TEST REPORT
IEC 60601-1-11
MEDICAL ELECTRICAL EQUIPMENT –

Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Report Number. .....:	**64.66T.14.169.01**
Date of issue .....:	**2014.12.05**
Total number of pages	**30**
Applicant's name.....:	**SHL Healthcare Ltd**
Address .....:	Room 810, Argyle centre, 688 Nathan Road, Kowloon, Hongkong
Test specification:	
Standard.....:	IEC 60601-1-11 (First Edition): 2010
Test procedure .....:	Voluntary Test
Non-standard test method……..:	N/A
Test Report Form No.....:	IEC60601_1_11B
Test Report Form Originator .....:	Underwriters Laboratories Inc.
Master TRF .....:	2011-06

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Test item description .....:	**Alternating Control Unit**
Trade Mark.....:	
Manufacturer .....:	**Invacare Operations UK Ltd.**
Model/Type reference.....:	**SoftAIR**
Ratings .....:	**220V-240V~, 50/60Hz, 0.3A**

Testing procedure and testing location:		
☒	**Testing Laboratory:**	
Testing location/ address..... :		**TÜV SÜD Certification and Testing (China) Co., Ltd. Guangzhou Branch / 5F, Communication Building 163 Pingyun Rd, Huangpu Ave. West 510656 Guangzhou CHINA**
☐	**Associated Laboratory:**	
Testing location/ address..... :		
Tested by (name + signature).....:		Vivian Li
Approved by (name + signature) .....:		Zack Shen
☐	**Testing procedure: TMP**	
Testing location/ address..... :		
Tested by (name + signature).....:		
Approved by (name + signature) .....:		
☐	**Testing procedure: WMT**	
Testing location/ address..... :		
Tested by (name + signature).....:		
Witnessed by (name + signature).....:		
Approved by (name + signature) .....:		
☐	**Testing procedure: SMT**	
Testing location/ address..... :		
Tested by (name + signature).....:		
Approved by (name + signature) .....:		
Supervised by (name + signature)....:		

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

See IEC 60601-1 Test Report: 64.66T.14.168.01 Attachment 1: Photo documents

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
All applicable tests **Exceptions:** **The following clauses / collaterals were not part of the manufacturers order and therefore excluded from this testing:** Clause 7.1 Usability of accompanying documents Clause 9 Usability of controls and instruments Clause 12 Additional requirements for EMC Collateral IEC 60601-1-9 environmental safety	**TÜV SÜD Certification and Testing (China) Co., Ltd. Guangzhou Branch** **Guangzhou Branch, 5F, Communication Building 163 Pingyun Rd, Huangpu Ave. West 510656 Guangzhou CHINA**

Summary of compliance with National Differences

List of countries addressed:

N/A

☐ The product fulfils the requirements of _____ (insert standard number and edition and delete the text in parenthesis or delete the whole sentence if not applicable)

Copy of marking plate

See IEC 60601-1 Test Report: 64.66T.14.168.01

Test item particulars.....:	
Classification of installation and use.....:	Stationary
Intended use (Including type of patient, application location)..... :	Provides pressure application and release to patients who are vulnerable to, or suffer from, press ulcers
Mode of operation ..... :	Continuous
Supply Connection .....:	Appliance coupler
Accessories and detachable parts included .....:	None
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A (Not applicable)
- test object does meet the requirement..... :	P (Pass)
- test object does not meet the requirement..... :	F (Fail)
Testing.....:	
Date of receipt of test item ..... :	2014.11.19
Date (s) of performance of tests ..... :	2014.11.19~11.30

- Normal condition..... : N.C.	- Single fault condition..... : S.F.C.
- Means of Operator protection ..... : MOOP	- Means of Patient protection ..... : MOPP

General remarks:

"(see Enclosure /Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.

This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report.

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

This Test Report Form is intended for the evaluation of medical electrical equipment and medical electrical systems used in the home healthcare environment in accordance with IEC 60601-1-11.
This Test Report Form can be used to complement the IEC 60601-1 Test Report.
The Risk Management Task Force reviewed and modified the Risk Management tables in this TRF.

Name and address of factory (ies) ..... :	MED&CARE (Shenzhen) Co., Ltd Bld.8, A-6 Tongfuyu Industrial Park, Bu-Chong, Shajing Town, Baoan District, Shenzhen, P.R.C.

General product information:

See IEC 60601-1 Test Report: 64.66T.14.168.01

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
4	**GENERAL REQUIREMENTS**		P
4.1	Characteristics of SUPPLY MAINS specified in 4.10.2 of Part 1 applied, except ME EQUIPMENT or ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT complied with the following:		P
	– Voltage for non-LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEMS did not exceed 110 % or was not below 85 % of NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% V).....:	Replaced.	—
	– Voltage for LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEMS did not exceed 110 % or was not below 80 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% V).....:		—
4.2.1	Permissible environmental conditions of transport and storage, after ME EQUIPMENT is removed from its protective packaging and subsequently between uses, indicated in instructions for use		P
	ME EQUIPMENT, except STATIONARY EQUIPMENT, after being removed from its protective packaging, and subsequently between uses, operated within its specified NORMAL USE after transport or storage in the following environmental temperature range,		P
	-25 °C without relative humidity control		N/A
	+70 °C at a non-condensing relative humidity up to 93 %		N/A
	For more restricted range of environmental transport and storage conditions between uses, the environmental conditions are:		P
	– Justified in the RISK MANAGEMENT FILE		N/A
	– Marked on the ME EQUIPMENT		N/A
	When not practicable, the more restricted range is disclosed in the instructions for use		P
	– Marked on the carrying case when the instructions for use indicate the ME EQUIPMENT is intended to be transported or stored in a carrying case between uses		N/A
	Environmental transport and storage test		P
	a) ME EQUIPMENT prepared for transportation or storage according to instructions for use (e.g., removal of batteries, emptying fluid reservoirs, etc.)		P
	b) ME EQUIPMENT exposed to its lowest specified environmental transport and storage conditions (temperature $^{0}_{-4}$ °C) (°C).....:	10℃	P

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– For at least 24 h or, ensure ME EQUIPMENT reached THERMAL STABILITY for at least 2 h		P
	c) ME EQUIPMENT exposed to its highest specified environmental transport and storage conditions (temperature $^{+4}_{0}$ °C and relative humidity ± 3 %) (°C, ± %) .....:	+40℃	P
	– For at least 24 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h		P
	Transition from low to high conditions made slowly enough to provide a non-condensing environment		P
	d) At the end of this conditioning period, ME EQUIPMENT allowed to return and stabilize at the operating conditions of NORMAL USE		P
	e) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE		P
4.2.2	The permissible environmental operating conditions are indicated in the instructions for use		P
	ME EQUIPMENT complied with its specifications and all the requirements of this standard when operated in NORMAL USE under the following environmental operating conditions, except as indicated in the instructions for use:		P
	– a temperature range of +5 °C to +40 °C (°C) .....:	+5 °C to +40 °C	P
	– a relative humidity range of 15 % to 93 %, non-condensing (% RH) .....:	15 % to 93 %	P
	– an atmospheric pressure range of 700 hPa to 1060 hPa (hPa).....:	700 hPa to 1060 hPa	P
	When more restricted range of environmental operating conditions are stated in the instructions for use, they are justified or marked as follows:	No more restricted range.	N/A
	– justified in the RISK MANAGEMENT FILE		N/A
	– marked on the ME EQUIPMENT, except when not practicable		N/A
	The more restricted range disclosed in the instructions for use; and		N/A
	– marked on the carrying case when the instructions for use indicated the ME EQUIPMENT is intended to be operated in a carrying case		N/A
	ME EQUIPMENT complied with its specifications and requirements of this standard when operated in NORMAL USE under the specified environmental operating conditions		P

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	When a more restricted range stated in the instructions for use, the RISK MANAGEMENT FILE inspected		N/A
	Environmental operating conditions test		P
	a) ME EQUIPMENT exposed to the ambient conditions		P
	– For at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h (h)		P
	b) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE		P
	c) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE while at the lowest specified atmospheric pressure		P
	d) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE while at the highest specified atmospheric pressure		P
	e) ME EQUIPMENT cooled to its lowest specified environmental operating conditions (temperature $^{0}_{-4}$ °C and relative humidity less than or equal to 15 %) (°C, RH %) .....:	5℃, RH15%	P
	f) ME EQUIPMENT held at its lowest specified environmental operating conditions for at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h (h)	6 h	P
	g) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE		P
	h) ME EQUIPMENT heated to its highest specified environmental operating conditions (temperature $^{+4}_{0}$ °C and relative humidity ± 3 %) (°C, RH %) .....:	40℃, RH93%	P
	i) ME EQUIPMENT held at its highest specified environmental operating conditions for at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h (h)	6 h	P
	j) ME EQUIPMENT evaluated to its specifications and ensured that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE		P
4.2.3	TRANSIT-OPERABLE ME EQUIPMENT maintain BASIC SAFETY and ESSENTIAL PERFORMANCE in the presence of condensation and thermal shock when instructions for use state a wider range of environmental operating conditions than indicated in 4.2.2	Not TRANSIT-OPERABLE ME EQUIPMENT.	N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Environmental operating conditions test		N/A
	a) ME EQUIPMENT was set up for operation according to INTENDED USE		N/A
	b) ME EQUIPMENT exposed to its lowest specified environmental operating conditions (temperature $^{0}_{-4}$ °C and relative humidity less than or equal to 15 %) (°C, RH %) .....:	N/A	N/A
	c) ME EQUIPMENT held at its lowest specified environmental operating conditions for at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h (h)		N/A
	d) ME EQUIPMENT exposed to its highest specified environmental operating conditions within 5 min (temperature $^{+4}_{0}$ °C and relative humidity ± 3 %) (°C, RH %) .....:	N/A	N/A
	e) ME EQUIPMENT maintained at the environmental conditions of d) above		N/A
	ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE until the ME EQUIPMENT reached THERMAL STABILITY, or for at least 2 h		N/A
	LEAKAGE CURRENT and dielectric strength testing were not included in the evaluation of BASIC SAFETY due to pollution degree ratings required by Part 1		N/A
	A separate test sample was, optionally, used for the following tests:		N/A
	f) ME EQUIPMENT was set up for operation according to INTENDED USE		N/A
	g) ME EQUIPMENT exposed to its highest specified environmental operating conditions (temperature $^{+4}_{0}$ °C and relative humidity ± 3 %) (°C, RH %) .....:	N/A	N/A
	h) ME EQUIPMENT held at its highest specified environmental operating conditions for at least 6 h or, ensured the ME EQUIPMENT reached THERMAL STABILITY for at least 2 h		N/A
	i) ME EQUIPMENT exposed to its lowest specified environmental operating conditions within 5 min (temperature $^{0}_{-4}$ °C and relative humidity ≤ 15 %) (°C, RH %) .....:	N/A	N/A
	j) ME EQUIPMENT maintained at the environmental conditions in i) evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE until the ME EQUIPMENT reached THERMAL STABILITY, or for at least 2 h		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Evaluation of BASIC SAFETY and ESSENTIAL PERFORMANCE repeated for two hours or until THERMAL STABILITY reached while ME EQUIPMENT was warming up or cooling down		N/A
5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		P
	In addition to the requirements of 5.9.2.1 of with IEC 60601-1 standard, accessibility determined as indicated below:		P
	ACCESSIBLE parts of ME EQUIPMENT identified by inspection and, when necessary, by testing		P
	When in doubt, an ACCESSIBLE PART of ME EQUIPMENT determined by a test with the small finger probe of Fig 1, applied in a bent or straight position as follows:		P
	– for all positions of the ME EQUIPMENT operating in NORMAL USE		P
	– after opening ACCESS COVERS and removal of parts, including lamps, fuses, and fuse holders when:		P
	i) the ACCESS COVERS could be opened without the use of a TOOL, or	No such access covers.	N/A
	ii) the instructions for use instructed a LAY OPERATOR to open the relevant ACCESS COVER		P
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		P
	ME EQUIPMENT intended for HOME HEALTHCARE ENVIRONMENT classified as follows, except for PERMANENTLY INSTALLED EQUIPMENT and as required by Part 1, Sub-clause 6.2:		P
	– CLASS II or INTERNALLY POWERED .....:	Class II equipment.	P
	– Not provided with a FUNCTIONAL EARTH TERMINAL	No FUNCTIONAL EARTH TERMINAL.	P
	– When equipped with APPLIED PARTS, they are TYPE BF or CF .....:	Type BF applied part.	P
7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		P
7.1	USABILITY of identification, marking, and ACCOMPANYING DOCUMENTS intended for LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION evaluated by an OPERATOR whose PROFILE included eight years of education		N/E
	ME EQUIPMENT and ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT are simple to use and do not require referencing complex ACCOMPANYING DOCUMENTS		N/E

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Results of USABILITY ENGINEERING PROCESS inspected		N/E
7.2	The ENCLOSURE is marked with the IP classification required by 8.3.1 .....:	IPX0. Symbol ISO 7000-0626 marked.	P
	Degree of protection provided by the ENCLOSURE marked on ENCLOSURE and the degree of protection provided by carrying case marked on carrying case when some or all of the protection against ingress of water or particulate matter is provided by a carrying case		N/A
	A carrying case not intended to provide protection against the ingress of water or particulate matter not marked	No carrying case.	N/A
	An ENCLOSURE, not providing the minimum required degree of protection against the ingress of water, is marked “keep dry”, or with symbol ISO 7000-0626 (2004-01) (Table C1, symbol 1):	Symbol ISO 7000-0626 marked.	P
	ENCLOSURE inspected, and tests and criteria of 7.1.2 and 7.1.3 of Part 1 applied .....:	Markings are clearly legible and durable after tests.	P
7.3	ACCOMPANYING DOCUMENTS		P
7.3.1	ACCOMPANYING DOCUMENTS indicate the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION should contact the MANUFACTURER or MANUFACTURER'S representative on the following issues:		P
	– Assistance in setting up, using, or maintaining the ME EQUIPMENT or ME SYSTEM when needed, or		P
	– To report unexpected operation or events		N/A
	ACCOMPANYING DOCUMENTS include a postal address and either a phone number or web address for the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION to contact the MANUFACTURER or MANUFACTURER'S representative		P
7.3.2	ACCOMPANYING DOCUMENTS include necessary details for healthcare professional to brief the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION on any known contraindication(s) to the use of ME EQUIPMENT or ME SYSTEM and any precautions to be taken including the following:		P
	– Precautions to be taken in the event of changes in the performance of ME EQUIPMENT or ME SYSTEM		P
	– Precautions to be taken regarding the exposure of the ME EQUIPMENT or ME SYSTEM to reasonably foreseeable environmental conditions		P

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

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.4.3	Instructions for use include easily understood diagrams, illustrations, or photographs of the fully assembled and ready-to-operate ME EQUIPMENT including all controls, visual INFORMATION SIGNALS, and indicators provided (see 7.1)		P
7.4.4	Instructions for use include:		N/A
	– Easily understood diagrams, illustrations, or photographs showing proper connection of the PATIENT to the ME EQUIPMENT, ACCESSORIES and other equipment (see 7.1)	No connection of patient to equipment.	N/A
	– the time from switching "ON" until the ME EQUIPMENT is ready for NORMAL USE, when it exceeds 15 s (see 15.4.4 of Part 1) (s).....:	Not exceeding 15s.	N/A
7.4.5	Instructions for use include a description of generally known conditions in the HOME HEALTHCARE ENVIRONMENT that can unacceptably affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT	See RISK MANAGEMENT Table 7.4.5	P
	The steps that can be taken by the LAY OPERATOR to identify and resolve the above conditions		P
	At least the following issues are also included as applicable		P
	- The effects of lint, dust, light (including sunlight), etc		N/A
	- A list of known devices or other sources that can potentially cause interference problems		P
	- The effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems	No sensor or electrode.	N/A
	- The effects caused by pets, pests or children		P
	The instructions for use explain the meaning of the IP classification marked on the ME EQUIPMENT, and on any carrying case provided with the ME EQUIPMENT as applicable		P
7.4.6	Instructions for use include a troubleshooting guide for use when there are indications of a ME EQUIPMENT malfunction during start-up or operation		P
	Troubleshooting guide discloses the necessary steps in the event of an ALARM CONDITION		P
7.4.7	Instructions for use for ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES for other than single use that can be contaminated by contact with PATIENT, body fluids, or expired gases, during INTENDED USE, indicate the following:		P

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Frequency of cleaning, cleaning and disinfection, or cleaning and sterilization, as appropriate, for ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES used on the same PATIENT including rinsing methods, drying, handling, and storage between uses (see 8.1 and 8.2); and		P
	– It is necessary to clean and disinfect, clean and sterilize the ME EQUIPMENT, ME SYSTEMS, parts, and ACCESSORIES for multiple PATIENT use between uses on different PATIENTS, including rinsing methods, drying, handling, and storage until re-use (see 8.1 and 8.2), or		N/A
	– ME EQUIPMENT, ME SYSTEMS and ACCESSORIES require professional hygienic maintenance prior to re-use and provide contact details for the source of these services (see 7.5.2)	Not requiring professional hygienic maintenance prior to re-use.	N/A
7.4.8	Instructions for use include:		P
	– EXPECTED SERVICE LIFE of the ME EQUIPMENT .....:	2 years.	P
	– EXPECTED SERVICE LIFE of parts and ACCESSORIES shipped with the ME EQUIPMENT .....:	No accessories.	N/A
	– SHELF LIFE of parts and ACCESSORIES shipped with ME EQUIPMENT when SHELF LIFE is less than the EXPECTED SERVICE LIFE .....:	No accessories.	N/A
7.4.9	Instructions for use include:		P
	– Information concerning the proper disposal of the ME EQUIPMENT, its parts and ACCESSORIES (see IEC 60601-1-9); and		P
	– A statement indicating the LAY RESPONSIBLE ORGANIZATION must contact its local authorities to determine the proper method of disposal of potentially bio hazardous parts and ACCESSORIES, as applicable	No potentially bio hazardous parts.	N/A
7.4.10	Instructions for use includes the recommended placement of the remote parts of the DISTRIBUTED ALARM SYSTEM, when applicable, to ensure the OPERATOR can be notified at all times by an appropriate element of DISTRIBUTED ALARM SYSTEM within its specified range	No alarm system.	N/A
7.5	Technical description		N/A
7.5.1	The technical description for PERMANENTLY INSTALLED CLASS I ME EQUIPMENT includes:	Not PERMANENTLY INSTALLED CLASS I ME EQUIPMENT.	N/A
	– A warning indicating the ME EQUIPMENT installation, including a correct PROTECTIVE EARTH CONNECTION, must only be carried out by qualified SERVICE PERSONNEL		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Specifications of the PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR		N/A
	– A warning to verify the integrity of the external protective earthing system		N/A
	– A warning to connect and verify that the PROTECTIVE EARTH TERMINAL of the PERMANENTLY INSTALLED ME EQUIPMENT is connected to the external protective earthing system		N/A
7.5.2	Technical description includes methods for cleaning and disinfection or cleaning and sterilization for ME EQUIPMENT and ACCESSORIES requiring professional hygienic maintenance prior to reuse (see 7.4.7):	No parts requiring professional hygienic maintenance.	N/A
	– Before and after any type of service PROCEDURE		N/A
	– When the ME EQUIPMENT is transferred to another PATIENT		N/A
8	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		P
8.1	A LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT can perform the cleaning or cleaning and disinfection PROCESSES when intended (see 7.4.7)		P
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS		N/E
8.2	A LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT can perform the cleaning and sterilization PROCESSES when intended (see 7.4.7)	No sterilization process.	N/A
	USABILITY of each such PROCESS pertaining to a LAY OPERATOR was investigated by the USABILITY ENGINEERING PROCESS		N/A
8.3	Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		N/A
8.3.1	TRANSIT-OPERABLE, HANDHELD, and BODY-WORN ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529:1989 for IP22	IPX0. Stationary equipment.	N/A
	All other ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529:1989 for IP21	IPX0. Stationary equipment.	N/A
	For PORTABLE ME EQUIPMENT intended to be used only with a carrying case, this requirement was, optionally, met with the ME EQUIPMENT in its the carrying case		N/A
	PORTABLE ME EQUIPMENT with the carrying case was inspected, and the tests of IEC 60529:1989 applied		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Maintenance of BASIC SAFETY and ESSENTIAL PERFORMANCE VERIFIED		N/A
8.3.2	ENCLOSURES of the non-ME EQUIPMENT parts of the ME SYSTEMS provide the degree of protection against harmful ingress of water or particulate matter equivalent to equipment complying with their respective IEC or ISO safety standards	Not ME system.	N/A
	Tests of IEC 60529:1989 conducted with the equipment placed in the least favourable position of NORMAL USE and the ENCLOSURES inspected		N/A
8.4	Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT and ME SYSTEM		N/A
	A LIFE SUPPORTING ME EQUIPMENT or ME SYSTEM maintained its ESSENTIAL PERFORMANCE for a sufficient time or for a sufficient number of PROCEDURES when loss or failure of SUPPLY MAINS or INTERNAL ELECTRICAL POWER SOURCE occurred	Not LIFE SUPPORTING ME EQUIPMENT or ME SYSTEM.	N/A
	The time or number of PROCEDURES remaining allowed alternative life-supporting methods to be employed		N/A
	Optionally, an INTERNAL ELECTRICAL POWER SOURCE was used to maintain ESSENTIAL PERFORMANCE .....:		N/A
	Optionally, independent means were used to provide ESSENTIAL PERFORMANCE .....:		N/A
	Instructions for use disclose the time or number of procedures available following a loss or failure of the electrical power supply		N/A
	Instructions for use describes the alternative life-supporting methods to be employed		N/A
	The technical description describes methods that can be employed for longer periods		N/A
	LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM with no INTERNAL ELECTRICAL POWER SOURCE is equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY ALARM CONDITION indicating power failure ..:		N/A
	LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM with an INTERNAL ELECTRICAL POWER SOURCE is equipped with an automatic switchover to INTERNAL ELECTRICAL POWER SOURCE and an ALARM SYSTEM that includes at least a LOW PRIORITY ALARM CONDITION indicating switch-over to INTERNAL ELECTRICAL POWER SOURCE		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM with an INTERNAL ELECTRICAL POWER SOURCE is equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION indicating the INTERNAL ELECTRICAL POWER SOURCE is nearing insufficient remaining power for operation		N/A
	TECHNICAL ALARM CONDITION provides sufficient time or sufficient number of procedures for a LAY OPERATOR to act		N/A
	A TECHNICAL ALARM CONDITION of at least LOW PRIORITY remained active until the INTERNAL ELECTRICAL POWER SOURCE returned to a level above the ALARM LIMIT or until depleted		N/A
	It was not possible to inactivate the visual ALARM SIGNAL of this TECHNICAL ALARM CONDITION		N/A
	Functional tests conducted, and the RISK MANAGEMENT FILE inspected .....:	N/A	N/A
9	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		N/E
	The RISKS associated with USABILITY in the HOME HEALTHCARE ENVIRONMENT when performing the USABILITY ENGINEERING PROCESS include at least the following considerations:		N/E
	– changes of controls		N/E
	– unexpected movement		N/E
	– potential for misconnection		N/E
	– potential for improper operation, or unsafe use		N/E
	– potential for confusion as to current operational mode		N/E
	– change in the transfer of energy or substance		N/E
	– exposure to biological materials, and		N/E
	– small parts being inhaled or swallowed		N/E
	Particular emphasis is placed on the limited training of a LAY OPERATOR with respect to the ability to intervene and maintain BASIC SAFETY and ESSENTIAL PERFORMANCE		N/E
	USABILITY ENGINEERING FILE inspected		N/E
10	**CONSTRUCTION OF ME EQUIPMENT**		P
10.1	Additional requirements for mechanical strength		P

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
10.1.1	Table 28, Mechanical strength test applicability, replaced by Table 1, Mechanical strength test applicability, non-TRANSIT-OPERABLE, and Table 2, Mechanical strength test applicability, TRANSIT-OPERABLE		P
10.1.2	ME EQUIPMENT, its parts, and mounting ACCESSORIES, intended for non-TRANSIT-OPERABLE use displayed adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, dropping and rough handling (not applicable to FIXED and STATIONARY ME EQUIPMENT)	Stationary ME equipment. Exempt from shock and vibration test.	N/A
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after mechanical tests		N/A
	OPERATOR-re-settable protective devices that can be reset without the use of a TOOL were, optionally, reset prior to the evaluation of BASIC SAFETY and ESSENTIAL PERFORMANCE		N/A
	a) Shock tests conducted in accordance with IEC 60068-2-27:2008		N/A
	b) Broad-band random vibration tests conducted in accordance with IEC 60068-2-64:2008, using the following conditions:		N/A
10.1.3	ME EQUIPMENT, parts, and mounting ACCESSORIES for TRANSIT-OPERABLE use displayed adequate mechanical strength when subjected to pushing, impact, dropping, rough handling, and rigorous conditions of PATIENT movement in NORMAL USE as well as transportation by trolleys, carts, road vehicles, trains, ships, and aircraft		N/A
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after the following tests:		N/A
	a) Shock tests conducted on other than HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-27:2008		N/A
	1) Test type: Type 1		N/A
	2) Test type: Type 2		N/A
	b) Shock tests conducted on HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-27:2008		N/A
	1) Test type: Type 1		N/A
	2) Test type: Type 2		N/A
	c) Broad-band random vibration test conducted on ME EQUIPMENT, parts, and mounting ACCESSORIES in accordance with IEC 60068-2-64:2008		N/A

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	d) Free fall tests conducted on PORTABLE and MOBILE ME EQUIPMENT, parts, and mounting ACCESSORIES per IEC 60068-2-31:2008, using PROCEDURE 1		N/A
	BASIC SAFETY and ESSENTIAL PERFORMANCE were maintained		N/A
10.2	ME EQUIPMENT equipped with a means for the OPERATOR to determine the state of INTERNAL ELECTRICAL POWER SOURCE when it is essential to maintain BASIC SAFETY, ESSENTIAL PERFORMANCE, or control the RISKS associated with the loss of ESSENTIAL PERFORMANCE	Mains powered equipment.	N/A
	The state of the INTERNAL ELECTRICAL POWER SOURCE is, optionally, indicated as		N/A
	– a number of procedures remaining		N/A
	– the remaining operating time		N/A
	– the percentage of the remaining operating time or energy; or		N/A
	– a "fuel" gauge		N/A
	The state of the INTERNAL ELECTRICAL POWER SOURCE continuously indicated or by OPERATOR action		N/A
	The instructions for use describe how to determine the state of the INTERNAL ELECTRICAL POWER SOURCE		N/A
10.3	Controls of ME EQUIPMENT that can affect BASIC SAFETY or ESSENTIAL PERFORMANCE protected from accidental or unauthorized changes or adjustments	No such control.	N/A
	OPERATOR-adjustable controls used for calibration include a means to prevent unintentional changes from the intended position		N/A

11	**PROTECTION AGAINST STRANGULATION OR ASPHYXIATION**		N/A
	Means provided to control the RISK of strangulation and asphyxiation of the PATIENT and others to an acceptable level	No such risk.	N/A
	EQUIPMENT and the RISK MANAGEMENT FILE inspected		N/A

12	**ADDITIONAL REQUIREMENTS FOR ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		N/E
	IEC 60601-1-2:2007 applied, except as follows:		N/E
12.1	Emissions classification		N/E
	ME EQUIPMENT and ME SYSTEMS intended for HOME HEALTHCARE ENVIRONMENT are Class B according to CISPR 11:2009		N/E

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
12.2	Protection of the PUBLIC MAINS NETWORK		N/E
12.3	Additional technical description requirements applicable to ME EQUIPMENT and ME SYSTEMS		N/E
	The instructions for use include the following statements in place of IEC 60601-1-2:2007, Sub-clauses 5.2.2.1 and 5.2.2.2		N/E
	a) a statement indicating this equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS, and		N/E
	b) a statement indicating wireless communications equipment can affect ME EQUIPMENT and should be kept at least a distance d away from the equipment		N/E
	The distance d is calculated by the MANUFACTURER from the 800 MHz to 2,5 GHz column of Table 5 or Table 6 of IEC 60601-1-2:2007, as appropriate		N/E
12.4	Additional requirements applicable to ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location		N/E
	Sub-clause 5.2.2.3 of IEC 60601-1-2:2007 not applied		N/E
12.5	Additional requirements for ELECTROSTATIC DISCHARGE (ESD) tests		N/E
	For the purposes of the ESD testing in 6.2.2.2 of IEC 60601-1-2:2007, ACCESSIBLE PARTS determined by points accessible by the standard test finger specified in Figure 6 of Part 1		N/E
	In 6.2.2.2 c) of IEC 60601-1-2:2007, the second sentence not applicable		N/E

13	**ADDITIONAL REQUIREMENTS FOR ALARM SYSTEMS OF ME EQUIPMENT AND ME SYSTEMS**		N/A
	IEC 60601-1-8:2006 applied except as follows:	No alarm system.	N/A
13.1	Each HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITION causes generation of auditory ALARM SIGNALS per IEC 60601-1-8:2006, except when equipment is connected to a DISTRIBUTED ALARM SYSTEM including the generation of auditory ALARM SIGNALS per IEC 60601-1-8:2006		N/A
13.2	Reducing the auditory ALARM SIGNAL volume below audible levels resulted in the following:		N/A
	- The indication of ALARM OFF or AUDIO OFF activated as specified in IEC 60601-1-8:2006		N/A

IEC 60601-1-11			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- For LIFE SUPPORTING ME EQUIPMENT and ME SYSTEM this action was not possible, except when the ALARM SYSTEM was connected to a DISTRIBUTED ALARM SYSTEM that included generation of auditory ALARM SIGNALS per IEC 60601-1-8:2006		N/A

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

4.2.1	RM RESULTS TABLE: Permissible environmental conditions of transport and storage		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	Chapter 5 in Risk Management Report (Document No: RM-2012001)	Safety issue analysis recorded	P
4.3	Appendix A, and Appendix B in Risk Management Report (Document No: RM-2012001)	Hazard analysis recorded	P
4.4	Appendix A, and Appendix B in Risk Management Report (Document No: RM-2012001)	Risk estimation recorded	P

4.2.2	RM RESULTS TABLE: Permissible environmental conditions under normal use		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			

7.4.1	RM RESULTS TABLE: Additional requirements for warning and safety notices		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	Chapter 5 in Risk Management Report (Document No: RM-2012001)	Safety issue analysis recorded	P
4.3	Appendix A, and Appendix B in Risk Management Report (Document No: RM-2012001)	Hazard analysis recorded	P
4.4	Appendix A, and Appendix B in Risk Management Report (Document No: RM-2012001)	Risk estimation recorded	P
5	Appendix B in Risk Management Report (Document No: RM-2012001)	Risk evaluation recorded	P
6.2	Appendix B, and Appendix C in Risk Management Report (Document No: RM-2012001)	Risk control option analysis recorded	P

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

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

Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3	Appendix A, and Appendix B in Risk Management Report (Document No: RM-2012001)	Hazard analysis recorded	P
4.4	Appendix A, and Appendix B in Risk Management Report (Document No: RM-2012001)	Risk estimation recorded	P
5	Appendix B in Risk Management Report (Document No: RM-2012001)	Risk evaluation recorded	P
6.2	Appendix B, and Appendix C in Risk Management Report (Document No: RM-2012001)	Risk control option analysis recorded	P

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

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

10.1.2a	**TABLE: Shock test (IEC 60068-2-27:2008), using the following conditions*:**		**N/A**
	Peak acceleration ..... :	150 m/s2 (15 g)	
	Duration ..... :	11 ms	
	Pulse shape ..... :	half-sine	
	Number of shocks ..... :	3 shocks per direction per axis (18 total)	

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

Supplementary information:

*(NOTE 1 This represents Class 7M1 as described in IEC TR 60721-4-7:2001 [6])

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

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

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

Supplementary information:

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

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

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

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

Supplementary information:

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

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

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

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

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

10.1.3b1	**TABLE: Shock test (IEC 60068-2-27:2008) on HAND-HELD ME EQUIPMENT parts, and mounting ACCESSORIES using the following conditions (Test Type 1):**		**N/A**
	Peak acceleration ..... :	300 m/s^2 (30 g)	
	Duration ..... :	11 ms	
	Pulse shape ..... :	half-sine	
	Number of shocks ..... :	3 shocks per direction per axis (18 total)	

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

Supplementary information:

*(NOTE 4 This represents Class 7M3 as described in IEC/TR 60721-4-7:2001. (Test Type 1)

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

10.1.3b2	**TABLE: Shock test (IEC 60068-2-27:2008) on HAND-HELD ME EQUIPMENT parts, and mounting ACCESSORIES using the following conditions (Test Type 2):**		**N/A**
	Peak acceleration ..... :	1000 m/s^2 (100 g)	
	Duration ..... :	6 ms	
	Pulse shape ..... :	half-sine	
	Number of shocks ..... :	3 shocks per direction per axis (18 total)	

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

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

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

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

Supplementary information:

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

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

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

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

Supplementary information:

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

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