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Test Report		Project Nr. PRE-201/2014/020
Name and address of Applicant		Piston Ltd. H-1033, Budapest, Szőlőkert u. 4/B
Name and address of Test Laboratory		Piston Ltd. H-1033, Budapest, Szőlőkert u. 4/B
Quality Management System		ISO 9001 and ISO 13485 by SGS Hungaria Kft. Systems & services certification
Device under test:	Ergospirometer	Type: PRE-201 Serial Nr.: 201-EOD-204-PROTO
Name and address of Manufacturer		Piston Ltd. H-1033, Budapest, Szőlőkert u. 4/B
Standards applied		Medical electrical equipment Part 1: General requirements for basic safety and essential performance: EN 60601-1:2006
Duration		Start of test: 17th July 2014 End of test: 18th July 2014
Test result		**The requirements are met**
Tested by 18th July 2012 Tamas HANKÓ Date Name Signature		Checked by 18th July 2014 László CSATÁR Date Name Signature

This test report relates to a.m. test item. Without permission of the test centre this report is not permitted to be duplicated in extracts.

1. Measuring equipment

Item	Device	Manufacturer	Type	Serial Nr.	Next calibration
1	High Voltage Test	SGS Electronic	HA 3300A	99032901	May 2015
2	Safety Test Equipment	Piston Ltd.	KT-01	9905-001	Feb 2015
3	Digital multimeter	Gold Star	DM 441B	7010036	July 2017

2. Abbreviations used

A: After humidity conditioning

B: Before humidity conditioning

N/A: test case does not apply to the test object

3. Sample functional description

Electrical medical equipment. Ergospirometer. Power supply from mains supply 230 V AC – 110mA AC.

Stationary equipment. Continuous operation.

Type B. Class I.

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict
4	**General requirements**		
4.1	Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.)		P
5	**General requirements for testing ME EQUIPMENT**		
5.1	Tests described in this standard are type tests		P
6	**Classification of ME EQUIPMENT and ME SYSTEMS**		
6.1	General		-
6.2	Protection against electric shock		-
	- External electrical power source:		-
	o Class I equipment		P
	o Class II equipment		N/A
	o Internally powered equipment		N/A
	- Applied parts:		-
	o Type B		P
	o Type BF		N/A
	o Type CF		N/A
6.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 60529	No IP classification given	N/A
6.4	Methods of sterilization or desinfection	By other methods validated and described by the manufacturer	P
6.5	Equipment for use in an oxygen rich environment.		N/A
6.7	Mode of operation:		-
	- continuous operation	No marking is provided, me equipment is assumed to be suitable for continuous operation.	P
	- short-time operation, specified operation; period :		N/A
	- intermittent operation, specified operation; rest period:		N/A
	- continuous operation with short-time, stated permissible loading time:		N/A
	- continuous operation with intermittent, stated permissible loading/rest time:		N/A
7	**ME EQUIPMENT identification, marking and documents**		
7.1	Usability of the identification, marking and documents		-
7.2	Marking on the outside of equipment or equipment parts		-
	1) Minimum requirements for marking on me equipment and on interchangeable		P
	2) Identification		P
	- Name and/or trademark of the manufacturer or supplier:	Piston Ltd.	P
	- Model or type reference:	PRE-201	P

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict
	3) Consult accompanying documents		N/A
	4) Accessories		P
	5) Me equipment intended to receive power from other equipment		N/A
	6) Connection to the supply mains	Yes	P
	- Internally powered equipment		N/A
	- Rated supply voltages or voltage range(s)	100-240V	P
	- Number of phases	1	P
	- Type of current	AC	P
	- Rated frequency or rated frequency range(s) (Hz)	50-60 Hz	P
	- Class II symbol		N/A
	7) Electrical input power from the supply mains (VA, W or A)	VA	P
	8) Output connectors		N/A
	- Mains power output		N/A
	- Other power sources		N/A
	9) IP classification		N/A
	10) Applied Parts		
	- Symbol 19, 20 and 21 from Table D.1 for applied parts classification	Type B applied parts Symbol 19	P
	- Symbol 25,26,27 from Table D.1 for defibrillation-proof with protection partly in patient cable		N/A
	- If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets		N/A
	11) Mode of operation (if no marking, suitable for continuous operation)	Suitable for continuous operation	P
	12) Types and rating of external accessible fuses:	2 x 0.63A T	P
	13) Physiological effects (safety signs and warning statements)		N/A
	- attention, consult accompanying documents		P
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N/A
	14) High voltage terminal devices		N/A
	15) Cooling conditions		N/A
	16) Mechanical stability		P
	17) Protective packaging		N/A
	- Marking(s) for unpacking safety hazard(s)		P
	- Equipment or accessories supplied sterile, marked as sterile		N/A
	18) External pressure source	0.5-1 BAR Cal. gas	P
	19) Functional earth terminals		N/A
	20) Removable protective means		N/A
7.3	Marking on the inside of equipment or equipment parts		-
	1) Heating elements or lampholders: Maximum power loading for heating elements or holders for heating lamps		N/A
	2) Dangerous voltage symbol	Near mains connector	P

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict
	3) Batteries		-
	- Type of battery and mode of insertion		N/A
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator		N/A
	4) Fuses accessible with a tool identified either by type and rating or by a reference to diagram		N/A
	5) Protective earth terminal		P
	6) Functional earth terminal		P
	7) Supply neutral conductor in permanently installed equipment (N)		P
	8) Statement for suitable wiring materials at temperatures over 75 °C		P
	Nominal voltage of permanently installed equipment		N/A
	Markings remain visible after connection and are not affixed to parts which have to be removed		P
	For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)		N/A
	Markings comply with IEC 60445		N/A
7.4	Marking of controls and instruments		-
	1) Mains switch clearly identified		P
	- ON and OFF positions marked according to Symbols 12, 13, 14 and 15 of table D1 or indicated by an adjacent indicator light		P
	2) Control devices		N/A
	- Indication of different positions of control devices and switches		N/A
	- Indication of the direction in which the magnitude of the function changes, or an indicating device		N/A
	- The functions of operator controls and indicators are identified		N/A
	3) Numeric indications of parameters are in SI units except for units listed in Table 1		P
7.5	Safety signs selected from ISO7010		P
7.6	Symbols		-
	Used symbols comply with Appendix D or IEC and/or or ISO publications (if applicable)		P
7.7	Colors of the insulation of conductors		-
	1) Protective earth conductor has green/yellow insulation		P
	2) All insulations of internal protective earth conductors are green/yellow at least at their terminations		P
	- Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N/A
	3) Only protective or functional earthing, or potential equalization conductors are green/yellow		P
	4) Color of neutral conductor:	Blue	P
	5) Colors of phase conductor(s), compliance with IEC 60227-1 and IEC 60245-1	Braun	P

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict
7.8	Indicator lights and push-buttons		-
	- Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action		P
	- Yellow used to indicate caution or attention required		N/A
	- Color red used only for push-buttons by which a function is interrupted in case of emergency		N/A
7.9	Accompanying documents		
7.9.1	General		P
	- Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Document available	P
	- Classifications specified in Clause 6 included in both the instructions for use and the technical description		P
	- Warning statements and the explanation of warning symbols provided in the accompanying documents		P
7.9.2	Instructions for use		
	1) General information provided in instructions for use		P
	2) Warning and safety notices		P
	3) Me equipment specified for connection to a separate power supply		N/A
	4) Electrical power source		P
	5) Me equipment description		P
	6) Installation		P
	7) Isolation from the supply mains		P
	8) Start-up procedure		P
	9) Operating instructions		P
	10) Messages		P
	11) Shutdown procedure		N/A
	12) Cleaning, disinfection and sterilization		P
	13) Maintenance		P
	14) Accessories, supplementary equipment, used material		P
	15) Environmental protection		P
	16) Reference to the technical description		P
7.9.3	Technical description		
	1) General		P
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use		P
	- Environmental conditions for transport and storage specified in accompanying documents and marked on packaging		P
	2) Replacement of fuses, power supply cords and other parts		P
	3) Circuit diagrams, component part lists, etc.		P
	4) Mains isolation		P

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict
8	**Protection against electrical HAZARDS from ME EQUIPMENT**		
8.1	Fundamental rule of protection against electrical hazards		P
8.2	Requirements related to power sources		P
8.3	Classification of applied parts	Type B applied part	P
8.4	Limitation of voltage and/or energy		N/A
	Voltage measured one sec after disconnection of the mains plug does not exceed 60V		P
	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ		P
	Marking provided for manual discharging		N/A
8.5	Separation		P
	Separation method of the applied part from live parts:		P
	1) basic insulation: applied part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		P
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N/A
	4) by double or reinforced insulation		N/A
	5) by protective impedances limiting current to applied part		N/A
	Additional leakage current test in single fault conditions	(See Table 8.7.4.5 to Table 8.7.4.8)	P
	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		P
	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		N/A
	Separation method of accessible parts other than applied parts from live parts:		P
	1) basic insulation: accessible part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		P
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N/A
	4) by double or reinforced insulation		N/A
	5) by protective impedances limiting current to accessible part		N/A
	Additional leakage current test in single fault conditions	(See Table 8.7.4.5 to Table 8.7.4.8)	P
	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N/A
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator		N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		N/A
8.6	Protective earthing, functional earthing and potential equalization		
	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal		P
	Protective earth terminals suitable for connection to the protective earth conductor		P

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict
	Potential equalization conductor		N/A
	- Readily accessible		N/A
	- Accidental disconnection prevented in normal use		N/A
	- Conductor detachable without the use of a tool		N/A
	- Power supply cord does not incorporate a potential equalization conductor		N/A
	- Connection means marked with Symbol 8, Table D.1		N/A
	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part ≤ 0.1 Ω	(See Table 8.6.4)	P
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part ≤ 0.1 Ω		N/A
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part ≤ 0.2 Ω		N/A
	If the impedance of protective earth connections other than in 8.6.4 a) exceeds 0.1 Ω, the allowable value of the touch current and the patient leakage current in single fault condition are not exceeded		N/A
	Functional earth terminal not used to provide protective earthing		N/A
	Class II equipment with isolated internal screens		N/A
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		N/A
	- functional earth terminal clearly marked		N/A
	- explanation of functional earth terminal provided in the accompanying documents		N/A
8.7	Leakage currents and patient auxiliary currents		-
	Leakage currents		P
	- earth leakage current	(see Table 8.7.4.5)	P
	- touch current	(see Table 8.7.4.6)	P
	- patient leakage current	(see Table 8.7.4.7)	P
	- patient auxiliary current	(see Table 8.7.4.8)	P
8.8	Insulation		-
	General		P
	Distance through insulation		P
	Dielectric strength	(see Table 8.8)	P
8.9	Creepage distances and air clearances		-
	Values: compliance with at least the values of Table 11 to Table 16 in the standard		P
	Creepage distances for slot insulation of motors at least 50% of the specified values		N/A
	Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuting does not produce a safety hazard		N/A
	Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts		N/A
8.10	Components and wiring assembly		-

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict
	List of critical components	(see Table 8.10)	P
	1. Fixing of components		P
	2. Fixing of wiring		P
	3. Connections between different parts of me equipment		P
	4. Cord-connected hand-held parts and cord-connected foot-operated control devices		P
	5. Mechanical protection of wiring		P
	6. Guiding rollers for insulated conductors		N/A
	7. Insulation of internal wiring		P
8.11	Mains parts, components and layout		-
	1. Isolation from the supply mains		P
	2. Multiple socket-outlets		N/A
	3. Power supply cords		
	- Application		P
	- Types		P
	- Cross-sectional area of power supply cord conductors		P
	- Appliance couplers		N/A
	- Cord anchorage		N/A
	- Cord guards		P
	4. Mains terminal devices		
	- General requirements for mains terminal devices		P
	- Arrangement of mains terminal devices		P
	- Fixing of mains terminals		P
	- Connections to mains terminals		P
	- Accessibility of the connection		P
	5. Mains fuses and over-current releases		P
	6. Internal wiring of the mains part		P
9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**		
9.1	Mechanical hazards		P
9.2	Moving parts		P
	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment		N/A
	Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation		N/A
	Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices		N/A
	Guides or safeguards are removable only with a tool		P
	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator		N/A
	Parts of equipment subject to mechanical wear are accessible for inspection		N/A
	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard		N/A

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict
	Means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard		N/A
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents		N/A
	Means for stopping of movements operate as a result of one single action		N/A
9.3	Surfaces, corners and edges		P
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered		P
9.4	Instability in normal use		-
	Equipment does not overbalance during normal use when tilted through an angle of 10º		P
	Equipment overbalances when tilted through an angle of 10º		N/A
	- does not overbalance when tilted through an angle of 5º in any position excluding transport		N/A
	- carry a warning notice stating that transport should only be undertaken in a certain position		N/A
	- in the position specified for transport does not overbalance when tilted to an angle of 10º		N/A
	Equipment or its parts with a mass of more than 20 kg is provided with:		N/A
	- suitable handling devices (grips etc.), or		N/A
	- instructions for lifting and handling during assembly		N/A
	b) On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons		N/A
9.5	Expelled parts		N/A
	Protective means are provided where expelled parts of the equipment could be a hazard		N/A
	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		N/A
9.6	Acoustic energy		P
9.7	Pressure vessels and parts subject to pressure		
	Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure	No pressure vessels to the equipment under test	N/A
	Maximum pressure does not exceed the maximum permissible working pressure for individual parts		N/A
	Unless excessive pressure cannot occur, pressure-relief device provided		N/A
	Pressure-relief device connected as close as possible to the pressure vessel		N/A
	Readily accessible for inspection		N/A
	Not capable of being adjusted or rendered inoperative without a tool		N/A
	Discharge opening located that the released material is not directed towards person		N/A
	Discharge opening located that operation will not deposit material which may cause a safety hazard		N/A
	Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure		N/A
	No shut-off valve between a pressure-relief device and the parts intended to be protected		N/A

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict
	Minimum number of cycles of operation: 100.000		N/A
9.8	Hazards associated with support systems		N/A
10	**Protection against unwanted and excessive radiation HAZARDS**		
10.1	X-Radiation		N/A
	Equipment not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5 mR)		N/A
10.2	Alpha, beta, gamma, neutron or other radiation		N/A
10.3	Microwave radiation		N/A
10.4	Laser and LED's		N/A
10.5	Other visible electromagnetic radiation		N/A
10.6	Infrared radiation		N/A
10.7	Ultraviolet radiation		N/A
11	**Protection against excessive temperatures and other HAZARDS**		
11.1	Equipment does not attain temperatures exceeding the values given in Table 22 over the range of ambient temperatures		P
	Equipment does not attain temperatures exceeding the values given in Table 23 and Table 24		P
	Applied parts not intended to supply heat have surface temperatures not exceeding 41ºC		P
	Guards to prevent contact with hot surfaces removable only with a tool		N/A
11.2	Fire prevention		P
	Strength and rigidity necessary to avoid a fire hazard		P
	Me equipment and me systems used in conjunction with oxygen rich environments		N/A
11.3	Constructional requirements for fire enclosures		N/A
11.4	Use with flammable anesthetics		N/A
11.5	Use with flammable agents		N/A
11.6	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection		N/A
	Equipment contain a liquid reservoir:	Only max. 5 ml	N/A
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min		N/A
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15º in the least favorable direction(s) (if necessary with refilling)		N/A
	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)		N/A
	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		N/A
	Equipment sufficiently protected against the effects of humidity		P
	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529		N/A
	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions		P
11.7	Biocompatibility		P
	Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1		P
11.8	Interruption of the power supply		P

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict
	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard		N/A
	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function		N/A
	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure		P
12	**Accuracy of controls and instruments and protection against hazardous outputs**		
12.1	Accuracy of controls and instruments		P
12.2	Usability		P
12.3	Alarm systems		P
12.4	Protection against hazardous output		N/A
	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally		N/A
13	**HAZARDOUS SITUATIONS and fault conditions**		
	Equipment is so designed and manufactured that even in single fault condition no safety hazards exist.		P
	The safety of equipment incorporating programmable electronic systems is checked.		N/A
	Failure of thermostats presents no safety hazards		N/A
	Short-circuiting of either part of double insulation presents no safety hazard		P
	Impairment of cooling: temperatures not exceeding 1.7 times the values of minus 17.5ºC		N/A
	Locking of moving parts presents no safety hazard		N/A
	Interruption and short-circuiting of motor capacitors presents no safety hazard		N/A
	Duration of motors locked rotor test		N/A
	Failure of one component at a time presents no safety hazard		P
	Overload of heating elements presents no safety hazard		N/A
	Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection		N/A
	Equipment with three-phase motors can safely operate with one phase disconnected		N/A
14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		
14.1	General		P
14.2	Documentation		P
14.3	Risk management plan		P
14.4	PEMS development life-cycle		P
14.5	Problem resolution		P
14.6	Risk management process		P
	- Identification of known and foreseeable hazards		P
	- Risk control		P
14.7	Requirement specification		P
14.8	Architecture		P
14.9	Design and implementation		P
14.10	Verification		P
14.11	PEMS validation		P
14.12	Modification		P
14.13	Connection of PEMS		P

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict

15	**Construction of ME EQUIPMENT**		
15.1	Arrangements of controls and indicators		P
15.2	Serviceability		P
15.3	Mechanical strength		P
	Sufficient rigidity of an enclosure tested by: force of 45 N		P
	Sufficient strength of an enclosure tested by: impact hammer		P
	On portable equipment carrying handles or grips withstand the requirements of the loading test		N/A
	No damage to parts of patient support and/or immobilization system after the loading test		N/A
	Hand held equipment or portable equipment parts are safe after drop test		P
	Mobile equipment is able to withstand rough handling		N/A
15.4	Me equipment components and general assembly		P
	Plugs for connection of patient leads are not interchangeable		P
	Temperature and overload control devices		N/A
	Temperature settings		N/A
	Batteries		N/A
	- Housing		N/A
	- Connection		N/A
	- Protection against overcharging		N/A
	- Lithium batteries		N/A
	- Current and voltage protection		N/A
	Indicators		P
	Pre-set controls		N/A
	Actuating parts of controls of me equipment		N/A
	Cord-connected hand-held and foot-operated control devices		N/A
	Internal wiring of me equipment		P
	- Cables and wiring protected against contact with a moving part		N/A
	- Wiring having basic insulation only protected by additional fixed sleeving		P
	- Components are not likely to be damaged in the normal assembly or replacement of covers		P
	- Movable leads are not bent around a radius of less than five times the outer diameter of the lead		P
	- Insulating sleeving adequately secured		P
	- Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material		P
	- Aluminum wires of less than 16 mm2 cross-section not used		P
	Oil containers		N/A
15.5	Mains supply transformers		N/A

16	**ME SYSTEMS**		
16.1	General requirements for the ME systems		P
16.2	Accompanying documents of an ME system		P
16.3	Power supply		N/A
16.4	Enclosures		P
16.5	Separation devices		N/A

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict
16.6	Leakage currents		P
	- Touch current		P
	- Earth leakage current of multiple socket-outlet		P
	- Patient leakage current		P
	- Measurements		P
	o General conditions for ME systems		P
	o Connection of the ME system to the measuring supply circuit		P
16.7	Protection against mechanical hazards		N/A
16.8	Interruption of the power supply to parts of an ME system		P
16.9	ME system connections and wiring		P
	- Connection terminals and connectors		P
	- Mains parts, components and layout		P
	o Multiple socket-outlet		N/A
	o Protective earth connections in ME systems		N/A
	o Protection of conductors		P
17	**Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS**		
	Equipment complies with IEC 60601-1-2	(see EMC test report)	P

Tables:

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict

8.6.4	**TABLE: protective earthing**				**Pass**
Test location		Test current [A]	Measured voltage [V]	Resistance [Ω]	Remarks
To earthing center point		25	0,256	0,01024	Allowed: 100 mΩ
To touchable conductive part		25	0,540	0,0246	Allowed: 100 mΩ
Supplementary information:					

8.7.4.2	**TABLE: power input (Figure F.1)**				**Pass**
Test condition	Supply Voltage [V]	Supply frequency [Hz]	Measured max. value [mA]	Power [W]	Remarks
S1: Close; **S5**: Pos1	230V	50	14,612	3,38	Measure mode
S1: Open; **S5**: Pos1	230V	50	<2	<0,5	
S1: Close; **S5**: Pos2	230V	50	14,748	3,41	Measure mode
S1: Open; **S5**: Pos2	230V	50	<2	<0,5	
S1: Close; **S5**: Pos1	230V	50	12,221	2,82	Standby mode
S1: Open; **S5**: Pos1	230V	50	<2	<0,5	
S1: Close; **S5**: Pos2	230V	50	12,345	2,85	Standby mode
S1: Open; **S5**: Pos2	230V	50	<2	<0,5	
Supplementary information:					

8.7.4.5	**TABLE: earth leakage current (Figure 13)**			**Pass**
Test condition	Supply Voltage [V]	Supply frequency [Hz]	Measured max. value [µA]	Remarks
S1: Close; **S5**: Pos1; **S10**: Close; **B**	252V	50	<20	Allowed: 5000 µA
S1: Close; **S5**: Pos1; **S10**: Open; **B**	252V	50	26	Allowed: 5000 µA
S1: Close; **S5**: Pos2; **S10**: Close; **B**	252V	50	<20	Allowed: 5000 µA
S1: Close; **S5**: Pos2; **S10**: Open; **B**	252V	50	27	Allowed: 5000 µA
S1: Open; **S5**: Pos1; **S10**: Close; **B**	252V	50	<20	Allowed: 10000 µA
S1: Open; **S5**: Pos1; **S10**: Open; **B**	252V	50	51	Allowed: 10000 µA
S1: Open; **S5**: Pos2; **S10**: Close; **B**	252V	50	<20	Allowed: 10000 µA
S1: Open; **S5**: Pos2; **S10**: Open; **B**	252V	50	51	Allowed: 10000 µA
S1: Close; **S5**: Pos1; **S10**: Close; **A**	252V	50	<20	Allowed: 5000 µA
S1: Close; **S5**: Pos1; **S10**: Open; **A**	252V	50	28	Allowed: 5000 µA
S1: Close; **S5**: Pos2; **S10**: Close; **A**	252V	50	<20	Allowed: 5000 µA
S1: Close; **S5**: Pos2; **S10**: Open; **A**	252V	50	28	Allowed: 5000 µA
S1: Open; **S5**: Pos1; **S10**: Close; **A**	252V	50	<20	Allowed: 10000 µA
S1: Open; **S5**: Pos1; **S10**: Open; **A**	252V	50	52	Allowed: 10000 µA
S1: Open; **S5**: Pos2; **S10**: Close; **A**	252V	50	<20	Allowed: 10000 µA
S1: Open; **S5**: Pos2; **S10**: Open; **A**	252V	50	52	Allowed: 10000 µA
Supplementary information:				

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict

8.7.4.6	**TABLE: touch current (Figure 14)**			**Pass**
Test condition	Supply Voltage [V]	Supply frequency [Hz]	Measured max. value [µA]	Remarks
S1: Close; **S5**: Pos1; **S10**: Close; **B**	255V	50	<20	Allowed: 100 µA
S1: Close; **S5**: Pos1; **S10**: Open; **B**	255V	50	25	Allowed: 100 µA
S1: Close; **S5**: Pos2; **S10**: Close; **B**	255V	50	<20	Allowed: 100 µA
S1: Close; **S5**: Pos2; **S10**: Open; **B**	255V	50	25	Allowed: 100 µA
S1: Open; **S5**: Pos1; **S10**: Close; **B**	255V	50	<20	Allowed: 500 µA
S1: Open; **S5**: Pos1; **S10**: Open; **B**	255V	50	50	Allowed: 500 µA
S1: Open; **S5**: Pos2; **S10**: Close; **B**	255V	50	<20	Allowed: 500 µA
S1: Open; **S5**: Pos2; **S10**: Open; **B**	255V	50	50	Allowed: 500 µA
S1: Close; **S5**: Pos1; **S10**: Close; **A**	255V	50	<20	Allowed: 100 µA
S1: Close; **S5**: Pos1; **S10**: Open; **A**	255V	50	26	Allowed: 100 µA
S1: Close; **S5**: Pos2; **S10**: Close; **A**	255V	50	<20	Allowed: 100 µA
S1: Close; **S5**: Pos2; **S10**: Open; **A**	255V	50	26	Allowed: 100 µA
S1: Open; **S5**: Pos1; **S10**: Close; **A**	255V	50	<20	Allowed: 500 µA
S1: Open; **S5**: Pos1; **S10**: Open; **A**	255V	50	52	Allowed: 500 µA
S1: Open; **S5**: Pos2; **S10**: Close; **A**	255V	50	<20	Allowed: 500 µA
S1: Open; **S5**: Pos2; **S10**: Open; **A**	255V	50	52	Allowed: 500 µA
Supplementary information:: S9, S12 are not applicable				

8.7.4.7	**TABLE: patient leakage current (Figure 17)**			**Pass**
Test condition	Supply Voltage [V]	Supply frequency [Hz]	Measured max. value [µA]	Remarks
S9: Pos1; A	255V	50	<20	Allowed: 100 µA
S9: Pos2; A	255V	50	<20	Allowed: 100 µA
S9: Pos1; B	255V	50	<20	Allowed: 100 µA
S9: Pos2; B	255V	50	<20	Allowed: 100 µA
Supplementary information: S1, S10, S7, S5, S13 not applicable for this device, metal foil is the patient connection				

8.7.4.8	**TABLE: patient auxiliary current (Figure 19)**			**N/A**
Test condition	Supply Voltage [V]	Supply frequency [Hz]	Measured max. value [µA]	Remarks
Supplementary information: device do not use auxiliary current				

EN 60601-1:2006			
Clause	Requirement + Test	Result - Remark	Verdict

8.8.3	TABLE: dielectric strength			Pass
Insulation under test; Insulation type		Reference voltage [V]	Test voltage [V]	Remarks
Signal input/output – metal foil		230	1500	No breakdown
Signal input/output – metal foil		230	3000	No breakdown
Supplementary information:				

8.10.	TABLE: list of critical component parts				Pass
Object/part No	Manufacturer	Type	Technical data	Standard(s)	Mark(s) of conformity
NFM-20-5	Meanwell	NFM-20-5	On DoC	On DoC	On DoC
Supplementary information:					