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TEST REPORT

EN 60601-1:2006
Medical electrical equipment. Part 1: General requirements for safety

LIETUVOS NACIONALINIS AKREDITACIJOS BIURAS
TESTING
ISO/IEC 17025 LA.01.007

Report Reference No:	**07-14B**
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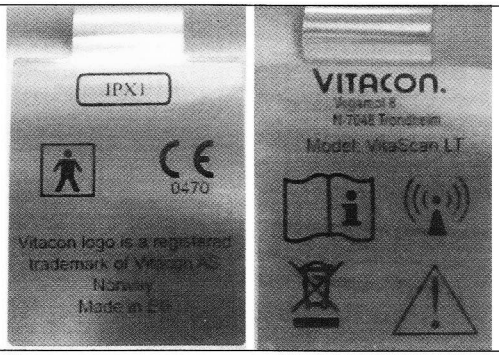
Testing location:	Savanoriu av. 271-253, LT-50131 Kaunas, Lithuania
Test methods:	LST EN 60601-1:2007 EN 60601-1:2006 IEC 60601-1:2005
Methods deviation:	Not applicable
Non-standard test methods:	Not applicable
Applicant:	Vitacon, AS
Address:	Vegamot 8B, N-7048 Trondheim, Norway
Name of test object:	**ULTRASOUND BLADDER MONITOR**
Trademark:	VITACON.
Type/model:	**Vitascan LT**
Serial No:	40439
Manufacturer:	Vitacon, AS
Made in:	Norway
Rating:	USB (5 Vdc), output: 2,35 MHz, 0,25 mW/cm^2
Copy of marking plate:	

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2. The test results relate only to the object tested.

SERTIKA

TEST REPORT No 07-14B

Description of test object function:	VitaScan LT is a B-mode ultrasonic instrument intended for non-invasive measurement of urinary bladder volume.

Classification

Safety classification:	III (USB power supply)
Type of applied part:	BF
Operation conditions:	Intermittent operation
Connection to mains supply:	Non-detachable power supply cord
Installation and use classification:	Hand-held
Degree of protection according IEC 529:	IPX1

Date of receipt of test item:	May 21, 2014
Initiation of the tests:	May 22, 2014
Conclusion of the tests:	May 30, 2014

Tests environmental conditions:

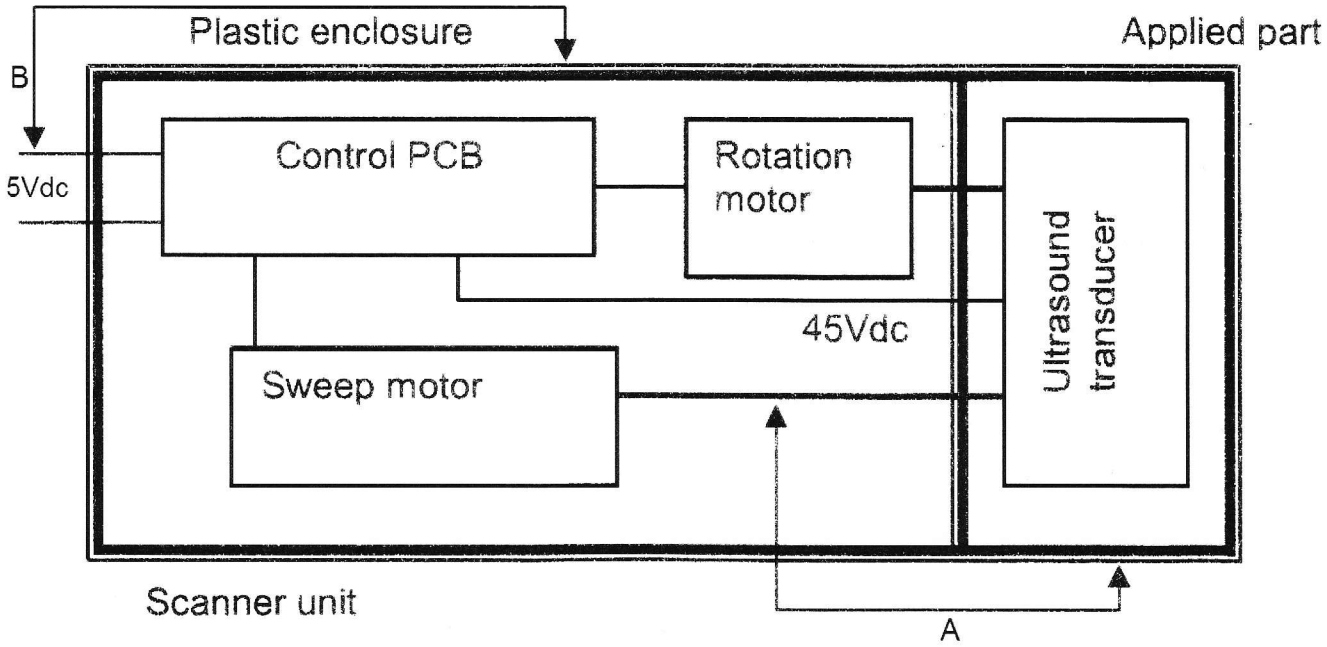
environmental temperature	+24°C ÷ +26°C;
a relative humidity	43 % ÷ 62 %;
an air pressure	1004 hPa ÷ 1017 hPa.

Possible test case verdicts:

P - The equipment complies with the requirement;
F - The equipment does not meet the requirement;
N.A. - The test does not apply to the equipment;
-- - There is no information, the parameter is not tested.

ANNEX 1: Photos of the test object

INSULATION DIAGRAM



Area	Insulation	Working voltage	Required creepage, mm	Measured creepage, mm	Required clearance, mm	Measured clearance, mm	Remarks
A	Reinforced	45Vdc	4,6	24,0	2,4	24,0	Power supply – applied part
B	Reinforced	5Vdc	2,0	2,6	2,0	5,0	Power supply - enclosure

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing.

SERTIKA

TEST REPORT No 07-14B

THE RESULTS OF THE TESTS AND EXAMINATIONS			
Clauses	**Requirements and parameters to be verified**	**The results of the tests and verifications**	**Ver-dict**
1	2	3	4
4	**GENERAL REQUIREMENTS**		
4.2	Risk management process for ME equipment or ME systems		
	A risk management process complying with ISO 14971 shall be performed.	VitaScan LT risk management file VIT199-002	P
	Manufacturer has:		
	Established a risk management process;		P
	Established acceptable levels of risk; and		P
	Demonstrated that the residual risk(s) is acceptable.		P
4.3	The manufacturer shall identify which functions of the ME equipment are essential performance.		P
4.4	The manufacturer shall state the expected service life of the ME equipment in the risk management file.	10 years	P
4.5	The manufacturer can justify that the residual risks that result from applying the alternative means are equal to or less than the residual risks that result from applying the requirements of this standard.		P
4.6	The risk management process shall include an assessment of whether parts that can come into contact with the patient but fall outside of the definition of applied parts shall be subject to the requirements for applied parts.	No such parts	N.A.
4.7	Single fault condition for ME equipment		
	ME equipment is considered single fault safe if:		
	a) it employs a single means for reducing a risk that has a negligible probability of failure, or		P
	b) a single fault condition occurs, but:		
	The initial fault will be detected during expected service life of the ME equipment and before a second means for reducing a risk fails; or		N.A.
	The probability that the second means of reducing the risk will fail during the expected service life is negligible.		N.A.
4.8	Components of ME equipment		
	Components shall comply with one of the following:		
	a) the applicable safety requirements of a relevant IEC or ISO standard;	(See attached Table 1)	P
	b) where there is no relevant IEC or ISO standard, the requirements of this standard have to be applied.	(See attached Table 1)	P
4.9	Use of components with high-integrity characteristics in ME equipment	Not used	N.A.
4.10.1	Source of power supply for ME equipment		
	ME equipment shall be suitable for connection to a supply mains, be specified for connection to a separate power supply or be powered by an internal electrical power source.	Powered via USB port	P
4.10.2	Supply mains for ME equipment		

	For ME equipment intended to be connected to supply mains, the following rated voltages shall not be exceeded:		
	250 V for hand-held equipment	5 Vdc	P
	250 V. d.c. or single-phase a.c. or 500 V polyphase a.c. for ME equipment and ME systems with a rated input <4 kVA; or		N.A.
	500 V for all other ME equipment		N.A.
4.11	Power input		
	The steady-state measured input of the ME equipment at rated voltage and at operating settings indicated in the instructions for use shall not exceed the marked rating by more than 10%	Connected to USB port which is limited to 500 mA	N.A.
5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		
5.9.2	Accessible parts		
5.9.2.1	Test finger		N.A.
5.9.2.2	Test hook		N.A.
7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		
7.1.1	Usability of the identification, marking and documents		
	The manufacturer shall address in a usability engineering process the risk of poor usability associated with the design of the ME equipment's identification, marking and documents.	Pass	P
7.1.2	The markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 shall be clearly legible.	Markings are clearly legible	P
7.1.3	The markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 shall be removable only with a tool or by appreciable force and shall be sufficiently durable to remain clearly visible during the expected service life.	The marking are durable	P
	Adhesive labels are not to have worked loose or become curled at the edges.	Pass	P
7.2	Marking on the outside of ME equipment		
7.2.1	If the size of ME equipment, part or accessory or the nature of its enclosure, does not allow affixation of all markings specified in 7.2.2 to 7.2.20, then at least the markings as indicated in 7.2.2, 7.2.5, 7.2.6, 7.2.10 and 7.2.13 shall be affixed and the remaining markings shall be recorded in full in accompanying documents.		N.A.
7.2.2	Identification		
	Me equipment and its detachable components shall be marked:		
	Name or trademark of manufacturer	Vitacon	P
	Model or type	Vitascan LT	P
	Software revision level or date of release	Software revision level is displayed on the Vitascan LT software	P
7.2.3	When appropriate, symbol ISO 7000-1641 (Table D.1, symbol 11) may be used to advise the operator to consult the accompanying documents	The symbol is present	P
	When consulting is a mandatory action, safety sign IEC 60878 Safety 01 (Table D.2, safety sign 10) shall be used.		N.A.
7.2.4	Accessories shall be marked with the name or trade-mark of their manufacturer and with a model reference.	No additional accessories	N.A.

7.2.5	ME equipment intended to receive power from other equipment		
	The model or type reference of the specified other equipment shall be marked adjacent to the relevant connection point.		N.A.
7.2.6	Me equipment shall be marked with the following information:		
	The rated supply voltages	Not required	N.A.
	Nature of supply and type of current	Not required	N.A.
	The rated supply frequency or rated frequency range in hertz	Not required	N.A.
	For class II ME equipment symbol ⧈	Not required	N.A.
7.2.7	Electrical input power from the supply mains		
	The rated input shall be given in amperes or volt-amperes or where the power factor exceeds 0.9, in watts	Not required	N.A.
7.2.8	Output connectors		
7.2.8.2	Output connectors intended to deliver power shall be marked with the following information:		N.A.
	Rated output voltage		N.A.
	Rated current or power (where applicable)		N.A.
	Output frequency (where applicable)		N.A.
7.2.9	IP classification	IPX1	P
7.2.10	The degree of protection against electric shock for all applied parts shall be marked with the relevant symbol.	Marked with BF symbol	P
	For defibrillation-proof applied parts, symbols (Table D.1, 25, 26, 27) shall be used	No defibrillation-proof applied parts	N.A.
	The relevant symbol shall be marked adjacent to or on the connector for the applied part.		N.A.
7.2.11	For ME equipment intended for non-continuous operation, the duty cycle shall be indicated.	Intermittent operation is factory default setting	N.A.
7.2.12	Where the fuse-holder is an accessible part, the type and full rating of the fuse shall be marked adjacent to the fuse-holder.	No accessible fuse holders	N.A.
7.2.13	Physiological effects	Marked with appropriate symbol – ultrasound energy	P
7.2.14	High voltage ⚠		N.A.
7.2.15	Cooling conditions		N.A.
7.2.16	Mechanical stability		N.A.
7.2.17	If special handling measures have to be taken during transport or storage, the packaging shall be marked accordingly (ISO 780).	The packaging is marked according to ISO 780	P
	The permissible environmental conditions for transport and storage shall be marked on the outside of the packaging (ISO 15223).		P
	Where premature unpacking of ME equipment or its parts could result in an unacceptable risk, the packaging shall be marked with a suitable safety sign.		N.A.
7.2.18	External pressure source		
	The rated maximum supply pressure from an external source shall be marked on the ME equipment adjacent to each input connector.		N.A.
7.2.19	A functional earth terminal shall be marked ⏚		N.A.

7.2.20	The removable protective means shall be marked to indicate the necessity for replacement when the relevant function is no longer needed.		N.A.
7.3	Marking on the inside of ME equipment or ME equipment parts		
7.3.1	The maximum power loading of heating elements or lampholders designed for use with heating lamps shall be marked near the heater or in the heater itself.		N.A.
7.3.2	High voltage parts marked with symbol  or 		N.A.
7.3.3	Batteries		
	The type of battery and mode of insertion	No batteries	N.A.
	For batteries intended to be changed only by service personnel with the use of a tool, an identifying marking referring to information stated in the accompanying documents is sufficient state the function and intended application of the equipment;		N.A.
7.3.4	Fuses and replaceable thermal cut-outs and over current releases that are accessible only by the use of a tool shall be identified either by type and full rating adjacent to the component, or by a reference information in the accompanying documents.	No fuses	N.A.
7.3.5	Protective earth terminals 		N.A.
7.3.6	Functional earth terminals 		N.A.
7.3.7	Supply terminals		
	Terminals shall be marked adjacent to the terminals unless it can be demonstrated that no hazardous situation can result if connections are interchanged.		N.A.
	If ME equipment is so small that the terminal markings cannot be affixed, they shall be included in the accompanying documents.		N.A.
	Terminals that are provided exclusively for the connection of the neutral supply conductor in permanently installed ME equipment shall be marked with **N.**		N.A.
	If marking for connection to a three-phase supply is necessary, it shall be according to IEC 60445.		N.A.
	Markings that are on or adjacent to electrical connection points shall not be affixed to parts that have to be removed to make connection.		N.A.
7.3.8	Temperature of supply terminals		
	If any point within a terminal box or wiring compartmer intended for connection of the power supply conductor for permanently installed ME equipment, attains temperature of more than 75°C during normal use, the ME equipment shall be marked with the following statement: "For supply connections, use wiring materials suitable for at least X °C.		N.A
7.4	Marking of controls and instruments		
7.4.1	Switches used to control power, including mains switches, shall have their "on" and "off" positions:		
	Marked with symbols and		N.A.
	indicated by an adjacent light indicator;		N.A.
	Indicated by other unambiguous means.		N.A.

SERTIKA

TEST REPORT No 07-14B

	If a push button with bistable positions is used:		
	It shall be marked with symbol . ⏻ .	The symbol is present	P
	The status shall be indicated by an adjacent light indicator; or	No light indicator	N.A.
	The status shall be indicated by other unambiguous means.	Status of the device is displayed on Vitascan LT software	P
	If a push button with momentary on position is used:		
	It shall be marked with symbol . ⏻ .		N.A.
	The status shall be indicated by an adjacent light indicator; or		N.A.
	The status shall be indicated by other unambiguous means.		N.A.
7.4.2	Control devices		
	Different positions of control devices and different positions of switches on ME equipment shall be indicated by figures, letters or other visual means		P
	If in normal use, the change of setting of a control could result in an unacceptable risk to the patient, such controls shall be provided with either:		
	an associated indicating device		N.A.
	an indication of the direction in which the magnitude of the function changes.		N.A.
7.4.3	Units of measure		
	Numeric indications of parameters on ME equipment shall be expressed in SI units according to ISO 31	The volume of bladder is expressed in milliliters (ml)	P
7.5	Safety signs		
	Markings used to convey a warning, prohibition or mandatory action that mitigates a risk that is not obvious to the operator shall be a safety sign selected from ISO 7010	No safety signs are needed	N.A.
	Where a safety sign is not available to indicate a particular desired meaning, the meaning may be obtained by one of the following methods:		
	a) Constructing a safety sign according to ISO 3864-1:2002;		N.A.
	b) Using the general warning sign ISO 7010:2003-W001;		N.A.
	c) Using the general prohibition sign ISO 7010:2003-P001 placed together with a supplementary symbol or text;		N.A.
	d) Using the general mandatory action sign ISO 7010:2003-M001 placed together with a supplementary symbol or text.		N.A.
7.6	Symbols		
7.6.1	The meanings of the symbols used for marking shall be explained in the instruction for use.	The meanings of symbols used are explained in the instructions	P
7.6.2	Symbols shall conform to the requirements in the referenced IEC or ISO publication		P
7.6.3	Symbols used for controls and performance shall conform requirements of the referenced IEC or ISO where the symbol is defined		P
7.7	Colours of the insulation of conductors		
7.7.1	A protective earth conductor shall be identified throughout its length by green and yellow coloured	No protective earth conductor	N.A.

	insulation.		
7.7.2	Any insulation on conductors inside ME equipment that form protective earth connections shall be identified by the colours green and yellow at least at the termination of the conductors.		N.A.
7.7.3	Identification by green and yellow insulation shall only be used for:		
	Protective earth conductors		N.A.
	Conductors as specified in 7.7.2		N.A.
	Potential equalization conductors		N.A.
	Functional earth conductors		N.A.
7.7.4	Conductors in power supply cords intended to be connected to the neutral conductor of the supply system shall be coloured "light blue".		N.A.
7.7.5	Colours of conductors in power supply cords shall be in accordance with IEC 60227 or IEC 60245.	No power supply cords	N.A.
7.8	Indicator lights and controls		
7.8.1	The colours of indicator lights and their meanings shall comply with Table 2		N.A.
7.8.2	The colour red shall be used only for a control by which a function is interrupted in case or emergency		N.A.
7.9	Accompanying documents		
7.9.1	ME equipment shall be accompanied by documents containing at least the instructions for use and technical description.		P
	The accompanying documents shall identify the ME equipment by including, as applicable, the following:		
	Name or trade-mark of manufacturer and an address to which the responsible organization can refer;		P
	Model or type reference		P
7.9.2	Instructions for use		
7.9.2.1	The instructions for use shall document:		
	The use of the ME equipment as intended by the manufacturer.		P
	The frequently used functions		P
	Any known contraindications to the use of the ME equipment.	Not inteneded for fetal use or pregnant patients	P
	The instructions for use shall be in a language that is acceptable to the intended operator.		P
7.9.2.2	For class I ME equipment, the instructions for use shall include a warning statement to the effect: "WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.	III class ME equipment supplied from limited-current supply source	N.A.
	The instructions for use shall provide the operator or responsible organization with warnings regarding any significant risks of reciprocal interference.		N.A.
	The instructions for use shall include information regarding potential electromagnetic or other interference.		P
	If the ME equipment is provided with an integral multiple socket-outlet, the instructions for use shall provide a warning statement of reduced level of safety.	No integral multiple socket-outlet	N.A.
7.9.2.3	If ME equipment is intended for connection to a separate power supply, either the power supply shall	The bladder monitor is connected to a laptop/computer	P

	be specified as part of the ME equipment or the combination shall be specified as an ME system.	(Dell XPS M1530 Model 9928L, or equivalent) and a medical isolation transformer (Tripp Lite IS250HG or equivalent). This combination is regarded as a medical electrical system.	
7.9.2.4	For mains-operated ME equipment with an additional power source not automatically maintained in a fully usable condition, the instructions for use shall include a warning statement referring to the necessity for periodic checking or replacement of such an additional power source.		N.A.
	If leakage from a battery would result in an unacceptable risk, the instructions for use shall include a warning to remove the battery if the ME equipment is not likely to be used for some time.		N.A.
	If an internal electrical power source is replaceable, the instructions for use shall state its specification.		P
	If loss of the power source would result in an unacceptable risk, the instructions for use shall contain a warning that the ME equipment must be connected to an appropriate power source.		P
7.9.2.5	The instructions shall include:		
	A brief description of the ME equipment		P
	How the ME equipment functions; and		P
	The significant physical and performance characteristics of the ME equipment		P
	If applicable, this description shall include the expected positions of the operator, patient and other persons near the equipment in normal use.		P
	The instructions for use shall include information on the materials or ingredients to which the patient or operator is exposed if such exposure can constitute an unacceptable risk.	No such materials or ingredients	N.A.
	The instructions for use shall specify any restrictions on other equipment to which a signal input/output part may be connected.		N.A.
7.9.2.6	Installation		
	If installation of the ME equipment or its parts is required, the instructions for use shall contain		
	A reference to where the installation instructions are to be found, or		N.A.
	Contact information for persons designated by the manufacturer as qualified to perform the installation.		N.A.
7.9.2.7	If an appliance coupler or separable plug is used as the isolation means to satisfy 8.11.1 a), the instructions for use shall contain an instruction not to position the ME equipment so that it is difficult to operate the disconnection device.		N.A.
7.9.2.8	The instructions for use shall contain the necessary information for the operator to bring the ME equipment into operation.		P
7.9.2.9	The instructions for use shall contain all information necessary to operate the ME equipment in accordance with its specification.		P
7.9.2.10	The instructions for use shall list all system		P

	messages, error messages and fault messages that are generated, unless these messages are self-explanatory.		
7.9.2.11	The instructions for use shall contain the necessary information for the operator to safely terminate the operation of the ME equipment.		P
7.9.2.12	For ME equipment parts or accessories that can become contaminated through contact with the patient or with body fluids or expired gases during normal use, the instructions for use shall contain:		
	Details about cleaning and disinfection or sterilization methods that may be used; and	Cleaning and disinfection methods are described	P
	List the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles.		N.A.
7.9.2.13	The instructions for use shall instruct the operator or responsible organization in sufficient detail concerning preventive inspection, maintenance and calibration to be performed by them, including the frequency of such maintenance.		P
7.9.2.14	The instructions for use shall include a list of accessories, detachable parts and materials that the manufacturer has determined are intended for use with ME equipment.	The list of components for Vitascan LT medical ultrasound system is presented	P
7.9.2.15	The instructions for use shall:		
	Identify any risks associated with the disposal of waste products, residues, etc. and of the ME equipment and accessories at the end of their expected service life; and		P
	provide advice on minimizing these risks.		P
7.9.2.16	The instructions for use shall contain the information specified in 7.9.3 or a reference to where the material is to be found.		P
7.9.3	Technical description		
7.9.3.1	This shall include:		
	The information required in 7.2;		P
	The permissible environmental conditions of use including conditions for transport and storage.	Operating: +10°C ÷ +25°C and 10–80% RH, storage: -30 ÷ +50°C and 20–90% RH non-condensing, 700-1060 hPa	P
	All characteristics of the ME equipment		P
	Any special installation requirements		P
	If liquid is used for cooling, the permissible range of values of inlet pressure and flow, and the chemical composition of the cooling liquid.		N.A.
	A description of the means of isolating the ME equipment from the supply mains, if such means is not incorporated in the ME equipment.		N.A.
	If applicable, a description of the means for checking the oil level in partially sealed oil-filled ME equipment or its parts.		N.A.
	A warning statement that addresses the hazards that can result from unauthorized modification of the ME equipment.		P
	If the technical description is separable from the instructions for use, it shall contain:		
	The information required in 7.2;		N.A.
	All applicable classifications specified in Clause 6,		N.A.

	any warning and safety notices and the explanation of safety signs;		
	A brief description of the ME equipment, how the ME equipment functions and its significant physical and performance characteristics.		N.A.
7.9.3.2	The technical description shall contain:		
	The required type and full rating of fuses	No fuses	N.A.
	For ME equipment having non-detachable power supply cord, a statement as to whether the power supply cord is replaceable by service personnel.	Power cord is detachable	N.A.
	Instructions for correct replacement of interchangeable or detachable parts that the manufacturer specifies as replaceable by service personnel; and		N.A.
	where replacement of a component could result in an unacceptable risk, appropriate warnings that identify the nature of hazard.		N.A.
7.9.3.3	The technical description shall contain a statement that the manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts.	The device is not serviceable by service personnel	N.A.
7.9.3.4	The technical description shall identify any means used to comply with the requirements of 8.11.1	Pass	P
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		
8.1	The limits specified in 8.4 shall not be exceeded for accessible parts in normal condition or single fault condition.	(see attached Table 5)	P
8.2	Requirements related to power sources		
8.2.1	If ME equipment is specified for connection to a separate power source, other than the supply mains, either the separate power source shall be considered as part of the ME equipment or the combination shall be considered as an ME system	Equipment may be connected to an ambulance power supply.	P
8.2.2	If ME equipment is specified for power supplied connection from an external d.c. power source, no hazardous situation, other than absence of essential performance, shall develop when a connection with a wrong polarity is made.	Connection is not polarity dependent	N.A.
8.3	Classification of applied parts		
	a) an applied part that is specified in the accompanying documents as suitable for direct cardiac application shall be a type CF applied part.		N.A.
	b) an applied part that includes a patient connection that is intended to deliver electrical energy or an electrophysiological signal to or from the patient shall be a type BF applied part or type CF applied part.		N.A.
	c) an applied part not covered by a) or b) shall be a type B applied part, type BF applied part or type CF applied part.	Type BF applied part	P
	d) For a part that is identified according to 4.6 as needing to be subject to the requirements for an applied part (except marking), the requirements for a type B applied part shall apply.	No such parts	N.A.
8.4.2	Accessible parts including applied parts		

	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 2 and 3.	(see attached Table 5)	P
	b) the leakage currents from, to or between accessible parts other than patient connections shall not exceed the limits of touch current specified in 8.7.3 c)		P
	c) For other parts the voltage to earth or other accessible parts shall not exceed 42,4 V peak a.c. or 60 V d.c. in normal condition or in single fault condition.		P
8.4.3	ME equipment intended to be connected to a power source by a plug		
	ME equipment or its parts intended to be connected to a power source by means of a plug shall be so designed that 1 s after disconnection of the plug the voltage between the pins of the plug and between either supply pin and the enclosure does not exceed 60 V or, if this value is exceeded, the charge does not exceed 45 µC.	Not connected to a power source by means of a plug	N.A.
8.4.4	Internal capacitive circuits		
	Conductive parts of capacitive circuits that become accessible after ME equipment has been de-energized and access covers as present in normal use have been removed immediately thereafter, shall not have a residual voltage exceeding 60 V or, if this value is exceeded, the shall not have a stored charge exceeding 45 µC.	No accessible capacitive circuits	N.A.
8.5	Separation of parts		
8.5.1.1	ME equipment shall have two means of protection to prevent applied parts and other accessible parts from exceeding the limits specified in 8.4	Solid insulation; creepage distances and air clearances	P
8.5.1.2	Means of patient protection.		
	Solid insulation forming a means of patient protection		P
	Creepage distances and air clearances forming a means of patient protection		P
	Protective earth connections forming a means of patient protection		N.A.
	A Y1 capacitor complying with IEC 60384-14		N.A.
8.5.1.3	Means of operator protection		
	Solid insulation forming a means of operator protection shall comply with the dielectric strength test according to 8.8; or comply with the requirements of IEC 60950-1 for insulation coordination.	No test for voltages below 60 Vdc	N.A.
	Creepage distances and air clearances forming a means of operator protection shall comply with the limits specified in Table 13 to Table 16; or comply with the requirements of IEC 60950-1 for insulation coordination.	See insulation diagram	P
	Protective earth connections forming a means of operator protection shall comply with the requirements of 8.6; or comply with the requirements and tests of IEC 60950-1 for protective earthing.		N.A.
	A Y2 or Y1 capacitor complying with IEC 60384-14 is considered equivalent to one means of operator		N.A.

	protection provided that it will pass the dielectric strength test.		
8.5.2	Separation of patient connections		
8.5.2.1	F-type applied parts		
	The patient connection of any F-type applied part shall be separated from all other parts, including the patient connection of other applied parts, by means equivalent to one means of patient protection.	Double insulation	P
	Any protective device connected between patient connections of an F-type applied part and the enclosur shall not operate below 500 V r.m.s.	No such protective devices	N.A.
8.5.2.2	Type B applied parts		
	The patient connection of a B-type applied part that is not protectively earthed shall be separated by one means of patient protection from metal accessible parts that are not protectively earthed.	BF type applied part	N.A.
8.5.2.3	Patient leads		
	Any connector for electrical connections on a patient lead that is at the end of the lead remote from the patient; and contains a conductive part that is not separated from all patient connection(s) by one means of patient protection for working voltage equal to the maximum mains voltage:		
	shall be constructed so that the said part cannot become connected to earth or possible hazardous voltage while the patient connections contact the patient.	No such connectors	N.A.
	The said part shall not come into contact with a flat conductive plate of not less than 100 mm diameter		N.A.
	The air clearance between connector pins and a flat surface shall be at least 0.5 mm		N.A.
	If able to be plugged into mains socket, the said part shall be protected from making contact with parts at mains voltage by insulating means providing a creepage distance of at least 1.0 mm and a dielectric strength of 1500 V and complying 8.8.4.1;		N.A.
	The straight unjointed test finger shall not make electrical contact with the said part if applied in the least favourable position against the access openings with the force of 10 N.		N.A.
8.5.5	Defibrillation-proof applied parts		
8.5.5.1	a) During a discharge of a cardiac defibrillator to a patient connected to a defibrillation-proof applied part, hazardous electrical energies, as determined by the peak voltages measured between the points Y1 and Y2 exceeding 1V, do not appear on:		
	The enclosure;		N.A.
	Any signal input/output part;		N.A.
	Metal foil test on which the ME equipment is placed; or		N.A.
	Patient connections of any other applied part;		N.A.
	b) Following exposure to the defibrillation voltage, and any necessary recovery time, the ME equipment shall comply with relevant requirements of this standard.		N.A.
8.5.5.2	Energy reduction test		
	Defibrillation-proof applied parts or patient connections of defibrillation-proof parts shall incorporate a means so that the defibrillator energy delivered to a 100Ω load is at least 90% of the energy	Single patient connection	N.A.

	delivered to this load with the ME equipment disconnected.		
8.6	Protective earthing, functional earthing and potential equalization of ME equipment		
8.6.2	The protective earth terminal shall be suitable for external protective earthing system either by a protective earth conductor in a power supply cord, or by a fixed protective earth conductor.		N.A.
	The clamping means of the protective earth terminal shall comply with the requirements of 8.11.4.3. It shall not be possible to loosen the clamping means without the aid of tool.		N.A.
	Screws for internal protective earth connections shall be completely covered or protected against accidental loosening from the outside of ME equipment.		N.A.
	Where an appliance inlet forms the supply connection to ME equipment, the earth pin of the appliance inlet shall be regarded as the protective earth terminal.		N.A.
	The protective earth terminal shall not be used for the mechanical connection between different parts of the ME equipment or the fixing of any component not related to protective earthing or functional earthing.		N.A.
8.6.3	Any protective earth connection shall not be used for a moving part	No moving parts	N.A.
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.		N.A.
	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.		N.A.
8.6.5	Conductive elements of ME equipment that have surface coatings of poorly conducting material such as paint, and between which electrical contact is essential to a protective earth connection, shall have the coatings removed at the point of contact		N.A.
8.6.6	The protective earth connection shall be made before and interrupted after the supply connections are made or interrupted.		N.A.
8.6.7	Potential equalization conductor		
	If ME equipment is provided with a terminal for the connection of a potential equalization conductor, the following requirements apply:		
	The terminal shall be accessible to the operator with the ME equipment in any position of normal use.		N.A.
	The risk of accidental disconnection shall be minimized in normal use.		N.A.
	The terminal shall allow the conductor to be detached without the use of a tool.		N.A.
	The terminal shall not be used for a protective earth connection.		N.A.
	The terminal shall be marked with symbol IEC 60417-		N.A.

	5021 (see Table D.1,symbol B).		
	The instructions for use shall contain information on th function and use of the potential equalization conducto together with a reference to the requirements of this Standard for ME systems.		N.A.
	The power supply cord shall not incorporate a potential equalization conductor.		N.A.
8.6.8	Functional earth terminal		
	A functional earth terminal of ME equipment shall not be used to provide a protective earth connection.	No functional earth terminal	N.A.
8.6.9	Class II ME equipment		
	If class II ME equipment with isolated internal screens is supplied with a power supply cord having three conductors, the third conductor shall be used only as the functional earth connection to a functional earth terminal for these screens and shall be coloured green and yellow.	No internal screens	N.A.
	The insulation of such internal screens and all internal wiring connected to them shall provide two means of protection.		N.A.
8.7	Leakage currents and patient auxiliary currents		
8.7.3	Allowable values		
	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 not less than 0,1 Hz.	(See attached Table 5)	P
	c) The allowable values of the touch current are 100 µA in normal condition and 500 µA in single fault condition.	(See attached Table 5)	P
	d) The allowable values of the earth leakage current are 5 mA in normal condition and 10 mA in single fault condition.	No earth connection	N.A.
	e) Regardless of waveform and frequency, no leakage current shall exceed 10 mA r.m.s.	Pass	P
8.7.4.9	ME equipment with multiple patient connections is investigated to ensure that the patient leakage current and the patient auxiliary current do not exceed the allowable values for normal condition while one or more patient connections are:		
	disconnected from the patient; and		N.A.
	disconnected from patient and earthed		N.A.
8.8	Insulation		
8.8.2	Distance through solid insulation or use of thin sheet material capacitors.		
	Solid insulation which forms supplementary insulation or reinforced insulation for a peak working voltage greater than 71 V shall either:		
	a) have a distance through insulation of at least 0,4 mm, or		N.A.
	b) not form part of an enclosure and not be subject to handling or abrasion during normal use, and comprise at least two layers of material, each of which will pass the appropriate dielectric strength test; or 3 layers of material, for which all combinations of two layers together will pass the appropriate dielectric strength test.		N.A.
8.8.3	Dielectric strength		
	The dielectric strength of solid electrical insulation of ME equipment shall be capable of withstanding the	(See attached Table 6)	P

	test voltages as specified in Table 6.		
8.8.4.1	Mechanical strength and resistance to heat		
	Resistance to moisture (see 11.6)	Pass	P
	Dielectric strength (see 8.8.3)	Pass	P
	Mechanical strength (see 15.3)	Pass	P
	Resistance to heat (see 8.8.4.1 a), b))	Pass (see Table 4)	P
8.8.4.2	Resistance to environmental stress		
	The insulating characteristics and mechanical strength of any means of protection shall be so designed that is not likely to be impaired by environmental stresses including deposition of dirt or by dust.		P
8.9	Creepage distances and air clearances		
8.9.1	Values	Pass (see insulation diagram)	P
8.9.3	Spaces filled by insulating compound		N.A.
8.10	Components and wiring		
8.10.1	Components of ME equipment, the unwanted movement of which could result in an unacceptable risk, shall be mounted securely to prevent such movement.	Motors are mounted securely inside the device	P
8.10.2	Conductors and connectors shall be so secured or insulated that accidental detachment shall not result in a hazardous situation.		P
8.10.3	Flexible cords detachable without the use of a tool and used for interconnection of different parts shall be provided with means for connection such that compliance of metal accessible parts with 8.4 is not compromised when a connection is loosened or broken.		N.A.
8.10.4	Cord-connected hand-held parts and cord-connected foot-operated control devices		
8.10.4.1	Limitation of operating voltages		
	Cord-connected hand-held and foot-operated control devices of ME equipment and their associated connection cords shall contain only conductors and components operating at voltages not exceeding 42,4 V peak a.c. or 60 V d.c. in circuits isolated from the mains part by two means of protection.	No such devices	N.A.
8.10.4.2	The connection and anchorage of a flexible cord to a hand-held or foot-operated control device of ME equipment, at both ends of the cable to the control device, shall comply with the requirements specified for power supply cords in 8.11.3		N.A.
8.10.5	Mechanical protection of wiring		
	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.	Internal cables are dequately protected	P
	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.		N.A.
8.10.6	Guiding rollers for insulated conductors		

	Guiding rollers of insulated conductors of ME equipment shall be constructed in such a manner that movable insulated conductors in normal use are not bent round a radius of less than 5 times the outer diameter of the lead concerned.		N.A.
8.10.7	Insulation of internal wiring		
	a) If insulating sleeving is needed on internal wiring, it shall be adequately secured.		N.A.
	b) Inside 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.		N.A.
	c) Insulated conductors 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.		N.A.
8.11	Mains parts, components and layout		
8.11.1	a) ME equipment shall have means to isolate its circuits electrically from the supply mains on all poles simultaneously.	USB connector	P
	b) Means for isolation either shall be incorporated in ME equipment or, if external, shall be subscribed in the technical description	Incorporated in the equipment	P
	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.	No mains switch	N.A.
	d) supply mains switch shall not be incorporated in a power supply cord or any other external, flexible lead.		N.A.
	e) The direction of movement of the actuator of a supply mains switch that is used to comply with 8.11.1 a) shall comply with IEC 60447.		N.A.
	f) in non-permanently installed ME equipment, 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).		N.A.
	g) a fuse or a semiconductor device shall not be used as an isolating means in the sense of this subclause.	Not used	N.A.
	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 over-current protection device.		N.A.
	i) any part within the enclosure of ME equipment with a circuit voltage exceeding 42,4V 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, shall be marked clearly.	No such parts	N.A.
8.11.2	Multiple socket outlets that are integral with ME equipment shall comply with the requirements of 16.2 d), second dash, and 16.9.2.1.		N.A.
8.11.3	Power supply cords		

8.11.3.1	The mains plug of ME equipment shall not be fitted with more than one power supply cord.	No power supply cords	N.A.
8.11.3.2	Any power supply cord of ME equipment shall be not less robust than ordinary tough rubber-sheathed flexible cord (IEC 60245-1, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1, designation 53).		N.A.
	A polyvinyl chloride insulated power supply cord shall not be used for ME equipment having external metal parts with a temperature exceeding 75°C and which can be touched in normal use by the cord	No external metal parts which could exceed temperature of 75°C	N.A.
8.11.3.3	Cross-sectional area of power supply cord conductors		
	The nominal cross-sectional area of conductors of any power supply cord of ME equipment shall be not less than that shown in Table 17.		N.A.
8.11.3.4	Appliance couplers complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6.		N.A.
8.11.3.5	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.	Protected	P
	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:		
	of insulating material, or		N.A.
	of metal, insulated from conductive accessible parts not protectively earthed by a means of protection, or		N.A.
	of metal provided with an insulating lining, which shall be affixed to the cord anchorage.		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.	Not clamped using directly bearing screws	P
	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.	No clamping srews are used	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.	No earth connections	N.A.
	f) The cord anchorage shall prevent the power supply cord from being pushed into the ME equipment or mains connector.	Pass (see Table 5)	P
8.11.3.6	Power supply cords of other than stationary ME equipment shall be protected against excessive bending at the inlet opening of the equipment by means of a cord guard of insulating material or by means of an appropriately shaped opening.	Pass, measured bending radius is 25 mm (allowable 6,75 mm)	P
8.11.4	Mains terminal devices		
8.11.4.1	Permanently installed ME equipment and ME equipment having a non-detachable power supply	Cord is not intended to be replaced by service personnel	N.A.

	cord that is replaceable by service personnel shall be provided with mains terminal devices that ensure reliable connection.		
8.11.4.2	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;	USB cord is not rewirable	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 materials		
	Terminals shall be fixed such that, when the means for clamping the conductors are tightened or loosened, the internal wiring is not subjected to stress and creepage distances and air clearances are not reduced below the values specified in 8.9.		N.A.
8.11.4.4	Connections to mains terminals		
	Terminals with clamping means for a rewirable flexible cord shall be so designed that the conductors are not damaged and cannot slip out when the clamping means are tightened.		N.A.
8.11.4.5	Accessibility of the connection		
	The space inside ME equipment designed for fixed wiring or a rewirable power supply cord shall be adequate to allow conductors to be easily introduced and connected, and covers, if any, to be fitted without damage to the conductors or their insulation.		N.A.
8.11.5	Mains fuses and over-current releases		
	A fuse or over-current release shall be provided in each supply lead for class I ME equipment and for class II ME equipment having a functional earth connection according to 8.6.9, and in at least one supply lead for other single-phase II ME equipment, except that:		
	for permanently installed ME equipment, the neutral conductor shall not be fused		N.A.
	A protective earth conductor shall not incorporate a fuse or over-current release		N.A.
	Protective devices shall have adequate breaking capacity to interrupt the maximum fault current which can flow.		N.A.
8.11.6	Internal wiring of the mains part		
	a) Internal wiring in a mains part between the mains terminal device 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	No mains part	N.A.
	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.		N.A.

9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		
9.2.2	Trapping zone		
	Where feasible, ME equipment with trapping zone shall comply with the requirements of one or more of the following:		
	Gaps as specified in 9.2.2.2; or		N.A.
	Safe distances as specified in 9.2.2.3; or		N.A.
	Guards and protective measures as specified in 9.2.2.4; or		N.A.
	Continuous activation as specified in 9.2.2.5		N.A.
9.2.2.2	A trapping zone is considered not to present a mechanical hazard if the gaps of the trapping zone comply with the dimensions specified in Table 20.		N.A.
9.2.2.3	A trapping zone is considered not to present a mechanical hazard if the distances separating the operator, patient and other persons from the trapping zones exceed the values specified in ISO 13852.		N.A.
9.2.2.4	Guards and protective measures		
	A trapping zone is considered not to present a mechanical hazard if guards and protective measures:		
	are of robust construction		N.A.
	are not easy to bypass or render non operational		N.A.
	do not introduce any additional unacceptable risk		N.A.
9.2.2.4.2	Fixed guards shall be securely held in place by systems that cannot be dismantled without the use of tool		N.A.
9.2.2.4.3	Movable guards that can be opened without the use of a tool:		
	shall remain attached to the ME equipment when the guard is open;		N.A.
	shall be associated with an interlock device that prevents the relevant moving parts from starting to move while the trapping zone is accessible and stops movement when the guard is opened;		N.A.
	shall be so designed that the absence or failure of one of their components prevents starting, and stops moving parts.		N.A.
9.2.2.4.4	Protective measures shall be designed and incorporated into the control system so that:		
	moving parts cannot start to move while they are in the reach of persons;		N.A.
	Once the ME equipment has started to move, the trapping zone cannot be reached, or, if the trapping zone is reached, system movement must stop.		N.A.
	If in a single fault condition of the protective measure, an unacceptable risk could arise, one or more emergency stopping device(s) shall be provided.		N.A.
9.2.2.5	Continuous activation		
	Where it is impractical to make the trapping zone inaccessible, a trapping zone is not considered to present a mechanical hazard if:		
	a) movement is in the operator's field of view;		N.A.
	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;		N.A.

	c) in a single fault condition of the continuous activation system an unacceptable risk could arise, one or more emergency stopping device(s) are provided in the ME equipment.		N.A.
9.2.2.6	The speed of movement(s) that position parts of the ME equipment or patient, where contact with the ME equipment could result in a hazardous situation, shall be limited so that the operator will have adequate control of positioning without resulting in an unacceptable risk.		N.A.
9.2.3	Other hazards associated with moving parts		
9.2.3.1	Controls shall be so positioned, recessed, or protected by other means so that they cannot be accidentally actuated, resulting in unacceptable risk.		N.A.
9.2.3.2	End stops or other stopping means shall be provided to act as the ultimate travel limiting measure in both normal condition and single fault condition.		N.A.
9.2.4	Emergency stopping devices		
	where it is considered necessary to have one or more emergency stopping device(s), the emergency stopping device shall comply with all the following requirements:		
	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.		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 coloured 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 (see Table D.1, symbol 1B) or the word "STOP".		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.
9.2.5	Means shall be provided to permit the release of the patient quickly and safely in the event of breakdown of the ME equipment or failure of the power supply, activation of a protective measure or emergency stopping.		N.A.

9.3	Rough surfaces, sharp corners and edges of ME equipment that could result in an unacceptable risk shall be avoided or covered.	No sharp corners or rough surfaces.	P
9.4	Instability hazards		
9.4.1	ME equipment, other than fixed ME equipment and hand-held ME equipment, intended to be placed on a surface such as a floor or a table shall not overbalance (tip over) or move unexpectedly, to the degree that it could present an unacceptable risk to the patient or operator.	Hand-held equipment	N.A.
9.4.2.1	ME equipment or its parts shall not overbalance when placed in any transport position of normal use on a plane inclined at an angle of 10° from the horizontal plane.	Hand-held equipment	N.A.
9.4.2.2	ME equipment or its parts shall not overbalance when placed in any position of normal use excluding any transport positions, on a plane inclined at an angle of 5° from the horizontal plane.	Hand-held equipment	N.A.
9.4.2.3	Instability from horizontal and vertical forces		
	a) ME equipment having mass of 25 kg or more, other than fixed ME equipment that is intended to be used on the floor, shall not overbalance due to pushing, leaning, resting etc.		N.A.
	Clearly legible warning of this risk.		N.A.
	b) ME equipment, other than fixed ME equipment that is intended to be used on the floor or table, shall not overbalance due to sitting or stepping unless a legible warning of this risk is provided.		N.A.
9.4.2.4	Castors and wheels		
9.4.2.4.1	The means used for transportation of mobile ME equipment shall not result in an unacceptable risk when the mobile ME equipment is moved or parked in normal use.	No castors or wheels	N.A.
9.4.2.4.2	The force required for moving mobile ME equipment along a hard and flat horizontal surface shall not exceed 200 N for one person.		N.A.
9.4.2.4.3	Mobile ME equipment exceeding 45 kg shall be able to pass over a 20 mm threshold without any unacceptable risk.		N.A.
9.4.3	Instability from unwanted lateral movement		
9.4.3.1	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.	Hand-held equipment	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.	Hand-held equipment	N.A.
	c) mobile ME equipment that is intended to be used on the floor shall not result in an unacceptable risk due to unwanted lateral movement.	Hand-held equipment	N.A.
9.4.3.2	a) Mobile ME equipment shall be provided with wheel locks or with a braking system appropriate to the intended modes of use and sufficient to ensure that unintended movement is prevented on an incline of	Hand-held equipment	N.A.

	5°.		
	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.		N.A.
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 or the accompanying documents shall indicate the points where it can be lifted safely.	Hand-held equipment	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		N.A.
	c) Carrying handles or grips furnished on portable ME equipment shall withstand loading equal to four times the weight of the ME equipment.		N.A.
9.5	Expelled parts hazard		
9.5.1	Where expelled parts could result in an unacceptable risk, the ME equipment shall be provided with a means for protecting against such risk.	No expelled parts.	N.A.
9.5.2	Any cathode ray tube shall comply with the applicable requirements of IEC 60065:2001 Clause 18; or IEC 61965.		N.A.
9.6	Acoustic energy (including infra- and ultrasound) and vibration		
9.6.1	ME equipment shall be designed so that human exposure to acoustic energy and vibration shall not result in an unacceptable risk.	Ultrasound energy applied does not result in any unacceptable risk	P
9.6.2.1	In normal use, the patient, operator and other persons shall not be exposed to acoustic energy from ME equipment, except sound from auditory alarm signals, exceeding the specified levels.		
	80 dBA for a cumulative exposure of 24 h over a 24 h period;	No acoustic energy	N.A.
	140 dB un-weighted sound pressure level for impulsive or impact acoustic energy (noise).		N.A.
9.6.2.2	Infrasound and ultrasound energy	Ultrasound energy is low and equals to 0,25mW/cm^2	P
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		
9.7.2	Pneumatic and hydraulic parts of ME equipment or accessories shall be so designed that:		
	no unacceptable risk results from loss of pressure or loss of vacuum;		N.A.
	no unacceptable risk results from a fluid jet caused by leakage or a component failure;		N.A.
	elements of the ME equipment or an accessory, and especially pipes and hoses, that can lead to an unacceptable risk shall be protected against harmful external effects;		N.A.
	reservoirs and similar vessels that can lead to an unacceptable risk are automatically depressurized when the ME equipment is isolated from its power supply.		N.A.

	All elements that can remain under pressure after isolation of the ME equipment or an accessory from its power supply and that could result in an unacceptable risk shall be provided with clearly identified exhaust devices, and a warning label drawing attention to the necessity of depressurizing these elements before any setting or maintenance activity.		N.A.
9.7.3	Maximum pressure		N.A.
9.7.4	The maximum pressure to which a part of ME equipment can be subjected in normal and single fault condition shall not exceed the maximum permissible working pressure for the part.		N.A.
9.7.5	Pressure vessels		
	A pressure vessel shall withstand a hydraulic test pressure if both the following conditions are met:		
	The pressure is greater than 50 kPa; and		N.A.
	The product of pressure and volume is greater than 200 kPa.		N.A.
9.7.6	Any pressure-control device responsible for regulating the pressure shall be capable of performing under rated load for 100 000 cycles of operation and shall prevent the pressure from exceeding 90 % of the setting of the pressure-relief device under any condition of normal use.		N.A.
9.7.7	Pressure-relief device		N.A.
	A pressure-relief device shall comply with all of the following requirements:		
	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.
9.8	Hazards associated with support systems		
9.8.1	The construction of the support, suspension or actuation system shall be designed based upon Table 21 and the total load.		N.A.
	Means of attachment of accessories shall be designed such that any possibility of incorrect attachment that could result in an unacceptable risk is avoided.		N.A.
	The risk analysis of support systems shall consider hazards arising from static, dynamic, vibration, impact and pressure loading, temperature and environmental conditions.		N.A.
	All likely failure effects shall be considered in the risk analysis.		N.A.

	The accompanying documents shall contain instructions on attachment of structures to a floor, wall, ceiling, etc.		N.A.
9.8.2	Tensile safety factor		
	Support systems shall maintain structural integrity during the expected service life.		N.A.
9.8.3	Strength of patient or operator support or suspension systems		
9.8.3.1	Unless otherwise stated by the manufacturer, supporting and suspending parts for adult human patients or operators shall be designed for a patient or operator having a minimum mass of 135 kg and accessories having a minimum mass of 15 kg.		N.A.
9.8.3.2	Static forces due to loading from persons		
	a) foot rest;		N.A.
	b) support/suspension where a patient or operator can sit.		N.A.
9.8.3.3	Dynamic forces due to loading from persons		N.A.
9.8.4	Systems with mechanical protective devices		
	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:		
	be designed on the basis of total load, which shall include the effects of the safe working load when applicable;		N.A.
	have tensile safety factors for all parts not less than those in row 7 of Table 21;		N.A.
	activate before travel produces an unacceptable risk;		N.A.
	take into account 9.2.5 and 9.8.4.3.		N.A.
9.8.4.2	If ME equipment can still be used after failure of the suspension or actuation means and activation of a mechanical protective device, it shall become obvious to the operator that the mechanical protective device has been activated		N.A.
9.8.4.3	If a mechanical protective device is intended to function only once, the following requirements shall be fulfilled:		
	further use of the ME equipment shall be impossible until the mechanical protective device has been replaced;		N.A.
	the accompanying documents shall instruct that once the mechanical protective device has been activated, service personnel are to be called, and the mechanical protective device must be replaced before the ME equipment can be used again;		N.A.
	the ME equipment shall be permanently marked with safety sign 7010-W001 (see Table D.2, safety sign 2);		N.A.
	The marking shall be adjacent to the mechanical protective device or so located that its relation to the mechanical protective device is obvious to the person performing service or repair.		N.A.
9.8.5	Systems without mechanical protective devices		N.A.

10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		
10.1.1	ME equipment not intended to produce diagnostic or therapeutic X-radiation.		N.A.
10.1.2	ME equipment intended to produce diagnostic or therapeutic X-radiation.		N.A.
10.2	Alpha, beta, gamma, neutron and other particle radiation.		N.A.
10.3	Microwave radiation		N.A.
10.4	Lasers and light emitting diodes (LEDs).		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	Excessive temperatures in ME equipment		
11.1.1	ME equipment parts shall not reach temperatures exceeding values given in Table 22 and Table 23	(See attached Table 8)	P
11.1.2.1	The temperature or the clinical effects shall be determined and documented in the risk management file.		P
11.1.2.2	If the surface temperature of an applied part exceeds 41°C, the maximum temperature shall be disclosed in the instructions for use and the clinical effects.	The temperature of the applied part does not exceed 41°C	N.A.
11.1.4	Guards intended to prevent contact with hot or cold accessible surfaces of ME equipment shall be removable only with the aid of tool.	No hot parts	N.A.
11.2	Fire prevention		
11.2.1	Enclosures shall have the strength and rigidity necessary to avoid a fire.	Enclosure has the necessary rigidity.	P
11.2.2.2	External exhaust outlets of an oxygen rich environment shall not be located so that risk of ignition occurs because of any electrical component.	Not intended to be used in oxygen rich environment	N.A.
11.2.2.3	Electrical connections within a compartment containing an oxygen rich environment under normal use shall not produce sparks because of loosening or breaking.		N.A.
11.2.3	Single fault conditions related to oxygen rich environments in conjunction with ME equipment and ME systems		
	Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2)		N.A.
	Failure of a barrier constructed in accordance with 11.2.2.1 b) 3)		N.A.
	Failure of a component that creates a source of ignition		N.A.
	Failure of insulation		N.A.
	Failure of pneumatic component that results in leakage of oxygen-enriched gas		N.A.
11.3	Constructional requirements for fire enclosures of ME equipment		
	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.		N.A.
	b) The fire enclosure shall meet the following requirements of Table 25 and Figure 38, 39.		N.A.

11.4	Me equipment, ME systems or their parts described in the accompanying documents for use with flammable anaesthetics or flammable anaesthetics with oxidants shall meet the applicable requirements of Annex G.	Not intended to be used with flammable anaesthetics or flammable anaesthetics with oxidants	N.A.
11.5	The manufacturer's risk management process shall address the possibility of fire and associated mitigations		P
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substance used with the ME equipment		
11.6.2	If ME equipment incorporates a reservoir or liquid storage chamber that is liable to be overfilled or to overflow in normal use, liquid overflowing from the reservoir or chamber shall not create an unacceptable risk.	No reservoir or liquid storage chamber	N.A.
11.6.3	ME equipment and ME systems requiring the handling of liquids in normal use shall be so constructed that spillage does not wet parts that could result in hazardous situation.	See 11.6.5 cl. below.	P
11.6.5	Enclosures of ME equipment and ME systems designed to give a specified degree of protection against harmful ingress of water shall provide this protection in accordance with the classification of IEC 60529.	Pass the testing for protection degree of IPX1 for horizontal direction.	P
11.6.6	ME equipment, systems and their parts shall be capable or withstanding, without damage or deterioration of safety provisions, the cleaning or disinfection processes.	Pass	P
	The manufacturer shall evaluate the effects of multiple cleanings/disinfections during the expected service life.	Evaluated in the risk management file	P
11.6.7	ME equipment, ME systems and their parts or accessories intended to be sterilized shall be assessed and documented according to ISO 11134, ISO 11135 or ISO 11137 as appropriate.	No parts which are intended to be sterilized.	N.A.
11.6.8	When applicable, the manufacturer shall address in the risk management process the risks associated with compatibility with substances used with the ME equipment.	Addressed in the risk management file	P
11.7	ME equipment, ME systems and their parts or accessories intended to come into direct or indirect contact with biological tissues, cells or body fluids shall be assessed and documented according to ISO 10993 series of standards.		P
11.8	ME equipment shall be so designed that an interruption and restoration of the power supply shall not result in a hazardous situation other than interruption of its intended function.	No hazardous situations arise	P
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		
12.1	When applicable, the manufacturer shall address in the risk management process the risks associated with accuracy of controls and instruments.		P
12.2	The manufacturer shall address in a usability engineering process the risk of poor usability.		P

12.3	When applicable, the manufacturer shall address in the risk management process the need for alarm systems as a means of risk control and address any risks associated with the operation or failure of the alarm system.		N.A.
12.4	Protection against hazardous output		
	The manufacturer shall address in the risk management process the risks associated with:		
12.4.1	Intentional exceeding of safety limits;		N.A.
12.4.2	Indication of parameters relevant to safety;		N.A.
12.4.3	Accidental selection of excessive output values;		N.A.
12.4.4	Incorrect output		P
12.4.5	Diagnostic or therapeutic radiation		
12.4.5.1	For ME equipment designed to produce radiation for diagnostic or therapeutic purposes, adequate provisions shall be made to protect patients, operators, other persons and sensitive devices from unwanted or excessive radiation emitted by the ME equipment.		N.A.
12.4.5.2	When applicable, the manufacturer shall address in the risk management process the risks associated with:		
	diagnostic X-rays;		N.A.
12.4.5.3	radiotherapy;		N.A.
12.4.5.4	ME equipment producing diagnostic or therapeutic radiation other than for diagnostic X-rays and radiotherapy;		N.A.
12.4.6	When applicable, the manufacturer shall address in the risk management process the risks associated with diagnostic or therapeutic acoustic pressure.	Diagnostic ultrasound pressure is low and unharmful (0,25mW/cm^2)	P
13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		
13.1.2	Emissions, deformation of enclosure or exceeding maximum temperature		
	The following hazardous situations shall not occur:		
	Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;		P
	Deformation of enclosures to such an extent that compliance with 15.3.1 is impaired;		P
	Temperatures of applied parts exceeding the allowed values identified in Table 24;		P
	Temperatures of ME equipment parts that are not applied parts but are likely to be touched, exceeding the allowable values in Table 23;		N.A.
	Exceeding the allowable values for other components and materials identified in Table 22 times 1.5 minus 12.5°C.		P
13.1.3	Exceeding leakage current or voltage limits		
	The following hazardous situations shall not occur:		
	Exceeding the limits for leakage current in single fault condition as indicated in 8.7.3		P
	Exceeding the voltage limits for the accessible parts including applied parts indicated in 8.4.2		P
13.2	Single fault conditions:		
13.2.2	Electrical single fault condition	Pass	P
13.2.3	Overheating of transformers in ME equipment	Pass	P
13.2.4	Failure of thermostats	No thermostats	N.A.

13.2.5	Failure of temperature limiting devices	No temperature limiting devices	N.A.
13.2.6	Leakage of liquid		N.A.
13.2.7	Impairment of cooling that could result in a hazard		N.A.
13.2.8	Locking of moving parts	Pass	P
13.2.9	Interruption and short circuiting of motor capacitors	No motor capacitors	N.A.
13.2.10	Additional test criteria for motor operated ME equipment.	Pass	P
13.2.11	Failures of components in ME equipment used in conjunction with oxygen rich environments.	The equipment is not intended to be used in oxygen rich environments.	N.A.
13.2.12	Failure of parts that might result in a mechanical hazard.	No such parts	N.A.
13.2.13	Overload		
13.2.13.1	After tests of 13.2.13.2 to 13.2.13.4, ME equipment, when cooled down to approximately room temperature, shall remain safe.		N.A.
13.2.13.2	ME equipment with heating elements		N.A.
13.2.13.3	ME equipment with motors		N.A.
13.2.13.4	ME equipment rated for non-continuous operation	Hand-held equipment	N.A.
14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		
14.2	In addition to the records and documents required by ISO 14971, the documents produced from application of Clause 14 shall be maintained and shall form part of the risk management file.		P
14.4	A PEMS development life-cycle shall be documented.		P
	The PEMS development life-cycle shall include a set of defined milestones.		P
	At each milestone, the activities to be completed and the verification methods to be applied to those activities shall be defined.		P
	Each activity shall be defined including its inputs and outputs.		P
	Each milestone shall identify the risk management activities that must be completed before that milestone.		P
	The PEMS development life-cycle shall be tailored for a specific development by making plans which detail activities, milestones and schedules.		P
	The PEMS development life-cycle shall include documentation requirements.		P
14.5	Where appropriate, a documented system for problem resolution within and between all phases and activities of the PEMS development life-cycle shall be developed and maintained.		P
14.6	Risk management process		
14.6.1	When compiling the list of known or foreseeable hazards, the manufacturer shall consider those hazards associated with software and hardware aspects of the PEMS.		P
14.6.2	Suitably validated tools and procedures shall be selected and identified to implement each risk control measure.		P
14.7	For the PEMS and each of its subsystems there shall be a documented requirement specification.		P

14.8	Architecture		
	For the PEMS and each of its subsystems, an architecture shall be specified that shall satisfy the requirement specification.		P
	Where appropriate, to reduce the risk to an acceptable level, the architecture specification shall make use of:		
	a) components with high-integrity characteristics;		N.A.
	b) fail-safe functions;		P
	c) redundancy;		N.A.
	d) diversity;		N.A.
	e) partitioning of functionality;		N.A.
	f) defensive design;		N.A.
	The architecture specification shall take into consideration:		
	g) allocation of risk control measures to subsystems and components of the PEMS;		N.A.
	h) failure modes of components and their effects;		P
	i) common cause failures;		P
	j) systematic failures;		P
	k) test interval duration and diagnostic coverage;		P
	l) maintainability;		N.A.
	m) protection from reasonably foreseeable misuse;		N.A.
	n) the network/data coupling spec., if applicable		N.A.
14.9	Design and implementation		
	Where appropriate, the design shall be decomposed into subsystems, each having both a design and test specification.		N.A.
	Descriptive data regarding the design environment shall be included in the risk management file.		N.A.
14.10	Verification is required for all functions that implement basic safety, essential performance or risk control measures.		P
14.11	A PEMS validation plan shall include the validation of basic safety and essential performance, and shall require checks for unintended functioning of the PEMS.	Validated	P
14.12	If any or all of a design results from a modification of an earlier design then either all of this clause applies as if it were a new design or the continued validity of any previous design documentation shall be assessed under a documented modification /change procedure.		N.A.
14.13	If the PEMS is intended to be connected by network/data coupling to other equipment that is outside the control of the PEMS manufacturer, the technical description shall:		
	a) specify the characteristics of the network/data coupling necessary for the PEMS to achieve its intended use;		N.A.
	b) list the hazardous situations resulting from a failure of the network/data coupling to provide the specified characteristics;		N.A.
	c) instruct responsible organization that:		
	Connection of the PEMS to a network/data coupling that includes other equipment could result in previously unidentified risks to patients, operators or third parties;		N.A.

	The responsible organization should identify, analyze, evaluate and control these risks;		N.A.
	Subsequent changes to the network/data coupling could introduce new risks and require additional analysis.		N.A.
15	**CONSTRUCTION OF ME EQUIPMENT**		
15.1	When applicable, the manufacturer shall address in the risk management process the risks associated with the arrangement of controls and indicators of ME equipment.	Not applicable	N.A.
15.2	Parts of ME equipment subject to mechanical wear, electrical and environmental degradation or ageing that could result in an unacceptable risk if allowed to continue unchecked for too long a period shall be accessible for inspection, replacement and maintenance.		P
15.3	Mechanical strength		
15.3.1	ME equipment or its parts shall have adequate mechanical strength and shall not result in an unacceptable risk due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling.	Mechanical strength is ensured	P
15.3.2	Push test	Pass	P
15.3.3	Impact test		N.A.
15.3.4	Drop test	Pass	P
15.3.5	Rough handling test		N.A.
15.3.6	Mould stress relief test	Pass	P
15.3.7	The ME equipment shall be so designed and constructed that during its expected service life any corrosion, ageing, mechanical wear, or degradation of biological materials due to the influence of bacteria, plants, animals and the like, shall not reduce its mechanical properties in way that results unacceptable risk.		P
15.4	ME equipment components and general assembly		
15.4.1	a) Plugs for connection of patient leads shall be so designed that they cannot be connected to other outlets on the same ME equipment.	No patient leads	N.A.
	b) Medical gas connections on ME equipment for different gases to be operated in normal use shall not be interchangeable.	No medical gas connections	N.A.
15.4.2.1	a) Thermal cut-outs and over-current releases with automatic resetting shall not be used in ME equipment if their use could result in a hazardous situation by such resetting;		N.A.
	b) thermal cut-outs with safety function that have to be reset by a soldering operation that can affect the operating value shall not be fitted;		N.A.
	c) where failure of a thermostat could constitute a hazard an independent non-self-resetting thermal cut-out shall additionally be provided;		N.A.
	d) loss of function of the ME equipment caused by operation of a thermal cut-out or over-current release shall not result in a hazardous situation;		N.A.

	e) capacitors or other spark-suppression devices 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;		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;		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.		N.A.
15.4.2.2	Where means are provided for varying the temperature setting of thermostats in ME equipment, the temperature setting shall be clearly indicated.		N.A.
15.4.3	Batteries		
15.4.3.1	Housings containing batteries from which gases that are likely to result in a hazard can escape during charging shall be ventilated.	No batteries	N.A.
	Battery compartments shall be designed to prevent accidental short circuiting of the battery.		N.A.
15.4.3.2	If a hazardous situation might develop by the incorrect connection or replacement of a battery, ME equipment shall be fitted with a means of preventing incorrect polarity of connection.		N.A.
15.4.3.3	Where overcharging of any battery of ME equipment could result in an unacceptable risk, the design shall prevent overcharging.		N.A.
15.4.3.4	Lithium batteries used in ME equipment that could become a hazard shall comply with the requirements of IEC 60084-4.		N.A.
15.4.3.5	An internal electrical power source in ME equipment shall be provided with an appropriately rated device for protection against fire caused by excessive currents.		N.A.
15.4.4	Unless it is otherwise apparent to the operator from the normal operating position, indicator lights shall be provided to indicate that ME equipment is ready for normal use.	The status of the equipment is displayed after the connection to USB and start of Vitascan LT software	P
	If equipment with a stand-by state or warm-up state whose duration exceeds 15 s, the ME equipment shall be provided with an additional indicator light.		N.A.
	Indicator lights shall be provided on ME equipment incorporating non-luminous heaters to indicate that the heaters are operational.		N.A.
	Indicator lights shall be provided on ME equipment to indicate that an output exists where accidental or prolonged operation of the output circuit could constitute a hazardous situation.		N.A.
	In ME equipment incorporating a means for charging an internal electrical power source, the charging mode shall be visibly indicated to the operator.		N.A.

15.4.5	When applicable, the manufacturer shall address in the risk management process the risks associated with pre-set controls.		N.A.
15.4.6.1	a) All actuating parts of ME equipment shall be so secured that they cannot be pulled off or work loose during normal use.	No actuating parts	N.A.
	b) Controls, the adjustment of which can result in a hazardous situation for the patient or operator while ME equipment is in use, shall be so secured that the indication of any scale always corresponds with the position of control.		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 use of a tool.		N.A.
15.4.6.2	Stops of adequate mechanical strength shall be provided on rotating or movable parts of controls, where necessary to prevent an unexpected change.		N.A.
15.4.7	Cord-connected hand-held and foot-operated control devices		
15.4.7.1	a) Hand-held devices shall comply with 15.3.4.1;		N.A.
	b) Foot operated control devices of ME equipment shall be able to support the weight of an adult human being.		N.A.
15.4.7.2	Hand-held and foot-operated control devices shall not result in an unacceptable risk by changing their control setting when accidentally placed in an abnormal position.		N.A.
15.4.7.3	a) Foot-operated control devices of ME equipment shall be at least IPX1 according to IEC 60529.		N.A.
	b) In ME equipment, enclosures of foot operated control devices that contain electrical circuits shall be classified at least IPX6 according to IEC 60529 if they are intended for normal use in areas where liquids are likely to be found.		N.A.
15.4.8	Aluminum wires of less than 16 mm^2 cross-section shall not be used in ME equipment.		N.A.
15.4.9	a) Oil containers in portable ME equipment shall be adequately sealed to prevent loss of oil in any position.	No oil containers	N.A.
	b) Oil containers in mobile ME equipment shall be sealed to prevent the loss of oil during transport but may be fitted with a pressure-release device that can operate during normal use.		N.A.
	c) Partially sealed oil-filled ME equipment or its parts shall be provided with means for checking the oil level so that leakage can be detected.		N.A.
15.5	Mains supply transformers of ME equipment and transformers providing separation in accordance with 8.5		
15.5.1.1	Transformers of ME equipment shall be protected against overheating in the event of short circuit or overload of any output winding.	No mains transformers	N.A.
15.5.1.2	Short-circuit test		N.A.
15.5.1.3	Overload test		N.A.
15.5.2	Dielectric strength		

	ME equipment transformer windings shall have adequate insulation to prevent internal short-circuits that could result in a hazardous situation.		N.A.
15.5.3	Transformers of ME equipment that form means of protection as required by 8.5 shall comply with IEC 61558-1:1997, subclause 5.12.		N.A.
16	**ME SYSTEMS**		
16.2	Documents shall include:		
	a) the accompanying documents for each item of ME equipment;		P
	b) the accompanying documents for each item of non-ME equipment;		N.A.
	c) the following information:		
	The specification of the ME system, including the use as intended by the manufacturer and a listing of all of the items forming the ME system;		P
	Instructions for the installation, assembly and modification of the ME system to ensure continued compliance with this standard;		P
	Instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or part of ME equipment;		N.A.
	Additional safety measures that should be applied, during installation of the ME system;		N.A.
	Which parts of the ME system are suitable for use within the patient environment;		N.A.
	Additional measures that should be applied, during preventive maintenance;		N.A.
	If a multiple socket-outlet is present and it is a separate item, a warning that it shall not be placed on the floor;	No multiple socket-outlets	N.A.
	A warning that an additional multiple socket-outlet or extension cord shall not be connected to the ME system;	No multiple socket-outlets	N.A.
	A warning to connect only items that have been specified as part of the ME system or that have been specified as being compatible with the ME system;	Recommended components are listed	P
	The maximum permitted load for any multiple socket-outlet(s) used with the ME system;	No multiple socket-outlets	N.A.
	An instruction that multiple socket- outlets provided with the ME system shall only be used for supplying power to equipment that is intended to form part of the ME system;	No multiple socket-outlets	N.A.
	An explanation of the risks of connecting non-ME equipment that has been supplied as a part of the ME system directly to the wall outlet when the non-ME equipment is intended to be supplied via a multiple socket-outlet with a separating transformer;	No multiple socket-outlets	N.A.
	An explanation of the risks of connecting any equipment that has not been supplied as a part of the ME system to the multiple socket-outlet;	No multiple socket-outlets	N.A.
	The permissible environmental conditions of use of the ME system including conditions for transport and storage; and	Storage: -30˚C +50˚C, 20-90% RH, 700 hPa-1060 hPa; operating: +10˚C +45˚C, 10-90% RH	P

	Instructions to the operator not to touch parts referred to in 16.4 and the patient simultaneously.		N.A.
	d)advice to the responsible organization:		
	To carry out all adjustment cleaning, sterilization and disinfection procedures specified therein; and		N.A.
	That the assembly of ME systems and modifications during the actual service life require evaluation to the requirements of this standard.		N.A.
16.3	If ME equipment is intended to receive its power from other equipment in an ME system, the instructions for use shall specify the other equipment sufficiently to ensure compliance with the requirements of this standard.		P
16.4	Parts of non-ME equipment in the patient environment that can be contacted by the operator after removal of covers without the use of a tool shall operate at a voltage not exceeding the voltage specified in 8.4.2 c) supplied from a source that is separated from the supply mains by two means of operator protection.	No such parts	N.A.
16.5	The separation device shall have the dielectric strength, creepage distances and air clearances required for one means of operator protection appropriate for the highest voltage occurring across the separation device during a fault condition.	Depends on the personal computer and isolation means that are used	N.A.
16.6	Leakage currents		
16.6.1	Touch current shall not exceed 100 µA in normal condition and 500 µA in the event of the interruption of any non-permanently installed protective earth conductor.	No earth connections	N.A
16.6.2	Earth leakage current of multiple socket-outlet shall not exceed 5 mA.	No multiple socket-outlets	N.A.
16.6.3	Patient leakage current	See Table 2	P
16.7	Protection against mechanical hazards		N.A.
16.8	An ME system shall be so designed that an interruption and restoration of the power to the ME system as whole, or any part of the ME system, shall not result in a hazardous situation other than interruption of its intended function.		N.A.
16.9	ME system connections and wiring		
16.9.1	Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a tool, shall be prevented where a hazardous situation could otherwise exist.	Incorrect connection is impossible	N.A.
16.9.2.1	a) A multiple socket-outlet shall:		
	Only allow connection by using a tool, or	No multiple socket-outlets	N.A.
	Be of a type that cannot accept mains plugs of any of the kinds specified in IEC/TR 60083, or		N.A.
	Be supplied via a separating transformer.		N.A.
	b) A multiple socket-outlet shall be marked:		
	With safety sign ISO 7010-W001 such that is visible in normal use;		N.A.

	Either individually or in combinations with the maximum allowed continuous output in amperes or volt-amperes, or		N.A.
	to indicate which equipment or equipment parts may be safely attached.		N.A.
	A multiple socket-outlet may be a separate item or an integral part of ME or non-ME equipment.		N.A.
	c) The multiple socket-outlet shall comply with IEC 60884-1 and the following requirements:		
	Creepage distances and air clearances shall comply with 8.9.		N.A.
	It shall be of class I construction and the protective earth conductor shall be connected to the earthing contacts in the socket-outlets.		N.A.
	Protective earth terminals and protective earth connections shall comply with 8.6, except that the total impedance of the protective earth path may be up to 400 mΩ, or higher if the conditions of 8.6.4 b) are satisfied.		N.A.
	Enclosures shall comply with 8.4.2 d)		N.A.
	Mains terminal devices and wiring shall comply with 8.11.4, if applicable.		N.A.
	Ratings of components shall not conflict with the conditions of use (see 4.8).		N.A.
	Design and construction of electrical connection terminals and connectors of multiple socket-outlets shall prevent the incorrect connection of accessible connectors that are removable without the use of a tool.		N.A.
	Requirements for the power supply cord as described in 8.11.3 shall be fulfilled.		N.A.
	d) If the multiple socket –outlet is combined with a separating transformer, the following additional requirements apply.		
	The separating transformer shall comply with the requirements of IEC 61558-2-1, except the requirements of maximum rated output power of 1 kVA and degree of protection IPX4 do not apply.		N.A.
	The separating transformer assembly shall be of class I construction.		N.A.
	The degree of protection against ingress of water as given in IEC 60529 shall be specified.		N.A.
	The separating transformer assembly shall be marked according to the requirements of 7.2 and 7.3		N.A.
	The multiple socket –outlet shall be permanently connected to the separating transformer or the socket –outlet of the separating transformer assembly shall be of a type that cannot accept mains plugs of any kinds identified in IEC/TR 60083.		N.A.
16.9.2.2	Protective earth connections shall be made so that the removal of any single item of equipment in the ME system will not interrupt the protective earthing of any other part of the ME system, without at the same time disconnecting the electrical supply to that part.		N.A.
16.9.2.3	Conductors that connect different items of equipment within an ME system shall be protected against mechanical damage.		N.A.

17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		
	The manufacturer shall address in the risk management process the risks associated with:		
	The electromagnetic phenomena existing at the locations where the ME equipment or ME system is intended to be used as indicated in the accompanying documents; and	Influence of EMI is mentioned in the risk management file.	P
	The introduction by the ME equipment or ME system of electromagnetic phenomena into the environment that might degrade the performance of other devices, electrical equipment and systems.	No introduction of electromagnetic phenomena into the environment	N.A.

Clause 4.8	Table 1: **LIST OF THE COMPONENTS RELATED TO SAFETY**			
Component	**Manufacturer**	**Type/model**	**Characteristics**	**Documentary evidence of acceptance**
USB cord	Ningbo Broad Telecommunication	2725	28AWGx1P+24AWGx2 C, 30Vac, PVC, V-1, +80°C	c UL us UL 758
Enclosure	DuPont	Surlyn 7930	Min thickness 1,0 mm	Tested in the equipment
PCB material	Isola	370HR	Min thickness 1,0 mm, V-0, +125°C	
Sweep and rotation motors	MotionKing	14HX1403-01A	Stepper motor, 0,3A, 3,6 Ncm, 0,9 deg/step	Tested in the equipment
Ultrasound transducer	Medelcom international	2,0/R4,7/U120-BW	45Vdc, Fc=2.35 MHz, MI max: 0.26, TI <0.02	Tested in the equipment

Clauses 8.7.3, 8.7.4	Table 2: **MAXIMUM MEASURED LEAKAGE CURRENTS**				
Type of leakage current	**In normal condition**		**In single fault condition**		**Verdict**
Enclosure leakage current	**Allowed leakage current, μA**	**Measured max leakage current, μA**	**Allowed leakage current, μA**	**Measured max leakage current, μA**	
Enclosure	100	4,8	500	7,2	P
Power button		1,2		1,7	P
Patient leakage current*	10	3,5	50	5,4	P

*Measured according to EN 60601-2-37:2008

Clause 8.8.3	Table 3: **DIELECTRIC STRENGTH**				
Insulation under test	**M.O.P.**	**Working voltage**	**Test voltage**	**Result** (pass/fail)	
				After moisture treatment	After cleaning
Applied part/USB power supply	Two	45 Vdc	1000 Vdc	Pass	Pass

Clause 8.8.4.1	Table 4: **BALL-PRESSURE TEST**		
Object under test	**Test type and condition**	**Remarks and results**	**Verdict**
Enclosure of ultrasound probe	75°C, 1h	Immersion diameter is 1,3 mm	Pass

Clause 8.11.3.5	Table 5: **CORD ANCHORAGE**				
Cord under test	**Mass of equipment**	**Pull**	**Torque**	**Remarks**	**Verdict**
USB cord	0,48 kg	30 N	0,1 Nm	Pass, displacement is 0,0 mm	Pass

SERTIKA

TEST REPORT No 07-14B

Clause 11.1.1	Table 6: **TEMPERATURE OF THE EQUIPMENT PARTS OR ITS ENVIRONMENT**				
Measuring point	**Measured temperature T, °C**	**Allowed max. temperature T, °C**	**Time of contact "t"**	**Remarks**	**Verdict**
Enclosure	36,0	60	10 s ≤ t <1 min	T_{amb} = 25°C	P
Power-up button	27,0	71	1 s ≤ t <10 s		P
Applied part	26,5	48	1 min ≤ t <10 min		P

Table 7: **LIST OF TEST EQUIPMENT**

Title of the test equipment	**Type**	**Equipment No**	**Calibration date**		**Comments**
			Last	**due**	
Multimeter	METRAHit 29S	ML6917	2013-03-04	2015-03-04	
Timer	CDC np.1a-2	0542592	2012-08-14	2017-08-14	
Caliper	M07042	01	2012-08-14	2017-08-14	
Metal ruller	GOST 427-75	14	2012-04-10	2017-04-10	
Force gauge	AFG 2500N	13-0369-09	2013-10-23	2016-10-23	
Ball-pressure device	-	03	2012-01-12	2015-01-12	
30 mm disc	-	43-1	2011-09-08	2016-09-08	
Inclined plane	-	21	2012-01-20	2015-01-20	
Adjustable transformer	MA4804	12778	2013-10-03	2015-10-03	
Digital thermometer FLUKE with probe	53 II	13013 80105	2012-08-22	2014-08-22	
International safety analyzer	601PRO	144041	2012-05-22	2017-05-22	
Oaken board (2 pcs.)	-	32	2013-03-08	2016-03-08	
Climatic test chamber	WK11–340/40	58226033560010	2013-03-08	2015-03-08	
ALMEMO temperature and humidity measuring system	MA2590-9 + FH A646-1	H03010002G + 02111106	2013-03-04	2015-03-04	
ALMEMO atmospheric pressure measuring system	MA2590-9 + FD A612-MA	H03010002G + 03050195	2013-03-04	2016-03-04	
Automatic dielectric strength test apparatus HIOKI	3153	030129067	2013-08-23	2015-08-23	
Water drop equipment	6600	48	2013-04-30	2018-04-30	

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ANNEX 1
TEST REPORT No. 07-14B

PHOTOS OF THE TEST OBJECT

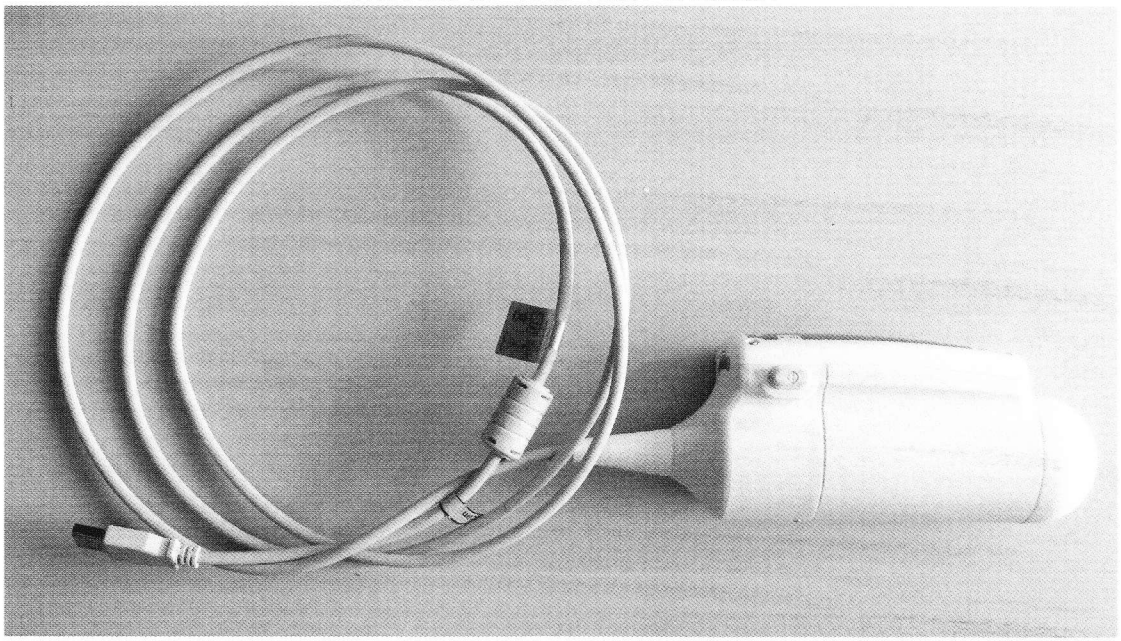

Fig. 1. General view of ultrasound bladder monitor VitaScan LT

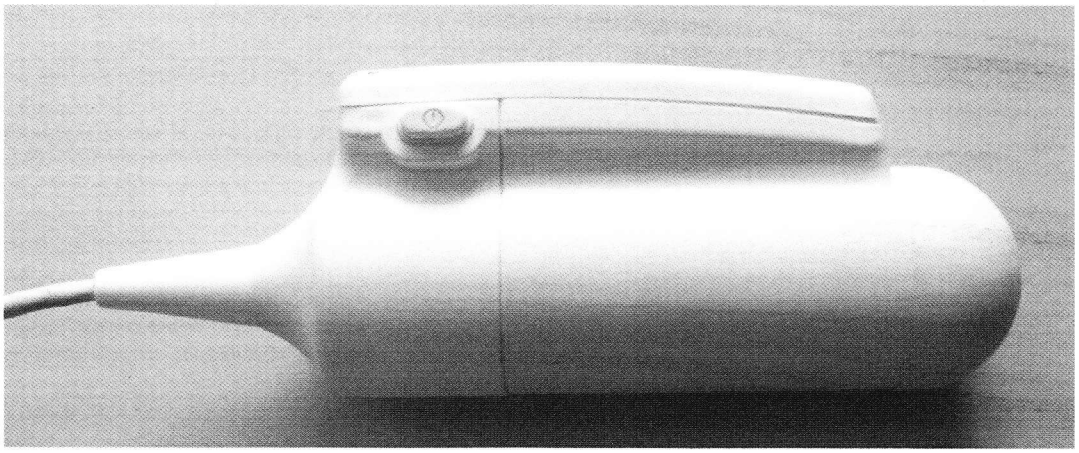

Fig. 2. Side view of ultrasound bladder monitor VitaScan LT

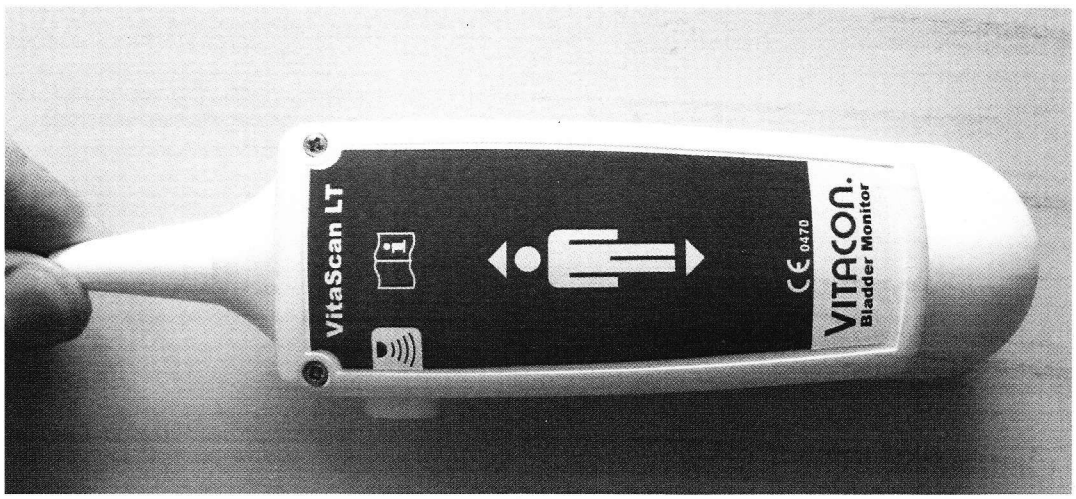

Fig. 3. Top view of ultrasound bladder monitor VitaScan LT