	Marking, labelling and information supplied by the manufacturer		Pass
4.12.1	General		Pass
4.12.2	Symbols		Pass
4.12.3	Marking		Pass
4.12.4	Label		Pass
4.12.5	Detachable components		Pass
4.12.6	Instructions for use		Pass

Figures

This section consists of 3 pages
including this page

Figure 1 Top & Bottom View

Figure 2 Internal View

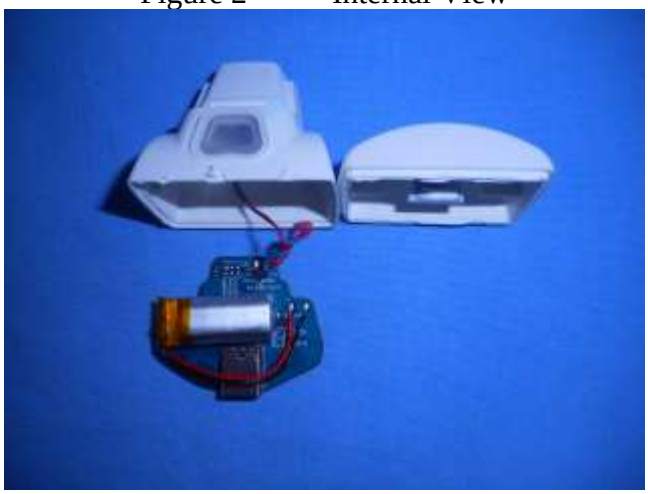


Figure 3 Front & Back View

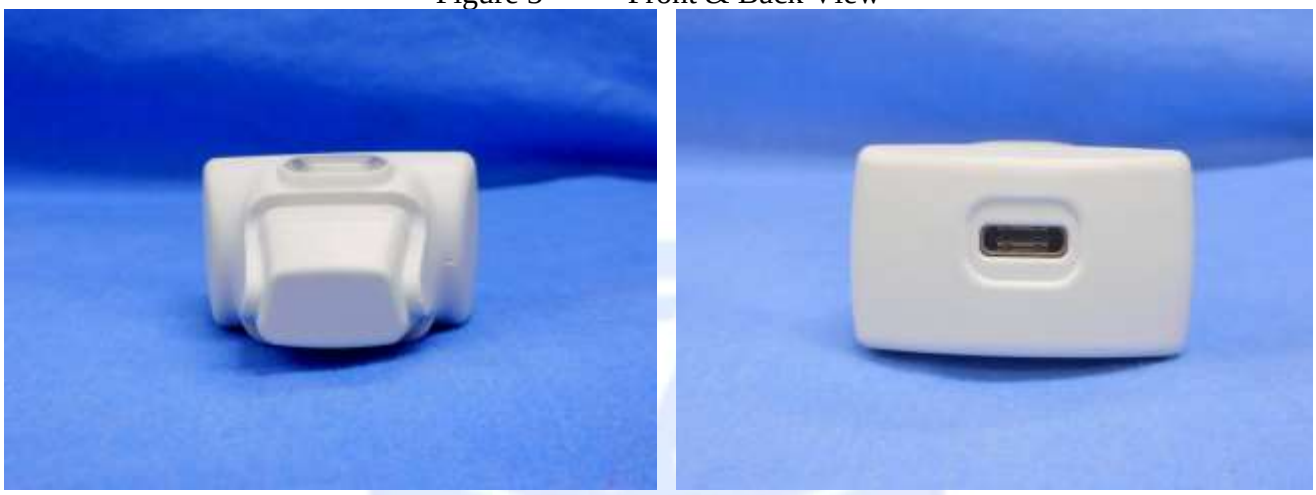
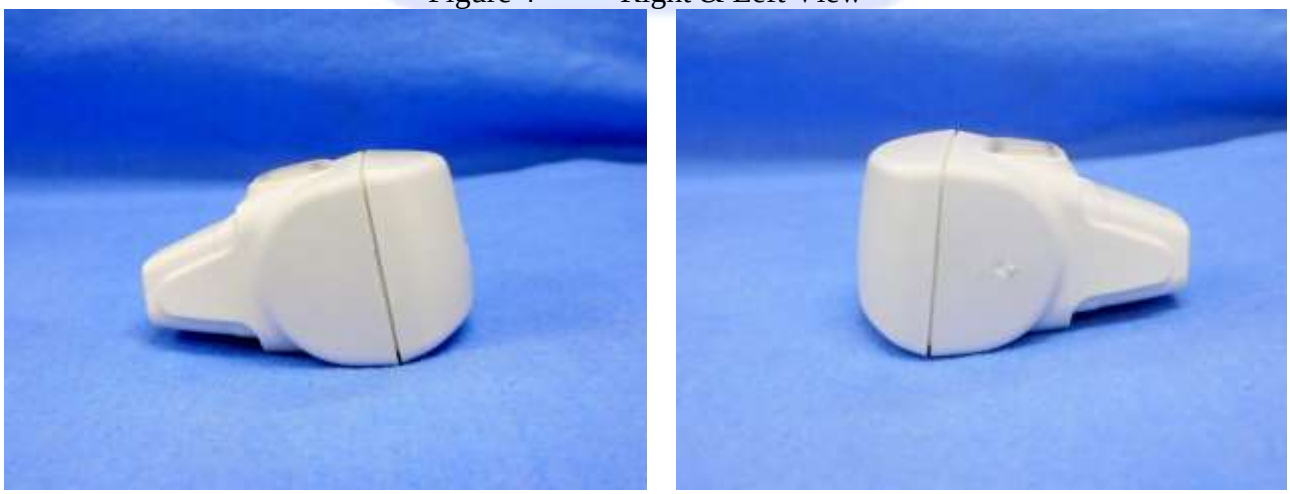


Figure 4 Right & Left View



Illustrations

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including this page

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Test Results

This section consists of 8 Pages
including this page

All tests were performed at:

Compatible Electronics, 20621 Pascal Way, Lake Forest, CA 92630 USA,

Description:	VPro Vibration Device
Model:	ASM-20018
Ratings:	Battery 3.7vDC 115mAh
Serial Number:	None
Pollution Degree:	2
Overvoltage Category:	I

Note: A power adapter with a USB output port was used as representative device for charging.

The following tests were carried out in the sequence specified in Annex B, following test procedure safety-D-1-11

Leakage Current	60601-1, Clause 8.7
Electric Strength	60601-1, Clause 8.8
Heating	60601-1, Clause 11.1
Drop Test - Handheld	60601-1, Clause 15.3

Test Equipment List

EQUIP No.	ASSETT No.	EQUIPMENT DESCRIPTION	EQUIPMENT MANUFACTURER	MODEL No.	SERIAL No.	LAST CAL	CAL DUE
1							
2	2697	Digital Multimeter	Fluke	73	77605234	3-21-19	3-21-20
3	2433	Digital Multimeter	Fluke	77	37655202	3-21-19	3-21-20
4	2376	Digital Multimeter	Fluke	77	48610715	3-21-19	3-21-20
5	2237	Digital Multimeter	Fluke	85	62700530	3-21-19	3-21-20
6	2129	True RMS Digital Multimeter	Fluke	87	58450372	3-21-19	3-21-20
7	5085	Ground Bond Tester	Slaughter	2660	3340043	3-21-19	3-21-20
8	2699	Leakage Current Tester	Simpson	228	N/A	3-21-19	3-21-20
9							
10	2075	Data Logger	Fluke	2620A-100	5230000	3-21-19	3-21-20
11	2001	Power Analyzer	Xitron	2501AH+INT	25014940002	3-21-19	3-21-20
12	2421	Oscilloscope	Tektronix	TDS360	B011930	3-21-19	3-21-20
13	2245	Force Gauge	Chatillon	DFM 100	25080	4-23-19	4-23-20
14	2035	Digital Caliper	Mitutoyo	CD-6”BS	0063787	3-21-19	3-21-20
15	2137	K/J Thermometer	Fluke	52	5880324	3-21-19	3-21-20
16	5089	Stop Watch	Athletic World	N/A	AW60448W	3-21-19	3-21-20
17	5087	Multimeter - Clamp-On	Triplett	9320-A	0356679	3-21-19	3-21-20
18							
19							
20	5030	Electronic Barometer	Weem & Plath	A4000.2	N/A	12-17-19	12-17-20
21	3311	Electric Strength Tester HiPot	Associated Research	03665	9320407	3-21-19	3-21-20
22	5435	Thermocouple Calibrator	Fluke	9100S	B22928	3-21-19	3-21-20
23	5437	Acoustic Meter	CEM	DT 8852	11083924	N/A	N/A
24	5438	Sound Level Calibrator	CEM	SC-05	11083904	5-14-18	5-14-21
25	2499	Hygrometer and Temperature	Abbeon Cal, Inc	HTAB169B	None	9/18/19	9/18/20
26	2503	Barometer	Abbeon Cal, Inc	BAR 130B	None	9/18/19	9/18/20
27	2374	Temperature Chamber	Despatch	16212A	149857	3-21-19	3-21-20
28	5439	Temp + Humidity Chamb	Thermotron	CH-5321	25881RF	3-21-19	3-21-20
29	5492	Chart Recorder	Honeywell	DR 4200	9607Y624398800005	N/A	N/A
30							
31	5489	Tachometer	SHIMPO	DT-107A -S12	B1550579R	8/20/2018	8/20/2021
32	5507	Oscilloscope Probe	Tektronix	P5122	None	3-21-19	3-21-20
33	5519	Leakage Current Tester	IKONIX	620L	9610533	10-9-2019	10-9-2020

Support Equipment List

EQUIP No.	ASSETT No.	EQUIPMENT DESCRIPTION	EQUIPMENT MANUFACTURER	MODEL No.	SERIAL No.	LAST P.M.	P.M. DUE
SE 1	2428	Autotransformer, Variac	Superior Electric CO	N/A	N/A	01-09-20	01-09-21
SE 2	2791	Power Supply - AC	Elgar	SW5250AE	13A1008	01-09-20	01-09-21
SE 3	1564	Isolation Transformer 115V	Solar Electronics Co.	7032-1	N/A	01-09-20	01-09-21
SE 4	2700	Isolation Transformer 230V	Solar Electronics Co.	7032-2	N/A	01-09-20	01-09-21
SE 5	5490	Step UP Transformer	Jefferson Electric	J8106	N/A	01-09-20	01-09-21
SE 6	2169	Step UP/DOWN Transformer	Compatible Electronics	CR-2000	N/A	01-09-20	01-09-21
SE 7							
SE 8	2153	Test Finger	Com-Power	FP-300	N/A	01-09-20	01-09-21
SE 9	2270	Impact Ball	Com-Power	SB-200	N/A	01-09-20	01-09-21
SE 10	2036	Capacitor Discharge Box	Compatible Electronics	CE-CD-101	N/A	01-09-20	01-09-21
SE 11	5491	Protractor	Craftsman	939840	N/A	01-09-20	01-09-21
SE 12	2034	Break-out Box	Compatible Electronics	CE-BO-101	1	01-09-20	01-09-21
SE 13	2126	Power Resistor Decade Box	Clarostat Mfg.	240-C	6956	01-09-20	01-09-21
SE 14	5176	DC Power Supply	Kikusui	PWR800L	MG002165	01-09-20	01-09-21
SE 15	5040	DC Power Supply	Kikusui	PAK60-6A	PF00526	01-09-20	01-09-21
SE 16	5436	Ball Pressure Tester	Com-Power	None	None	01-09-20	01-09-21
SE 17							

Project No: 20LF2841 *Model No: ASM-20018* *Tested By: Victor P*
Date: 02-24-20 *Equip Used: SE1, 3, 20, 33* *Results: Pass*

Leakage Current (Post Humidity Soak)

REFERENCE

- 60601-1 Clause 8.7

METHOD

The unit was connected to 264V, 60 Hz (max rated voltage+10%). The unit was placed on an insulating surface and all connections to external equipment were disconnected to prevent stray leakage paths.

ENVIRONMENT

- Temperature 23ºC Relative Humidity 44% Barometric Pressure 101 kPa

RESULTS

Test Voltage: 264**Vac, 60Hz**

Primary to Power Button

Neutral S1	Switch e	Touch Current		
		P[1] Forward (µA)	P[1] Reverse (µA)	Limit (µA)
Closed	Closed	0.4	0.4	100
Open	Closed	0.9	0.9	500

Primary to Bottom Enclosure

Neutral S1	Switch e	Touch Current		
		P[1] Forward (µA)	P[1] Reverse (µA)	Limit (µA)
Closed	Closed	0.5	0.5	100
Open	Closed	0.9	0.9	500

Primary to Front Enclosure

Neutral S1	Switch e	Touch Current		
		P[1] Forward (µA)	P[1] Reverse (µA)	Limit (µA)
Closed	Closed	0.6	0.6	100
Open	Closed	1.0	1.0	500

USB Connector to Power Button

Neutral S1	Switch e	Touch Current		
		P[1] Forward (µA)	P[1] Reverse (µA)	Limit (µA)
Closed	Closed	0	0	100
Open	Closed	0.1	0.1	500

USB Connector to Bottom Enclosure

Neutral S1	Switch e	Touch Current		
		P[1] Forward (µA)	P[1] Reverse (µA)	Limit (µA)
Closed	Closed	0	0	100
Open	Closed	0	0	500

USB Connector to Front Enclosure

Neutral S1	Switch e	Touch Current		
		P[1] Forward (µA)	P[1] Reverse (µA)	Limit (µA)
Closed	Closed	0	0	100
Open	Closed	0	0	500

Project No: 20LF2841 *Model No: ASM-20018* *Tested By: Victor P*
Date: 02-24-20 *Equip Used: 20, 21,* *Results: Pass*

Electric Strength (Post Humidity Soak)

REFERENCE

- 60601-1, Clause 8.8.3

METHOD

While the unit was in a well-heated condition, an ac or dc potential was gradually increased from zero to the test potential given below. The voltage was applied and maintained for a period of one minute between the points indicated.

ENVIRONMENT

- Temperature 25°C Relative Humidity 40% Barometric Pressure 101kPa

RESULTS

From	To	Insulation	Test Voltage	Breakdown	
Primary	Power Button	R	4.25kV	N	
Primary	Bottom Enclosure	R	4.25kV	N	
Primary	Front Enclosure	R	4.25kV	N	
USB Connector	Power Button	S	1.41kV	N	
USB Connector	Bottom Enclosure	S	1.41kV	N	
USB Connector	Front Enclosure	S	1.41kV	N	

Project No: 20LF2841 *Model No: ASM-20018* *Tested By: Victor P*
Date: 02-24-20 *Equip Used: SE1, 3, 10, 20* *Results: Pass*

Heating

REFERENCE

- 60601-1, Clause 11.1.1 Excessive Temperatures in ME Equip.

METHOD

The sample was connected to a source of supply as noted below and operated until temperatures became stable. Temperatures were measured using the thermocouple method.

Test	Operating Condition	Environment		Test Duration	Input	
		RH %	BP		Voltage	Frequency
A	Continuous operation, until Temperature Stabilized	43	101	1 Hr, 15 Min	5Vdc Battery	N/A
B	Charging mode operational run	40	101	2 Hr 5 Min	264Vac	60

RESULTS

Thermocouple			Test			
No.	Location	ID	A	B	C	D
			Temperature °C			
1	Room Ambient		23	23.8		
2	Power Button	04	28.4	25.7		
3	USB Connection	12	27.2	25.2		
4	Front Enclosure	24	30.9	25.4		
5	Bottom Enclosure	28	26.0	24.9		

Project No: 20LF2841 *Model No: ASM-20018* *Tested By: Victor P*
Date: 02-25-20 *Equip Used: 14, 20* *Results: Pass*

Drop Test – Hand-held

REFERENCE

- 60601-1 Clause 15.3.4.1

METHOD

The sample to be tested, with any SAFE WORKING LOAD in place, is allowed to fall freely once from each of three different starting orientations encountered during NORMAL USE from the height at which the ME EQUIPMENT is used (as specified in the ACCOMPANYING DOCUMENTS), or from a height of 1 m, whichever is greater, onto a 50 mm +/-5 mm thick hardwood board (hardwood > 600 kg/m3) lying flat on a concrete or a similar rigid base.

After the test, the HAND-HELD ME EQUIPMENT and ME EQUIPMENT parts that are HAND-HELD shall not result in an unacceptable RISK.

ENVIRONMENT

- Temperature: 27ºC Relative Humidity: 45% Barometric Pressure: 101 kPa

RESULTS

Drop No.	Impacted Area	Observation
1	Front of enclosure	No damage or hazardous condition
2	Back of enclosure	No damage or hazardous condition
3	Side of enclosure	No damage or hazardous condition

Appendix A

Laboratory Accreditations and Recognitions

LABORATORY ACCREDITATIONS AND RECOGNITIONS

For US, Canada, Australia/New Zealand, Japan, Taiwan, Korea, and the European Union, Compatible Electronics is currently accredited by NVLAP to ISO/IEC 17025.

For the most up-to-date version of our scopes and certificates please visit

http://celectronics.com/quality/scope/

Quote from ISO-ILAC-IAF Communiqué on 17025:

"A laboratory's fulfilment of the requirements of ISO/IEC 17025:2005 means the laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations. The management system requirements in ISO/IEC 17025:2005 (Section 4) are written in language relevant to laboratory operations and meet the principles of ISO 9001:2008 Quality Management Systems — Requirements."

Appendix B

Component Datasheets and Certificates

This Appendix consists of 11 Pages
including this page

Item 1	Enclosure Plastics	1 Page
Item 2	Li-ion Battery Pack	3 Pages
Item 3	PCB Material	1 Page

Notes:
1. For any components not covered in this section, the manufacturer will provide verification of component certification upon request.
2. Item numbers refer to the item numbers used in List of Safety Critical Components in this report.

Item 1 Enclosure Plastics

Component - Plastics
File Number: E56070

CHI MEI CORPORATION
59-1 SAN CHIA, JEN TE, TAINAN 717 TW

Polylac: PA-747(+)

Acrylonitrile Butadiene Styrene (ABS), pellets

(+) - Optional prefix or suffix; may be used to denote usage of 0-0.5 percent acid scavengers. For PC-110(+), Optional the suffix except L, N, U, V, T, and F. For Grades PC-6015(+), PB-1202(+), Maybe none or replace by one alphabet to indicate the color.

Flammability	Value	Test Method
Flame Rating		
1.50 mm, ALL	HB	UL 94
3.00 mm, ALL	HB	UL 94
3.00 mm, ALL	HB40	IEC 60695-11-10, -20
1.50 mm, ALL	HB75	IEC 60695-11-10, -20
Electrical	**Value**	**Test Method**
Hot-wire Ignition (HWI)		UL 746
1.50 mm	PLC 4	
3.00 mm	PLC 4	
High Amp Arc Ignition (HAI)		UL 746
1.50 mm	PLC 0	
3.00 mm	PLC 0	
Comparative Tracking Index (CTI)	PLC 1	UL 746
High Voltage Arc Tracking Rate (HVTR)	PLC 0	UL 746
Arc Resistance	PLC 7	ASTM D495
Thermal	**Value**	**Test Method**
RTI Elec		UL 746
1.50 mm	85.0 °C	
3.00 mm	85.0 °C	
RTI Imp		UL 746
1.50 mm	80.0 °C	
3.00 mm	80.0 °C	
RTI Str		UL 746
1.50 mm	85.0 °C	
3.00 mm	85.0 °C	

Form Number: E56070-245718

Report Date: 6/23/1983
Last Revised: 5/22/2012

ANSI/UL 94 small-scale test data does not pertain to building materials, furnishings and related contents. ANSI/UL 94 small-scale test data is intended solely for determining the flammability of plastic materials used in the components and parts of end-product devices and appliances, where the acceptability of the combination is determined by UL.

Item 2 Li-ion Battery Pack

IEC IECEE CB SCHEME

Ref. Certif. No.
JPTUV-076795

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE

CERTIFICAT D'ESSAI OC

Product Produit	Li-ion polymer battery
Name and address of the applicant Nom et adresse du demandeur	Renata SA Kreuzenstrasse 30,4452 Itingen, Switzerland
Name and address of the manufacturer Nom et adresse du fabricant	SYNergy ScienTech Corp. 7F, No. 9, Park Ave. II, Hsinchu Science Park, Hsinchu 30075 Taiwan
Name and address of the factory Nom et adresse de l'usine	SYNergy ScienTech Corp. 7F, No. 9, Park Ave. II, Hsinchu Science Park, Hsinchu 30075 Taiwan
Ratings and principal characteristics Valeurs nominales et caractéristiques principales	3.7V, 110mAh, 0.4Wh
Trademark (if any) Marque de fabrique (si elle existe)	Trade mark see test report.
Type of Manufacturer's Testing Laboratories used Type de programme du laboratoire d'essais constructeur	N/A
Model / Type Ref. Ref. de type	ICP501421PS-01
Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire, peuvent être indiqués sur la 2ème page)	
A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	IEC 62133:2012 See Test Report for National Differences
As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat	17062190 001

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification

TÜVRheinland®

TÜV Rheinland Japan Ltd.
Global Technology Assessment Center
4-25-2 Kita-Yamata, Tsuzuki-ku
Yokohama 224-0021 Japan
Phone + 81 45 914-3886
Fax + 81 45 914-3354
Mail: info@jpn.tuv.com
Web: www.tuv.com

Date: 23.11.2016

Signature: Dipl.-Ing. (FH) C. Padel

Item 2 Li-ion Battery Pack

ONLINE CERTIFICATIONS DIRECTORY

BBCV2.MH14002
Lithium Batteries - Component

If you notice a change to your BBCV2 Listing Card, click here to learn more.

Page Bottom

Lithium Batteries - Component

See General Information for Lithium Batteries - Component

RENATA SA MH14002
KREUZENSTRASSE 30
4452 ITINGEN, SWITZERLAND

Model No.	Primary Type[a]	Max Abnormal Charging Current mA	Max Abnormal Charging Voltage, V dc	Replacement [b],[c]
1000-(g)(h)	Lithium/manganese dioxide	25	12	User
1000-7 (h)	Lithium/manganese dioxide	25	12	User
250-(g)(h)	Lithium/manganese dioxide	25	12	User
320A (h)	Lithium/manganese dioxide	5	12	User
338A (h)	Lithium/manganese dioxide	25	12	User
500-(g)(h)	Lithium/manganese dioxide	25	12	User
CR1025 (i)	Lithium/manganese dioxide	5	12	User
CR1216 (i)	Lithium/manganese dioxide	5	12	User
CR1216 MFR (i)(k)	Lithium/manganese dioxide (Coin)	3.5	-	User
CR1220 (i)	Lithium/manganese dioxide	25	12	User
CR1220 MFR (i)(k)	Lithium/manganese dioxide (Coin)	10	-	User
CR1225 (i)	Lithium/manganese dioxide	25	12	User
CR1616 (i)	Lithium/manganese dioxide	25	12	User
CR1616 MFR (i)(k)	Lithium/manganese dioxide (Coin)	4	-	User
CR1620 (i)	Lithium/manganese dioxide	25	12	User
CR1620 MFR (i)(k)	Lithium/manganese dioxide (Coin)	2.5	-	User
CR1632 (i)	Lithium/manganese dioxide (Coin)	25	12	User
CR1632 MFR (j)	Lithium/manganese dioxide (Coin)	4	-	User
CR2016 (i), CR2016-MFR (i)	Lithium/manganese dioxide	25	12	User
CR2016 MFR (j)	Lithium/manganese dioxide (Coin)	10	-	User

Item 2 Li-ion Battery Pack

ICP402050	Lithium ion	420	4.4	3
ICP422339	Lithium ion	350	4.4	3
ICP501022	Lithium ion	80	4.4	3
ICP501230	Lithium ion	130	4.4	3
ICP501233	Lithium ion	175	4.4	1
ICP501421	Lithium ion	120	4.4	1
ICP502030	Lithium ion	46	4.4	3
ICP521630	Lithium ion	250	4.4	3
ICP543759	Lithium ion	1320	4.4	1
ICP552030	Lithium ion	300	4.4	3
ICP581323	Lithium ion	145	4.4	1
ICP582930	Lithium ion	450	4.4	3
ICP602823	Lithium ion	345	4.4	3
ICP606168	Lithium ion (Pouch)	2800	4.4	1
ICP621333	Lithium ion	240	4.4	1
ICP622540	Lithium ion	600	4.4	3
ICP631519	Lithium ion (Pouch)	110	4.4	1
ICP631524	Lithium ion (Pouch)	160	4.4	1
ICP631530	Lithium ion (Pouch)	225	4.4	1
ICP641414	Lithium ion	95	4.4	3
ICP641620	Lithium ion	165	4.4	1
ICP651321	Lithium ion	120	4.4	3
LMR2016 (#)	Lithium ion (Coin)	300	5.0	1

[a] These cells and batteries are not rechargeable. The circuit containing these cells or batteries is to contain a protective component that prevents charging. The circuitry is to include a current-limiting component intended to protect the cell or battery, in the event the protective component malfunctions, from a charging current in excess of the maximum abnormal charging current indicated.

[b] User - These primary cells and batteries are intended for use in applications subject to replacement by a user.

[c] Technician - These primary cells and batteries are intended for use in applications subject to replacement only by a trained service technician.

[d] These cells and batteries are rechargeable. The circuitry containing these cells or batteries is to contain protective components intended to protect the cells or batteries from currents in excess of the maximum charging current and voltage indicated.

[e] The Max Charging Voltage noted in the column is the maximum voltage employed during the abnormal charging test of the secondary lithium ion cell. However, the maximum recommended charging voltage for lithium ion cells is 4.2 V, unless indicated otherwise.

[f] Test Compliance - The cells comply with the tests in UL 1642 as noted:

1 - Complies with all single-cell tests

2 - Complies with all single-cell tests except the impact test

3 - Complies with all single-cell tests except the projectile test

4 - Complies with all single-cell tests except the crush test

(#) - These cells may have various insulating tube, ring or tape.

(g) - Followed by one or two digit number denoting the presence of a diode within the module or module orientation.

(h) - The power modules and cells may have a two letter suffix which denotes type of solder tab or wire lead or the mode of packaging or an additional letter and three digit suffix which denotes type of solder tab or wire lead.

(i) - These cells may have an additional (2) two alphanumeric characters prefix which denotes the amount of cells connected electrically together, up to three alphanumeric characters suffix which denotes type of solder tab or wire lead or the mode of packaging or (6) six/(7) seven alphanumeric characters suffix with format xxxx-y/xxxx-yy which denotes type of solder tab or wire lead where xxxx is the type and y/yy the revision level.

(j) - Cell model numbers may be followed by an optional slash (/) and single or multiple alphanumeric characters (i.e. letters and/or numbers), which denote optional features such as various mounting tabs, connecting leads or plugs, packaging, etc.

Item 3 PCB Material

iq.ul.com

Materials for Use in Fabricating Recognized Printed Wiring Boards E98983

Guide Information

NAN YA PLASTICS CORP CCL DEPT ELECTRONIC MATERIAL DIV

201 TUNG HWA N RD. TAIPEI 10508 TW

NP-175FR, NP-175FTL, NP-155FR, NP-155FTL, NP-180FR, NP-180FTL, NP-175FMR, NP-175FMTL, NP-155FMR, NP-155FMTL, NP-175FBH, NP-155FBH

Industrial laminates furnished as sheets

ANSI Type	Color	Min Build Up Thk(mm)	Flame Class	RTI Elec (°C)	RTI Mech (°C)	HWI	HAI	HVTR	CTI	Meets 746E Non-HAL	Meets 746E DSR
FR-4.0	NC	0.20	V-0	130	130	0	0	-	-	-	Yes
		0.38	V-0	130	130	0	0	-	-	-	Yes
		0.64	V-0	130	140	0	0	-	-	-	Yes
		1.40	V-0	130	140	0	0	-	3	-	Yes

Report Date: 1986-05-15
Last Revised: 2019-04-12

IEC and ISO Test Methods

Test Name	Test Method	Units	Thk (mm)	Value
Flammability	IEC 60695-11-10	Class (color)	0.20	V-0 (NC)
			0.38	V-0 (NC)
			0.64	V-0 (NC)
			1.40	V-0 (NC)
IEC Comparative Tracking Index	IEC 60112	Volts (Max)	-	-

Tradenames/Trademarks for File E98983: NP

Appendix C

Required Modifications

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